SUBJECT: Chapter 1 of the Medicare Prescription Drug Benefit Manual


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Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously posted to http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage or http://www.cms.hhs.gov/manuals/ and disseminated via the Health Plan Management System (HPMS). However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.


II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED)

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III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

IV. ATTACHMENTS:

- Business Requirements
- Manual Instruction
- Confidential Requirements
- One-Time Notification
- Recurring Update Notification

*Unless otherwise specified, the effective date is the date of service.

†This Chapter is only designated as “NEW” for purposes of incorporation into this manual maintenance and numbering system.
Prescription Drug Benefit Manual

Chapter 1: Introduction and General Provisions

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(Rev.5, 09-26-08)

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10 – Introduction
(Rev.5, Issued: 09-26-08, Effective: 09-26-08, Implementation: 09-26-08)

This chapter provides an introduction to Pub. 100-18, Prescription Drug Benefit Manual, including:

- Background regarding the establishment of the Voluntary Prescription Drug Benefit Program (Part D);

- Definitions of important concepts used throughout the manual; and

- Part D sponsor cost-sharing in beneficiary education and enrollment-related costs

Pub. 100-18 sets forth consolidated policy and operational guidance based on the current Part D program regulations. Except where specifically noted, the requirements in the manual apply to all Part D sponsors, including prescription drug plans (PDPs), Medicare Advantage prescription drug plans (MA-PD plans), and cost plans offering Part D coverage.

10.1 – Background
(Rev.5, Issued: 09-26-08, Effective: 09-26-08, Implementation: 09-26-08)

Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) amended Title XVIII of the Social Security Act (the Act) by establishing the Voluntary Prescription Drug Benefit Program (Part D). Effective January 1, 2006, Part D is an optional prescription drug benefit for individuals who are entitled to Medicare benefits under Part A or enrolled in Medicare benefits under Part B. Beneficiaries who qualify for both Medicare and Medicaid (full-benefit dual eligibles) will automatically receive the Medicare drug benefit. The MMA also provides for assistance with premiums and cost sharing to eligible low-income beneficiaries.

The regulations governing the Part D program are set forth in 42 CFR Part 423 – Voluntary Medicare Prescription Drug Benefit. There are a number of places in which Part D statutory provisions incorporate by reference specific sections of the Act that govern the Medicare Part C program (also known as the Medicare Advantage, or MA program, and formerly the Medicare+Choice, or M+C, program). The MA regulations are set forth at 42 CFR Part 422. Since the same organizations that offer MA coordinated care plans will also be required to offer MA-PD plans, Part 423 adopts the same organizational structure as Part 422. Wherever possible, CMS modeled the prescription drug regulations on the parallel provisions of the part 422 regulations.

Generally, Part D coverage is provided under PDPs, which offer only prescription drug coverage, or through MA-PD plans, which offer prescription drug coverage that is integrated with the health care coverage they provide to Medicare beneficiaries under Part C. As described in chapter 5, section 20.4.3, PDPs must offer a basic prescription drug benefit (defined in chapter 5 section 20.4.2.1). As described in chapter 5, section 20.4.4, MA organizations must offer either a basic benefit or broader coverage for no additional cost. If this required level of coverage is
offered, MA-PDs or PDPs (but not fallback PDPs), may also offer supplemental benefits (defined in [chapter 5, section 20.4.2.1]) under enhanced alternative coverage for a supplemental premium. Organizations offering drug plans have flexibility in the design of the prescription drug benefit packages, including the establishment of formularies. The MMA also provides for subsidy payments to sponsors of qualified retiree prescription drug plans (the retiree drug subsidy, or RDS) to encourage retention of non-Part D employer-sponsored benefits.

Since the MMA’s enactment, several statutes have modified or amended the Part D program. These statutes include the QI, TMA, and Abstinence Programs Extension and Hurricane Katrina Unemployment Relief Act of 2005; the Tax Relief and Health Care Act (TRHCA) of 2006; and the Medicare Improvements for Patients and Providers Act of 2008.

10.2 – Process for Issuing Updates to Part D Guidance
(Rev.5, Issued: 09-26-08, Effective: 09-26-08, Implementation: 09-26-08)

Pub. 100-18 is the primary resource for consolidated policy guidance from the Centers for Medicare and Medicaid Services (CMS) regarding the Part D program. For detailed MA and cost plan program guidance, Medicare managed care organizations should also consult Pub. 100-16 (Medicare Managed Care Manual).

While Pub. 100-18 and Pub. 100-16 chapters are updated regularly to ensure that they contain detailed and current information, Part D sponsors should monitor and familiarize themselves with other sources of Part D policy and operational program guidance – particularly between Pub. 100-18, chapter updates and for chapters that have not yet been issued. Part D sponsors should monitor CMS regulations, including both preamble and regulation text; policy and operational guidance, including memoranda and other communications issued via the Health Plan Management System; and the annual call letter with instructions for the upcoming contract year.

The annual call letter is a key element of the guidance that CMS provides to help organizations bid and contract for the upcoming contract year. It is issued in the early spring of each year in advance of the bid submission deadline in June and contains important new information and operational requirements for Part C, Part D, and cost plan contractors.

20 – Definitions
(Rev.5, Issued: 09-26-08, Effective: 09-26-08, Implementation: 09-26-08)

The following definitions apply to terms that appear throughout the various chapters of the manual. Definitions with a more limited application are included in the specific chapters of the manual.

Actuarial equivalence: A state of equivalent value demonstrated through the use of generally accepted actuarial principles and in accordance with section 1860D–11(c) of the Act and with CMS actuarial guidelines.
Brand name drug: A drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(c)), including an application referred to in section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 USC 355(b)(2)).

Cost plan: A plan operated by a Health Maintenance Organization (HMO) or Competitive Medical Plan (CMP) in accordance with a cost-reimbursement contract under section 1876(h) of the Act.

Eligible fallback entity or fallback entity: An entity defined at 42 CFR 423.855.


Formulary: The entire list of drugs covered by a Part D plan.

Full-benefit dual eligible individual: Has the meaning given the term at 42 CFR 423.772, except where otherwise provided.

Generic drug: A drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(j)) is approved.

Insurance risk: For a participating pharmacy, risk of the type commonly assumed only by insurers licensed by a State and does not include payment variations designed to reflect performance-based measures of activities within the control of the pharmacy, such as formulary compliance and generic drug substitutions, nor does it include elements potentially in the control of the pharmacy (for example, labor costs or productivity).

MA: Stands for Medicare Advantage, which refers to the program authorized under Part C of title XVIII of the Act.

MA plan: Has the meaning given the term in 42 CFR 422.2.

MA–PD plan: An MA plan that provides qualified prescription drug coverage.

Medicare prescription drug account: The account created within the Federal Supplementary Medical Insurance Trust Fund for purposes of Medicare Part D.

Monthly beneficiary premium: The amount calculated under 42 CFR 423.286 for Part D plans other than fallback prescription drug plans, and 42 CFR 423.867(a) for fallback prescription drug plans.

Program of All-Inclusive Care for the Elderly (PACE) Plan: A plan offered by a PACE organization.

PACE organization: Has the meaning given the term at 42 CFR 460.6.

Part D eligible individual: An individual who meets the requirements at 42 CFR 423.30(a).
Part D plan (or Medicare Part D plan): A PDP, an MA-PD plan, a PACE plan offering qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage.

Part D plan sponsor or Part D sponsor: A PDP sponsor, MA organization offering a MA-PD plan, a PACE organization offering a PACE plan including qualified prescription drug coverage, and a cost plan offering qualified prescription drug coverage.

PDP region: A prescription drug plan region as determined by CMS under 42 CFR 423.112.

PDP sponsor: A nongovernmental entity that is certified under 42 CFR Part 423 as meeting the requirements and standards of 42 CFR Part 423 that apply to entities that offer prescription drug plans. This includes fallback entities.

Prescription drug plan or PDP: Prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in 42 CFR 423.272 and that is offered by a PDP sponsor that has a contract with CMS that meets the contract requirements under subpart K of 42 CFR 423. This includes fallback prescription drug plans.

Service area: For: (1) a prescription drug plan, an area established in 42 CFR 423.112(a) within which access standards under 42 CFR 423.120(a) are met; (2) an MA-PD plan, an area that meets the definition of MA service area as described in 42 CFR 422.2, and within which access standards under 42 CFR 423.120(a) are met; (3) a fallback prescription drug plan, the service area described in 42 CFR 423.859(b); (4) a PACE plan offering qualified prescription drug coverage, the service area described in 42 CFR 460.22; and (5) a cost plan offering qualified prescription drug coverage, the service area defined in 42 CFR 417.1. Service area does not include facilities in which individuals are incarcerated.

Subsidy-eligible individual: A full subsidy eligible individual (as defined at 42 CFR 423.772) or other subsidy eligible individual (as defined at 42 CFR 423.772(d)).

Tiered cost-sharing: A process of grouping Part D drugs into different cost sharing levels within a Part D sponsor’s formulary.

30 – Cost-Sharing in Beneficiary Education and Enrollment-Related Costs
(Rev. 5, Issued: 09-26-08, Effective: 09-26-08, Implementation: 09-26-08)

As provided under 42 CFR 422.6 and 42 CFR 423.6, CMS charges and collects cost-sharing – or “user fees” – from MA organizations and PDP sponsors for the purpose of defraying part of the ongoing costs of the national beneficiary education campaign that includes developing and disseminating print materials, the 1-800-MEDICARE telephone line, community based outreach to support State health insurance assistance programs, other enrollment and information activities required under section 1851 of the Act, and counseling assistance under section 4360 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 103-66). For more information about the procedures CMS follows to determine and assess annual user fees to MA organizations and PDP sponsors, refer to Pub. 100-16, chapter 1, section 40.
40 – Financial Relationships Between PDP Sponsors, Health Care Professionals, and Pharmaceutical Manufacturers

(Rev.5, Issued: 09-26-08, Effective: 09-26-08, Implementation: 09-26-08)

The financial relationships that exist between or among PDP sponsors, health care professionals (including physicians and pharmacists), or pharmaceutical manufacturers may be subject to the Federal anti-kickback statute and, if the relationship involves a physician, the physician self-referral statute. Nothing in 42 CFR Part 423 should be construed as implying that financial relationships described therein meet the requirements of the anti-kickback statute or physician self-referral statute or any other applicable Federal or State law or regulation. All such relationships must comply with applicable laws.

In addition to the provisions in 42 CFR Part 423, under section 6(a)(1) of the Inspector General Act of 1978, as amended, the Department of Health and Human Services (DHHS) Office of the Inspector General (OIG) has access to all records, reports, audits, reviews, documents, papers and other materials to which DHHS has access that relate to programs and operations for which the Inspector General has responsibilities under the Inspector General Act. The provisions in these regulations do not limit the OIG’s authority to fulfill the Inspector General’s responsibilities under Federal law.

50 – Employee Retirement Income Security Act of 1974 (ERISA) Application and Requirements

(Rev.5, Issued: 09-26-08, Effective: 09-26-08, Implementation: 09-26-08)

The rules contained in 42 CFR Part 423 apply for purposes of Title I of the MMA, and no inference should be drawn from anything in 42 CFR Part 423 regarding the applicability of Title I of ERISA. In addition, nothing in 42 CFR Part 423 should be construed as relieving a plan administrator or other fiduciary of obligations under Title I of ERISA.
# Medicare Marketing Guidelines

For Medicare Advantage Plans\(^1\), Medicare Advantage Prescription Drug Plans, Prescription Drug Plans, and Section 1876 Cost Plans

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\(^1\) While Medicare Advantage “plans” are specific benefit packages offered by a Medicare Advantage organization, in this chapter, “plan” is used both to refer to the MA plan and to the MA organization offering the plan.
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Introduction

The Medicare Marketing Guidelines (MMG) implement the Centers for Medicare & Medicaid Services’ (CMS) marketing requirements and related provisions of the Medicare Advantage Organization (MA) (also referred to as Plan), Medicare Prescription Drug Plan (PDP) (also referred to as Part D Sponsor), and except where otherwise specified 1876 cost contract (also referred to as Plans) rules, (i.e., Title 42 of the Code of Federal Regulations, Parts 422, 423, and 417). These requirements do not apply to Program of All-Inclusive Care for the Elderly (PACE) plans or section 1833 cost plans. These requirements also apply to Medicare-Medicaid Plans (MMPs), except as modified or clarified in state-specific marketing guidance for each state’s demonstration. State-specific guidance is considered an addendum to the MMG. State-specific marketing guidance for MMPs will be posted to http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialModelstoSupportStatesEffortsinCareCoordination.html as it is finalized.

The term “marketing,” is referenced at Section 1851(h) and 1860 D-4 of the Social Security Act (the Act), as well as in CMS regulations. The scope of the definition extends beyond the public’s general concept of advertising materials.

Pursuant to 42 CFR section 417.428, section 422.2260, and section 423.2260, marketing materials include any materials developed and/or distributed by those entities covered by the MMG which are targeted to Medicare beneficiaries. While not an exhaustive list, the following materials fall under CMS’ purview per the definition of marketing:

- General audience materials such as general circulation brochures, direct mail, newspapers, magazines, television, radio, billboards, yellow pages or the Internet.
- Marketing representative materials such as scripts or outlines for telemarketing or other presentations.
- Presentation materials such as slides and charts.
- Promotional materials such as brochures or leaflets, including materials circulated by physicians, other providers, or third-party entities.
• Membership communications and communication materials including membership rules, subscriber agreements, member handbooks and wallet card instructions to enrollees.

• Communications to members about contractual changes, and changes in providers, premiums, benefits, plan procedures, etc.

• Membership activities, (e.g., materials on plan policies, procedures, rules involving non-payment of premiums, confirmation of enrollment or disenrollment, or non-claim specific notification information).

• The activities of a Plan’s/Part D Sponsor’s employees, independent agents or brokers, Third Party Marketing Organizations (TMO) (downstream contractors) or other similar type organizations that are contributing to the steering of a potential enrollee toward a specific plan or limited number of plans, or may receive compensation directly or indirectly from a Plan/Part D Sponsor for marketing activities.

In addition, 42 CFR section 417.428, section 422.2268, and section 423.2268 define the standards for marketing. Thus, CMS’ authority for marketing oversight, and the MMG, encompasses not only marketing materials but also marketing/sales activities. As Plans/Part D Sponsors implement their programs, they should consider the following guiding principles:

• Plans/Part D Sponsors are responsible for ensuring compliance with CMS’ current marketing regulations and guidance, including monitoring and overseeing the activities of their subcontractors, downstream entities, and/or delegated entities.

• Plans/Part D Sponsors are responsible for full disclosure when providing information about plan benefits, policies, and procedures.

• Plans/Part D Sponsors are responsible for documenting compliance with all applicable MMG requirements.

It is important to note that the marketing guidance set forth in this document is subject to change as policy, communication technology, and industry marketing practices continue to evolve. Any new rulemaking or interpretative guidance, (e.g., annual Call Letter or HPMS guidance memoranda), may supersede the marketing guidance provided in this document. Specific questions regarding a marketing material or marketing practice should be directed to the Plan’s/Part D Sponsor’s Account Manager or designated Marketing Reviewer.
Note: Marketing for an upcoming plan year may not occur prior to October 1.

20 – Materials Not Subject To Review

42 CFR 422.2260, 422.2262, 423.2260, 423.2262

The following items are materials that are not subject to review by CMS, should not be uploaded into HPMS, and do not require a material ID number. However, Plans/Part D Sponsors are still responsible for maintaining such materials so as to make them available upon CMS request.

- Privacy notices (which are subject to enforcement by the Office for Civil Rights)
- OMB Forms
- Press releases that do not include any plan-specific information (examples of plan-specific information include information about benefits, premiums, co-pays, deductible, benefits, how to enroll, networks)
- Certain member newsletters unless sections are used to enroll, disenroll, and communicate with members on product specific information (examples of product specific information include benefits or coverage, membership operational policies, rules and/or procedures)
- Blank letterhead/fax coversheets that do not include promotional language
- General health promotion materials that do not include any specific plan related information (examples of general health promotion materials include health education and disease management materials). In general, health promotion materials should meet CMS’ definition of “educational” (Refer to 70.8, Educational Events)
- Non-Medicare beneficiary-specific materials that do not involve an explanation or discussion of Part D, MA, or section 1876 cost plans (examples of materials within this category include notice of check return for insufficient funds, letter stating Medicare ID number provided was incorrect, billing statements/invoices, sales, and premium payment coupon book)
• *Documents to recruit or train* sales/marketing representatives  

• Medication Therapy Management (MTM) program materials (*see Appendix 1*)  

• Ad hoc Enrollee Communications Materials (see definition in Appendix 1)  

• Materials used at educational events for the education of beneficiaries and other interested parties (*refer also to 70.8*)  

• Coordination of Benefits notifications (as provided in Chapter 14 of the Medicare Prescription Drug Benefit Manual)  

• Health Risk Assessments  

• Mail order pharmacy election forms  

• Member surveys  

• Value-Added Items and Services (VAIS materials (refer to Chapter 4 of the Medicare Managed Care Manual)  

• Communicating preventive services to members  

• Mid-year Change Enrollee Notifications (Refer to 60.8)

### 30 - *Plan/Part D Sponsor* Responsibilities

#### 30.1 - Limitations on Distribution of Marketing Materials

42 CFR 422.2262(a), 423.2262(a), 422.2260, 423.2260, 422.2268(e), 423.2268(e)

A *Plan/Part D Sponsor* is prohibited from advertising outside of its defined service area unless such advertising is unavoidable. For situations in which this cannot be avoided, (e.g., advertising in print or broadcast media with a national audience or with an audience that includes some individuals outside of the service area, such as a Metropolitan Statistical Area that covers two regions), *Plans/Part D Sponsors* are required to clearly disclose their service area.

If there are any changes or corrections made to final materials (e.g., the benefit or cost-sharing information differs from that in the approved bid),
**Plans/Part D Sponsors** must correct those materials for prospective enrollees and may be required to send errata sheets/addenda/reprints to current members. In cases where non-compliance is discovered, the **Plan/Part D Sponsor** may be subject to compliance or enforcement actions, including intermediate sanctions and civil money penalties.

Joint enterprises must market their plans under a single name throughout a region. Joint enterprise marketing materials may only be distributed where one or more of the contracted **Plans/Part D Sponsors** creating the single entity is licensed by that State as a risk-bearing entity or qualifies for a waiver under 42 CFR 423.410 or 42 CFR 422.372. All marketing materials must be submitted under the joint enterprise’s contract number and follow CMS requirements.

**30.2 - Co-branding**

42 CFR 422.2268(n), 423.2268(n)

Input any co-branding relationships, including any changes in or newly formed co-branding relationships, prior to marketing its new relationship, in the Health Plan Management System (HPMS). **Plans/Part D Sponsors should reference the HPMS user guide for instructions on entering co-branding information.**

**30.2.1 - Co-branding with Providers or Downstream Entities**

42 CFR 422.2262(a), 422.2268(n), 423.2262(a), 423.2268(n)

**Plans/Part D Sponsors** are prohibited from displaying the names and/or logos of co-branded providers on the **Plan’s/Part D Sponsor’s** member identification card, unless the provider names and/or logos are related to a member’s selection of a specific provider/provider organization, (e.g., physicians, hospitals, and pharmacies).

**Plans/Part D Sponsors** that choose to co-brand with providers must include on marketing materials (other than ID cards) the **language in section 50.9**. Neither the **Plan/Part D Sponsor** nor its co-branding partners, whether through marketing materials or other communications, may imply that the co-branding partner is endorsed by CMS, or that its products or services are Medicare-approved. Co-branded marketing materials must be submitted to CMS by the Plan/Part D Sponsor.

**NOTE:** Consistent with the National Council for Prescription Drug Program’s (NCPDP’s) “Pharmacy and/or Combination ID Card”
standard, the Pharmacy Benefit Manager (PBM) name may be included on a member ID card.

30.2.2 – Plan/Part D Sponsor’s Relationships with State Pharmaceutical Assistance Programs (SPAP)

A Plan’s/Part D Sponsor’s logo may be used in connection with the coverage of benefits provided under an SPAP and may contain an emblem or symbol indicating such a relationship.

30.3 – Plan/Part D Sponsor Responsibility for Subcontractor Activities and Submission of Materials for CMS Review

42 CFR 422.504(e)(2), 423.505, 422.2262(a), 423.2262(a)

Plans/Part D Sponsors are responsible for all marketing materials used by their subcontractors to market their plan(s). All marketing materials used by Plans/Part D Sponsors or their subcontractors must be submitted by the Plan/Part D Sponsor (or its designee) to CMS for review and approval (or acceptance).

Employer group health plans should refer to section 130 of this chapter, Chapter 9 of the Medicare Managed Care Manual, and Chapter 12 of the Prescription Drug Benefit Manual for more guidance.

Materials created by agents or brokers that mention plan specific benefits must be submitted by the Plan/Part D Sponsor to CMS. Materials that include an agent’s/broker’s phone number should clearly indicate that calling the agent/broker number will direct an individual to a licensed insurance agent/broker. Business cards are excluded from this requirement.

Materials that only indicate the products (e.g., HMO, PPO, or PDP) an agent sells are not required to be submitted to CMS. Please note that this guidance in no way precludes the application by the Plans/Part D Sponsors of more stringent rules or contractual obligations in order to further restrict agent or broker communication and activities.

30.4 - Anti-Discrimination

42 CFR 422.110, 422.2268(c), 423.2268(c)

Plans/Part D Sponsors may not discriminate based on race, ethnicity, national origin, religion, gender, age, mental or physical disability, health status, claims experience, medical history, genetic information, evidence of
insurability or geographic location. *Plans/Part D Sponsors* may not target beneficiaries from higher income areas or state or otherwise imply that they are available only to seniors rather than to all Medicare beneficiaries. Only SNPs and MMPs may limit enrollment to dual-eligibles, institutionalized individuals, or individuals with severe or disabling chronic conditions and/or may target items and services to corresponding categories of beneficiaries. Basic services and information must be made available to individuals with disabilities, upon request.

**30.5 - Requirements Pertaining to Non-English Speaking Populations**

**42 CFR 422.110(h)(1), 423.128(d)(1)(iii), 422.2264(e), 423.2264(e)**

All Plans’/Part D Sponsors’ call centers must have interpreter services available to call center personnel to answer questions from non-English speaking or limited English proficient (LEP) beneficiaries. Call centers are those centers that receive calls from current and prospective enrollees. This requirement is in place regardless of the percentage of non-English speaking beneficiaries in a service area.

*Plans/Part D Sponsors* must make the marketing materials *identified in* sections 30.6, 30.7, 30.10, and the Part D Transition Letter(s) available in any language that is the primary language of at least five (5) percent of a Plan’s/Part D Sponsor’s plan benefit package service area. **CMS strongly encourages Plans/Part D Sponsors to translate ad-hoc communications upon request.**

NOTE: The member ID card is excluded from this requirement.

Final populated versions of all materials must be uploaded into HPMS.

**30.5.1 – Multi-Language Insert**

**42 CFR 422.111(h), 422.2262(c), 422.2264(a), 423.128(d) 423.2262(c), 423.2264(a)**

The Multi-Language Insert is a document that contains information translated into multiple languages: (e.g., Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese).

"We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us
Regardless of the 5 percent service area threshold (See 30.5), all Plans/Part D Sponsors must include the CMS created Multi-Language Insert with the Summary of Benefits (SB), Annual Notice of Change /Evidence of Coverage (ANOC/EOC), and the enrollment form. Plans/Part D Sponsors have the option to incorporate the Multi-Language Insert as part of these materials or to provide as a separate document.

Please see Appendix 3. The Multi-Language Insert cannot be modified except to include additional languages and/or inserting the Plan/Part D Sponsor logo/name. If a Plan/Part D Sponsor chooses to include additional languages on the insert, they must do so by translating the statement referenced above.

Note: D-SNPs who work with States that have more stringent language requirements must work with CMS to determine whether those requirements can be incorporated into the CMS Multi-Language Insert or may be met another way.

30.6 - Required Materials with an Enrollment Form

42 CFR 422.111, 423.128

When a beneficiary is provided with enrollment instructions/form, s/he must also receive Star Ratings information (as specified in 30.10), the SB, and the Multi-Language Insert (see section 30.5.1).

NOTE: When a Plan/Part D Sponsor enrolls a beneficiary online, it must make these materials available electronically, (e.g., via website links) to the potential member prior to the completion and submission of the enrollment request.

30.7 - Required Materials for New and Renewing Members at Time of Enrollment and Thereafter

42 CFR 422.111, 423.128, 422.2264, 423.2264

- ANOC/EOC or EOC as applicable (required annually by Plan/Part D Sponsor, see, section 60.7 for additional information)
- Low Income Subsidy (LIS) Rider (Part D Sponsors only, see the Prescription Drug Benefit Manual, Chapter 13, section 70.2 for
additional information, including timeframes, http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html

- Comprehensive formulary or abridged formulary including information on how the beneficiary can obtain a complete formulary (Part D sponsors only, see section 60.5 for additional information)

- Pharmacy directory (For all Part D Sponsors, this is required at time of enrollment; see section 60.4.1 for additional information)

- Provider directory (For all plan types except PDPs, this is required at time of enrollment; see section 60.4.2 for additional information)

- Membership Identification Card (required only at time of enrollment and as needed or required by Plan/Part D Sponsor post enrollment; see section 60.2 for additional information)

Excluding the LIS Rider, these documents must be provided to all new enrollees no later than ten (10) calendar days from receipt of CMS confirmation of enrollment or by the last day of the month prior to the effective date, whichever is later. Plans/Part D Sponsors should refer to the date of the Transaction Reply Report (TRR) that has the notification to identify the start of the ten (10) calendar day timeframe.

30.7.1 – Mailing Materials to Addresses with Multiple Members

42 CFR 422.111, 423.128, 422.2264, 423.2264

Every member must receive the materials noted in 30.7 at the time of enrollment. Plans/Part D Sponsors may combine the mailing of these materials to members at the same address after receiving consent from all the members. Individuals in apartment buildings are only considered to be at the “same address” if the apartment number is the same. Individuals living in community residences, (e.g., group homes or nursing facilities), must each receive their own materials, regardless of whether they have the same address.

Note: Plans/Part D Sponsors may not mail one membership identification card to an address where multiple members reside; all enrollees must receive individual membership identification cards.

30.8 - Hold Time Messages

42 CFR 422.2268(f) and 423.2268(f)
Hold time messages (messages played when an enrollee or prospective enrollee is on hold when calling the plan) that promote the plan or include benefit information must be submitted in HPMS for review as marketing materials.

30.9 – Member Referral Programs

42 CFR 422.2268(a),(b), and (d), 423.2268(a),(b), and (d)

The following general guidelines apply to referral programs under which a Plan/Part D Sponsor solicits leads from members for new enrollees. These include gifts that would be used to thank members for devoting time to encourage enrollment.

- A Plan/Part D Sponsor can ask for referrals from members, including names and mailing addresses, but cannot request phone numbers or email addresses. Plans/Part D Sponsors may use member provided referral names and mailing addresses to solicit potential new members by conventional mail only.

- Any solicitation for leads, including letters sent from Plans/Part D Sponsors to members, cannot announce that a gift will be offered for a referral.

- Gifts must be of nominal value (refer to section 70.1.1 - Nominal Gifts).

30.10 - Star Ratings Information from CMS

42 CFR 422.2264(a)(4), 423.2264(a)(3)

Plan/Part D Sponsors must provide overall Star Ratings information to beneficiaries through the standardized Star Ratings information document. The Star Ratings information document must be distributed with any enrollment form and/or the SB. This document must also be available on plan websites.

To create this document, Plan/Part D Sponsors must download Star Rating information from HPMS using the following navigation path: HPMS Homepage > Quality and Performance > Part C Performance Metrics or Part D Performance Metrics and Reports > Part C or D Star Ratings Template.

Plan/Part D Sponsors have the option to add their plan logo to the document. No additional alterations may occur unless otherwise directed by CMS.
Star Ratings are generally issued in October of each year. Plans/Part D Sponsors will be required to use updated Star Ratings information within 15 days of the release of the updated information.

New Plans/Part D Sponsors that do not have any Star Ratings information are not required to provide Star Ratings information until the new contract year.

30. 10.1 – Referencing Star Ratings in Marketing Materials

42 CFR 422.2268(e), 423.2268(e)

- Plans/Part D Sponsors may only reference a contract’s individual measures in conjunction with its highest Rating (MAPD- Overall Rating, MA only- Part C summary Rating and PDP- Part D summary Rating) in marketing materials. Plans/Part D Sponsors may not use their Star Rating in a lower category or measure to imply higher overall or summary Star Ratings in their marketing materials. For example, a Plan/Part D Sponsor that received an overall rating of 2 stars, and a 5-Star Rating in the category of customer service may not promote itself as a “5-Star plan.”

- Plans/Part D Sponsors must use their Star Ratings in marketing materials in a manner that does not mislead beneficiaries into enrolling in plans based on inaccurate information.

- Plans/Part D Sponsors that are assigned a Low Performer Icon (LPI) by CMS may not attempt to discredit or refute their LPI status by only showcasing a higher overall Star Rating. If an MA-PD plan has been assigned an LPI, due to either low Part C and/or Part D ratings, the organization must clearly indicate its LPI status when referencing its Star Rating. For example, an MA-PD that has a 3-Star overall Rating but has an LPI because of its low Part C ratings may advertise that its overall Star Rating is 3 but must also include that it has a LPI for low Part C or Part D performance. In addition, the organization must state that its LPI status means that it received a 2.5 star or below summary Rating in either Part C and/or Part D ratings for the last three years. In cases where the organization received an LPI due to alternating low performance on Part C and Part D ratings the most recent low rating must be noted.

- Plans/Part D Sponsors must include the disclaimer noted in section 50.14 on materials that refer to Star Rating.
• **Plans/Part D Sponsors** may direct beneficiaries to [www.Medicare.gov](http://www.Medicare.gov) for more information on Star Ratings.

• **Plans/Part D Sponsors** cannot encourage beneficiaries to enroll, based on the argument that if they are dissatisfied with the plans, they can later request SEPs and change to higher rated plans.

• **Plans/Part D Sponsors** with 5-star ratings may not target marketing activities specifically to beneficiaries enrolled in poor performing plans nor direct them to request special enrollment periods.

• **Plans/Part D Sponsors** with an overall 5-Star Rating have the option to include CMS’ gold star icon on marketing materials. The icon must be included in a way that is not misleading and makes it clear to the audience that the 5-Star Rating is for a specific contract(s), as applicable. **CMS will provide the gold star icon to Plans/Part D Sponsors** every fall.

• **Plans/Part D Sponsors** with one or more contracts with an overall 5-Star Rating should not create or disseminate materials in a way that implies that all of its contracts achieved this rating. **Materials should list specific contracts with overall 5-Star Ratings.**

• **Plans/Part D Sponsors** may only market their Star Ratings for contracts in that geographic service area as specified in section 30.1 - Limitations on Distribution of Marketing Materials.

**NOTE:** **Plans/Part D Sponsors** are responsible for translating Star Ratings information as specified in section 30.5. Translation of Star Ratings information will not be considered an alteration of the document.

**30.10.2** – Plans with an Overall 5-Star Rating

42 CFR 422.2264(a)(4), 423.2264(a)(3)

**Plans/Part D Sponsors** with an overall 5-Star rating may market their ability to enroll beneficiaries through the 5-Star special enrollment period (SEP).

If a **Plan/Part D Sponsor** with an overall 5-Star rating is assessed a rating of less than 5-Stars for the upcoming year, the **Plan/Part D Sponsor** must discontinue marketing for the purposes of accepting enrollments under the 5-Star SEP by November 30 of the current year.
40 - General Marketing Requirements

40.1 - Marketing Material Identification

42 CFR 422.2262(a)(1)(i) and (c), 423.2262(a)(1)(i) and (c), 422.2264, 423.2264

*Plans/Part D Sponsors* are required to place a unique marketing material identification number on all marketing materials (except as indicated below).

The material ID is made up of two parts: (1) Plan’s/Part D Sponsors’ contract or MCE number, (i.e., H for MA or section 1876 cost plans, R for regional PPO plans (RPPOs), S for PDPs, or Y for Multi-Contract Entity (MCE) identifier) followed by an underscore; and (2) any series of alpha numeric characters chosen at the discretion of the Plan/Part D Sponsor. Use of the material ID on marketing materials must be immediately followed by the status of either approved, pending (for websites only), or accepted (e.g., Y1234_drugx38 Approved). *Please note that Plans/Part D Sponsors should include approved or accepted statuses only after the material is approved or accepted and not when submitting the material for review.*

The following marketing materials do not require a marketing material ID number on them:

- The member ID card (although PDP or MA-PD member ID cards must include the CMS contract number and Plan Benefit Package (PBP) number on them).
- Envelopes, radio ads, outdoor advertisements, banner or banner-like ads, and social media comments and posts.

**NOTE:** Refer to section 90.2.3 for additional guidance on the multi-plan material ID requirements.

40.1.1 - Marketing Material Identification Number for Non-English or Alternate Format Materials

42 CFR 422.2264(e), 423.2264(e)

Non-English or alternate format materials must be given a unique material ID *using the method* outlined above. When submitting these materials, *Plans/Part D Sponsors* must designate that they are non-English or alternate format versions in HPMS.
40.2 - Font Size Rule

42 CFR 422.2264 *(a)(1)*, 423.2264 *(a)(1)*

All text included on materials, including footnotes, must be printed with a font size equivalent to or larger than Times New Roman twelve (12)-point. The equivalency standard applies to both the height and width of the font.

Exceptions:

- Television Ads
- ID cards
- Internal tracking numbers
- Logos/logos with taglines
- If a **Plan/Part D Sponsor** publishes a notice to close enrollment in the Public Notices section of a newspaper, the **Plan/Part D Sponsor** does not need to use twelve (12)-point font and can instead use the font normally used by the newspaper for its Public Notices section.

Note: Because neither CMS nor the **Plan/Part D Sponsor** has any control over the actual screen size shown on individuals’ computer screens that can be adjusted by the user, for internet marketing materials, the twelve (12)-point font requirement refers to how the **Plan/Part D Sponsor** codes the font for the Web page rather than how it actually appears on the user’s screen.

40.3 - Reference to Studies or Statistical Data

42 CFR 422.2264, 422.2268(e), 423.2264, 423.2268(e)

**Plans/Part D Sponsors** may only compare their plan to another **Plan/Part D Sponsor** by referencing a study or statistical data as described below.

- **Plans/Part D Sponsors** must provide the study sample size, number of **Plan/Part D Sponsor** surveyed, publication date, and page number in the HPMS marketing material transmittal comments field when uploading the document that includes the reference.

**Plans/Part D Sponsors** must provide the following information, either in the text or as a footnote, on marketing pieces *(including but not limited to informational scripts)* that mention a study:
• The source and date of the study.
• Information about the Plan’s/Part D Sponsor’s relationship with the entity that conducted the study.
• The study sample size and number of plans surveyed (unless the study that is referenced is a CMS study).
• Reference information (e.g., publication, date, page number) for CMS studies.

**40.4 - Prohibited Terminology/Statements**

42 CFR 422.2264, 423.2264, 422.2268(e), 423.2268(e)

CMS prohibits the distribution of marketing materials that are materially inaccurate, misleading, or otherwise make material misrepresentations.

**Plans/Part D Sponsors** may not:

• Claim that they are recommended or endorsed by CMS, Medicare, or the Department of Health & Human Services (DHHS).

• Use absolute superlatives, (e.g., “the best,” “highest ranked,” “rated number 1”), unless they are substantiated with supporting data provided to CMS as a part of the marketing review processes or they are used in logos/taglines. If the material is submitted via the file & use program, the supporting data must be included, along with the materials that use an absolute superlative.

• Compare their Plan/Plan Sponsor to another Plan/Plan Sponsor by name unless they have written concurrence from all Plans/Part D Sponsors being compared (e.g., studies or statistical data as described in section 40.3). This documentation must be included when the material is submitted in HPMS.

**Plans/Part D Sponsors** may:

• State that the Plan/Part D Sponsor is approved for participation in Medicare programs and/or it is contracted to administer Medicare benefits.

• Use the term “Medicare-approved” to describe their benefits and services within their marketing materials.

• Use qualified superlatives, (e.g., “one of the best,” “among the highest rank”).
40.5 - Product Endorsements/Testimonials

Product endorsements and testimonials will not be considered misleading if they adhere to the following:

- The speaker must identify the Plan’s/Part D Sponsor’s product by name.
- A Medicare beneficiary may endorse a Plan/Part D Sponsor or promote a specific product, provided the individual is a current member of the plan being endorsed or promoted.
- If an individual is paid to endorse or promote the plan or product, this must be clearly stated (e.g., “paid endorsement”).
- If an individual, such as an actor, is paid to portray a real or fictitious situation, the ad must clearly state it is a “Paid Actor Portrayal.”
- The endorsement or testimonial cannot use any quotes by physicians, health care providers, and/or by Medicare beneficiaries not enrolled in the plan.
- The endorsement or testimonial cannot use negative testimonials about other Plans/Part D Sponsors.

40.6 - Hours of Operation Requirements for Marketing Materials

Plan/Part D Sponsor hours of operation should be listed on every material where a customer service number is provided for current and prospective enrollees to call. Similarly, Plan/Part D Sponsor must list the hours of operation for 1-800-MEDICARE on every material where 1-800-MEDICARE or Medicare TTY appears (i.e., 24 hours a day/7 days a week).

Note: The hours of operation need to only be listed once in conjunction with the customer service number and 1-800-MEDICARE; they do not need to be listed every time a customer service number is provided.

- The Plan/Part D Sponsor customer service number must be a toll-free number.
• Customer service call center hours must be the same for all individuals regardless of whether they speak another language or use assistive devices for communication.

• ID cards are excluded from this requirement.

Refer to section 80.1 for additional guidance for customer call centers.

40.7 - Use of TTY Numbers

Section 501 and Section 504 of the Rehabilitation Act

A TTY number must appear in conjunction with the Plan’s/Part D Sponsor’s customer service number in the same font size and style as the other phone numbers except as outlined below. Plans/Part D Sponsors can either use their own TTY number or State relay services, as long as the number included is accessible from TTY equipment. TTY customer service numbers must be toll-free.

Exceptions:

• Outdoor advertising (ODA) or banner/banner-like ads.

• The Multi-language Insert (Appendix 3).

• Radio ads and radio sponsorships (e.g., "sponsoring” an hour of public radio)

• In television ads, the TTY number may be a different font size/style than other phone numbers to limit possible confusion. Plans/Part D Sponsors may use various techniques to distinguish between TTY and other phone numbers on a television ad (such as using a smaller font size for the TTY number than for the other phone numbers).

40.8 - Marketing of Multiple Lines of Business

42 CFR 422.2268(h) and (f), 423.2268(h) and (f)

Although Plans/Part D Sponsors cannot market non-health related products to prospective members during an MA or Part D sales activity or multiple lines of business not identified prior to the appointment without documenting a second scope of appointment (see § 70.9.3), they may provide marketing materials describing other lines of business (both health-related and non-health-related) when marketing covered plans, provided that such materials
are in compliance with applicable State law governing the other lines of business. When doing so, Plans/Part D Sponsors are encouraged to adhere to the requirements set forth in this section, as well as section 160.

**40.8.1 - Multiple Lines of Business - General Information**

42 CFR 422.2268(e), 423.2268(e)

*Plan/Part D Sponsor* marketing materials sent to current members describing other health-related lines of business must contain instructions that describe how individuals may opt out of receiving such communications. *Plans/Part D Sponsors* must ensure individuals (including non-members) who ask to opt out of receiving future marketing communications are not sent such communications. In marketing multiple lines of business, *Plans/Part D Sponsors* must comply with the Health Insurance Portability and Accountability Act (HIPAA) rules (outlined generally in Appendix 2) and the guidance in section 160 regarding use of beneficiary information.

*Plans/Part D Sponsors* that advertise multiple lines of business within the same marketing document must keep the organization’s *Medicare* lines of business clearly and understandably distinct from the other products.

*Plans/Part D Sponsors* must not include enrollment applications for competing lines of business (e.g., MA-PD or MA plans and Medigap products), or for other non-Medicare lines of business in mailings that combine Medicare plan information with other product information.

**40.8.2 - Multiple Lines of Business - Exceptions**

42 CFR 422.2268, 423.2268

*Plans/Part D Sponsors* that send out non-renewal notices may only provide information regarding other Medicare products (such as other MA-PDs available in the service area) to those members receiving the non-renewal notice. These additional materials must be a separate enclosure within the same envelope. Enrollment applications are prohibited from being provided with non-renewal information.

**40.8.3 - Marketing Materials from Third Parties that Provide Non-Benefit/Non-Health Services**

42 CFR 422.2268, 423.2268

*Third parties that provide non-benefit/non-health services* ("Non-benefit/non-health service providing third party entities") are organizations
or individuals that supply non-benefit related information to Medicare beneficiaries or a Plan’s/Part D Sponsor’s membership, which is paid for by the Plan/Part D Sponsor or the non-benefit/non-health service-providing third party entity.

Example A: Company XYZ promotes health and wellness and develops materials targeted to the Medicare population.

Example B: An individual that provides summaries of Plans/Part D Sponsors or highlights Plans/Part D Sponsors using CMS statistical data or other research data sources available to them and offers their services and/or materials to the Plans/Part D Sponsors. The Plan/Part D Sponsor would distribute or allow the non-benefit/non-health servicing third party individual to distribute the materials to their plan membership and/or to prospective enrollees.

Example C: Materials created by organizations like the Red Cross and Asthma Coalition.

If a non-benefit/non-health service-providing third party wishes to develop and/or provide information to a Plan’s/Part D Sponsor’s members and/or prospective enrollees, plans must require that the entity submit its materials to the Plan/Part D Sponsor who will ensure compliance with the MMG requirements. See section 50.13.

40.9 - Providing Materials in Different Media Types

42 CFR 422.64, 422.111, 423.48, and 423.128;

Plans/Part D Sponsors may provide materials using different media types (e.g., electronic or portable media like email, CD, or DVD). However, Plans/Part D Sponsors must receive consent prior to providing materials in this format (i.e., individuals must opt-in). When requesting consent, the Plan/Part D Sponsor must specify to the beneficiary the media type and the documents to be sent in such media format.

In addition, Plans/Part D Sponsors electing to provide any materials using different media types must:

- Provide hard copies of all member materials available to members upon request.

NOTE: Requests for hard copies of plan web pages are excluded from this requirement.
• Inform members of the option and give them the choice to opt-in. If a member no longer wishes to receive plan communications through electronic or portable media, they must be able to opt-out upon request.

• Document each member’s choice of media type and (opt-in) election to receive plan communications using that type.

• Have safeguards in place to ensure that member contact information is current, communication materials are delivered and received timely and appropriately, and important materials are identified in a way that members understand their importance.

• Have a process for automatic mailing of hard copies when electronic versions or choice of media types are undeliverable, (e.g., an expired e-mail account).

• Ensure compliance with HIPAA.

40.10 - Standardization of Plan Name Type

42 CFR 422.2268 (q), 423.2268 (q), sections 1851(h)(6) and 1860D-4(l)(3)

Plans/Part D Sponsors must include the plan type in each plan’s name using standard terminology. Plans/Part D Sponsors enter and maintain their plan names in HPMS. Plans/Part D Sponsors must include the plan type on all marketing materials when the plan name is mentioned.

To ensure the consistent use of standardized plan type terminology across all Plans/Part D Sponsors, the plan type label must be placed at the end of each plan name. For instance, an HMO plan named “Golden Medicare Plan” would appear as follows: “Golden Medicare Plan (HMO).”

Plans/Part D Sponsors that have incorporated the plan type at the end of the plan name (e.g., Gold Plan PFFS) are not required to repeat the plan type in the plan name.

Inclusion of the plan type is not required throughout an entire document. However, plans must include the plan type on the front page or at the beginning of the document. Model documents to which the only modification is the addition of the required plan name type will be considered a model without modification.
50 - Marketing Material Types and Applicable Disclaimers

42 CFR 422.2262(c), 422.2264, 423.2262(c), 423.2264

In general, CMS groups marketing materials into two distinct categories – those materials directed to potential enrollees and communications to existing members. Unless otherwise noted, the disclaimers described in this section are required on all marketing materials created by the Plan/Part D Sponsor regardless of the intended audience. Disclaimers must be prominently displayed on the material and must be of similar font size and style (refer to section 40.2 for more information).

50.1 - Federal Contracting Disclaimer

42 CFR 422.2264(c), 423.2264(c)

All marketing materials must include the statement that the Plan/Part D Sponsor contracts with the Federal government.

Plans/Part D Sponsors must use a contracting statement either in the text of the piece or at the end/bottom of the piece. The statement should include the legal or marketing name, the type of plan (e.g., HMO, PPO, PFFS, PDP), and who the contract is with (e.g., Medicare, Federal Government, State Medicaid program).

An example of this statement follows: “[Plan’s/Part D Sponsor’s legal or marketing name] is an HMO plan with a Medicare contract. Enrollment in [Plan’s/Part D Sponsor’s legal or marketing name] depends on contract renewal.”

NOTE: Banner and banner-like ads, envelopes, outdoor advertising, and radio, television and internet banner ads do not need to include the Federal contracting disclaimer.

50.2 - Disclaimers When Benefits Are Mentioned

42 CFR 422.111(a) and (b), 423.128(a) and (b)

The following disclaimers must be used when benefit information is included in marketing materials:
• “The benefit information provided is a brief summary, not a complete description of benefits. For more information contact the plan.”

• “Limitations, copayments, and restrictions may apply.”

• “[Benefits, formulary, pharmacy network, provider network, premium and/or co-payments/co-insurance] may change on January 1 of each year.”

50.3 – Disclaimers When Plan Premiums Are Mentioned
42 CFR 422.111(a)(2), 422.2264(a), 423.128(a)(2), 423.2264(a)

All plan materials that mention plan premium information must include the following disclaimer:

“You must continue to pay your Medicare Part B premium.”

NOTE: This statement is required even if the plan premium is $0. This disclaimer is not required if the Part B premium is entirely paid by rebates under the plan. D-SNPs where the State pays the Part B premium should indicate that the Part B premium is covered for full-dual members.

50.4 – Disclaimer on Availability of Non-English Translations
42 CFR 422.2264(e), 423.2264(e)

Plans/Part D Sponsors that meet the five (5) percent threshold for language translation (Refer to section 30.5) must place the following alternate language disclaimer on all materials.

• “This information is available for free in other languages. Please call our customer service number at [insert customer service and TTY numbers, and hours of operation].”

The alternate language disclaimer must be placed in both English and all non-English languages that meet the five (5) percent threshold for the Plan Benefit Packages (PBP) related to the document. The non-English disclaimer must be placed below the English version and in the same font size as the English version.

NOTE: ID cards are excluded from this requirement.
50.5 - SNP Materials

SNP plans must place a disclaimer related to enrollment eligibility on any materials targeting potential enrollees. Some examples are:

- “This plan is available to anyone with Medicare who meets the Skilled Nursing Facility (SNF) level of care and resides in a nursing home.”
- “This plan is available to anyone with Medicare who has been diagnosed with HIV/AIDS.”
- “This plan is available to anyone who has both Medical Assistance from the State and Medicare.”

Plans/Part D Sponsors may not discuss numeric SNP approval scores in marketing materials or press releases. Plans/Part D Sponsors may only include the following information related to their NCQA SNP approval:

“[Insert Plan Name] has been approved by the National Committee for Quality Assurance (NCQA) to operate as a Special Needs Plan (SNP) until [insert last contract year of NCQA approval] based on a review of [insert Plan Name’s] Model of Care.”

50.6 - Dual Eligible SNP Materials
42 CFR 422.4(a)(1)(iv), 422.111(b)(2)(iii), 422.2264, 423.2264

The following disclaimer must be on any D-SNP materials targeting potential enrollees that mention cost-sharing information. The disclaimer is not required on materials for beneficiaries residing in the territories.

- “[premiums],[ co-pays],[ co-insurance], and [deductibles] may vary based on the level of Extra Help you receive. Please contact the plan for further details.”

50.7 –Private Fee-for-Service Plans

PFFS materials designed to target potential members must include the following disclaimer:

- “A Private Fee-for-Service plan is not Medicare supplement insurance. Providers who do not contract with our plan are not required to see you except in an emergency.”
50.8 –Medicare Medical Savings Accounts (MSAs)

422.2264(a)(4), 423.2264(a)(3)

MSA materials designed to target potential members must include the following disclaimers:

- “MSA Plans combine a high deductible Medicare Advantage Plan and a trust or custodial savings account (as defined and/or approved by the IRS). The plan deposits money from Medicare into the account. You can use this money to pay for your health care costs, but only Medicare-covered expenses count toward your deductible. The amount deposited is usually less than your deductible amount, so you generally have to pay out-of-pocket before your coverage begins.”

- “Medicare MSA Plans don’t cover prescription drugs. If you join a Medicare MSA Plan, you can also join any separate Medicare Prescription Drug Plan.”

- “There are additional restrictions to join an MSA plan, and enrollment is generally for a full calendar year unless you meet certain exceptions. Those who disenroll during the calendar year will owe a portion of the account deposit back to the plan. Contact the plan at [insert customer service and TTY] for additional information.”

50.9 - Disclaimer for Materials that are Co-branded with Providers
42 CFR 422.2268(n), 423.2268(n)

Plans/Part D Sponsors that choose to enter into co-branding relationships with network providers are required to include the following disclaimer:

- “Other <Pharmacies/Physicians/Providers> are available in our network.”

50.10 - Disclaimer on Advertisements and Invitations to Sales/Marketing Events
42 CFR 422.2268(e) and (o), 423.2268(e) and (o)

Advertisements and invitations to sales/marketing events (in any form of media) used to invite beneficiaries to attend a group session with the possibility of enrolling those individuals must include the following two statements on marketing materials:

- “A sales person will be present with information and applications.”
• “For accommodation of persons with special needs at sales meetings call <insert phone and TTY number>.”

50.11 - Disclaimer on Promoting a Nominal Gift
42 CFR 422.2268(b), 423.2268(b)

*Plans/Part D Sponsors* must include a written statement on all marketing materials promoting drawings, prizes or any promise of a free gift that there is no obligation to enroll in the plan. For example:

- “Eligible for a free drawing and prizes with no obligation.” or
- “Free drawing without obligation.”

50.12 – Disclaimer for Plans Accepting Online Enrollment Requests
42 CFR 422.2262(c), 423.2262(c)

*Plans/Part D Sponsors* accepting enrollment requests through the Online Enrollment Center (OEC), must state the following disclaimer on their websites:

“Medicare beneficiaries may also enroll in <plan name> through the CMS Medicare Online Enrollment Center located at [http://www.medicare.gov](http://www.medicare.gov).”

50.13 - Disclaimer When Using Third Party Materials
42 CFR 422.2264, 423.2264

CMS does not review materials developed by a *non-benefit/non-health service providing* third-party entity that is not affiliated or contracted with the Plan/Part D Sponsor. An affiliation is defined as a mutual agreement of understanding (includes, but is not limited to parent organization relationships). *Plans/Part D Sponsors* choosing to provide marketing materials and/or services created by non-benefit/non-health service providing third-party entities must include the following disclaimer on all materials:

- “Medicare has neither reviewed nor endorsed this information”

The disclaimer must be prominently displayed at the bottom center of the first page of the material, or in the case of a website, on each page, and be a similar font size and style as the message.
50.13.1 – Disclaimer When Third Parties List a Subset of Plan Options

Any materials from a third party providing information on a subset of plan choices must prominently display the following disclaimer on all materials.

- “This is not a complete listing of plans available in your service area. For a complete listing please contact 1-800-MEDICARE (TTY users should call 1-877-486-2048), 24 hours a day/7 days a week or consult www.medicare.gov.”

This disclaimer must be prominently displayed on all material (or on each webpage) that lists, compares, or names available plans.

Plans/Part D Sponsors are responsible for ensuring that non-benefit/non-health service providing third-party entities comply with all MMG requirements prior to distributing materials to the Plan’s/Part D Sponsor’s membership. For further details on what CMS considers a non-benefit/non-health service providing third-party entity, please refer to section 40.8.3.

50.14 – Disclaimer When Referencing Star Ratings Information

Plans/Part D Sponsors must include the following disclaimer on all materials referencing Star Ratings information:

“Medicare evaluates plans based on a 5-Star rating system. Star Ratings are calculated each year and may change from one year to the next.”

50.15 – Pharmacy Directory Disclaimers

- If a directory is a subset of a service area, Part D sponsors must advise members that: “This directory is for <geographic area>.”

- If a Part D Sponsor lists pharmacies in its network but outside the service area, the sponsor must advise members that: “We also list pharmacies that are in our network but are outside <geographic area>.”

50.16 – Mailing Statements

42 CFR 422.2268(e), 422.2272(b), 423.2268(e), 423.2272(b)

In order to ensure that beneficiaries can quickly and easily identify the contents of a Plan’s/Part D Sponsor’s mailing, all Plans/Part D Sponsors that mail information to prospective or current Medicare beneficiaries must prominently display one of the following four statements on the front of the
envelope or if no envelope is being sent, the mailing itself. Plans/Part D Sponsors may meet this requirement through the use of ink stamps or stickers, in lieu of pre-printed statements. Any delegated or sub-contracted entities and downstream entities that conduct mailings on behalf of a Plan/Part D Sponsor must comply with this requirement.

1. Advertising pieces – “This is an advertisement”
2. Plan information – “Important plan information”
3. Health and wellness information – “Health and wellness or prevention information”
4. Non-health or non-plan information - “Non-health or non-plan related information”

All mailings should include one of these four mailing statements. If a mailing is not advertising or a health and wellness mailing, but is related to an enrollee’s plan, Plans/Part D Sponsors should categorize it as a plan information mailing. However, if the mailing contains non-health or non-plan related information (refer to section 160.4 for examples), a Plan/Part D Sponsor should use the “non-health or non-plan related information” mailing statement. Plans/Part D Sponsors may not modify these mailing statements and must use them verbatim.

In addition, Plans/Part D Sponsors must ensure that their plan name or logo is included on every envelope to current and prospective enrollees (either on the front envelope or on the mailing when no envelope accompanies the mailer).

CMS does not require resubmission of envelopes based only on a change in the envelope size. If a plan uses the same mailing statement on 3 different mailing packages (e.g., 8 x 12 envelope, letter size envelope, and box) the envelope with each mailing statement only needs to be submitted once, provided the required mailing statement remains unchanged and additional information is not included.

**NOTE:** Plans/Part D Sponsors are not required to include the material ID on envelopes; however all envelopes must be submitted to HPMS with an associated marketing material ID number.

**NOTE:** Envelopes containing additional information (e.g., advertising) must be submitted for review.

50.17 – **Disclaimer for Other Formulary Documents**
The following disclaimer must be displayed prominently on the cover of other formulary documents referenced in section 60.5.4: “This is not a complete list of drugs covered by our plan. For a complete listing, please call <Customer Service Phone and TTY Numbers/> or visit <website address>”.

60 - Required Documents

60.1 - Summary of Benefits (SB)

42 CFR 422.111(b)(2), 423.128(b)(2)

The SB is a standardized document that should be generated via HPMS. Plans/Part D Sponsors are required to include the SB when providing an enrollment form and also upon request. Additionally, Plans/Part D Sponsors must provide the multi-language insert any time they distribute an SB (see 30.5.1).

The SB allows beneficiaries to more easily compare the benefits offered by different Plans/Part D Sponsors and includes the following:

- **Section (I):** An introduction and the beneficiary information section, informing prospective enrollees of important aspects of enrolling in the plan.

- **Section (II):** A benefit comparison matrix, which is an output report of the Plan’s/Part D Sponsor’s PBP. Section (III): An optional free-form text area. This section is limited to six pages and can be used by plans to further describe special features of the program.

- **Section (IV) or Medicaid Benefits:** D-SNPs must provide each prospective enrollee prior to enrollment with a comprehensive written statement that describes:

  - The benefits that the individual is entitled to under Title XIX (Medicaid);
  - The cost-sharing protections that the individual is entitled to under Title XIX (Medicaid);
  - The description of the benefits and cost-sharing protections that are covered under the D-SNP.

Plans/Part D Sponsors must ensure that the language for sections I and II are identical to the SB report in HPMS. Any deviation from this language, outside of an approved hard copy change or global hard copy change, will
make the material non-compliant. Deviations include, but are not limited to, insertion of footnotes, plan specific clarifications, or format alterations, except as indicated in the SB instructions. All sections of the SB must be submitted to CMS as one document under the File & Use process. SBs may not be submitted as a template.

**Plans/Part D Sponsors** must obtain any hard copy change request approval prior to submitting their SBs. Hard copy change requests must be submitted in HPMS using the SB Hard Copy Change module.

**Plans/Part D Sponsors** offering more than one plan may describe several plans in the same document by displaying the benefits for different plans in separate columns within Section II of the benefit comparison matrix. Since the PBP will only print Sections I and II of the SB for one plan, **Plans/Part D Sponsors** will have to create a side-by-side comparison matrix for two (or more) plans by manually combining the information into a chart. **Plans/Part D Sponsors** can use a comparison matrix and still submit the document under File & Use. **Plans/Part D Sponsors** must also modify Section I (introduction) to accurately reflect the plans that have been added to Section II.

NOTE: Annually, CMS will release technical specifications for the SB including global hard copy changes, requirements for specific plan types, and instructions for submission.

### 60.2 - ID Card Requirements

42 CFR 417.427, 422.111(i), 423.120(c)

*All Plans/Part D Sponsors must create ID cards following the National Council for Prescription Drug Program (NCPDP) or Workgroup for Electronic Data Interchange (WEDI) standards.*

Combination health and drug plan ID cards must follow the WEDI standard and must include the required information in 60.2.1 and 60.2.2 below, except as provided in 60.2.3.

All **Plans/Part D Sponsors** must issue and reissue (as appropriate) member identification cards that members may use to access covered services under the plan.
Plans/Part D Sponsors must ensure that the member identification number on the ID card is not the SSN or Healthcare Insurance Claim Number (HICN) of the enrolled member.

Plans/Part D Sponsors must include the CMS contract number and PBP number on the member ID card.

ID cards are not required to include:

- The marketing material identification number
- Hours of operation of the customer service center
- Disclaimers noted in section 50

(Refer to section 30.2.1 regarding co-branding requirements related to ID cards.)

60.2.1 – Health Plan ID Card Requirements

Other than exceptions cited in section 60.2.3, the health plan member identification card (for MA or 1876 cost plans) must meet the standards for medical ID cards in the most recent version of the WEDI Health Identification Card Implementation Guide. Visit www.wedi.org to find the Guide.

Health plan ID cards must also include:

- The Plan website address.
- The Plan’s customer service number.
- The phrase “Medicare limiting charges apply” (on PPO and PFFS cards only).

60.2.2 – Part D Sponsor ID Card Requirements

Other than any exceptions cited in section 60.2.3, the Part D Sponsor member identification card must meet the most recent version of the NCPDP’s “Pharmacy and/or Combination ID Card” standard. This standard is based on the American National Standards Institute ANSI INCITS 284-1997 standard titled Identification Card – Health Care Identification Cards.

The front of the Part D Sponsor ID Card must include the Medicare Prescription Drug Benefit Program Mark (Refer to section 150 for more information).
60.2.3 Health Plan Identification Number (HPID)

Regulations published by CMS’ Office of E-Health Standards and Services (OESS) require plans to obtain a National Health Plan Identifier (CMS-0040-F). 77 Fed. Reg. 54664 (Sept. 5, 2012), as corrected 77 Fed. Reg. 60629 (Oct. 4, 2012). This identifier is an important element of both the NCPDP and WEDI standards and, when compliance with the HPID rule is required, will be used on the health plan identification cards that MAOs and Medicare cost-based contractors issue to plan members and the Part D identification cards issued by PDPs. Therefore, until compliance with the HPID rule is required, MA plans and Part D Sponsors are expected to comply with all of the ID card requirements found in the MMG and NCPDP/WEDI standards except for the HPID and machine-readable technology requirements (magnetic strip or bar code).

60.3 - Additional Materials Enclosed with Required Post-Enrollment Materials

42 CFR 422.111, 423.128

Unless otherwise directed, plan sponsors are permitted to enclose other materials related to benefits or plan operations in their post-enrollment packages (e.g., health education newsletters, Medication Therapy Management Program (MTMP) materials, mail service forms for Part D drugs, etc.). These materials: Must be distinctly separate (e.g., folded or different color pages) from the required document within the mailing envelope, may not include advertising materials (e.g., materials advertising additional products such as Medigap by the plan sponsor), and must comply with all relevant laws and regulations.

NOTE: Additional materials may not be included in the ANOC/EOC mailing unless otherwise specified.

60.4 - Directories

42 CFR 422.111(b)(3)(i), 422.111(e), 423.128(b)(5), 422.2260, 423.2260
**Plans/Part D Sponsors** must send a Provider and Pharmacy Directory (as applicable) at the time of enrollment and at least every three years after that. Additionally, **Plans/Part D Sponsors** must make directories available upon beneficiary request and ensure that websites contain current directories at all times.

MA-PD plans and section 1876 cost plans that offer prescription drug coverage may combine the model provider and model pharmacy directories in one document; this is not considered a modification to the model, as long as no other changes are made.

MA, MAPD, Part D, and 1876 cost plans must include information regarding all contracted network providers and/or pharmacies in **directories at the time of enrollment**. Directories must include information about the number, mix, and distribution of network providers and/or pharmacies. Plans may have directories for each of the geographic areas they serve, (e.g., metropolitan areas, surrounding county areas), provided that all directories together cover the entire service area.

**NOTE:** Employer/Union-only Group Waiver Plans (EGWP) can direct members to their employer for information on the available providers. Employer/Union-only Group Waiver Plans (EGWP) must comply with requirements to mail directories and post directories on their plan website that are generally applicable to all MA and PDP plans.

Plans must, and **Part D Sponsors are expected to**, make a good faith effort to provide written notice of termination of a contracted provider/pharmacy at least thirty (30) calendar days before the termination effective date to all members who regularly use the provider/pharmacy’s services. This is true whether the termination was for or without cause. When a contract termination involves a primary care professional, all members who are patients of that primary care professional must be notified.

In instances where significant changes to the provider/pharmacy network occur, the organization must send a special mailing immediately. In general, plans can define “significant changes” when determining whether a special mailing is necessary. However, CMS may also determine if a mailing is needed and direct plans to conduct such a mailing.

See section 100 for additional website requirements.

**60.4.1 - Pharmacy Directories**

42 CFR 423.128(b)(5), 423.128 (c)(1)(E)
Part D sponsors must provide information about the number, mix, and distribution (addresses) of network pharmacies from which enrollees may reasonably be expected to obtain covered Part D drugs. Part D sponsors may have pharmacy directories for each of the geographic areas they serve (e.g., metropolitan areas, surrounding county areas) provided that all directories together cover the entire service area.

*Part D sponsors must advise beneficiaries that they generally must use network pharmacies to receive plan coverage. If the network consists of preferred and non-preferred pharmacies, the sponsor must identify the preferred pharmacies and indicate that members may save on cost-sharing at preferred pharmacies. For more information, visit Chapter 5 of the Prescription Drug Benefit Manual, section 50.9 ([http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html](http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html)).*

The pharmacy directory must advise enrollees that they can either visit the website or call the plan for additional information and provide contact information on both the front and back cover pages.

### 60.4.1.1 – Information about Pharmacies

The pharmacy directory must:

- **Provide the pharmacy name, address, and phone number for all network pharmacies except:**
  - **For chain pharmacies**, sponsors have the option to provide a toll-free customer service number and a TTY number that a member can call to get the locations and phone numbers of the chain pharmacies nearest to their home. If a chain pharmacy does not have a toll-free number, Part D Sponsors should include a central number for the pharmacy chain. If the chain pharmacy does not have a central number for members to call, then plans must list each chain pharmacy location and phone number in the directory. If the chain pharmacy does not have a TTY number, Part D Sponsors are instructed to list the TRS Relay number 711. Part D Sponsors should not list their own customer service number as a pharmacy phone number or TTY number.

- **Identify type of pharmacy** (e.g., retail, mail order, long-term care, home infusion, I/T/U).

- **Identify which pharmacies provide an extended day supply of medications.**
• Part D sponsors may indicate which of their network pharmacies support e-prescribing in their pharmacy directories. Model directories that include e-prescribing information will still be considered model.

60.4.2 - Provider Directories

42 CFR 422.111(b)(3)(i), 422.111(e)

If a plan chooses to develop a non-model provider directory, the directory must contain all information and follow all instructions within the CMS model provider directory.

Plans may print a separate directory for each sub-network and disseminate this information to members in that particular sub-network. This practice is permissible as long as the directory clearly states that the lists of providers for other networks is available and will be provided to members upon request.

Plans may publish separate PCP and specialty directories provided both directories are given to enrollees at the time of enrollment.

60.5 - Formulary and Formulary Change Notice Requirements

42 CFR 423.120(b)(5), 423.128(b)(4), 423.2262(a), 423.2268(e)

Part D sponsors must provide a list of drugs, known as a formulary, to members at the time of enrollment and at least annually thereafter. While the print version of the formulary may be abridged, each Plan/Part D Sponsor must provide a comprehensive formulary on its website. See Chapter 6 of the Prescription Drug Benefit Manual for program guidance regarding formularies, change notices, and utilization management (http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html).

Part D sponsors are responsible for ensuring that each formulary marketed for a specific plan is consistent with the HPMS formulary file approved by CMS for that plan:

• Each covered drug must be displayed at the correct cost-sharing tier and with the approved utilization management edits, (i.e., prior authorization, step therapy or quantity limits).

• The formulary drug category and class must be consistent.
The applicable HPMS approved formulary file submission ID number, which is the HPMS formulary submission ID number of the approved formulary that is being marketed, and version number must be included.

Any drug adjudicated as a formulary drug at the point of sale must be included in the Part D sponsor’s marketing materials. This applies to drugs that exist on the approved HPMS formulary as well as drugs covered as Part D formulary enhancements to the approved formulary. Generally, these drugs are expected to relate to newly approved brand or generic drugs (including new formulations and strengths) that do not currently reside on the Formulary Reference File (FRF), but that would likely be added during subsequent FRF updates. These marketed formulary drug enhancements must be added to the HPMS formulary once the drugs are represented on the FRF.

A Part D sponsor may market enhancements (such as adding a newly available drug to the formulary), but not negative changes, to its formulary prior to receiving CMS approval. For more details, see Chapter 6 of the Prescription Drug Manual, section 30.3 (http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html).

In the event that a marketing discrepancy is identified, the Part D Sponsor must continue to cover the drug(s) at the more favorable cost share or with less restrictive utilization management for the affected enrollee (as defined in 42 CFR 423.100) through the end of the contract year.

60.5.1 - Abridged Formulary

42 CFR 423.128, 423.2262(c), 423.2268(e)

Part D sponsors are expected to provide abridged formulary document that include at a minimum:

- Plan Name on cover page
- “<Year> Formulary (List of Covered Drugs)” on cover page
- “PLEASE READ: THIS DOCUMENT CONTAINS INFORMATION ABOUT THE DRUGS WE COVER IN THIS PLAN” on cover page
- Advise members that the document includes a partial list of drugs; that members can visit the website or call the plan for a complete list of covered drugs.
• **Contact information on both the front and back cover pages.**

• The following statement: “Note to existing members: This formulary has changed since last year. Please review this document to make sure that it still contains the drugs you take.”

• The definition of a formulary as compared to an abridged formulary (42 CFR 423.4 defines “formulary” as “the entire list of Part D drugs covered by a Part D plan”).

• An explanation of how to use the Part D Sponsor’s formulary document.

• The following statement: “<Part D Plan Sponsor Name> covers both brand name drugs and generic drugs. A generic drug is approved by the FDA as having the same active ingredient as the brand name drug. Generally, generic drugs cost less than brand name drugs.

• A statement describing the Part D Sponsor’s general utilization management procedures.

• A statement that if a drug is not on the formulary, members may contact the Part D sponsor to obtain a list of alternatives or to apply for exceptions to coverage rules.

• An explanation of how to obtain an exception to the Part D Sponsor’s formulary, utilization management tools or tiered cost sharing

• A description of the Part D Sponsor’s drug transition policy.

• A statement that members may contact the Part D Sponsor for additional information or questions on the formulary.

• A chart (the CMS-approved formulary) of covered drugs organized by therapeutic category that includes at least two covered drugs for each therapeutic class. Exceptions to this include when only one drug exists in the category or class or in the case where two drugs exist in the category or class, and one is clinically superior to the other. The category or class names must be the same as those found on the CMS-approved Part D Sponsor formulary.

**NOTE:** While Part D Sponsors must ensure that at least two drugs per therapeutic class are included within the abridged formulary, Part D Sponsors have the option to include the therapeutic classes as subheadings within the abridged formulary, as this level of detail may
be confusing for beneficiaries. The row of the chart must include at least the three items described below.

- **Drug Name:** We suggest capitalizing brand name drugs, (e.g., LIPITOR) and listing generic drugs in lowercase italics, (e.g., penicillin). Part D Sponsors may include the generic name of a drug next to the brand name of the drug. The abridged formulary may only consist of drugs included on the CMS approved HPMS formulary. Formulary drug enhancements described in section 60.5 may not be included in the abridged formulary document.

- **Tier Placement:** Part D Sponsors that provide different levels of coverage for drugs depending on their tier should include a column indicating the drug’s tier placement and the corresponding tier label description (e.g., Generic or Preferred Brand), from the approved PBP. Part D Sponsors may also choose to include a column providing the co-payment or co-insurance amount for each tier.

- **Utilization Management (UM):** Part D Sponsors must indicate any applicable UM tools (e.g., prior authorization, step therapy, and quantity limit restrictions), for the drug. A description of the indicator used to describe the UM tools must be provided somewhere within the document (e.g., in footnotes). For example, a Part D Sponsor may choose to designate a prior authorization on a drug by placing an asterisk next to the name of the drug.

  **NOTE:** Every beneficiary must be able to tell by examining the formulary whether a specific drug is covered—including those drugs that have varying dosage forms or strengths at different formulary statuses, tier placements, and/or utilization management procedures (e.g., prior authorization, step therapy, quantity limit, or other restrictions). If there are differences in formulary status, tier placement, quantity limit, prior authorization, step therapy, or other restrictions for a drug based on its differing dosage forms or strengths, the formulary must clearly identify how it will treat the different formulations of that same drug.

- An index listing drugs in alphabetical order that directs the reader to the page containing complete information for that drug, (e.g., name,
tier placement, and utilization management strategy); this is because many beneficiaries may only know the name of their prescription and not its therapeutic class.

- **A symbol or abbreviation, as well as an explanation, to identify any utilization management restrictions, drugs that are available via mail-order, excluded drugs, free first fill drugs, limited access drugs, drugs covered in the coverage gap, and drugs covered under the medical benefit (for home infusion drugs only).**

- **Part D Sponsors may not include OTC drugs in the formulary table, but are expected to provide a separate list or table.**

### 60.5.2 - Comprehensive Formulary

42 CFR 423.4, [423.120](#), 423.128(c)(1)(v)

The comprehensive formulary must include the same information provided within the abridged formulary document, except that the comprehensive formulary must include the entire list of drugs covered by the Part D plan (*for instance, drugs covered as an enhancement*) and *would not inform* beneficiaries that they can obtain a comprehensive formulary by contacting the Part D Sponsor. Drugs adjudicated at the point of sale as formulary drugs that are not found on the CMS approved HPMS formulary must be included in the comprehensive formulary. This may include drugs that are not found on the CMS approved HPMS formulary as described in section 60.5.

### 60.5.3 - Changes to Printed Formularies

42 CFR [423.120(b)](#), 423.128(a)-(c)

Part D sponsors will be expected to update all impacted abridged and comprehensive printed formularies with any *applicable* formulary changes.

Part D sponsors may make any necessary formulary changes via errata sheets mailed to affected members. While Part D sponsors retain the flexibility to utilize other processes for notifying beneficiaries of non-maintenance changes to their printed formularies, CMS expects Part D sponsors to send out errata sheets with formulary changes no less than monthly to the extent that any negative formulary changes have occurred and that affected members will receive a hard copy of such changes (website
updates alone will not suffice). Errata sheets must include a statement explaining that the plan will continue to cover the drugs in question for enrollees taking the drug at the time of change for the remainder of the plan year as long as the drug continues to be medically necessary and prescribed by the member’s physician and was not removed for safety reasons. Refer to the Prescription Drug Manual, Chapter 6, sections 30.3.3.3 and 30.3.4.1. This requirement does not extend to mid-year maintenance changes defined in section 30.3.3.2 of the Prescription Drug Manual (http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html). Changes to previously printed formularies resulting from mid-year maintenance changes may be made at the time of the next printing. This is not a substitute for the required advance 60 days’ notice to affected beneficiaries.

**60.5.4 - Other Formulary Documents**

42 CFR 423.128(b)(4)

In addition to comprehensive and abridged formularies, Part D Sponsors may choose to develop a formulary that lists all of their preferred drugs or is tailored to individuals with specific chronic conditions, as long as these items supplement the two required documents rather than replace them and include the disclaimer in section 50.17.

**60.5.5 - Provision of Notice to Beneficiaries Regarding Formulary Changes**

42 CFR 423.120(b)(5)

Part D Sponsors must provide at least sixty (60) days’ notice or a 60-day supply with notice to affected beneficiaries before removing a Part D drug from the Part D Sponsor’s formulary, (e.g., adding prior authorization, quantity limits, step therapy or other restrictions on a drug), or moving a drug to a higher cost-sharing tier. **Sixty day notice must be provided in writing unless a beneficiary has affirmatively elected to receive electronic notice. In such instances, Part D Sponsors can determine the most effective means by which to communicate the 60-day notice of formulary change information to beneficiaries, including electronic means.** Part D sponsors should refer to *Chapter 6 of the Prescription Drug Manual*, section 30.3.4 (http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html).
60.5.6 - Provision of Notice to Other Entities Regarding Formulary Changes

42 CFR 423.120(b)(5)

Prior to removing a covered Part D drug from its formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug, a Part D sponsor must provide at least sixty (60) days’ notice to CMS, State Pharmaceutical Assistance Programs, entities providing other prescription drug coverage, authorized prescribers, network pharmacies, and pharmacists prior to the date such change becomes effective. Part D sponsors should refer to Prescription Drug Benefit Manual, Chapter 6, section 30.3.4.2 of (http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html).

60.6 - Part D Explanation of Benefits

42 CFR 423.128(e)

Part D sponsors must ensure that enrollees who utilize their prescription drug benefits in a given month receive their Explanation of Benefits (EOB) by the end of the month following the month in which they utilized their prescription drug benefits.

If a Part D Sponsor chooses to develop a non-model EOB, the EOB must contain all information and follow all instructions within the CMS model.

NOTE: An EOB does not need to be generated by the Part D Sponsor when retroactive changes apply to prior benefit year prescription fills. For example, a plan’s final EOB for CY 2013 must be sent in January 2014, for December 2013 fills. Once the final EOB for CY 2013 has been sent, sponsors are not required to send an EOB for any retroactive adjustments for prior benefit year fills (prescription fills made prior to December 31, 2013).

60.7 - Annual Notice of Change (ANOC) and Evidence of Coverage (EOC)

42 CFR 422.111(a)(3), 422.111(d)(2), 423.128 (a)(3)

Except as outlined below, all Plans/Part D Sponsors must send the ANOC/EOC for member receipt by September 30 of each year. New enrollees with an effective date of October 1, November 1, or December 1, should receive both an EOC for the current contract year and an ANOC/EOC
for the upcoming contract year. New enrollees with an effective date of January 1 or later must receive an EOC for the contract year of coverage. Additional materials may not be included in the ANOC/EOC mailing unless otherwise specified. Stand-alone EOC’s do not need to be resubmitted in HPMS.

D-SNPs may choose to send the ANOC for member receipt by September 30 and the EOC for member receipt by December 31. D-SNPs that choose this option must also send an SB with the ANOC. D-SNPs that send a combined ANOC/EOC for member receipt by September 30 are not required to send an SB to current members.

Section 1876 cost plans that do not offer Part D benefits must send the ANOC/EOC for member receipt by December 1 of each year.

Employer/union group plans must send the ANOC and EOCs for member receipt no later than fifteen (15) days before the beginning of the employer/union sponsor’s open enrollment period (refer to Chapter 9 of the Medicare Managed Care Manual and Chapter 12 of the Prescription Drug Benefit Manual).

To ensure that Plans/Part D Sponsors are mailing their ANOC/EOC timely, Plans/Part D Sponsors must indicate the actual mail date in HPMS within 15 days of mailing. Plans/Part D Sponsors that mail in waves should enter the actual date for each wave. For instructions on meeting this requirement, refer to the Update Material Link/Function section of the Marketing Review Users Guide in HPMS.

Plans/Part D Sponsors must use the standardized ANOC/EOC errata model to correct any errors and must submit the errata model for review via HPMS. Plans/Part D Sponsors must ensure corrected versions of the EOC are on their websites. Plans/Part D Sponsors are not required to post the ANOC or the ANOC/EOC errata model on websites.

60.8 – Other Mid-Year Changes Requiring Enrollee Notification
42 CFR 422.111(d)(3)

Plans must notify enrollees of a change in coverage at least 30 days before the intended effective date of the change. When a National Coverage Determination (NCD) or legislative benefit change takes effect mid-year, Plans must ensure access to the NCD item or service by furnishing or arranging for the service as of the effective date of the NCD or legislative benefit change. This requirement is applicable regardless of whether
provider payment is the responsibility of the plan or Original Medicare, as described in detail in the Medicare Managed Care Manual, Pub 100-16, Chapter 4, section 90.4 (General Rules for NCDs). All NCDs are effective on the date the decision memorandum is released, (i.e., the same as the date it is posted to the National Coverage Analysis page of the Medicare Coverage Center website at http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?list_type=nca). Plans are required to notify all enrollees of the change in coverage. If payment for the covered service is the responsibility of Original Medicare, the enrollee must be told that he or she can receive this service from any Medicare provider.

Plans may use a variety of mechanisms to inform enrollees of the change in coverage. At a minimum, the notice must be provided on the plan website within 30 days, with subsequent publication in the next plan newsletter or other mass mailing not specifically dedicated to the NCD notification. Alternatively, Plans may choose to provide this information to enrollees in a targeted way, such as via email or one-time mailings specific to this issue. NCD communications do not need to be submitted in HPMS.

For more information on NCD and legislative benefit changes, please see Chapter 4 of the Medicare Advantage manual.

70 - Promotional Activities, Rewards, Incentives, Events and Outreach

70.1 - Promotional Activities

42 CFR 422.2268, 423.2268

Generally, promotional activities are designed to attract the attention of prospective members and/or encourage retention of current members. In addition to the guidance on nominal gifts, any promotional activities or items offered by Plans/Part D Sponsors:

- Must have only nominal value (i.e., be worth $15) based on the fair market value of the item or less, with a maximum aggregate of $50 per person, per year;
- Must be offered to all people regardless of enrollment and without discrimination;
- Must not be items that are considered a health benefit, (e.g., a free checkup);
• Must not be tied directly or indirectly to the provision of any other covered item or service.

Note: Plans/Part D Sponsors should track and document items given to current members. Plans/Part D Sponsors are not required to track pre-enrollment promotional items on a per person basis; however, they may not willfully structure pre-enrollment activities with the intent to give people more than $50 per year.

70.1.1 - Nominal Gifts

42 CFR 422.2268 (a) and (b), 423.2268 (a) and (b)

Plans/Part D Sponsors may offer gifts to potential enrollees as long as the gifts are of nominal value and provided regardless of enrollment.

The following rules must be followed when providing gifts:

• If a nominal gift is one large gift (e.g., a concert, raffle, drawing), the total fair market value must nominal per person (i.e., be $15 or less when it is divided by the estimated attendance). For planning purposes, anticipated attendance may be used, but must be based on actual venue size, response rate, or advertisement circulation.

• Nominal gifts may not be in the form of cash or other monetary rebates, even if their worth is less than $15. Cash gifts include charitable contributions made on behalf of potential enrollees, and those gift certificates and gift cards that can be readily converted to cash, regardless of dollar amount.

NOTE: Plans/Part D Sponsors should refer to the Office of Inspector General’s website regarding advisory opinions on gift cards.

70.2 - Rewards and Incentives

42 CFR 422.2268, 423.2268

Rewards and incentives may be offered to current members for Medicare covered preventive services that have a zero dollar cost-share. Please see below for links to information about Medicare covered preventive services at zero dollar cost-share. Plans/Plan sponsors are not bound by the $50 maximum when structuring reward and incentive programs.

Reward and incentive items must:
• Be offered in connection with the whole service, (e.g., a plan sponsor may offer a reward for participating in the smoking cessation program but not offer multiple awards for attending each smoking cessation class.);

• Be offered to all eligible members without discrimination;

• Have a monetary cap not to exceed $15 per reward item (based on the retail value of the item);

• Be tracked and documented during the contract year;

• Comply with all relevant fraud and abuse laws, including, when applicable, the anti-kickback statute and civil monetary penalty prohibiting inducements to beneficiaries; and

Additionally, reward and incentive items cannot:

• Be items that are considered a health benefit, (e.g., a free checkup);

• Be items that consist of lowering or waiving co-pays;

• Be offered in the form of cash or other monetary rebates;

• Be used to target potential enrollees (e.g., used in pre-enrollment advertising, marketing, or promotion of the plan);

• Be tied directly or indirectly to the provision of any other covered item or service.

Please refer to the resources below for the most current listing of Medicare covered preventive services with a zero dollar cost-share.

• Coverage email updates page, sorted by year - https://www.cms.gov/CoverageGenInfo/EmailUpdates/list.asp#TopOfPage

• Main Coverage Center page - https://www.cms.gov/center/coverage.asp

• Sign-up for the coverage listserv - https://www.cms.gov/InfoExchange/03_listserv.asp#TopOfPage
70.3 - Exclusion of Meals as a Nominal Gift

Plans/Part D Sponsors may not provide or subsidize meals at sales/marketing events.

Plans/Part D Sponsors are, however, allowed to provide refreshments and light snacks. Plans/Part D Sponsors should use their best judgment on the appropriateness of food products provided and should ensure that items provided could not be reasonably considered a meal and/or that multiple items are not being “bundled” and provided as if a meal.

Meals may be provided at educational events, provided the event meets CMS’ strict definition of an educational event, and complies with the nominal gift requirement in section 70.1.1.

70.4 - Unsolicited E-mail Policy

E-mails are direct contact by the Plan/Part D Sponsor. A Plan/Part D Sponsor may not send e-mails unless an individual has agreed to receive those e-mails. Furthermore:

- Plans/Part D Sponsors are prohibited from renting and purchasing e-mail lists to distribute information about MA, PDP, or section 1876 cost plans.
- Plans/Part D Sponsors may not e-mail individuals at e-mail addresses obtained through friends or referrals.
- Plans/Part D Sponsors must provide an opt-out process for enrollees to no longer receive e-mail communications.

70.5 - Marketing through Unsolicited Contacts

In general, Plans/Part D Sponsors may not market through unsolicited direct contact, including but not limited to:
• Door-to-door solicitation, including leaving information such as a leaflet or flyer at a residence or car.

• Approaching beneficiaries in common areas, (e.g., parking lots, hallways, lobbies, sidewalks, etc.).

• Telephonic or electronic solicitation, including leaving electronic voicemail messages or text messaging.

   NOTE: Agents/brokers who have a pre-scheduled appointment which becomes a “no-show” may leave information at the no-show beneficiary/individual’s residence.

The prohibition on marketing through unsolicited contacts does not extend to mail and other print media (e.g., advertisements, direct mail).

In addition, permission given to be called or otherwise contacted must be event-specific, and may not be treated as open-ended permission for future contacts.

70.6 - Telephonic Contact

42 CFR 422.2268(d)-(f), 423.2268(d)-(f)

Agents may contact their own clients and Plans/Part D Sponsors may contact current members at any time to discuss plan business.

Prohibited telephonic activities include, but are not limited to, the following:

• Bait-and-switch strategies - making unsolicited calls about other business as a means of generating leads for Medicare plans.

• Calls based on referrals. If an individual would like to refer a friend or relative to an agent or Plan/Part D Sponsor, the agent or Plan/Part D Sponsor may provide contact information such as a business card that the individual may give to the friend or family member. Otherwise, as instructed in section 30.9, a referred individual needs to contact the plan or agent/broker directly.

• Calls to former members who have disenrolled, or to current members who are in the process of voluntarily disenrolling (except as permitted below), to market plans or products. Members who are voluntarily disenrolling from a plan should not be contacted for sales purposes or be asked to consent in any format to further sales contacts.
• Calls to beneficiaries who attended a sales event, unless the beneficiary gave express permission at the event for a follow-up call (including documentation of permission to be contacted).

• Calls to beneficiaries to confirm receipt of mailed information, except as permitted below.

Plans/Part D Sponsors may do the following:

• Call beneficiaries who submit enrollment applications to conduct quality control and agent/broker oversight activities.

• Call their members or use third-parties to contact their current members. Examples of allowed contacts include, but are not limited to, calls to members aging-in to Medicare from commercial products offered by the same sponsoring organization and calls to an organization’s existing Medicaid plan members to talk about its Medicare products.

• Call members to promote other Medicare plan types, (e.g., sponsors may contact their PDP members to promote their MA-PD offerings; sponsors that are also Medigap issuers may market their MA, PDP, or cost plan products to their Medigap customers), and discuss plan benefits.

• Call their members to discuss educational events.

• Call their members to conduct normal business related to enrollment in the plan, including calls to members who have been involuntarily disenrolled to resolve eligibility issues.

• Call former members after the disenrollment effective date to conduct disenrollment surveys for quality improvement purposes. Disenrollment surveys may be done by phone or sent by mail, but neither calls, nor mailings, may include sales or marketing information.

• Under limited circumstances and subject to advance approval from the appropriate CMS Regional Office, call LIS-eligible members that a plan is prospectively losing due to reassignment to encourage them to remain enrolled in their current plan.

• Call individuals who have expressly given permission for a plan or sales agent to contact them, for example, by filling out a business reply card (BRC) or asking a customer service representative (CSR) to have an agent contact them. This permission applies only to the entity
from which the individual requested contact, for the duration of that transaction, for the scope of product, (e.g., MA-PD plan or PDP), previously discussed or indicated in the reply card.

- Return phone calls or messages, as these are not unsolicited.
- **Call** their members via an automated telephone notification to inform them about general plan information such as the AEP dates, availability of flu shots, upcoming plan changes, and other important plan information.

### 70.7 - Outbound Enrollment and Verification Requirements

42 CFR 422.2272(b), 423.2272(b)

*All Plans/Part D Sponsors are required to maintain a system to ensure that individuals requesting enrollment understand the plan rules. As part of that system, Plans/Part D Sponsors are expected to conduct outbound enrollment and verification (OEV) calls for enrollment requests in which an independent or employed agent/broker provided plan-specific information to the individual, thus influencing the individual’s plan choice and/or assisting in a subsequent enrollment request. This includes any enrollment request submitted to the plan by an agent/broker or those enrollment requests including indication of broker involvement, such as either a name, phone number or other contact information for the agent/broker. It is important for the Plan’s/Part D Sponsor’s sales staff to obtain from the individual the best phone number to be used for verification and to provide a description of the enrollment verification process to the applicant during the enrollment request process.*

OEV calls **are expected to** be made to the applicant after the sale has occurred; they **are not expected to** be made at the point of sale. The **Plan/Part D Sponsor is expected to** ensure that the verification calls are not conducted by sales agents and that sales agents are not physically present with the applicant at the time of the verification call. **Plans/Part D Sponsors** may not use automated calling technologies to conduct these outbound calls; CMS expects OEV calls to be interactive.

The following agent/broker-**assisted** enrollments are excluded from the OEV call project:

- Enrollments into employer or union sponsored plans
• Plan-to-plan switches within a parent organization involving the same plan type or product type (e.g., PFFS to PFFS, D-SNP to D-SNP, PDP to PDP).

Plans/Part D Sponsors are expected to make a minimum of three documented attempts to contact the applicant by telephone within fifteen (15) calendar days of receipt of the enrollment request; the first two attempts are expected to be made within the first 10 days. If the enrollment request is incomplete upon initial receipt, Plans/Part D Sponsors are expected to concurrently conduct the OEV process while attempting to obtain the information needed to complete the enrollment request.

Plans/Part D Sponsors are not expected to delay processing the enrollment request (including, but not limited to, activation of benefits and submission of enrollment request data to CMS) while completing the OEV process. If the Plan/Part D Sponsor does not have all the information required to complete the enrollment process at the time of the OEV call, it should obtain that information during the call. If the Plan/Part D Sponsor makes a determination to deny an enrollment request prior to completing the OEV process, it is expected to discontinue the OEV process. If the Plan/Part D Sponsor receives a transaction reply report (TRR) from CMS rejecting the enrollment prior to completing the OEV process, it is expected to suspend the OEV process but must resume if the Plan/Part D Sponsor determines the rejection to be erroneous, such that the enrollment will be resubmitted to CMS.

Plans/Part D Sponsors that are unable to successfully complete the outbound verification on the second attempt are expected to send the applicant an enrollment verification letter, in addition to any other required enrollment notice, such as enrollment acknowledgement and confirmation notices, and in addition to making the third documented outbound verification call attempt within the 15 day timeframe. CMS expects that both the telephone script and the enrollment verification letter will inform beneficiaries that they are expected to notify the Plan/Part D Sponsor of their intent to cancel the processing of their enrollment within seven (7) calendar days from the date of the letter or phone call or by the day before the enrollment effective date, whichever is later. For AEP enrollment requests, the cancellation date is December 31. (For more details on the election periods that apply in this situation, see Chapter 2 and Chapter 3 section 30 http://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/)

70.8 - Educational Events
42 CFR 422.2268(l), 423.2268(l)
An educational event is an event designed to inform Medicare beneficiaries about Medicare Advantage, Prescription Drug or other Medicare programs and does not include marketing, (i.e., the event sponsor does not steer, or attempt to steer, potential enrollees toward a specific plan or limited number of plans). Educational events may be hosted by the Plan/Part D Sponsor or an outside entity and are held in a public venue. These events cannot be held at in-home or one-on-one settings.

Educational events may not include any sales activities such as the distribution of marketing materials or the distribution or collection of plan applications. Educational events must be explicitly advertised as “educational,” otherwise, they will be considered by CMS as sales/marketing events.

The intent of this guidance is not to preclude Plans/Part D Sponsors from educating beneficiaries about their products; rather, it is to ensure that events that are advertised as “educational” comply with CMS’ requirements. More specifically, Plans/Part D Sponsors may provide education at a sales or marketing event, but may not market or sell at an educational event.

Materials distributed or made available at an educational event must be free of plan-specific information, (including plan-specific premiums, co-payments, or contact information), and any bias toward one plan type over another.

The following are examples of acceptable materials and activities by Plans/Part D Sponsors or their representatives at an educational event:

- A banner with the plan name and/or logo displayed.
- Promotional items, including those with plan name, logo, and toll-free customer service number and/or website. Promotional items must be free of benefit information and consistent with CMS’ definition of nominal gift.
- Respond to questions asked at an educational event.

In order to ensure that the educational event does not include any sales activities and is not considered by CMS to be a sales/marketing event, Plans/Part D Sponsors or their representatives should not:

- Discuss plan-specific premiums and/or benefits.
- Distribute plan specific materials.
• Distribute or display business reply cards, scope of appointment forms, enrollment forms, or sign-up sheets.

• Set up individual sales appointments or get permission for an outbound call to the beneficiary.

• Attach business cards or plan/agent contact information to educational materials, unless requested by the beneficiary.

• Advertise an educational event and then have a marketing/sales event immediately following in the same general location, (e.g., same hotel).

NOTE: If Plans/Part D Sponsors hold member-only educational events, they may not conduct enrollment or sales activities at these events. Additionally, any marketing of these events must be done in a way that reasonably targets only existing members, (e.g., direct mail flyers), and not the mass marketplace, (e.g., radio or newspaper ad).

70.9 - Marketing/Sales Events

42 CFR 422.2268, 423.2268

Marketing/sales events are events designed to steer, or attempt to steer, potential enrollees toward a plan or limited set of plans. At marketing/sales events, plan representatives may discuss plan specific information and collect applications.

There are two main types of marketing/sales events: formal and informal.

Formal marketing/sales events are typically structured in an audience/presenter style with a sales person or plan representative formally providing specific Plan/Part D Sponsor information via a presentation on the products being offered.

Informal marketing/sales events are conducted with a less structured presentation or in a less formal environment. They typically utilize a table, kiosk or a recreational vehicle (RV) that is manned by a Plan/Part D Sponsor representative who can discuss the merits of the plan’s products.

• Plans/Part D Sponsors must submit all sales scripts and presentations for approval to CMS prior to their use during the marketing/sales event.

At a marketing/sales event, Plans/Part D Sponsors may not:
• Conduct health screening or other like activities that could give the impression of “cherry picking.”

• Require beneficiaries to provide any contact information as a prerequisite for attending the event. This includes requiring an email address or any other contact information as a condition to RSVP for an event online or through mail. Plans should clearly indicate on any sign-in sheets that completion of any contact information is optional.

• Use personal contact information obtained to notify individuals of raffle or drawing winnings for any other purpose.

70.9.1 – Notifying CMS of Scheduled Marketing Events

42 CFR 422.2268, 423.2268, 422.504(f)(2), 423.505(f)(2)

Plans/Part D Sponsors must notify CMS of all formal and informal marketing/sales events via HPMS prior to advertising the event or seven (7) calendar days prior to the event’s scheduled date, whichever is earlier. Changes to marketing/sales events, (e.g., cancellations and room changes), should be updated in HPMS at least forty-eight (48) hours prior to the scheduled event.

Cancellations - Notification of cancelled sales events should be made, whenever possible, more than forty-eight (48) hours prior to the originally scheduled date and time of the event. Plans/Part D Sponsors should notify beneficiaries of event cancellations according to the following requirements. (The method used to notify beneficiaries of the cancellation may vary depending on the individual plan’s circumstances.)

1. If a sales event is cancelled less than forty-eight (48) hours before its originally scheduled date and time, the Plan/Part D Sponsor must:

   • Cancel the event in HPMS.

   • Ensure a representative is present at the site of the cancelled sales event, at the time that the event was scheduled to occur, to inform attendees of the cancellation and distribute information about the Plan/Part D Sponsor. The representative should remain on site at least 15 minutes after the scheduled start of the event.

   NOTE: If the event was cancelled due to inclement weather, a representative is not required to be present at the site.
2. If a sales event is cancelled more than forty-eight (48) hours before the originally scheduled date and time, the Plan/Part D Sponsor must:

- Cancel the event in HPMS.
- Notify beneficiaries of the cancellation by the same means the Plan/Part D Sponsor used to advertise the event. A representative is not required to be present at the site.

Example of reasonable notification:

If an announcement of the sales event was made in the newspaper, then it is reasonable to announce the cancellation through the same newspaper.

70.9.2 - Personal/Individual Marketing Appointments

42 CFR 422.2268(f)-(h), 423.2268(f)-(h)

Personal/individual marketing appointments typically take place in the beneficiary’s home; however, these appointments can also take place in other venues such as a library or coffee shop. Appointments must follow the scope of appointment guidance (See section 70.9.3).

All one-on-one appointments with beneficiaries are considered sales/marketing events. However, one-on-one appointments are not entered into the marketing events module.

The Plan’s/Part D Sponsor’s representative may not do the following:

- Discuss plan options that were NOT agreed to by the beneficiary.
- Market non-health care related products (such as annuities or life insurance).
- Ask a beneficiary for referrals.
- Solicit/accept an enrollment request (application) for a January 1st effective date prior to the start of the Annual Enrollment Period (AEP) unless the beneficiary is entitled to another enrollment period.

70.9.3 - Scope of Appointment

42 CFR 422.2262, 422.2268(g) and (h), 423.2262 423.2268 (g) and (h)
When conducting marketing activities, a Plan/Part D Sponsor may not market any health care related product during a marketing appointment beyond the scope that the beneficiary agreed before the meeting with that individual. The Plan/Part D Sponsor must document the scope of the agreement before the appointment. Distinct lines of plan business include MA, PDP and Cost Plan products. If a Plan/Part D Sponsor would like to discuss additional products during the appointment that the beneficiary did not agree to discuss in advance, they must document it 48-hours in advance, when practicable. If it is not practicable and the beneficiary requests to discuss other products, the Plan/Part D Sponsor must document a second scope of appointment for the additional product type to continue the marketing appointment.

To further clarify the requirements around documentation:

- The documentation can be in writing, in the form of a signed agreement by the beneficiary, or a recorded oral agreement. Plans/Part D Sponsors are allowed and encouraged to use a variety of technological means to fulfill the scope of appointment requirement, including conference calls, fax machines, designated recording line, pre-paid envelopes, and e-mail, etc.

- A beneficiary may set a scope of appointment at a marketing/sales event for a future appointment.

NOTE: All business reply cards (BRC) used for documenting beneficiary scope of appointment or agreement to be contacted must be submitted to CMS for review and approval. Additionally, Plans/Part D Sponsors should include a statement on the BRC informing the beneficiary that a sales person may call as a result of their returning a BRC.

NOTE: Marketing/sales events, as defined in section 70.9 do not require documentation of beneficiary agreement.

70.9.4 - Beneficiary Walk-ins to a Plan or Agent/Broker Office or Similar Beneficiary-Initiated Face-to-Face Sales Event

42 CFR 422.2268(g) and (h), 423.2268 (g) and (h)

In instances where a beneficiary visits a Plan/Part D Sponsor or an agent/broker office on his/her own accord, the Plan/Part D Sponsor or agent/broker must document the scope of appointment prior to discussing MA, PDP, or cost plans.
70.10 - PFFS Plan Provider Education and Outreach Programs

42 CFR 422.114

PFFS Plans *should* conduct effective outreach to providers to help them understand how PFFS plans work and to overcome any resistance that may be particularly caused by concerns about the timeliness and accuracy of payments. They *should* clearly inform providers about how to obtain their terms and conditions of payment, how to get payment or coverage questions quickly answered, and how to appeal payment decisions.

70.10.1 - PFFS Plan Terms and Conditions of Payment Contact and Website Fields in HPMS

42 CFR 422.114

HPMS allows PFFS plans to directly provide CMS with their plan terms and conditions of payment contact and website information. All PFFS Plans must complete the data entry for these fields in HPMS and update the information as needed *in order for CMS to make the determinations required under 42 CFR 422.114.*

The “PFFS Terms and Conditions of Payment Contact for Public website” field should be populated with the contact that will facilitate provider access to the MAO’s PFFS plan terms and conditions of payment. Use the following navigation path in HPMS to enter the appropriate information for this new contact: HPMS Homepage > Contract Management > Contract Management > Select a Contract Number > Contact Data.

The “PFFS Terms and Conditions of Payment website” field should be populated with the web address for where the Plan maintains its PFFS plan terms and conditions of payment. Use the following navigation path in HPMS to enter the appropriate information for this new web address: HPMS Homepage > Contract Management > Basic Contract Management > Select a Contract Number > Org. Marketing Data.

70.11 - Marketing in the Health Care Setting

42 CFR 422.2268(j) and (k), 423.2268 (j) and (k)

*Plans/Part D Sponsors* and providers with whom they have a relationship(contractual or otherwise) that assist beneficiaries with plan selection should ensure that provider assistance results in plan selection that is always in the best interest of the beneficiary. Providers that have entered
into co-branding relationships with Plans/Part D Sponsors must also follow these guidelines.

Plans/Part D Sponsors may not conduct sales activities in healthcare settings except in common areas. Common areas where marketing activities are allowed include areas such as hospital or nursing home cafeterias, community or recreational rooms, and conference rooms. If a pharmacy counter area is located within a retail store, common areas would include the space outside of where patients wait for services from or interact with pharmacy providers and obtain medications.

Plans/Part D Sponsors are prohibited from conducting sales presentations, distributing and accepting enrollment applications, and soliciting Medicare beneficiaries in areas where patients primarily receive health care services or are waiting to receive health care services. These restricted areas generally include, but are not limited to, waiting rooms, exam rooms, hospital patient rooms, dialysis center treatment areas (where patients interact with their clinical team and receive treatment), and pharmacy counter areas (where patients interact with pharmacy providers and obtain medications). The prohibition against conducting marketing activities in health care settings extends to activities planned in health care settings outside of normal business hours.

Plans/Part D Sponsors are only permitted to schedule appointments with beneficiaries residing in long-term care facilities (including nursing homes, assisted living facilities, board and care homes, etc.) upon request by the beneficiary. Plans/Part D Sponsors may use providers to make available and/or distribute plan marketing materials as long as the provider and/or the facilities distributes or makes available Plan/Part D Sponsor marketing materials for all plans with which the provider participates. CMS does not expect providers to proactively contact all participating plans; rather, if a provider agrees to make available and/or distribute plan marketing materials they should do so if the Plan/Part D Sponsor indicates the provider must accept future requests from other Plans/Part D Sponsors with which they participate. Plans/Part D Sponsors may also provide materials for providers to display posters or other materials in common areas such as the provider’s waiting room. Additionally, Plans/Part D Sponsors may provide materials to long-term care facilities to provide materials in admission packets announcing all plan contractual relationships.

Long term care facility staff are permitted to provide residents that meet the I-SNP criteria an explanatory brochure for each I-SNP with which the facility contracts. The brochure can explain about the qualification criteria and the benefits of being enrolled in an I-SNP. The brochure may have a reply card.
or telephone number for the resident or responsible party to call to agree to a meeting or request additional information.

70.11.1 - Provider-Based Activities

42 CFR 422.2268(j), 423.2268(j)

CMS is concerned with Plans/Part D Sponsors engaging in provider marketing activities because:

- Providers may not be fully aware of all plan benefits and costs.
- Providers may confuse the beneficiary if the provider is perceived as acting as an agent of the plan versus acting as the beneficiary’s provider.
- Providers may face conflicting incentives when acting as a Plan/Part D Sponsor representative.

To the extent that a provider can assist a beneficiary in an objective assessment of his/her needs and potential options to meet those needs, they may do so. Plans/Part D Sponsors may allow contracted providers to engage in discussions with beneficiaries should a beneficiary seek advice. However, Plans/Part D Sponsors must ensure that contracted providers are aware of their responsibility to remain neutral when assisting with enrollment decisions and do not:

- Offer scope of appointment forms.
- Accept Medicare enrollment applications.
- Make phone calls or direct, urge or attempt to persuade beneficiaries to enroll in a specific plan based on financial or any other interests of the provider.
- Mail marketing materials on behalf of Plans/Part D Sponsors.
- Offer anything of value to induce plan enrollees to select them as their provider.
- Offer inducements to persuade beneficiaries to enroll in a particular plan or organization.
- Conduct health screening as a marketing activity.
• Accept compensation directly or indirectly from the plan for beneficiary enrollment activities.

• Distribute materials/applications within an exam room setting.

*Plans/Part D Sponsors may allow contracted providers to:

• Provide the names of *Plans/Part D Sponsors* with which they contract and/or participate (See section 70.11.2 for additional information on provider affiliation).

• Provide information and assistance in applying for the LIS.

• Make available and/or distribute plan marketing materials.

• Refer their patients to other sources of information, such as SHIPs, plan marketing representatives, their State Medicaid Office, local Social Security Office, CMS’ website at [http://www.medicare.gov/](http://www.medicare.gov/) or 1-800-MEDICARE.

• Share information with patients from CMS’ website, including the “Medicare and You” Handbook or “Medicare Options Compare” (from [http://www.medicare.gov](http://www.medicare.gov)), or other documents that were written by or previously approved by CMS.

**70.11.2 - Provider Affiliation Information**

42 CFR 422.2262(a), 422.2268, 423.2262(a), 423.2268

*Plans/Part D Sponsors may allow contracted providers to* announce new or continuing affiliations for specific *Plans/Part D Sponsors* through general advertising, (e.g., radio, television, websites).  *Plans may allow contracted providers to* make new affiliation announcements within the first 30 days of the new contract agreement.  *Plans may allow contracted providers to announce to patients once, through direct mail, e-mail, or phone, a new affiliation which names only one Plan/Part D Sponsor. Plans with continuing affiliations may continue to use contracted providers to distribute written materials only if the Plan ensures that contracted providers include a list of all plans with which the provider contracts in additional direct mail and or email communications.*

Any affiliation communication materials that describe plans in any way, (e.g., benefits, formularies), must be approved by CMS and must include the appropriate disclaimer (refer to section 50).  Multiple *Plans/Part D Sponsors* can either have one *Plan/Part D Sponsor* submit the material on behalf of all
the other Plans/Part D Sponsors, or have the piece submitted and approved by CMS prior to use for each Plan/Part D Sponsor mentioned. Materials that indicate the provider has an affiliation with certain Plans/Part D Sponsors and that only list plan names and/or contact information do not require CMS approval.

70.11.3 - SNP Provider Affiliation Information

42 CFR 422.2268, 423.2268

Plans/Part D Sponsors may allow contracted providers to feature SNPs in a mailing announcing an ongoing affiliation. This mailing may highlight the provider’s affiliation or arrangement by placing the SNP affiliations at the beginning of the announcement and may include specific information about the SNP and must include the appropriate disclaimer (refer to section 50). This includes providing information on special plan features, the population the SNP serves, or specific benefits for each SNP. The announcement must list all other SNPs with which the provider is affiliated.

70.11.4 - Comparative and Descriptive Plan Information

42 CFR 422.2268, 423.2268

Plans/Part D Sponsors may allow contracted providers to distribute printed information provided by a Plan/Part D Sponsor to their patients comparing the benefits of all of the different plans with which they contract. Materials must include the appropriate disclaimer (refer to section 50). Materials may not “rank order” or highlight specific plans and should include only objective information. Such materials must have the concurrence of all Plans/Part D Sponsors involved in the comparison and must be approved by CMS prior to distribution (i.e., these items are not be subject to File & Use). The Plans/Part D Sponsors must determine a lead Plan to coordinate submission of these materials to CMS for review (refer to section 90.2 for more information on submission of marketing materials).

70.11.5 - Comparative and Descriptive Plan Information Provided by a Non-Benefit/Non-Health Service Providing Third-Party

42 CFR 422.2268, 423.2268

Plans/Part D Sponsors may allow contracted providers to distribute printed information comparing the benefits of different Plans/Part D Sponsors (all or a subset) in a service area when the comparison is done by an objective third party, (e.g., SHIPs, State agency or independent research
organizations that conduct studies). For more information on non-benefit/non-health service providing third party providers, refer to section 40.8.3.

80 - Telephonic Activities and Scripts

80.1 - Customer Service Call Center Requirements

42 CFR 422.111(h)(1), 423.128(d)(1)

*Plans/Part D Sponsors* must operate a toll-free call center for both current and prospective enrollees seven (7) days a week, at least from 8:00 A.M. to 8:00 P.M., according to the time zones for the regions in which they operate. Current and prospective enrollees must be able to speak with a live customer service representative. *Plans/Part D Sponsors* may use alternative technologies on Thanksgiving and Christmas Day. For example, a *Plan/Part D Sponsor* may use an interactive voice response system or similar technologies to provide the required information listed below, and/or allow a beneficiary to leave a message in a voice mail box. A customer service representative must then return the call in a timely manner, no more than one business day later.

NOTE: From February 15 to September 30, *Plans/Part D Sponsors* may use alternative technologies on Saturdays, Sundays, and Federal holidays.

Call centers must meet the following operating standards:

- Provide information in response to inquiries outlined in section 80.2-80.4.
- Follow an explicitly defined process for handling customer complaints.
- *Provide interpreter service to all non-English speaking and limited English proficient beneficiaries.*
- Inform callers that interpreter services are “free.”
- *Provide TTY service to all hearing impaired beneficiaries.*
- Limit average hold time to two (2) minutes. The average hold time is defined as the time spent on hold by the caller following the interactive
voice response (IVR) system, touch tone response system, or recorded greeting and before reaching a live person.

- Answer eighty (80) percent of incoming calls within thirty (30) seconds.
- Limit the disconnect rate of all incoming calls to five (5) percent.

For Pharmacy Technical Help or Coverage Determinations and Appeals Call Center requirements refer to Appendix 4.

**80.2 – Requirements for Informational Scripts**

42 CFR 422.111(c), 422.2262, 422.2264, 422.2264(e), 423.128(c), 423.2262, 423.2264, 423.2264(e)

Informational scripts may not ask the beneficiary if s/he wants to be transferred to a sales/enrollment department nor can the Plan’s/Part D Sponsor’s call center staff automatically transfer the call. CMS recognizes that, in some instances, a beneficiary may initiate a request for information and subsequently request enrollment into a plan. CMS expects that informational calls will only lead to sales/enrollment calls (or transfer to the appropriate sales/enrollment department) at the request of the beneficiary.

Example: A beneficiary calls customer service and requests to hear information about a particular plan. Based on the information provided, the beneficiary states that s/he wants to enroll in the plan. The customer service representative may process the enrollment and/or transfer the call to the appropriate area for processing because the beneficiary initiated the request.

Any change in the nature of a call from informational to sales/telephonic enrollment must clearly inform the beneficiary regarding the change. This must be done with the full and active concurrence of the beneficiary, ideally with a yes/no question.

*Plans/Part D Sponsors are not required to enter informational scripts into HPMS. However, they must retain all scripts and make them available upon request to CMS. Note that informational scripts must be written in a way that does not: mislead or confuse Medicare beneficiaries, or misrepresent the Part D Sponsor.* At a minimum, Plans/Part D Sponsors must develop scripts that respond to inquiries from prospective and current enrollees about the following subjects:

- Best Available Evidence (BAE) policy *(applicable to Part D Sponsors)*
• Request for pre-enrollment information
• Benefit information
• Cost-sharing information
• Formulary information
• Pharmacy information, including whether a beneficiary’s pharmacy is in the Plan’s/Part D Sponsor’s network
• Provider information, including whether a beneficiary’s physician is in the Plan’s/Part D Sponsor’s network
• Out-of-network coverage
• Claims submission, processing and payment
• Formulary transition process
• Grievance, organization/coverage determination (including exceptions) and appeals process
• Information on extra help, including how the beneficiary can obtain extra help
• Current TROOP status (for Part D plans and MA-PDPs)
• Information on how to obtain needed forms
• Information on replacing a member identification card
• Service area information

Plans/Part D Sponsors may NOT:

• Include information about other lines of business in scripts.

NOTE: Plans/Part D Sponsors can ask if the caller would like to receive information about other lines of business offered by the Plan/Part D Sponsor.

• Request beneficiary identification numbers (e.g., Social Security number, bank account numbers, credit card number, HICN) except as required to verify membership, determine enrollment eligibility or process an enrollment request).
• Use language in scripts that imply they are endorsed by Medicare, calling on behalf of Medicare, or that Medicare asked them to call the member.

NOTE: Plans may not transfer outbound calls to inbound lines for telephone enrollment.

80.3 - Requirements for Enrollment Scripts/Calls

42 CFR 422.60 (c), 423.32 (b)

Plans/Part D Sponsors are required to enter enrollment scripts into HPMS. CMS expects sponsors to incorporate in their scripts all relevant requirements outlined in these Medicare Marketing Guidelines (e.g., hours of operation, TTY number, etc.).

Telephone enrollment scripts must be submitted in their entirety (bullets or talking points are not acceptable). In developing and submitting enrollment scripts Plans/Part D Sponsors must:

• Follow all requirements described in the CMS Eligibility and Enrollment Guidance in Chapters 2 and 17d of the Medicare Managed Care Manual, as well as Chapter 2 of the Medicare Prescription Drug Benefit Manual.

• Clearly state the individual is requesting enrollment into [plan name] and the plan type.

• Provide confirmation of having accepted the telephone enrollment request, such as a confirmation tracking number or other tracking mechanism.

• Provide a statement that the individual will receive a notice acknowledging receipt of the enrollment, (e.g., acknowledging request for additional information or denial of enrollment).

• Provide contact information for questions including toll-free telephone and TTY numbers.

NOTE: Plans may not conduct outbound telephonic enrollment except as required to perform outbound enrollment and verification calls (refer to section 70.7).
80.4 Requirements for Telephone Sales Scripts (Inbound or Outbound)

42 CFR 422.2262, 422.2264, 422.2268, 423.2262, 423.2264, 423.2268

Any telephone sales scripts must be submitted to HPMS verbatim (bullets or talking points are unacceptable). Plans must follow all telephone guidance in marketing through unsolicited contacts as noted in sections 70.4 and 70.5. This guidance extends to all downstream contractors.

In addition, inbound calls made directly to a sales department or sales agent must clearly inform the beneficiary if/when the nature of the call moves from a sales presentation to telephonic enrollment. This must be done with the full and active concurrence of the Medicare beneficiary, ideally with a yes/no question.

Sales calls must include a privacy statement clarifying that the beneficiary is not required to provide any health related information to the plan representative unless it will be used to determine enrollment eligibility.

90 - The Marketing Review Process

90.1 – Plan/Part D Sponsor Responsibilities

42 CFR 422.2262, 422.2264, 423.2262, 423.2264

Plans/Part D Sponsors are responsible for conducting a quality check and ensuring that all materials are consistent with this chapter and all other relevant CMS issued guidance and instructions prior to submitting materials for review to CMS. Generally, CMS does not review marketing materials for typographical or grammatical errors, unless such errors render the marketing materials inaccurate or misleading.

90.2 - Material Submission Process

42 CFR 422.2262, 423.2262

Plans/Part D Sponsors are required to submit materials for review through the Marketing Module of HPMS, which is an automated tool used to enter, track, and maintain marketing materials submitted to CMS for review and approval. The HPMS Marketing Module User Guide provides extensive information on how to use HPMS.
If there are any changes or corrections to materials, (e.g., the benefit or cost-sharing information differs from that in the approved bid), the Plan/Part D Sponsor will be required to correct those materials for prospective enrollees and send errata sheets/addenda/reprints to current members within a reasonable timeframe. If CMS finds that the sponsor failed to comply with applicable rules and guidance, we may take compliance action, including intermediate sanctions and civil money penalties.

Under extraordinary circumstances, and with prior approval from CMS, marketing materials may be submitted outside of HPMS. The review period begins when CMS receives the materials.

90.2.1 - Submission of Non-English Materials or Alternative Formats

42 CFR 422.2262, 422.2264(e), 423.2262, 423.2264(e)

Non-English materials must be based on previously approved English versions of the same material.

Any changes or revisions that are made to the English version should be accurately reflected in non-English materials and re-submitted as required.

90.2.2 - Submission of Websites for Review

42 CFR 422.2262, 422.2264, 423.2262, 423.2264

Plans/Part D Sponsors must submit all MA, 1876 cost plan, and PDP websites for review. Plans/Part D Sponsors should submit their websites via links in a Word document. CMS expects reviewers to have an opportunity to review the link(s) provided as the information will be displayed on the internet. Therefore, the reviewer should be able to conduct the review online using the links provided in the Word document. Submitting screen shots or text in a word document is not acceptable. If the option to view online is not feasible, the organization should contact the Account Manager prior to submission to request and receive permission to submit information other than through a live link.

Once a Plan’s/Part D Sponsor’s website is reviewed and approved in its entirety, a Plan/Part D Sponsor may update specific pages of this same website by submitting only the pages to be changed via links on a Word document. Any updates to pages should be submitted with their own unique material ID and date stamped accordingly.
Plans/Part D Sponsors may make the website available for public use during the CMS review period; however, Plans/Part D Sponsors must include the status pending on their website until CMS has either approved/disapproved it. Use of the website while under CMS review applies only to the website text and not documents contained on the website, (e.g., a plan may not post an unapproved member handbook on the website).

If any portion of a Plan’s/Part D Sponsor’s website is disapproved, the Plan/Part D Sponsor must remove the disapproved portion immediately.

See section 100 for required website content.

90.2.3 – Submission of Multi-Plan Materials

42 CFR 422.2262, 423.2262

Multi-Plan Materials are those materials that are created by a third-party on behalf of several Plans/Part D Sponsors (e.g., a PBM who creates a Part D EOB that will be used by multiple Part D Sponsors). Plans/Part D Sponsors must follow these procedures when submitting multi-plan marketing materials. Plans/Part D Sponsors will be held accountable for the marketing practices of their third party organizations and must ensure that all materials developed on their behalf are compliant with CMS marketing requirements.

Relevant terms for this process include:

- **Primary Material** -- The base marketing material that serves as a model for submission by multiple Plans/Part D Sponsors.

- **Auxiliary Material** -- The secondary marketing materials developed based on the CMS-approved Primary Material.

- **Coordinating Entity (CE)** -- The third party entity that develops the Primary Material for use by the Plans/Part D Sponsors with which it contracts.

- **Lead Plan/Part D Sponsor (LP)** -- Contracted Plan/Part D Sponsor that submits the Primary Material for CMS review.

- **Non-Lead Plan/Part D Sponsor (NLP)** -- Contracted Plan/Part D Sponsor that produces and submits to CMS the Auxiliary Material, based on the approved Primary Material.

The CE develops marketing materials in accordance with CMS requirements and coordinates with the LP to obtain CMS’ approval on multi-plan marketing materials (the CMS Lead Region will be the region that has account
management oversight and marketing review of the LP). Upon approval, the LP will inform the CE, who then provides the NLPs with the primary material’s material ID and submission code, so the NLPs may upload their auxiliary materials in HPMS. Communications should occur via email for tracking and documentation purposes.

The LP must insert the following in the comments field:

- ”MULTIPLAN MARKETING MATERIAL PRIMARY”. This standardized text must be inserted in the first line of the comments field.
- The name and role of the CE who created the material (e.g., ABC FMO or XYZ PBM) must be inserted in the second line of the comments field.
- A list of all multi-contract entity (MCE) or contract numbers for which the material is applicable.
- Any applicable information related to the piece that will assist CMS with the review.

The material ID for multi-plan marketing materials is made up of three parts. The first part of the material identification number is the Plan’s/Part D Sponsor’s contract number. The second part of the identifier must be the word “MULTIPLAN”. The third part of the identifier is any series of alpha numeric characters chosen at the discretion of the Plan/Part D Sponsor.

If a material is disapproved, the CE must resubmit disapproved pieces through the same LP.

When a NLP receives direction from a CE that a multi-plan “Primary” material has been approved/accepted, the NLP should upload the “Auxiliary” material in HPMS using the same category that was selected for the “Primary” material. All NLPs must submit the previously approved/accepted piece WITHOUT MODIFICATION except as allowable by CMS. Permissible modifications are restricted to populating variable elements and adding a plan name/logo.

When submitting, the NLP must insert the following in the comments field:

- “MULTIPLAN MARKETING MATERIAL AUXILLARY”. This standardized text must be inserted in the first line of the comments field.
- The name and role of the CE who created the material.
• A brief description of the material’s previous submission history, including the “Primary” material ID (e.g., This Multiplan website was previously approved by CMS on Month/Day/Year. It was initially submitted by ABC123 Health Care under material ID [x].).

The material ID should be identical to the previously approved/accepted “Primary” material, with the exception of the NLP’s contract number used in place of the LP’s contract number.

NLP multi-plan auxiliary marketing materials submitted for CMS review may not be used until approval from the Plan’s/Part D Sponsor’s CMS reviewer is received. Materials submitted File & Use may not be distributed until the five calendar waiting period has passed.

NOTE: There may be instances where a CE wants to use a material for a Plan/Part D Sponsor not identified in the original LP submission (e.g., if the CE solidifies a contract with a new Plan/Part D Sponsor). To do so, the NLP should submit the material and provide an explanation in the comments of HPMS for why it was not listed in the initial listing of contract numbers (e.g., they were not contracted with the CE during the initial submission). The name, phone, and email contact of the CE should also be included.

90.3 - Material Status

42 CFR 422.2262, 423.2262

All marketing materials in HPMS have a status: approved, disapproved, deemed, or withdrawn.

90.3.1 - Approved

42 CFR 422.2262, 423.2262

CMS approval of a material submission indicates that it is approved for use in the format in which it was submitted and may be distributed by a Plan/Part D Sponsor. However, CMS may at any time require a Plan/Part D Sponsor to change any previously approved marketing materials if found to be inaccurate, altered, or otherwise non-compliant.

NOTE: Prior to having an executed contract with CMS, a Plan’s/Part D Sponsor’s marketing material dispositions will be considered “conditionally” approved.
90.3.2 - Disapproved
42 CFR 422.2262, 423.2262

CMS disapproval of a material submission indicates that the material does not comply with the MMG, or with applicable regulations, laws, or other relevant guidance. CMS will provide a reason for the disapproval in HPMS.

90.3.3 - Deemed
42 CFR 422.2262(a)(1), 423.2262(a)(1), 422.2266, 423.2266

If CMS does not approve or disapprove marketing materials within the specified review time frame, the materials are deemed approved and the following will apply:

- Materials subject to a forty-five (45) day review period will be given the status of “deemed” on the forty-sixth (46th) day.
- Materials subject to a ten (10) day review period will be given a status of “deemed” on the eleventh (11th) day.
- Plans/Part D Sponsors that do not have a final contract will receive a conditional deemed approval. After the contract is awarded, the materials disposition will be changed to “deemed” and can then be used.

The status of “deemed” means that a Plan/Part D Sponsor may use the material.

90.3.4 - Withdrawn
42 CFR 422.2262, 423.2262

A Plan/Part D Sponsor can request to withdraw a marketing submission prior to CMS acting upon that marketing submission (e.g., prior to beginning its review). Plans/Part D Sponsors should submit a written request to their CMS Regional Office Account Manager or Marketing Reviewer stating the reason(s) for the withdrawal.

90.4 - Resubmitting Previously Disapproved Pieces
42 CFR 422.2262, 423.2262

To expedite the review of previously disapproved pieces, Plans/Part D Sponsors should clearly indicate all changes/updates made to a material
when it is resubmitted. Plans/Part D Sponsors may meet this requirement by highlighting any text changes and/or inserting notes to altered areas on the material. Plans/Part D Sponsors may develop an alternative process for identifying changes, (e.g., bulleting all changes made within the comments section of HPMS when submitting the material), provided they discuss alternatives with and receive approval from the Account Manager.

90.5 - Time Frames for Marketing Review

42 CFR 422.2262(a) 423.2262(a)

Based on the material type, and as indicated by HPMS, marketing materials submitted for prospective CMS review will have a review timeframe of 10 or 45 days. The marketing review time period begins on the date a material is submitted to HPMS. If, on the 11th or 46th day (as applicable), a decision has not been rendered by CMS, the material will be “deemed” approved.

The review period restarts each time an individual marketing material is submitted to CMS for review.

90.6 - File & Use Program

42 CFR 422.2262(b), 423.2262(b)

Plans/Part D Sponsors using the File & Use process must submit File & Use eligible marketing materials to CMS at least five (5) calendar days prior to distribution and certify that the materials comply with this chapter.

The HPMS Marketing Module identifies those materials that qualify for File & Use under the material code look-up functionality.

A Plan/Part D Sponsor may submit File & Use materials prior to executing a contract with CMS. By executing the CMS contract, the appropriate officer of the Plan/Part D Sponsor is attesting to his/her Plan’s/Part D Sponsor’s compliance with the File & Use Certification requirements.

90.6.1 - Restriction on the Manual Review of File & Use Eligible Materials

42 CFR 422.2262(b), 423.2262(b)

Plans/Part D Sponsors using File & Use must submit at least ninety (90) percent of marketing materials that qualify for File & Use under this process; meaning that they cannot request a manual review of more than ten (10) percent of materials that qualify for File & Use (including, but not limited to
model materials that qualify for File & Use submission). CMS will continue to monitor compliance with this requirement.

90.6.2 - Loss of File & Use Certification Privileges

42 CFR 422.2262(b), 423.2262(b)

A Plan/Part D Sponsor may lose File & Use Certification status or face compliance action if it:

- Submits or uses materials that do not meet the requirements of this chapter;
- Fails to file material(s) at least five (5) calendar days prior to distribution or publication; or

If CMS revokes a Plan’s/Part D Sponsor’s File & Use Certification privileges, the Plan/Part D Sponsor may be reinstated after the Account Manager and/or Marketing Reviewer has determined through manual review that the compliance concerns have been resolved.

90.6.3 - File & Use Retrospective Monitoring Reviews

42 CFR 422.2262(b), 422.2264, 423.2262(b), 422.2264

CMS will periodically conduct retrospective reviews of materials that were submitted under File & Use to ensure compliance by those plans that utilize this feature.

90.7 - Model Materials

42 CFR 422.2262 (c), 423.2262 (c)

CMS has developed model materials that are optional for use by Plans/Part D Sponsors; these are considered non-standardized model materials. Plans/Part D Sponsors that choose to modify the model language must ensure that all content contained in the model is included in the non-model document. Model documents modified by the Plan/Part D Sponsor are subject to a forty-five (45) day review period. Plans/Part D Sponsors are required to include the disclaimers from section 50 in their modified model documents. Generally, model documents used without modification will result in a ten (10) day marketing review period or may be submitted via File & Use.

“Without modification” means the Plan/Part D Sponsor used CMS model language verbatim except where indicated and allowed by CMS, (e.g.,
variable fields). To facilitate review, Plans/Part D Sponsors must indicate the model/exhibit title and applicable CMS chapter/manual or HPMS memorandum date within the comments section of HPMS.

The following allowable alterations to CMS model materials will still render the material eligible for the ten (10) day review period or submission via File & Use:

- Populating variable fields,
- Adding fields to populate with a name, address, date, or member ID,
- Correcting grammatical errors,
- Changing the font,
- Adding any applicable disclaimers,
- Adding the customer service phone number and/or hours of operation where references are made to call customer service,
- Adding the plan name/logo,
- Adding a table of contents or index to the pharmacy/provider directory, and
- Adding the CMS marketing material identification number.

Unless otherwise required, Plans/Part D Sponsors may choose to retain the title of the model document or modify the title to make it more beneficiary friendly. Any reference to the words “exhibit,” “model,” or “appendix” contained within the title of the model document must be removed. Any other modifications made to the document will make the material subject to the standard forty-five (45) day review process and/or ineligible for File & Use submission.

**NOTE:** D-SNPs may remove references to LIS from CMS model materials.

### 90.7.1 - Standardized Language

42 CFR 422.2262(c), 423.2262(c)

Standardized language refers to language developed by CMS which is mandatory for use by Plans/Part D Sponsors and cannot be modified in any way.
90.7.2 - Required Use of Standardized Materials
42 CFR 422.2262(c), 423.2262(c)

Standardized materials are documents that a Plan/Part D Sponsor must use without changing the content, format, or order. CMS allows Plans/Part D Sponsors to make the following changes to standardized materials:

- Populating variable fields,
- Correcting grammatical errors,
- Adding the customer service phone number where references are made to call customer service,
- Adding the plan name/logo, and
- Adding the CMS marketing material identification number.

90.8 - Template Materials
42 CFR 422.2262, 423.2262

A “template material” is a marketing material that includes placeholders for variable data to be populated at a later time by the Plan/Part D Sponsor. CMS classifies template materials as either standard templates or static templates.

When submitting templates, Plans/Part D Sponsors must show how the placeholders in template materials will be populated by inserting the name of the field or listing all variables (e.g., “<date>”, “<$10.00 Copay/$15.00 Copay>”).

Changes to previously approved non-variable text in a template must be submitted for review and approval by CMS. If there are any changes or corrections to final materials, (e.g., the benefit or cost-sharing information differs from that in the approved bid), the Plan/Part D Sponsor will be required to correct those materials for prospective enrollees and send errata sheets/addenda/reprints to current members by a reasonable timeframe. In cases of non-compliance, the Plan/Part D Sponsor may be subject to penalties including intermediate sanctions and civil money penalties.

NOTE: Identical materials submitted separately and not noted as template materials are subject to separate reviews.
90.8.1 - Standard Templates

42 CFR 422.2262, 423.2262

A standard template is a marketing material that includes placeholders for variable data (e.g., plan specific benefits, premiums, or cost sharing) to be populated and resubmitted in HPMS at a later time. Within thirty (30) days of use, Plans/Part D Sponsors must submit final, populated versions of standard templates in the HPMS Marketing Module using the associated “Final Expedited Review” code. Plans/Part D Sponsors must enter the Material ID of the standard template in the “Template Material ID” field. Plans/Part D Sponsors must indicate in the notes section in HPMS that the submission is a template. (Refer to the HPMS Users’ Guide technical template submission instructions.)

90.8.2 - Static Templates

42 CFR 422.2262, 423.2262

A static template is a marketing material that includes placeholders for variable data fields that can be submitted in HPMS and do not have to be resubmitted once they are populated. In order to be considered a static template, ALL variable data fields within the material must be exempt from resubmission in HPMS as noted below. Since static templates are not resubmitted, Plans/Part D Sponsors are not required to indicate that the submission is a template when submitting the material in HPMS.

The following variable data fields are exempt from the template resubmission requirement:

- Dates;
- Events;
- Addresses, phone or fax numbers;
- Hours of operation;
- Organization or company names;
- Plan/Part D Sponsor name;
- Logos;
- Agent/Agency;
• Federal contracting statement/disclaimer
• Persons’ names and pronoun variations;
• URLs;
• Member specific variables, (i.e., case numbers, drug specific references and organization/coverage determination decisions); and
• Co-branding information
• Photos
• Email addresses and web addresses
• LIS Rider
• OEV Scripts and Letters
• Page number references

90.8.3 - Template Materials Quality Review and Reporting of Errors

42 CFR 422.2262, 422.2264, 423.2262, 423.2264

CMS may conduct retrospective reviews, quality checks, or audits of populated templates. When errors are discovered by a Plan/Part D Sponsor, the Plan/Part D Sponsor must report the errors to its Account Manager. In addition, Plans/Part D Sponsors may be required to remedy the error by providing beneficiaries with updated information via errata sheets or addenda.

NOTE: Any materials, such as errata sheet or addenda, must be reviewed and approved by CMS prior to their use.

90.9 - Review of Materials in the Marketplace

42 CFR 422.504(f)(2), 422.2268, 423.2268, 423.505(f)

CMS periodically conducts reviews of Plan/Part D Sponsor materials. Reviews could include, but are not limited to, the following activities:

• Review of on-site marketing facilities, products, and activities during regularly scheduled contract compliance monitoring visits.
Random review of actual marketing pieces as they are used in the marketplace.

100 - Plan/Part D Sponsor Websites and Social/Electronic Media

42 CFR 422.111(h), 422.2264, 422.2268, 423.128(d), 423.2264, 423.2268

Plans/Part D Sponsors are expected to maintain their current contract year website for beneficiaries through December 31 of each year. They are expected not to include content on their website or on social/electronic media (e.g., Facebook, Twitter, YouTube, LinkedIn, Scan Code, or QR Code) for the next contract year prior to October 1.

All Plan/Part D Sponsor websites must be clear and easy to navigate. Any marketing materials that include a web address for the Plan’s/Part D Sponsor’s website are expected to link directly to the organization’s Medicare-specific pages.

Plans/Part D Sponsors are expected to post materials needed to make an informed decision (e.g., SB) in such a manner as to allow beneficiaries the ability to read them prior to accessing an enrollment form.

Plans/Part D Sponsors should not provide links to foreign drug sales. This includes links from advertisements that may appear on the website.

If a Plan/Part D Sponsor posts information required in sections 100.1 and 100.2 to a social media site, it is expected to also be posted on the Plan’s/Part D Sponsor’s official website. For example, members of the public should be able to learn about the requirements in those sections without having to join a third-party social media website.

Events held through social media must adhere to the guidelines set forth in section 70.9.

100.1 - General Website Requirements

All Plan/Part D Sponsor websites are expected to:

- Maintain a separate and distinct section of their website for Medicare information if the Plan/Part D Sponsor markets other lines of business.

- Include the plan’s toll-free customer service number and hours of operation, TTY number, and either a physical address or Post Office Box.
• Include the status pending until CMS has granted an approval/disapproval (Refer to 90.2.2). *If a portion of the Plan’s/Part D Sponsor’s website is disapproved, the disapproved portion must be removed from the website immediately.*

• If there is a link on the Plan’s/Part D Sponsor’s website that will take an individual to non-Medicare information the individual must be notified that by clicking on the link s/he will be leaving the Medicare information.

• Include a date/stamp on the bottom of each Web page with the date the page was last updated.

• Clearly label any links. When there is a link to a previously approved marketing material (e.g., SB, formulary, pharmacy/provider directory), the Plan/Part D Sponsor is expected to post the actual material, rather than duplicating the material’s content on the website. These materials must also retain their original Material ID.

• *For Plans/Part D Sponsors with service areas that meet the 5% language threshold, the website must post all required translated materials identified in sections 30.6, 30.7, and 30.10.*

100.2 - Required Content
All Plan/Part D Sponsor website content should be reviewed monthly and updated as necessary, and must include:

• Information on beneficiaries’ and Plans’/Part D Sponsors’ rights and responsibilities upon disenrollment.

• Service area listing.

• A list of premiums and cost-sharing (e.g., co-payments, co-insurance and deductibles) including any conditions and limitations.

• A list of any out-of-network coverage rules.

• Instructions on how to appoint a representative and link to the CMS Appointment of Representative Form (CMS Form-1696).

• A description of and information on how to file a grievance, an organization/coverage determination, and an appeal. This information must include:
  • Procedures for filing an organization/coverage determination.
• Phone number(s) for receiving oral requests.
• Mailing address for written requests.
• Fax number for written requests.
• Links, if applicable to any forms created by the Plan/Part D Sponsor for appeals and grievances.
• Information on how to obtain an aggregate number of grievances, appeals, and exceptions filed with the Plan/Part D Sponsor.
• Contact numbers that enrollees and/or physicians can use for process or status questions.
• A direct link to the Medicare.gov website where a beneficiary can enter a complaint in lieu of calling 1-800-Medicare.

• The materials in Section 100.2.1.

Part D sponsor website content must include:

• A direct link to CMS’ Best Available Evidence policy on the CMS website.
• Direct links to the Request for Medicare Prescription Drug Determination Request Form(s) for enrollees and Providers found on CMS’ Part D appeals webpage.
• Quality assurance policies and procedures, including Medication Therapy Management (MTM) information, and drug and/or utilization management information.
• Information about MTM programs including:
  • Plans’/Part D Sponsors’ eligibility criteria and conditions for which MTM programs are available,
  • High level summary of services offered as part of the MTM program,
  • A statement clarifying that these programs are not considered a benefit, and
  • A statement informing beneficiaries to contact the Plan’s/Part D Sponsor’s customer service for additional information.
• The materials in Section 100.2.2.

PFFS Plan websites must include:

• A link to Plan’s/Part D Sponsor’s Terms and Conditions of Payment

MSA Plan websites must include the following statements:

• “You must file Form 1040, US Individual Income Tax Return, along with Form 8853, “Archer MSA and Long-Term Care Insurance Contracts” with the Internal Revenue Service (IRS) for any distributions made from your Medicare MSA account to ensure you aren’t taxed on your MSA account withdrawals. You must file these tax forms for any year in which an MSA account withdrawal is made, even if you have no taxable income or other reason for filing a Form 1040. MSA account withdrawals for qualified medical expenses are tax free, while account withdrawals for non-medical expenses are subject to both income tax and a fifty (50) percent tax penalty.”

• “Tax publications are available on the IRS website at http://www.irs.gov or from 1-800-TAX-FORM (1-800-829-3676).”

100.2.1 – Required Documents for All Plans/Part D Sponsors

All Plans/Part D Sponsors must post the following materials:

• Summary of Benefits

• Enrollment Instructions and Forms

• Multi-language Insert

• Evidence of Coverage (most current version)

• Provider and/or Pharmacy Directory as applicable

• Privacy Notice under the HIPAA Privacy Rule (privacy notices are subject to enforcement by the Office for Civil Rights)

• CMS Star Ratings document

• Any form developed to be used by physicians when providing a supporting statement for an exceptions request

• Any form developed by the Plan/Part D Sponsor to be used by a physician or enrollee to satisfy a prior authorization or other utilization management requirement.
100.2.2 – Required Documents for Part D Sponsors

Part D Sponsors must post the following materials online:

- Current Comprehensive Formulary (updated at least monthly if changes are made to the formulary), including when applicable:
  - Prior authorization criteria
  - Step therapy criteria
- LIS Premium Summary Chart
- Prescription Drug Transition Policy

100.3 - Electronic Enrollment

Except as described below, all Plans/Part D Sponsors must accept enrollment in a plan through the Online Enrollment Center (OEC).

- Medicare Savings Account (MSA) plans, and 800 series employer group waiver plans cannot accept enrollment through the OEC.
- SNPs and Religious Fraternal Benefit plans may, but are not required to, accept enrollment through the OEC.
- Section 1876 cost plans may, but are not required to, accept enrollment through the OEC.

Plans/Part D Sponsors may develop and offer enrollment requests electronically. (See Chapter 2 of the Medicare Managed Care Manual, Chapter 17d of the Medicare Managed Care Manual, and Chapter 3 of the Prescription Drug Manual for specific electronic enrollment website requirements).

Third party entities (on behalf of the Plan/Part D Sponsor) may make electronic enrollment available to potential enrollees via the Plan’s/Part D Sponsor’s electronic device or software (including a website) or the OEC ONLY. Plans/Part D Sponsors using enrollment software on mobile devices (e.g., smartphones or tablets) must submit the mobile pages following the website submission guidance (see 90.2.2).

Enrollment via an agent/broker website is not permitted.

100.4 – Online Provider Directory Requirements

MA, MA-PD, and section 1876 cost plans must post a printable provider directory applicable for all products defined by service areas or general geographic area. This may be accomplished by:
• Posting a searchable “master” provider directory that represents the complete network for the Plan/Part D Sponsor.

• Posting individual provider directories by product and/or service area (e.g., mirroring those that will be printed for the Plan’s/Part D Sponsor’s membership).

• Using a search engine. If a Plan/Part D Sponsor uses a search engine on its website, it must include all the requirements in the model Directory.

100.5 – Online Formulary, Utilization Management (UM), and Notice Requirements

42 CFR 423.128(d)(2)(ii)

The requirements in this section apply to online versions of formularies, including UM documents, and notice in Part D Plans and MA-PD Plans.

Plan formularies must display all information contained within the HPMS formulary files. Plans will be allowed to make minor modifications to address issues such as abbreviations and/or grammatical truncation.

The information in the website formulary is expected to meet all of the requirements listed below. Utilization management documents are expected to, at a minimum, fulfill the requirements listed in the first four bullets as well as any other applicable requirements listed below.

• Be available at the start of each new contract year enrollment period.

• Be updated at least once per month.

• Be available through a link to a downloadable document. In addition, Part D sponsors may provide an on-line formulary search tool but such tools cannot be used as a substitute for the required downloadable documents.

• Indicate when the document and search tool (if available) was last updated by including the phrase, “Updated MM/YYYY” or “No changes made since MM/YYYY”; explain that members can contact the sponsor for the most recent list of drugs; and provide the sponsor phone number, hours, and web address.

• Define a comprehensive formulary (either in a link or through an introductory screen).
• Provide an explanation of how to use the search tool, *if available*.

• **Be accessible by a drug name search.**

• The document is expected to explain or link to an explanation of how to obtain an exception to the Part D sponsor’s formulary, utilization management tools, or (if applicable) tiered cost sharing. This is expected to be provided when search results indicate a drug is not covered.

• **Part D Sponsors may include formulary and non-formulary alternatives; however, the formulary alternatives are expected to be clearly marked as formulary drugs without the need for further navigation. If not all formulary alternatives will be listed, the Part D Sponsor is expected to include the following disclaimer: “This is not a complete list of all formulary alternatives covered by the Part D sponsor for the drug you have selected.”**

Each search result that appears in the downloadable format or search tool is expected to meet all the requirements bulleted below.

• **Indicate whether a drug is covered, its tier placement, and any applicable utilization management requirements. If quantity limit restrictions apply, the quantity limit amount and days’ supply is expected to be displayed. If prior authorization or step therapy restrictions are applicable, then the criteria is expected to also be included.**

• For drugs with a Part B versus D administrative prior authorization requirement, the following statement *is expected to* be included: “This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination”.

• **When the online formulary search tool results indicate a drug is not covered, explain or link to an** explanation of how to obtain an exception to the Part D sponsor’s formulary, utilization management tools or tiered cost sharing. This information or a link to this information *is expected to* be included in both an introductory screen and when search results indicate a drug is not covered.

• **Provide** an indicator to identify mail-order availability, excluded drugs, free first fill drugs, limited access drugs, drugs covered in the coverage gap, and drugs covered under the medical benefit (for home infusion drugs only).
Online notices: When applicable, Part D sponsors must provide online the notice associated with removing or changing a Part D drug, adding prior authorization, quantity limits, step therapy, changing the cost sharing status, or any other restrictions on a drug. This information must be maintained on the website until the next annual mailing of the updated formulary.

The online formulary change notice must meet all requirements for written notice specified in the Prescription Drug Manual, Chapter 6, section 30.3.4 (http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html), which includes name of drug, nature of the change (removed or changed drug to preferred or cost-sharing status), reason for the change, list of alternative drugs and expected cost-sharing, and information on obtaining coverage determination or exception thereto.

110 - Reserved

120 - Marketing and Sales Oversight and Responsibilities

120.1 - Compliance with State Licensure and Appointment Laws

42 CFR 422.2272(c), 423.2272(c)

In engaging marketing representatives to sell Medicare products, Plans/Part D Sponsors must comply with applicable State licensure and/or appointment laws.

120.2 - Plan Reporting of Terminated Agents

42 CFR 422.2272(c)-(e); 423.2272(c)-(e)

Plans/Part D Sponsors must report the termination of any brokers or agents and the reasons for the termination to the State in which the broker or agent has been appointed in accordance with the State appointment law.

When Plans/Part D Sponsors discover incidents of unlicensed agents or brokers submitting enrollment applications, they must terminate the relationship with agent/broker and report the agent/broker to the authority in the State where the application was submitted. Additionally, Plans/Part D Sponsors must notify any beneficiaries that were enrolled in their plans by unqualified agents or brokers (e.g., unlicensed, not appointed, or has not completed the annual training/testing) and advise those beneficiaries of the
agents’ and brokers’ status. Beneficiaries may request to make a plan change under 42 CFR 422.62(b)(3) or 423.38(c)(8)(i).

120.3 - Agent/Broker Training and Testing

42 CFR 422.2274(b) and (c), 423.2274(b) and (c)

Plans/Part D Sponsors must ensure that all brokers and agents (regardless of whether employed or independent) selling Medicare products are trained and tested annually on Medicare rules and regulations and on details specific to the plan products that they sell.

Specifications for training/testing criteria and documentation requirements will be provided annually by CMS. Plans/Part D Sponsors must ensure that their training and testing programs are designed and implemented in a way that maintains the integrity of the training and testing, and must have the ability to provide this information to CMS upon request.

120.4 - Agent/Broker Compensation

42 CFR 422.2274(a), 423.2274(a)

CMS has established limits on agent and broker compensation in order to ensure that compensation does not create incentives for agents and brokers to assist beneficiaries with plan selection using criteria other than the beneficiaries’ health care needs and preferences. These limits apply to MA organizations, Part D sponsors, and section 1876 cost plans that market through independent brokers or agents. These compensation rules are designed to eliminate inappropriate moves of beneficiaries from one plan to another. These compensation rules do not apply to employed agents or employer group plans.

120.4.1 - Definition of Compensation

42 CFR 422.2274, 423.2274

Compensation includes monetary or non-monetary remuneration of any kind relating to the sale or renewal of a policy including, but not limited to, commissions, bonuses, gifts, prizes, awards, and finder’s fees.

Compensation DOES NOT include:

- The payment of fees to comply with State appointment laws
- Training
• Certification

• Testing costs

• Reimbursement for mileage to, and from, appointments with beneficiaries

• Reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials

120.4.2 - Compensation Types

42 CFR 422.2274(a), 423.2274(a)

The regulations provide for two types of compensation -- initial compensation and renewal compensation.

Initial compensation is offered for the beneficiary’s initial year of enrollment in a plan. Renewal compensation is equal to fifty (50) percent of the initial compensation amount and is paid in the five (5) years following a beneficiary’s initial year of enrollment in a plan. It is also paid when a beneficiary enrolls in a different plan but one that is a “like plan type” following the initial year of enrollment.

NOTE: Renewal compensation will apply whether or not the new enrollment is in a plan offered by the same or a new (receiving) organization, (e.g., the member moves to a different plan within the same parent organization).

A “like plan type” enrollment includes:

• A PDP to another PDP

• An MA or MA-PD to another MA or MA-PD

• A section 1876 cost plan to another section 1876 cost plan

An “unlike plan type” enrollment includes:

• An MA or MA-PD plan to a PDP or section 1876 cost plan

• A PDP to a section 1876 cost plan or an MA (or MA-PD) plan

• A section 1876 cost plan to an MA (or MA-PD) plan or PDP
NOTE: For dual enrollments, (e.g., enrollment in an MA-only plan and a stand-alone PDP), the compensation rules apply independently to each plan. However, when dual enrollments are replaced by an enrollment in a single plan, compensation is paid based on the MA movement, (e.g., movement from an MA-only plan and PDP to an MA-PD plan would be compensated at the renewal compensation amount for the MA to MA-PD “like plan type” move).

120.4.3 - Compensation Cycle (6-Year Cycle)

42 CFR 422.2274(a), 423.2274(a)

*Plans/Part D Sponsors* are required to pay independent agents/brokers on a 6-year compensation cycle. The first year is the initial year followed by 5 renewal years. If during a 6-year cycle, a plan member moves to a plan of a different plan type, the agent or broker may receive an initial compensation and the six (6)-year cycle starts over again. Once the compensation cycle expires, it does not restart until the beneficiary enrolls into another plan. *Plans/Part D Sponsors* may continue to pay agents or brokers renewal compensation beyond the six (6)-year cycle at the plan’s discretion, as described in section 120.4.5. The monthly MARx agent/broker compensation report that is generated when an enrollment occurs will provide *Plans/Part D Sponsors* with the information necessary to determine whether they should make an initial or renewal payment.

120.4.4 - Developing and Implementing a Compensation Strategy

42 CFR 422.2274(a), 423.2274(a)

Following is specific guidance for *Plans/Part D Sponsors* as they develop or modify their agent/broker compensation strategy.

*Plan year and compensation payments*

- *Plans/Part D Sponsors* cannot pay agent/brokers for the entire 6-year compensation cycle upfront, but may pay them annually, quarterly, monthly, or more frequently. *Plans may advance payments during the AEP for the coming plan year, but cannot otherwise make payments for more than one year at a time. Compensation may only be paid for a beneficiary’s months of enrollment.*

- CMS defines "year" as a plan year, meaning January 1 through December 31. *Regardless of when a beneficiary enrolls into a plan during the year, for purposes of the 6-year compensation cycle, the year ends on December 31.*
For example, if a beneficiary’s enrollment is effective on September 1, then the initial year for that beneficiary ends on December 31, even though the beneficiary has only been in the plan for four (4) months. In January of the next year, the plan would begin paying renewal payments to the agent that assisted this beneficiary.

- When a beneficiary changes plans during the initial year, the Plan/Part D Sponsor must pay the agent/broker at the initial compensation level during that calendar year but must pay a pro-rated amount based upon the number of months the beneficiary is enrolled.

- When a beneficiary enrolls in a plan after January 1 and has no prior plan history (as indicated on the MARX agent/broker compensation report), Plans/Part D Sponsors may pay the full year initial compensation amount or a pro-rated amount based upon the number of months the beneficiary is enrolled.

- The movement by a beneficiary from an employer group plan to an individual plan (either within the same Plan/Part D Sponsor or between different Plan/Part D Sponsors) counts as an initial enrollment.

- When a beneficiary enrolls in an MA-PD plan, compensation should be paid using the MA compensation amount. MA-PD Plans should not pay both the MA and PDP compensation amounts.

- Compensation for dual enrollments should be paid independently, (e.g., when a beneficiary enrolls in both a section 1876 cost plan and a stand-alone PDP, compensation should be paid for both enrollments).

**Calculating compensation**

- Bonuses (announced or unannounced prior to payment) must be included in compensation schedules and fall within CMS rules. A bonus does not fall outside CMS rules even if it was not announced to agents or brokers in advance.

- Referral/finder’s fees are part of total compensation. They are not subject to the six (6)-year compensation cycle.

**Employed agents and exclusively contracted agents**

- CMS compensation requirements do not apply to employed agents.

- If a contracted agent represents a single Plan/Part D Sponsor and is paid a fixed amount of money that does not vary based on enrollment, that agent may be considered employed for purposes of applying CMS agent/broker compensation requirements.
Terminating compensation payments

- **Plans/Part D Sponsors** must not pay agents who are no longer appointed to sell in the State (if required), have not been annually trained and tested per the plan’s policies and procedures with a passing score of at least eighty-five (85) percent, or have been terminated for cause by the plan.

- A **Plan/Part D Sponsor** will have the opportunity prior to each contract year to determine that it will no longer use independent agents and brokers. When a **Plan/Part D Sponsor** and/or a contracted independent agent or broker elect to terminate their contract, any remaining cycle years of existing business will be governed by the terms of that contract.

120.4.5 - Compensation Calculation

42 CFR 422.2274(a), 423.2274(a)

The aggregate compensation amount paid for selling or servicing an enrollee during each of the five individual renewal years of a six (6)-year cycle must be fair-market value (FMV) for the work performed and no more, and no less, than fifty (50) percent of the aggregate compensation amount paid for that beneficiary in the initial year of the six (6)-year. In addition, all parties should ensure that their compensation arrangements including arrangements with TMOs and other similar type entities comply with all fraud and abuse laws, including the Federal anti-kickback statute.

120.4.6 - Recovering Compensation Payments (Charge-backs)

42 CFR 422.2274(a)(4)(ii), 423.2274(a)(4)(ii)

Plans are required to recover compensation payments from agents under two circumstances: 1) when a beneficiary disenrolls from a plan within the first three months of enrollment (rapid disenrollment) and 2) any other time a beneficiary is not enrolled in a plan.

NOTE: When a member enrolls in a plan effective October 1, November 1, or December 1, and subsequently changes plans effective January 1 of the following year, this is not considered a rapid disenrollment. Therefore, **Plans/Part D Sponsors** cannot recover (charge-back) agent compensation payments. If, however, a beneficiary enrolls in October and disenrolls in December, then the
Plan/Part D Sponsor should charge back because of a rapid disenrollment.

Plans/Part D Sponsors should pay only for the actual months the beneficiary is enrolled in the plan. Plans/Part D Sponsors should not recover funds when a beneficiary disenrolls within the first three months under the circumstances described below:

- Disenrollment from Part D due to:
- Other creditable coverage
- Institutionalization
- Under the following exceptional circumstances:
  - Gains/drops employer/union sponsored coverage
  - Because of a CMS sanction against the plan
  - Because of plan terminations
  - Because of a non-renewing section 1876 cost plan
  - During the Medigap trial period
  - In order to coordinate with Part D enrollment periods
  - In order to coordinate with an SPAP
- Due to following changes in status:
  - Becoming dually eligible for both Medicare and Medicaid
  - Qualifying for another plan based on special needs
  - Becoming LIS eligible
  - Qualifying for another plan based on a chronic condition
  - Moves into or out of institution
- Due to an auto- or facilitated enrollment
- Involuntarily disenrollment for one of the following reasons:
  - Death
• Moves out of the service area
• Non-payment of premium
• Loss of entitlement
• Retroactive notice of Medicare entitlement
• Contract violation
• Plan non-renewal or termination
• When moving to a plan with a 5-Star rating or out of a low performing plan.

120.4.7 - Adjustments to Compensation Schedules

42 CFR 422.2274(a)(5) and (6); 422.2274(f); 423.2274(a)(5) and (6); 423.2274(f)

_Plans/Part D Sponsors_ must notify CMS annually whether they intend to use independent agents/brokers for the upcoming plan year and the amounts they will pay them.

_Plans/Part D Sponsors_ must pay independent agents/brokers an amount that is at or below the adjusted fair market value cut-off amounts (released each spring by CMS).

120.5 - Third Party Marketing Entities

42 CFR 422.2274(a), 423.2274(a)

If the _Plan/Part D Sponsor_ contracts with a third party entity such as a TMO or a similar type of entity to sell its insurance products or perform services, (e.g., training, customer service, or agent recruitment), the amount paid to the third-party for the enrollment must be consistent with the compensation requirements _for agents and brokers_ (See section 120.4). The amount paid to the third-party for other services must be of FMV and must not exceed an amount that is commensurate with the amounts paid by the _Plan/Part D Sponsor_ to a third party for similar services during each of the previous two (2) years.

120.6 - Additional Marketing Fees

42 CFR 422.2274(a), 423.2274(a)
A *Plan/Part D Sponsor* may not charge a beneficiary or allow its marketing representatives to charge a beneficiary a marketing fee. All costs associated with the marketing of a plan are the responsibility of the *Plan/Part D Sponsor*.

**120.7 - Activities That Do Not Require the Use of State-Licensed Marketing Representatives**

42 CFR 422.2272(c), 423.2272(c)

CMS clarifies that the following activities *conducted by a plan customer service representative* do not require the use of a State-licensed marketing representative *because they are not marketing activities*. However, *if Plans/Part D Sponsors use licensed agents/brokers (employed or contracted) as customer service representatives, they cannot act as both a customer service representative and a sales/marketing agent/broker.*

*Activities that do not require the use of a State licensed customer service representative include:*

- Providing factual information
- Fulfilling a request for materials
- Taking demographic information in order to complete an enrollment application at the initiative of the prospective enrollee
- “For-cause” review of materials and activities when complaints are made by any source, and CMS determines it is appropriate to investigate.
- “Secret shopper” activities where CMS requests *Plan/Part D Sponsor* materials such as enrollment packets.

**130 - Employer/Union Group Health Plans**

sections 1857(i) and 1860D-22(b) of the Social Security Act, 42 CFR 422.2276, 423.2276

As provided in section 10.1 of Chapter 9 of the Medicare Managed Care Manual and section 10.1 of Chapter 12 of the Prescription Drug Benefit Manual, CMS has authority under sections 1857(i) and 1860D-22(b) of the Social Security Act to waive or modify requirements that hinder the design
of, the offering of, or the enrollment in employment-based Medicare plans offered by employers and unions to their members. Waivers and modifications may be granted to Plans offering “individual” PDPs or MA plans, or Plans offering customized employer group PDPs or MA plans offered exclusively to employer/union group health Plans (known as employer/union-only group waiver plans, or EGWPs). CMS has issued various employer group waivers and/or modifications to the Medicare Part C and Part D rules for marketing and disclosure/dissemination of information to Medicare beneficiaries. For specific guidance regarding these waivers or modifications of marketing and disclosure/dissemination of information requirements for employer/union-sponsored group health plans, please refer to Chapter 9 of the Medicare Managed Care Manual, and Chapter 12 of the Prescription Drug Benefit Manual.

Plans offering employer group health plans are no longer required to submit informational copies of their dissemination materials to CMS at the time of use. However, as a condition of CMS providing these particular waivers or modifications, CMS reserves the right to request and review these materials in the event of beneficiary complaints or for any other reason it determines to ensure the information accurately and adequately informs Medicare beneficiaries about their rights and obligations under the plan. For more information about these requirements, refer to Chapter 9 of the Medicare Managed Care Manual, and Chapter 12 of the Prescription Drug Benefit Manual.

Table 130-1. Marketing Provisions – Employer/Union Group Plans

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<thead>
<tr>
<th>Marketing Provisions that apply to Employer/Union Group Plans</th>
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<tbody>
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<td>These requirements are applicable for the transaction between the agent/broker selling the plan to the employer/union. All activities conducted by the employer/union or its designees to sign up individual employees to the plan(s) selected by the employer/union are excluded from these provisions.</td>
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<th>Provision</th>
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<td>Nominal Gifts</td>
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<td>Co-branding</td>
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</table>
140 - Medicare Medical Savings Account (MSA) Plans

42 CFR 422.2264, 423.2264

MSAs must comply with all applicable guidance set forth in this chapter.

Additionally, MSA plans may not:

- Imply that the plan operates as a supplement to Medicare.
- Use the term “network” to describe a list of contracted preferred providers.

See section 100 for additional MSA requirements related to websites.

150 - Use of Medicare Mark for Part D Sponsors

Section 1140 of the Social Security Act

All Part D Sponsors will sign a licensing agreement to use the official Medicare Mark via the HPMS contracting module. All applicant and renewing Part D sponsors sign the Medicare Mark licensing agreements via the HPMS electronic signature process. The license agreement is effective for a single contract year and Part D sponsors must renew annually to continue using the Medicare Mark logo.

150.1 - Authorized Users for Medicare Mark

Section 1140 of the Social Security Act
All Part D Sponsors are authorized to use the Medicare Prescription Drug Benefit Program Mark only after electronically executing the Medicare Mark License Agreement in HPMS. In certain circumstances, the Medicare Mark License Agreement may be signed in hard copy rather than electronically. Only a CEO, CFO, or COO who is designated as an authorized signer in HPMS is eligible to execute the Medicare Mark License Agreement. Part D Sponsors may use the mark on marketing materials consistent with this chapter.

150.2 - Use of Medicare Prescription Drug Benefit Program Mark on Items for Sale or Distribution

Section 1140 of the Social Security Act

All Part D Sponsors may use the Medicare Prescription Drug Benefit Program Mark on items they distribute, provided the item(s) follow(s) guidelines for nominal gifts, as provided in Appendix 1 and section 70.1.1. Items with the Medicare Prescription Drug Benefit Program Mark cannot be sold for profit.

150.3 - Approval to Use the Medicare Prescription Drug Benefit Program Mark

Section 1140 of the Social Security Act

The process to grant authorized users access to the Medicare Prescription Drug Benefit Program Mark for use on Part D marketing materials is described below.

1. The Part D Sponsor electronically signs the Medicare Mark License Agreement in HPMS (or signs a hardcopy, as applicable).

2. CMS counter-signs the Part D Sponsor’s contract.

3. CMS sends the Medicare Mark URL to the Part D Sponsor.

After receipt of the URL, organizations may begin using the mark on marketing materials (including the Part D membership ID card) that are required to be submitted to CMS for review.

Requests to distribute other items (materials that are not included in this chapter) bearing the Medicare Prescription Drug Benefit Program Mark must be submitted to CMS at least thirty (30) days prior to the anticipated date of distribution. Requests should be sent to: CMS External Affairs Office/Visual & Multimedia Communications Group at 7500 Security Blvd., Baltimore, MD 21244-1850, Mail Stop: C1-16-03.
Once a request has been approved the following will apply: 1) approval will be effective for a period not to exceed one year; and 2) approval will be granted only for those items for which use of the mark was requested in the request letter and for which written approval was granted.

150.4 - Restrictions on Use of Medicare Prescription Drug Benefit Program Mark

Section 1140 of the Social Security Act

Unless otherwise approved, no individuals, organizations, and/or commercial firms may distribute materials bearing the Medicare Prescription Drug Benefit Program Mark.

Unauthorized use of the Medicare Prescription Drug Benefit Program Mark should be reported immediately so that appropriate legal action can be taken. Reports of unauthorized use should be referred to CMS’s External Affairs Office at 7500 Security Blvd., C1-16-03, Baltimore, MD 21244-1850, or by telephone to 410.786.7214.

150.5 - Prohibition on Misuse of the Medicare Prescription Drug Benefit Program Mark

Section 1140 of the Social Security Act

42 U.S.C. section 1320b-10 prohibits the misuse of the Medicare name and marks. In general, it authorizes the Inspector General of the Department of Health and Human Services (DHHS) to impose penalties on any person who misuses the term Medicare or other names associated with DHHS in a manner which the person knows or should know gives the false impression that it is approved, endorsed, or authorized by DHHS. Offenders are subject to fines of up to $5,000 per violation or in the case of a broadcast or telecast violation, $25,000.

150.6 - Mark Guidelines

Section 1140 of the Social Security Act

The Medicare Prescription Drug Benefit Program Mark is a logotype comprised of the words Medicare Rx with the words Prescription Drug Coverage directly beneath.
Always use reproducible art available electronically. Do not attempt to recreate the Program Mark or combine it with other elements to make a new graphic. Artwork will be supplied in .EPS, .TIFF or .JPG format after notification of approval into the program. Other file formats are available from CMS’s Office of External Affairs upon request.

150.6.1 - Mark Guidelines - Negative Program Mark

Section 1140 of the Social Security Act

The Medicare Prescription Drug Benefit Program Mark may be reversed out in white. The entire mark must be legible.

150.6.2 - Mark Guidelines - Approved Colors

Section 1140 of the Social Security Act

The two (2)-color mark is the preferred version. It uses PMS 704 (burgundy) and sixty-five (65) percent process black. It is recommended that if the CMS mark is used in conjunction with the brand mark, that the black versions of those logos be used.

The 1-color version in grayscale is acceptable. The mark elements are one-hundred (100) percent black except for the word “Medicare” which is fifty-five (55) percent black.
The 1-color version in one-hundred (100) percent black also is acceptable.

150.6.3 - Mark Guidelines on Languages
Section 1140 of the Social Security Act

The Spanish version of the Medicare Prescription Drug Benefit Program Mark may be used in place of the English language version on materials produced entirely in Spanish. The two (2)-color version is preferred, but the grayscale, black and negative versions may be used.

150.6.4 - Mark Guidelines on Size
Section 1140 of the Social Security Act

To maintain clear legibility of the Program Mark, never reproduce it at a size less than one (1) inch wide. The entire mark must be legible.

1"  

150.6.5 - Mark Guidelines on Clear Space Allocation
Section 1140 of the Social Security Act

The clear space around the Medicare Prescription Drug Benefit Program Mark prevents any nearby text, image or illustration from interfering with the legibility and impact of the mark. The measurement “x” can be defined as
the height of the letter “x” in “Rx” in the Program Mark. Any type or graphic elements must be at least “x” distance from the mark as shown by the illustration.

150.6.6 - Mark Guidelines on Bleed Edge Indicator

Section 1140 of the Social Security Act

The Program Mark may not bleed off any edge of the item. The mark should sit at least one-eighth (1/8) inch inside any edges of the item.

150.6.7 - Mark Guidelines on Incorrect Use

Section 1140 of the Social Security Act

Following are rules for preventing incorrect use of the Medicare Prescription Drug Benefit Program Mark:

- Do not alter the position of the mark elements.
- Do not alter the aspect ratio of the certification mark. Do not stretch or distort the mark.
- Always use the mark only as provided in the CMS approval/license agreement.
- Do not rotate the mark or any of its elements.
- Do not alter or change the typeface of the mark.
- Do not alter the color of any of the mark elements.
- Do not position the mark near other items or images. Maintain the clear space allocation.
- Do not position the mark to bleed off any edge. Maintain one-eighth (1/8) inch safety from any edge.
- Do not use any of the mark elements to create a new mark or graphic.
• Do not use the mark on background colors, images or other artwork that interfere with the legibility of the mark.

150.7 – *Mark Guidelines for Part D Standard Pharmacy ID Card Design*

Section 1140 of the Social Security Act

Usage of the Medicare Prescription Drug Benefit Program Mark on an *ID Card* must be consistent with section 60.2 of this chapter.

160 - Allowable Use of Medicare Beneficiary Information Obtained from CMS

All MA, Part D, PACE, and section 1876 cost plans sign a data use attestation under which they agree that they will restrict the use of Medicare data to those purposes directly related to the administration of the Medicare managed care and/or outpatient prescription drug benefits for which they have contracted with CMS to administer. *Plans/Part D Sponsors* also agree not to use that information to develop, market, or operate lines of business unrelated to their Medicare plan operations.

For purposes of these Data Use Attestations, CMS-provided data includes information provided by beneficiaries in the course of their enrollment in a Medicare plan as well as data obtained solely as a result of access to CMS systems granted to the contracting organization or sponsor because it is a
Part C, Part D, PACE or section 1876 cost plan contractor. Except in cases in which the enrollee gave information as part of a commercial relationship prior to enrollment in the Medicare plan, the contracting organization or sponsor was only given the information on the application as a result of the contract with CMS.

While *Plans/Part D Sponsors* with a previous commercial relationship with Medicare beneficiaries (and employers offering Medicare plans) may have obtained their personal data through that relationship, and therefore are not obligated to follow the Data Use Agreement *in connection with such data*, we encourage *Plans/Part D Sponsors* to follow these data use guidelines as a good business practice for protecting beneficiaries from potentially unwelcome marketing and other communications. Examples of what is considered a previous commercial relationship include membership in such products as:

- Long-term care insurance
- Life-insurance policies
- Non-Medicare employer or retiree plans
- Medigap policies

While it is important to protect Medicare beneficiaries from potentially unwelcome marketing and other communications, we also recognize Plan/Part D Sponsors’ interest in contacting their enrollees on issues unrelated to the specific plan benefit that they contract with CMS to provide. This section contains additional guidance for *Plans/Part D Sponsors* on the distribution of other types of non-plan related information.

**160.1 - When Prior Authorization from the Beneficiary Is Not Required**

*Plan/Part D Sponsor* marketing materials describing health-related lines of business to current members do not require prior authorization (See 40.11 for additional information). Examples of health-related information that do not require prior authorization include:

- Long-term care insurance
- Separate dental or vision policies
- Health-related value-added items and services (VAIS)
• Information about current plan coverage or other Medicare products offered by the Plan/Part D Sponsor

• Plan and health information in monthly newsletters

• Information on disease management programs

• Mailings describing benefits changes

• Information on Medicaid and other community or social services program

160.2 - When Prior Authorization from the Beneficiary Is Required

Plans/Part D Sponsors must obtain authorization from an enrollee prior to using or disclosing the enrollee’s protected health information for marketing purposes. For exceptions, see Appendix 2, Multiple Lines of Business - HIPAA Privacy Rule. Examples of non-health related issues plans may communicate after receiving prior authorization (“opt-in”) of current enrollees include:

• Accident-only policies

• Life insurance policies

• Annuities

• Volunteer or community activities

• Pending State or Federal legislation

• Joining grassroots advocacy organizations and information about such advocacy

160.3 - Obtaining Prior Authorization

Following are examples of how the prior authorization required under section 160.2 may be obtained. With any of these examples, Plans/Part D Sponsors must receive the member’s “opt-in” authorization prior to sending any non-plan or non-health related information, and Plans/Part D Sponsors should keep evidence of authorization for audit purposes.

• Plans/Part D Sponsors may send, at their own expense, written requests to enrollees to obtain the beneficiary’s authorization for the organization or sponsor to contact him/her for purposes unrelated to plan benefits administration or CMS contract execution. The beneficiary must sign and return the request before the plan can send non-plan related materials or information. This authorization may also
be obtained by directing a beneficiary to a website to provide the requisite consent. Note that if the plan uses a website for the “opt-in” process, the link from the plan’s Medicare product website must inform the beneficiary that he or she is leaving the Medicare product website and going to the non-Medicare product website, as provided in section 100.1. Once a beneficiary “opts-in,” the Plans/Part D Sponsors must be clear that the beneficiary will receive additional information that may be non-plan or non-health related.

- Beneficiaries can complete a prior authorization in person at marketing events, health fairs, or other public venues.
- Beneficiaries can complete the prior authorization over the telephone, provided the authorization is recorded. The call must be a beneficiary-initiated inbound telephone call and scripts for such calls must comply with all guidance in section 80.
- Beneficiaries can complete the prior authorization via an email to the plan, provided that the authorization includes an electronic signature.

Regardless of the method by which the prior authorization is obtained, (e.g., written, telephonic, on a website), the following rules apply:

- The request must include one or more types of information for which authorization is being sought. If authorization is being sought for more than one type of information, a check box (or verbal agreement, if a telephonic authorization) needs to be assigned to each type of information. Furthermore, the type of information can only be described in general terms. For example, “Check the boxes of the types of information you would like to receive: life insurance, long-term care insurance, pending State and Federal legislation, grass-roots advocacy.”

- The request for authorization should not include any non-plan or non-health related content, nor should it be included in the same mailing as information on non-health related issues, unless the Plan/Part D Sponsor has previously received prior authorization to send that particular non-health related information to that member. For example, a request for authorization to send information about life insurance should not include a statement like “Make sure your spouse’s future is secure, with a life insurance policy from us,” and/or should not be sent with documents that include details about the life insurance policy.
• The request for authorization can be included in the same mailing as plan-related or health-related mailings to members, as provided in the MMG. The request for authorization may not be included on the enrollment form (whether in hard copy or in electronic forms available via the plan’s website) or made during the processing of a telephonic enrollment.

• The request for authorization should not be confusing or misleading to members by purporting to have current plan benefit information or by suggesting that the content includes official information from the Medicare program.

• These requests for authorization are not subject to review by CMS, and should not be uploaded into HPMS. However, per section 20, Plans/Part D Sponsors are still responsible for ensuring that all materials intended for Medicare beneficiaries meet the requirements of this chapter and applicable law (e.g., the HIPAA Privacy Rule).

• CMS is adopting the same requirements for these authorizations as are required by the HIPAA Privacy Rule. Additional details on what is required for an acceptable attestation can be found at 45 CFR 164.508.

160.4 - Sending Non-plan and Non-health Information Once Prior Authorization is Received

Non-plan and non-health related content can be provided to members once prior authorization is received.

• Non-health related content cannot be delivered with plan-related materials; including in mailings, on websites, or during outbound telephone calls related to current plan information.

• Health-related content can be included with plan-related materials.

In addition, these materials should include the disclaimer, “Medicare has neither reviewed, nor endorses, this information.”
Appendix 1 - Definitions

422.111; 422.2260; 423.2260, 422.2268, 423.128, 423.2268

The following definitions apply for purposes of the MMG only.

Ad hoc Enrollee Communication Materials

Ad hoc enrollee communication materials are informational materials that are targeted to current enrollees, are customized or limited to a subset of enrollees, apply to a specific situation or cover member-specific claims processing or other operational issues, and which do not include information about the plan’s benefit structure. These materials are not considered marketing materials and should be in a clear, accurate and standardized format. Examples of these materials include the following:

- Letters about a shortage of formulary drugs due to a manufacturer recall letter
- Letters to communicate that a beneficiary is receiving a refund or is being billed for underpayments
- Letters describing member-specific claims processing issues
- Customer service correspondence pertaining to unique questions or issues that affect an individual or small subset of the plan’s enrollment

Note, model enrollment/disenrollment materials are not considered ad hoc enrollee communications.

Advertising

Advertising materials are primarily intended to attract or appeal to a potential Plan/Part D Sponsor enrollee. Advertising materials contain less detail than other marketing materials, and may provide benefit information at a level to entice a potential enrollee to request additional information.

Alternate Formats

Alternate formats are used to convey information to beneficiaries with disabilities (e.g., Braille, large print, and audio).

Banner and Banner-Like Advertisements

Banner advertisements are typically used in television ads, and flash information quickly across a screen with the sole purpose of enticing a
prospective enrollee to contact the Plan/Part D Sponsor to enroll or for more information. A “banner-like” advertisement is usually in some media other than television, e.g., outdoor advertising and internet banner ads, and is intended to be very brief and to entice someone to call the Plan/Part D Sponsor or to alert someone that information is forthcoming.

Co-Branding

Co-branding is defined as a relationship between two or more separate legal entities, one of which is an organization that sponsors a Medicare plan. Co-branding means when the Plan/Part D Sponsor displays the name(s) or brand(s) of the co-branding entity or entities on its marketing materials to signify a business arrangement. Co-branding arrangements allow a Plan/Part D Sponsor and its co-branding partner(s) to promote enrollment in the plan. Co-branding relationships are entered into independent of the contract that the Plan/Part D Sponsor has with CMS.

Direct mail

Direct mail is information sent to a beneficiary to attract attention or interest to a potential enrollee and allow him/her to request additional information.

Educational Event

Educational events are designed to inform Medicare beneficiaries about Medicare Advantage, Prescription Drug or other Medicare programs and do not include marketing (i.e., the event sponsor does not steer, or attempt to steer, potential enrollees toward a specific plan or limited number of plans).

Enrollment Materials

Enrollment materials are materials used to enroll or disenroll a beneficiary from a plan, or materials used to convey information specific to enrollment and disenrollment issues such as enrollment and disenrollment notices.

Joint Enterprise

A joint enterprise is a group of organizations that are State-licensed as risk-bearing entities that jointly enter into a single contract with CMS to offer a Regional Preferred Provider Organization (RPPO) plan or PDP in a multi-State region. The participating organizations contract with each other to create a single “joint enterprise” and are considered an “entity” for purposes of offering a RPPO or PDP.

Marketing
Marketing is the act of steering, or attempting to steer, a potential enrollee towards a plan or limited number of plans, or promoting a plan or a number of plans.

Marketing Materials

Marketing materials are any materials targeted to Medicare beneficiaries that:

1. Promote the Plan/Part D Sponsor, or any MA plan, MA-PD plan, section 1876 cost plan, or PDP offered by the Plan/Part D Sponsor.

2. Inform Medicare beneficiaries that they may enroll, or remain enrolled in, an MA plan, MA-PD plan, section 1876 cost plan, or PDP offered by the Plan/Part D Sponsor.

3. Explain the benefits of enrollment in an MA plan, MA-PD plan, section 1876 cost plan, or PDP or rules that apply to enrollees.

4. Explain how Medicare services are covered under an MA plan, MA-PD plan, section 1876 cost plan or PDP plan, including conditions that apply to such coverage.

Marketing/Sales Event

Marketing/sales events are events designed to steer, or attempt to steer, potential enrollees toward a plan or a limited set of plans. At marketing/sales events, the Plan/Part D Sponsor may promote specific benefits/premiums and/or services offered by the plan. Plans/Part D Sponsors may conduct a formal event where a presentation is provided to Medicare beneficiaries or an informal event where Plans/Part D Sponsors are only distributing health plan brochures and pre-enrollment materials. Plans/Part D Sponsors may also accept enrollment forms and perform enrollment at marketing/sales events.

Marketing Appointments

Marketing appointments are individual appointments designed to steer or, attempt to steer, potential enrollees toward a plan or limited number of plans. All individual appointments between an agent and a beneficiary are considered marketing/sales appointments regardless of the content discussed.

Medication Therapy Management (MTM)

MTM program materials are:
• Materials provided to members enrolled in the MS or PDP plan;
• Materials that address issues unique to individual members; and
• The Part D MTM program comprehensive medication review summary in CMS’ standardized format that is provided to a beneficiary

Note: MTM materials must not include any marketing messages, or promotional messages.

Model Document

Model documents are materials for which CMS has provided model language which, when used without modification, qualifies for a 10-day review or for submission through the File & Use process.

Multi Contract Entities (MCE)

MCE is a designation available for Plans/Part D Sponsors that have multiple MA/PDP contracts with CMS. Being designated as an MCE allows a Plan/Part D Sponsor to submit template materials to CMS that are representative of all or a selection of the Plan’s/Part D Sponsor’s contracts.

Nominal Value

Nominal value is defined as an individual item/service worth $15 or less (based on the retail value of the item).

Outdoor Advertising (ODA)

Outdoor advertising is outdoor marketing material intended to capture the attention of a passing audience (e.g., billboards, signs attached to transportation vehicles), and to influence them to request more detailed information on the product being advertised.

Post-Enrollment Marketing Materials

Post-enrollment marketing material is a subset of marketing materials used by a Plan/Part D Sponsor to convey benefits or operational information to current enrollees.

Pre-Enrollment Marketing Materials

Pre-enrollment marketing material is a subset of marketing materials used prior to enrollment. Pre-enrollment materials may contain plan rules and/or benefit information.
Promotional Activities

Promotional activities are activities performed by a Plan/Part D Sponsor, or by an individual or organization on a Plan’s/Part D Sponsor’s behalf, to inform current and potential enrollees of the products available.

Scripts

Scripts are standardized text to provide information. Generally speaking, CMS categorizes scripts as either informational in nature or related to sales/enrollment. Informational scripts are designed to respond to beneficiary questions and requests and provide objective information about the plan and Medicare program. Sales and enrollment scripts are intended to steer a beneficiary towards a plan or a limited number of plans and those used to enroll a beneficiary into a plan.

Standardized Language

Standardized language is language developed by CMS or another Federal agency that is mandatory for use by the Plan/Part D Sponsor and cannot be modified except as noted by CMS (e.g., ANOC/EOC, SB, Plan Ratings).

State Pharmaceutical Assistance Program (SPAP)

An SPAP is a state program which helps pay drug plan premiums and/or other drug costs for people with Medicare.

Template Materials

Template materials are any marketing materials that include placeholders for variable data to be populated at a later time.

Third Party Marketing Organization (TMO)

Third-party marketing organizations are entities such as a Field Marketing Organization (FMO), General Agent (GA), or similar type of organization that has been retained to sell or promote a Plan’s/Part D Sponsor’s Medicare products on the Plan’s/Part D Sponsor’s behalf either directly or through sales agents or a combination of both.

Value Added Items and Services (VAIS)

VAIS are non-benefit items and services provided to a Plan’s/Part D Sponsor’s enrollees. An item or service is classified as a VAIS if the cost, if any, incurred to the Plan/Part D Sponsor in providing the item or service, is solely administrative. A cost is not automatically classified as administrative
simply because it is either minimal or non-medical. The cost, if any, must be intrinsically administrative; the cost must cover such items as clerical or equipment and supplies related to communication (such as phone and postage), or database administration (such as verifying enrollment or tracking usage).
Appendix 2 – Related Laws and Regulations

(Not an exhaustive list)

**Americans with Disabilities Act of 1990**

*Federal agencies are required to provide notice concerning the need for reasonable accommodation for its beneficiaries, as well as providing those accommodations.*

**Use of the Medicare Name**

Section 1140 of the Social Security Act

Under Section 1140 of the Social Security Act, 42 U.S.C. 1320b–10, it is forbidden for any person to use words or symbols, including “Medicare,” “Centers for Medicare & Medicaid Services,” “Department of Health and Human Services,” or “Health & Human Services” in a manner that would convey the false impression that the business or product mentioned is approved, endorsed, or authorized by Medicare or any other government agency. This rule extends to Plans, Part D sponsors, and downstream contractors that may be directly or indirectly involved in marketing Medicare plans. *Plans/Part D Sponsors* should ensure that their subcontractors are not using the Medicare name in a misleading manner.

**Privacy and Confidentiality**

42 CFR 422.118, 423.136

*Plans/Part D Sponsors* and providers are responsible for following all Federal and State laws regarding confidentiality and disclosure of patient information to *Plans/Part D Sponsors* for marketing purposes. This obligation includes compliance with the provisions of the HIPAA Privacy Rule and its specific rules regarding uses and disclosures of beneficiary information. HIPAA and privacy documents (e.g., a HIPAA/privacy document for a beneficiary’s signature in a provider’s office) are not considered marketing documents and therefore do not need to be submitted in HPMS. Refer to section 20 regarding materials not subject to review. Additional information on the HIPAA Privacy Rule and its disclosure requirements can be found at [http://www.hhs.gov/ocr/privacy/](http://www.hhs.gov/ocr/privacy/).

**Multiple Lines of Business - HIPAA Privacy Rule**

45 CFR 160, 164
Plans/Part D Sponsors are not required to obtain authorization from enrollees to use or disclose an enrollee’s protected health information with regard to providing communication about replacements of or enhancements to the Plan’s/Part D Sponsor’s benefits or the Plan’s/Part D Sponsor’s health-related value-added products and services that are only available to plan enrollees, but are not part of the enrollee’s plan of benefits. These categories are explicitly noted as exceptions to the definition of marketing in the HIPAA Privacy Rule. See, 45 FR 5566 at 5592. In complying with these exceptions, Plans/Part D Sponsors may be able to use and disclose protected health information to make communications to enrollees about other health-related lines offered provided by the covered entity.

However, Plans/Part D Sponsors must obtain written authorization from an enrollee prior to using or disclosing the enrollee’s protected health information for any communications that encourage the recipients to buy or use a product or service that does not fall within the exceptions to the definition of marketing under the HIPAA Privacy Rule. For example, enrollee authorization is likely needed if the product is a pass-through of a discount available to the public at large, such as an accident-only policy, a life insurance policy, or an item or service that is not health-related.

Telephonic Contact

Federal Trade Commission’s Requirements for Sellers and Telemarketers apply including:

- Federal Communications Commission rules and applicable State law
- National-Do-Not-Call Registry
- “Do not call again” requests, and
- Federal and State calling hours

Use of Federal Funds

(Division F, Title V, section 503(b), Departments of Labor, HHS, and Education Appropriations Act, 2009, as enacted by section 5, Omnibus Appropriations Act, 2009, Pub. L. 111-8, 123 Stat. 524, 802 (March 11, 2009))

CMS prohibits the use of Federal funds for non-plan related activities that are designed to influence State or Federal legislation or appropriations, by MAOs, Part D sponsors, section 1876 cost plans, PACE plans, and MA demonstration plans. Specifically, the Department of Health and Human
Services’ Annual Appropriations Acts states that no appropriated funds may be used to pay the “salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.”

**Section 508 of the Rehabilitation Act**

(Section 508 of the Rehabilitation Act (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 (P.L. 105-220), August 7, 1998)

All *Plans/Part D Sponsors* are required to have an internet website that is compliant with web-based technology and information standards for people with disabilities as specified in section 508 of the Rehabilitation Act. For additional information, please go to the following website address: [http://www.section508.gov](http://www.section508.gov).

NOTE: These Federal requirements are extended to all *Plans/Part D Sponsors* through the requirements for non-discrimination under Federal grants and programs (29 USC section 794).

**Mailing Standards**

*Plans/Part D Sponsors* must comply with the mailing standards of the United States Postal Service contained in the Domestic Mail Manual.

**Plain Writing Act of 2010**

(P.L. 111-274, 124 STAT. 2861 (October 13, 2010))

*Plans/Part D Sponsors* are required to write all Medicare publications, forms, and publicly distributed documents in a clear, concise, and well-organized manner.
Appendix 3 – Multi-Language Insert

Multi-language Interpreter Services

**English**: We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1-xxx-xxx-xxxx]. Someone who speaks English/Language can help you. This is a free service.

**Spanish**: Tenemos servicios de intérprete sin costo alguno para responder cualquier pregunta que pueda tener sobre nuestro plan de salud o medicamentos. Para hablar con un intérprete, por favor llame al [1-xxx-xxx-xxxx]. Alguien que hable español le podrá ayudar. Este es un servicio gratuito.

**Chinese Mandarin**: 我们提供免费的翻译服务，帮助您解答关于健康或药物保险的任何疑问。如果您需要此翻译服务，请致电1-xxx-xxx-xxxx。我们的中文工作人员很乐意帮助您。这是一项免费服务。

**Chinese Cantonese**: 您對我們的健康或藥物保險可能存有疑問，為此我們提供免費的翻譯服務。如需翻譯服務，請致電1-xxx-xxx-xxxx。我們講中文的人員將樂意為您提供幫助。這是一項免費服務。


**French**: Nous proposons des services gratuits d'interprétation pour répondre à toutes vos questions relatives à notre régime de santé ou d'assurance-médicaments. Pour accéder au service d'interprétation, il vous suffit de nous appeler au [1-xxx-xxx-xxxx]. Un interlocuteur parlant Français pourra vous aider. Ce service est gratuit.


**German**: Unser kostenloser Dolmetscherservice beantwortet Ihren Fragen zu unserem Gesundheits- und Arzneimittelplan. Unsere Dolmetscher


Russian: Если у вас возникнут вопросы относительно страхового или медикаментного плана, вы можете воспользоваться нашими бесплатными услугами переводчиков. Чтобы воспользоваться услугами переводчика, позвоните нам по телефону [1-xxx-xxx-xxxx]. Вам окажет помощь сотрудник, который говорит по-русски. Данная услуга бесплатная.

Arabic: إننا نقدم خدمات المترجم الفوري المجانية للإجابة عن أي أسئلة تتعلق بالصحة أو جدول الأدوية لدينا. للحصول على مترجم فوري، ليس عليك سوى الاتصال بنا على [1-xxx-xxx-xxxx]. سيقوم شخص بمساعدتك. هذه خدمة مجانية ما يتحدث العربية.

Arabic²: إننا نقدم خدمات المترجم الفوري المجانية للإجابة عن أي أسئلة تتعلق بالصحة أو جدول الأدوية لدينا. للحصول على مترجم فوري، ليس عليك سوى الاتصال بنا على [1-xxx-xxx-xxxx]. سيقوم شخص بمساعدتك. هذه خدمة مجانية ما يتحدث العربية.

Hindi: हमारे स्वास्थ्य या दवा की योजना के बारे में आपके किसी भी प्रश्न के जवाब देने के लिए हमारे पास है एक हृदयविशेषज्ञ सेवाएं. उपलब्ध है: एक हृदयविशेषज्ञ प्राप्त करने के लिए, वस्तु हमें [1-XXX-XXX-XXXX] पर फोन करें. कोई भी बीमा सेवा जो हिंदी में बोलता है आपकी मदद कर सकता है: यह एक सुपरनूतस सेवा है.

Italian: È disponibile un servizio di interpretariato gratuito per rispondere a eventuali domande sul nostro piano sanitario e farmaceutico. Per un interprete, contattare il numero [1-xxx-xxx-xxxx]. Un nostro incaricato che parla Italiano fornirà l'assistenza necessaria. È un servizio gratuito.

Português: Dispomos de serviços de interpretação gratuitos para responder a qualquer questão que tenha acerca do nosso plano de saúde ou de medicação. Para obter um intérprete, contacte-nos através do número [1-xxx-xxx-xxxx]. Irá encontrar alguém que fale o idioma Português para o ajudar. Este serviço é gratuito.

French Creole: Nou genyen sèvis entèprèt gratis pou reponn tout kesyon ou ta genyen konsènan plan medikal oswa dwòg nou an. Pou jwenn yon entèprèt, jis rele nou nan [1-xxx-xxx-xxxx]. Yon moun ki pale Kreyòl kapab ede w. Sa a se yon sèvis ki gratis.

Polish: Umożliwiamy bezpłatne skorzystanie z usług tłumacza ustnego, który pomoże w uzyskaniu odpowiedzi na temat planu zdrowotnego lub

¹ Please note that Arabic and Hindi text appear in the MMG word version of the MMG only.
dawkowania leków. Aby skorzystać z pomocy tłumacza znającego język polski, należy zadzwonić pod numer [1-xxx-xxx-xxxx]. Ta usługa jest bezpłatna.

Japanese: 当社の健康 健康保険 と薬品 對策 薬プランに関するご質問にお答えするために、無料 の通訳サービスがあります ございます。通訳をご用命になるには、[1-xxx-xxx-xxxx] にお電話ください。日本語を話す人 者が支援いたします。これは無料の サービスです。
Appendix 4 – Pharmacy Technical Help/Coverage Determinations and Appeals Call Center Requirements

Pharmacy Technical Help Call Center Requirements

42 CFR 423.128(d)(1)

*Part D Sponsors* must operate a toll-free pharmacy technical help call center or make available call support to respond to inquiries from pharmacies and providers regarding the beneficiary’s Medicare prescription drug benefit; inquiries may pertain to operational areas such as claims processing, benefit coverage, claims submission, and claims payment. This requirement can be accommodated through the use of on-call staff pharmacists or by contracting with the organization’s PBM during non-business hours as long as the individual answering the call is able to address the call at that time. The call center must operate or be available during the entire period in which the *Part D Sponsor’s* network pharmacies in its plans’ service areas are open, (e.g., *Part D Sponsors* whose pharmacy networks include twenty-four (24) hour pharmacies must operate their pharmacy technical help call centers twenty-four (24) hours a day as well).

The pharmacy technical help call center must meet the following operating standards:

- Average hold time not to exceed two (2) minutes. The average hold time is defined as the time spent on hold by the caller following the interactive voice response (IVR) system, touch tone response system, or recorded greeting and before reaching a live person.

- Eighty (80) percent of incoming calls answered within thirty (30) seconds.

- Disconnect rate of all incoming calls not to exceed five (5) percent.

*Part D Sponsor Coverage Determinations and Appeals Call Center Requirements*

423.128(b)(7), 423.128(d)(1)(iv), 423.566(a)

All *Part D Sponsors* must operate a toll-free call center with live customer service representatives available to respond to providers or enrollees for information related to coverage determinations (including exceptions and prior authorizations), appeals. *Part D Sponsors* are required to provide immediate access to the coverage determination and redetermination
processes via their toll-free call centers. The call centers must operate during normal business hours and never less than from 8:00 a.m. to 6:00 p.m., Monday through Friday; according to the time zones for the regions in which they operate. Part D Sponsors are expected to accept requests for coverage determinations/redeterminations outside of normal business hours, but are not required to have live customer service representatives available to accept such requests outside normal business hours. Additional details are available in Chapter 18 of the Prescription Drug Benefit Manual.

Voicemail may be used outside of normal business hours and the voice mail message should:

- Indicate that the mailbox is secure.
- List the information that must be provided so the case can be worked, (e.g., provider identification, beneficiary identification, type of request (coverage determination or appeal), physician support for an exception request, and whether the member is making an expedited or standard request).
- For coverage determination calls (including exceptions requests), articulate and follow a process for resolution within twenty-four (24) hours of call for expedited requests and seventy-two (72) hours for standard requests.
- For appeals calls, information should articulate the process information needed and provide for a resolution within seventy-two (72) hours for expedited appeal requests and seven (7) calendar days for standard appeal requests.
This guidance update is effective for contract year 2012. All enrollments with an effective date on or after January 1, 2012, must be processed in accordance with the revised guidance requirements, including new model enrollment forms and notices, as appropriate. Organizations may, at their option, implement any aspect of this guidance prior to the required implementation date. Please note that all clarifications to Special Election Periods (SEPs) are effective immediately upon release of this new guidance, with the exception of the SEP to Enroll in a Part D Plan with a Plan Performance Rating of Five Stars, which is effective December 8, 2011.

The revisions made on August 30, 2013, are effective for contract year 2014. All enrollments with an effective date on or after January 1, 2014, must be processed in accordance with the changes made in this revision as appropriate. Organizations may, at their option, implement any of these changes, including new model notices, prior to the required implementation date.

It is expected that Organizations will assure that all requirements outlined in this chapter regarding communications made with beneficiaries/members, including the use of the model notices, are also in compliance with the standards and guidelines as established in the Medicare Marketing Guidelines.

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The following definitions relate to topics addressed in this guidance:

**Application Date** – For paper enrollment forms and other enrollment request mechanisms, the application date is the date the enrollment request is initially received by the sponsor as defined below. Sponsors must use this date in the appropriate field when submitting enrollment transactions to CMS. A summary of application dates for CMS enrollment transactions is provided in Appendix 3 of this guidance.

- For requests sent by mail, the application date is the date the application is received by the sponsor (postmark is irrelevant).
- For requests received by fax, the application date is the date the fax is received on the sponsor’s fax machine.
- For requests submitted to sales agents, including brokers, the application date is the date the agent/broker receives (accepts) the enrollment request and not the date the sponsor receives the enrollment request from the agent/broker. For purposes of enrollment, receipt by the agent or broker employed by or contracting with the sponsor, is considered receipt by the plan, thus all CMS required timeframes for enrollment processing begin on this date.
- For requests accepted by approved telephonic enrollment mechanisms, the application date is the date of the call. The call must have followed the approved script, included a clear statement that the individual understands he or she is requesting enrollment, and have been recorded.
- For requests made via the Medicare.gov Online Enrollment Center (OEC), the application date is the date CMS “stamps” on the enrollment request at the time the individual completed the OEC process. This is true regardless of when a sponsor ultimately retrieves or downloads the request.
- For electronic enrollment requests, the application date is the date the applicant completes the request through the sponsor’s electronic enrollment process. This is true regardless of when a sponsor ultimately retrieves or downloads the request.
- For all enrollments into employer group or union sponsored plans using the SEP EGHP, the application date used on the transaction submitted to CMS will always be the 1st of the month prior to the effective date of enrollment for all mechanisms at all times. For the purposes of providing notices and meeting other...
timeframe requirements provided in this guidance, use the date the sponsor receives the request. For example, if a valid group enrollment mechanism file is received by the sponsor on January 24th for enrollments effective February 1st, the receipt date for the provision of required notices is January 24th and the application date submitted on the enrollment transactions is January 1st.

**Authorized Representative/Legal Representative** – An individual who is the legal representative or otherwise legally able to act on behalf of an enrollee, as the law of the State in which the beneficiary resides may allow, in order to execute an enrollment or disenrollment request; e.g., court appointed legal guardians, persons having durable power of attorney for health care decisions, or individuals authorized to make health care decisions under state surrogate consent laws, provided they have the authority to act for the beneficiary in this capacity (see §40.2.1). Form CMS-1696 may not be used to appoint an authorized representative for the purposes of enrollment and disenrollment. This form is solely for use in the claims adjudication or claim appeals process, and does not provide broad legal authority to make another individual’s healthcare decisions.

**Auto–Enrollment** – The process by which full benefit dual eligible individuals are enrolled into a Part D Plan by CMS (§40.1.4 (A) (1)). See definition of Full Benefit Dual Eligible Individual.

**Cancellation of Enrollment Request** - An action initiated by the beneficiary to cancel an enrollment request. To be valid, the cancellation request must be received by the sponsor before the enrollment effective date. When an enrollment request has been appropriately cancelled, the election period used to make the request remains available for use within the appropriate time frame.

**Completed Election** - An enrollment request is considered complete when:

1. The form/request is signed by the beneficiary or legal representative (refer to §40.2.1 for a discussion of who is considered to be a legal representative), or the enrollment request mechanism is completed;
2. For enrollments, evidence of entitlement to Medicare Part A or enrollment in Medicare Part B is obtained by the sponsor (see below for definition of “evidence of Medicare Part A and Part B coverage”);
3. All necessary elements on the form are completed (for enrollments, see Appendix 2 for a list of elements that must be completed) or when the enrollment request mechanism is completed as CMS directs, and, when applicable;
4. Certification of a legal representative’s authority to make the enrollment request is obtained by attestation (refer to §40.2.1).

**Denial of Enrollment Request** - Occurs when a sponsor determines that an individual is not eligible to make an enrollment request (e.g., the individual is not entitled to Medicare Part A or enrolled in Part B, the individual resides outside of the plan’s service area, the
individual is not making the enrollment request during an election period, etc.), and therefore determines it should not submit the enrollment request transaction to CMS.

**Effective Date of Coverage/Enrollment** – The date on which an individual’s coverage in a Prescription Drug plan begins. The PDP sponsor must determine the effective date of enrollment for all enrollment requests. Instructions for determining the correct effective date of coverage can be found in §30.4.

**Election** - Enrollment in, or voluntary disenrollment from, a Part D plan. The term “election” is used to describe either an enrollment or voluntary disenrollment. If the term “enrollment” is used alone, however, then the term is used deliberately, i.e., it is being used to describe only an enrollment, and not a disenrollment. The same applies when the term “disenrollment” is used alone, i.e., the term is being used to describe only a disenrollment, and not an enrollment.

**Election Period** – The time(s) during which an eligible individual may request to enroll in or disenroll from a Part D plan. The type of election period determines the effective date of the Part D coverage. There are several types of election periods, all of which are defined under §30.

**Enrollment Request Mechanism** - A method used by individuals to request to enroll in a Part D plan. Several model individual enrollment forms are provided in the Exhibits at the end of this guidance. An individual who is a member of a Part D plan and who wishes to elect another Part D plan, even if it is offered by the same parent organization, must complete a new election during a valid enrollment period to enroll in the new Part D plan. However, that individual may use a short enrollment form to make the election in place of the comprehensive individual enrollment form, or, may complete the election via the Internet, as described in §30.1.2 of this guidance, or by telephone, as described in §30.1.3 of this guidance, if the sponsor offers these options. In addition, sponsors may want to collaborate with Employer/Union Group Health Plans (EGHPs) to use a single enrollment form (or other CMS approved method, if available) for EGHP members. Beneficiaries or their legal representatives must complete an enrollment request mechanism (e.g. enrollment form) to enroll in a Part D plan.

**Evidence of Entitlement (Medicare Part A or Part B Coverage)** - For the purposes of completing an enrollment request, the sponsor must verify Medicare entitlement for all enrollment requests using either the Batch Eligibility Query (BEQ) process or MARx online query (M232 screen) or its equivalent. Therefore, the applicant is not required to provide evidence of entitlement to Medicare Part A or enrollment in Part B with the enrollment request. If CMS systems do not show Medicare entitlement, the sponsor must consider the individual’s Medicare ID card as evidence of Medicare entitlement. If CMS systems do not show Medicare entitlement and the individual’s Medicare ID card is not available, the sponsor must consider an SSA award letter that shows the Medicare HICN and effective date of Part A/B as evidence of Medicare entitlement (see §§20.1 & 40.2, subsection B).
**Facilitated Enrollment** – The process by which other LIS beneficiaries who are eligible for the low income subsidy are enrolled in a Part D plan. “Other LIS” eligible individuals are defined as those deemed automatically eligible for LIS because they are QMB-only, SLMB-only, QI (i.e. eligible only for Medicaid payment of Medicare premium and/or cost-sharing), SSI-only (Medicare and Supplemental Security Income (SSI), but no Medicaid) or those who apply for LIS at the Social Security Administration or State Medicaid Agency and are determined eligible for LIS (see §40.1.4 (A) (2)).

**Full Benefit Dual Eligible Individual** - For purposes of Medicare Prescription Drug benefits (Part D), is a Medicare beneficiary who is determined eligible by the state for medical assistance for full benefits under title XIX of the Social Security Act for the month under any eligibility category covered under the State plan or comprehensive benefits under a demonstration under section 1115 of the Act, or medical assistance under section 1902(a)(10)(C) of the Act (medically needy) or section 1902(f) of the Act (States that use more restrictive eligibility criteria than are used by the SSI program) for any month if the individual was eligible for medical assistance in any part of the month.

**Good Cause** – This term refers to the standards established in § 60.2.4 under which an individual may be reinstated into his/her Part D plan when involuntarily disenrolled for failure to pay the plan’s premium or the Part D-Income Related Monthly Adjustment Amount (Part D-IRMAA) premium amount.

**Incarceration** – This term refers to the status of an individual who is confined to a correctional facility, such as a jail or prison. An individual who is incarcerated is considered to be residing outside of the service area for the purposes of Part D plan eligibility, even if the correctional facility is located within the plan’s service area. Beneficiaries who are in Institutions for Mental Disease (IMDs), such as individuals who are confined to state hospitals, psychiatric hospitals, or the psychiatric unit of a hospital, are not considered to be incarcerated as CMS defines the term for the purpose of Part D plan eligibility. These individuals are therefore not excluded from the service area of a Part D plan on that basis.

**Institutionalized Individual** - An individual who resides in a facility as described in §30.3.8, subsection 5.

**Involuntary Disenrollment** – Disenrollment made necessary due to the sponsor’s determination that the individual is no longer eligible to remain enrolled in a Part D plan, or when the sponsor otherwise initiates disenrollment (e.g. failure to pay plan premiums, plan termination). Procedures regarding involuntary disenrollment are found in §§50.2, 50.3, & 50.4.3.

**Late Enrollment Penalty** - An amount added to the Part D plan premium of an individual who did not obtain creditable prescription drug coverage when s/he was first eligible for Part D or who had a break in creditable prescription drug coverage of at least 63 consecutive days. The LEP is considered a part of the plan premium.
MA–PD plan – A Medicare Advantage plan (PBP) that provides Medicare prescription drug coverage.

Part D-Income Related Monthly Adjustment Amount (Part D-IRMAA) – A premium amount separate from the Part D plan’s monthly premium for individuals who have incomes over a certain amount. The Social Security Administration assesses the amount annually based on the enrollee’s available tax information. The plan does not collect the Part D-IRMAA as part of its premium. Typically, individuals pay the Part D-IRMAA through their Social Security, Office of Personnel Management or Railroad Retirement Board (RRB) benefit withholding. Some enrollees are directly billed for their Part D-IRMAA through invoices sent by CMS or the RRB. All Part D enrollees who are assessed the Part D-IRMAA are required to pay the IRMAA even if the Part D coverage is provided through an EGHP.

Passive Enrollment – A process by which a beneficiary is informed that he or she will be considered to have made a request to enroll in a new Part D plan by taking no action. CMS will determine when passive enrollment is appropriate and will initiate contact through the Part D sponsor’s CMS account manager in order to inform a sponsor if they are eligible to enact passive enrollment (§20.5).

PDP sponsor – Refer to Chapter 1 (General Provisions) for a definition of PDP sponsor, Part D sponsor, or Part D plan.

Plan Performance Rating – A CMS-assigned rating, measured in stars from one to five, indicates a sponsor’s quality and performance based on criteria established by CMS. A star rating of one star indicates poor performance, while a star rating of five stars indicates exemplary performance. The Plan Performance Rating (or “overall rating”) is publicly available on Medicare.gov. CMS assigns the rating in October for the following year based on the sponsor’s most recent quality and performance data.

Receipt of Enrollment Request – Part D plan sponsors may receive enrollment requests through various means, as described in §40.1. The sponsor must date as received all enrollment requests as soon as they are initially received. This date will be used to determine the election period in which the request was made, which in turn will determine the effective date of the request. Please refer to the definition of “Application Date” in this section for specific information regarding the correct date to report as the application date on enrollment transactions submitted to CMS.

Reinstatement - An action that may be taken by CMS to correct an erroneous disenrollment from a Part D plan. The reinstatement corrects an individual’s records by canceling a disenrollment or cancellation of enrollment to reflect no gap in enrollment in a Part D plan. A reinstatement may result in retroactive disenrollment from another Part D plan or Medicare managed care plan.

Rejection of Enrollment Request - Occurs when CMS has rejected an enrollment request submitted by the Part D sponsor. The rejection could be due to the sponsor
incorrectly submitting the transactions, to system error, or to an individual’s ineligibility to elect the Part D plan.

**Service Area** – For a stand-alone Medicare prescription drug plan, the service area is the CMS-approved geographic area from which the plan sponsor is permitted to accept enrollment requests.

**System Error** - A “system error” is defined for the purposes of this guidance as an unintended error or delay in enrollment request processing that is clearly attributable to a system such as Social Security Administration (SSA) systems, Railroad Retirement Board (RRB) systems, or CMS systems, and is related to Medicare entitlement information or other information required to process a Part D enrollment request.

**Voluntary Disenrollment** – Disenrollment initiated by a member or his/her authorized representative (§§30.5, 50.1).
In general, an individual is eligible to enroll in a Medicare prescription drug plan (PDP) if:

1. The individual is entitled to Medicare Part A and/or enrolled in Part B, provided that he/she will be entitled to receive services under Medicare Part A and/or Part B as of the effective date of coverage under the plan;

2. The individual has current Part D eligibility in CMS systems; and

3. The individual permanently resides in the service area of a PDP.

An individual who is living abroad or is incarcerated is not eligible for Part D as he or she cannot meet the requirement of permanently residing in the service area of a Part D plan.

A PDP sponsor may not impose any additional eligibility requirements as a condition of enrollment other than those permitted by CMS.

Individuals may request enrollment in a Part D plan only during an enrollment period, as described in §30. A PDP sponsor cannot deny a valid enrollment request from any Part D eligible individual residing in its service area, except as provided in this guidance. Individuals enrolling in a Medicare Advantage Prescription Drug (MA-PD) plan are subject to the procedures provided in the MA Enrollment and Disenrollment Guidance (MMCM, Chapter 2).

Individuals in a cost-based HMO/CMP have the option to enroll in a standalone PDP, regardless of whether Part D is offered as an optional supplemental benefit by the cost plan. Individuals enrolling in a Part D plan that is offered as an optional supplemental benefit in a Cost-based HMO/CMP plan must do so according to the requirements for enrollment in a PDP contained in this guidance. Such an individual must be a cost plan member to enroll in the cost plan’s optional supplemental Part D benefit.

A PDP sponsor may not deny enrollment to otherwise eligible individuals covered under an employee benefit plan. However, if an individual enrolls in a PDP and continues to enroll in an employer/union plan for which the retiree drug subsidy (RDS) is claimed, the retiree drug subsidy will terminate, at which point coordination of benefits (COB) rules will apply.

A Part D eligible individual may not be enrolled in more than one Part D plan at the same time. A Part D eligible individual may not be simultaneously enrolled in a PDP and a Medicare Advantage (MA) plan except for a MA Private Fee-For-Service (PFFS) plan that does not offer the Part D benefit, a Medicare Medical Savings Account (MSA), or unless otherwise provided under CMS waiver authority.
The PFFS exception is applied at the plan level (i.e. the PBP or “plan benefit package” level). An individual enrolled in an MA PFFS plan that does not offer Part D may enroll in a stand-alone PDP, even if the same MA organization offers other plans (including PFFS plans) that include a prescription drug benefit.

20.1 - Entitlement to Medicare Parts A and/or B

To be eligible for Part D and to enroll in a PDP, an individual must be entitled to Medicare Part A or enrolled in Part B as of the effective date of coverage under the PDP. §40.2 provides information on verification of Medicare entitlement.

20.2 - Place of Permanent Residence

An individual is eligible for Part D and able to enroll in a PDP if he/she permanently resides in the service area (region) of the PDP. A temporary stay in the PDP’s service area does not enable the individual to enroll. An individual who is living abroad or is incarcerated does not meet the requirement of permanently residing in the service area of a Part D plan (even if the correctional facility is located within the plan service area). Individuals who are confined in state hospitals, IMDs (Institutions for Mental Disease), psychiatric hospitals, or the psychiatric unit of a hospital are not considered to be "incarcerated" as CMS defines that term, and are therefore not excluded on that basis from the service area of a Part D plan. Thus, they are eligible for Part D, provided that they meet the other Part D eligibility requirements.

A permanent residence is normally the primary residence of an individual. Generally, permanent residence is established by the address provided by the individual, but a PDP sponsor may request additional information, such as voter’s registration records, driver’s license records (where such records accurately establish current residence), tax records, or utility bills if there is a question. Such records must establish the permanent residence address, and not the mailing address, of the individual. If an individual puts a Post Office Box as his/her place of residence on the enrollment request, the PDP sponsor must contact the individual to confirm that the individual lives in the service area. If there is a dispute over where the individual permanently resides, the PDP sponsor should determine whether, according to the law of the State, the person would be considered a resident of that State. Additional instructions regarding disenrollment of members who may live out of the sponsor’s service can be found in §50.2.1 of this guidance.

Separately, individuals may have mailing addresses that may or may not be within the geographic plan service area. If an individual requests that mail be sent to an alternate address, such as that of a relative for example, PDP sponsors should make every effort to accommodate these requests, and should use this address to provide the required notices in this guidance and other plan mailings as appropriate. The model PDP enrollment forms provided in this guidance include a mechanism to collect an alternate mailing address. Use of an alternate mailing address does not eliminate or change the residency requirement for the purposes of PDP eligibility.
In the case of homeless individuals, a Post Office Box, an address of a shelter or clinic, or the address where the individual receives mail (e.g., social security checks) may be considered the place of permanent residence.

Additional information regarding residence for individuals that are auto enrolled or facilitated enrolled is provided in §50.2.1 of this guidance.

20.3 - Completion of Enrollment Request

Unless otherwise specified by CMS, an eligible individual enrolls in a PDP by completing and submitting an enrollment request to the PDP organization, providing all of the required information to complete enrollment within required time frames. Furthermore, transferring from one PBP to another within the same organization is still an enrollment request and must be handled as any other enrollment request. An individual who switches from one benefit package to another with the same PDP sponsor must complete an enrollment request within the required time frames. Such individuals may use a short enrollment form to request enrollment in the new plan offered by the same parent organization. For the purpose of determining the appropriate use of the short enrollment form or model plan selection form, CMS defines parent organization as the contract numbers (S#) and legal entities that are owned and operated by a single organization. Enrollment request formats include paper enrollment forms and other mechanisms approved by CMS and offered by the PDP organization. The model enrollment form is provided in Exhibit 1. The model short enrollment form is provided in Exhibit 1b.

Except as permitted by CMS for individuals enrolling in a PDP by other means, a PDP sponsor must deny enrollment to any individual who does not properly complete an enrollment request within required time frames. Procedures for completing enrollment requests are provided in §40.2.

20.4 – Other Coverage Through an Employer/Union Group

CMS systems will compare Part D enrollment transactions to information regarding the existence of employer or union coverage for which the beneficiary is also being claimed for the Retiree Drug Subsidy (RDS). If there is a match indicating that the individual may have such other coverage, the enrollment will be conditionally rejected by CMS systems with a transaction reply code (TRC) 127 (see CMS’ Plan Communications User Guide for information on TRCs).

Within 10 calendar days of receipt of the Code 127 conditional rejection, the PDP sponsor must contact the individual by phone or letter to confirm the individual’s intent to enroll in Part D (see Exhibit 5), and that the individual understands the implications of enrollment in a Part D plan on his or her employer/union coverage. The individual will have 30 calendar days from the date he or she is contacted or notified to respond. The PDP sponsor may contact the individual in writing (see Exhibit 5) or by phone and must document this contact and retain it with the record of the individual’s enrollment request.
If the individual indicates that s/he is fully aware of any consequence to his/her employer/union coverage brought about by enrolling in the Part D Plan, and confirms s/he still wants to enroll, the PDP sponsor must update the transaction with the appropriate “flag” (detailed instructions for this activity are included with CMS systems guidance) and re-submit it for enrollment. The effective date of enrollment will be based on the receipt of the beneficiary’s initial enrollment request, not when the individual confirms that s/he wants to enroll. This effective date may be retroactive in the event that the confirmation step occurs after the effective date. In these cases, sponsors may utilize the Code 61 enrollment transaction code to submit the enrollment transaction directly to CMS as provided in the Plan Communications User Guide (PCUG).

PDP sponsors are encouraged to closely monitor their outreach efforts and to follow up with applicants prior to expiration of the 30 day timeframe. If the individual does not respond in 30 days, or responds and declines the enrollment, the enrollment must be denied. A denial notice must be provided (see Exhibit 6).

When an employer or union group sponsored PDP is replacing an existing RDS plan offered by that employer or union group, the PDP sponsor may receive the Code 127 conditional rejection. In these cases it is not necessary to contact each individual, as described above. The PDP sponsor must resubmit the transactions updated with the appropriate flag.

PDP sponsors should work in close collaboration with employer/union sponsors who are replacing RDS coverage with Part D coverage to ensure that all individuals are aware of the change and have the information they need.

Further information about employer/union sponsored group health plans can be found in Chapter 12 of this manual.

20.5 – Passive Enrollment by CMS

Under Medicare laws and regulations, Medicare beneficiaries must make an enrollment request to enroll in a Part D plan, and CMS specifies the form and manner in which such enrollment requests are made. CMS has determined that it is legally permissible to provide for enrollment in a Part D plan under a passive enrollment request process in specific, limited circumstances generally associated with either immediate plan terminations or in other situation where CMS determines that remaining enrolled in the plan would pose potential harm to members.

Passive enrollment is a process by which a beneficiary is informed that he or she will be considered to have made a request to enroll in a new Part D plan by taking no action. CMS will determine when passive enrollment is appropriate and will initiate contact through the Part D sponsor’s CMS account manager. CMS will provide specific instructions directly to the affected sponsor(s), including instructions on required beneficiary notifications, any required transaction submissions to CMS and information to be provided to affected beneficiaries regarding other enrollment options, if applicable.
In evaluating whether such CMS-directed enrollee movements are appropriate, a key factor is the determination as to whether the receiving plan is essentially equivalent to (or better than) the current plan from an overall perspective. Another important goal is to ensure that individuals do not unintentionally lose Part D coverage. The following are some of the key criteria that may be used to determine whether a new plan offering will be considered comparable to or better than the current plan:

- New plan premium not significantly higher
- New plan’s Part D benefit and formulary structure would be equivalent to or of higher value than current plan
In order for a PDP sponsor to accept an election, a valid request must be made during an election period (see § 10 for the definition of “election”). It is the responsibility of the PDP sponsor to determine the enrollment period of each enrollment or disenrollment request. To make this determination, the plan sponsor may need to contact the individual directly. The plan may incorporate specific statements regarding eligibility of an election period with the enrollment or disenrollment request (see Exhibit 1a for optional use with enrollment mechanisms and Exhibit 9a for optional use with disenrollment mechanisms). However, if this information is not provided with the request, the plan must attempt to contact the individual by phone or other communication mechanism, and determine within the seven (7) day requirement if s/he is eligible to make an election at that time (see Exhibits 3 & 11a). Use of Exhibit 5 for the sole purpose of requesting information regarding an applicant’s eligibility for an election period must include a due date that is no later than seven calendar days from the date the enrollment request was received.

Enrollment requests the plan is not denying must be submitted to CMS within seven (7) calendar days of the plan’s receipt of the completed enrollment request. (Section 40.3)

Note: A plan sponsor’s determination about an individual’s eligibility for an election period is separate from a determination regarding whether an enrollment/disenrollment request is complete. See Section 40.2.2 for information pertaining to incomplete enrollment requests.

There are 3 periods in which an individual may enroll in and/or disenroll from a PDP:

- The Initial Enrollment Period for Part D (IEP for Part D);
- The Annual Election Period (AEP);
- All Special Enrollment Periods (SEP).

During the AEP, individuals may enroll in and disenroll from a PDP plan, or choose another PDP plan. Depending on the SEP, an individual may be limited to enrolling in or disenrolling from a PDP plan. Individuals may enroll in a PDP during the IEP for Part D. Each individual has one election per enrollment period; once an enrollment or disenrollment becomes effective, the election has been used.

Unless a CMS-issued enrollment sanction or a CMS-approved capacity limit applies, all PDP sponsors must accept enrollments into their PDP plans during the AEP, an IEP for Part D, and an SEP. PDP enrollment periods coordinate with similar periods in Medicare Advantage (MA) to accommodate enrollment in MA plans with a Part D benefit (MA-PD plans).
The last enrollment or disenrollment choice made during an enrollment period, determined by the date a request was received by the PDP sponsor, will be the choice that becomes effective. As outlined in CMS’ systems guidance for PDP sponsors (and MA organizations), the enrollment transaction will include this information (the “application date”).

30.1 – Initial Enrollment Period for Part D (IEP for Part D)

The initial enrollment period for Part D is the period during which an individual is first eligible to enroll in a Part D plan. In general, an individual is eligible to enroll in a Part D plan when an individual is entitled to Part A OR enrolled in Part B, AND lives in the service area of a Part D plan.

At the beginning of the Part D program, there was an IEP for Part D for all current Medicare beneficiaries and individuals who became eligible for Medicare in January 2006 that began on November 15, 2005 and ended May 15, 2006.

Individuals who are becoming eligible for Medicare will have an Initial Enrollment Period for Part D that is the 7 month period surrounding Medicare eligibility (same as the IEP for Part B). The IEP for Part B is the 7-month period that begins 3 months before the month an individual meets the eligibility requirements for Part B and ends 3 months after the month of eligibility. See 42 CFR §407.14.

Those not eligible to enroll in a Part D plan at any time during their initial enrollment period for Medicare Part B have an initial enrollment period for Part D that is the 3 months before becoming eligible for Part D, the month of eligibility, and the three months following eligibility to Part D.

Individuals eligible for Medicare prior to age 65 (such as for disability) will have another Initial Enrollment Period for Part D based upon attaining age 65.

If a Medicare entitlement determination is made retroactively, eligibility for Part D begins with the month in which the individual received notification of the retroactive entitlement decision. Therefore, the Part D IEP begins the month the individual receives the notice of the Medicare entitlement determination and continues for three additional months after the month the notice is provided. The effective date is generally the first day of the month after the PDP sponsor receives a completed enrollment request.

Ultimately, CMS provides a Part D eligibility effective date and maintains it in CMS systems.
Example 1 -- IEP for Part D surrounding 65th birthday:

Example 2 -- IEP for working individual:
Mr. Hackerman’s 65th birthday is March 23, 2010. He is currently working, and while he signed up for his Medicare Part A benefits, effective March 1, 2010, he declined his enrollment in Part B, given his working status. He is eligible for Part D since he has Part A and lives in the service area. Even though he did not enroll in Part B, his Part B IEP is still the 3 months before, the month of, and the 3 months following his 65th birthday – that is, December 2009 – June 2010. Hence, his IEP for Part D is also December 2009 – June 2010.

Example 3 -- IEP exception for Part D:
Mr. Duke lived in Italy at the time of his 65th birthday, which occurred on August 3, 2008. His Part B initial enrollment period began on May 1, 2008, and ended November 30, 2008. He plans to return to the U.S. to reside permanently in June 2010. Since he lived out of the U.S. and was not eligible to enroll in a Part D plan during his IEP for Part B, his initial enrollment period for Part D will occur when he meets all the eligibility requirements for Part D, that is, when he has Part A or B and lives in a plan service area. His IEP for Part D is March 2010 – September 2010.

Example 4 -- IEP for retroactive Medicare determination:
Mr. Schlosser received notification of his Medicare determination on June 15, 2010. He was informed in this notice that Medicare Part A will be effective as of July 1, 2009. Therefore, his Part D initial enrollment period begins in June 2010 and ends September 30, 2010.

Once an individual uses his/her IEP for Part D enrollment and this enrollment becomes effective, this enrollment period ends. Refer to the table in §30.4 of this guidance for effective date information.

30.2 – Annual Election Period (AEP)

Beginning in 2011, the AEP is from October 15 through December 7 of every year. It is also referred to as the “Fall Open Enrollment” season and the “Open Enrollment Period for Medicare Advantage AND Medicare prescription drug coverage” in Medicare beneficiary publications and other tools. Plan sponsors may use these descriptions of the AEP in their member materials as well as in materials for prospective members.

There is one AEP enrollment/disenrollment choice available for use during this period. An enrollment/disenrollment election cannot be changed after the end of the AEP.

Refer to §§30.4 and 30.5 for effective date information.
30.3 - Special Enrollment Period (SEP)

Special enrollment periods constitute periods outside of the usual IEP for Part D or AEP when an individual may elect a plan or change his or her current plan election. As detailed below, there are various types of SEPs, including SEPs for dual eligible individuals, for individuals whose current plan terminates, for individuals who change residence and for individuals who meet “exceptional conditions” as CMS may provide, consistent with §1860D-1(b) of the Act and §423.38(c) of the Part D regulations.

Depending on the nature of the particular special election period, an individual may take a variety of actions, including:

- Discontinuing enrollment in an MA plan and enrolling in Original Medicare with a new Part D plan
- Joining a Part D plan for the first time
- Switching from one Part D plan to another Part D plan

Certain SEPs may be limited to an enrollment or disenrollment request. If the individual disenrolls from (or is disenrolled from) the PDP, the individual may subsequently enroll in a new Part D plan within the SEP time period. Once the individual’s enrollment in a new Part D plan becomes effective, the SEP ends for that individual even if the time frame for the SEP is still in effect. In other words, the SEP ends when the individual’s enrollment in a new Part D plan becomes effective or when the SEP time frame ends, whichever comes first, unless specified otherwise for an SEP.

Note: An individual’s eligibility for an SEP does not convey eligibility to enroll in the plan; in addition to having a valid enrollment period an individual must also meet all applicable Part D eligibility criteria.

It is generally the responsibility of the PDP sponsor to determine whether the individual is eligible for the SEP. The exception to this determination requirement would be enrollment and disenrollment requests completed by or approved by CMS. To make this determination, the organization may need to contact the individual directly. The plan may incorporate specific statements regarding eligibility of an SEP with the enrollment or disenrollment request (see Exhibit 1a for optional use with enrollment mechanisms and Exhibit 9a for optional use with disenrollment forms). However, if this information is not provided with the request, the plan must contact the individual to determine if they are eligible to make an election at that time. Unless otherwise required in this guidance, the organization MUST accept verbal or written confirmation from the individual regarding the conditions that make him or her eligible for the SEP. Organizations that obtain this information on the enrollment or disenrollment request are not required to obtain an additional verbal or written confirmation of SEP eligibility.

For enrollment requests obtained during a face-to-face interview or telephone request, the determination of SEP eligibility can be made at that time. For enrollment requests made using paper, internet or the Medicare OEC (without accompanying CMS approval), the
sponsor is not required to contact the applicant to confirm SEP eligibility if the enrollment request includes the applicant’s attestation of SEP eligibility.

If SEP eligibility is obtained orally (by phone or in person), the sponsor must document this contact and retain this with the enrollment record. If the sponsor obtains this confirmation through a written notice, such notice must include the option (and information) needed to call the sponsor and confirm this information verbally. If the sponsor is not able to obtain this confirmation before the end of the required timeframe for processing an enrollment request, the sponsor must deny the enrollment or disenrollment request and provide the individual a denial notice (see Exhibit 6).

The following are examples of questions that might be used to determine eligibility for an SEP:

<table>
<thead>
<tr>
<th>Type of SEP?</th>
<th>Examples of Questions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in Residence</td>
<td>Have you recently moved? If so, when? Where did you move from?</td>
</tr>
<tr>
<td>Employer/Union Group Health Plan</td>
<td>Do you currently have (or are leaving) coverage offered by an employer or union? Have you recently lost such coverage?</td>
</tr>
<tr>
<td>Disenroll from Part D to enroll in</td>
<td>Are you a member of TriCare? Do you want to obtain VA benefits?</td>
</tr>
<tr>
<td>Creditable Coverage</td>
<td></td>
</tr>
<tr>
<td>Dual Eligible</td>
<td>Do you currently have Medicaid coverage? Does your state pay for your Medicare premiums? Did you recently receive a yellow letter from Medicare (for full duals)? Have you recently lost coverage under Medicaid?</td>
</tr>
<tr>
<td>Other Low Income Subsidy</td>
<td>Do you receive extra help? Have you recently received a green letter from Medicare? Did you receive a letter from Medicare letting you know that you automatically qualify for extra help? Do you receive SSI cash benefits without Medicaid?</td>
</tr>
</tbody>
</table>
How much do you pay for your prescriptions?

Institutionalized
- Are you moving into or are you a current resident of an institution, such as a nursing facility or long-term care hospital?
- Are you moving out of such a facility?

PACE
- For enrollment – are you currently enrolled in a special plan called “PACE”?

Please note that the time frame of an SEP denotes the time frame during which an individual may make an enrollment or disenrollment request. It does not necessarily correspond to the effective date of the actual enrollment or disenrollment. For example, if an SEP exists for an individual from May through July, then a PDP sponsor must receive an enrollment or disenrollment request from that individual sometime between May 1 and July 31 in order to consider the request to have been made during the SEP. However, the type of SEP will dictate the effective date of coverage, and that effective date of coverage can occur after July 31. The following discussion of SEPs and their corresponding effective dates will demonstrate this concept more fully.

### 30.3.1 - SEPs for Changes in Residence

An SEP for changes in residence exists for these scenarios:

1. individuals who are no longer eligible to be enrolled in a PDP due to a change in permanent residence outside of the PDP’s service area;
2. individuals who were not eligible for Part D because they have been out of the U.S. and have now moved back to the U.S.;
3. individuals who were not eligible for Part D because they were incarcerated and have now been released;
4. individuals who will have new Medicare health or Part D plans available to them as result of a permanent move.

The SEP permits enrollment elections only; it begins on either the date of the permanent move or on the date the individual provides notification of such move. Since individuals who do not permanently reside in the plan service area are ineligible for the plan and must be disenrolled, a SEP is not needed to effectuate an involuntary disenrollment for that reason (see §50.2.1). Individuals who move and have new Medicare health or Part D plans available to them as a result of the move, but continue to reside in the current plan service area, may use this SEP to enroll in any MA or Part D plan for which they are eligible in their new place of residence. It is the individual’s responsibility to notify the organization that he/she is permanently moving.
When the individual notifies the organization of a permanent move out of the plan service area, the SEP begins either the month before the individual’s permanent move, if the individual notifies the organization in advance, or the month the individual provides the notice of the move, if the individual has already moved. The SEP continues for two months following the month it begins or two months following the month of the move, whichever is later.

If the plan learns from CMS or U.S. Post Office (as described in §50.2.1) that the individual has been out of the service area for over twelve months and the plan has not been able to confirm otherwise with the individual, the SEP will begin at the beginning of the twelfth month and continues through to the end of the fourteenth month.

The effective date of the enrollment is determined by the date the PDP sponsor receives the enrollment request. The individual may choose an effective date of up to three months after the month in which the PDP sponsor receives the enrollment request. However, the effective date may not be earlier than the date the individual moves to the new service area and the PDP sponsor receives the completed enrollment request.

**Example 1:**
A beneficiary is a member of a PDP in Florida and intends to move to Arizona on June 18. An SEP exists for this beneficiary from May 1 through August 31.

A. If a PDP sponsor in Arizona receives a completed enrollment form from the beneficiary in May and since the individual is not moving to the new service area until June 18th, the beneficiary can choose an effective date of July 1, August 1, or September 1.

B. If the PDP sponsor receives the completed enrollment form from the beneficiary in June (the month of the move) the beneficiary can choose an effective date of July 1, August 1, or September 1.

C. If the PDP sponsor receives the completed enrollment form in July, the beneficiary can choose an effective date of August 1, September 1, or October 1.

**Example 2:**
A beneficiary resides in Florida and is currently in Original Medicare and not enrolled in a PDP. The individual intends to move to Maryland on August 3. An SEP exists for this beneficiary from July 1 through October 31.

At the time the individual enrolls in a PDP, the individual must provide the specific address where s/he will permanently reside upon moving into the service area, so that the PDP sponsor can determine that the individual meets the residency requirements for enrollment in the plan.
**Disenrollment from Previous PDP**

Please keep in mind that a member of a PDP who moves permanently out of the service area must be involuntarily disenrolled from the plan. A member of a PDP who resides out of the service area for over twelve months must be involuntarily disenrolled from the plan. CMS has established an SEP that allows an individual adequate time to choose a new PDP, given the fact that the individual will no longer be enrolled in the original PDP after the month of the move or after the twelfth month (whichever is appropriate). Unless an individual elects new coverage during a valid enrollment period, he/she will be enrolled in Original Medicare without Medicare prescription drug coverage. If the individual does not elect new prescription drug coverage for an effective date immediately after the termination of the old coverage, he/she may be subject to a Part D late enrollment penalty (LEP). See Chapter 4 of the Medicare Prescription Drug Manual for more information.

**30.3.2 – SEP for Dual-eligible Individuals or Individuals Who Lose Their Dual-eligibility**

There is an SEP for individuals who are entitled to Medicare Part A and/or Part B and receive any type of assistance from the Title XIX (Medicaid) program. This also includes individuals often referred to as “partial duals” who receive cost sharing assistance under Medicaid (e.g. QMB, SLMB, etc). This SEP begins the month the individual becomes dually-eligible and exists as long as s/he receives Medicaid benefits. This SEP allows an individual to enroll in, or disenroll from, a Part D plan. The effective date of the individual’s enrollment in their new plan would be the first of the month following receipt of an enrollment request. However, as described in 40.1.4, the effective date for auto-enrollments may be retroactive.

In addition, PDP eligible individuals no longer eligible for benefits under Title XIX benefits will have an SEP beginning with the month they receive notice of the loss of eligibility plus two additional months to make an enrollment choice in another PDP, an MA-PD, or to disenroll entirely from Part D.

**30.3.3 - SEPs for Contract Violation**

In the event an individual is able to demonstrate to CMS that the PDP of which he/she is a member substantially violated a material provision of its contract under Part D, the individual may disenroll from the PDP and enroll in another Part D plan. Substantial violations in relation to the individual include, but are not limited to:

- failure to provide the individual on a timely basis benefits available under the plan;
- failure to provide benefits in accordance with applicable quality standards; or
- the PDP sponsor (or its agent) materially misrepresented the PDP when marketing the PDP.
The SEP will begin once CMS determines that a violation has occurred. Its length will depend on whether the individual immediately enrolls in a new Part D plan upon disenrollment from the original PDP.

We note that in some case-specific situations, CMS may process a retroactive disenrollment for these types of disenrollments. If the disenrollment is not retroactive, an SEP exists such that an individual may elect another Part D plan during the last month of enrollment in the PDP sponsor, for an effective date of the month after the month the new PDP sponsor receives the completed enrollment request.

**EXAMPLE**
On January 16, CMS determines, based on a member’s allegations, that the PDP sponsor substantially violated a material provision of its contract. As a result, the member will be disenrolled from the PDP on January 31. An SEP exists for this beneficiary beginning January 16 and lasting until the end of January. The beneficiary promptly applies for a new Part D plan, and the new PDP sponsor receives a completed enrollment request on January 28 for a February 1 effective date.

If the individual in the above example did not enroll in another PDP on January 28th, s/he would have an additional 90 calendar days from the effective date of the disenrollment from the first PDP to elect another PDP. The individual may choose an effective date of enrollment in a new PDP beginning any of the three months after the month in which the PDP sponsor receives the completed enrollment request. However, the effective date may not be earlier than the date the PDP sponsor receives the completed enrollment request.

**EXAMPLE**
On January 16, CMS determines, based on a member’s allegations that the PDP sponsor substantially violated a material provision of its contract. As a result, the member disenrolls from the PDP on January 31. A 90-day SEP continues to exist for the beneficiary from February 1 through April 30. In this example, a new PDP sponsor then receives a completed enrollment request from the individual on April 15. The beneficiary may choose an effective date of May 1, June 1, or July 1.

If the disenrollment is retroactive, CMS will provide the beneficiary with the time frame for his/her SEP to enroll in another Part D plan. Depending on the circumstance surrounding the contract violation, CMS may determine a retroactive enrollment into another plan is warranted.

**30.3.4 - SEPs for Non-renewals or Terminations**

In general, SEPs are established to allow members affected by PDP non-renewals or terminations ample time to make a choice of another PDP. Effective dates during these SEPs are described below. CMS has the discretion to modify this SEP as necessary for any non-renewal or termination when the circumstances are unique and warrant a need for a modified SEP.
In particular:

- **Non-renewals** - An SEP exists for members of a PDP that will be affected by a plan or contract non-renewal that is effective January 1 of the contract year. For this type of non-renewal, PDP sponsors are required to provide advance notice to affected members within timeframes specified by CMS. In order to provide sufficient time for members to evaluate their options, the SEP begins December 8 and ends on the last day in February of the following year.

  Enrollment requests received from December 8 through December 31 will have an effective date of January 1. Enrollment requests received in January will have an effective date of February 1. Enrollment requests received in February will have an effective date of March 1.

- **PDP Sponsor Termination of Contract and Terminations/Contract Modifications by Mutual Consent** - An SEP exists for members of a PDP who will be affected by a termination of contract by the PDP sponsor or a modification or termination of the contract by mutual consent (see 42 CFR §423.508 for contract requirements regarding terminations). For this type of termination or modification, PDP sponsors are required to give notice to affected members at least 60 calendar days prior to the proposed date of termination or modification. To coordinate with the notification time frames, the SEP begins two months before the proposed termination effective date, and ends one month after the month in which the termination occurs.

  Please note that if an individual does not enroll in another PDP before the termination effective date, he/she will be disenrolled on the effective date of the termination. However, the SEP will still be in effect for one month after the effective date of the termination should the individual wish to subsequently enroll in a PDP (for a prospective, not retroactive, effective date).

  Beneficiaries affected by these types of terminations may request an effective date of the month after notice is given, or up to two months after the effective date of the termination. However, the effective date may not be earlier than the date the new PDP sponsor receives the enrollment request.

**EXAMPLE**
If a PDP sponsor contract terminates for cause on April 30, an SEP lasts from March 1 through May 31. In this scenario, a beneficiary could choose an effective date of April 1, May 1, or June 1 in a new PDP; however, the effective date may not be earlier than the date the new PDP sponsor receives the enrollment request.

- **CMS Termination of PDP Sponsor Contract** - An SEP exists for members of a PDP that will be affected by PDP sponsor contract terminations by CMS (see 42 CFR §423.509 for contract requirements on terminations). For this type of termination, PDP sponsors are required to give notice to affected members at least
30 calendar days prior to the effective date of the termination (see 42 CFR §423.509(b)(1)(ii)). To coordinate with the notification time frames, the SEP begins 1 month before the termination effective date and ends 2 months after the effective date of the termination.

Please note that if an individual does not enroll in a new PDP before the termination effective date, he/she will be disenrolled on the effective date of the termination. However, the SEP will still be in effect for two months after the effective date of the termination should the individual wish to subsequently enroll in another PDP (for a prospective, not retroactive, effective date).

Beneficiaries affected by these types of terminations may choose an effective date of up to three months after the month of termination. However, the effective date may not be earlier than the date the new PDP sponsor receives the enrollment request.

**EXAMPLE**

If CMS terminates a PDP sponsor contract effective June 30, an SEP lasts from June 1 through August 31. In this scenario, a beneficiary could choose an effective date of July 1, August 1, or September 1; however, the effective date may not be earlier than the date the new PDP sponsor receives the enrollment request.

- **Immediate Terminations By CMS** - CMS will establish the SEP during the termination process for immediate terminations by CMS (see 42 CFR §423.509(b) (2) for immediate termination requirements), where CMS provides notice of termination to the PDP enrollees and the termination may be mid-month.

Note: Plan consolidations are neither terminations nor non-renewals. Thus, individuals affected by plan consolidations are not eligible for the SEP for non-renewals or terminations. Please see the annual CMS Call Letter and other CMS end-of-year guidance for more information about plan consolidations.
30.3.5 - SEP for Involuntary Loss of Creditable Prescription Drug Coverage

This SEP applies to individuals who involuntarily lose creditable prescription drug coverage, including a reduction in the level of coverage so that it is no longer creditable, not including any such loss or reduction due to the individual’s failure to pay premiums. The SEP permits enrollment in a PDP and begins with the month in which the individual is advised of the loss of creditable coverage and ends 2 months after either the loss (or reduction) occurs or the individual received the notice, whichever is later. The effective date of this SEP may be the first of the month after the request or, at the beneficiary’s request, may be prospective; however, it may be no more than 2 months from the end of the SEP.

30.3.6 - SEP for Individuals Not Adequately Informed about Creditable Prescription Drug Coverage

This SEP applies to individuals who were not adequately informed of the creditable status of drug coverage provided by an entity required to give such notice, or a loss of creditable coverage. This SEP permits one enrollment in, or disenrollment from, a PDP on a case-by-case basis. This SEP begins the month the individual receives CMS approval of the SEP and continues for two additional months following this approval.

30.3.7 - SEP for Enrollment/Non-enrollment in Part D due to an Error by a Federal Employee

An individual whose enrollment or non-enrollment in Part D is erroneous due to an action, inaction or error by a Federal Employee is provided an SEP. This SEP permits enrollment in or disenrollment from a PDP on a case-by-case basis. This SEP begins the month the individual receives CMS approval of the SEP and continues for two additional months following this approval.

30.3.8 - SEPs for Exceptional Conditions

CMS has the legal authority to establish SEPs when an individual or group of individuals meets exceptional conditions specified by CMS, including on a case-by-case basis. The SEPs CMS has established include:

1. SEP EGHP (Employer/Union Group Health Plan) - An SEP exists for individuals enrolling in employer/union group-sponsored Part D plans, for individuals to disenroll from a Part D plan to take employer/union-sponsored coverage of any kind, and for individuals disenrolling from employer/union-sponsored coverage (including COBRA coverage) to enroll in a Part D plan. The SEP EGHP may be used when the EGHP allows the individual to make changes to their plan choices, such as during the employer’s or union’s “open season,” or at other times the employer or union allows.
This SEP is available to individuals who have (or are enrolling in) an employer or union plan and ends 2 months after the month the employer or union coverage ends.

The individual may choose the effective date of enrollment or disenrollment, up to 3 months after the month in which the individual completes an enrollment or disenrollment request. However, the effective date may not be earlier than the first of the month following the month in which the request was made. The effective date also may not be earlier than the first day of the individual’s entitlement to Medicare.

Refer to §30.4 for additional information for situations in which an individual is determined eligible for more than one election period, one of which includes the SEP EGHP.

Keep in mind that all PDP eligible individuals, including those in EGHPs, may enroll in a PDP during the IEP for Part D, AEP and during any other SEP. The SEP EGHP does not eliminate the right of these individuals to enroll or disenroll during these time frames. Additionally, §60.5 outlines special processes that are available for enrollment into or disenrollment from EGHP sponsored Part D plans.

2. SEP for Individuals Who Disenroll in Connection with a CMS Sanction - On a case-by-case basis, CMS will establish an SEP if CMS sanctions a PDP sponsor, and an enrollee disenrolls in connection with the matter that gave rise to that sanction. The start/length of the SEP, as well as the effective date, is dependent upon the situation.

3. SEP for Individuals Enrolled in Cost Plans that are Non-renewing their Contracts
An SEP will be available to enrollees of HMOs or CMPs that are not renewing their §1876 cost contracts for the area in which the enrollee lives.

This SEP is available only to Medicare beneficiaries who are enrolled in an HMO or CMP under a §1876 cost contract that will no longer be offered in the area in which the beneficiary resides. Beneficiaries electing to enroll in a PDP via this SEP must meet PDP eligibility requirements.

This SEP begins December 8 of the current contract year and ends on the last day of February of the following year.

Enrollment requests received from December 8 through December 31 will have an effective date of January 1. Enrollment requests received in January will have an effective date of February 1. Enrollment requests received in February will have an effective date of March 1.

4. SEP for Individuals in the Program of All-inclusive Care for the Elderly (PACE) - Individuals may disenroll from a PDP at any time in order to enroll in PACE, including the PACE Part D benefit. In addition, individuals who disenroll from PACE have an SEP for up to 2 months after the effective date of PACE disenrollment to enroll in a PDP. The effective date would be dependent upon the situation.
5. SEP for Institutionalized Individuals – An SEP will be provided to an individual who moves into, resides in, or moves out of a:

- Skilled nursing facility (SNF) as defined in §1819 of the Act (Medicare);
- Nursing facility (NF) as defined in §1919 of the Act (Medicaid);
- Intermediate care facility for the mentally retarded (ICF/MR) as defined in §1905(d) of the Act;
- Psychiatric hospital or unit as defined in §1861(f) of the Act;
- Rehabilitation hospital or unit as defined in §1886(d)(1)(B) of the Act;
- Long-term care hospital as defined in §1886(d)(1)(B) of the Act; or
- Hospital that has an agreement under §1883 of the Act (a swing-bed hospital).

In addition, for individuals who move out of one of the facilities listed above, the individual will have an SEP for up to 2 months after he/she moves out of the facility. This SEP permits an individual to enroll in, or disenroll from, a Part D plan. The effective date is the first of the month following the month in which the enrollment/disenrollment request is received, but not prior to the month residency begins.

Please note the definition of “institution” here differs from that used in determining when an institutionalized full-benefit dual eligible qualifies for the low-income subsidy copayment level of zero.

6. SEP for Individuals Who Enroll in Part B during the Part B General Enrollment Period (GEP) – An SEP will be provided to individuals who are not entitled to premium free Part A and who enroll in Part B during the General Enrollment Period for Part B (January – March) for an effective date of July 1st. The SEP will begin April 1st and end June 30th, with an effective date of July 1st.

7. SEP for Non-Dual Eligible Individuals with LIS and Individuals who Lose LIS - Individuals who qualify for LIS (but who do not receive Medicaid benefits) have an SEP that begins the month the individual becomes eligible for LIS and exists as long as s/he is eligible for LIS. This SEP allows an individual to enroll in, or disenroll from, a Part D plan at any time. Because this coverage is effective the first of the month, the SEP would permit beneficiaries to change enrollment on a monthly basis, if they so choose. The effective date for enrollments under this SEP will be prospective, effective the first day of the month following receipt of the enrollment request by the plan.

Example: An individual is awarded LIS and CMS facilitates his enrollment into a PDP, effective October 1st; in November, the individual decides he would rather be enrolled in another PDP and submits a request in November. He does so using this SEP and his enrollment is effective December 1st.

Individuals who lose their LIS eligibility for the following calendar year will have an SEP to make a change during January – March. Those individuals who lose eligibility
for LIS during the year outside of this annual process will have an SEP that begins the
month they are notified by the PDP and continues for two months.

8. Part D SEPs to Coordinate With MA Enrollment Periods – The following Part D
SEPs are established to coordinate with election periods in the MA program. More
information about MA election periods can be found in MA Enrollment and
Disenrollment Guidance (MMCM Chapter 2).

A. SEP for MA-PD enrollee using the MA SEP65 - MA eligible individuals who
elect an MA plan during the initial coverage election period (ICEP) surrounding their
65th birthday have an SEP called the “SEP65.” The SEP65 allows the individual to
disenroll from the MA plan and elect the Original Medicare plan any time during the
12-month period that begins on the effective date of coverage in the MA plan. If the
individual using the SEP65 is disenrolling from an MA-PD plan, he or she may (but
is not required to) use this Part D SEP to enroll in a PDP plan. This SEP must be
used at the same time the SEP65 is used.

B. SEP for Individuals Who Dropped a Medigap Policy When They Enrolled
For the First Time in an MA Plan, and Who Are Still in a “Trial Period” –
Individuals who dropped a Medigap policy when they enrolled for the first time in an
MA plan are provided a guaranteed right to purchase another Medigap policy if they
disenroll from the MA plan while they are still in a “trial period.” In most cases, a
trial period lasts for 12 months after a person enrolls in an MA plan for the first time.
If the individual is using this SEP to disenroll from an MA-PD plan, there is a Part D
SEP to permit a one-time enrollment into a PDP. This SEP opportunity may only be
used in relation to the MA SEP described here and begins the month they disenroll
from the MA-PD plan and continues for two additional months.

C. SEP for an MA-PD enrollee using the MA Open Enrollment Period for
Institutionalized Individuals (OEPI) to disenroll from an MA-PD plan -
Individuals that meet the definition of “institutionalized” as it is provided in, and
applies to, section 30.3.2 of MA Enrollment and Disenrollment Guidance (MMCM,
Chapter 2) are eligible for the OEPI election period. An individual disenrolling from
an MA-PD plan has an OEPI to enroll in a PDP. This OEPI begins with the month
the individual requests disenrollment from the MA-PD plan and ends on the last day
of the second month following the month MA-PD membership ended.

D. SEP to enroll in a PDP - MA enrollees using the MADC to disenroll from MA
– MA enrollees using the Medicare Advantage Disenrollment Period (MADP) to
disenroll from MA from January 1 through February 14 may request enrollment in a
PDP at any time during the MADP. This SEP permits one enrollment and ends when
the individual has enrolled in the PDP. An individual may use this SEP to request
enrollment in a PDP subsequent to having submitted a disenrollment request from the
MA plan during the MADP or may simply request enrollment in the PDP, resulting in
automatic disenrollment from the MA plan. Individuals enrolled in MA-only PFFS
plans must request disenrollment from the MA-only plan in order to be eligible for
this SEP, as enrollment in a PDP will not result in automatic disenrollment from the MA plan.

The effective date of this SEP is always prospective for the first of the month following receipt of the enrollment request. Therefore, an individual who uses this SEP in January will have an effective date of February 1, while an individual who uses this SEP from February 1 through February 14 will have an effective date of March 1. The SEP ends when the individual enrolls in a PDP or after February 14, whichever comes first.

E. SEP for enrollment into MA SNPs or enrollment into a PDP after loss of special needs status - CMS is establishing an SEP to allow for disenrollment from a PDP at any time in order to enroll in an MA SNP. In addition, CMS will provide an SEP to enroll in a PDP for those who are no longer eligible for a SNP because they no longer meet special needs status (as outlined in MA Enrollment and Disenrollment Guidance – MMCM, Chapter 2). This SEP begins the month the individual’s special needs status changes and ends the earlier of when the beneficiary makes an election or three months after the effective date of the involuntary disenrollment. The effective date would be dependent upon the situation.

F. SEP for Enrollment into a Chronic Care SNP and for Individuals found ineligible for a Chronic Care SNP - CMS will provide an SEP (for MA and Part D) for those individuals with severe or disabling chronic conditions to enroll in a SNP designed to serve individuals with those conditions. This SEP will apply as long as the individual has the qualifying condition and will end once s/he enrolls in a SNP. Once the SEP ends, that individual may make enrollment changes only during applicable MA election periods. In addition, individuals enrolled in a Chronic Care SNP who have a severe/disabling chronic condition which is not a focus of their current SNP are eligible for this SEP. Such individuals have an opportunity to enroll in a Chronic Care SNP that focuses on this other condition. Eligibility for this SEP ends at the time the individual enrolls in the new SNP.

Individuals who are found after enrollment not to have the qualifying condition necessary to enroll in a chronic/disabling condition Special Needs MA-PD Plan will have an SEP to enroll in a different MA-PD plan or MA-only plan with accompanying Part D coverage. This would normally occur when the required post enrollment verification with a provider did not confirm the information provided on the pre-enrollment assessment tool. This SEP begins when the plan notifies the individual of the failure to qualify and extends through the end of that month as well as the following two months. The SEP ends when the individual makes an enrollment election or on the last day of the second of the two months following notification. Any enrollments made during this election period are for prospective effective dates.

G. SEP for Individuals Involuntarily Disenrolled from an MA-PD plan due to loss of Part B - Individuals who are involuntarily disenrolled from an MA-PD plan
due to loss of Part B but who continue to be entitled to Part A have a SEP to enroll in
a PDP. The SEP begins when the individual is advised of the loss of Part B and
continues for two additional months.

H. SEP for Individuals Using the 5-Star SEP to Enroll in a 5-Star Plan without
Part D Coverage – Individuals who use the 5-star SEP to enroll in a 5-star Medicare
Advantage-only Private Fee-for-Service plan or a 5-star cost plan have a SEP to
enroll in a PDP or in the cost plan’s optional supplemental Part D benefit, for which
they are eligible. The PDP selected using this coordinating SEP does not have to be 5-
Star rated. However, individuals may not use this coordinating SEP to disenroll from
the plan in which they enrolled using the 5-star SEP.

This SEP beings the month the individual uses the 5-Star SEP and continues for two
additional months.

Note: Individuals who use the 5-Star SEP to enroll in a Medicare Advantage
coordinated care plan are not eligible for this coordinating Part D SEP and must wait
until their next valid election period in order to enroll in a plan with Part D coverage.

9. SEP for Individuals who belong to a Qualified SPAP or who lose SPAP eligibility
-- Individuals who belong to a qualified SPAP are eligible for an SEP to make one
enrollment choice at any time through the end of each calendar year (i.e., once per
calendar year). SPAP members, or the State acting as the authorized representative of
members, may use this SEP to enroll in a Part D plan outside of existing enrollment
opportunities, allowing them, for example, to join a Part D plan upon becoming a
member of an SPAP, or to switch to another Part D plan.

In addition, individuals no longer eligible for SPAP benefits will have an SEP beginning
either the month they lose eligibility or are notified of the loss, whichever is earlier,
and ends two months after either the month of the loss of eligibility or the notification of
the loss, whichever is later. This SEP permits an enrollment choice in another PDP or
MA-PD.

10. Full-Benefit Dual Eligible individuals With Retroactive Uncovered Months – In
limited instances, a full-benefit dual eligible voluntarily enrolls in a Part D plan in the
month(s) before the individual would otherwise have been auto-enrolled. Due to the
earlier enrollment a coverage gap may occur. To reduce the impact of the coverage gap,
the beneficiary may enroll in the Limited Income NET program for those retroactive
months per Section 40.1.4.B.

11. SEP for Disenrollment from Part D to Enroll in or Maintain
Other Creditable Coverage - Individuals may disenroll from a Part D plan (including
PDPs and MA-PDs) to enroll in or maintain other creditable drug coverage (such as
TriCare or VA coverage). The effective date of disenrollment is the first day of the
month following the month a disenrollment request is received by the Part D plan.
12. SEP for Individuals disenrolling from a Cost plan who also had the Cost plan optional supplemental Part D benefit – Individuals who disenroll from a cost plan and the cost plan’s optional supplemental Part D benefit have an SEP to enroll in a PDP. This SEP begins the month the individual requests disenrollment from the cost plan and ends when the individual makes an enrollment election or on the last day of the second month following the month cost plan membership ended, whichever is earlier.

13. SEP to Enroll in an MA Plan, PDP or Cost Plan With a Plan Performance Rating of Five (5) Stars – An eligible individual may enroll in an MA plan, PDP or cost plan with a Plan Performance Rating of five (5) stars during the year in which that plan has the 5-star overall rating, provided the enrollee meets the other requirements to enroll in that plan (e.g., living within the service area as well as requirements regarding end-stage renal disease). Individuals may use the 5-Star SEP to disenroll from a Medicare Advantage plan by enrolling in a 5-Star cost plan that is open for enrollment.

Example: Cost plan A has an overall rating of 5 stars for 2012 and is open for enrollment. An individual enrolled in a MA plan uses this SEP to enroll in cost plan A. Cost plan A submits the enrollment transaction to MARx using the “R” election type code, and the MA plan B accepts and processes the subsequent disenrollment per the TRR.

As overall ratings are assigned for the plan contract year (January through December), possible enrollment effective dates are the first of the month from January 1 to December 1 during the year for which the plan has been assigned an overall rating of 5 stars. An individual may use this SEP only one time between December 8 of the year prior to the year in which the plan sponsor has been granted a 5-star overall rating and November 30 of the year in which the sponsor has been granted a 5-star overall rating. The enrollment effective date is the first of the month following the month in which the plan receives the enrollment request.

Example 1: Plan X has an overall rating of 4.5 stars in 2012 and 5 stars for 2013. An individual could use this SEP to request enrollment in Plan X starting on December 8, 2012 for an effective date of January 1, 2013. An individual could not use the SEP to enroll in Plan X for an effective date on or before December 1, 2012, as the enrollment effective dates available during that period are prior to the calendar year for which Plan X has been assigned a 5-star overall rating.

Example 2: Plan Y has an overall rating of 5 stars for 2013 but has lost that 5-star rating for 2014. A beneficiary could use this SEP to request enrollment in Plan Y for the first of the following month until November 30, 2013, with the last possible effective date available being December 1, 2013. The beneficiary could not use the SEP to enroll in Plan Y on or after December 1, 2013, as the enrollment effective dates available during that period are after the calendar year for which Plan Y has been assigned a 5-star overall rating.
Eligible individuals can switch from a PDP, an MA plan, a cost plan or Original Medicare to an MA-only plan, an MA-PD plan, a cost plan or a PDP that has a 5-star overall rating.

An individual using this SEP can enroll in an MA-only plan, an MA-PD plan, cost plan or a PDP with a 5-star overall rating even if coming from Original Medicare (with or without concurrent enrollment in a PDP). Individuals enrolled in a plan with a 5-star overall rating may also switch to a different plan with a 5-star overall rating. An individual in an MA-only or MA-PD coordinated care plan who switches to a PDP with a 5-star overall rating will lose MA coverage and will revert to Original Medicare for basic medical coverage.

Regardless of whether the individual has Part D coverage prior to use of this SEP, any individual who enrolls in a 5-star Medicare Advantage private Fee-for-Service plan without prescription drug coverage or a 5-star cost plan is eligible for coordinating Part D SEP to enroll in a PDP. (See Chapter 3, Section 30.3.8 #8, letter H of the Medicare Prescription Drug Benefit Manual for more information.)

Note that use of this SEP does not guarantee Part D coverage. If an individual in either an MA-PD plan or a PDP chooses to enroll in an MA-only coordinated care plan with a 5-star overall rating, that individual would lose Part D coverage and then must wait for a subsequent enrollment period to obtain Part D coverage under the normal enrollment rules. Late enrollment penalties might also apply.

### 30.4 - Effective Date of Enrollment

With the exception of some SEPs and when enrollment periods overlap, generally beneficiaries may not request their effective date of enrollment in a PDP. Furthermore, unless provided for under an SEP (e.g. EGHP or full dual retroactive as discussed in the previous section), the effective date can never be prior to the receipt of an enrollment request by the PDP sponsor. An enrollment cannot be effective prior to the date the beneficiary (or their legal representative, if applicable) completed the enrollment request. The effective date also may not be earlier than the first day of the individual’s entitlement to Medicare. This section includes procedures for handling situations when a beneficiary chooses an enrollment effective date that is not allowable based on the requirements outlined in this section.

To determine the proper effective date, the PDP sponsor must determine which enrollment period applies to each individual before the enrollment may be transmitted to CMS. This period may be determined by reviewing information such as the individual’s date of birth, Medicare card, and by the date the PDP sponsor receives the enrollment request.

Once the PDP sponsor identifies the enrollment period, the PDP sponsor must determine the effective date. In addition, PDP enrollments for EGHP sponsored PDP plans and full
benefit dual eligible enrollments may be retroactive under certain circumstances (refer to §60.5 for more information on EGHP retroactive effective dates).

Examples for determining the effective date:

A. On August 18, 2010, Mrs. Jones submits an enrollment request to a PDP sponsor. Her enrollment form shows she became entitled to Medicare Parts A and B in March 2002. She has indicated on her enrollment form that she lives in a long-term care facility. What is her effective date?

Explanation: Since the date the request was received is August 18, 2010, this is not an AEP request. The entitlement date for Medicare Parts A and B shows that she is not in her IEP for Part D. That leaves only an SEP. Mrs. Jones indicated that she resides in a long-term care facility, so this enrollment request can be processed under the SEP for Institutionalized Individuals (see §30.3.8, item # 5). The effective date for this enrollment is September 1, 2010.

B. Mr. Doe calls a PDP sponsor for information about Part D on October 3, 2010. The PDP representative discusses the PDP plans available and the enrollment requirements, including when an individual may enroll. Mr. Doe tells the representative that he is retiring and his employer coverage will end on October 31, 2010. He submits an enrollment request on October 24, 2010. His entitlement to Medicare Parts A and B is June 1, 1998. He indicates on the request that he does not reside in a long-term care facility.

Explanation: Since the date the request was received is October 24, 2010, this is not an AEP request. The entitlement date for Medicare Parts A and B shows he is not in his IEP for Part D. No other details on the request itself point to any specific enrollment period, however we know that he has retired and his employer sponsored commercial coverage is ending. The enrollment can be processed using the SEP EGHP (see §30.3.8, item # 1). Mr. Doe can choose an effective date of up to 3 months after the month in which the request is made. The PDP sponsor contacts Mr. Doe, confirms his retirement, explains the SEP EGHP and asks him about the effective date. Since his employer coverage is ending on October 31, 2010, he requests a November 1, 2010, effective date.

Effective dates for Enrollment Periods:

<table>
<thead>
<tr>
<th>Part D Enrollment Period</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual Election Period (AEP)</td>
<td>January 1&lt;sup&gt;st&lt;/sup&gt; of following year.</td>
</tr>
</tbody>
</table>

The AEP begins on October 15 and continues through December 7 of every year.

Individuals have one AEP enrollment to use – once this enrollment is effective, the AEP has been used.
**Initial Enrollment Period for Part D (IEP for Part D)**
For individuals that become Part D eligible after January 2006, generally the IEP for Part D is concurrent with the initial enrollment period for Part B. (Note: The Initial Enrollment Period for Part B begins 3 months prior to the month of Medicare eligibility, and ends on the last day of the third month following the month of Medicare eligibility.)

Example: Mrs. Jones is eligible for Medicare on July 1, 2010. Her Part B Initial Enrollment Period is April 1, 2010 through October 31, 2010. Therefore her IEP for Part D is also April 1, 2010 through October 31, 2010.

If individuals had not been eligible to enroll in a Part D plan at any time during their initial enrollment period for Medicare Part B or those not eligible for Part D during first Medicare initial enrollment period for Part D that occurred from November 15, 2005 through May 15, 2006, their IEP for Part D is the 3 months before becoming eligible for Part D, the month of eligibility, and the three months following eligibility to Part D.

Individuals eligible for Medicare prior to age 65 (such as for disability) will have another IEP for Part D based upon attaining age 65.

**Special Enrollment Periods (SEP)**
SEPs for PDP enrollment and disenrollment choices are described in section 30.3 of this guidance.

| Enrollment requests made prior to the month of eligibility are effective the first day of the month of eligibility. |
| Enrollment requests made during or after the first month of eligibility are effective the 1st of the month following the month the request was made. |

Effective dates are dependent upon the individual SEP and circumstances.

| It is possible for an individual to make an enrollment request when s/he is eligible for more than one election period resulting in more than one possible effective date. If a sponsor receives an enrollment request and determines the applicant is eligible for more than one election period, the sponsor must allow the individual to choose the enrollment effective date (see exception in the next paragraph regarding the IEP for Part D). To accomplish this, the sponsor must attempt to contact the individual, and must document its attempt(s), to determine the individual’s preferred effective date. **Note:** This requirement does not apply to beneficiary requests for enrollment into an employer/union sponsored plan using the group enrollment mechanism, as these may be submitted to CMS with the EGHP SEP election type code. |
| If one of the election periods for which the individual is eligible is the IEP for Part D, the individual may not choose an effective date any earlier than the month of entitlement to Medicare Part A and/or enrollment in Part B. |
EXAMPLE
If an individual’s IEP for Part D starts in November, (i.e., he will be entitled to Medicare Part A and Part B in February) and a PDP sponsor receives an enrollment request from that individual during the AEP, then the individual may NOT choose a January 1 effective date (for the AEP) and must instead be given a February 1 effective date (for the IEP for Part D) because January 1st is earlier than the month of entitlement to Medicare Part A and/or enrollment in Part B.

If an individual is eligible for more than one enrollment period but does not indicate a preferred effective date, or the organization is unable to contact the individual, the PDP sponsor must assign an effective date using the following ranking of enrollment periods. The enrollment period with the highest rank determines the effective date in this situation.

Individuals eligible for the SEP EGHP and one or more other election periods who make an election via the employer or union election process will be assigned an effective date according to the SEP EGHP, unless the individual requests a different effective date that is allowed by one of the other elections periods for which s/he is eligible.

Ranking of Enrollment Periods: (1 = Highest, 3 = Lowest)
1. IEP for Part D
2. SEP
3. AEP

30.5 - Effective Date of Voluntary Disenrollment

PDP enrollees may voluntarily disenroll from a PDP during the AEP and SEP as described in §§20.2 and 20.3 of this guidance. With the exception of some SEPs and when enrollment periods overlap, generally beneficiaries may not choose the effective date of disenrollment. This section includes procedures for handling situations when a beneficiary chooses a disenrollment effective date that is not allowable based on the requirements outlined in this section.

A PDP enrollee may disenroll through the PDP sponsor or 1-800-MEDICARE. If an enrollee enrolls in a new PDP, during an available enrollment period, while still enrolled in another PDP, he/she will automatically be disenrolled from the old PDP and enrolled in the new PDP by CMS systems with no duplication or delay in coverage. Further, individuals enrolled in any MA plan (except for an MA Private Fee-For-Service (PFFS) plan that does not offer a Part D benefit or a Medicare Medical Savings Account (MSA) plan) will be disenrolled from that MA plan upon successful enrollment in a PDP.

As with enrollments, it is possible for an individual to make a disenrollment request when more than one enrollment period applies. Therefore, in order to determine the proper
Effective dates for voluntary disenrollment are as follows. (Refer to §§50.2 and 50.3 for effective dates for involuntary disenrollment.)

<table>
<thead>
<tr>
<th>Enrollment Period</th>
<th>Effective Date of Disenrollment*</th>
<th>Do PDP sponsors have to accept disenrollment requests in this enrollment period?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annual Election Period</td>
<td>January 1 of the following year.</td>
<td>Yes</td>
</tr>
<tr>
<td>Special Enrollment Period</td>
<td>Varies, as outlined in §20.3</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*NOTE: CMS may allow up to 90 days retroactive payment adjustments for EGHP sponsored PDP disenrollments. Refer to §60.5 for more information.

As stated previously, individuals generally cannot choose the effective date of disenrollment. The enrollment/disenrollment period during which the request is received dictates the effective date. If an individual requests a disenrollment date that is not permissible, the PDP sponsor should advise the individual and process the request according the requirements in this guidance.
A PDP sponsor must accept all enrollment requests it receives, regardless of whether they are received in a face-to-face interview, by mail, by facsimile, through CMS auto-enrollment or facilitated enrollment processes, or through other mechanisms defined by CMS (and offered by the PDP sponsor). PDP sponsors may accept faxed enrollment requests and need not obtain the original.

Upon receiving an enrollment request, a PDP sponsor must provide within 10 calendar days, one of the following:

- Notice of acknowledgement (as described in section 40.4.1);
- Request for additional information (as described in 40.2.2);
- Notice of denial (as described in 40.2.3).

If a sponsor uses the combined acknowledgment/confirmation notice, the sponsor may send the notice of rejection within 7 calendar days of receiving the Transaction Reply Report (TRR) indicating a rejection instead of sending the above items (as described in 40.4.2).

The individual (or his/her legal representative) must complete an enrollment request and include all the information required to process the enrollment, or an enrollment may be generated by other processes specified by CMS. Furthermore, the individual must submit the election to the PDP during a valid enrollment period.

Unless otherwise directed in this guidance, the PDP sponsor must provide notice in response to information received from CMS on the TRR that contains the earliest notification.

**Special Rule for the Annual Election Period (AEP):**

PDP sponsors may not solicit submission of paper enrollment forms or accept telephone or on-line enrollment requests prior to the beginning of the AEP. Brokers and agents under contract to PDP sponsors may not accept or solicit submission of paper enrollment forms prior to the start of the AEP. PDP sponsors and their brokers and agents also should remind beneficiaries that they cannot submit enrollment requests prior to the start of the AEP.

Despite these efforts, CMS recognizes that PDP sponsors may receive unsolicited paper enrollment forms prior to the start of the AEP, given that marketing activities may begin prior to this date. To be considered unsolicited, the PDP sponsor must have received the paper AEP enrollment request directly from the applicant and not through a sales agent or broker. Other enrollment request mechanisms may not be accepted prior to the actual start of the AEP. Paper AEP enrollment requests received prior to the start of the AEP for which there is indication of sales agent or broker involvement in the submission of the request (i.e., the name or contact information of a sales agent or broker) must be
investigated by the organization for compliance with the requirements in the Medicare Marketing Guidelines. If a PDP sponsor receives unsolicited paper enrollment forms on or after October 1st but prior to the start of the AEP, it must retain and process them as follows:

- Within 7 calendar days of the receipt of a complete paper enrollment request, the plan must provide the beneficiary with a written notice that acknowledges receipt of the enrollment request (Exhibit 2), and indicates that the enrollment will take effect on January 1st effective date of the following year.

- For unsolicited AEP enrollment requests received prior to the start of the AEP, sponsors must submit all transactions to CMS systems (MARx) on the first day of the AEP with an “application date” of the same date. For example, unsolicited AEP paper enrollment requests received October 1 through October 14 must be submitted on October 15th with an application date of October 15th of the current year in the appropriate field on the enrollment transaction. If a beneficiary has submitted more than one AEP paper enrollment request prior to the start of the AEP, the beneficiary will be enrolled in a plan based on the first application that is processed.

- Once the PDP sponsor receives a MARx TRR from CMS indicating whether the individual’s enrollment has been accepted or rejected, the PDP sponsor must meet the remainder of the requirements (e.g., sending a notice of the acceptance or rejection of the enrollment within 10 calendar days following receipt of the TRR) provided in Section 40.4.

**Note:** If sponsors receive incomplete unsolicited AEP paper enrollment requests prior to the start of the AEP, they must follow existing guidance for working with beneficiaries to complete the applications.

Again, this policy applies only to unsolicited paper enrollment forms requesting an AEP enrollment for January 1st. To help ensure a successful AEP season, it is imperative that sponsors follow these steps and submit valid enrollment transactions promptly as directed.

**40.1 - Format of Enrollment Requests**

All PDP sponsors must have, at minimum, a paper enrollment form available for potential enrollees to request enrollment in a PDP. PDP sponsors may also accept enrollment elections made via the on-line enrollment center hosted by CMS, as well as requests for enrollment as described in §§40.1.1 – 40.1.6.

No PDP enrollment request vehicle, regardless of format, may include any question regarding health screening information.
The PDP sponsor’s enrollment vehicle(s) must include important information that the individual acknowledges, including:

- Understands the requirement to continue to keep Medicare Part A or B
- Agrees to abide by the PDP sponsor’s membership rules as outlined in material provided to the member;
- Consents to the disclosure and exchange of information necessary for the operation of the Part D program;
- Understands that enrollment in the PDP automatically disenrolls him/her from any other PDP or MA plan (as described in §20 of this guidance) in which he/she is enrolled; and
- Knows he/she has the right to appeal service and payment denials made by the organization.

Please refer to Appendix 2 for a complete listing of required elements that must be included on enrollment mechanisms and Exhibits 1 – 1b for complete information on the required statements.

The plan premium is not required on the enrollment mechanism unless it is part of the plan name. Sponsors may include the premium on the enrollment mechanism if they choose to do so, but they must do so consistently for all PBPs listed on the enrollment mechanism.

Refer to §60.8 for requirements regarding retention of enrollment requests.

40.1.1 - Paper Enrollment Forms

All PDP sponsors must, as a minimum standard, have a paper enrollment form that complies with CMS’ guidelines in format and content and a process as described in this guidance for accepting it. A model enrollment form is included in Exhibit 1 and Exhibit 1b.

40.1.2 – Electronic Enrollment

PDP sponsors may develop and offer electronic enrollment mechanisms made available via a plan owned electronic device or secure internet website.

The following guidelines, in addition to all other program requirements, apply to electronic enrollment mechanisms:

- Submit all materials, web pages, and images (e.g. screen shots) related to the electronic enrollment process for CMS approval following the established process
for the review and approval of marketing materials and other enrollment request mechanisms.

- Provide beneficiaries with all the information required by CMS’ marketing guidelines for the Part D program.

- At a minimum, comply with CMS’ data security policies (found at: https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/InformationSecurity/Information-Security-Library.html on the web). The PDP sponsor may also include additional security provisions to ensure the appropriate handling of protected health information (PHI).

- Advise each individual at the beginning of the electronic enrollment process that he/she is completing an actual enrollment request to the PDP sponsor.

- Capture the same data as required on the model enrollment form (see Exhibit 1, 1b and Appendix 2). For enrollment requests from one plan to another plan within the same parent organization, the data required on the model short enrollment form are sufficient, provided the plan can verify that the individual is currently enrolled in the parent organization at the time the individual submits the enrollment request.

- As part of any electronic enrollment process, include a clear and distinct step that requires the applicant to activate an “Enroll Now,” or “I Agree,” type of button or tool. By taking this affirmative step, the individual indicates his/her intent to enroll. It must also be made clear to the applicant that, by taking this action, he or she agrees to the release and authorization language as provided on the model enrollment form (see Exhibit 1 and 1b), and attests to the truthfulness of the data provided. The process must also remind the individual of the penalty for providing false information.

- The mechanism must capture an accurate time/date stamp at the time the applicant activates the step in the previous bullet (i.e. “Enroll Now/I Agree” button or tool). The PDP sponsor will use this data to establish the application date for the enrollment request. This time stamp also marks the start of the seven day timeframe for processing the enrollment request, as it is at this time that the enrollment request is considered by CMS to be received by the PDP sponsor.

- If a legal representative is completing this enrollment request, s/he must attest that s/he has such authority to make the enrollment request and that proof of this authority is available upon request by the PDP sponsor or CMS.

- Inform the individual of the effects of completing the electronic enrollment, including that s/he will be enrolled (if approved by CMS), and that s/he will receive notice (of acceptance or denial) following submission of the enrollment to CMS.

- Include a tracking mechanism (e.g., a confirmation number) to provide the individual with evidence that the PDP sponsor has received the electronic enrollment request.

- Optionally, may request or collect premium payment or other payment information, such as a bank account number or credit card numbers.

- Maintain electronic records that are securely stored and readily reproducible for the period required in §60.8 of this chapter. The PDP sponsor’s record of the
enrollment request must exist in a format that can be easily, accurately and quickly reproduced for later reference by each individual member and/or CMS. A data extract file alone is not acceptable.

- The option of electronic enrollment, other than the CMS Online Enrollment Center described below, is limited to requests submitted via an electronic device or software (including web pages) owned by the PDP sponsor. For example, electronic enrollment via the PDP sponsor’s website is permissible, but electronic enrollment via other means, such as a broker website or non-plan owned electronic mechanism, is not permitted.

**Medicare Online Enrollment Center**

In addition to the process described above, CMS offers an online enrollment center (OEC) through the www.medicare.gov website and the 1-800-MEDICARE Call Center for enrollment into Medicare prescription drug plans. The date and time “stamped” by the Medicare Online Enrollment Center will serve as the application date for purposes of determining the election period and enrollment effective date. PDP sponsors must promptly retrieve enrollment requests from the OEC and should check for requests at least daily.

**40.1.3 - Enrollment via Telephone**

PDP sponsors may accept enrollment requests into one or more of its PDPs via an incoming (in-bound) telephone call to a plan representative or agent. The following guidelines must be followed, in addition to all other program requirements:

- Enrollment requests may only be accepted from/during an incoming (or in-bound) telephone call from a beneficiary to a plan representative or agent.
- The PDP sponsor must ensure that the telephonic enrollment request is effectuated entirely by the beneficiary or his/her authorized representative, and that the plan representative, sales agent or broker is not physically present with the beneficiary or present on the phone at the time of the request.
- Individuals must be advised that they are completing an enrollment request.
- Each telephonic enrollment request must be recorded and include statements of the individual’s agreement to be recorded, required elements necessary to complete the enrollment (as described in Appendix 2), and a verbal attestation of the intent to enroll. If the request is made by someone other than the beneficiary, the recording must include the attestation regarding the individual’s authority under State law to complete the request, in addition to the required contact information. All telephonic enrollment recordings must be reproducible and maintained as provided in §60.8 of this guidance.
- Include a tracking mechanism to provide the individual with evidence that the telephonic enrollment request was received (e.g. a confirmation number).
- Collection of financial information is prohibited at any time during the call.
• A notice of acknowledgement and other required information must be provided to 
the individual as described in §40.4 of this guidance.

• Telephonic enrollment requests into a plan offered by the same parent organization 
may be based on the model short enrollment form (Exhibit 1b) or the model plan 
selection form (Exhibit 1c) instead of the comprehensive individual enrollment 
form.

The PDP sponsor must ensure that all Part D eligibility and enrollment requirements 
provided in this guidance are met.

Scripts for completing an enrollment request in this manner must be developed by the 
PDP sponsor must contain the required elements for completing an enrollment request as 
described in Appendix 2 of this guidance, and must obtain CMS approval following 
existing marketing material approval procedures prior to use.

40.1.4 - Auto- and Facilitated Enrollment

CMS auto-enrolls and facilitates enrollment of certain LIS beneficiaries into PDPs. 
“Auto-Enrollment” is the process that refers to full-benefit dual eligible individuals. 
“Facilitated Enrollment” is the process that refers to other LIS beneficiaries. The primary 
differences between the two are the populations and the enrollment effective date.

Starting January 1, 2010, CMS implemented the Limited Income Newly Eligible 
Transition (NET) demonstration, in which it contracts with a single PDP sponsor to cover 
all periods of retroactive auto/facilitated enrollments. The Limited Income NET 
demonstration contractor is competitively procured. As a result, all auto/facilitated 
enrollments to qualified PDPs as described below will have prospective effective dates.

A. Populations

1. Auto-Enrollment.

Full-benefit dual eligible individuals who have not elected a Part D plan will be auto- 
enrolled into one by CMS. Full-benefit dual eligible individuals are defined as those 
eligible for comprehensive Title XIX Medicaid benefits as well as eligible for Medicare 
Part D. This includes those who are eligible for comprehensive Medicaid benefits plus 
Medicaid payment of Medicare Part B premiums and/or cost-sharing (sometimes known 
as QMB-plus or SLMB-plus). CMS will use data provided by State Medicaid Agencies 
to identify full-benefit dual eligible individuals. Please note that full-benefit dual eligible 
individuals do not include those eligible only for Medicaid payment of Medicare cost- 
sharing (i.e. QMB-only, SLMB-only, or QI).

Full-benefit dual eligible individuals who will be auto-enrolled into a PDP pursuant to 
this section include those enrolled in:

- Original Medicare;
• A Medicare Advantage Private Fee-for-Service (MA-PFFS) plan that does not offer a Part D benefit;
• An 1876 cost plan that does not offer a Part D optional supplemental benefit;
• Medical Savings Account; or
• An 1833 Health Care Prepayment Plan (HC-PP); and
• Who do not meet any of the conditions listed below.

This excludes full-benefit dual eligible individuals who:
• Live in any of the five U.S. territories
• Live in another country
• Are inmates in a correctional facility
• Have opted out of auto-enrollment into a Part D plan
• Are already enrolled in a Part D plan

Note: Beneficiaries enrolled in a Program of All Inclusive Care for the Elderly (PACE) receive all their Medicare benefits, including Part D benefits, through their PACE organization, so they do not need to be auto-enrolled
• Are not eligible to enroll in a PDP because they are enrolled in a Medicare Advantage plan, other than an MA-PFFS plan that does not offer Part D or an MSA plan. CMS will instead direct Medicare Advantage organizations to facilitate the enrollment of these individuals into an MA-PD plan or PDP offered by the same MA organization; please see Section 40.1.5 of MA Enrollment and Disenrollment Guidance (MMCM, Chapter 2).
• Are enrolled in a section 1876 cost plan that offers a Part D optional supplemental benefit (these individuals will be auto-enrolled instead into the cost plan’s Part D optional supplemental benefit, as is described in Chapter 17, Subpart D, of the Medicare Managed Care Manual).

For modified auto-enrollment procedures for full-benefit dual eligible individuals for whom employers claim a retiree drug subsidy, please see section 40.1.4.H.

2. Facilitated Enrollment

Other LIS eligible individuals are defined as those deemed automatically eligible for LIS because they are QMB-only, SLMB-only, QI (i.e. only eligible for Medicaid payment of Medicare premiums and/or cost-sharing); SSI-only (Medicare and Supplemental Security Income [SSI], but no Medicaid); or those who apply for LIS at the Social Security Administration (SSA) or a State Medicaid Agency and are determined eligible for LIS. This includes those who apply and are determined eligible for either the full or partial subsidy. CMS will use data submitted by SSA to identify SSI-only and those who apply for LIS and are determined eligible by SSA. CMS will use data from State Medicaid Agencies to identify those who are QMB-only, SLMB-only, QI, or who apply for LIS and are determined eligible by the State.

Other LIS eligible individuals that will be enrolled into PDPs pursuant to this section include those enrolled in:
• Original Medicare;
• A Medicare Advantage Private Fee-for-Service (MA-PFFS) plan that does not offer a Part D benefit;
• An 1876 cost plan that does not offer a Part D optional supplemental benefit;
• A Medical Savings Account (MSA); or
• An 1833 HCPP; and
• Who do not meet any of the conditions listed below.

This excludes other LIS eligible individuals who:
• Live in any of the five U.S. territories
• Live in another country
• Are individuals for whom the employer is claiming the retiree drug subsidy
• Are inmates in a correctional facility
• Have opted out of facilitated enrollment into a Part D plan
• Are already enrolled in a Part D plan

Note: Beneficiaries enrolled in a Program of All Inclusive Care for the Elderly (PACE) receive all their Medicare benefits, including Part D benefits, through their PACE organization, so they do not need to be auto-enrolled
• Are not eligible to enroll in a PDP because they are enrolled in a Medicare Advantage plan other than an MA-PFFS plan that does not offer Part D or an MSA plan. CMS will instead direct Medicare Advantage organizations to facilitate the enrollment of these individuals into an MA-PD plan or PDP offered by the same MA organization; please see Section 40.1.5 of MA Enrollment and Disenrollment Guidance (MMCM, Chapter 2)
• Are enrolled in an 1876 cost plan that offers a Part D optional supplemental benefit (these individuals will be facilitated enrolled instead into the cost plan’s Part D optional supplemental benefit, as is described in Chapter 17, Subpart D, of the Medicare Managed Care Manual).

B. Qualifying PDPs

A PDP qualifies to receive auto/facilitated enrollments in a given region if it meets all the following criteria:
• offers basic prescription drug coverage
• has a premium at or below the low-income premium subsidy amount in the PDP region
• meets the “Requirements Critical for Ensuring Effective Enrollment of Dual Eligible individuals” issued August 31, 2006.

PDPs that qualify to receive auto/facilitated enrollments may not decline to accept such enrollments. Qualifying PDPs must accept all individuals assigned by CMS who had been previously involuntarily disenrolled by the plan for non-payment of premiums.
Only PDPs with defined standard, actuarially equivalent standard, or basic alternative benefit packages will be included. CMS will not auto/facilitate enroll beneficiaries into PDPs with enhanced alternative benefit packages, even if their premium is at or below the low-income premium subsidy amount for the region. In addition, CMS will not auto/facilitate enroll beneficiaries into an employer-sponsored PDP. Finally, CMS will not auto/facilitate enroll beneficiaries into PDPs that volunteer to waive the “de minimis” amount over the regional LIS benchmark.

Plans that qualify to receive auto/facilitated enrollments in the current year, but will not in the following year will no longer receive new auto- or facilitated enrollments starting in October of the current year. This avoids the need to immediately reassign these beneficiaries to a different plan.

PDPs that do not qualify in the current year, but do qualify in the following year, will start receiving PDP Notification Files and TRRs with auto/facilitated enrollments starting November of the current year (with effective dates no earlier than January 1 of the following year).

Starting January 1, 2010, only the Limited Income NET contractor will qualify to receive auto/facilitated enrollments for retroactive periods of time. The Limited Income NET contractor will not keep these individuals on a prospective basis.

C. Auto/Facilitated Enrollment Process

CMS performs the auto/facilitated enrollment process each day it receives a source file from a State Medicaid Agency or Social Security Administration. The procedures for auto- and facilitated enrollment into PDPs are identical, and work as follows:

1. CMS will identify full-benefit dual eligible individuals to be auto-enrolled and other LIS eligible individuals to be facilitated enrolled. CMS uses LIS deemed reason code, which indicates the person was a full benefit dual eligible sometime during the past year, to define those being auto-enrolled. LIS deemed code and LIS applicant data are used to identify those who need to be facilitated enrolled.

2. CMS will identify PDPs that qualify to receive auto/facilitated enrollments.

3. CMS will assign beneficiaries to a plan in a two-step process. The first level of assignment is at the PDP sponsoring organization (PDP Sponsor) level. The second level of assignment is to an individual PDP offered by the PDP Sponsor. This will result in approximately the same proportion of auto-enrollees at the PDP Sponsor level.

At the first level of assignment, CMS will identify PDP sponsors that offer at least one qualifying PDP in the region. If more than one PDP sponsor in a region meets this criteria, CMS will auto/facilitate enroll on a random basis among available PDP sponsors. Please note that if two or more PDP sponsors are owned...
by the same parent organization, they are treated as a single organization for purposes of this first step of auto/facilitated enrollment.

At the second level of assignment, CMS will identify the qualifying PDPs offered by each sponsor in the region. If a given PDP sponsor only has one such PDP in the region, all the beneficiaries assigned to the PDP sponsor will be assigned to that one PDP. If the PDP sponsor offers more than one such PDP in the region beneficiaries will be randomly assigned first among the contracts within the sponsoring organization (if there are more than one with a qualifying PDP), and then among the qualifying PDPs a contract offers.

This method of random enrollment will result in full-benefit dual eligible individuals and other LIS beneficiaries being assigned in approximately equal proportions among available PDP sponsors, not PDPs. Since PDP sponsors may offer different numbers of PDPs that meet the auto/facilitated enrollment criteria, auto/facilitated enrollment proportions may vary at the PDP level.

**EXAMPLE:**

There are 4 PDP-sponsoring organizations in a region that offer one or more plans with premiums at or below the low income premium subsidy amount. The numbers of PDPs with an appropriate premium are as follows:

- Organization A—1 PDP
- Organization B—1 PDP
- Organization C—2 PDPs
- Organization D—3 PDPs

Step 1: The auto/facilitated enrollment population would first be divided equally and randomly among the four PDP sponsors. Thus, each PDP sponsor would be assigned 25 percent of the available population.

Step 2: Within each PDP sponsor, the population would again be divided equally and randomly. Thus, all of Organization A’s enrollees would be assigned to its one appropriate PDP; the same would be true for Organization B; 50 percent of the population assigned to Organization C would be assigned randomly to each of its two plans; and 33.3 percent of the population assigned to Organization D would be assigned randomly to each of its three plans.

PDPs with premiums below the low-income subsidy amount will not be treated more favorably than those with premiums equal to the low-income premium subsidy amount. A PDP’s other beneficiary charges – copayment levels, deductibles, etc. – will not be a factor in determining whether it qualifies for auto/facilitated enrollment provided the PDP offers basic prescription drug coverage.
4. CMS will calculate the effective date as the first day of the second month after the current month (see section 40.1.4.D below for details), create a code 61 enrollment transaction for each auto and facilitated enrollment, and submit it to the MARx system.

5. Immediately after auto/facilitated enrollment occurs, the PDP will receive the preliminary “PDP notification file” identifying those assigned, including addresses and full names. CMS does not maintain phone number data on beneficiaries, so this information cannot be transmitted to PDP sponsors. This file ensures PDPs are notified of new auto/facilitated enrollees prior to beneficiaries receiving CMS’ auto/facilitated enrollment notice. Since auto/facilitated enrollment can occur daily, these files may be transmitted as frequently as daily.

6. The PDP will then be notified via TRR of the auto/facilitated enrollment confirmed processed by MARx, including the effective date.


D. Effective Date

Starting January 1, 2010, all auto/facilitated enrollments generated by CMS into qualifying PDPs will have prospective effective dates. Specifically, the effective date will be the first day of the second month after CMS identifies the person.

Example: Throughout 2010, an individual is eligible for Part D. On July 14, 2010, the State sends data to CMS identifying the person as a full or partial dual, or SSA sends data to CMS identifying the person as a new SSI-only or LIS applicant, retroactive to March 1, 2010. CMS randomly auto/facilitate enrolls the person into a qualifying PDP effective September 1, 2010. If the person was a full dual or SSI-only, CMS creates a second auto/facilitated enrollment transaction into the Limited Income NET contractor for March 1 – August 31, 2010.

CMS will calculate the auto/facilitated enrollment effective date, which will be conveyed to plans in the PDP Notification File and the TRR. CMS will ensure that any beneficiary choice will “trump” facilitated enrollment by creating an artificially early application receipt date for systems processing purposes.

For retroactive periods, CMS will auto/facilitate enroll full-benefit dual eligible individuals and SSI-only beneficiaries into the Limited Income NET contractor. Please see below for details on when retroactive periods of coverage are necessary and how they are calculated.

1. Retroactive Auto/Facilitated Enrollments for Full Duals and SSI-Only
Full-benefit dual eligible individuals and SSI-only beneficiaries may qualify to be retroactively auto/facilitated enrolled by CMS into the Limited Income NET contractor. Partial dual eligible individuals and LIS applicants do not qualify for retroactive assignments.

For full-benefit dual eligible individuals who are Medicaid eligible first and then subsequently become Medicare eligible, the effective date of auto-enrollment will be the first day of Part D eligibility. This effective date ensures there is no coverage gap between the end of Medicaid prescription drug coverage and the start of Medicare prescription drug coverage. CMS will make every effort to identify these individuals prior to the start of their Part D eligibility, so that we can notify beneficiaries and plans prospectively of auto-enrollment. However, in cases where we cannot do so, the enrollment may be retroactive. Please note that Part D eligibility always falls on the first day of the relevant month.

Example: An individual has Medicaid coverage throughout 2010. On March 15, 2010, the State sends data identifying the person as a prospective full dual, who will become Medicare Part D eligible in May, 2010. That night, CMS randomly auto-enrolls the person into a qualifying PDP effective May 1, 2010. The last day of eligibility for Medicaid prescription drug coverage is April 30, 2010.

Retroactive eligibility for Medicare Parts A and/or B will not result in retroactive effective dates for auto-enrollment. This is because Medicare Part D eligibility cannot be retroactive. If eligibility for Part A and/or B is retroactive, Part D eligibility is effective the first day of the month in which the beneficiary received notification of retroactive Medicare Part A/B entitlement (see §10).

Example: An individual has Medicaid coverage throughout 2010. In May 2010, the individual is notified that s/he is entitled to Medicare Part A and/or B retroactive to November, 2009. The last day of eligibility for Medicaid prescription drug coverage is April 30, 2010; the first day of Part D eligibility is May 1, 2010. The person is included on a state MMA file on May 20; CMS auto-enrolls the beneficiary into the Limited Income NET contractor for May 1 through June 30, 2010; and randomly auto-enrolls her/him into a qualifying PDP effective July 1, 2010.

For those who are Medicare eligible first, and then subsequently become Medicaid eligible, auto-enrollment will be effective the first day of the month the person became Medicaid eligible (i.e. achieved full-benefit dual status), or January 1, 2006, whichever is later. For this population, there are no data that can be used to identify them prospectively, so the effective date will likely always be retroactive. Please note that auto-enrollment will only occur if the beneficiary is not already enrolled in a Part D plan; if the person is already in a Part D plan, the only impact of becoming newly eligible for Medicaid is that the individual will be deemed eligible for the full low-income subsidy.
Example: An individual is Medicare Part D eligible through 2010. The person applies for Medicaid in August 2010, is determined in October, 2010 to be Medicaid-eligible back to August 1, 2010, and is included on a state MMA file in October. Because the person has Medicare, she/he is not eligible for Medicaid prescription drug coverage (note she/he remains eligible for other Medicaid benefits). CMS auto-enrolls the beneficiary into the Limited Income NET contractor retroactive to August 1, 2010, and randomly into a qualifying PDP effective December 1, 2010.

Example: An individual becomes Medicare Part D eligible in May 2010. That same month, the individual applies for Medicaid. In August 2010, the State Medicaid Agency awards Medicaid eligibility effective February 1, 2010 (Medicaid eligibility may be retroactive to three months before the month of application), and includes the person on a state MMA file in August. In this scenario, Medicaid prescription drug coverage is effective February 1 – April 30, 2010. CMS auto-enrolls the beneficiary into the Limited Income NET contractor retroactive to May 1, 2010, and randomly auto-enrolls the person into a qualifying PDP effective October 1, 2010.

CMS will auto-enroll full-benefit dual eligible individuals who have disenrolled, either voluntarily or involuntarily, from a Part D plan and failed to enroll in a new plan (unless they affirmatively declined or opted-out of auto-enrollment). The effective date will be retroactive to the month after the disenrollment effective date of the previous Part D plan enrollment.

Example: A full-benefit dual eligible or SSI-only eligible disenrolls from a Part D plan (either voluntarily or involuntarily), effective March 31, 2010. In the April auto/facilitated enrollment run, CMS auto/facilitate enrolls the person into the Limited Income NET contractor effective April 1, and randomly into a qualifying PDP effective June 1, 2010.

In limited instances, a full-benefit dual eligible voluntarily enrolls in a Part D plan in the month(s) before the individual would otherwise have been auto-enrolled, or CMS auto/facilitates enrollment of a beneficiary with a given effective date, but subsequently data become available that shows the effective date should have been earlier. Individuals with active elections in a Part D plan are not included in CMS’ auto-enrollment process, so the auto-enrollment process does not create an enrollment for the uncovered month(s). In these instances, the beneficiary contacts the Limited Income NET contractor to request coverage for the uncovered month(s) in the past. The current PDP must refer beneficiaries with uncovered months in the past to the LINET contractor to request coverage.

The PDP must move up the effective date of a facilitated enrollment by a month if the LIS beneficiary requests this in a timely fashion, i.e. before the start of the earlier month. The PDP must accept these requests verbally and in writing; it cannot limit such request to written requests. The beneficiary can contact the plan by telephone or in writing to make this request. If the person is a partial dual eligible, the SEP under section 30.3.2 should be used. If the person is an SSI-only eligible or an individual who applied and
was determined eligible for LIS by SSA or a State Medicaid Agency, the SEP under section 30.3.8 #7 is available.

Example: CMS facilitates enrollment of an Other LIS eligible in May, 2010, effective July 1, 2010. The beneficiary receives the facilitated enrollment notice in May, and by May 31 requests the PDP makes the facilitated enrollment effective June 1. The PDP submits an enrollment transaction to do so.

E. CMS Notice Provided to Auto/Facilitated Enrolled Beneficiaries:

CMS will notify the beneficiary that she/he will be auto/facilitated enrolled in a given PDP on the auto/facilitated enrollment effective date unless s/he chooses another Part D plan (either another PDP, or an MA-PD plan, a PACE organization, or an 1876 cost plan that offers a Part D optional supplemental benefit), or opts out of auto/facilitated enrollment into a Part D plan altogether. For beneficiaries who have a retroactive period of auto/facilitated enrollment, the notice will provide information on obtaining coverage for those periods through the Limited Income NET contractor. Auto-enrollment notices will be on yellow paper; facilitated notices will be on green paper. If the beneficiary does not take either action, the person’s silence will be deemed consent with the auto/facilitated enrollment, and it will take effect on the effective date. Additionally, all LIS and dual eligible individuals have a Special Enrollment Period (SEP) that permits them to change Part D plans at any time, even after the auto/facilitated enrollment takes effect (refer to section 30.3.2 and 30.3.8, #7 of this guidance).

CMS has created an exception to the auto-enrollment procedures for full benefit dual eligible individuals who CMS knows to be enrolled in a qualifying employer group plan and for whom CMS has approved the group health plan sponsor to receive the Retiree Drug Subsidy (RDS) (see section 40.1.4.H). CMS will provide notice to such individuals of their choices and advise them to discuss the potential impact of Medicare Part D coverage on their group health plan coverage. This notice informs such individuals that they will be deemed to have declined to enroll in Part D unless they affirmatively enroll in a Part D plan or contact CMS and confirm that they wish to be auto-enrolled in a PDP. Individuals, who elect not to be auto-enrolled, may enroll in Medicare Part D at a later time if they choose to do so.

F. PDP Notice and Information Provided to Auto/Facilitated Enrolled Beneficiaries:

PDPs must send a notice confirming the auto-enrollment (see Exhibit 24) or facilitated notice (see Exhibit 25) within 10 calendar days after receiving CMS confirmation of the enrollment from the TRR or the PDP Notification File with addresses of auto/facilitated enrollees, whichever is later.

PDPs must also send a modified version of the pre- and post-enrollment materials that must be provided to those who voluntarily enroll in a PDP. If the address indicates the beneficiary is outside the PDP region, please follow procedures in section 50.2.1.4.
Prior to the effective date, the PDP must send each individual who has been auto/facilitated enrolled:

- Proof of health insurance coverage so that he/she may begin using the plan services as of the effective date;

  **NOTE:** This is not the same as the Evidence of Coverage document described in CMS’ marketing guidelines. This evidence may be in the form of member cards, the enrollment form, and/or a notice to the member. If the PDP sponsor does not provide the member card prior to the effective date, it must provide it as soon as possible after the effective date.

- The charges for which the prospective member will be liable, e.g., any premiums, coinsurance, fees or other amounts (including general information about the low income subsidy);

- The effective date of coverage and how to obtain services prior to the receipt of an ID card (if the PDP sponsor has not yet provided the ID card); AND

- A Summary of Benefits or Evidence of Coverage. Those who are auto/facilitated enrolled still need to make a decision whether to stay with the plan into which they have been auto-enrolled or change to another one that better meets their needs. Providing the Summary of Benefits or Evidence of Coverage, which is generally considered pre-enrollment marketing material, ensures that those auto/facilitated enrolled have a similar scope of information as those who voluntarily enroll.

The requirement in §40.4.2 (see also Exhibits 4 and 7) to inform the beneficiary of whether the enrollment was accepted or rejected does not apply to auto/facilitated enrollments, since CMS generates these transactions and they are already confirmed at the point when the sponsor is notified via the TRR.

There may be certain times during the month death information is updated in CMS records after the auto-assignment/enrollment process has occurred, resulting in auto-enrollment of individuals with a deceased code. In cases where the PDP sponsor receives an auto-enrollment with a deceased code, the PDP sponsor must send a notice to the estate of the member (see Exhibit 13a).

PDPs do not need to send the 30-day Coordination of Benefits survey for new enrollees whether they are auto or facilitated enrolled; they only need to conduct the annual survey.

**G. Opt Out:**

Full-benefit dual eligible and other LIS eligible individuals may opt out of (affirmatively decline) auto/facilitated enrollment into a Part D plan. The primary means for doing so is by calling 1-800-MEDICARE. However, the beneficiary may also call the PDP into
which he/she has been auto/facilitated enrolled. The PDP may accept the request verbally; a written request is not required. The entity contacted by the beneficiary must inform the individual of the implications of his/her request. In addition, a follow-up notice must be provided that confirms the request to opt-out, and explains the consequences (see Exhibit 26). The entity then sends a Code 51 disenrollment transaction and sets the Part D Opt-Out Flag (field 38) to Y (opt-out of auto-enrollment).

The beneficiary may opt-out either prior to the auto/facilitated enrollment effective date, or once enrolled in a Part D plan (whether voluntarily or auto/facilitated enrolled into it). If the beneficiary makes the request prior to the effective date of auto/facilitated enrollment, then the entity receiving the opt-out request will submit a disenrollment transaction (with specific coding indicating that the transaction is an opt-out). This will cancel the auto/facilitated enrollment, and the person will never be enrolled. The PDP sponsor should then send the model notice in Exhibit 26. If the beneficiary makes the request after the effective date of enrollment in the plan, then the request results in a disenrollment effective the last day of the month in which the request was made, and the model notice in Exhibit 26a should be used.

Please note that an individual who opts-out does not permanently surrender his or her eligibility for, or right to enroll in, a Part D plan; rather, this step ensures the person is not included in future monthly auto/facilitated enrollment processes.

If the beneficiary decides she/he wants to obtain the Part D benefit in the future, she/he does so simply by enrolling in a new plan. LIS eligible individuals have a Special Enrollment Period, so they can enroll at anytime; they are not limited to the AEP. The enrollment request will be effective the first of the month following the month in which the Part D plan receives the enrollment request.

H. Special Procedures for Full Benefit Dual Eligible individuals with Retiree Drug Subsidy

CMS has created an exception to the auto-enrollment process for full-benefit dual eligible individuals who are qualifying covered retirees and for whom CMS has approved the group health plan sponsor to receive the Retiree Drug Subsidy (RDS). The exception process includes:

- CMS identifies the full-benefit dual eligible individuals with RDS and excludes them from automatic enrollment in a Part D plan; and
- CMS sends a notice (see section 40.1.4.E) to these individuals
  - Informing them of their choices and that they need to proactively enroll in a Part D plan, if they wish to do so:
  - Suggesting that these individuals discuss the potential impact of their decision, on both drug and medical retiree benefits for themselves and their families, with the appropriate staff of the qualified retiree prescription drug plan; and
Indicating that they will be deemed to decline enrollment in Part D unless they affirmatively enroll in a Part D plan or contact CMS and confirm they wish to be auto-enrolled into a Part D plan.

40.1.5 - Re-Assignment of Certain LIS Beneficiaries

CMS has the discretion to re-assign LIS beneficiaries, including situations in which their current plan will have a premium above the low-income premium subsidy amount (i.e., benchmark) in the following year, unless the plan volunteers to waive the de minimis amount of the premium above the benchmark. CMS will conduct the reassignment in the fall of each year, and ensure all affected LIS beneficiaries are notified. Affected PDPs are not responsible for initiating any enrollment or disenrollment transactions for reassigned beneficiaries, except for re-enrollment of beneficiaries who opt to remain in their current plan, as described below. Affected PDPs are only responsible for responding to the CMS enrollment transaction promptly when they receive it and for providing appropriate beneficiary notices and materials, also as described below.

A. Population to be Re-Assigned

CMS will reassign beneficiaries enrolled in “Losing” PDPs who meet all of the following criteria:

For PDPs that offered a basic benefit and premium below the regional LIS benchmark in the current year, but will lose to reassign because they will have a premium in the following year that will be above the benchmark amount (unless they volunteer to waive the de minimis amount above the benchmark):

- They will continue to be eligible for 100% premium subsidy LIS in the following year.
  - Individuals may qualify for 100% premium subsidy because they were deemed eligible for LIS (i.e., because they were a full benefit dual eligible, Medicare Savings Program participant, or Supplemental Security Income (SSI) recipient), OR because they applied and were found eligible for the 100% LIS premium subsidy).
- They were originally enrolled by CMS into their current PDP, i.e. through auto/facilitated enrollment, or reassignment.
- They do not live in a U.S. territory.

For PDPs that are non-renewing (terminating):

- All current LIS enrollees who will continue to have LIS in the following year, regardless of premium subsidy amount, and regardless of whether the individual was assigned to or voluntarily enrolled in a plan.

The actual reassignment process is typically run on a single day in early October. CMS will only reassign beneficiaries who meet the above criteria as of the day of the
reassignment run. CMS does not subsequently “sweep” for individuals who may meet the criteria at later points in time.

B. “Losing” PDPs

A PDP will lose LIS beneficiaries to re-assignment if it meets any of the following criteria:

- The PDP has beneficiaries originally auto/facilitated enrolled or reassigned by CMS and there will be a new premium liability in the following year for those eligible for 100% premium subsidy under LIS. The premium increase would be due to the premium going above the LIS benchmark
  - Per 1860D-14(a)(5) of the Social Security Act, the PDP will not lose beneficiaries if
    - The plan’s premium is within a “de minimis” amount of the LIS benchmark, and
    - The plan voluntarily agrees not to collect the de minis premium amount over the benchmark (see section 40.1.5.B.1 below for additional details)
  - The PDP is terminating for the following year.

As part of determining whether a terminating PDP should be included in reassignment, CMS determines whether it is truly non-renewing (i.e. all beneficiaries will be disenrolled with no automated enrollment into another PDP), or whether beneficiaries are actually being cross-walked to a different PDP. If the latter, CMS will perform the following additional steps:

- Determine if the PDP had a premium below the LIS regional benchmark and a basic benefit in the current year.
  - If it does not, then the PDP will be carved out of reassignment (i.e. not considered “terminating” for purposes of reassignment), and all beneficiaries will be cross-walked.
  - If it does, CMS will determine whether the PDP to which beneficiaries are cross-walked qualify as a “Gaining” PDP per section 40.1.5.G.
    - If so, the beneficiaries will not be included in reassignment, and all beneficiaries will be cross-walked, since the plan to which they are being cross-walked will have no premium for those with 100% premium liability.
    - If not, beneficiaries who meet the criteria for reassignment due to premium increase in section 40.1.5.A above will be reassigned (to ensure they have no new premium liability the following year); the remaining beneficiaries will be cross-walked.

CMS account managers will contact losing plans in September to confirm the plan is aware it will lose beneficiaries due to reassignment. Plans that are uncertain about whether they will lose to reassignment should contact their CMS account manager to confirm.
Volunteering for “De Minimis”

As noted above, per section 1860D-14(a)(5) of the Social Security Act, a PDP or Medicare Advantage with Prescription Drug (MA-PD) plan may volunteer to waive the portion of the monthly adjusted basic beneficiary premium that is up to a de minimis amount above the LIS benchmark for a subsidy eligible individual. The de minimis amount may not be waived from the enhanced portion of a Part D premium applicable to the enhanced benefit.

CMS will announce the de minimis amount in August, when the benchmarks are released. We will determine the de minimis amount taking into consideration the goal of minimizing reassignments without undue cost to the Medicare Trust Fund.

CMS will not reassign LIS members from plans that volunteer to waive the de minimis amount. However, for continuing Part D plans, we only reassign beneficiaries originally assigned to a zero-premium PDP that will have a new premium liability in the following year. We do not reassign beneficiaries from continuing MA plans, regardless of the level of the Part D premium. As a result, while any Part D plan that qualifies may volunteer to waive the de minimis premium, we anticipate that the only Part D plans that are likely to volunteer are those continuing PDPs that would otherwise lose beneficiaries to reassignment.

A Part D sponsor will volunteer to waive de minimis premium amount on a plan by plan basis. The Sponsor may opt to volunteer for one plan benefit package that qualifies and not another. For each plan benefit package for which a Sponsor volunteers, the Sponsor agrees to waive the de minimis premium amount for all LIS beneficiaries with 100% premium subsidy in that plan benefit package. This includes any member for any month in the contract year for which the individual is 100% premium subsidy eligible. The Part D sponsor will be responsible for identifying these members based on existing data already transmitted by CMS, and ensuring no premium is charged to them.

Plans with de minimis premiums must inform CMS of their intent to participate in the voluntary de minimis program within five business days after the de minimis amount is released. Specific dates will be provided when the de minimis amount is announced. Plans will inform CMS of their intention to participate through HPMS. A de minimis link will be available from the left navigation bar in HPMS under Plan Bids/Bid Submission/CY2011/Manage Plans. All organization users with the bid download/upload access type associated with a contract number will have access to the de minimis page for qualifying plans under the contract number. The default value will be unchecked (i.e., “No”) so a plan must select the checkbox to indicate that it wants to volunteer to participate.

The HPMS screenshot will appear as follows:

A prescription drug plan (PDP) or Medicare Advantage Plan with Prescription Drug coverage (MA-PD) that offers basic Part D coverage may volunteer to waive the portion of the monthly
adjusted basic beneficiary premium that is a de minimis amount above the low-income subsidy (LIS) benchmark for an LIS eligible individual. CMS will not reassign LIS members from PDPs that volunteer to waive the de minimis amount. (Please note: CMS does not reassign LIS beneficiaries from MA-PD plans that are renewing).

For plan year 2011, the de minimis amount will be $___.

To volunteer to waive the de minimis amount for LIS beneficiaries with 100% premium subsidy:

1. Select the contract number(s) for which you have access.
2. Select the checkbox next to each plan for which you volunteer to waive the de minimis amount.

   Please Note: The checkbox will only be available for plans that have a Part D premium that is within the de minimis amount of the LIS benchmark in their region.

Plans will have until <date> to volunteer to participate in de minimis

C. Re-assignment Process

CMS will attempt to reassign beneficiaries within the same organization wherever possible. First, CMS will identify other qualified plans in the same region offered under the same contract number, or if that is not available, under a different contract number sponsored by the same parent organization. If the organization has more than one such plan in that region, CMS will randomly reassign beneficiaries among those plans. CMS will first attempt to identify a benchmark PDP within the same organization; only if none are available will it assign to a PDP within the same organization that volunteers to waive the de minimis amount above the benchmark.

If the organization does NOT offer another qualifying PDP, CMS will randomly reassign affected beneficiaries to other PDP sponsors that have at least one qualifying PDP in that region. CMS will follow the two-step process used under auto/facilitated enrollment, i.e. random distribution first at the sponsor level, then randomly among qualifying plans within the sponsor (see section 40.1.4.C). CMS will not randomly reassign to de minimis plans.

Reassignment usually takes place in early October. CMS will send a preliminary file of reassignees to “gaining” and “losing” plans in mid-October. This file shall be used by plans for purposes of identifying beneficiaries who will be receiving CMS’ blue reassignment letters; for “gaining” plans to obtain full name and address data; and for “losing” plans to identify the appropriate ANOC per section 40.1.5.E. The final confirmation will be received via TRR in late November.

Please note: beneficiaries are not always assigned to a “gaining” PDP that serves the same region as the “losing” PDP. CMS will use the beneficiary’s state of residence to determine where the beneficiary needs to be reassigned. CMS determines state of residence first by checking if a state submitted the person on a recent state MMA file; if the person was not included on a recent state MMA file, CMS then uses the beneficiary address on its system. It is possible that, since originally assigned to a plan, a
beneficiary’s address had changed, so s/he must be reassigned to a new region. As a result, when reassignment is to another plan within the same organization, sponsors may not see all beneficiaries from the “losing” plan moved to the “gaining” plan. In addition, PDPs in regions with no “losing” plans may gain a few beneficiaries from reassignment. Finally, “gaining” plans may receive reassignees that appear to reside outside the region (based on beneficiary address), but who are not. For these individuals, sponsors should follow the procedures in section 50.2.1.4.

CMS may conduct a second reassignment for LIS beneficiaries in non-renewing Medicare Advantage plans (see section 40.1.8 of Chapter 2 of the Medicare Advantage Manual). In this second reassignment, “gaining” PDP’s will receive a second round of reassignees.

D. CMS Notification to Beneficiaries

CMS will ensure that all beneficiaries being re-assigned are notified. These notices will be on blue paper, and will instruct beneficiaries who are being reassigned because of a premium increase to contact their current plan if they wish to remain with the plan for the following year. Per section 1860D-14(c), CMS will also provide reassigned beneficiaries with information on formulary differences between the individual’s former plan and new plan (with respect to the individual’s drug regimen), as well as a description of the right to coverage determination, exception, reconsideration, appeal, or grievance. The model CMS notice will be available on the following web page in the fall of each year: http://www.cms.gov/LimitedIncomeandResources/LISNoticesMailings/list.asp#TopOfPage

E. Plan Communication to Affected Beneficiaries

“Losing” PDPs are responsible for sending an appropriate ANOC, as follows:

- If individuals are being reassigned within the same organization, the ANOC should be for the following year’s plan, and include the Evidence of Coverage and LIS Rider.
- If the PDP is losing beneficiaries to a different PDP sponsoring organization, it may, at its discretion, use the alternate ANOC in Exhibit 30; it need not send the Evidence of Coverage or LIS Rider.
  - If it chooses to use the standard ANOC, it should use the version applicable to the plan in which the beneficiary is currently enrolled, and shall include the Evidence of Coverage and LIS Rider.

“Losing” PDPs should make their best effort to identify individuals who will be lost to reassignment for purposes of providing the appropriate ANOC. Plans may identify potential reassignees by identifying those that meet both of the following conditions:

Individuals initially assigned by CMS (enrollment source = A [auto-enrollment], C [facilitated enrollment] or H [reassignment]; or TRCs 117, 118, or 212A)
Individual has 100% premium subsidy in following year (per the TRR or monthly LIS history report)

Terminating PDPs should send a termination notice as instructed in the Call Letter.

Additionally, “losing” plans will be required to send a letter confirming disenrollment from the plan due to re-assignment within 10 calendar days from receiving disenrollment confirmation on a TRR (See Exhibit 10(b) for model letter).

“Gaining” PDPs are responsible for providing enrollment confirmation (See Exhibit 29) and enrollment materials to beneficiaries within 10 calendar days of receiving confirmation of reassignment on a TRR.

“Gaining” PDPs do not need to send the 30-day Coordination of Benefits survey for new enrollees whether they are auto or facilitated enrolled; they only need to conduct the annual survey.

F. Requests for “Re-Enrollment” in the “Losing” Plan

CMS’ notices to affected beneficiaries will instruct them to contact their current plan if they wish to remain with the plan for the following year. If a reassigned beneficiary contacts the plan and indicates that s/he wishes to remain enrolled despite incurring premium liability, the plan must take a new enrollment election in accordance with §40.1.1 – 40.1.3 and §40.2 f. For the new enrollment, use the actual application date, which should be no earlier than October 15 of the current year; an election type of “S” (Special Enrollment Period), and an effective date of January 1 of the following year.

As part of this enrollment, the plan must confirm and document the beneficiary’s understanding of the financial liability s/he will incur by remaining with the plan for the following year. **However, DO NOT transmit these enrollment elections to CMS until a TRR is received confirming the beneficiary’s disenrollment from the plan in late November.** If the “re-enrollment” transaction is sent in before disenrollment due to reassignment is confirmed, the transaction will be rejected as “beneficiary already enrolled.” For beneficiaries re-enrolling in their current plan, the sponsor need not send a disenrollment confirmation letter, but must send the standard enrollment confirmation letter in section 40.4.

G. “Gaining” PDPs

PDPs that qualify for auto- and facilitated enrollment (see section 40.1.4.B) with effective dates starting January 1 of the following year will also qualify to receive those LIS beneficiaries reassigned as described above. Qualifying PDPs must meet the “Requirements Critical for Ensuring Effective Enrollment of Dual Eligible individuals” issued August 31, 2006. The only time CMS will reassign to a de minimis PDP is when a
PDP sponsoring organization does not offer a benchmark PDP in the region, but does offer a de minimis PDP.

40.1.6 - Group Enrollment Mechanism for Employer/Union Sponsored PDPs

CMS will allow a PDP sponsor to accept enrollment requests into an employer or union sponsored PDP using a group enrollment process that includes providing CMS with any information it has on other insurance coverage for the purposes of coordination of benefits, as well as creditable coverage history it has on each beneficiary group enrolled for purposes of assessing the late enrollment penalty.

It is the PDP sponsor’s responsibility to ensure the group enrollment process meets all applicable PDP enrollment requirements. PDP sponsors must ensure that any contracts and/or other arrangements and agreements with employers and unions intending to use the group enrollment process make these requirements clear.

The group enrollment process must include notification and materials to each beneficiary as follows:

- Beneficiaries participate in the group enrollment mechanism by receiving advance notice that the employer/union intends to enroll them for a prospective date in a PDP that the employer/union is offering; and
- That the beneficiary may affirmatively opt out of such enrollment; how to accomplish that; and any consequences to employer/union benefits opting out would bring; and
- This notice must be provided by the PDP sponsor, or the employer or union acting on its behalf, not less than 21 calendar days prior to the effective date of the beneficiary’s enrollment in the group sponsored PDP.
- Additionally, the notification materials provided must include a summary of benefits offered under the employer/union sponsored PDP, an explanation of how to get more information about the PDP, and an explanation on how to contact Medicare for information on other Part D options that might be available to the beneficiaries. Each individual must also receive the information contained on page 3 of Exhibit 1 of this guidance.

The PDP sponsor must ensure all of the above requirements are met prior to submission of the enrollment transactions to CMS. For enrollments processed using the SEP EGHP, the application date is the first day of the month prior to the effective date of the group enrollment for all mechanisms at all times. This will ensure that any subsequent beneficiary-generated enrollment request will supersede the group enrollment in CMS systems. For the purposes of providing notices and meeting other timeframe requirements, PDP sponsors will use the date the organization receives the request. For example, if a valid group enrollment mechanism file is received by the organization on January 24th for enrollments effective February 1st, the receipt date for the provision of
required notices is January 24th and the application date submitted on the enrollment transactions is January 1st.

The employer or union must provide in the group enrollment file(s) all the information required for the PDP sponsor to submit a complete enrollment request transaction to CMS, including permanent residence information (refer to Appendix 2 for a complete list of the elements required for an enrollment transaction to be considered complete). Records must be maintained as outlined in §60.8 of this chapter.

40.1.7 - Enrollment for Beneficiaries in Qualified State Pharmaceutical Assistance Programs (SPAPs)

CMS will allow sponsors to accept enrollment requests in an agreed-upon electronic file format from qualified SPAPs, provided the SPAP has met the following requirements:

- The SPAP must attest, as required by section 40.2.1 of this guidance that it has the authority under state law to enroll on behalf of its members.
- The SPAP must coordinate with the sponsor to provide the required data elements for the sponsor to process and submit an enrollment request to CMS.
- The SPAP must provide a notice to its members in advance of submitting the requests for a prospective date that explains that the SPAP is enrolling on their behalf, how the enrollment works with the SPAP and how individuals can decline such enrollment.

In return, PDPs that agree to accept enrollment requests from SPAPs in this format are required to process them like any other enrollment and in accordance with notification timeframes. Additionally, the sponsor must ensure the SPAP has met the above requirements prior to submission of the enrollment transaction to CMS. It is important for the PDP sponsor to work with the contact at the SPAP in the event that the plan encounters any problems processing the enrollment request in the format provided. Because the SPAP is the authorized representative of the beneficiary, the sponsor is responsible for following up with the SPAP if the enrollment is incomplete in any way (to obtain missing information) or if the enrollment is conditionally rejected due to the existence of the employer/union drug coverage (to confirm that the individual understands the implications of enrolling in a Part D plan).

Special note for SPAP enrollment requests during the AEP - For enrollment processing purposes for the AEP, the application date must be set to October 15th. This will ensure that subsequent beneficiary-generated enrollment requests made during the AEP will supersede the SPAP enrollment in CMS systems.

40.2 - Processing the Enrollment Request

If an enrollment request is completed during a face-to-face interview, the PDP sponsor should use the individual’s Medicare card to verify the spelling of the name, and to confirm the correct recording of sex, Health Insurance Claim Number, and dates of
entitlement to Medicare Part A and/or enrollment in Part B. If the form is mailed or faxed to the PDP sponsor, or for on-line or other enrollment processes, the PDP sponsor should verify this information with the individual via telephone or other means, or request that the individual include a copy of his/her Medicare card when mailing in the enrollment request. Regardless of whether or not the sponsor has reviewed the Medicare Identification card, the sponsor must still validate and verify Medicare entitlement as described in item “B” below in this section.

Appendix 2 lists all the elements that must be provided in order to consider the enrollment request complete. If the PDP sponsor receives an enrollment request that contains all these elements, the PDP sponsor must consider the enrollment request complete even if all other data elements on the enrollment request are not provided. If a PDP sponsor has received CMS approval for an enrollment request mechanism that contains data elements in addition to those on the model paper enrollment form included in this guidance, the enrollment request must be considered complete even if those additional elements are not provided.

If a PDP sponsor receives an enrollment request that does not have all necessary elements required in order to consider it complete, it must not immediately deny the enrollment. The PDP sponsor must check available CMS systems (e.g. either the BEQ or MARx online query) for information to complete an enrollment before requiring the beneficiary to provide the missing information. For example, if a beneficiary failed to fill out the “sex” field on the enrollment and the PDP sponsor has access to this information via available systems, the sponsor must not request the information from the beneficiary. If the required but missing information is not available via CMS systems, the enrollment request is considered incomplete and the PDP sponsor must follow the procedures outlined in §40.2.2 in order to complete the enrollment request.

The following should also be considered when completing an enrollment:

A. **Permanent Residence Information** - The PDP sponsor must obtain the individual’s permanent residence address to determine that he/she resides within the PDP plan’s service area. If an individual puts a Post Office Box as his/her place of residence on the enrollment request, the PDP sponsor must consider the enrollment election incomplete and must contact the individual to determine place of permanent residence. If the applicant claims permanent residency in two or more states or if there is a dispute over where the individual permanently resides, the PDP sponsor should consult the State law in which the PDP sponsor operates and determine whether the enrollee is considered a resident of the State.

B. **Entitlement Information** – Following the procedures outlined in the CMS Plan Communications User Guide, PDP sponsors must verify Part D eligibility/Medicare entitlement by either the Batch Eligibility Query (BEQ) process or the MARx online query (M232 screen) or its equivalent for all enrollment requests except enrollment requests from a current enrollee of a PDP
who is requesting enrollment into another PDP offered by the same parent organization with no break in coverage (i.e. “switching plans”).

Individuals are not required to provide evidence of entitlement to Medicare Part A and/or enrollment in Part B with their enrollment request. If the systems (BEQ or MARx on-line query) indicate that the individual is entitled to Medicare Part A and/or enrolled in Part B, then no further documentation of Medicare entitlement from the individual is needed.

When neither the BEQ, the MARx online query, nor MAPDIUI (Medicare Advantage Prescription Drug Interactive User Interface) beneficiary eligibility query shows Medicare eligibility for Part D, the PDP organization must consider the individual’s Medicare ID card to be evidence of Medicare entitlement. When neither BEQ/MARx/MAPDIUI query nor the Medicare ID card is available, the sponsor must consider an SSA award letter that shows Medicare entitlement (including start dates) as evidence of Medicare entitlement.

Please refer to §20 for more information about the relationship between Medicare A & B entitlement and the start of Part D eligibility.

If the PDP sponsor is not able to verify entitlement as described above, refer to §40.2.3 for additional procedures.

C. Effective Date of Coverage - The PDP sponsor must determine the effective date of enrollment as described in §30.4 for all enrollment requests. If the individual fills out an enrollment request in a face-to-face interview or through telephone enrollment, then the PDP sponsor representative may advise the individual of the proposed effective date, but must also stress to the individual that it is only a proposed effective date and that the individual will hear directly from the PDP sponsor to confirm the actual effective date of enrollment. The PDP sponsor must notify the member of the effective date of enrollment prior to the effective date (refer to §40.4 for more information and a description of exceptions to this rule).

If an individual submits an enrollment request with an unallowable effective date, or if the PDP sponsor allowed the individual to select an unallowable effective date, the PDP sponsor must notify the individual in a timely manner and explain that the enrollment must be processed with a different (allowable) effective date of enrollment. The organization should resolve the issue with the individual as to the correct effective date, and the notification must be documented. If the individual refuses to have the enrollment processed with the correct effective date, the beneficiary can cancel the enrollment according to the procedures outlined in §60.1.

PDP sponsors must ensure enrollees have access to plan benefits as of the effective date of enrollment the PDP sponsor has determined and may not delay
provision of plan benefits in anticipation of the submission to or reply from CMS systems.

For auto/facilitated enrollments, refer to section §40.1.4 of this guidance for more information.

D. **Health Related Information** - PDP sponsors may not ask health screening questions during the enrollment process.

E. **Statement of Understanding and Release of Information** - The PDP sponsor must include the information contained in **Exhibit 1** on page 3 under the heading “Please read and sign below” in all of its enrollment request vehicles.

F. **Signature and Date on Paper Enrollment Forms** - When a paper enrollment form is used, the individual must sign the enrollment form. If the individual is unable to sign the form, a legal representative must sign the enrollment form (refer to §40.2.1 for more information). If a legal representative signs the form for the individual, then he or she must attest on the form that he or she has the authority under State law to effect the enrollment request on behalf of the individual and that a copy of the proof of other authorization required by State law that empowers the individual to effect an enrollment request on behalf of the applicant is available upon request by the PDP sponsor or CMS. Acceptable documentation includes items such as court-appointed legal guardianship or durable power of attorney.

The individual and/or legal representative should also write the date he/she signed the enrollment request; however, if he/she inadvertently fails to include the date on a paper enrollment form, or if an alternate enrollment mechanism is used, then the date of receipt that the PDP sponsor notes on the enrollment request will serve as the “signature date” of the request.

If a paper enrollment form is submitted and the signature is not included, the PDP sponsor may verify with the individual with a phone call and document the contact, rather than return the paper enrollment form as incomplete. The documentation of this contact will complete the enrollment request (assuming all other required elements are complete).

When an enrollment request mechanism other than paper is used, the individual or his or her legal representative must complete the enrollment mechanism process, including the attestation of legal representative status as described above. A pen-and-ink signature is not required.

G. **Other Signatures** - If the PDP sponsor representative helps the individual fill out the enrollment request, then the PDP sponsor representative must clearly indicate his/her name on the enrollment form and indicate his/her relationship to the
individual. However, the PDP sponsor representative does not have to include his/her name on the form when:

- He/she pre-fills the individual’s name and mailing address when the individual has requested that an enrollment form be mailed to him/her,
- He/she fills in the “office use only” block, and/or
- He/she corrects information on the enrollment form after verifying information (see “final verification of information” below).

The PDP sponsor representative does have to include his/her name on the form if he/she pre-fills any other information, including the individual’s phone number.

**H. Old Enrollment Requests** - If the PDP sponsor receives an enrollment request that was completed more than 30 calendar days prior to the PDP sponsor’s receipt of the request, the PDP sponsor is encouraged to contact the individual to re-affirm intent to enroll prior to processing the enrollment and to advise the beneficiary of the upcoming effective date.

**I. Determining the Application Date** – The PDP sponsor must date as received all enrollment requests as soon as they are initially received. The application date is the date the enrollment request is initially received by the PDP sponsor, except for requests submitted via the CMS On-line Enrollment Center, requests made into employer or union-sponsored plans, and auto or facilitated enrollments (refer to §10 for definitions of “receipt of enrollment request,” “completed enrollment request” and “application date”). If the request received is incomplete, follow the instructions provided in section 40.2.2 below.

Part D plans must use the application date in the appropriate field when submitting enrollment transactions to CMS. Appendix 3 of this guidance provides a summary of application dates for CMS enrollment transactions.

**J. Correction of Information** - The PDP sponsor may find that it must make corrections to an individual’s enrollment request. For example, an individual may have made an error in writing his or her telephone number or may have transposed a digit in his or her date of birth. The PDP sponsor should make this type of correction to the enrollment request (e.g. the enrollment form) when necessary, and the individual making those corrections should place his/her initials and the date next to the corrections. A separate “correction” sheet, signed and dated by the individual making the correction, or an electronic record of a similar nature, may be used by the PDP sponsor (in place of the initializing procedure described in the prior sentence), and should become a part of the enrollment file. These types of corrections will not result in the PDP sponsor having to co-sign the enrollment form.
K. Sending the Enrollment to CMS – For all complete enrollment requests, the PDP sponsor must transmit the appropriate enrollment transaction to CMS within the time frames prescribed in §40.3, and must send the individual the information described in §30.4 within the required time frames. Processes for submitting transactions are provided in CMS systems guidance.

L. Premium Payment and Withhold options
At minimum, PDP sponsors must include on all enrollment request mechanisms the option for individuals to: 1) pay plan premiums by being billed directly by the plan or 2) have the premiums withheld from their SSA/RRB benefit check. The plan may also choose to offer other payment methods, such as automatic deduction from the individual’s bank or other financial institution or from a credit card.

The enrollment mechanism must advise the individual that if s/he does not select a premium payment option, the default action will be direct bill.

Railroad Retirement Board (RRB) enrollees may also submit requests to have their premiums withheld from their RRB retirement payments. Sponsors must offer this option on all enrollment mechanisms as well.

On the enrollment mechanism, PDP sponsors must also include in this section a statement that advises those individuals who qualify for extra help that if the extra help does not cover the entire plan premium, the individual is responsible for the amount that Medicare does not cover.

Model language has been provided on Exhibits 1 and 1b to reflect the required options.

At this time, OPM is unable to process withhold requests.

40.2.1 - Who May Complete an Enrollment Request
A Medicare beneficiary is generally the only individual who may execute a valid request for enrollment in, or disenrollment request from, a PDP. However, another individual could be the legal representative or appropriate party to execute an enrollment or disenrollment request as the law of the State in which the beneficiary resides may allow. CMS will recognize State laws that authorize persons to effect a Part D enrollment or disenrollment request for Medicare beneficiaries. Persons authorized under State law may include court-appointed legal guardians, persons having durable power of attorney for health care decisions, or individuals authorized to make health care decisions under state surrogate consent laws, provided they have authority to act for the beneficiary in this capacity.

If a Medicare beneficiary is unable to sign an enrollment form or disenrollment request or complete an enrollment request mechanism due to reasons such as physical limitations or
illiteracy, State law would again govern whether another individual may execute the request on behalf of the beneficiary. Usually, a court-appointed guardian is authorized to act on the beneficiary’s behalf. If there is uncertainty regarding whether another person may sign for a beneficiary, PDP sponsors should check State laws regarding the authority of persons to sign for and make health care treatment decisions for other persons.

When someone other than the Medicare beneficiary completes an enrollment or disenrollment request, he or she must:

1) Attest that he or she has the authority under State law to do so;
2) Attest that proof of authorization, if any, required by State law that empowers the individual to effectuate an enrollment or disenrollment request on behalf of the individual is available upon request by CMS. Part D sponsors cannot require such documentation as a condition of enrollment or disenrollment; and
3) Provide contact information.

The sponsor must retain the record of this attestation as part of the record of the enrollment or disenrollment request. CMS will provide a sample attestation as part of the model enrollment form (Exhibit 1).

If a sponsor has reason to believe that an individual making an election on behalf of a beneficiary may not be authorized under State law to do so, the sponsor should contact its CMS account manager with all applicable documentation regarding State Law and the case in question. The account manager may request supporting documentation from the individual making the election.

When an authorized representative completes an enrollment request on behalf of a beneficiary, the PDP sponsor should inquire regarding the preference for the delivery of required notifications and other plan materials (i.e. sending mail to the beneficiary directly or to the representative, or both) and make reasonable accommodations to satisfy these wishes.

Representative payee status, as designated by SSA, is not necessarily sufficient to enroll or disenroll a Medicare beneficiary. Where PDP sponsors are aware that an individual has a representative payee designated by SSA to handle the individual’s finances, PDP sponsors should contact the representative payee to determine his/her legal relationship to the individual, and to ascertain whether he/she is the appropriate person, under State law, to execute the enrollment or disenrollment request.

40.2.2 - When the Enrollment Request Is Incomplete

When the enrollment request is incomplete, the PDP sponsor must document its efforts to obtain the missing information or documentation needed to complete the enrollment request. The sponsor must make this determination and notify the individual within 10 calendar days of the receipt of the request that additional documentation is needed for the
enrollment request, unless the required but missing information can be obtained via CMS systems.

Note: An enrollment request is considered complete even if the only information missing is the eligibility for the election period. In such circumstances, the plan must contact the individual to assure they have a valid election period before processing the enrollment. (See Section 30 for more information regarding eligibility for election periods and Section 40 for enrollment processing requirements.)

For incomplete IEP enrollment requests received prior to the month of entitlement to Part A or enrollment in Part B, additional documentation to make the request complete must be received during the first three months of the IEP, or within 21 calendar days of the request for additional information (whichever is later). For incomplete IEP enrollment requests received during the month of entitlement to Part A or enrollment in Part B or later, additional documentation to make the request complete must be received by the end of the month in which the enrollment request was initially received, or within 21 calendar days of the request for additional information (whichever is later).

For incomplete AEP elections, additional documentation to make the request complete must be received by December 7, or within 21 calendar days of the request for additional information (whichever is later). For all other enrollment periods, additional documentation to make the request complete must be received by the end of the month in which the enrollment request was initially received, or within 21 calendar days of the request for additional information (whichever is later).

Examples

• Ms. Stears’ 65th birthday is April 20, 2011. She is eligible for Medicare Part A and Part B beginning April 1, 2011 and has decided to enroll in Part B beginning on April 1. Her IEP for Part D begins on January 1, 2011 and ends on July 31, 2011. She submits an incomplete IEP enrollment request on January 15, 2011, and the sponsor requests the required but missing information on January 20, 2011. The enrollment request must be denied if the required information is not received by March 31, 2011.

• Ms. Mohan’s 65th birthday is June 10, 2011. She is eligible for Medicare Part A and Part B beginning June 1, 2011 and has decided to enroll in Part B beginning on June 1. Her IEP for Part D begins on March 1, 2011 and ends on September 30, 2011. She submits an incomplete ICEP enrollment request on July 5, 2011, and the sponsor requests the required but missing information on July 7, 2011. The enrollment request must be denied if the required information is not received by July 31, 2011.

When an incomplete enrollment request is received near the end of a month or an enrollment period, the use of the full 21 calendar day period to complete the request may extend beyond CMS systems plan submission “cut-off” date (these dates are provided in
the CMS Plan Communications User Guide). PDP sponsors may utilize a code 61 enrollment transaction to directly submit the request to CMS as provided in the CMS Plan Communications User Guide.

If additional documentation needed to make the request complete is not received within the timeframe above, the organization must deny the enrollment request using the procedures outlined in §40.2.3.

**Requesting Information from the Applicant** - To obtain information to complete the enrollment, the PDP sponsor must contact the individual to obtain the information within 10 calendar days of receipt of the enrollment request (see Exhibit 3). If the contact is made orally (by phone), the PDP sponsor must document the contact and retain the documentation in its records. While CMS has provided a model notice, we would encourage plans to obtain information by the most expedient means available. The PDP sponsor must explain to the individual that if the information is not received within the timeframes described above, the enrollment will be denied. If the PDP sponsor denies the enrollment request, the sponsor must provide the individual with a notice of denial of enrollment (see Exhibit 6).

If all documentation is received within allowable time frames and the enrollment request is complete, the PDP sponsor must transmit the enrollment to CMS within the time frames prescribed in §40.3, and must provide the individual with the information described in §40.4

**Optional Exception for Dual-Eligible Individuals and Individuals who Qualify for the Low Income Subsidy** - For enrollment requests submitted by dually eligible individuals and individuals who qualify for the low income subsidy (LIS), a PDP sponsor may consider an enrollment request complete if there are premium amounts due to the sponsor from a prior enrollment, even if the sponsor has a policy to consider such enrollment requests incomplete.

The PDP sponsor has the discretion to implement this exception to dually eligible individuals and individuals who qualify for LIS within each of its plans. If the sponsor offers this exception in one of its plans, it must apply the policy to all such individuals who request enrollment in that plan.

**40.2.3 - PDP Sponsor Denial of Enrollment**

For enrollment requests that do not require additional information from the applicant, a PDP sponsor must deny an enrollment within 10 calendar days of receiving the enrollment request based on its own determination of the ineligibility of the individual to elect the PDP plan (e.g. individual not having a valid enrollment period to elect a plan). For incomplete enrollment request that require information from the applicant and for which the applicant fails to provide the information within the required time frame, an a PDP sponsor must deny the enrollment within 10 calendar days of the expiration of the time frames described in §40.2.2.
PDP sponsor denials occur **before** the organization has transmitted the enrollment to CMS. For example, it may be obvious that the individual is not eligible to elect the plan due to place of residence. This “up-front” denial determination must be within 10 calendar days from the date of receipt of an enrollment request.

**Notice Requirement** - The organization must provide a notice of denial to the individual that includes an explanation of the reason for the denial (see Exhibit 6). This notice must be provided within 10 calendar days of either 1) receipt of the enrollment request or 2) expiration of the time frame for receipt of requested additional information, as described in the following examples:

- A PDP sponsor receives an AEP enrollment request from an individual on December 1\(^{st}\) and determines on that same day that the individual is ineligible due to place of residence. The organization must provide the notice of denial within 10 calendar days from December 1\(^{st}\).

- A PDP sponsor receives an enrollment request from an individual on January 7 and is unable to determine, through direct contact with the beneficiary or the beneficiary’s authorized representative, that the beneficiary has a valid enrollment period available. The sponsor should send a notice of denial within ten calendar days from January 7.

- A PDP sponsor receives an AEP enrollment request on December 1\(^{st}\) from an individual, identifies the enrollment request as incomplete, and on December 2 notifies the individual of the need for additional information. The beneficiary does not submit the information by December 23 (as required under §40.2.2), which means the organization must deny the enrollment. The organization should send notice of denial within ten calendar days from December 23.

**40.3 - Transmission of Enrollments to CMS**

For all enrollment requests effective January 1, 2008, and after that the organization is not denying per the requirements in §40.2.3, the PDP sponsor must submit the information necessary for CMS to add the beneficiary to its records as an enrollee of the PDP sponsor within 7 calendar days of receipt of the completed enrollment request. CMS system “down” days are included in the calculation of the completed enrollment request. For the purpose of assessing compliance with this requirement, CMS will count the enrollment request receipt date as “day zero” and the following day as “day one.” All enrollment requests must be processed in chronological order by date of receipt of the enrollment request.

PDP sponsors are encouraged to submit transactions on a flow basis and as early as possible to resolve the many data issues that arise from late submissions. However, if the organization misses the cutoff date, it must still submit the transactions within the required 7-day time frame.
NOTE: The 7-day requirement to submit the transaction does not delay the effective date of the individual’s enrollment in the PDP, i.e., the effective date must be established according to the procedures outlined in §30.4.

More detail on how PDP sponsors must submit transmissions to CMS are contained in the Medicare Advantage and Prescription Drug Plans Plan Communications User Guide.

40.4 - Information Provided to Member

Much of the enrollment information that a PDP sponsor must provide to the enrolling individual must be provided prior to the effective date of enrollment. However, some information will be provided after the effective date of coverage. A member’s coverage begins on the effective date regardless of when the member receives all the information the plan sends.

As discussed previously (section 30), the PDP sponsor must provide required notices in response to information received by CMS on the TRR that provides the earliest notification. Sponsors may choose to send notifications based on the availability of each Batch Completion Summary Status (BCSS) file if they desire. However, in no case may use of the BCSS for this purpose extend any timeframe established in this guidance. Sponsors choosing to utilize the BCSS for certain required beneficiary notifications must do so consistently.

The PDP sponsor may provide the required notices described in §§40.4.1 and 40.4.2 in a single (“combination”) notice (see Exhibit 2b). The combination notice takes the place of separate acknowledgement and confirmation notices and, as such, requires expedited issuance. To use the combination notice, the sponsor must be able to provide this notice within 7 calendar days of availability of the TRR. Additionally, when following this option to use the combination notice, if the PDP sponsor is unable to ensure that the beneficiary will receive this combination notice prior to the enrollment effective date (or within timeframes for incomplete enrollment requests or enrollments received at the end of the month), the sponsor still must ensure that the beneficiary has the information required in §40.4.1 within these timeframes described therein.

If an individual’s enrollment includes a request for SSA or RRB premium withhold and was processed after the monthly cut-off for payment, the sponsor must submit the request for premium withhold separate from the enrollment request. Plans should resubmit the request for premium withhold timely to assure the individual can have premium withholding at the next possible effective date. Additionally, the sponsor must inform the individual that:

- If his/her request for premium withholding is approved, it will start in 1-2 months;
- The effective date for premium withholding will not be retroactive;
• The member will be responsible for paying the sponsor directly for all premiums due from the enrollment effective date until the month in which premium withholding begins; and

• For plans implementing §50.3.1, failure to pay premiums for months in which premium withholding is not in effect will result in disenrollment from the plan.

### 40.4.1 - Prior to the Effective Date of Enrollment

Prior to the effective date of enrollment, the PDP sponsor must provide the member with all the necessary information about being a Medicare member of the PDP, including the PDP rules, and the member’s rights and responsibilities (an exception to this requirement is described in §40.4.2.). In addition, the PDP sponsor must provide the following to the individual:

• For paper enrollment requests, a copy of the completed paper enrollment form, if the individual does not already have a copy of the form;

• For enrollment requests submitted via the internet, evidence that the online enrollment request was received (e.g., a confirmation number);

• For enrollments submitted via telephonic enrollment, evidence that the telephonic enrollment request was received (e.g., a confirmation number);

• A notice acknowledging receipt of the enrollment request providing the expected effective date of enrollment (see Exhibit 2). This notice must be sent no later than 10 calendar days after receipt of the completed enrollment request; and

• Proof of health insurance coverage so that he/she may begin using the plan services as of the effective date. This proof must include the 4Rx data necessary to access benefits.

**NOTE:** This proof of coverage is not the same as the Evidence of Coverage document described in CMS’ marketing guidelines. The proof of coverage provided may be in the form of member ID cards, the enrollment form, and/or a notice to the member (refer to Exhibit 2, which is a model letter with optional language that would allow the member to use the letter as proof of coverage until he/she receives a member card. As of the effective date of enrollment, plan systems should indicate active membership.
Regardless of whether an enrollment request is made in a face-to-face interview, by fax, by mail, or by any other mechanism defined and allowed by CMS, the PDP sponsor must explain:

- The charges for which the prospective member will be liable, e.g., any premiums (this includes any Part D late enrollment penalty), coinsurance, fees or other amounts; (including general information about the low income subsidy).

- The prospective member’s consent to the disclosure and exchange of necessary information between the PDP sponsor and CMS.

- The potential for member liability if it is found that the member is not eligible for Part D at the time coverage begins and the member has used PDP services after the effective date.

- The effective date of coverage and how to obtain services prior to the receipt of an ID card (if the PDP sponsor has not yet provided the ID card).

Requirements for providing information to individuals enrolled via the auto-enrollment and facilitated enrollment processes are outlined §40.1.4.

40.4.2 - After the Effective Date of Coverage

CMS recognizes that for some enrollment requests, the PDP sponsor will be unable to provide the materials to the individual, including notification of the effective date, prior to the effective date, as generally required in §30.4.1. These cases will usually occur only when an enrollment request is received by the PDP sponsor in the last few days of a month, and the effective date is the first of the upcoming month. In these cases, the PDP sponsor still must provide the individual all materials described above no later than 10 calendar days after receipt of the enrollment request. In these cases, the PDP sponsor is also strongly encouraged to call these new members as soon as possible (such as within 1 - 3 calendar days) to provide the effective date, information to access benefits and explain the PDP rules. The member’s coverage will be active on the effective date regardless of whether or not the member has received all the information by the effective date.

Acceptance/Rejection of Enrollment - Once the PDP sponsor receives a TRR from CMS indicating whether the individual’s enrollment has been accepted or rejected, the PDP sponsor must notify the individual of CMS’ acceptance or rejection of the enrollment within 10 calendar days of the availability of the TRR that contains the earliest notification of the acceptance/rejection (see Exhibits 4 and 7). The enrollment confirmation notice must explain the charges for which the prospective member will be liable, e.g., any premiums, coinsurance, fees or other amounts; and any amount that is attributable to the Medicare deductible and coinsurance. For those eligible for the low-income subsidy, the enrollment confirmation notice must specify the limits applicable to the level of subsidy to which the person is entitled.
There are exceptions to this notice requirement for certain types of transaction rejections. These exceptions exist so as not to penalize the individual for a systems issue or delay, such as a plan transmission or keying error. In addition, this notice requirement does not apply to the scenario in which a transaction rejection due to no Medicare Part A and/or no Medicare Part B is received but the PDP sponsor has evidence to the contrary. In this case, the PDP sponsor must request a retroactive enrollment correction from CMS (or its designee) within the timeframes provided in the Standard Operating Procedures for the CMS Retroactive Processing Contractor. If CMS (or its designee) is unable to process the enrollment correction due to its determination that the individual indeed does not have Medicare Part A or Part B, the PDP sponsor must reject the enrollment and must notify the individual of the rejection within 10 calendar days after CMS’ (or its designee’s) determination. Retroactive enrollments are covered in more detail in §60.3.

If a PDP sponsor rejects an enrollment request and later receives additional information from the individual substantiating his/her eligibility, the PDP sponsor must obtain a new enrollment request from the individual in order to enroll the individual, and must process the enrollment with a current (i.e., not retroactive) effective date. Refer to §60.3 for more information regarding retroactive enrollments.

40.5 - Enrollments Not Legally Valid

When an enrollment is not legally valid, a retroactive action may be necessary (refer to §§50.3 and 50.5 for more information). In addition, a reinstatement to the plan in which the individual was originally enrolled may be necessary if the invalid enrollment resulted in an individual’s disenrollment from his/her original plan of choice.

An enrollment that is not complete is not legally valid. In addition, an enrollment is not legally valid if it is later determined that the individual did not meet eligibility requirements at the time of enrollment. For example, an enrollment is not legally valid if a PDP sponsor or CMS determines at a later date that an incorrect permanent address was provided at the time of enrollment and the actual permanent address is outside the PDP’s service area.

There are also instances in which an enrollment that appears to be complete can turn out to be legally invalid. In particular, CMS does not regard an enrollment as actually complete if the individual, or his/her legal representative, did not intend to enroll in the PDP. If there is evidence that the individual did not intend to enroll in the PDP, the PDP sponsor should submit a retroactive disenrollment request to CMS (or the CMS Retroactive Processing Contractor). Evidence of lack of intent to enroll by the individual may include:

- An enrollment request signed by the individual when a legal representative should be signing;
- Request by the individual for cancellation of enrollment before the effective date (refer to §60.1.1 for procedures for processing cancellations).
Payment of the premium does not necessarily indicate an informed decision to enroll. For example, the individual may believe that he/she was purchasing a supplemental health insurance policy, as opposed to enrolling in a PDP.
50 - Disenrollment Procedures
42 CFR 423.36 & 423.44

Except as provided for in this section, a PDP sponsor may not, either orally or in writing or by any action or inaction, request or encourage any enrollee to disenroll from a PDP. While a PDP sponsor may contact members to determine the reason for disenrollment, the PDP sponsor must not discourage members from disenrolling after they indicate their desire to do so. The PDP sponsor must apply disenrollment policies in a consistent manner for similar members in similar circumstances.

All notice requirements are summarized in Appendix 1. The PDP sponsor must provide disenrollment notices in response to transaction replies received from CMS based upon the TRR.

NOTE: It is not necessary for a Part D sponsor to send a notice of disenrollment to beneficiaries whose plan benefit package (PBP) number is changed as part of a CMS-approved plan renewal. The annual notice of change that the PDP sends to the beneficiaries as part of the end-of-year activities serves this function. Instructions and information on the annual notice of change can be found in§60.7 of Chapter 3 of the Medicare Managed Care Manual.

50.1 - Voluntary Disenrollment by an Individual

A member may request disenrollment from a PDP only during one of the periods outlined in §§30.2 and 30.3. The member may disenroll by:

1. Enrolling in another plan (during a valid enrollment period);
2. Giving or faxing a signed written notice to the PDP sponsor, or through the member’s employer/union group, where applicable;
3. Submitting a request via Internet to the PDP sponsor (if the PDP sponsor offers such an option);
4. Calling 1-800-MEDICARE.

If a member verbally requests disenrollment from the PDP, the PDP sponsor must instruct the member to make the request via one of the methods outlined above. The PDP sponsor may send a disenrollment form to the member upon request (see Exhibits 8 and 9).

The disenrollment request must be dated when it is received by the PDP sponsor.

When someone other than the Medicare beneficiary completes a disenrollment request, he or she must:
1. Attest that he or she has the authority under State law to make the disenrollment request on behalf of the individual;

2. Attest that proof of this authorization (if any), as required by State law that empowers the individual to effect a disenrollment request on behalf of the applicant is available upon request by the PDP sponsor or CMS; and

3. Provide contact information.

50.1.1 – Requests Submitted via Internet

The PDP sponsor has the option to allow members to submit disenrollment requests via the Internet; however, certain conditions must be met. The PDP sponsor must, at a minimum, comply with the CMS security policies - found at http://www.hhs.gov/informationsecurity/.

The PDP sponsor may also include additional security provisions. The CMS policies indicate that with regard to receiving such disenrollments via the Internet, an acceptable method of encryption must be utilized to provide for confidentiality and integrity of this data, and that authentication or identification procedures are employed to assure that both the sender and recipient of the data are known to each other and are authorized to receive and decrypt such information.

In addition, CMS policies also require PDP sponsors to provide the CMS Office of Information Services with a pro forma notice of intent to use the Internet for these purposes. The notice is essentially an attestation that the sponsor is complying with the required encryption, authentication, and identification requirements. The effective date of the request is determined by the election period in which the valid request was received by the sponsor. The election period is determined by the date the request is received at the site designated by the sponsor.

The option of online disenrollment is limited to requests submitted via the PDP sponsor’s website. Online disenrollment via other means, such as a broker website, as well as disenrollment requests submitted via email, are not permitted.

CMS reserves the right to audit the PDP sponsor to ascertain whether it is in compliance with the security policy.

50.1.2 – Request Signature and Date

When requesting voluntary disenrollment by submitting a written request, the individual must sign the disenrollment request. If the individual is unable to sign, a legal representative must sign the request (refer to §40.2.1 for more detail on who may complete enrollment and disenrollment requests). If the request is not signed, see section 50.4.2 for information to complete the disenrollment request.
The individual and/or legal representative should write the date he/she signed the
disenrollment request; however, if he/she inadvertently fails to include the date, then the
date of receipt that the PDP sponsor places on the request form will serve as the signature
date.

If a written disenrollment request is received and the signature is not included, the
sponsor may verify with the individual with a phone call and document the contact, rather
than return the written request as incomplete.

50.1.3 – Effective Date of Disenrollment

The election period during which a valid request to disenroll was received by the PDP
organization will determine the effective date of the disenrollment request; refer to §30.5
for information regarding disenrollment effective dates.

With the exception of some SEPs and when periods overlap, individuals may not choose
the effective date of disenrollment. Instead, the PDP sponsor is responsible for assigning
the appropriate effective date based on the enrollment period. During face-to-face
disenrollments, or when a beneficiary calls about a disenrollment, the PDP sponsor staff
are responsible for ensuring that a beneficiary does not attempt to choose an effective
date that is not allowed under the requirements outlined in §30.5.

If an individual submits a disenrollment request with an unallowable effective date, the
PDP sponsor must contact the beneficiary to explain that the disenrollment must be
processed with a different effective date. The organization should resolve the issue with
the beneficiary as to the correct effective date, and the contact must be documented. If
the beneficiary refuses to have the disenrollment processed with the correct effective
date, the beneficiary may cancel the disenrollment according to the procedures outlined
in §60.2.2 prior to the effective date.

50.1.4 – PDP Sponsor Denial of Voluntary Disenrollment Request

If the PDP sponsor receives a disenrollment request that it must deny, the PDP sponsor
must notify the enrollee within 10 calendar days of the receipt of the request, and must
include the reason for the denial (see Exhibit 11).

A PDP sponsor may deny a voluntary request for disenrollment only when:

1. The request was made outside of an allowable period as described in §20 of this
guidance; or
2. The request was made by someone other than the enrollee and that individual is
not the enrollee’s legal representative (as described in §30.2.1).
3. The request was incomplete and the required information) is not provided within
the required time frame.
50.1.5 – Notice Requirements

After the member submits a disenrollment request, the PDP sponsor must provide the individual a disenrollment notice within ten (10) calendar days of the date the request to disenroll was received (see Exhibit 10). The disenrollment notice must include an explanation that the individual remains enrolled in the PDP until the effective date of the disenrollment. For these types of disenrollments (i.e., disenrollments in which the individual has disenrolled directly through the PDP sponsor, PDP sponsors are encouraged, but not required, to follow up with a confirmation of disenrollment letter after receiving CMS confirmation of the disenrollment via the TRR.

Since Medicare beneficiaries have the option of disenrolling through 1-800-MEDICARE, or by enrolling in another Part D plan, the PDP sponsor will not always receive a request for disenrollment directly from the individual but will instead learn of the disenrollment through the TRR. If the PDP sponsor learns of the disenrollment from the TRR (as opposed to through the receipt of a request from the enrollee), the PDP sponsor must send a notice of confirmation of the disenrollment to the individual within 10 calendar days of the availability of the TRR (see Exhibit 10a). The disenrollment confirmation notice is not required for automatic disenrollments resulting from an individual’s enrollment in a PBP within the same Part D contract.

For denials of voluntary disenrollment requests as described in §50.1.4, the denial notice must be sent within 10 calendar days of the date the disenrollment request was received. It must also include the reason for denial (see Exhibit 11).

50.2 - Required Involuntary Disenrollment

A PDP organization must disenroll an individual from a PDP in the following cases.

1. A change in residence (including incarceration) makes the individual ineligible to be an enrollee of the PDP (§50.2.1)
2. The individual loses entitlement to Medicare (§50.2.2.);
3. The individual dies (§50.2.3); 4. The PDP contract is terminated, the PDP sponsor discontinues offering a PDP or reduces the plan service area such that the individual no longer resides in the plan service area (§50.2.4);
5. The individual materially misrepresents information to the PDP sponsor regarding reimbursement for third-party coverage (§50.2.5) ; or
6. The member fails to pay his/her Part D-IRMAA to the government and CMS notifies the PDP to effectuate the disenrollment (§50.2.6).

Incarceration – An individual who is incarcerated is considered to be residing outside the plan service area, even if the correctional facility is located within the plan service area. However, sponsors must disregard past periods of incarceration that have been
served to completion if those periods have not already been addressed by a sponsor or by CMS.

**Notice Requirements** - In situations where the sponsor disenrolls the member involuntarily on any basis except death, loss of entitlement, or failure to pay Part D-IRMAA, notices of the upcoming disenrollment meeting the following requirements must be sent. All disenrollment notices must:

1. Advise the member that the sponsor is planning to disenroll the member and why such action is occurring;
2. Be mailed to the member before submission of the disenrollment transaction to CMS; and
3. Include an explanation of the member’s right to a hearing under the sponsor’s grievance procedures. (This explanation is not required if the disenrollment is a result of plan termination or service area reduction, since a hearing would not be appropriate for that type of disenrollment. There are different notice requirements for terminations and area reductions, which are provided in separate instructions to sponsors.)

### 50.2.1 - Sponsor Receives Notification of Possible Residence Change

The Part D sponsor must disenroll an individual when an individual (or legal representative) notifies the PDP that he or she has moved and no longer resides in the service area of a PDP. The sponsor must retain documentation of the permanent change of address and disenroll the individual. If the sponsor offers another PDP in the region into which the beneficiary has moved, the sponsor may use this opportunity to inform the beneficiary of its other PDP product(s).

If the PDP sponsor learns of a beneficiary address change that is outside the PDP service area from either CMS (i.e. a state and county code change on the TRR) or from the U.S. Postal Service (USPS), it must follow the “Researching and Acting on a Change of Address” procedures outlined below.

An SEP, as defined in §20.3.1, applies to individuals who are disenrolled due to a change in residence. An individual may choose another MA or Part D plan (either a PDP or MA-PD) during this SEP.

### 50.2.1.1 – General Rule

The Part D sponsor must disenroll a member if:

1. He/she permanently moves out of the service area;
2. The member’s temporary absence from the service area exceeds 12 consecutive months;

3. The member is incarcerated and, therefore, out of area.

50.2.1.2 – Effective Date

Disenrollment is effective on the first of the month following the month in which the individual (or his or her legal representative) notifies the PDP sponsor that s/he has moved and no longer resides in the plan service area. In the case of an individual who provides advance notice of the move, the disenrollment will be the first of the month following the month in which the individual indicates he/she will be moving. In the case of incarcerated individuals, sponsors may receive notification of the individual’s out-of-area status via a TRR; disenrollment is effective the first of the month following the sponsor's confirmation of a current incarceration. If the member establishes that a permanent move occurred retroactively and requests retroactive disenrollment (not earlier than the 1st of the month after the move), the sponsor can submit this request to CMS (or its designee) for consideration of retroactive action.

Disenrollment as a result of receiving information from either CMS or the U.S. Post Office that the individual has not confirmed will be effective the first day of the calendar month after 12 months have passed.

50.2.1.3 - Researching and Acting on a Change of Address

Within ten calendar days of receiving information from either CMS or the USPS that a beneficiary may no longer reside in the service area, a PDP sponsor must make an attempt to contact the member to determine the beneficiary’s permanent residence and must document its efforts in doing so (may use Exhibit 33 if contacting the member in writing). The requirement to attempt to contact the member does not apply to a prospective enrollment for which the sponsor receives either transaction reply code 011 (Enrollment Accepted) or 100 (PBP Change Accepted as Submitted) accompanied by transaction reply code 016 (Enrollment Accepted – Out of Area) on the same TRR, as these represent new enrollments for which the organization recently confirmed the individual's permanent residence in the plan service area. In the case of incarcerated individuals, the PDP may also confirm the individual’s out-of-area (i.e. incarcerated) status with public sources (such as a state/federal government entity or other public records) rather than direct contact with the individual. The PDP sponsor may accept either written or verbal confirmation that an individual has moved out of the service area, as long as the PDP sponsor applies the policy consistently among all members. PDP sponsors may disregard past periods of incarceration that have been served to completion and have not already been addressed by a plan or CMS.

If a sponsor confirms an individual’s current incarceration status but does not obtain the start date of the current incarceration, the sponsor must disenroll the individual prospectively for the first of the month following the date on which the current
incarceration was confirmed. If a sponsor confirms an individual’s current incarceration status as well as the start date of the current incarceration, the sponsor must disenroll the individual for the first of the month following the start date of the incarceration. If that disenrollment effective date is outside the range of effective dates allowed by MARx (based on the current calendar month), the sponsor must submit the retroactive disenrollment request to the CMS Retroactive Processing Contractor (see §60.4).

If the PDP sponsor does not receive confirmation from the member (or his or her legal representative) within a 12 month period, the PDP sponsor must initiate disenrollment. The 12 month period will begin on the date the change of address is identified (e.g. through the TRR or forward address notification from the USPS).

When researching changes of address, CMS encourages sponsors to utilize resources available to them, including any CMS systems interfaces, internet search tools, address information from provider claims, etc.

50.2.1.4 – Special Procedures for Auto and Facilitated Enrollees Whose Address Is Outside the PDP Region

CMS assigns most beneficiaries based on the State Medicaid Agency that reports the individual as dual eligible, even if that state is different than that in the address on CMS’ systems. In addition, beneficiaries may move after auto/facilitated enrollment occurs. If the PDP sponsor discovers that an individual whom CMS had auto/facilitated enrolled or reassigned has an address outside of the PDP sponsor’s region (e.g. via a state and county code change on the TRR or the USPS), the PDP sponsor must make an attempt to determine the beneficiary’s permanent residence and must document its efforts in doing so. The PDP sponsor may accept either written or verbal confirmation that an individual has moved out of the service area, as long as the PDP sponsor applies the policy consistently among all members.

If the sponsor confirms the move is temporary, the PDP sponsor must retain the individual as a member.

If the sponsor confirms the move is permanent and has a PDP in the new region that offers a basic benefit package (i.e. other than enhanced) with a premium at or below the low-income premium subsidy amount for that region, the PDP organization may submit an enrollment transaction to enroll the beneficiary in that PDP prospectively (See Exhibit 27). Sponsors must use the first day of the month prior to the enrollment effective date as the application date and an enrollment source code data value of “B.” In this event, no enrollment form or other election is necessary. However, an enrollment form is necessary if the beneficiary chooses to enroll into another type of plan (e.g. enhanced) in the new region.

If the sponsor confirms the move is permanent and does not have a PDP in the new region that offers a basic benefit package with a premium at or below the low-income premium subsidy amount for that region, the PDP sponsor must inform the beneficiary...
that s/he must enroll in a PDP that serves the area where s/he now resides. The Sponsor must disenroll the beneficiary, effective the first of following month (see Exhibit 28).

If the sponsor is unable to contact the auto/facilitated enrolled beneficiary, or receives no response, the PDP sponsor must not disenroll the beneficiary. This includes situations in which the beneficiary’s address is listed as a P.O. Box.

50.2.1.5 - Procedures for Developing Addresses for Members Whose Mail is Returned as Undeliverable

If an address is not current, the USPS will return any materials mailed first-class by the sponsor as undeliverable.

Note: For auto and facilitated enrollees, CMS provides PDP sponsors with mailing addresses as maintained in CMS systems. These addresses are not always current, and in cases where the beneficiary has a representative payee, the address of the payee will be the address of record in CMS systems.

In the event that any member materials are returned as undeliverable, the PDP sponsor must take the following steps:

1. If the USPS returns mail with a new forwarding address, forward plan materials to the beneficiary and advise the plan member to change his or her address with the Social Security Administration.
2. If the sponsor receives documented proof from the USPS of a beneficiary change that is outside of the PDP region or mail is returned without a forwarding address, follow the procedures outlined in § 50.2.1.3.
3. If the beneficiary uses his or her drug coverage at a pharmacy in the plan’s network, the sponsor may choose to follow up with the pharmacy to obtain the member’s current address.
4. If the sponsor is successful in locating the beneficiary, advise the beneficiary to update records with the Social Security Administration by:
   a. Calling their toll-free number, 1-800-772-1213. TTY users should call 1-800-325-0778 weekdays from 7:00 a.m. to 7:00 p.m. EST;
   b. Going to http://www.ssa.gov/changeaddress.html on the SSA website; or
   c. Notifying the local SSA field office. A beneficiary can get addresses and directions to SSA field offices from the Social Security Office Locator which is available on the Internet at: http://www.socialsecurity.gov/locator.
A PDP sponsor is expected to continue to mail materials to the *member’s address of record*. If the postal service returns a piece of beneficiary communication to the organization, the plan should document the return and retain the returned material. It should continue to send future communications to that same address, as a forwarding address may become available at a later date. Additionally, CMS encourages the PDP sponsor to continue to research addresses as described in the “Researching and acting on change of address” above.

50.2.1.6 – Notice Requirements

1. **Part D sponsor notified of out-of-area permanent move** - When the sponsor receives notice of a permanent change in address from the individual, it must provide notification of disenrollment to the member. This notice to the member, as well as the disenrollment transaction to CMS, must be sent within 10 calendar days of the PDP sponsor’s learning of the permanent move.

2. **Out of area for 12 months** - When the individual has been out of the service area for 12 months after the date the sponsor learned of the change in address from either CMS or the USPS and the sponsor has not be able to obtain confirmation, the sponsor must provide notification of the upcoming disenrollment to the individual. Sponsors are encouraged to follow up with members and to issue interim notices prior to the expiration of the 12 month period.

The notice of disenrollment must be provided within the first ten calendar days of the 12th month. The notice should advise the member to notify the PDP sponsor as soon as possible if the information is incorrect. The transaction to CMS must be sent within 3 business days following the disenrollment effective date.

CMS strongly encourages that sponsors send a final confirmation of disenrollment notice to the member to ensure the individual does not continue to use plan services.

50.2.2 - Loss of Eligibility for Part D

An individual who is no longer entitled to either Medicare Part A and/or Part B benefits may not remain enrolled in a PDP. The sponsor will be notified by CMS that part D eligibility has ended. CMS will make the disenrollment effective the first day of the month following the last month of Part D eligibility.

**Notice Requirements** – Notice must be provided when the disenrollment is due to the loss of entitlement to either Medicare Part A or Part B (see Exhibit 14) so that any erroneous disenrollments can be corrected as soon as possible. In cases of erroneous disenrollment and notification, see §60.2.1.
50.2.3 - Death

CMS will disenroll an individual from a PDP sponsor upon his/her death and CMS will notify the Part D sponsor that the individual has died. This disenrollment is effective the first day of the calendar month following the month of death. Sponsors may not submit disenrollment transactions to CMS in response to the apparent death of a member. If the eligibility query shows a date of death, sponsors must submit the enrollment only when the date of death is equal to or greater than the effective date. In the anticipation at official notification from CMS via the TRR, the sponsor may, at its discretion, make note of the reported death in internal plan systems in order to suppress premium bills and member notices.

Notice Requirements - Following the receipt of a CMS notification (via TRR) of disenrollment due to death, a notice must be sent to the member or the estate of the member (see Exhibit 13) so that any erroneous disenrollments can be corrected as soon as possible. The sponsor must send this notice within 10 days of the notification via the TRR. In cases of erroneous disenrollment and notification, refer to §60.2.1.

50.2.4 - Terminations/Nonrenewals

The PDP sponsor must disenroll an individual from a PDP if the PDP contract is terminated, the PDP sponsor discontinues offering the PDP or the PDP sponsor reduces the plan service area such that the individual no longer resides in the plan service area. An individual who is disenrolled under these provisions has an SEP, as described in §30.4.3, to enroll in a different Part D plan.

Notice Requirements - The PDP sponsor must give each affected individual a written notice of the effective date of the termination, and include a description of alternatives for obtaining benefits under the Medicare program. CMS will provide further guidance to affected sponsors, as required by 42 CFR 423.507 - 423.509.

50.2.5 - Material Misrepresentation Regarding Third-Party Reimbursement

If a PDP enrollee intentionally withholds or falsifies information about third-party reimbursement coverage, CMS requires that the individual be disenrolled from the PDP. Involuntary disenrollment for this reason requires CMS approval. The PDP sponsor must submit any information it has regarding the claim of material misrepresentation to its CMS account manager for review. Disenrollment for material misrepresentation of this information is effective the first of the month following the month in which the enrollee is notified of the disenrollment, or as CMS specifies.
50.2.6 – Failure to Pay a Part D-Income Related Monthly Adjustment Amount (Part D-IRMAA)

Individually with Part D-IRMAA must pay this additional premium directly to the government, not to their Part D plan sponsor. CMS has established a 3-month initial grace period before individuals who fail to pay their Part D-IRMAA will be disenrolled from their Part D plan. CMS will report the disenrollments to the organization via the daily TRR using a specific Transaction Reply Code (TRC). The effective date of the disenrollment is the first of the month following the end of the initial grace period.

Example: Ms. Jones must pay a Part D-IRMAA. CMS bills Ms. Jones her monthly Part D-IRMAA amount in March, April and May. Ms. Jones does not pay all the Part D-IRMAA amounts owed by the due date of the May bill. CMS generates a disenrollment and sends the plan a specific TRC via the daily TRR. The effective date of the disenrollment will be June 1.

The Part D sponsor must send each affected individual a written notice of the disenrollment within ten (10) calendar days of receipt of the TRR indicating disenrollment for non-payment of the Part D-IRMAA.

Note: CMS plans to begin disenrollments for failure to pay Part D-IRMAA in March, with an effective date of April 1, 2012.

Cost Plans Offering Supplemental Part D Benefit – Individuals, enrolled in a cost contract and an optional supplemental Part D benefit offered by the cost plan, who fail to pay their assessed Part D-IRMAA to CMS will be disenrolled from the cost contract. CMS will report the disenrollment to the organization via the TRR using a specific TRC.

Similar to instances in which a cost plan enrollee is automatically disenrolled when s/he enrolls in a standalone PDP, CMS directs cost plans to submit a transaction to CMS to enroll the individual in the cost contract without the Part D optional supplemental benefit (i.e. “cost-only PBP”). The action the cost plan takes to submit an enrollment transaction to return the individual to the Cost-only plan should be transparent to the individual. The cost plan must send each affected individual a written notice of the loss of the Part D optional supplemental benefit within ten (10) calendar days of receipt of the TRR indicating disenrollment for non-payment of the Part D-IRMAA.

Notice Requirements – Part D plan sponsors are required to notify members of their disenrollment due to failure to pay Part D-IRMAA (see Exhibit 21a.)

When an individual fails to pay both Part D-IRMAA and the plan premium, and the disenrollment effective dates are the same, the TRC for the disenrollment action will reflect the first disenrollment transaction that is processed by MARx. For example, if the plan-generated disenrollment transaction, resulting from the failure to pay plan premiums, is processed by MARx before CMS initiates a disenrollment transaction for failure to pay Part D-IRMAA, the TRC will reflect the plan-generated disenrollment.
Thus, plans would issue Exhibit 21 as outlined in Section 50.3 regarding notice requirements.

Similarly, if the CMS-generated disenrollment transaction for failure to pay Part D-IRMAA is processed first, plans will receive the TRC reflecting this action. In such cases, CMS will be unable to process the plan-generated disenrollment transaction (because the individual is already disenrolled), however, plans may review their own billing records to determine if an individual was slated for disenrollment for non-payment of plan premiums. If so, and the effective date of the disenrollment matches the Part D-IRMAA disenrollment effective date, plans have three options for notifying beneficiaries:

1. Plans may send the notice for failure to pay Part D-IRMAA (Exhibit 21a);
2. Plans may send both the notice for failure to pay Part D-IRMAA (Exhibit 21a) and the plan notice for failure to pay premiums (Exhibit 21); or
3. Plans may send the plan notice for failure to pay premiums and include information regarding the Part D-IRMAA disenrollment (Exhibit 21).

Reinstatement for “Good Cause” – Individuals involuntarily disenrolled from their PDP for failure to pay Part D-IRMAA have the opportunity to ask CMS for reinstatement into the PDP from which they were disenrolled. CMS may reinstate enrollment, without interruption of coverage, if the individual demonstrates “good cause” and pays all Part D-IRMAA and plan sponsor owed amounts (both past due and monthly amounts during the request period) within 3 calendar months after the disenrollment effective date (see §60.2.4). Members from cost plans who are disenrolled may also request reinstatement for “good cause” for only the Part D optional benefit, following Section 60.2.4.

50.3 - Optional Involuntary Disenrollments

A PDP sponsor may disenroll a member from a PDP it offers if:

- Premiums are not paid on a timely basis (§50.3.1);
- The member engages in disruptive behavior (§50.3.2); or
- The member provides fraudulent information on an enrollment request, or if the member permits abuse of an enrollment card in the PDP (§50.3.3).

Notice Requirements - In situations where the PDP sponsor disenrolls the member involuntarily for any of the reasons addressed above, the PDP sponsor must send notice of the upcoming disenrollment that meets the following requirements:

- Advises the member that the PDP sponsor is planning to disenroll the member and why such action is occurring;
- Provides the effective date of termination; and
• Includes an explanation of the member’s right to a hearing under the PDP sponsor’s grievance procedures.

Unless otherwise indicated, all notices must be mailed to the member before submission of the disenrollment transaction to CMS.

50.3.1 - Failure to Pay Premiums

Part D sponsors may not disenroll a member who fails to pay plan cost sharing under this provision. However, a sponsor has two options when a member fails to pay plan premiums (this includes any Part D late enrollment penalty per Chapter 4 of the Prescription Drug Benefit Manual).

For each of its Part D plans (i.e. each PBP), the Part D sponsor must take action consistently among all members, i.e., a sponsor may have different policies among its different Part D plans, but it may not have different policies within a plan.

The Part D sponsor may:

1. Do nothing, i.e., allow the member to remain enrolled in the same PDP;

2. Disenroll the member after a grace period and proper notice.

If a PDP sponsor chooses to disenroll members for failure to pay premiums, it must apply its disenrollment policy consistently to all members of a plan including applying a consistent grace period of no less than two (2) months. Additionally, the organization must promptly effectuate such disenrollments at the end of the plan’s grace period for payment of premiums.

The PDP sponsor may increase the length of the initial grace period or establish a policy of not disenrolling members for failure to pay the plan premium during the calendar year. For example, a PDP sponsor may increase the grace period from 2 months to 6 months to ease the burden for individuals affected by a natural disaster; however, it must provide this extended grace period to everyone in the PBP and not only those in the area affected by the natural disaster. A sponsor must report any changes to its policy for disenrollment for failure to pay premiums to its CMS account manager before implementing such changes.

If the sponsor chooses to disenroll the member, this action may only be accomplished by the sponsor after the sponsor makes a reasonable effort to collect the payment and notice has been provided to the member (as described below). If payment has not been received within a grace period, the individual will be disenrolled.

Sponsors may not disenroll members for failure to pay premiums (or notify them of impending disenrollment) in cases where the member has requested that premiums be withheld from his/her Social Security benefit check until the sponsor receives a TRR
indicating that the member’s request has been rejected. The sponsor must then notify the member of the premium owed, provide the appropriate grace period, and comply with other applicable requirements prior to disenrolling the member.

**Sponsors may not involuntarily disenroll any individuals who are considered to be in premium withhold status by CMS.** Individuals who have requested premium withhold are considered to remain in premium withhold status until either (1) CMS notifies the sponsor that the premium-withhold request has rejected, failed, or been unsuccessful; or (2) the member requests that he/she be billed directly. Only after one of these actions occurs may a member’s status be changed to “direct bill.” Once the member is considered to be in “direct bill” status, the sponsor must notify the member of the premium owed and provide the appropriate grace period, as described below. Sponsors must always provide members the opportunity to pay premiums owed before initiating any disenrollment action.

However, even if a member’s premium payment status has been changed to “direct bill” and the member can demonstrate that SSA or RRB has withheld Part C and/or Part D premiums during the coverage month(s) in question, the member will be considered to remain in premium withhold status.

**Example 1 – Incorrect Continuation of Premium Withhold:** Individual was enrolled in Plan A and selected premium withhold. Individual subsequently enrolls in Plan B and does not select premium withhold. Upon receiving a direct bill from Plan B, the individual provides Plan B with proof that a premium deduction continues from his SSA or RRB benefit check. Since the member provided Plan B with evidence that a premium amount is currently being deducted from his check, Plan B cannot initiate the process to disenroll the individual for failure to pay premiums. Plan B must work with CMS to obtain appropriate premium reimbursement.

Further, an individual will continue to be considered in premium withhold status if a plan is notified by CMS that the member’s request for premium withholding is not successful as a result of systems/fund transfer issues between CMS and the Social Security Administration (SSA) or the Railroad Retirement Board (RRB), or between CMS and the sponsor. CMS recognizes that in some instances sponsors have not received premium amounts in their monthly CMS plan payment for members who have elected Social Security withholding; however, sponsors cannot hold their members responsible for such issues, nor penalize them by attempting to disenroll them from their plan. Therefore, the sponsor may not initiate the billing (and subsequent disenrollment process, if necessary) until a member is in “direct bill” status.

**Example 2 – Incorrect Data Due to Systems Miscommunication:** An individual requests premium withhold, and Plan A correctly submits the request to CMS. The transaction request is submitted successfully by CMS to SSA and the appropriate premium amount is deducted from the individual’s SSA benefit check. However, due to a systems issue between CMS and SSA, the premium withhold data is not
correctly reflected in CMS systems. Thus, CMS does not pay the correct premium amount to Plan A. Plan A must work with CMS to obtain appropriate premium reimbursement and may not initiate the disenrollment process for the individual for failure to pay premiums while the premium continues to be withheld.

CMS reminds sponsors that they may not disenroll a member or initiate the disenrollment process if the sponsor has been notified that a State Pharmaceutical Assistance Program (SPAP) or other payer intends to pay the entire Part D premium on behalf of an individual (Section 50.6 of Chapter 14 of the PDP Manual).

While the sponsor may accept partial payments, it has the right to ask for full payment within the grace period. If the member does not pay the required amount within the grace period, the effective date of disenrollment is the first day of the month after the grace period ends. The PDP sponsor has the right to take action to collect the unpaid premiums from the beneficiary at any point during or after this process.

If a member is disenrolled for failure to pay premiums and attempts to re-enroll in the organization, the PDP sponsor may require the individual to pay any outstanding premiums owed to the PDP sponsor before considering the enrollment request to be “complete.”

If the individual is involuntarily disenrolled for failure to pay premiums, in order to re-enroll in that plan, or to enroll in another, the individual must request enrollment during a valid period. Payment of past due premiums after the disenrollment date does not create an opportunity for reinstatement into the plan from which the individual was disenrolled for failure to pay premiums.

**Calculating the Grace Period**

A PDP sponsor must provide plan enrollees with a grace period of not less than 2 calendar months; however, it may provide a grace period that is longer than 2 calendar months, at its discretion (e.g. sponsors may elect to provide a 3-month initial grace period to match the Part D-IRMAA initial grace period.) The grace period must be a whole number of calendar months and cannot include fractions of months.

The grace period must be a minimum of 2 calendar months that begins on the 1st day of the month for which the premium is unpaid. The sponsor is required to have billed the member prior to the start of the grace period for the actual premium amount due, with such notice/bill specifying the due date for that amount. The sponsor must also provide the member with an opportunity to pay. For new enrollees, a PDP sponsor must wait until notified by CMS of the actual premium which the beneficiary is responsible for paying directly before the individual can be notified of/billed for the amount due; for these individuals, the due date cannot be until after the sponsor receives notification from CMS as to the beneficiary’s premium and notifies the individual of the amount due. The grace period can then begin no earlier than the first day of the month on or after the due date.
PDP sponsors have the following options in calculating and applying the grace period. The organization must apply the same option for all members of a plan.

**Option 1 - PDP sponsors may consider the grace period to end not less than 2 calendar months after the first day of the month for which premium is unpaid.**

If the overdue premium and all other premiums that become due during the grace period (in accordance with the terms of the member’s agreement with the PDP sponsor) are not paid in full by the end of the grace period, the PDP sponsor may terminate the member’s coverage.

As mentioned previously, the individual must be notified/billed of the actual premium amount due before the premium can be considered “unpaid.” For new enrollees, at a minimum, this cannot occur until CMS notifies the PDP sponsor of the total premium due from the individual. Upon CMS notification, the PDP sponsor would bill the individual of the amount due, with a prospective due date.

Under this scenario, PDP sponsors are encouraged to send subsequent notices as reminders or to show that additional premiums are due. Subsequent notices, therefore, should determine the expiration date of the grace period by reference to this date. Notice requirements are summarized in this section under the heading “notice requirements.”

**Example A:** Plan XYZ has a 2 month grace period for premium payment. Plan member Mr. Stone’s premium was due on February 1, 2010. He did not pay this premium and on February 7th, the PDP sponsor sent an appropriate notice. Mr. Stone ignores this notice and any subsequent premium bills. The grace period is the months of February and March. If Mr. Stone does not pay his plan premium before the end of March, he will be disenrolled as of April 1, 2010.

**Example B:** Plan QRS has a 3 month grace period for premium payment. Plan member Mrs. Monsoon’s premium was due on July 1, 2010. She did not pay this premium and on July 6th, the PDP sponsor sent an appropriate notice. Mrs. Monsoon ignores this notice and subsequent premium bills. The grace period is the months of July, August and September. If Mrs. Monsoon does not pay her owed premiums by the end of this period (September 30), she will be disenrolled effective October 1, 2010.

The PDP sponsor must state that it requires the member to make full payment within the grace period, and pay all premiums falling due within that period, in its initial delinquency notice to the member if it chooses this policy.

**Option 2 - PDP sponsors may use a “rollover” approach in applying the grace period.**

Under this scenario, the grace period would begin on the first of the month for which the premium is unpaid, but if the member makes a premium payment within the grace period, the grace period stops and is revised to reflect the new disenrollment date, depending on
the number of months for which premiums are received. The member would then have a new grace period beginning on the 1st day of the next month for which the premium is due. The subsequent notice also would have to be sent within 15 calendar days, as described below, of the next premium due date. This process continues until the member’s balance for delinquent premiums is paid in full or until the grace period expires with no premium payments being made, at which time the sponsor may disenroll the member.

Sponsors are not required to issue new notices each time the member submits a partial premium payment (i.e. less than one month’s premium), since this would not result in a change in the proposed disenrollment date. However, since payment of at least one month’s past-due premium causes the disenrollment date to “roll over” (i.e. move forward) commensurate with the number of month’s premium received, sponsors must issue a notice warning of the potential for involuntary disenrollment (see Exhibit 19) which includes the new disenrollment date whenever payment of at least one month’s premium is received during the grace period. These subsequent notices are required to be sent within 15 calendar days of the premium due date that follows receipt of the premium payment.

**Example:** Plan WXY has decided to offer a two month grace period for non-payment of plan premiums and has chosen the “rollover” approach to calculating the grace period. A member fails to pay his January premium due January 1. The sponsor sends a notice to the member on January 7th stating that his coverage will be terminated if the outstanding premium is not paid within the grace period. The notice advises him that his termination date would be March 1. The member then pays the January premium, but does not pay the February premium. The grace period is recalculated to begin on the 1st of the next month for which the premium is unpaid (February 1). On February 9th the sponsor sends a notice to the member reflecting the new grace period and the new anticipated termination date of April 1st. The member pays off his balance in full before the grace period expires; therefore, the member’s coverage in the PDP remains intact.

**Notice Requirements** - If it is the sponsor’s policy to disenroll the member when a member has not paid plan premiums, the sponsor must send an appropriate written notice of non-payment of premium to the member *within 15 calendar days* of the premium due date (see Exhibit 19).

The sponsor may send interim notices after the initial notice. In addition to the notice requirements outlined in §60.3, this notice must:

- Alert the member that the premiums are delinquent;
- Provide the member with an explanation of disenrollment procedures advising the member that failure to pay the premiums within the grace period that began on the 1st of the month for which premium was unpaid will result in termination, and the proposed effective date of this action; and
Explain whether the sponsor requires full payment within the grace period (including the payment of all premiums falling due during the intervening days, when and as they become due, according to the terms of the membership agreement) in order to avoid termination.

If a notice is returned to the organization as undeliverable, the sponsor should immediately implement its procedure for researching a potential change of address (see sections 50.2.1.4 and 50.2.1.5) as well. The beneficiary may have moved out of the service area. If the sponsor confirms the permanent move such that a disenrollment date earlier than the end of the grace period is required, the sponsor must disenroll the beneficiary for the earlier disenrollment date.

If a member does not pay within the grace period, and the sponsor’s policy is to disenroll the member, the sponsor must notify the member in writing providing the effective date of the member’s disenrollment (see Exhibit 20) and submit a disenrollment transaction to CMS. The disenrollment notice to the individual and the transaction to CMS must be sent within 3 business days following the last day of the grace period; however, in no case may the disenrollment notice to the individual be sent after the transaction is submitted to CMS. In the event the sponsor submits a disenrollment request to CMS and later learns that payment was received timely, a reinstatement request must be submitted to CMS (or its designee). In addition, the sponsor must send final confirmation of disenrollment to the member within 10 calendar days of receiving the TRR (see Exhibit 21).

Optional Exception for Individuals who Qualify for Low Income Subsidy (LIS)

Sponsors have the option to retain individuals who qualify for the low income subsidy who fail to pay premiums even if the PDP sponsor has a policy to disenroll members for non-payment of premiums.

The PDP sponsor has the discretion to offer this option to individuals who qualify for the low income subsidy within each of its PDPs. If the PDP sponsor offers this option in one of its PDPs, it must apply the policy to all such individuals in that PDP.

Example: “If you have Medicaid or extra help in paying for your Medicare prescription drugs and are having difficulty paying your plan premiums or cost sharing, please contact us.”

The sponsor must document this policy internally and have it available for CMS review.

50.3.2 - Disruptive Behavior

The PDP sponsor may request to disenroll a member if his/her behavior is disruptive to the extent that his/her continued enrollment in the PDP substantially impairs the PDP sponsor’s ability to arrange for or provide services to either that particular member or other members of the PDP. However, the PDP sponsor may only disenroll a member for disruptive behavior after it has met the requirements of this section and with CMS’
approval. The PDP sponsor may not disenroll a member because he/she exercises the option to make treatment decisions with which the PDP sponsor disagrees. The PDP sponsor may not disenroll a member because he/she chooses not to comply with any treatment regimen developed by the PDP sponsor or any health care professionals associated with the PDP sponsor.

Before requesting CMS’ approval of disenrollment for disruptive behavior, the PDP sponsor must make a serious effort to resolve the problems presented by the member. Such efforts must include providing reasonable accommodations, as determined by CMS, for individuals with mental or cognitive conditions, including mental illness and developmental disabilities. The PDP sponsor must also inform the individual of his or her right to use the organization’s grievance procedures.

The PDP sponsor must submit documentation of the specific case to CMS for review. This includes documentation:

- Of the disruptive behavior;
- Of the PDP sponsor’s serious efforts to resolve the problem with the individual;
- Of the PDP sponsor’s effort to provide reasonable accommodations for individuals with disabilities, if applicable, in accordance with the Americans with Disabilities Act;
- Establishing that the member’s behavior is not related to the use, or lack of use, of medical services;
- Describing any extenuating circumstances cited under 42 CFR §423.44(d)(2)(iii) and (iv);
- That the PDP sponsor provided the member with appropriate written notice of the consequences of continued disruptive behavior (see Notice Requirements); and
- That the PDP sponsor then provided written notice of its intent to request involuntary disenrollment (see Notice Requirements).

The PDP sponsor must submit to the CMS Regional Office:

- The above documentation;
- The thorough explanation of the reason for the request detailing how the individual’s behavior has impacted the PDP sponsor’s ability to arrange for or provide services to the individual or other members of the PDP;
- Statements from providers describing their experiences with the member; and
• Any information provided by the member.

The PDP sponsor may request that CMS consider prohibiting re-enrollment in the PDP (or PDPs) offered by the PDP sponsor in the service area.

The PDP sponsor’s request for involuntary disenrollment for disruptive behavior must be complete, as described above. The CMS Regional Office will review this documentation and consult with CMS Central Office (CO), including staff with appropriate clinical or medical expertise, and decide whether the organization may involuntarily disenroll the member. Such review will include any documentation or information provided either by the organization and the member (information provided by the member must be forwarded by the organization to the CMS RO). CMS will make the decision within 20 business days after receipt of all the information required to complete its review. CMS will notify the PDP sponsor within 5 (five) business days after making its decision.

The Regional Office will obtain Central Office concurrence before approving an involuntary disenrollment. The disenrollment is effective the first day of the calendar month after the month in which the organization gives the member a written notice of the disenrollment, or as provided by CMS.

If the request for involuntary disenrollment for disruptive behavior is approved, CMS may require the PDP sponsor to provide reasonable accommodations to the individual in such exceptional circumstances that CMS deems necessary. An example of a reasonable accommodation in this context is that CMS could require the PDP sponsor to delay the effective date of involuntary disenrollment to coordinate with an enrollment period that would permit the individual an opportunity to obtain other coverage. If necessary, CMS will establish an SEP on a case-by-case basis.

Notice Requirements

The disenrollment for disruptive behavior process requires 3 (three) written notices:

• Advance notice to inform the member that the consequences of continued disruptive behavior will be disenrollment;

• Notice of intent to request CMS’ permission to disenroll the member; and

• A planned action notice advising that CMS has approved the PDP sponsor’s request.

Advance Notice

Prior to forwarding an involuntary disenrollment request to CMS, the PDP sponsor must provide the member with written notice describing the behavior it has identified as disruptive and how it has impacted the sponsor’s ability to arrange for or provide services to the member or to other members of the plan. The notice must explain that his/her continued behavior may result in involuntary disenrollment, and that cessation of the
undesirable behavior may prevent this action. The notice must also inform the individual of his or her right to use the organization’s grievance procedures. The PDP sponsor must include a copy of this notice and the date it was provided to the member in any information forwarded to CMS.

NOTE: If the disruptive behavior ceases after the member receives notice and then later resumes, the PDP sponsor must begin the process again. This includes sending another advance notice.

Notice of Intent

If the member’s disruptive behavior continues despite the PDP sponsor’s efforts, then the PDP sponsor must notify him/her of its intent to request CMS’ permission to disenroll him/her for disruptive behavior. This notice must also advise the member of his/her right to use the organization’s grievance procedures and to submit any information or explanation. The PDP sponsor must include a copy of this notice and the date it was provided to the member in any information forwarded to CMS.

Planned Action Notice

If CMS permits a PDP sponsor to disenroll a member for disruptive behavior, the PDP sponsor must provide the member with a written notice that contains, in addition to the notice requirements outlined in §50.3, a statement that this action was approved by CMS and meets the requirements for disenrollment due to disruptive behavior described above. The PDP sponsor may only provide the member with this required notice after CMS notifies the PDP sponsor of its approval of the request.

The PDP sponsor can only submit the disenrollment transaction to CMS after providing the notice of disenrollment (Planned Action Notice) to the individual. The disenrollment is effective the first day of the calendar month after the month in which the PDP sponsor gives the member a written notice of the disenrollment, or as provided by CMS.

50.3.3 - Fraud and Abuse

A PDP sponsor may request to cancel the enrollment of a member who knowingly provides fraudulent information on the enrollment request that materially affects the member’s eligibility to enroll in the plan. The sponsor may also request to disenroll a member who intentionally permits others to use his/her enrollment card to obtain services or supplies from the plan or any authorized plan provider. Such a disenrollment is effective the first day of the calendar month after the month in which the sponsor gives the member the written notice.

With such a disenrollment request, the sponsor must immediately notify the CMS RO so the Office of the Inspector General may initiate an investigation of the alleged fraud and/or abuse.
**Notice Requirements** - The PDP sponsor must give the member a written notice of the disenrollment that contains the information required at §50.3.

### 50.4 - Processing Disenrollments

Procedures for processing voluntary and involuntary disenrollments are described below.

#### 50.4.1 - Voluntary Disenrollments

After receipt of a completed disenrollment request from an enrollee, the PDP sponsor is responsible for submitting disenrollment transactions to CMS in a timely, accurate fashion. Such transmissions for disenrollment requests must occur within 7 calendar days of receipt of the completed disenrollment request, in order to ensure the correct effective date.

The PDP sponsor must maintain a system for receiving, controlling, and processing voluntary disenrollments from the PDP sponsor. This system should include:

- Dating each disenrollment request as of the date it is received (regardless of whether the request is complete at the time it is received by the PDP sponsor) to establish the date of receipt;

- Dating supporting documents for disenrollment requests as of the date they are received;

- Determining if the voluntary request is valid according to the requirements in §50.1 of this guidance;

- Processing disenrollment requests in chronological order by date of receipt of completed disenrollment requests;

- Transmitting disenrollment information to CMS within 7 calendar days of the receipt of the completed disenrollment request from the individual or the employer/union group (whichever applies);

- For disenrollment requests received by the PDP sponsor, to notify the member in writing within 10 calendar days after receiving the member’s written request, to acknowledge receipt of the completed disenrollment request, and to provide the effective date (see Exhibit 10). PDP sponsors are encouraged, but not required, to follow up with a confirmation of disenrollment letter after receiving CMS confirmation of the disenrollment from the TRR.

When the voluntary disenrollment request is denied, the PDP sponsor must send written notice within 10 calendar days of the receipt of the request and include the reason for denial (see Exhibit 11).
• For all other voluntary disenrollments (i.e. voluntary disenrollments made by the beneficiary through 1-800-MEDICARE, or by enrolling in another Medicare health plan or PDP, which the PDP sponsor would not learn of until receiving the TRR), the PDP sponsor must notify the member in writing to confirm the effective date of disenrollment within 10 calendar days of the availability of the TRR (see Exhibit 11).

50.4.2 - When the Disenrollment Request is Incomplete

When the disenrollment request is incomplete, the PDP sponsor must document all efforts to obtain additional documentation to complete the disenrollment request and have an audit trail to document why additional documentation was needed before the request could be considered complete. The organization must make this determination, and, within 10 calendar days of receipt of the disenrollment request, must notify the individual that additional information is needed.

If a written disenrollment request is submitted and the signature is not included, the PDP sponsor may verify with the individual with a phone call and document the contact, rather than return the written request as incomplete.

For AEP elections, additional documentation to make the request complete must be received by December 7, or within 21 calendar days of the request for additional information (whichever is later). For all other enrollment periods, additional documentation to make the request complete must be received by the end of the month in which the disenrollment request was initially received, or within 21 calendar days of the request for additional information (whichever is later).

50.4.3 - Involuntary Disenrollments

The PDP sponsor is responsible for submitting involuntary disenrollment transactions to CMS in a timely, accurate fashion.

The PDP sponsor must maintain a system for controlling and processing involuntary disenrollments from the PDP sponsor. This includes:

• Maintaining documentation leading to the decision to involuntarily disenroll the member; and

• For all involuntary disenrollments except disenrollments due to death and loss of entitlement to Medicare Parts A and/or B, notifying the member in writing of the upcoming involuntary disenrollment, including providing information on grievances rights, as provided in the applicable section of this guidance.

In addition, PDP sponsors must send confirmation of involuntary disenrollment to ensure the member discontinues use of PDP sponsor services after the disenrollment date.
50.5 - Disenrollments Not Legally Valid

When a disenrollment request that is not legally valid has been processed, a reinstatement action may be necessary (refer to §60.2 for more information on reinstatements). In addition, the reinstatement may result in a retroactive disenrollment from another plan. Since optional involuntary disenrollments (as stated in §50.3) are considered legal and valid disenrollments, individuals would not qualify for reinstatements in these cases.

A voluntary disenrollment that is not complete is not legally valid. In addition, there are instances in which a disenrollment that appears to be complete can turn out to be legally invalid. For example, automatic disenrollments due to an erroneous death indicator or an erroneous loss of Medicare Part A or Part B indicator are not legally valid.

CMS also does not regard a voluntary disenrollment as actually complete if the member or his/her legal representative did not intend to disenroll from the PDP. If there is evidence that the member did not intend to disenroll from the PDP, the PDP sponsor should submit a reinstatement request to CMS (or its designee). Evidence that a member did not intend to disenroll may include:

- A disenrollment request signed by the member when a legal representative should be signing for the member; or
- Request by the member for cancellation of disenrollment before the effective date (refer to §60.1 for procedures for processing cancellations).

Discontinuation of payment of premiums does not necessarily indicate that the member has made an informed decision to disenroll.

In contrast, CMS believes that a member’s deliberate attempt to disenroll from a plan (e.g., sending a written request for disenrollment to the PDP sponsor, or calling 1-800-MEDICARE) implies intent to disenroll. Therefore, unless other factors indicate that this disenrollment is not valid, what appears to be a deliberate, member-initiated disenrollment should be considered valid.

50.6 - Disenrollment Procedures for Employer /Union Sponsored Coverage Terminations

The employer/union establishes criteria for its retirees to participate in the employer/union sponsored PDP plan. These criteria are exclusive of the eligibility criteria for PDP enrollment. Eligibility criteria to participate and receive employer/union sponsored benefits may include spouse/family status, payment to the employer/union of the individual’s part of the premium, or other criteria determined by the employer/union. For this reason, when the contract between an employer or union group and a PDP sponsor is terminated, or the employer/union determines that a beneficiary is no longer eligible to participate in the employer/ union sponsored plan, the PDP sponsor has the
option to follow one of two procedures to disenroll beneficiaries from the current employer/union sponsored PDP plan in which the individual is enrolled:

For both of these options, the PDP sponsor must ensure that the employer/union agrees to the following:

- The employer/union will provide the PDP sponsor with timely notice of contract termination or the ineligibility of the individual to participate in the employer/union group. Such notice must be prospective, not retroactive.

- The employer/union must provide a prospective notice to its members alerting them of the termination event and of other insurance options that may be available to them through their employer/union.

**Option 1:** Enroll the individual(s) in another PDP (i.e. individual plan) offered by the same PDP sponsor, unless the individual(s) make other choice. The individual must be eligible to enroll in this plan, including residing in the plan’s service area.

- Beneficiaries may elect another PDP or MA-PD offered by the employer or union, disenroll from the PDP, or join another PDP or MA-PD plan as an individual member, if he/she chooses, instead of electing the individual PDP offered by the same PDP sponsor.
  - If the beneficiary prefers not to be enrolled in the individual plan, he/she may contact the sponsor.
  - If the beneficiary would prefer enrolling in a different PDP or MA-PD plan as an individual member, he/she would submit an enrollment request to his/her newly chosen PDP or MA organization.

- If the individual takes no other action, he/she will become a member of the individual plan offered by the same PDP sponsor that offered the employer/union sponsored plan.

- **PDP Notice requirements** -- The PDP sponsor (or the employer or union acting on its behalf) must provide prospective notice to the beneficiary that his/her plan is changing, including information about benefits, premiums, and/or copayments, at least 21 calendar days prior to the effective date of enrollment in the individual plan.
Option 2: Disenroll individual(s) from the PDP sponsor following prospective notice.

- **PDP Notice requirements** - The PDP sponsor (or the employer or union, acting on its behalf) must provide prospective notice to the beneficiary that his/her plan enrollment is ending at least 21 calendar days prior to the effective date of the disenrollment. The notice must include information about other individual plan options the beneficiary may choose and how to request enrollment.

- If the employer/union group sponsored plan was a PDP, the individual must be advised that the disenrollment action means that the individual will not have Medicare drug coverage. Notice must include information about the potential for late-enrollment penalties that may apply in the future.

The PDP sponsor must outline in its written policies and procedures the option(s) it follows and must apply the same option for all members of a particular employer/union sponsored plan. It is the PDP sponsor’s responsibility to ensure that the required elements of the disenrollment procedures described above are understood by the employer/union and are part of the agreement with each employer/union, including contract termination notification requirements.

**50.6.1 – Group Disenrollment for Employer/Union Sponsored PDPs**

CMS has provided, under our authority to waive or modify Part D requirements that hinder the design of, the offering of, or the enrollment in an employer or union sponsored Part D retiree plans, a process for group disenrollment from employer or union sponsored PDPs.

CMS will allow and employer or union group to disenroll its retirees from a PDP using a group disenrollment process.

The group disenrollment process must include notification to each beneficiary as follows:

- All beneficiaries must be notified that the group intends to disenroll them from the PDP that the group is offering; and
- This notice must be provided not less than 21 calendar days prior to the effective date of the beneficiary’s disenrollment from the group sponsored PDP.

Additionally, the information provided must include an explanation on how to contact Medicare for information on other Part D options that might be available to the beneficiaries.
The employer or union group must have and provide all the information required for the PDP sponsor to submit a complete disenrollment request transaction to CMS as described in this and other CMS Part D systems guidance.

NOTE: This process applies to employer/union group direct contract PDP sponsors and MA Organizations and PDP sponsors that offer employer/union group-only plans.
60 - Post-Enrollment Activities
42 CFR 423.32 & 423.36

Post-enrollment activities occur after the PDP sponsor receives the enrollment request from the individual.

60.1 - Cancellations

Cancellations may be necessary in cases of mistaken enrollment or disenrollment made by an individual. Unless otherwise directed by CMS, requests for cancellations can only be accepted prior to the effective date of the enrollment or disenrollment request. For employer or union groups, cancellations properly made to the employer or union prior to the effective date of the election being canceled are also acceptable.

If a cancellation occurs after CMS records have changed, retroactive disenrollment and reinstatement actions may be necessary.

If a beneficiary verbally requests a cancellation of an enrollment or disenrollment request, the PDP sponsor must document the request and process the cancellation. PDP sponsors may request that the cancellation be made in writing to the PDP sponsor, however, they may not delay processing of a cancellation until the request is made in writing if they have already received a verbal request from the individual of the desire to cancel the enrollment or disenrollment.

60.1.1 - Cancellation of Enrollment

An individual’s enrollment can be cancelled only if the sponsor receives the cancellation request prior to the effective date of the enrollment, unless otherwise directed by CMS.

To ensure the cancellation is honored, the PDP sponsor should not transmit the enrollment to CMS. If, however, the organization had already transmitted the enrollment transaction by the time it receives the valid request for cancellation, it must submit a cancellation transaction to CMS to cancel the now-void enrollment transaction from the CMS enrollment system. In the event the cancellation transaction fails or the PDP sponsor has other difficulty, the PDP sponsor must submit the request to cancel the action to the CMS Retroactive Processing Contractor in order to cancel the enrollment.

The PDP sponsor may submit a transaction to cancel only those enrollment transactions it submitted. To submit an action to cancel an enrollment, the PDP sponsor must submit a transaction code 80 (cancellation of enrollment), with the effective date equal to the effective date of the enrollment being cancelled.

When canceling an enrollment the PDP sponsor must provide a notice to the individual that states that the cancellation is being processed. This notice should be sent within 10 calendar days of the receipt of the cancellation request (see Exhibit 22). This notice must inform the individual that the cancellation should result in the individual remaining
enrolled in the health plan in which he/she was originally enrolled, assuming the individual remains eligible to be enrolled in that plan.

If the member’s request for cancellation occurs after the effective date of the enrollment, the cancellation generally cannot be processed. (An exception to this is a cancellation requested during the Outbound Education and Verification (OEV) process.) The PDP sponsor must inform the beneficiary that he/she is a member of its plan. If he/she wants to return to the other PDP he/she will have to submit an enrollment request during a valid election period for a prospective enrollment effective date.

Regardless of the plan personnel receiving the request, the plan must document all contact with the beneficiary associated with the cancellation request.

When an organization receives TRR notification of an individual’s reinstatement, the organization has ten (10) days to send the individual a written notice of reinstatement (Exhibit 22a).

60.1.2 - Cancellation of Disenrollment

A voluntary disenrollment request can be cancelled by the individual only if the request for cancellation is made prior to the effective date of the disenrollment, unless otherwise directed by CMS.

To ensure the cancellation is honored, the PDP sponsor should not transmit the disenrollment to CMS. If, however, the organization had already transmitted the disenrollment by the time it receives the verbal request for cancellation, it must submit a cancellation of disenrollment transaction, transaction code 81, to CMS to cancel out the now-void disenrollment transaction. In the event the PDP sponsor has submitted the disenrollment and is unable to submit the transaction code 81, or has other difficulty, the PDP sponsor then the organization should contact CMS (or the CMS Retroactive Processing Contractor) in order to cancel the disenrollment.

A PDP sponsor may submit a transaction to cancel only those disenrollment transactions it submitted. To submit an action to cancel a disenrollment, the PDP sponsor must submit a transaction code 81 (cancellation of disenrollment), with the effective date equal to the effective date of the disenrollment being cancelled.

The PDP sponsor must send a letter to the member that states that the cancellation is being processed and instructs the member to continue using PDP services (see Exhibit 23). This notice should be sent within 10 calendar days of receipt of the cancellation request. When an organization receives TRR notification of an individual’s reinstatement, the organization has ten (10) days to send the individual a written notice of reinstatement (Exhibit 22a).

If the member’s request for cancellation occurs after the effective date of the disenrollment, then the cancellation cannot be processed. In some cases, reinstatement
due to a mistaken disenrollment will be allowed, as outlined in §60.2.2. If a reinstatement will not be allowed, the PDP sponsor should instruct the member to fill out and sign a new enrollment form to re-enroll with the PDP sponsor during an enrollment period (described in §30), and with a current effective date, using the appropriate effective date as prescribed in §30.5.

60.1.3 – When A Cancellation Transaction is Rejected by CMS Systems (TRC 284)

When a PDP sponsor receives a TRC 284 (Cancellation Rejected), while the cancellation remains valid, it could not be processed automatically in CMS’ systems. The PDP sponsor must investigate the circumstances behind the rejection. If the rejection was due to incorrect data on the transaction, the PDP sponsor must correct the data and resubmit it to CMS. If the rejection was not due to such an error, and the request to cancel is valid, the PDP sponsor must promptly submit the request to CMS (or its designee) for resolution.

60.2 - Reinstatements

Reinstatements may be necessary if a disenrollment is not legally valid (refer to §50.5 to determine whether a disenrollment is not legally valid). The most common reasons warranting reinstatements are:

1. Disenrollment due to erroneous death indicator,
2. Disenrollment due to erroneous loss of Medicare Part A or Part B indicator,
3. Reinstatements Based on Beneficiary Cancellation of New Enrollment;
4. Plan error, and
5. Demonstration of “good cause” for failure to pay premiums (plan and/or Part D-IRMAA) timely.

When a disenrolled individual contacts the PDP sponsor to state that he/she was disenrolled due to items 1, 2 or 4 listed above, and states that he/she wants to remain a member of the PDP, then the PDP sponsor must instruct the member in writing to continue to use PDP services (refer to Exhibit 15, 16, 17 and 18). The PDP must send the notice within ten (10) calendar days of the individual’s contact with the sponsor to report the erroneous disenrollment. Accordingly, plan systems should indicate active membership as of the date the organization instructs the individual to continue to use plan services.

When a disenrolled individual contacts the plan sponsor about either item 3 (reinstatement based on enrollment cancellation) or 5 (“good cause”), plans should follow the guidance outlined below pertaining to those unique situations.
A reinstatement is viewed as a correction necessary to “erase” an invalid disenrollment action and to ensure no gaps in coverage occur. As such, a reinstatement does not require an election period. Therefore, reinstatements may be made retroactively. Payment alone of past due premiums after the disenrollment date does not create an opportunity for reinstatement into the plan from which the individual was disenrolled for failure to pay premiums.

CMS (or its designee), will review requests for reinstatement on a case-by-case basis. Within ten (10) calendar days of receipt of TRR confirmation of the individual’s reinstatement, the sponsor must send the member notification of the reinstatement (Exhibit 22a).

60.2.1 - Reinstatements for Disenrollment Due to Erroneous Death Indicator or Due to Erroneous Loss of Part D Eligibility Indicator

A member can be reinstated if he/she was disenrolled due to an erroneous death or loss of Part D eligibility indicator since he/she was always entitled to remain enrolled. Although sponsors may request that individuals provide evidence of Medicare entitlement by a particular date, erroneous disenrollments must be corrected and the corresponding reinstatements processed, regardless of the date on which the individual disputes the erroneous disenrollment or provides evidence of Medicare entitlement.

To request consideration for reinstatement following disenrollment due to erroneous death indicator or erroneous loss of Part D eligibility, the PDP sponsor must submit to CMS (or its designee) a copy of the letter to the member informing him/her to continue to use PDP coverage until the issue is resolved. The reinstatement request must indicate the date on which this letter was sent to the member. Refer to model letters in Exhibits 15 and 16. When a sponsor receives TRR notification of an individual’s reinstatement, the sponsor has ten (10) days to send the individual a written notice of reinstatement (Exhibit 22a).

CMS will attempt to automatically reinstate beneficiaries that were auto-disenrolled by a report of date of death if there is a subsequent date of death correction that impacts the plan enrollment.

60.2.2 - Reinstatements Based on Beneficiary Cancellation of New Enrollment

As stated in §50.5, deliberate member-initiated disenrollments imply intent to disenroll. Therefore, reinstatements generally will not be allowed if the member deliberately initiated a disenrollment. An exception is made for those members who were automatically disenrolled because they enrolled in another plan but subsequently cancelled the enrollment in the new plan before the effective date.
In this situation, that is, if an individual has since changed his/her mind and wants to remain enrolled in the previous plan, the individual must cancel the enrollment into the new plan, as described in section 60.1.1. When a cancellation of enrollment in a new plan is properly made, the associated automatic disenrollment from the previous PDP becomes invalid. Upon successful cancellation of enrollment in the new plan, CMS systems will attempt to automatically reinstate enrollment in the previous plan. Because this process is automatic, it is generally not necessary to request reinstatement via the Regional Office or Retroactive Processing Contractor. Within ten (10) days of receipt of TRR confirmation of the individual’s reinstatement, the sponsor must send the member notification of the reinstatement (Exhibit 22a).

In cases where the valid cancellation request is not processed timely or CMS systems cannot complete the request, the new plan must submit a request to the Retroactive Processing Contractor to cancel the enrollment. This request will require complete documentation, including evidence that the beneficiary requested cancellation of enrollment in the new plan within required timeframes.

If the previous plan becomes aware of an unsuccessful reinstatement, the previous plan may contact a CMS Account Manager to investigate the issue with the new plan.

If the disenrolled individual contacts the previous plan requesting to remain a member of that plan, the plan sponsor should inform the individual that reinstatement of enrollment is an option only if the individual successfully cancels enrollment in the “new” plan; accordingly, the plan sponsor should refer the individual to the “new” plan to inquire about his or her options.

60.2.3 - Reinstatements Due to Mistaken Disenrollment Due to Plan Error

A disenrollment that is not the result of either a valid voluntary request or a valid circumstance that requires involuntary disenrollment is erroneous. When an erroneous disenrollment is the result of plan error, the plan must reinstate the individuals who were disenrolled.

In the case of an erroneous disenrollment by the sponsor that is a result of an error on the part of the sponsor, the sponsor must restore the enrollment in its records. Additionally, the sponsor must cancel the disenrollment action from CMS’s records, if the sponsor had previously submitted such a transaction to CMS. Organizations must use the disenrollment cancellation function to complete this action for effective dates within the parameters that CMS systems allow for such corrections. For effective dates outside these parameters, the sponsor must process the request according to the guidance for processing retroactive enrollment and disenrollment requests including full documentation and explanation as required.
Within ten (10) days of receipt of TRR confirmation of the individual’s reinstatement, the sponsor must send the member written notification of the reinstatement (Exhibit 22a).

60.2.4 - Reinstatements Based on “Good Cause” Determination for Failure to Pay Plan Premiums or Part D-IRMAA

If an individual has been involuntarily disenrolled for failure to pay either plan premiums (under §50.3.1) or Part D-IRMAA (under §50.2.6), s/he may request reinstatement by CMS no later than 60 calendar days following the effective date of disenrollment. Reinstatement will occur only under the following circumstances:

1. Individual requests reinstatement with CMS within the first 60 days of disenrollment effective date;
2. CMS determines that the individual meets the criteria specified and receives a favorable determination by CMS;
3. Individual pays all owed plan premiums and/or Part D-IRMAA amounts in full within the three month grace period (both past due amounts and the premium amounts that accrue for the months during the request for reinstatement).

The timeframe for the good cause reinstatement process is three months from the effective date of disenrollment.

Reinstatement of enrollment for “good cause” is provided only in rare circumstances in which the beneficiary or his/her authorized representative was unable to make timely payment due to circumstances over which they had no control and they could not reasonably have been expected to foresee. Examples of circumstances that may constitute “good cause” include:

- Federal government error caused the payment to be missed or late;
- Prolonged illness, hospitalization or institutionalization of the beneficiary;
- Death or serious illness of spouse or other family member; or
- Loss of the beneficiary’s home or severe impact by fire, or other exceptional circumstance outside the beneficiary’s control (e.g. affected individual resides in a federal disaster area).

Examples of circumstances that would not constitute “good cause” include:

- Allegation that bills or warning notices were not received due to unreported change of address, out of town for vacation, visiting out of town family, etc;
- Authorized representative did not pay timely on member’s behalf;
- Lack of understanding of the ramifications of not paying plan premiums or Part D-IRMAA;
- Could not afford to pay premiums at the time of delinquency/disenrollment

For the purpose of determining “good cause” for members with authorized representatives, the criteria for both favorable and unfavorable determinations apply as though the authorized representative is the member. Thus, as noted above, failure to make
timely payment by an authorized representative alone is not grounds for a favorable “good cause” determination and reinstatement.

An individual who is not assessed Part D-IRMAA remains disenrolled from the plan and does not have access to services until one of the following occurs:
- The plan receives full payment of all required amounts to satisfy a CMS-determined, favorable good cause case for failure to pay plan premiums,
- The plan is contacted by the CMS caseworker, or
- The reinstatement occurs and is reported on the TRR.

An individual who is assessed Part D-IRMAA remains disenrolled from the plan and does not have access to services until reinstatement occurs and is reported on the TRR or the plan is contacted by the CMS caseworker after they have successfully updated the beneficiary’s enrollment record in MARx. Once a reinstatement occurs, the individual’s disenrollment will be cancelled and his/her coverage will be continuous, assuming the individual continues to be eligible for enrollment in that plan.

Individuals who lose their cost plan optional supplemental Part D benefit as a result of failure to pay the premium associated with the optional supplemental Part D benefit to the cost plan or the assessed Part D-IRMAA amount to CMS may request reinstatement of the Part D benefit for good cause. This option is available only to individuals who fail to pay the premium associated with their Part D optional supplemental benefit but continue to pay the basic plan premium and are therefore not disenrolled from the cost contract. Reinstatement for good cause is not an option for individuals who are disenrolled from the cost contract for failure to pay the premiums associated with both the basic and optional supplemental benefit(s).

**Process for “Good Cause” Determinations:**

When a disenrolled member contacts the plan sponsor because s/he was disenrolled due to failure to pay plan or Part D-IRMAA premiums and states that s/he “has a good reason for not paying the premiums”, the plan sponsor must advise the individual to contact 1-800-MEDICARE (1-800-633-4227; TTY: 1-877-486-2048) within 60 calendar days of the disenrollment effective date to make the “good cause” reinstatement request. The organization should also inform the individual that in order to be reinstated, s/he must meet specific “good cause” standards and must pay all overdue and current owed premiums (including both the plan premium and Part D-IRMAA) within 3 months of the disenrollment date in order for reinstatement may occur.

Note: In cases where the involuntary disenrollment for failure to pay plan premiums is the result of plan error, plans should follow the reinstatement process outlined in Section 60.3.3. Plans should not refer these individuals to 1-800-MEDICARE to request reinstatement for “good cause.”

Once a request is made with CMS via 1-800-MEDICARE, a CTM case will be generated for CMS caseworker action. The CMS caseworker will contact the individual and make a “good cause” determination. If the individual provides any documentation to the plan
regarding the inability to make timely payment, the plan must provide that documentation to CMS (through the plan account manager) so that it may be considered in making the determination. CMS will notify the individual of the determination and, if favorable, explain the general process, including payment responsibilities and timing. Plans are required to provide more specific information to the individual, as outlined below. Notes of the “good cause” reinstatement request will be captured in the CTM for CMS and plan viewing. (Note: Requests for reinstatement are not considered complaints against the plan, therefore, these types of CTM cases are excluded from tracking for the purposes of plan ratings.)

If CMS makes a favorable determination, a notation will be made in the CTM “good cause” request case. CMS will communicate directly with plans regarding approved good cause determinations. If there are amounts owed to the plan for past due premiums, the plan must send notification to the beneficiary within 3 business days of being informed of the approved good cause determination. This notice will specify the amount owed, the date by which payment must be received for reinstatement (i.e., last day of the third month following effective date of disenrollment), and where to send payment (or other payment options such as credit card or direct withdrawal from a bank account)(See Exhibit 21b). Even if an individual has received a favorable good cause determination, the actual reinstatement will not occur until all required payments are made, provided they are received within three months of the disenrollment effective date. Within ten (10) calendar days of receipt of TRR confirmation of the individual’s reinstatement, the plan sponsor must send the member notification of the reinstatement (See Exhibit 22a).

In cases where an individual pays all premium amounts but does not receive a favorable “good cause” determination or receives a favorable good cause determination but does not pay the plan premium and/or the Part D-IRMAA owed within three months of the disenrollment effective date, s/he may not be reinstated. In both of these cases, the plan may re-enroll the individual for a prospective enrollment effective date at the beneficiary’s request, if s/he has a valid election period (i.e., AEP, SEP, etc.), following enrollment procedures outlined in Sections 30 and 40.

Example A: Mr. Smith is disenrolled for failure to pay plan premiums on April 1. Mr. Smith contacts Medicare and makes his request on April 15 and receives a favorable good cause determination on April 23. Mr. Smith is not assessed a Part D-IRMAA and only owes plan premiums. The plan notifies Mr. Smith of the amount he owes by June 30 in order to be reinstated into the plan. Mr. Smith pays the amount due on June 15. Mr. Smith is reinstated into the plan. (Note: If Mr. Smith did not pay his owed amount by June 30, he would not be reinstated.)

Example B: Mr. Smith is disenrolled for failure to pay plan premiums on December 1. Mr. Smith contacts Medicare and makes his request on December 20 and receives a favorable good cause determination on January 4. Mr. Smith is also delinquent on his Part D-IRMAA. CMS notifies Mr. Smith of the amount he owes by February 28 for Part D-IRMAA. The plan notifies Mr. Smith of the amount he owes by February 28 in order to be reinstated into the plan. Mr. Smith pays his Part D-IRMAA owed amount on
February 7. Mr. Smith pays his plan premium owed amount on February 25. Mr. Smith is reinstated into the plan. (Note: If Mr. Smith did not pay either of his owed amounts by February 28, he would not be reinstated.)

Example C: Mr. Smith is disenrolled for failure to pay plan premiums on July 1. Mr. Smith mails in his past due amounts to the plan on July 30. He contacts Medicare and makes his request on August 10, and does not receive a favorable good cause determination. Mr. Smith may not be reinstated.

Example D: Mr. Smith is disenrolled for failure to pay plan premiums on November 1. Mr. Smith mails in his owed amounts to the plan on December 15, but does not request reinstatement with CMS. Thus, Mr. Smith does not have a favorable good cause determination, and he may not be reinstated.

Example E: Mr. Smith is disenrolled for failure to pay Part D-IRMAA on August 1. He contacts Medicare and makes his request on September 29 and receives a favorable good cause determination on October 5. Mr. Smith is also delinquent on his plan premiums. CMS notifies Mr. Smith of the amount he owes by October 31 for Part D-IRMAA. The plan also notifies Mr. Smith of the amount he owes by October 31 for plan premiums. Mr. Smith pays his Part D-IRMAA owed amount on October 25. Mr. Smith pays his plan premium owed amount on November 5. Mr. Smith may not be reinstated. (Note: If Mr. Smith had paid both his owed Part D-IRMAA and plan premiums by October 31, he would have been reinstated.)

The above examples apply for disenrollments for either failure to pay plan premiums or failure to pay Part D-IRMAA.

60.3 - Retroactive Enrollments

If an individual has fulfilled all enrollment requirements, but the PDP sponsor or CMS is unable to process the enrollment for the required effective date (as outlined in §30.4), CMS (or its designee) will process a retroactive enrollment.

In addition, auto-enrollment for full-benefit dual eligible as described in §30.1.4 may be retroactive to ensure no coverage gap between the end of Medicaid coverage for Part D drugs and the beginning of Medicare drug coverage.

In other limited cases, CMS may determine that an individual is eligible for an SEP due to an extraordinary circumstance beyond his/her control (e.g. a fraudulent enrollment request or misleading marketing practices) and may also permit a retroactive enrollment in a PDP as necessary to prevent a gap in coverage or liability for the late enrollment penalty.

Unlike a reinstatement, which is a correction of records to “erase” an action, a retroactive enrollment is viewed as an action to enroll a beneficiary into a plan for a new time period.
Occasionally, obtaining the information necessary to complete an enrollment request within the allowable timeframes will extend beyond the CMS systems cut-off date for transaction submission, thus making the effective date of enrollment “retroactive” to the current payment month. Sponsors must use the Code 61 enrollment transaction to submit the enrollment transaction directly to CMS within the Current Calendar Month transaction processing timeframe.

When a valid request for enrollment has not been communicated to CMS successfully within the required timeframes in this guidance and the Current Calendar Month transaction submission timeframe, sponsors are required to submit the appropriate documentation to CMS (or its designee) for manual review and potential action. The request for a retroactive enrollment should be made within the timeframes provided in the Standard Operating Procedures for the CMS Retroactive Processing Contractor. When an individual has fulfilled all enrollment requirements, but the sponsor or CMS has been unable to process the enrollment in a timely manner, the following documentation must be submitted to CMS (or its designee):

- A copy of signed completed enrollment form (the form must have been signed by the beneficiary (or authorized representative) and received by the sponsor prior to the requested effective date of coverage, in order to effectuate the requested effective date of coverage);

  Or

- A copy of the enrollment request record (the record must show that the election was made and received by the sponsor prior to the requested effective date of coverage).

In the event that CMS determines that the sponsor did not notify the member that he/she must use plan services during the period covered by the retroactive enrollment request, a retroactive enrollment request may be denied.

If the request for retroactive enrollment action is due to plan error, the sponsor must provide a clear and detailed explanation of the plan error including why the retroactive action is necessary to correct the error. The explanation must include clear information regarding what the sponsor has communicated to the affected beneficiary throughout the period in question. The sponsor must also include any relevant information or documentation supporting the requested correction. Such information could include a copy of the enrollment request form (or clear evidence of the use of another enrollment mechanism) and evidence of notices sent to the beneficiary related to or caused by the error.

**Special note regarding CMS Regional Office Casework actions**

When a sponsor is directed by CMS, such as via an RO caseworker, to submit a retroactive enrollment or disenrollment request to resolve a complaint, the sponsor must provide the following 2 (two) items as documentation to CMS (or its designee):
• A screen print from the Complaint Tracking Module (CTM) or other documentation showing the CMS RO decision and direction to submit the request to the CMS Retroactive Processing Contractor
• A copy of the enrollment or disenrollment request, if one is available. Occasionally, due to the nature of casework, this item may not be available. When that occurs, the organization should submit a brief statement of explanation for the missing documentation.

60.4 - Retroactive Disenrollments

If an enrollment was never legally valid (§40.5) or if a valid request for disenrollment was properly made, but not processed or acted upon (as outlined in the following paragraph), which includes not only system error, but plan error), CMS (or its designee) may also process a retroactive disenrollment if the reason for the disenrollment is related to a permanent move out of the plan service area (as outlined in §50.2.1), a contract violation, or other limited exceptional conditions established by CMS (e.g. fraudulent enrollment or misleading marketing practices).

When a valid request for disenrollment has not been communicated to CMS successfully within the required timeframes in this guidance and the Current Calendar Month transaction submission timeframe, sponsors are required to submit the appropriate documentation to CMS (or its designee) for manual review and potential action.

Retroactive disenrollments can be submitted to CMS (or its designee) by the beneficiary or a PDP sponsor. Requests from a PDP sponsor must include supporting evidence (e.g. a copy of the disenrollment request) and an explanation as to why the disenrollment was not processed correctly. PDP sponsors must submit retroactive disenrollment requests to CMS (or its designee) as soon as possible. If CMS (or its designee) approves a request for retroactive disenrollment, the PDP sponsor must return any premium paid by the member for any month for which CMS processed a retroactive disenrollment. In addition, CMS will retrieve any capitation payment for the retroactive period.

A retroactive request must be submitted by the PDP sponsor (or by the member) in cases where the PDP sponsor has not properly processed a required involuntary disenrollment or acted upon the member’s request for disenrollment as required in §40.4.1 of these instructions. A disenrollment request would be considered not properly acted upon or processed if the effective date is a date other than as required in §30.5.

If the request for retroactive disenrollment action is due to the sponsor’s discovery of an incarcerated status (as per § 50.2.1.3) with a retroactive start date, the sponsor must provide confirmation of the incarcerated status including the start date. Such confirmation could include documentation of telephonic communications.

If the request for retroactive disenrollment action is due to plan error, the sponsor must provide a clear and detailed explanation of the plan error including why the retroactive action is necessary to correct the error. The explanation must include clear
information regarding what the sponsor has communicated to the affected beneficiary throughout the period in question, including evidence that the beneficiary was notified prospectively of the disenrollment. The sponsor must also include any relevant information supporting the requested correction. Such information could include a copy of the disenrollment request and evidence of notices sent to the beneficiary related to or caused by the error in question and which demonstrate that the retroactive disenrollment is appropriate under the circumstances.

60.5 - Retroactive Transactions for Employer/Union Group Health Plan (EGHP) Members

In some cases a Part D sponsor that has both a Medicare contract and a contract with an EGHP arranges for the employer or union to process elections for Medicare-entitled group members who wish to make elections under the Medicare contract. However, there can be a delay between the time the member completes the election through the EGHP and when the election is received by the PDP sponsor. Therefore, retroactive transactions for these routine delays may be necessary and are provided for under this section. Errors made by an EGHP, such as failing to forward a valid enrollment or disenrollment election within the timeframes described below, must be submitted to CMS (or its designee) for review within the timeframes provided in the Standard Operating Procedures for the CMS Retroactive Processing Contractor. Repeated errors may indicate an ongoing problem and therefore will be forwarded to the PDP sponsor’s CMS Account Manager for compliance monitoring purposes. The PDP sponsor’s agreement with the EGHP must include the need to meet the requirements provided in this chapter that ensure the timely submission of enrollment and disenrollment requests to reduce the need for retroactivity and to help avoid errors.

60.5.1 - EGHP Retroactive Enrollments

The effective date of EGHP enrollments cannot be earlier than the date the enrollment request was completed by the individual. The effective date may be retroactive up to, but not exceeding, 90 days from the date the PDP received the request (which was completed prior to the effective date) from the employer or union group.

EXAMPLE

In March 2007, the CMS system processing date was March 13, 2007. Enrollments processed by CMS for the March 13, 2007 due date were for the prospective April 1, 2007, payment. For EGHPs, an effective date of March 1, February 1, or January 1 would reflect 30, 60, and 90 days of retroactive payment adjustment, respectively. Therefore, if a completed EGHP enrollment were to be received on March 5, 2007, the retroactive effective date could be January 1, February 1, or March 1, as long as the enrollment request was completed prior to the effective date.

No retroactive enrollments may be made unless there has been a valid enrollment request and the PDP sponsor (or EGHP) provided him/her with the explanation of enrollee rights at the time of enrollment. The PDP sponsor should submit such enrollments using the
appropriate transaction code. Please refer to the Medicare Advantage and Prescription Drug Plan Communications User Guide (PCUG) for more information. The ability to submit limited EGHP retroactive enrollment transactions is to be used only for the purpose of submitting a retroactive enrollment into an EGHP made necessary due to the employer’s delay in forwarding the completed enrollment request to the Part D organization.

60.5.2 - EGHP Retroactive Disenrollments

The PDP sponsor must submit a retroactive disenrollment request to CMS (or its designee) if an EGHP does not provide the PDP sponsor with timely notification of a member’s requested disenrollment. Up to a 90-day retroactive payment adjustment is possible in such a case to conform to the adjustments in payment described under 42 CFR 422.308(f)(2). The EGHP notification is considered untimely if it does not result in a disenrollment effective date as outlined in §30.5.

The PDP sponsor must submit a disenrollment notice (i.e., documentation) to CMS (or its designee) demonstrating that the disenrollment request was made in a timely fashion (i.e., prospectively), but that the EGHP was late in providing the information to the PDP sponsor. Such documentation may include an enrollment request made by the member for a different plan and given to the EGHP during the EGHP’s open enrollment season. Such documentation should be sent to CMS (or its designee) as soon as possible.

60.6 – Multiple Transactions

Multiple transactions occur when CMS receives more than one enrollment (or disenrollment) request for the same individual with the same effective date in the same reporting period. An individual may not be enrolled in more than one PDP at any given time (however, an individual may be simultaneously enrolled in a cost plan and a separate PDP plan or in certain MA plan types and a separate PDP plan).

Generally, the last enrollment request the beneficiary makes during an enrollment period will be accepted as the PDP into which the individual intends to enroll. If an individual requests enrollment in more than one PDP for the same effective date and with the same application date, the first transaction successfully processed by CMS will take effect. Because simultaneous enrollment in a PDP and certain MA plan types is permitted, CMS systems will accept such enrollments.

Generally, given the use of the application date to determine the intended enrollment choice, retroactive enrollments will not be processed for multiple transactions that reject because enrollment requests have the same application date.

EXAMPLES

- Two PDP sponsors receive enrollment requests from one individual. PDP #1 receives a form on December 4th and PDP #2 receives a form on December 10.
Both organizations submit enrollment transactions, including the applicable effective date and application date. The enrollment in PDP #2 will be the transaction that is accepted and will be effective on January 1 because the application date on the enrollment transaction is the later of the two transactions submitted. Both plans receive the appropriate reply on the TRR.

- Two PDP sponsors receive enrollment requests from one individual for a January 1 effective date. PDP #1 receives a paper enrollment form with all required information on December 5th. The beneficiary completed an enrollment request for PDP #2 by telephone on the same day, December 5th. Both enrollment requests have the same application date, since they were received by the PDP sponsors on the same date. Both enrollments were submitted to CMS prior to the December cut-off date. PDP #1 transmitted the enrollment to CMS on December 5th, the day it received the enrollment request; however, PDP #2 waited December 8th to transmit the enrollment to CMS. The enrollment for PDP #1 will be the transaction that is effective on January 1, as it was the first transaction successfully processed by CMS.

In the event a rejection for a multiple transaction is reported to the PDP sponsor, the sponsor may contact the individual. If the individual wishes to enroll in a PDP offered by the sponsor that received the multiple transactions reject, s/he must submit a new enrollment request during a valid enrollment period.

60.7 - User Interface (UI) Transactions Reply Codes (TRC) – Communications with Beneficiaries

Upon receipt of a TRR, PDP sponsors must update their records to accurately reflect each individual’s enrollment status. Sponsors are also required to provide certain notices and information to beneficiaries when enrollment status is confirmed or changes. In the case of UI-TRC replies, the standard operating procedures for providing these notices and/or information may not fit some of the unique situations many UI enrollment changes address.

The table below provides guidelines for communicating with beneficiaries when enrollment changes are reported to PDP sponsors using the “700 series” TRCs that result from UI enrollment changes. In all cases, PDP sponsors will need to review the situations carefully to determine the necessity and appropriateness of sending notices. Some UI enrollment change processes will result in multiple 700-series TRCs being reported. PDP sponsors must determine the final disposition of the beneficiary to ensure the correct message is provided in any notice sent. CMS encourages plans to communicate directly (such as by telephone) with the beneficiary, in addition to any required notice or materials. When it is necessary to send a notice, organizations must issue the notice within ten calendar days of receipt of the TRR.
<table>
<thead>
<tr>
<th>TRC</th>
<th>Beneficiary Communication Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>701 – New UI Enrollment</td>
<td>Plans may use existing confirmation notices as provided in CMS enrollment guidance. If such notice has already been provided with the same information, it is not necessary to provide it a second time.</td>
</tr>
<tr>
<td>702 – New UI Fill-in Enrollment</td>
<td>Plans must use Exhibit 31, “Enrollment Status Update”. Include the date range covered by the new fill-in period.</td>
</tr>
<tr>
<td>703 – UI Enrollment Cancel</td>
<td>If a cancellation notice applicable to this time period has already been provided, it is not necessary to provide it a second time. If notice has not been provided, plans may use the existing cancellation of enrollment notice as provided in CMS enrollment guidance. If the specific situation warrants, plans may use Exhibit 31 instead, providing information that clearly indicates that the enrollment period in question has been cancelled. Include information about the refunding of plan premiums, if applicable.</td>
</tr>
<tr>
<td>704 – UI Enrollment Cancel - PBP Change</td>
<td>If the UI action is a correction to a plan submission error, you may have already provided the correct plan (PBP) information; if that’s the case, it is not necessary to send it a second time. If the beneficiary has not received information about the specific plan (PBP), you must send the materials required in CMS enrollment guidance that you would provide for any new enrollment. You must also send Exhibit 31 describing the plan change including the effective date. Ensure that you communicate clearly the impact of the change on plan premiums, cost sharing, and provider networks. It is not necessary to confirm with a notice the associated “enrollment canceled” TRC that will accompany the enrollment into the new plan (PBP).</td>
</tr>
<tr>
<td>705 – New UI Enrollment - PBP Change</td>
<td>Follow the guidance provided above for TRC 704.</td>
</tr>
<tr>
<td>706 – UI Enrollment Cancel - Segment change</td>
<td>Plan (PBP) segment changes only apply to MA plans. Provide updated materials reflecting the new elements of the changed segment, such as premium and cost sharing increases or decreases.</td>
</tr>
<tr>
<td>707- UI New enrollment - Segment Change</td>
<td>Follow the guidance above for TRC 706.</td>
</tr>
<tr>
<td>708 – UI End Date Assigned</td>
<td>This UI action has the same effect as a plan submitted disenrollment (code 51) transaction. Generally, plans should follow existing CMS enrollment guidance for providing notice and confirmation of the disenrollment. However, since many UI initiated changes are retroactive, plans may have already provided notice (with correct effective dates) and if so, need not provide it a second time. Additional clarification may be...</td>
</tr>
</tbody>
</table>
appropriate depending on the specifics of the case.

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>709 – UI Earlier Start Date</td>
<td>An existing enrollment period in the plan has changed to start earlier than previously recorded. If the plan has already provided notice reflecting this effective date of enrollment, it is not necessary to provide it a second time. When the individual has not already received notice reflecting this effective date, plans may use existing confirmation of enrollment notices where there is confidence that such notice will not cause undue confusion. Alternatively, plans may use Exhibit 31, including in it the new effective date and information about additional premium liability (ensure flexibility in allowing payment arrangements where necessary). Plans must also ensure individuals are fully aware of how to access coverage of services for the new time period, including their right to appeal.</td>
</tr>
<tr>
<td>710 – UI Later Start Date</td>
<td>An existing enrollment period start date has been changed to start on a later date. Plans must use Exhibit 31. Plans must explain the change in the effective date of coverage, and provide information on the refunding of any premiums paid. Plans must also explain the impact on any paid claims from the time period affected.</td>
</tr>
<tr>
<td>711 – UI Earlier End Date</td>
<td>An enrollment period end date has been changed to occur earlier. Plans must use Exhibit 31. Plans must explain the change in the effective date of the end coverage, and provide information on the refunding of any premiums paid. Plans must also explain the impact on any paid claims from the time period affected.</td>
</tr>
<tr>
<td>712 – UI Later End Date</td>
<td>An enrollment period end date has been changed to occur later. Plans must use Exhibit 31. Plans must explain the change in the effective date of the end of coverage, and provide information on any premiums the individual may owe for the extended period. Plans must also ensure beneficiaries are fully aware of how to access coverage of services for the new time period.</td>
</tr>
<tr>
<td>713 – UI Removed End Date</td>
<td>An enrollment period that previously had an end date is now open (and ongoing). Plans must use Exhibit 22a to explain the change and that enrollment in the plan is now continuous. Plans must provide information on any plan premiums and ensure beneficiaries are fully aware of how to access coverage of services for the new time period and going forward.</td>
</tr>
</tbody>
</table>

**60.8 - Storage of Enrollment and Disenrollment Request Records**

PDP sponsors are required to retain records of enrollment and disenrollment requests (i.e. copies of enrollment forms, etc.) for the current contract period and 10 (ten) prior periods, as stated at 42 CFR §423.505(e)(1)(iii).
It is appropriate to allow for storage on microfilm, as long as microfilm versions of enrollment forms and disenrollment requests showing the signature and the date are available to reviewers. Similarly, other technologies that would allow the reviewer to access signed forms and other enrollment elections may also be allowed, such as optically scanned forms stored on disk.

Records of PDP enrollment and disenrollment elections made by any other election mechanism (as described in §30.1) must also be retained as above.
APPENDICES
Summary of PDP Notice and Data Element Requirements
Appendix 1: Summary of Notice Requirements

This Exhibit is intended to be a summary of notice requirements. For exact detail on requirements and time frames, refer to the appropriate sections within this Guidance.

<table>
<thead>
<tr>
<th>Notice</th>
<th>Section</th>
<th>Required?</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare Prescription Drug Plan Individual Enrollment Form (Exh. 1)</td>
<td>40.1.1</td>
<td>Yes¹</td>
<td>NA</td>
</tr>
<tr>
<td>Information to include on or with Enrollment Mechanism -- Attestation of Eligibility for an Enrollment Period (Exh. 1a)</td>
<td>30</td>
<td>No</td>
<td>NA</td>
</tr>
<tr>
<td>Short Enrollment Form (Exh. 1b)</td>
<td>20.3</td>
<td>No</td>
<td>NA</td>
</tr>
<tr>
<td>Model Plan Selection Form for Switch From Plan to Plan Within Parent Organization (Exh. 1c)</td>
<td>20.3</td>
<td>No</td>
<td>NA</td>
</tr>
<tr>
<td>Acknowledge Receipt of Enrollment Request (Exh. 2)</td>
<td>40.4.1</td>
<td>Yes²</td>
<td>10 calendar days of receipt of completed enrollment request</td>
</tr>
<tr>
<td>Acknowledge Receipt of Enrollment Request – Enrollment in another Plan Within the Same PDP Organization (Exh. 2a)</td>
<td>40.4.1</td>
<td>Yes</td>
<td>10 calendar days of receipt of completed enrollment request</td>
</tr>
<tr>
<td>Acknowledge Receipt of Enrollment and Confirmation of Enrollment (Exh. 2b)</td>
<td>40 and 40.4</td>
<td>Yes³</td>
<td>7 calendar days of availability of TRR</td>
</tr>
<tr>
<td>Confirmation of Enrollment (Exh. 4)</td>
<td>40.4.2</td>
<td>Yes⁴</td>
<td>10 calendar days of availability of TRR</td>
</tr>
<tr>
<td>Individuals Identified on CMS Records As Members of Employer/Union Receiving Employer Subsidy (Exh. 5)</td>
<td>20.4</td>
<td>Yes</td>
<td>10 calendar days of availability of TRR</td>
</tr>
<tr>
<td>PDP Organization Denial of</td>
<td>40.2.3</td>
<td>Yes</td>
<td>10 calendar days of receipt of</td>
</tr>
</tbody>
</table>

¹ Other CMS approved enrollment election mechanisms may take the place of an enrollment form
² Unless combine acknowledgment & confirmation notice, per section 40.4
³ Required if the PDP sponsor has chosen to provide a single notice in response to the TRR, as described in section 40 and 40.4
⁴ Required unless combined acknowledgment/confirmation notice is issued
<table>
<thead>
<tr>
<th>Notice</th>
<th>Section</th>
<th>Required?</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrollment (Exh. 6)</td>
<td></td>
<td></td>
<td>enrollment request OR expiration of time frame for requested additional information</td>
</tr>
<tr>
<td>CMS Rejection of Enrollment (Exh. 7)</td>
<td>40.4.3</td>
<td>Yes</td>
<td>10 calendar days of availability of TRR</td>
</tr>
<tr>
<td>Send Out Disenrollment Form/Disenrollment Form (Exh. 8 – 9)</td>
<td>50.1</td>
<td>No</td>
<td>NA</td>
</tr>
<tr>
<td>Information to include on or with Disenrollment Form -- Attestation of Eligibility for an Election Period (Exh. 9a)</td>
<td>30.3</td>
<td>No</td>
<td>NA</td>
</tr>
<tr>
<td>Acknowledgement of Receipt of Voluntary Disenrollment Request from Member (Exh. 10)</td>
<td>50.1.5</td>
<td>Yes</td>
<td>10 calendar days of receipt of request to disenroll</td>
</tr>
<tr>
<td>Final Confirmation of Voluntary Disenrollment Identified Through TRR (Exh. 10a)</td>
<td>50.1.5</td>
<td>Yes</td>
<td>10 calendar days of availability of TRR</td>
</tr>
<tr>
<td>Confirm Disenrollment Identified Through TRR – Reassigned LIS (Exh. 10b)</td>
<td>40.1.5</td>
<td>Yes</td>
<td>10 calendar days of availability of TRR</td>
</tr>
<tr>
<td>PDP Denial of Disenrollment (Exh. 11)</td>
<td>50.1.5</td>
<td>Yes</td>
<td>10 calendar days of receipt of disenrollment request</td>
</tr>
<tr>
<td>Model Notice to Request Information (Disenrollment) (Exh. 11a)</td>
<td>30, 50.4.2</td>
<td>No</td>
<td>NA</td>
</tr>
<tr>
<td>CMS Rejection of Disenrollment (Exh. 12)</td>
<td>50.1.5</td>
<td>Yes</td>
<td>10 calendar of availability of TRR</td>
</tr>
<tr>
<td>Disenrollment Due to Death (Exh. 13)</td>
<td>50.2.3</td>
<td>Yes</td>
<td>10 calendar days of availability of TRR</td>
</tr>
<tr>
<td>PDP Model Notice for auto-enrollments provided by CMS with recent deceased code (Exh. 13a)</td>
<td>40.1.4.D</td>
<td>Yes</td>
<td>10 calendar days of availability of TRR</td>
</tr>
<tr>
<td>Disenrollment Due to Loss of Medicare Part A and/or Part B (Exh. 14)</td>
<td>50.2.2</td>
<td>Yes</td>
<td>10 calendar days of availability of TRR</td>
</tr>
<tr>
<td>Notices on Terminations/Nonrenewals</td>
<td>note⁵</td>
<td>Yes</td>
<td>Follow requirements in 42 CFR 423.506 - 423.512</td>
</tr>
<tr>
<td>Advanced Warning of Potential Disenrollment Due to Disruptive</td>
<td>50.3.2</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

⁵ Provided under separate CMS guidance
<table>
<thead>
<tr>
<th>Notice</th>
<th>Section</th>
<th>Required?</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Behavior (no exhibit)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intent to request CMS’ permission to disenroll the member</td>
<td>50.3.2</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Confirmation of Disenrollment for Disruptive Behavior (no exhibit)</td>
<td>50.3.2</td>
<td>Yes</td>
<td>Before disenrollment transaction submitted to CMS</td>
</tr>
<tr>
<td>Disenrollment for Fraud &amp; Abuse (no exhibit)</td>
<td>50.3.3</td>
<td>Yes</td>
<td>Before disenrollment transaction submitted to CMS</td>
</tr>
<tr>
<td>Offering Beneficiary Services, Pending Correction of Erroneous Death Status (Exh. 15)</td>
<td>60.2, 60.2.1</td>
<td>Yes</td>
<td>10 calendar days of initial contact with member</td>
</tr>
<tr>
<td>Offering Beneficiary Services, Pending Correction of Erroneous Medicare Part A and/or Part B Termination (Exh. 16)</td>
<td>60.2, 60.2.1</td>
<td>Yes</td>
<td>10 calendar days of initial contact with member</td>
</tr>
<tr>
<td>Offering Reinstatement of Beneficiary Services, Pending Correction of Disenrollment Status Due to Plan Error (Exh. 17)</td>
<td>60.2, 60.2.3</td>
<td>Yes</td>
<td>10 calendar days of initial contact with member</td>
</tr>
<tr>
<td>Closing Out Request for Reinstatement (Exh. 18)</td>
<td>60.2</td>
<td>Yes</td>
<td>10 calendar days after information was due to organization</td>
</tr>
<tr>
<td>Failure to Pay Plan Premiums - Advance Notification of Disenrollment or Reduction in Coverage (Exh. 19)</td>
<td>50.3.1</td>
<td>Yes</td>
<td>Within 15 calendar days after the 1st of the month for which delinquent premiums due</td>
</tr>
<tr>
<td>Failure to Pay Plan Premiums - Notification of Involuntary Disenrollment (Exh. 20)</td>
<td>50.3.1</td>
<td>Yes</td>
<td>3 business days following the last day of the grace period</td>
</tr>
<tr>
<td>Failure to Pay Plan Premiums - Confirmation of Involuntary Disenrollment (Exh. 21)</td>
<td>50.3.1</td>
<td>Yes</td>
<td>10 calendar days of availability of TRR</td>
</tr>
<tr>
<td>Involuntary Disenrollment by CMS for Failure to Pay Part D-IRMAA (Exh. 21a)</td>
<td>50.2.6</td>
<td>Yes</td>
<td>10 calendar days of availability of TRR</td>
</tr>
<tr>
<td>Favorable “Good Cause” Determination – Notification of Premium Amount Due for Reinstatement (Exh. 21b)</td>
<td>60.2.4</td>
<td>Yes</td>
<td>3 business days of receipt of CTM notification of favorable “good cause” determination</td>
</tr>
<tr>
<td>Acknowledgement of Request to Cancel Enrollment (Exh. 22)</td>
<td>60.1.1</td>
<td>Yes</td>
<td>10 calendar days of request</td>
</tr>
<tr>
<td>Notice</td>
<td>Section</td>
<td>Required?</td>
<td>Timeframe</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>-------------------</td>
<td>-----------</td>
<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Confirmation of Reinstatement After Cancelling a Request to Enroll in Another Plan or Reinstatement for Favorable “Good Cause” Determination (Exh. 22a)</td>
<td>60.1.1, 60.1.2, 60.2.1, 60.2.2</td>
<td>Yes</td>
<td>10 calendar days of TRR indicating reinstatement</td>
</tr>
<tr>
<td>Acknowledgement of Request to Cancel Disenrollment (Exh. 23)</td>
<td>60.1.1</td>
<td>Yes</td>
<td>10 calendar days of request</td>
</tr>
<tr>
<td>Inform member of Auto-enrollment (Exh. 24)</td>
<td>40.1.4.D</td>
<td>Yes</td>
<td>10 calendar days of availability of TRR or address report, whichever is later</td>
</tr>
<tr>
<td>Inform member of Facilitated Enrollment (Exh. 25)</td>
<td>40.1.4.D</td>
<td>Yes</td>
<td>10 calendar days of availability of TRR or address report, whichever is later</td>
</tr>
<tr>
<td>Request to Decline Part D (Exh. 26)</td>
<td>40.1.4.E &amp; 40.1.4.E</td>
<td>Yes</td>
<td>10 calendar days of request</td>
</tr>
<tr>
<td>PDP Acknowledgement of Request to Disenroll from PDP and Opt-Out of Part D After Effective Date (Exh. 26a)</td>
<td>40.1.4.G</td>
<td>Yes</td>
<td>10 calendar days of request</td>
</tr>
<tr>
<td>Auto and Facilitated Enrollees Who Permanently Reside in another Region Where the PDP Sponsor Offers another PDP at or below the Low-Income Premium Subsidy Amount for that Region (Exh. 27)</td>
<td>50.2.1</td>
<td>No</td>
<td>10 calendar days of availability of TRR</td>
</tr>
<tr>
<td>Auto and Facilitated Enrollees Who Permanently Reside in another Region Where PDP Sponsor Does Not offer another PDP at or below the Low-Income Premium Subsidy Amount for that Region (Exh. 28)</td>
<td>50.2.1</td>
<td>Yes</td>
<td>10 calendar days of confirmation that individual does not reside in region</td>
</tr>
<tr>
<td>Reassignment Confirmation (Exh. 29)</td>
<td>40.1.5.E</td>
<td>Yes</td>
<td>10 calendar days of availability of TRR</td>
</tr>
<tr>
<td>Optional Notice for “Losing Plan” to LIS Beneficiaries Re-Assigned to a Different PDP Sponsor (in lieu of ANOC) (Exh. 30)</td>
<td>40.1.5.E</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Notice</td>
<td>Section</td>
<td>Required?</td>
<td>Timeframe</td>
</tr>
<tr>
<td>-----------------------------------------------------------------------</td>
<td>---------</td>
<td>-----------</td>
<td>---------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Enrollment Status Update -- For use with Transaction Reply Codes (TRC) from User Interface (UI) changes (Exh. 31)</td>
<td>60.7</td>
<td>As necessary</td>
<td>10 calendar days of availability of TRR</td>
</tr>
<tr>
<td>Model Employer/Union Group Enrollment Mechanism Notice</td>
<td>40.1.6</td>
<td>Yes</td>
<td>Minimum 21 calendar days prior to effective date of enrollment</td>
</tr>
<tr>
<td>Research Potential Out of Area Status (Exh. 33)</td>
<td>50.2.1.3</td>
<td>Yes</td>
<td>10 calendar days of receipt of information indicating potential out-of-area status</td>
</tr>
<tr>
<td>PDP Model Notice for Disenrollment Due Out of Area Status (Exh. 34)</td>
<td>50.2.1.3</td>
<td>Yes</td>
<td>Within the first ten calendar days of the 12th month</td>
</tr>
<tr>
<td>PDP Notice of Disenrollment Due to Out of Area Status (Exh 35)</td>
<td>50.2.1.3</td>
<td>Yes</td>
<td>Within 10 calendar days of confirmation that out-of-area move was permanent</td>
</tr>
</tbody>
</table>
## Appendix 2: Summary of Data Elements Required for Plan Enrollment Mechanisms and Completed Enrollment Requests

All data elements with a “Yes” in the “Beneficiary response required on enrollment request” column are necessary in order for the enrollment request to be considered complete.

<table>
<thead>
<tr>
<th>Data Element</th>
<th>Required on enrollment mechanism?</th>
<th>Beneficiary response required on enrollment request?</th>
</tr>
</thead>
<tbody>
<tr>
<td>PDP Plan name</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Beneficiary name</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Beneficiary Birth Date</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Beneficiary Sex</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Beneficiary Telephone Number</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Permanent Residence Address</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Mailing Address</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Name of person to contact in emergency, including phone number and relationship to beneficiary (Optional Field)</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>E-mail address</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Beneficiary Medicare number</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Additional Medicare information contained on sample Medicare card, or copy of card</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Plan Premium Payment Option</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Other insurance COB information</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Long term care question</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Beneficiary signature and/or Beneficiary Representative Signature</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Date of signature</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

6 If the enrollment mechanism will be used for multiple plans (PBPs), all plan names must be listed in a way that permits the applicant to clearly indicate his/her plan choice.

7 We recognize that the PDP needs, at a minimum, the Medicare number in order to verify entitlement to Part A and/or enrollment in Part B; we have accounted for the need for this data element under data element number 4.

8 Response defaults to direct bill if applicant fails to provide information

9 Refer to CMS COB guidance for additional information

10 Applicable only to requests made using a paper enrollment form. If signature is missing, plan may follow up and document, as described in Section 30.2. F
<table>
<thead>
<tr>
<th>Data Element</th>
<th>Required on enrollment mechanism?</th>
<th>Beneficiary response required on enrollment request?</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 Authorized Representative contact information (if not signed by beneficiary)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>19 Information provided under “please read and sign below”</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>All elements provided in model language must be included on enrollment request mechanisms.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Option -- can be provided as narrative or listed as statements of understanding</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20 Release of Information</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>All elements provided in model language must be included on enrollment request mechanisms.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>21 Option to request materials in language other than English or in other formats</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

11 As explained in §40.2, the beneficiary and/or legal representative should provide the date s/he completed the enrollment form; however, if s/he inadvertently fails to include the date on the enrollment request, then the date of receipt that the PDP assigns to the enrollment request may serve as the signature date of the form. Therefore, the signature date is not a necessary element.
Appendix 3: Setting the Application Date on CMS Enrollment Transactions

The application date submitted on enrollment transactions plays a key role in CMS system edits that ensure the beneficiary’s choice of plan is honored. The application date is always a date prior to the effective date of enrollment.

<table>
<thead>
<tr>
<th>Election Mechanism</th>
<th>Application Date</th>
<th>Special Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paper Enrollment Forms §50.1.1</td>
<td>The date the paper request is initially received</td>
<td>Paper requests submitted to or collected by sales agents or brokers are received by the PDP sponsor on the date the agent or broker receives the form.</td>
</tr>
<tr>
<td>Enrollment forms received by Fax §50.1.1</td>
<td>The date the fax is received on the PDP sponsor’s Fax machine</td>
<td></td>
</tr>
<tr>
<td>Medicare.gov Online Enrollment Center (OEC) §50.1.3</td>
<td>The date “stamped” by CMS on the request</td>
<td></td>
</tr>
<tr>
<td>PDP electronic enrollment §40.1.2</td>
<td>The date the request is completed via the sponsor’s electronic enrollment process</td>
<td>The electronic enrollment process must capture the application date as the day that the individual completes the request as part of the process itself.</td>
</tr>
<tr>
<td>Approved Telephonic Enrollment §50.1.4</td>
<td>The date of the call</td>
<td></td>
</tr>
</tbody>
</table>

Other Special Processes for Application Dates

<table>
<thead>
<tr>
<th>All enrollment requests into employer or union sponsored plans using the SEP EGHP, regardless of mechanism used</th>
<th>1&lt;sup&gt;st&lt;/sup&gt; day of the month prior to the effective date of enrollment</th>
<th>This applies to all mechanisms including §§50.1.3 and 50.1.7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auto and Facilitated Enrollment §50.1.6</td>
<td>For Part D plans, the application date is set by CMS.</td>
<td>For Cost plans conducting auto- &amp; facilitated enrollment per section 50.1.1 of Chapter 17-D, set the application date to the 1&lt;sup&gt;st&lt;/sup&gt; of the month prior to the effective date of the auto/facilitated enrollment.</td>
</tr>
<tr>
<td>SPAP enrollment requests as permitted in §50.1.8 made during the AEP</td>
<td>October 15&lt;sup&gt;th&lt;/sup&gt;</td>
<td>The effective date of enrollment is the following January 1&lt;sup&gt;st&lt;/sup&gt;</td>
</tr>
</tbody>
</table>
This section contains model exhibits for plan issued notices to beneficiaries regarding enrollment matters. PDP sponsors may make the following modifications to CMS model materials and still submit the material to CMS under the ten (10) day review period: populating variable fields, correcting grammatical errors, changing the font (within standards described in the CMS marketing guidelines), adding the plan name/logo, and adding the CMS marketing material identification number.

For more information on CMS marketing and mailing requirements as well as the instructions for submitting model documents for review, see Sections 90.3.6 and 90.7.3 of the CMS marketing guidelines.
Exhibit 1 - PDP Model Enrollment Form

[Logo/Name of the Medicare Drug Plan]

<PDP Name> Medicare Prescription Drug Plan Individual Enrollment Form
Please contact <plan name> if you need information in another language or format (Braille).

To Enroll in <PDP name>, Please Provide the Following Information:

**[Required if form used for multiple plans: Please check which plan you want to enroll in:]**

- [ ] Product ABC  $XX per month
- [ ] Product XYZ  $XX per month

<table>
<thead>
<tr>
<th>LAST name:</th>
<th>FIRST Name:</th>
<th>Middle Initial</th>
<th>Sex:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>[ ] M [ ] F</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Birth Date:</th>
<th>Home Phone Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>(MM/DD/YYYY)</td>
<td>(________)</td>
</tr>
</tbody>
</table>

Permanent Residence Street Address (P.O. Box is not allowed):

<table>
<thead>
<tr>
<th>City:</th>
<th>State:</th>
<th>ZIP Code:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Mailing Address (only if different from your Permanent Residence Address):

<table>
<thead>
<tr>
<th>Street Address:</th>
<th>City:</th>
<th>State:</th>
<th>ZIP Code:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Emergency contact: [Optional field] ________________

Phone Number: [Optional field] __________ Relationship to You [Optional field] __________

[optional field] E-mail Address:

Please Provide Your Medicare Insurance Information

Please take out your Medicare card to complete this section.

- Please fill in these blanks so they match your red, white and blue Medicare card
- OR -
- Attach a copy of your Medicare card or your letter from Social Security or the Railroad Retirement Board.

You must have Medicare Part A or Part B (or both) to join a Medicare prescription drug plan.

**SAMPLE ONLY**

<table>
<thead>
<tr>
<th>Name:</th>
<th>Medicare Claim Number</th>
<th>Sex</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Is Entitled To</th>
<th>Effective Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>HOSPITAL (Part A)</td>
<td>______________</td>
</tr>
<tr>
<td>MEDICAL (Part B)</td>
<td>______________</td>
</tr>
</tbody>
</table>

<Contract#, alpha-numeric identifier, "CMS Approved/File & Use" [date] (as applicable)>
Paying Your Plan Premium

You can pay your monthly plan premium (including any late enrollment penalty you may owe) by mail <insert optional methods: “Electronic Funds Transfer (EFT)”, “credit card”> each month <insert optional intervals, if applicable, for example “or quarterly”>. You can also choose to pay your premium by automatic deduction from your Social Security or Railroad Retirement Board benefit check each month. If you are assessed a Part D-Income Related Monthly Adjustment Amount, you will be notified by the Social Security Administration. You will be responsible for paying this extra amount in addition to your plan premium. You will either have the amount withheld from your Social Security or Railroad Retirement Board benefit check or be billed directly by Medicare. Do NOT pay the Part D-IRMAA extra amount to <PDP name>.

People with limited incomes may qualify for extra help to pay for their prescription drug costs. If you qualify, Medicare could pay for 75% or more of your drug costs including monthly prescription drug premiums, annual deductibles, and co-insurance. Additionally, those who qualify won’t have a coverage gap or a late enrollment penalty. Many people are eligible for these savings and don’t even know it. For more information about this extra help, contact your local Social Security office, or call Social Security at 1-800-772-1213. TTY users should call 1-800-325-0778. You can also apply for extra help online at www.socialsecurity.gov/prescriptionhelp.

If you qualify for extra help with your Medicare prescription drug coverage costs, Medicare will pay all or part of your plan premium. If Medicare pays only a portion of this premium, we will bill you for the amount that Medicare doesn’t cover.

If you don’t select a payment option, you will receive a bill each month <optional language in place of “bill each month”: “coupon book” or “payment book”>.

Please select a premium payment option:

☐ Receive a bill <option: “coupon”, “payment” book, etc>

☐ Electronic funds transfer (EFT) from your bank account each month. Please enclose a VOIGNED check or provide the following:

Account holder name: ______________________
Bank routing number: _ _ _ _ _ _ _ _ _ Bank account number: _ _ _ _ _ _ _ _ _ _ _ _
Account type: □ Checking □ Saving

☐ Credit Card. Please provide the following information:

Type of Card: _______________________________
Name of Account holder as it appears on card: _________________________
Account number: _____________________________________________
Expiration Date: _ _/ _ _/ _ _ _ _ (MM/YYYY)>

☐ Automatic deduction from your monthly Social Security/Railroad Retirement Board benefit check. (The Social Security/Railroad Retirement Board deduction may take two or more months to begin. In most cases, if Social Security/the Railroad Retirement Board accepts your request for automatic deduction, the first deduction from your Social Security/Railroad Retirement Board benefit check will include all premiums due from your enrollment effective date up to the point withholding begins. If Social Security/the Railroad Retirement Board does not approve your request for automatic deduction, we will send you a paper bill for your monthly premiums.)
Please Answer the Following Questions:

1. Some individuals may have other drug coverage, including other private insurance, TRICARE, Federal employee health benefits coverage, VA benefits, or State pharmaceutical assistance programs.

Will you have other prescription drug coverage in addition to <PDP name>?  □ Yes  □ No
If “yes”, please list your other coverage and your identification (ID) number(s) for this coverage:

Name of other coverage:                                  ID # for this coverage:                                  Group # for this coverage:
_____________________________                         __________________________                 __________________________ _

2. Are you a resident in a long-term care facility, such as a nursing home?  □ Yes  □ No
If “yes” please provide the following information:
Name of Institution: ____________
Address & Phone Number of Institution (number and street):__________________

Please check one of the boxes below if you would prefer that we send you information in a language other than English or in another format:

___  <include list of available languages>
___  <include list of other formats (e.g. Braille, audio tape, or large print)>

Please contact <PDP name> at <phone number> if you need information in another format or language than what is listed above. TTY users should call <TTY number>. Our office hours are <insert days and hours of operation>.

Please Read This Important Information

If you are a member of a Medicare Advantage Plan (like an HMO or PPO), you may already have prescription drug coverage from your Medicare Advantage Plan that will meet your needs. By joining <PDP name>, your membership in your Medicare Advantage Plan may end. This will affect both your doctor and hospital coverage as well as your prescription drug coverage. Read the information that your Medicare Advantage Plan sends you and if you have questions, contact your Medicare Advantage Plan.

If you currently have health coverage from an employer or union, joining <PDP Name> could affect your employer or union health benefits. You could lose your employer or union health coverage if you join <PDP name>. Read the communications your employer or union sends you. If you have questions, visit their website, or contact the office listed in their communications. If there isn’t information on whom to contact, your benefits administrator or the office that answers questions about your coverage can help.

Please Read and Sign Below:

By completing this enrollment application, I agree to the following:

<PDP Name> is a Medicare drug plan and has a contract with the Federal government. I understand that this prescription drug coverage is in addition to my coverage under Medicare; therefore, I will need to keep my Medicare Part A or Part B coverage. It is my responsibility to inform <PDP name> of any prescription drug coverage that I have or may get in the future. I can only be in one Medicare prescription drug plan at a time – if I am currently in a Medicare Prescription Drug Plan, my enrollment in <PDP name> will end that enrollment.

<Contract#, alpha-numeric identifier, "CMS Approved/File & Use" [date] (as applicable)> 136
Enrollment in this plan is generally for the entire year. Once I enroll, I may leave this plan or make changes if an enrollment period is available, generally during the Annual Enrollment Period (October 15 – December 7), unless I qualify for certain special circumstances.

<PDP Name> serves a specific service area. If I move out of the area that <PDP Name> serves, I need to notify the plan so I can disenroll and find a new plan in my new area. I understand that I must use network pharmacies except in an emergency when I cannot reasonably use <PDP name> network pharmacies. Once I am a member of <PDP Name>, I have the right to appeal plan decisions about payment or services if I disagree. I will read the Evidence of Coverage document from <PDP name> when I get it to know which rules I must follow to get coverage.

I understand that if I leave this plan and don’t have or get other Medicare prescription drug coverage or creditable prescription drug coverage (as good as Medicare’s), I may have to pay a late enrollment penalty in addition to my premium for Medicare prescription drug coverage in the future.

I understand that if I am getting assistance from a sales agent, broker, or other individual employed by or contracted with <PDP name>, he/she may be paid based on my enrollment in <PDP name>.

Counseling services may be available in my state to provide advice concerning Medicare supplement insurance or other Medicare Advantage or Prescription Drug Plan options, medical assistance through the state Medicaid program, and the Medicare Savings Program.

**Release of Information:**

By joining this Medicare prescription drug plan, I acknowledge that <PDP Name> will release my information to Medicare and other plans as is necessary for treatment, payment and health care operations. I also acknowledge that <PDP Name> will release my information, including my prescription drug event data, to Medicare, who may release it for research and other purposes which follow all applicable Federal statutes and regulations. The information on this enrollment form is correct to the best of my knowledge. I understand that if I intentionally provide false information on this form, I will be disenrolled from the plan.

If you are the authorized representative, you must sign above and provide the following information:

<table>
<thead>
<tr>
<th>Signature:</th>
<th>Today’s Date:</th>
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</table>

If signed by an authorized individual (as described above), this signature certifies that: 1) this person is authorized under State law to complete this enrollment and 2) documentation of this authority is available upon request by Medicare.
Medicare Prescription Drug Plan Use Only:

Plan ID #: ________________
Effective Date of Coverage: ________________ IEP: _______ AEP: _______ SEP (type): ______
Name of Plan Representative/agent/broker: ________________________________

[optional space for other administrative information needed by plan]
Exhibit 1a – Information to Include on or with Enrollment Mechanism - Attestation of Eligibility for an Enrollment Period

Referenced in section: 30

Typically, you may enroll in a Medicare Prescription Drug Plan only during the annual enrollment period from October 15 through December 7 of each year. Additionally, there are exceptions that may allow you to enroll in a Medicare Prescription Drug Plan outside of the annual enrollment period.

Please read the following statements carefully and check the box if the statement applies to you. By checking any of the following boxes you are certifying that, to the best of your knowledge, you are eligible for an Enrollment Period. If we later determine that this information is incorrect, you may be disenrolled.

☐ I am new to Medicare.

☐ I recently moved outside of the service area for my current plan or I recently moved and this plan is a new option for me. I moved on (insert date) ____________________________.

☐ I recently returned to the United States after living permanently outside of the U.S. I returned to the U.S. on (insert date) ____________________________.

☐ I have both Medicare and Medicaid or my state helps pay for my Medicare premiums.

☐ I get extra help paying for Medicare prescription drug coverage.

☐ I no longer qualify for extra help paying for my Medicare prescription drug coverage. I stopped receiving extra help on (insert date) ____________________________.

☐ I live in or recently moved out of a Long-Term Care Facility (for example, a nursing home or long term care facility). I moved/will move into/out of the facility on (insert date) ________________.

☐ I recently left a PACE program on (insert date) ________________________________________.

☐ I recently involuntarily lost my creditable prescription drug coverage (as good as Medicare’s). I lost my drug coverage on (insert date) ________________.

☐ I am leaving employer or union coverage on (insert date) ____________________________.

☐ I belong to a pharmacy assistance program provided by my state.

☐ My plan is ending its contract with Medicare, or Medicare is ending its contract with my plan.

☐ I am making this enrollment request between January 1 and February 14, and I recently ended my enrollment in a Medicare Advantage plan. I left my Medicare Advantage plan on (insert date) ____________________________.

If none of these statements applies to you or you’re not sure, please contact <plan name> at <phone number> to see if you are eligible to enroll. We are open <insert days and hours of operation>. TTY users should call <TTY number>.  

<Contract#, alpha-numeric identifier, “CMS Approved/File & Use” [date] (as applicable)>
**Exhibit 1b – Model Short Enrollment Form (“Election” may also be used)**

This form may be used in place of the model individual enrollment form when a member of a PDP sponsor is enrolling into another plan benefit package offered by the same parent organization.

Referenced in section(s): 20.3, 40.1.2, Appendix 1

<table>
<thead>
<tr>
<th>Name of Plan You are Enrolling In:</th>
<th>______________________________</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Name:</th>
<th>Medicare Number:</th>
<th>[Note: may use “member number” instead of “Medicare number”]</th>
</tr>
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<tbody>
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<table>
<thead>
<tr>
<th>Home Phone Number:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Permanent Street Address (P.O. Box is not allowed):</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>City:</th>
<th>State:</th>
<th>ZIP Code:</th>
</tr>
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<table>
<thead>
<tr>
<th>Mailing Address</th>
<th>(only if different from your Permanent Street Address):</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Street Address:</th>
<th>City:</th>
<th>State:</th>
<th>ZIP Code:</th>
</tr>
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</tbody>
</table>

**Please fill out the following:**

I am currently a member of the ________ plan in <PDP name> with a monthly premium of $________.

I would like to change to the ________ plan in <PDP name>. I understand that this plan has different prescription benefits and a monthly premium of $________.

**Please check one of the boxes below if you would prefer us to send you information in a language other than English or in another format:**

___ [include list of available languages]

___ [include list of other formats (e.g. Braille, audio tape, or large print)]

Please contact <plan name> at <phone number> if you need information in another format or language than what is listed above. Our office hours are <insert days and hours of operation>. TTY users should call <TTY number>.

<table>
<thead>
<tr>
<th>Your Plan Premium</th>
</tr>
</thead>
</table>

You can pay your monthly plan premium (including any late enrollment penalty you may owe) by mail <insert optional methods: “Electronic Funds Transfer (EFT)”, “credit card”> each month <insert optional intervals, if applicable, for example “or quarterly”>. You can also choose to pay your premium by automatic deduction from your Social Security or Railroad Retirement Board benefits check each month.

If you are assessed a Part D-Income Related Monthly Adjustment Amount, you will be notified by the Social Security Administration. You will be responsible for paying this extra amount in addition to your plan premium. You will either have the amount withheld from your Social Security or Railroad Retirement Board benefit check or be billed directly by Medicare. DON’T pay <plan name> the Part D-IRMAA extra amount.

People with limited incomes may qualify for extra help to pay for their prescription drug costs. If you qualify, Medicare could pay for 75% or more of your drug costs including monthly prescription drug premiums, annual
deductibles, and co-insurance. Additionally, those who qualify won’t have a coverage gap or a late enrollment penalty. Many people qualify for these savings and don’t even know it. For more information about this extra help, contact your local Social Security office or call Social Security at 1-800-772-1213. TTY users should call 1-800-325-0778. You can also apply for extra help online at www.socialsecurity.gov/prescriptionhelp.

If you qualify for extra help with your Medicare prescription drug coverage costs, Medicare will pay all or part of your plan premium. If Medicare pays only a portion of this premium, we will bill you for the amount that Medicare doesn’t cover.

If you don’t select a payment option, you will get a bill each month <optional language in place of “bill each month”: “coupon book” or “payment book”>.

**Please select a premium payment option:**

- [ ] Get a bill <option: Include other optional methods, such as EFT & credit card>
- [ ] Automatic deduction from your monthly Social Security/Railroad Retirement Board benefit check. (The Social Security/Railroad Retirement Board deduction may take two or more months to begin. In most cases, if Social Security/the Railroad Retirement Board accepts your request for automatic deduction, the first deduction from your Social Security/Railroad Retirement Board benefit check will include all premiums due from your enrollment effective date up to the point withholding begins. If Social Security/the Railroad Retirement Board does not approve your request for automatic deduction, we will send you a paper bill for your monthly premiums.)

**Please Read and Sign Below:**

<PDP name> is a Medicare prescription drug plan and has a contract with the Federal government.

I understand that if I am getting assistance from a sales agent, broker, or other individual employed by or contracted with <plan name>, he/she may be compensated based on my enrollment in<plan name>.

**Release of Information:** By joining this Prescription Drug Plan, I acknowledge that the Prescription Drug Plan will release my information to Medicare and other plans as is necessary for treatment, payment and health care operations. I also acknowledge that <plan name> will release my information, including my prescription drug event data, to Medicare, who may release it for research and other purposes which follow all applicable Federal statutes and regulations. The information on this enrollment form is correct to the best of my knowledge. I understand that if I intentionally provide false information on this form, I will be disenrolled from the plan. I understand that Medicare beneficiaries are generally not covered under Medicare while out of the country except for limited coverage near the U.S. border.

I understand that beginning on the date [name of plan] coverage begins, I must get all of my prescription drug services from <plan name>. Prescription drugs authorized by <plan name> and contained in my <plan name> Evidence of Coverage document (also known as a member contract or subscriber agreement) will be covered. Without authorization, NEITHER MEDICARE NOR <Plan Name> WILL PAY FOR THE SERVICES.

I understand that my signature (or the signature of the person authorized to act on behalf of the individual under the laws of the State where the individual resides) on this application means that I have read and understand the contents of this application. If signed by an authorized individual (as described above), this signature certifies that: 1) this person is authorized under State law to complete this enrollment and 2) documentation of this authority is available upon request by Medicare.
<table>
<thead>
<tr>
<th>Signature:</th>
<th>Today’s Date:</th>
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</thead>
</table>

If you are the authorized representative, you must sign above and provide the following information:

**Name:** ______________________

**Address:** _______________________________________________

**Phone Number:** (___) ____- _____

**Relationship to Enrollee** ______________________

---

**Medicare Prescription Drug Plan Use Only:**

**Plan ID #:** __________

**Effective Date of Coverage:** __________  **IEP:** ______  **AEP:** ______  **SEP (type):** ______

**Name of Plan Representative/agent/broker:** ______________________

[optional space for other administrative information needed by plan]
Exhibit 1c: Model Plan Selection Form for Switch from Plan to Plan within Parent Organization

Referenced in section(s): 10, 40, 40.1, 40.2

Dear <plan name> Member:

<Introduction - In the introduction of cover letter, PDP sponsor may include language regarding plan choices, description of plans, differences, etc.>.

To make a change in the Medicare Prescription Drug plan you have with <name of PDP sponsor>, fill out the enclosed plan selection form to make your choice. Check off the plan you want, and sign the form. Then mail the completed form back to us <optional: in the postage-paid envelope> by <date>.

Please be aware that you can change Part D plans only at certain times during the year. Between October 15th and December 7th each year, anyone can join our plan. Generally, you may not make changes at other times unless you meet certain special exceptions, such as if you move out of the plan’s service area, want to join a plan in your area with a 5-star rating, or qualify for extra help paying for prescription drug coverage.

If you qualify for extra help with your prescription drug costs you may enroll in, or disenroll from, a plan at any time. If you lose this extra help during the year, your opportunity to make a change continues for two months after you are notified that you no longer qualify for extra help.

If you select another plan and we receive your completed selection form by <date>, your new benefit plan will begin in <month/year>. Your monthly plan premium will be <premium amount> and you may continue to use any <current plan name> pharmacies.

Complete the attached form only if you wish to change plans.

To help you with your decision, we have also included <Year> <Summary of Benefits or benefit overview> for the available options.

If you have any questions, please call <plan name> at <phone number - if plan is planning to have informational meetings - include information about time/place of meetings >. TTY users should call <TTY number>. We are open <insert days/hours of operation and, if different, TTY hours of operation>.

Thank you.
Plan Selection Form

Date:  
Member Name:  
Member Number:

I want to transfer from my current Part D plan to the Part D plan I have selected below. I understand that if this form is received by the end of any month, my new plan will generally be effective the 1st of the following month.

Please check the appropriate box below <list all available plans>:

____ <Name of Plan>  
<monthly premium amount>  
<brief description of benefit - include items such as: deductible, copays, etc.>

____ <Name of Plan>  
<monthly premium amount>  
<brief description of benefit - include items such as: deductible, copays, etc.>

<table>
<thead>
<tr>
<th>Your Plan Premium</th>
</tr>
</thead>
<tbody>
<tr>
<td>You can pay your monthly plan premium by mail &lt;insert optional methods: “Electronic Funds Transfer (EFT)”&gt;, “credit card”&gt; each month &lt;insert optional intervals, if applicable, for example “or quarterly”&gt;. You can also choose to pay your premium by automatic deduction from your Social Security/Railroad Retirement Board benefit check each month.</td>
</tr>
</tbody>
</table>

People with limited incomes may qualify for extra help to pay for their prescription drug costs. If eligible, Medicare could pay for 75% or more of your drug costs including monthly prescription drug premiums, annual deductibles, and co-insurance. Additionally, those who qualify will not be subject to the coverage gap or a late enrollment penalty. Many people are eligible for these savings and don’t even know it. For more information about this extra help, contact your local Social Security office or call 1-800-MEDICARE (1-800-633-4227), 24 hours per day, 7 days per week. TTY/TDD users should call 1-877-486-2048.

If you are assessed a Part D-Income Related Monthly Adjustment Amount, you will be notified by the Social Security Administration. You will be responsible for paying this extra amount in addition to your plan premium. You will either have the amount withheld from your Social Security or Railroad Retirement Board benefit check or be billed directly by Medicare. DON’T pay <plan name> the Part D-IRMAA extra amount.

If you qualify for extra help with your Medicare prescription drug coverage costs, Medicare will pay all or part of your plan premium for this benefit. If Medicare pays only a portion of this premium, we will bill you for the amount that Medicare does not cover.

If you don’t select a payment option, you will receive a bill each month <optional language in place of “bill each month”: “coupon book” or “payment book”>.

<Contract#, alpha-numeric identifier, “CMS Approved/File & Use” [date] (as applicable)>  144
Please select a premium payment option:

☐ Receive a bill <option: Include other optional methods, such as EFT & credit card>

☐ Automatic deduction from your monthly Social Security/Railroad Retirement Board benefit check. (The Social Security/Railroad Retirement Board deduction may take two or more months to begin. In most cases, if Social Security/the Railroad Retirement Board accepts your request for automatic deduction, the first deduction from your Social Security/Railroad Retirement Board benefit check will include all premiums due from your enrollment effective date up to the point withholding begins. If Social Security/the Railroad Retirement Board does not approve your request for automatic deduction, we will send you a paper bill for your monthly premiums.)

Please check one of the boxes below if you would prefer us to send you information in a language other than English or in another format:

___ <include list of available languages>

___ <include list of other formats (e.g. Braille, audio tape, or large print)>

Please contact <plan name> at <phone number> (TTY users should call TTY number) if you need information in another format or language than what is listed above. Our office hours are <insert days and hours of operation>.

<table>
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<tr>
<th>Signature:</th>
<th>Today’s Date:</th>
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If you are the authorized representative, you must sign above and provide the following information:

Name: __________________________________________
Address: ________________________________________
Phone Number: (___) ____- _________________
Relationship to Enrollee ________________________

Please mail this form to:
<Insert mailing address>
Exhibit 2 - PDP Model Notice to Acknowledge Receipt of Completed Enrollment

Referenced in section: 40.4.1

<Member #>
<RxID>
<RxGroup>
<RxBin>
<RxPCN>

<Date>
Dear <Name of Member>:

Thank you for enrolling in <PDP name>. <PDP name> is a Prescription Drug Plan that is approved by Medicare. Your enrollment will be effective on <effective date>.

How will this coverage work?
As of <effective date>, you should begin using <PDP name> network pharmacies to fill your prescriptions. If you use an out-of-network pharmacy and there is not an emergency, <PDP name> may not pay for your prescriptions. [Optional language: This letter is proof of your <PDP name> coverage. You should show this letter at the pharmacy until you get your Member ID card from us.]

How much is my premium?
Medicare must approve all enrollments and calculate your premium amount. When Medicare approves your enrollment into <PDP name>, we will send you a letter to confirm your enrollment in <PDP name>. You will get a separate letter from <PDP name> once Medicare calculates your premium. You should not wait to get these confirmation letters before you begin using <PDP name> network pharmacies on <effective date>. If Medicare rejects your enrollment, <PDP name> will bill you for any prescriptions you received through us.

[PDP plans without a premium – do not use the following Q&A:
Will <PDP name> bill me directly for my premiums or will my premiums be deducted from my Social Security/Railroad Retirement Board check?
Your enrollment form included the options for paying your plan premium. If you chose to have your <PDP name> premium withheld from your Social Security or Railroad Retirement Board benefit check, we may have to send you a bill for your first month or two of enrollment if the deduction doesn’t start right away or doesn’t start at all. If you didn’t choose this option, we will bill you for your monthly premiums. Generally you must stay with the premium payment option you choose for the rest of the year. If you have any questions about how to pay your plan premium, please contact us at <toll-free number> <days and hours of operation>. TTY/TDD users should call <toll-free TTY number>. [PDPs that disenroll for nonpayment of premium include the following sentence: “Members who fail to pay the monthly premium may be disenrolled from <PDP name>”].]
What is extra help?
People with limited incomes may qualify for extra help to pay for their prescription drug costs. If you qualify, Medicare could pay for 75% or more of your drug costs including monthly prescription drug premiums, annual deductibles, and co-insurance. Additionally, those who qualify won’t have a coverage gap or a late enrollment penalty. Many people qualify for these savings and don’t even know it. For more information about this extra help, contact your local Social Security office, or call Social Security at 1-800-772-1213. TTY users should call 1-800-325-0778. You can also apply for extra help online at www.socialsecurity.gov/prescriptionhelp.

What if I have other health coverage?
If you have other health coverage, such as from an employer or union, joining <PDP Name> may change how your current coverage works. Read the communications your other health coverage sends you. If you have questions, visit their website, or contact the office listed in their communications. If there is no information on whom to contact, your benefits administrator or the office that answers questions about your coverage can help. If you have other prescription drug coverage, such as through an employer plan, you shouldn’t cancel your other coverage yet. Keep your other coverage until you receive the confirmation letter from us.

What if I have Medigap (Medicare Supplemental Insurance) coverage?
If you have a Medigap (Medicare Supplement Insurance) policy that includes prescription drug coverage, you must contact your Medigap Issuer to let them know that you have joined a Medicare prescription drug plan. Your Medigap Issuer will remove the prescription drug coverage portion of your policy and adjust your premium. Call your Medigap Issuer for details.

When can I make changes to my Medicare prescription drug coverage?
Medicare limits when you can make changes to your coverage. From October 15 through December 7 each year, you can enroll in a new Medicare Prescription Drug Plan or Medicare Health Plan for the following year. You may not enroll in a new plan during other times of the year unless you meet certain special exceptions, such as if you move out of <PDP name>’s service area, want to join a plan in your area with a 5-star rating, or you qualify for extra help with your prescription drug costs.

If you qualify for extra help with your prescription drug costs you may enroll in, or disenroll from, a plan at any time. If you lose this extra help during the year, your opportunity to make a change continues for two months after you are notified that you no longer qualify for extra help.

If you have questions about how or when to disenroll from <PDP name>, please call our customer service department.

Where can I fill my prescriptions?
Please remember that you should use <PDP name> network pharmacies to fill your prescriptions beginning on <effective date>. If you use an out-of-network pharmacy, except in an emergency, <PDP name> may not pay for your prescriptions. You can find network pharmacies in your area by looking in your pharmacy directory or by calling customer service at the number below. [Optional language: You can also visit the <plan/organization name> website at <plan website address>.]
What if I have more questions?
If you have any questions, please contact customer service at <toll-free number> <days and hours of operation>. TTY/TDD users should call <toll-free TTY number>.

Thank you.
Exhibit 2a - Model Notice to Acknowledge Receipt of Completed Enrollment Request for another Plan in the Same Parent Organization

Referenced in section: 40.4.1

Dear <Member>:

Thank you for the request to change your enrollment from <former PDP name> to <new PDP name>. <New PDP name> is a Prescription Drug Plan that is approved by Medicare. Your enrollment will be effective on <effective date>.

How will this coverage work?
As of <effective date>, you should begin using <new PDP name> network pharmacies to fill your prescriptions. If you use an out-of-network pharmacy and there is not an emergency, <new PDP name> may not pay for your prescriptions. [Optional language: This letter is proof of insurance that you should show to your pharmacy until you get your Member ID card from us.]

How much is my premium?
Medicare must approve all enrollments and calculate your premium amount. When Medicare approves your enrollment, we will send you a letter to confirm your enrollment with <new PDP name>. You will get a separate letter from <PDP name> once Medicare calculates your premium. But, you should not wait to get these confirmation letters before you begin using <new PDP name> network pharmacies on <effective date>.

When can I make changes to my prescription drug coverage?
Generally, you may not enroll in a new plan during other times of the year unless you meet certain special exceptions, such as if you move out of <PDP name>’s service area, want to join a plan in your area with a 5-star rating, or you qualify for extra help in paying for your prescription drug costs (see below). From October 15 through December 7 each year, you can enroll in a new Medicare Prescription Drug Plan or Medicare Health Plan for the following year. If you qualify for extra help with your prescription drug costs you may enroll in, or disenroll from, a plan at any time. If you lose this extra help during the year, your opportunity to make a change continues for two months after you are notified that you no longer qualify for extra help.

If you have questions about how or when to disenroll from <new PDP name>, please call our customer service department at the phone number at the end of this letter.
What is extra help?
People with limited incomes may qualify for extra help to pay for their prescription drug costs. If you qualify, Medicare could pay for 75% or more of your drug costs including monthly prescription drug premiums, annual deductibles, and co-insurance. Additionally, those who qualify won’t have a coverage gap or a late enrollment penalty. Many people qualify for these savings and don’t even know it. For more information about this extra help, contact your local Social Security office, or call Social Security at 1-800-772-1213. TTY users should call 1-800-325-0778. You can also apply for extra help online at www.socialsecurity.gov/prescriptionhelp.

[PDP plans without a premium – do not use the following Q&A:
Will <plan name> bill me for my premiums or will my premiums be deducted from my Social Security/Railroad Retirement Board check?
Your enrollment form included the options for paying your plan premium. If you chose to have your monthly premium for this plan withheld from your Social Security or Railroad Retirement Board payment, we may have to send you a bill for your first month or two of enrollment if the deduction doesn’t start right away or doesn’t start at all. If you did not choose this option, we will bill you for your monthly premium. Generally you must stay with the premium payment option you choose for the rest of the year. If you have any questions about how to pay your plan premium, please contact us at <toll-free number> <days and hours of operation>. TTY/TDD users should call <toll-free TTY number>. [PDPs that disenroll for nonpayment of premium include the following sentence: “Members who fail to pay the monthly premium may be disenrolled from <PDP name>”].

Where can I fill my prescriptions?
Please remember that you should use <new PDP name> network pharmacies to fill your prescriptions beginning on <effective date>. If you use an out-of-network pharmacy, except in an emergency, <new PDP name> may not pay for your prescriptions. You can find network pharmacies in your area by looking in your pharmacy directory or by calling customer service at the number below. [Optional language: You can also visit the <plan/organization name> website at <plan website address>].

What if I have more questions?
If you have any questions, please contact customer service at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>.

Thank you.

<Contract#, alpha-numeric identifier, “CMS Approved/File & Use” [date] (as applicable)>
Exhibit 2b - PDP Model Notice to Acknowledge Receipt of Completed Enrollment and to Confirm Enrollment

Referenced in section: 40.4.1

Dear <Name of Member>:

Thank you for enrolling in <PDP name>. <PDP name> is a Prescription Drug Plan that is approved by Medicare. Medicare has approved your enrollment in <PDP name> beginning <effective date>.

How will my coverage work?
As of <effective date>, you should begin using <PDP name> network pharmacies to fill your prescriptions. If you use an out-of-network pharmacy except in an emergency, <PDP name> may not pay for your prescriptions. You can find network pharmacies in your area by looking in your pharmacy directory or by calling our customer service department. [Optional language: You can also visit the <plan/organization name> website at <plan website address>.] [Optional language: This letter is proof of insurance that you should show to your pharmacy until you get your Member ID card from us.]

How much is my premium?
[Insert the following if no low-income subsidy: The premium for your plan is: [insert premium]. If you think you qualify for extra help with your prescription drug costs, but you don’t have or can’t find proof, please call <PDP name> at the number provided at the end of this letter.

[Insert if low-income subsidy applicable: What are my costs since I qualify for extra help? Because you qualify for extra help with your prescription drug costs, you will pay no more than:

- <plan premium less premium assistance for which individual is eligible> per month for your <PDP name> premium,
- <insert appropriate LIS deductible amount > for your yearly prescription drug plan deductible,
- <insert appropriate LIS copay amount> when you fill a prescription.
If you believe this is incorrect and you have proof that that the extra help amounts should be different, please call <PDP name> at the number provided at the end of this letter.]
Will I pay a late enrollment penalty as part of my premium?

[Insert the following for new members with an existing LEP: Your premium continues to reflect a late enrollment penalty amount that was based on information sent by your previous plan. Your plan should have told you about this penalty. If you have questions about the late enrollment penalty, call <plan name> at the number provided at the end of this letter. You can also get information by visiting www.medicare.gov on the web or by calling 1-800-MEDICARE (1-800-633-4227), 24 hours a day/7 days a week. TTY users should call 1-877-486-2048.] If we determine that your penalty needs to be adjusted, we will notify you of your new monthly premium.]

[If previous paragraph not applicable, insert the following for all other new members:]

The late enrollment penalty is an amount added to your monthly Medicare drug plan (Part D) premium for as long as you have Medicare prescription drug coverage. This penalty is required by law and is designed to encourage people to enroll in a Medicare drug plan when they are first eligible or keep other prescription drug coverage that meets Medicare’s minimum standards. You may owe a late enrollment penalty if you didn’t join a Medicare drug plan when you were first eligible for Medicare Part A and/or Part B, and:

- You didn’t have other prescription drug coverage that met Medicare’s minimum standards; OR
- You had a break in coverage of at least 63 days.

If we determine that you owe a late enrollment penalty, we will notify you of your new monthly premium amount.]

[Part D plans without a premium – do not use the following paragraph:]

Will <plan name> bill me for my premiums or will my premiums be deducted from my Social Security check?

Your enrollment form included the options for paying your plan premium. If you chose to have your <PDP name> premium withheld from your Social Security or Railroad Retirement Board benefit check, we may have to send you a bill for your first month or two of enrollment if the deduction doesn’t start right away or doesn’t start at all. If you didn’t choose this option, we will bill you for your monthly plan premiums. Generally you must stay with the premium payment option you choose for the rest of the year. If you have any questions about how to pay your plan premium, please contact us at <toll-free number> <days and hours of operation>. TTY/TDD users should call <toll-free TTY number>. [PDPs that disenroll for nonpayment of premium include the following sentence: “Members who fail to pay the monthly premium may be disenrolled from <PDP name>”.

[Insert if low-income subsidy NOT applicable:]

What is extra help?

People with limited incomes may qualify for extra help to pay for their prescription drug costs. If you qualify, Medicare could pay for 75% or more of your drug costs including monthly prescription drug premiums, annual deductibles, and co-insurance. Additionally, those who qualify won’t have a coverage gap or a late enrollment penalty. Many people qualify for these
savings and don’t even know it. For more information about this extra help, contact your local Social Security office, or call Social Security at 1-800-772-1213. TTY users should call 1-800-325-0778. You can also apply for extra help online at www.socialsecurity.gov/prescriptionhelp.

What if I have Medigap (Medicare Supplemental Insurance) coverage?
If you have a Medigap (Medicare Supplement) policy that includes prescription drug coverage, you must contact your Medigap Issuer to let them know that you have joined a Medicare prescription drug plan. Your Medigap Issuer will remove the prescription drug coverage portion of your policy and adjust your premium. Call your Medigap Issuer for details.

What if I have more questions?
If you have any questions, please contact <PDP name> at <toll-free number> <days and hours of operation>. TTY/TDD users should call <toll-free TTY number>.

Thank you.
Exhibit 3 - Model Notice to Request Information

Referenced in section: 30, 40.2.2

<Date>

Dear <Name of Member>:

Thank you for applying with <PDP name>. We cannot process your enrollment until we get the following information from you:

_______  Proof that you have Medicare Part A and/or Part B. Please send us a copy of your Medicare card as proof of your Medicare coverage.

_______  Other: ___________________________________________________

You will need to provide this information to <PDP name> by <date>. You can contact us by phone with this information by calling <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>. Or, you may also fax it to us at <fax number> or send it to us at <address>. If you cannot send this information by <date>, we will have to deny your request to enroll in our Plan.

Generally, you may not enroll in a new plan during other times of the year unless you meet certain special exceptions, such as if you move out of <PDP name>’s service area, want to join a plan in your area with a 5-star rating, or if you qualify for extra help with your prescription coverage (see below). From October 15 through December 7 each year, you can enroll in a new Medicare Prescription Drug Plan or Medicare Health Plan for the following year.

People with limited incomes may qualify for extra help to pay for their prescription drug costs. If you qualify, Medicare could pay for 75% or more of your drug costs including monthly prescription drug premiums, annual deductibles, and co-insurance. Additionally, those who qualify won’t have a coverage gap or a late enrollment penalty. Many people qualify for these savings and don’t even know it. For more information about this extra help, contact your local Social Security office, or call Social Security at 1-800-772-1213. TTY users should call 1-800-325-0778. You can also apply for extra help online at www.socialsecurity.gov/prescriptionhelp.

If you qualify for extra help with your prescription drug costs you may enroll in, or disenroll from, a plan at any time. If you lose this extra help during the year, your opportunity to make a change continues for two months after you are notified that you no longer qualify for extra help.

If you have any questions, please contact <PDP name> at <toll-free number> <days and hours of operation>. TTY/TDD users should call <toll-free TTY number>.

Thank you.
Exhibit 4 - PDP Model Notice to Confirm Enrollment

Referenced in section: 40.4.2

Dear <Name of Member>:

Medicare has approved your enrollment in <PDP name> beginning <effective date>.

How will my coverage work?
As of <effective date>, you should begin using <PDP name> network pharmacies to fill your prescriptions. If you use an out-of-network pharmacy, except in an emergency, <PDP name> may not pay for your prescriptions. You can find network pharmacies in your area by looking in your pharmacy directory or by calling our customer service department at the number at the end of this letter. [Optional language: You can also visit the <plan/organization name> website at <plan website address>.]

[Optional language: This letter is proof of insurance that you should show to your pharmacy until you get your Member ID card from us.]

[Insert the following if no low-income subsidy:]

How much is my premium?
The monthly premium for your plan is <premium amount>.

What is extra help?
People with limited incomes may qualify for extra help to pay for their prescription drug costs. If you qualify, Medicare could pay for 75% or more of your drug costs including monthly prescription drug premiums, annual deductibles, and co-insurance. Additionally, those who qualify won’t have a coverage gap or a late enrollment penalty. Many people qualify for these savings and don’t even know it. For more information about this extra help, contact your local Social Security office, or call Social Security at 1-800-772-1213. TTY users should call 1-800-325-0778. You can also apply for extra help online at www.socialsecurity.gov/prescriptionhelp.

If you think you qualify for extra help with your prescription drug costs, but you don’t have or can’t find proof, please contact <PDP name> at the number provided at the end of this letter.]
What are my costs since I qualify for extra help?
Because you qualify for extra help with your prescription drug costs, you will pay no more than:
- <plan premium less premium assistance for which individual is eligible> per month for your <PDP name> premium,
- <insert appropriate LIS deductible amount> for your yearly prescription drug plan deductible,
- <insert appropriate LIS copay amount> when you fill a prescription covered by <PDP name>.

If you believe this is incorrect and you have proof that the extra help amounts should be different, please contact <PDP name> at the phone number provided at the end of this letter.

Will I pay a late enrollment penalty as part of my premium?
[Insert the following for new members with an existing LEP:] Your premium continues to reflect a late enrollment penalty amount that was based on information sent by your previous plan. Your plan should have told you about this penalty. If you have questions about the late enrollment penalty, call <plan name> at the phone number provided at the end of this letter. You can also get information by visiting www.medicare.gov or by calling 1-800-MEDICARE (1-800-633-4227), 24 hours a day/7 days a week. TTY users should call 1-877-486-2048. If we determine that your penalty needs to be adjusted, we will notify you of your new monthly premium.

[If previous paragraph not applicable, insert the following for all other new members:] The late enrollment penalty is an amount added to your monthly Medicare drug plan (Part D) premium for as long as you have Medicare prescription drug coverage. This penalty is required by law and is designed to encourage people to enroll in a Medicare drug plan when they are first eligible or keep other prescription drug coverage that meets Medicare’s minimum standards. You may owe a late enrollment penalty if you didn’t join a Medicare drug plan when you were first eligible for Medicare Part A and/or Part B, and:

- You didn’t have other prescription drug coverage that met Medicare’s minimum standards; OR
- You had a break in coverage of at least 63 days.

If we determine that you owe a late enrollment penalty, we will notify you of your new monthly premium amount.

[Part D plans without a premium – do not use the following paragraph:] Will <plan name> bill me for my premiums or will my premiums be deducted from my Social Security/Railroad Retirement Board check?
Your enrollment form included the options for paying your plan premium. If you chose to have your <PDP name> premium withheld from your Social Security or Railroad Retirement Board benefit check, we may have to send you a bill for your first month or two of enrollment if the deduction doesn’t start right away or doesn’t start at all. If you didn’t choose this option, we will bill you for your monthly premiums. Generally you must stay with the premium payment option you choose for the rest of the year. If you have any questions about how to pay your plan...
premium, please contact us at <toll-free number> <days and hours of operation>. TTY/TDD users should call <toll-free TTY number>. [PDPs that disenroll for nonpayment of premium include the following sentence: “Members who fail to pay the monthly premium may be disenrolled from <PDP name>”.]

What if I have a Medigap policy?
If you have a Medigap (Medicare Supplement) policy that includes prescription drug coverage, you must contact your Medigap Issuer to let them know that you have joined a Medicare prescription drug plan. Your Medigap Issuer will remove the prescription drug coverage portion of your policy and adjust your premium. Call your Medigap Issuer for details.

What if I have more questions?
If you have any questions, please contact <PDP name> at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>.

Thank you.
Exhibit 5 - PDP Model Notice to Individuals Identified on CMS Records As Members of Employer/Union Group Receiving Employer Subsidy

Referenced in section: 20.4

<Date>

Dear <Member>:

Thank you for applying with <PDP name>. To finalize your enrollment, we would like you to confirm that you want to be enrolled in <PDP name>.

Medicare has informed us that you belong to an employer or union group health plan that includes prescription drug coverage that is as good as Medicare prescription drug coverage.

It is important that you consider your decision to enroll in our Plan carefully. If you have health coverage from an employer or union, joining <PDP Name> may change how your current coverage works. You could lose your employer or union health coverage, and if you have a spouse or dependents, their coverage also could be lost. Read the communications your employer or union sends you. If you have questions, visit their website, or contact the office listed in their communications. If there is no information on whom to contact, your benefits administrator or the office that answers questions about your coverage can help.

If you have already discussed this decision with your employer or union contact and have decided that you would like to be a member of <PDP name>, please call <PDP name> at the phone number provided below. Your enrollment won’t be complete until you call and confirm this information.

We must hear from you to enroll you in our plan. If we don’t hear from you within 30 days from the date of this notice, we won’t process your enrollment.

To confirm your enrollment and your effective date of <effective date>, or if you have any questions, please call <PDP name> at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>.

Thank you.
Exhibit 6 - PDP Model Notice for Denial of Enrollment

Referenced in section: 40.2.3

<Date>

Dear <Name of Beneficiary>:

Thank you for applying with <PDP name>. We cannot accept your request for enrollment in <PDP name> because of the reason(s) checked below.

1. _____ You have neither Medicare Part A nor Part B.
2. _____ Your permanent residence is outside of our service area.
3. _____ You attempted to enroll outside of an enrollment period.
4. _____ We didn’t get the information we requested from you within the timeframe listed in our request.
5. _____ The request was made by someone other than the beneficiary and that individual isn’t the beneficiary’s authorized representative.
6. _____ You have drug coverage such as from an employer or union and you told us you don’t want to join <PDP name>.

If <PDP name> paid for any of your prescriptions, we will bill you for the amount we paid.

If item 3 is checked, remember that you can enroll in and disenroll from a Medicare prescription drug plan only at certain times during the year. If you meet certain special exceptions, such as if you move out of <PDP name>’s service area, want to join a plan in your area with a 5-star rating, you may enroll in a new plan. Otherwise, you can only enroll in a plan, disenroll from a plan, or switch plans from October 15th through December 7th of each year.

People with limited incomes may qualify for extra help to pay for their prescription drug costs. If you qualify, Medicare could pay for 75% or more of your drug costs including monthly prescription drug premiums, annual deductibles, and co-insurance. Additionally, those who qualify won’t have a coverage gap or a late enrollment penalty. Many people qualify for these savings and don’t even know it. For more information about this extra help, contact your local Social Security office, or call Social Security at 1-800-772-1213. TTY users should call 1-800-325-0778. You can also apply for extra help online at www.socialsecurity.gov/prescriptionhelp.

If you qualify for extra help with your prescription drug costs you may enroll in, or disenroll from, a plan at any time. If you lose this extra help during the year, your opportunity to make a change continues for two months after you are notified that you no longer qualify for extra help.
If any of the checked items are wrong, or if you have any questions, please contact <PDP name> at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>.

Thank you.
Exhibit 7 – PDP Model Notice for CMS Rejection of Enrollment

Referenced in section: 40.4.2

<Date>

Dear <Name of Beneficiary>:

[If sending in place of combined acknowledgement/confirmation notice, insert the following sentence: Thank you for your request to enroll in <plan name>.

Medicare has denied your enrollment in <PDP name> due to the reason(s) checked below.

1. _____ You have neither Medicare Part A nor Part B.

2. _____ You requested to enroll in a different Plan for the same effective date, which canceled your enrollment with <PDP name>.

3. _____ You attempted to enroll outside of an enrollment period.

If <PDP name> paid for any of your prescriptions, we will bill you for the amount we paid.

If item 3 is checked, remember that you can enroll in and disenroll from a Medicare prescription drug plan only at certain times during the year. If you meet certain special exceptions, such as if you move out of <PDP name>’s service area or want to join a plan in your area with a 5-star rating, you may enroll in a new plan. Otherwise, you can only enroll in a plan, disenroll from a plan, or switch plans from October 15th through December 7th of each year.

People with limited incomes may qualify for extra help to pay for their prescription drug costs. If you qualify, Medicare could pay for 75% or more of your drug costs including monthly prescription drug premiums, annual deductibles, and co-insurance. Additionally, those who qualify won’t have a coverage gap or a late enrollment penalty. Many people qualify for these savings and don’t even know it. For more information about this extra help, contact your local Social Security office, or call Social Security at 1-800-772-1213. TTY users should call 1-800-325-0778. You can also apply for extra help online at www.socialsecurity.gov/prescriptionhelp.

If any of the checked items are wrong, or if you have any questions, please contact <PDP name> at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>.

Thank you.

<Date>
Exhibit 8 - PDP Model Notice to Send Out Disenrollment Form

Referenced in section: 50.1

<Date>

Dear <Member>:

Attached is the <PDP name> disenrollment form you requested. Please read the important instructions in this letter regarding requesting disenrollment from <PDP name>.

When can I disenroll from <PDP name>? Medicare will only allow you to disenroll at certain times during the year. After we receive your disenrollment form, <PDP name> will let you know if you can disenroll at this time. If you can disenroll, we will also tell you the effective date of your disenrollment.

Until your disenrollment date, you should keep using <PDP name> network pharmacies to fill your prescriptions. If you use an out-of-network pharmacy except in an emergency, <PDP name> may not pay for your prescriptions. After your disenrollment date, <PDP name> won’t cover your prescription drugs.

When can I make changes to my Medicare coverage?
From October 15 through December 7 each year, you can enroll in a new Medicare Prescription Drug Plan or Medicare Health Plan for the following year. You may not enroll in a new plan during other times of the year unless you meet certain special exceptions, such as if you move out of <PDP name>’s service area, want to join a plan in your area with a 5-star rating, or you qualify for extra help in paying for your prescription drug costs (see below). If you qualify for extra help, you may enroll in, or disenroll from, a plan at any time. If you lose this extra help during the year, your opportunity to make a change continues for two months after you are notified that you no longer qualify for extra help.

What is extra help? People with limited incomes may qualify for extra help to pay for their prescription drug costs. If you qualify, Medicare could pay for 75% or more of your drug costs including monthly prescription drug premiums, annual deductibles, and co-insurance. Additionally, those who qualify won’t have a coverage gap or a late enrollment penalty. Many people qualify for these savings and don’t even know it. For more information about this extra help, contact your local Social Security office, or call Social Security at 1-800-772-1213. TTY users should call 1-800-325-0778. You can also apply for extra help online at www.socialsecurity.gov/prescriptionhelp.

When should I submit a disenrollment request? You should not fill out the attached form if you are planning to enroll, or have enrolled, in another Medicare Prescription Drug Plan or Medicare Advantage Prescription Drug Plan. Enrolling in a prescription drug plan or a Medicare Advantage-Prescription Drug Plan will automatically disenroll you from <PDP name>.

<Contract#, alpha-numeric identifier, “CMS Approved/File & Use” [date] (as applicable)>
You **should** fill out the attached form only if you no longer want Medicare prescription drug coverage and want to disenroll from this coverage completely.

If you would like to disenroll from `<PDP name>`, please fill out the form, sign it, and send it back to us in the enclosed envelope. You can also fax a signed and dated form to us at `<fax number>`.

Instead of sending a disenrollment request to `<plan name>` you can call 1-800-MEDICARE (1-800-633-4227), 24 hours a day, 7 days a week, to disenroll by telephone. TTY users should call 1-877-486-2048.

By disenrolling from `<PDP name>`, you are disenrolling from your Medicare prescription drug coverage. You may have to pay a late enrollment penalty in addition to your premium for Medicare Prescription Drug coverage if you join a Medicare Drug Plan in the future. For information about the Medicare plans available in your area, call 1-800-MEDICARE (1-800-633-4227), 24 hours per day, 7 days per week. TTY users should call 1-877-486-2048.

If you have any questions, please call `<PDP name>` at `<toll-free number> <days and hours of operation>`. TTY users should call `<toll-free TTY number>`.

Thank you.

Attachment
Exhibit 9 - PDP Model Disenrollment Form

Referenced in section: 50.1

Please fill out and carefully read all information below before signing and dating this disenrollment form. We will notify you of your effective date after we get this form from you.

Instead of sending a disenrollment request to <plan name> you can call 1-800-MEDICARE (1-800-633-4227), 24 hours a day, 7 days a week, to disenroll by telephone. TTY users should call 1-877-486-2048.

<table>
<thead>
<tr>
<th>Last Name:</th>
<th>First Name:</th>
<th>Middle Initial:</th>
<th>□ Mr. □ Mrs. □ Miss □ Ms.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Member ID:</td>
<td></td>
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<table>
<thead>
<tr>
<th>Birth Date:</th>
<th>Sex:</th>
<th>Home Phone Number:</th>
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By completing this disenrollment request, I agree to the following:

<PDP name> will notify me of my disenrollment date after they get this form. I understand that until my disenrollment is effective, I must continue to fill my prescriptions at <PDP name> network pharmacies to get coverage. I understand that there are limited times in which I will be able to join other Medicare plans, unless I qualify for certain special circumstances. I understand that I am disenrolling from my Medicare Prescription Drug Plan and, if I don’t have other coverage as good as Medicare, I may have to pay a late enrollment penalty for this coverage in the future.

Signature* _______________________________ Date: ______________

*Or the signature of the person authorized to act on behalf of the individual under the laws of the State where the individual resides. If signed by an authorized individual (as described above), this signature certifies that: 1) this person is authorized under State law to complete this disenrollment and 2) documentation of this authority is available upon request by Medicare.

If you are the authorized representative, you must provide the following information:

Name: __________________________
Address: ______________________________
Phone Number: (___) ____- _____
Relationship to Enrollee __________________________

<Contract#, alpha-numeric identifier, “CMS Approved/File & Use” [date] (as applicable)> 164
Exhibit 9a: Information to include on or with Disenrollment Form – Attestation of Eligibility for an Election Period

Referenced in section: 30.3

Typically, you may disenroll from a Medicare prescription drug plan only during the annual enrollment period from October 15 through December 7 of each year. There are exceptions that may allow you to disenroll from a Medicare prescription drug plan outside of this period.

Please read the following statements carefully and check the box if the statement applies to you. By checking any of the following boxes you are certifying that, to the best of your knowledge, you are eligible for an Election Period.

☐ I have both Medicare and Medicaid or my state helps pay for my Medicare premiums.

☐ I get extra help paying for Medicare prescription drug coverage.

☐ I no longer qualify for extra help paying for my Medicare prescription drugs. I stopped receiving extra help on (insert date) ________________.

☐ I am moving into, live in, or recently moved out of a Long-Term Care Facility (for example, a nursing home or long term care facility). I moved/will move into/out of the facility on (insert date) ________________.

☐ I am joining a PACE program on (insert date) ________________.

☐ I am joining employer or union coverage on (insert date) ________________.

If none of these statements applies to you or you’re not sure, please contact <plan name> at <phone number> (TTY users should call <TTY number>) to see if you are eligible to disenroll. We are open <insert days and hours of operation>.
Exhibit 10 - PDP Model Notice to Acknowledge Receipt of Voluntary Disenrollment Request from Member

Referenced in section: 50.1.5

<Date>

Dear <Member>:

We received your request to disenroll from <PDP name>. You will be disenrolled starting <effective date>. Therefore, beginning <effective date>, <PDP name> won’t cover your prescription drugs.

Until <effective date>, you should keep using <PDP name> network pharmacies to fill your prescriptions. If you use an out-of-network pharmacy, except in an emergency, <PDP name> may not pay for your prescriptions.

What should I do now?
If you have already enrolled in another Medicare Prescription Drug Plan (or a Medicare Advantage Plan with prescription drug coverage), you should receive confirmation of your enrollment from your new Plan. If you have not enrolled in another Medicare Plan, you should consider enrolling in one. If you do not enroll in a new plan at this time or you do not have or obtain creditable prescription drug coverage (as good as Medicare’s), you may have to pay a late enrollment penalty if you enroll in Medicare prescription drug coverage in the future.

What if my premium was being deducted from my Social Security benefit check?
If your Medicare Part D premium is being deducted from your Social Security/Railroad Retirement Board benefit, please allow up to 3 months for us to process a refund. If you have not received a refund from Social Security/the Railroad Retirement Board within 3 months of this letter, you should contact 1-800-MEDICARE.

When can I make changes to my Medicare coverage?
From October 15 through December 7 each year, you can enroll in a new Medicare Prescription Drug Plan or Medicare Health Plan for the following year. Generally, you may not enroll in a new Plan during other times of the year unless you meet certain special exceptions, such as if you move out of <PDP name>’s service area, want to join a plan in your area with a 5-star rating, or you qualify for extra help in paying for your prescription drug costs (see below). If you qualify for extra help, you may enroll in, or disenroll from, a plan at any time. If you lose this extra help during the year, your opportunity to make a change continues for two months after you are notified that you no longer qualify for extra help.

What is extra help?
People with limited incomes may qualify for extra help to pay for their prescription drug costs. If you qualify, Medicare could pay for 75% or more of your drug costs including monthly prescription drug premiums, annual deductibles, and co-insurance. Additionally, those who qualify won’t have a coverage gap or a late enrollment penalty. Many people qualify for these savings and don’t even know it. For more information about this extra help, contact your local...
Social Security office, or call Social Security at 1-800-772-1213. TTY users should call 1-800-325-0778. You can also apply for extra help online at www.socialsecurity.gov/prescriptionhelp.

**Where can I get more information?**

For information about the Medicare plans available in your area, call 1-800-MEDICARE (1-800-633-4227), 24 hours per day, 7 days per week. TTY users should call 1-877-486-2048.

If you have any questions, please call <PDP name> at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>.

Thank you.
Dear <Name of Member>:

This is to confirm your disenrollment from <PDP name>. Beginning <effective date>, <PDP name> won’t cover your prescription drugs.

What should I do now?
If you have already enrolled in another Medicare Prescription Drug Plan (or a Medicare Advantage Plan with prescription drug coverage), you should get confirmation of your enrollment from your new Plan. If you haven’t enrolled in another Medicare Plan, you should consider enrolling in one. If you don’t enroll in a new Plan at this time, or you don’t have or get creditable prescription drug coverage (as good as Medicare’s), you may have to pay a late enrollment penalty if you enroll in Medicare prescription drug coverage in the future.

What if my premium was being deducted from my Social Security/Railroad Retirement Board benefit check?
If your Medicare Part D premium is being deducted from your Social Security/Railroad Retirement Board benefit, please allow up to 3 months for us to process a refund. If you have not received a refund from Social Security/the Railroad Retirement Board within 3 months of this letter, you should contact 1-800-MEDICARE.

When can I make changes to my Medicare coverage?
From October 15 through December 7 each year, you can enroll in a new Medicare Prescription Drug Plan or Medicare Health Plan for the following year. Generally, you may not enroll in a new Plan during other times of the year unless you meet certain special exceptions, such as if you move out of <PDP name>’s service area, want to join a plan in your area with a 5-star rating, or you qualify for extra help in paying for your prescription drug costs (see below). If you qualify for extra help with your prescription drug costs you may enroll in, or disenroll from, a plan at any time. If you lose this extra help during the year, your opportunity to make a change continues for two months after you are notified that you no longer qualify for extra help.

What is extra help?
People with limited incomes may qualify for extra help to pay for their prescription drug costs. If you qualify, Medicare could pay for 75% or more of your drug costs including monthly prescription drug premiums, annual deductibles, and co-insurance. Additionally, those who qualify won’t have a coverage gap or a late enrollment penalty. Many people qualify for these savings and don’t even know it. For more information about this extra help, contact your local Social Security office, or call Social Security at 1-800-772-1213. TTY users should call 1-800-325-0778. You can also apply for extra help online at www.socialsecurity.gov/prescriptionhelp.
**Where can I get more information?**
For information about the Medicare plans available in your area, call 1-800-MEDICARE (1-800-633-4227), 24 hours per day, 7 days per week. TTY users should call 1-877-486-2048.

If you think you didn’t disenroll from <PDP name> and you want to stay a member of our plan, please call us right away at <toll-free number> <days and hours of operation> so we can make sure you stay a member of <PDP name>. Medicare gives you only 30 days from the date of this letter to contact us. TTY users should call <toll-free TTY number>.

Thank you.
Dear <Name of Member>:

This is to confirm your disenrollment from <PDP name>. Beginning <effective date>, <PDP name> won’t cover your prescription drugs. You got a blue letter from Medicare in October explaining that Medicare will switch you to another Medicare drug plan starting January 1, <following calendar year>. This is because it will cost you more if you stay in <PDP name>.

If you haven’t already, you should soon get a letter from your new plan confirming your enrollment that will take effect on January 1, <following calendar year>.

You can call this new plan with questions about their coverage, formulary, and pharmacy list.

If you have questions about why Medicare changed your plan or other Medicare plans available in your area, you can call 1-800-MEDICARE (1-800-633-4227), 24 hours per day, 7 days per week. TTY users should call 1-877-486-2048).

If you have questions about this disenrollment from <PDP name> or you want to remain a member of our plan, please call <PDP name> at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>.

Thank you.
Exhibit 11 - PDP Notice for Part D Plan Denial of Disenrollment

Referenced in section: 50.1.5

<Date>

Dear <Member>:

We recently got your request to disenroll from <PDP name>. We cannot accept your request for disenrollment for the reason checked below:

1. _____ You attempted to make a change to <PDP name> outside of an enrollment period. Medicare limits when and how often you can make changes to your coverage.

2. _____ The request was made by someone other than the enrollee and that individual isn’t the enrollee’s authorized representative.

3. _____ We didn’t get the information we requested from you within the timeframe listed in our request.

From October 15 through December 7 each year, you can enroll in a new Medicare Prescription Drug Plan or Medicare Health Plan for the following year. Generally, you may not enroll in a new plan during other times of the year unless you meet certain special exceptions, such as if you move out of <PDP name>’s service area, want to join a plan in your area with a 5-star rating, or you qualify for extra help in paying for your prescription drug costs (see below). If you qualify for extra help with your prescription drug costs you may enroll in, or disenroll from, a plan at any time. If you lose this extra help during the year, your opportunity to make a change continues for two months after you are notified that you no longer qualify for extra help.

People with limited incomes may qualify for extra help to pay for their prescription drug costs. If you qualify, Medicare could pay for 75% or more of your drug costs including monthly prescription drug premiums, annual deductibles, and co-insurance. Additionally, those who qualify won’t have a coverage gap or a late enrollment penalty. Many people qualify for these savings and don’t even know it. For more information about this extra help, contact your local Social Security office, or call Social Security at 1-800-772-1213. TTY users should call 1-800-325-0778. You can also apply for extra help online at www.socialsecurity.gov/prescriptionhelp.

If you have any questions, please call <PDP name> at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>.

Thank you.
Exhibit 11a: Model Notice to Request Information (Disenrollment)

Referenced in section(s): 30, 50.4.2

Dear <Name of Member>:

We received your request to disenroll from <PDP name>. However, it is missing information that will help us to determine if we can accept your request. We cannot process your disenrollment without this information.

Please review the checked item(s) below and contact us immediately.

_____ Medicare requires that you sign your written disenrollment request. The request we received from you didn’t include a signature. Please call us at the number below to confirm that you want to disenroll from <plan name>.

_____ During certain times of the year, Medicare doesn’t let you disenroll unless you meet certain special exceptions, such as if you qualify for extra help with your prescription drug costs. Please call us at the number below to help us determine if you’re able to disenroll at this time.

_____ The request we received was from someone other than you and that individual isn’t listed as your authorized representative. Please call us at the number below so that we may confirm your request to disenroll.

_____ Other: ______________________________________________

If you have any questions about the information in this letter or would like to provide us with information to help us process your disenrollment request, you may contact us by telephone or mail:

<PDP name>
<mailing address>
<toll free number and days/hours of operation>
<TTY toll-free number>

You may also fax us information at <fax number>.

If we don’t get this information, we will have to deny your request to disenroll from our plan.

Instead of sending a disenrollment request to <plan name> you can call 1-800-MEDICARE (1-800-633-4227), 24 hours a day, 7 days a week, to disenroll by telephone. TTY users should call 1-877-486-2048. If you’re receiving coverage through your employer, you should contact your employer instead of calling 1-800-MEDICARE.

Thank you.
Exhibit 12 - PDP Model Notice for CMS Rejection of Disenrollment

Referenced in section: 50.1.5

<Date>

Dear <Member>:

Medicare has denied your disenrollment from <PDP name> because you have attempted to make a change to your plan outside of an enrollment period. Medicare limits when and how often you can make changes to your coverage.

From October 15 through December 7 each year, you can enroll in a new Medicare Prescription Drug Plan or Medicare Health Plan for the following year. Generally, you may not enroll in a new Plan during other times of the year unless you meet certain special exceptions, such as if you move out of <PDP name>’s service area, want to join a plan in your area with a 5-star rating, or you qualify for extra help with your prescription drug costs (see below). If you qualify for extra help with your prescription drug costs you may enroll in, or disenroll from, a plan at any time. If you lose this extra help during the year, your opportunity to make a change continues for two months after you are notified that you no longer qualify for extra help.

People with limited incomes may qualify for extra help to pay for their prescription drug costs. If you qualify, Medicare could pay for 75% or more of your drug costs including monthly prescription drug premiums, annual deductibles, and co-insurance. Additionally, those who qualify won’t have a coverage gap or a late enrollment penalty. Many people qualify for these savings and don’t even know it. For more information about this extra help, contact your local Social Security office, or call Social Security at 1-800-772-1213. TTY users should call 1-800-325-0778. You can also apply for extra help online at www.socialsecurity.gov/prescriptionhelp.

If you believe this information is wrong, or if you have any questions, please call <PDP name> at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>.

Thank you.
Exhibit 13 - PDP Model Notice of Disenrollment Due to Death

Referenced in section: 50.2.3

<Date>

To the Estate of <Member>:

Medicare told us about the death of <Name of Member>. Please accept our condolences.

<Member>’s coverage in <PDP name> ended as of <disenrollment effective date>. If plan premiums were paid for any month after <disenrollment effective date>, we will issue a refund to the Estate within 30 days of this letter.

If the Medicare Part D premium was being deducted from <Name of Member>’s Social Security benefit, please allow up to 3 months for us to process a refund. If the estate has not received a refund from Social Security within 3 months of this letter, a representative of the estate should contact 1-800-MEDICARE.

If this information is wrong, please contact your local Social Security office to have their records corrected. You can call Social Security at 1-800-772-1213 from 7:00 am to 7:00 pm, Monday to Friday. TTY users should call TTY 1-800-325-0778. If you have any questions, please call <PDP name> at <phone number>. TTY users should call <TTY/TDD number>. We are open <days and hours of operation>.

Thank you.
Exhibit 13a - PDP Model Notice for auto-enrollments provided by CMS with recent deceased code

Referenced in section: 40.1.4.F.

<Date>

To the Estate of <Member>:

Medicare told us about the death of <Name of Member>. Please accept our condolences.

We are sending this letter because Medicare had enrolled <Name of Member> in <PDP name>, a plan that provides Medicare prescription drug coverage. Because of this report of death, <Name of Member>’s coverage in <PDP name> ends as of <disenrollment effective date>. If plan premiums were paid for any month after <disenrollment effective date>, we will issue a refund to the Estate within 30 days of this letter.

If this information is wrong, please contact your local Social Security office to have their records corrected. You can call Social Security at 1-800-772-1213 from 7:00 am to 7:00 pm, Monday to Friday. TTY users should call 1-800-325-0778. If you have any questions, please call <PDP name> at <phone number>. TTY users should call <TTY number>. We are open <days and hours of operation>.

Thank you.
Exhibit 14 - PDP Model Notice of Disenrollment Due to Loss of Part D Eligibility

Referenced in section:  50.2.2

<Date>

Dear <Member>:

Medicare has told us that you no longer have Medicare <Insert A and/or B as appropriate>. Therefore, your membership in <PDP name> ended on <disenrollment effective date>. If your plan premium was paid for any month after <disenrollment effective date>, we will send you a refund within 30 days of this letter.

If you haven’t already done so, please contact your local Social Security office to have their records corrected. Or, you can call Social Security at 1-800-772-1213 from 7:00 AM to 7:00 PM, Monday to Friday. TTY users should call 1-800-325-0778.

If this information is wrong, and you want to stay a member of our plan, please contact us. If you have any questions, please call <PDP name> at <phone number>. TTY users should call <TTY number>. We are open <days and hours of operation>.

Thank you.
Exhibit 15 - PDP Model Notice to Offer Beneficiary Services, Pending Correction of Erroneous Death Status

Referenced in section: 60.2, 60.2.1

<Date>

Dear <Member>:

Medicare’s records incorrectly show you as deceased.

If you haven’t already done so, please go to your local Social Security office and ask them to correct your records. After you do this, please send us written proof at <address>. When we get this proof, we will share it with Medicare.

In the meantime, you should keep using <PDP name> network pharmacies to fill your prescriptions. If you use an out-of-network pharmacy, except in an emergency, <PDP name> may not pay for your prescriptions. You can find network pharmacies in your area by looking in your pharmacy directory or by calling our customer service number below. [Optional language: You can also visit the <plan/organization name> website at <plan website address>.]

If you have any questions, please call <PDP name> at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>.

Thank you for your continued membership in <PDP name>.

<Date>
Exhibit 16 - PDP Model Notice to Offer Beneficiary Services, Pending Correction of Erroneous Medicare Termination

Referenced in section: 60.2, 60.2.1

<Date>

Dear <Member>:

On <date of request>, you told us that your enrollment in Medicare <insert Part A and/or Part B as appropriate> was ended in error and that you want to stay a member of <PDP name>.

[Sponsors that are able to verify current Medicare entitlement may omit the following:
To do this, please complete the following three steps no later than <insert date: 60 days from date of disenrollment notice>:

1. Contact your local Social Security office and ask them to correct their records. Or, you can call Social Security at 1-800-772-1213 from 7:00 AM to 7:00 PM, Monday to Friday. TTY users should call 1-800-325-0778.

2. Ask Social Security to give you a letter that says they have corrected your records.

3. Send the letter from Social Security to us at: <address of PDP name> in the enclosed postage-paid envelope. You may also fax this information to us at <fax number>. When we get this letter, we will tell Medicare to correct its records.]

[Sponsors that are able to verify current Medicare entitlement insert: Social Security corrected the error. We will tell Medicare to correct its records.]

In the meantime, you should keep using <PDP name> network pharmacies to fill your prescriptions to get <PDP name> prescription coverage. You can find network pharmacies in your area by looking in your pharmacy directory or by calling our customer service number below. [Optional language: You can also visit the <plan/organization name> website at <plan website address>.]

[Sponsors that are able to verify current Medicare entitlement may omit the following:
If we learn that you don’t have Medicare <insert Part A and/or Part B as appropriate>, or if we don’t get proof that you have Medicare by <insert date: 60 days from date of disenrollment notice>, you will have to pay for any prescription drugs you filled after <disenrollment date>.]

If you have any questions or need help, please call <PDP name> at <phone number>. TTY users should call <TTY number>. We are open <days and hours of operation>.

Thank you for your continued membership in <PDP name>.
Exhibit 17 - Model Notice to Offer Reinstatement of Beneficiary Services, Pending Correction of Disenrollment Status Due to Plan Error

Referenced in section: 60.2, 60.2.2

<Date>

Dear <Member>:

Thank you for letting us know you want to remain a member of <PDP name> after we mistakenly [select one based on circumstance: disenrolled you from/cancelled your enrollment in] our plan. [Insert brief summary of the plan error that caused the disenrollment.] We apologize for the inconvenience. We have changed our records to show that you are still a member of <PDP name>. You should keep using your <PDP name> pharmacies to fill your prescriptions.

If you have any questions, please call <PDP name> at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>.

Thank you for your continued membership in <plan name>.

Thank you.
Exhibit 18 - PDP Model Notice to Close Out Request for Reinstatement

Referenced in section: 60.2

<Date>

Dear <Beneficiary>:

We cannot process your request to be reinstated in <PDP name> because we haven’t gotten the information we requested. As discussed in our letter dated <date of letter>, you were required to send us this information by <date placed on notice in Exhibit 16> to remain a member of our plan.

You were no longer a member of our plan as of <effective date>. If <PDP name> paid any costs for prescriptions you filled after <effective date>, we will bill you for the amount we paid.

Please remember that if you don’t have Medicare prescription drug coverage or creditable prescription drug coverage (as good as Medicare’s), you may have to pay a late enrollment penalty if you enroll in Medicare prescription drug coverage in the future.

If you have any questions, please call <PDP name> at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>.

Thank you.
Exhibit 19 - PDP Model Notice on Failure to Pay Plan Premiums - Advance Notification of Disenrollment

Referenced in section: 50.3.1

<Date>

Dear <Member>:

Our records show that we haven’t gotten payment for your <PDP name> plan premium as of <date>. If we don’t get payment by <insert last day of grace period>, we will have to disenroll you from <PDP name>. To avoid disenrollment, you must pay <amount due to avoid disenrollment> by <insert last day of grace period>. If we do not receive your payment by <insert last day of grace period>, we will ask Medicare to disenroll you from <PDP name> beginning <effective date>.

This letter applies only to your <PDP name> benefits. Your other Medicare benefits won’t be affected if you are disenrolled from <PDP name>.

If you don’t want to be a member of <PDP name> and don’t want any other Medicare drug plan, you may be able to disenroll from <PDP name>. However, Medicare limits when you can make changes to your coverage. You can only enroll in a new plan or disenroll from <PDP name> from October 15 through December 7 each year unless you meet certain special exceptions, such as if you move out of <PDP name>’s service area, want to join a plan in your area with a 5-star rating, or you qualify for extra help with your prescription drug costs. Also, if you don’t have or get other coverage that is at least as good as Medicare drug coverage (also referred to as “creditable coverage”), you may have to pay a late enrollment penalty for Medicare prescription drug coverage in the future.

People with limited incomes may qualify for extra help to pay for their prescription drug costs. If you qualify, Medicare could pay for 75% or more of your drug costs including monthly prescription drug premiums, annual deductibles, and co-insurance. Additionally, those who qualify won’t have a coverage gap or a late enrollment penalty. Many people qualify for these savings and don’t even know it. For more information about this extra help, contact your local Social Security office, or call Social Security at 1-800-772-1213. TTY users should call 1-800-325-0778. You can also apply for extra help online at www.socialsecurity.gov/prescriptionhelp.

If you qualify for extra help with your prescription drug costs you may enroll in, or disenroll from, a plan at any time. If you lose this extra help during the year, your opportunity to make a change continues for two months after you are notified that you no longer qualify for extra help.

If you want to disenroll from <PDP name> now, you should do one of the following:

1. Send us a written request at <address>.

2. Call 1-800-MEDICARE (1-800-633-4227), 24 hours per day, 7 days per week. TTY users should call 1-877-486-2048. TTY users should call 1-877-486-2048.

If you paid the premium recently and you think we have made a mistake, or if you have any questions, please call <PDP name> at <toll-free number>, <days and hours of operation>. TTY users should call <toll-free TTY number>. Thank you.

<Date>

<Contract#, alpha-numeric identifier, “CMS Approved/File & Use” [date] (as applicable)>
Exhibit 20 - PDP Notice of Failure to Pay Plan Premiums - Notification of Involuntary Disenrollment (REVISED)

Referenced in section: 50.3.1

<Date>

Dear <Member>:

On <date of notification letter>, we mailed you a letter stating that your plan premium was overdue. The letter said that if you didn’t pay your premium, we would disenroll you from <PDP name>. Since we didn’t get that payment, we have asked Medicare to disenroll you. Your disenrollment from <PDP name> will be effective <effective date>. After <effective date>, <PDP name> won’t cover your prescription drugs.

This letter only applies to your <PDP name> benefits. Your other Medicare benefits aren’t affected by your disenrollment from <PDP name>. [Cost plans where individual is losing optional supplemental Part D benefit only, replace prior sentence with: This letter only applies to your prescription drug coverage. You will still have health coverage through <cost plan name>.]

What if I think there’s been a mistake?
If you think that we have made a mistake, please call us at <phone number>. You also have the right to ask us to reconsider your disenrollment through the grievance procedure written in your <insert “Member Handbook” or “Evidence of Coverage,” as appropriate>.

I had an emergency that kept me from sending my payment. What can I do?
You can ask Medicare to review this decision if you can show “good cause” (a good reason) for not paying your premiums. A good reason would have to be an emergency or unexpected situation. If Medicare approves your request, you will have to pay all owed premium amounts within 3 months of your disenrollment in order to get your coverage back. Call Medicare at 1-800-MEDICARE (1-800-633-4227) anytime, 24 hours a day, 7 days a week, to make a request as soon as possible, but no later than <insert the date that is 60 calendar days after the disenrollment effective date>. TTY users should call 1-877-486-2048.

When can I get Part D coverage?
Medicare limits when you can make changes to your coverage. From October 15 through December 7 each year, you can enroll in a new Medicare Prescription Drug Plan or Medicare health plan for the following year. You may not enroll in a new plan during other times of the year unless you meet certain special exceptions, such as you move out of <PDP name>’s service area, want to join a plan in your area with a 5-star rating, or you qualify for extra help with your prescription drug costs.

Please remember, if you don’t have or get other coverage that is at least as good as Medicare drug coverage (also referred to as “creditable coverage”), you may have to pay a late enrollment penalty if you enroll in Medicare prescription drug coverage in the future.
Can I get help paying my premiums and other out-of-pocket costs?
People with limited incomes may qualify for extra help to pay for their prescription drug costs. If you qualify, Medicare could pay for 75% or more of your drug costs including monthly prescription drug premiums, annual deductibles, and co-insurance. Additionally, those who qualify won’t have a coverage gap or a late enrollment penalty. Many people qualify for these savings and don’t even know it. For more information about this extra help, contact your local Social Security office, or call Social Security at 1-800-772-1213. TTY users should call 1-800-325-0778. You can also apply for extra help online at www.socialsecurity.gov/prescriptionhelp.

For more information:
If you have any questions or if you have recently sent us a payment, please call <PDP name> at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>.

Thank you.
Exhibit 21 - PDP Notice of Failure to Pay Plan Premium - Confirmation of Involuntary Disenrollment (REVISED)

Referenced in section: 50.3.1

<Date>

Dear <Member>:

Medicare has confirmed your disenrollment from <PDP name> because you didn’t pay your plan premium. Your disenrollment begins <effective date>. As of <effective date>, <PDP name> won’t cover your prescription drugs.

What if I think there’s been a mistake?
If you think that we have made a mistake, please call us at <phone number>. You also have the right to ask us to reconsider your disenrollment through the grievance procedure written in your <insert “Member Handbook” or “Evidence of Coverage,” as appropriate>.

I had an emergency that kept me from sending my payment. What can I do?
You can ask Medicare to review this decision if you can show “good cause” (a good reason) for not paying your premiums. A good reason would have to be an emergency or unexpected situation. If Medicare approves your request, you will have to pay all owed premium amounts within 3 months of your disenrollment in order to get your coverage back. Call Medicare at 1-800-MEDICARE (1-800-633-4227) anytime, 24 hours a day, 7 days a week, to make a request as soon as possible, but no later than <insert the date that is 60 calendar days after the disenrollment effective date>. TTY users should call 1-877-486-2048.

When can I get Part D coverage?
Medicare limits when you can make changes to your coverage. From October 15 through December 7 each year, you can enroll in a new Medicare Prescription Drug Plan or Medicare health plan for the following year. You may not enroll in a new plan during other times of the year unless you meet certain special exceptions, such as you move out of <PDP name>’s service area, want to join a plan in your area with a 5-star rating, or you qualify for extra help with your prescription drug costs.

Please remember, if you don’t have or get coverage that is at least as good as Medicare drug coverage (also referred to as “creditable coverage”), you may have to pay a late enrollment penalty if you enroll in Medicare prescription drug coverage in the future.

Can I get help paying my premiums and other out-of-pocket costs?
People with limited incomes may qualify for extra help to pay for their prescription drug costs. If you qualify, Medicare could pay for 75% or more of your drug costs including monthly prescription drug premiums, annual deductibles, and co-insurance. Additionally, those who qualify won’t have a coverage gap or a late enrollment penalty. Many people qualify for these savings and don’t even know it. For more information about this extra help, contact your local Social Security office, or call Social Security at 1-800-772-1213. TTY users should call 1-800-325-0778. You can also apply for extra help online at www.socialsecurity.gov/prescriptionhelp.
If you qualify for extra help with your prescription drug costs you may enroll in, or disenroll from, a plan at any time. If you lose this extra help during the year, your opportunity to make a change continues for two months after you are notified that you no longer qualify for extra help.

**For more information:**
If you have any questions, please call <PDP name> at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>.

Thank you.
Exhibit 21a: Notification of Involuntary Disenrollment by the Centers for Medicare & Medicaid Services for Failure to Pay the Part D-Income Related Monthly Adjustment Amount (REVISED)

Referenced in section: 50.2.6

Important – You have been disenrolled from your Medicare Prescription Drug Plan

<Date>

Dear <Member>:

Medicare has disenrolled you from <Part D plan sponsor name> because you didn’t pay the extra amount (called the Part D-Income Related Monthly Adjustment Amount or Part D IRMAA). As of <effective date>, you will no longer have prescription drug coverage. Since the disenrollment has already happened, you can’t pay the owed amounts now to keep your Part D coverage.

Before you were disenrolled, Medicare (or the Railroad Retirement Board) sent you notices that showed the amount that you owed and provided information on how to pay this amount. If your plan premium was paid for any month after <disenrollment effective date>, you’ll get a refund from us within 30 days of this letter.

This decision was made by Medicare, not by <Part D plan sponsor name>.

What if I think there’s been a mistake?
If you paid the Part D-IRMAA or think that there has been a mistake, please call Medicare at 1-800-MEDICARE (1-800-633-4227).

I had an emergency that kept me from sending my Part D-IRMAA payment. What can I do?
You can ask Medicare to review this decision if you can show “good cause” (a good reason) for not paying your premiums. A good reason would have to be an emergency or unexpected situation. If Medicare approves your request, you will have to pay all owed plan premium amounts and all owed Part D-IRMAA amounts within 3 months of your disenrollment in order to get your coverage back. Call Medicare at 1-800-MEDICARE (1-800-633-4227) anytime, 24 hours a day, 7 days a week, to make a request as soon as possible, but no later than <insert the date that is 60 calendar days after the disenrollment effective date>. TTY users should call 1-877-486-2048.

Please remember, if you don’t request reinstatement within 60 days, you will not get your coverage back and will have to wait for another opportunity to enroll in a Part D plan. If you don’t get your coverage back and go without other coverage that is at least as good as Medicare drug coverage (also referred to as “creditable coverage”), you may have to pay a late enrollment penalty in addition to the monthly Part D-IRMAA and plan premium if you enroll in Medicare prescription drug coverage in the future.

When can I get Part D coverage?

<Contract#, alpha-numeric identifier, “CMS Approved/File & Use” [date] (as applicable)>
Medicare limits when you can make changes to your coverage. **From October 15 through December 7 of each year**, you can enroll in a new Medicare Prescription Drug Plan or Medicare health plan for the following year. You may not enroll in a new plan during other times of the year unless you meet certain special exceptions, such as you move out of the plan’s service area, want to join a plan in your area with a 5-star rating, or you qualify for extra help with your prescription drug costs.

**Who can I call to get more information?**
You can call 1-800-MEDICARE (1-800-633-4227), 24 hours a day/7 days a week, if you have questions about your disenrollment because you didn’t pay the Part D-IRMAA. TTY users should call 1-877-486-2048. You can also call <Part D plan sponsor name> at <phone number> if you have questions about your plan’s premium. TTY users should call <TTY number>. We are open <days and hours of operation>.

Thank you.
Exhibit 21b: Model Notice on Favorable “Good Cause” Determination – Notification of Premium Amount Due for Reinstatement

Referenced in section: 60.2.4

Dear <Name of Member>:

Medicare has notified us that you have received a favorable decision regarding your request for reinstatement into <plan name>. Our records show that we haven’t gotten payment for your plan premium as of <premium due date>. In order for your coverage to be reinstated, we must receive payment in the amount of <enter amount owed> no later than <date 3 months from the effective date of disenrollment>.

[Sponsors that will disenroll all members use the following sentences: If we don’t get payment by <date 3 months from the effective date of disenrollment>, you will remain disenrolled from <plan name>.]

[Sponsors may elect to mail a payment coupon with the letter. PDP sponsors who include the coupon with the letter, insert the following sentences: You can mail your payment to us using the enclosed coupon. Be sure to make full payment of your owed amount and include your member number on the check.]

[Sponsors that do not include a payment coupon with the letter, insert the following sentences: You can mail your payment to us at the following address: <billing address>. Be sure to make full payment of your owed amount and include your name and member number on the check.]

[If disenrollment was due to failure to pay Part D-IRMAA premiums and the beneficiary also owed the PDP sponsor premiums, sponsors insert the following sentences: In addition to the plan premiums you owe, you must also pay <Medicare or RRB> your amount due for the Part D-Income Related Monthly Adjustment Amount. <Medicare or RRB> will send you a letter regarding the amount you owe and how you can pay. You must pay <Medicare or RRB> this amount by <date 3 months from the effective date of disenrollment> to be reinstated.]

Remember, there are limits to when and how often you can change the way you get Medicare:

- **From October 15 through December 7**, anyone with Medicare can switch from one way of getting Medicare to another for the following year, including adding or dropping Medicare prescription drug coverage.

- **From January 1 through February 14**, anyone enrolled in a Medicare Advantage Plan (except an MSA plan) has an opportunity to disenroll from that plan and return to Original Medicare. Anyone who disenrolls from a Medicare Advantage plan during this time can join a stand-alone Medicare Prescription Drug Plan during the same period.
Generally, you will only be able to make changes during these two times, unless you meet certain special exceptions, such as if you move out of the plan’s service area, want to join a plan in your area with a 5-star rating, or qualify for extra help paying for prescription drug coverage. If you qualify for extra help, you may enroll in, or disenroll from, a plan at any time. If you lose this extra help during the year, your opportunity to make a change continues for two months after you are notified that you no longer qualify for extra help.

Thank you.
Exhibit 22 - Model Acknowledgement of Request to Cancel Enrollment Request

Referenced in section: 60.1.1

<Date>

Dear <Member>:

As you requested, we have cancelled your request to enroll with <PDP name>.

IMPORTANT: If you were enrolled in another Medicare Prescription Drug Plan or a Medicare Health Plan (such as a Medicare HMO or PPO) before enrolling with <PDP name>, you should be automatically enrolled back into that plan.

If you don’t receive an enrollment acknowledgement letter from your previous plan within two (2) weeks of receiving this letter, please contact them to confirm your enrollment. They may request a copy of this letter for their records.

Medicare limits when you can make changes to your coverage. From October 15 through December 7 each year, you can enroll in a new Medicare Prescription Drug Plan or Medicare health plan for the following year. Generally, you may not enroll in a new plan during other times of the year unless you meet certain special exceptions, such as if you move out of <PDP name>’s service area, want to join a plan in your area with a 5-star rating or you qualify for extra help with your prescription drug costs.

People with limited incomes may qualify for extra help to pay for their prescription drug costs. If you qualify, Medicare could pay for 75% or more of your drug costs including monthly prescription drug premiums, annual deductibles, and co-insurance. Additionally, those who qualify won’t have a coverage gap or a late enrollment penalty. Many people qualify for these savings and don’t even know it. For more information about this extra help, contact your local Social Security office, or call Social Security at 1-800-772-1213. TTY users should call 1-800-325-0778. You can also apply for extra help online at www.socialsecurity.gov/prescriptionhelp.

If you qualify for extra help with your prescription drug costs you may enroll in, or disenroll from, a plan at any time. If you lose this extra help during the year, your opportunity to make a change continues for two months after you are notified that you no longer qualify for extra help.

Please remember that if you don’t have or get prescription drug coverage that is at least as good as Medicare’s (also referred to as “creditable coverage”), you may have to pay a late enrollment penalty if you enroll in Medicare prescription drug coverage in the future.

If you have any questions, please call <PDP name> at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>.

Thank you.
Exhibit 22a - Model Confirmation of Reinstatement (REVISED)

Dear <member name>:

Please be sure to keep this letter for your records.

Medicare has enrolled you back in <plan name> with no break in coverage as of <effective date>.

You should keep using your <plan name> pharmacy for your health care.

[Insert one of the following depending on plan policy: We will be sending you a new membership card and other important documents for <plan name>. or You can continue using the <plan name> membership card that you currently have. or If you no longer have your membership card, contact us at the number below to get a new card.]

[Insert information regarding plan premiums required to maintain enrollment, or use the following language: The monthly premium for <plan name> is <monthly premium amount>. You must pay this premium amount each month to remain enrolled in our plan. For more information regarding our disenrollment policy for non-payment of plan premiums, please see our policy written in your <insert “Member Handbook” or “Evidence of Coverage,” as appropriate>.] Please call <plan name> at <phone number> if you have any questions. TTY users should call <TTY number>. We are open <days and hours of operation>.

Thank you for your continued membership in <plan name>. 

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Exhibit 23 - Model Acknowledgement of Request to Cancel Disenrollment Letter

Referenced in section: 60.1.2

<Date>

Dear <Member>:

As you requested, we have cancelled your disenrollment with <PDP name>. Thank you for your continued membership in our plan.

You should continue to fill your prescriptions at <PDP name> network pharmacies. If you use an out-of-network pharmacy, except in an emergency, <PDP name> may not pay for your prescriptions. You can find network pharmacies in your area by looking in your pharmacy directory or by calling our customer service number below. [Optional language: You can also visit the <plan/organization name> website at <plan website address>.]

IMPORTANT: If you submitted an enrollment request to another Prescription Drug Plan or a Medicare Advantage Plan, you may appear on their records as being enrolled in their plan. Since you have told us you want to stay enrolled in <PDP name>, you will need to contact the other plan to ask them to cancel your enrollment before your enrollment takes effect. They may ask you to write them a letter for their records.

Medicare limits when you can make changes to your coverage. From October 15 through December 7 each year, you can enroll in a new Medicare Prescription Drug Plan or Medicare health plan for the following year. Generally, you may not enroll in a new Plan during other times of the year unless you meet certain special exceptions, such as if you move out of <PDP name>’s service area, want to join a plan in your area with a 5-star rating, or you qualify for extra help with your prescription drug costs.

People with limited incomes may qualify for extra help to pay for their prescription drug costs. If you qualify, Medicare could pay for 75% or more of your drug costs including monthly prescription drug premiums, annual deductibles, and co-insurance. Additionally, those who qualify won’t have a coverage gap or a late enrollment penalty. Many people qualify for these savings and don’t even know it. For more information about this extra help, contact your local Social Security office, or call Social Security at 1-800-772-1213. TTY users should call 1-800-325-0778. You can also apply for extra help online at www.socialsecurity.gov/prescriptionhelp.

If you qualify for extra help with your prescription drug costs you may enroll in, or disenroll from, a plan at any time. If you lose this extra help during the year, your opportunity to make a change continues for two months after you are notified that you no longer qualify for extra help.

If you have any questions, please call <PDP name> at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>.

Thank you.

<Date, alphabet-numeric identifier, “CMS Approved/File & Use” [date] (as applicable)>
Dear <insert member name>.

You are getting this letter because Medicare is enrolling you in our <PDP name>, and your coverage begins <effective date>. Medicare is also mailing you a yellow letter about your enrollment. Please keep both letters for your records.

[Optional: You can use this letter as proof of your prescription drug coverage when you go to the pharmacy until you get your Member ID card from us.]

What are my costs in this plan?
Because you qualify for extra help with your prescription drug costs, you will pay no more than the following:
  - $0 per month for your <PDP name> premium,
  - $0 for your yearly prescription drug plan deductible,
  - <insert applicable copay levels> when you fill a prescription covered by our plan.

If you believe this is incorrect and you have proof that the extra help amounts should be different, please contact <PDP name> at the number below.

What if Medicaid used to pay for my prescription drugs?
Remember, if Medicaid used to pay for your prescription drugs, Medicaid won’t continue to cover the drugs it used to. Some state Medicaid programs may cover the few prescriptions that won’t be covered under Medicare prescription drug coverage. But even if your state Medicaid program covers a few prescriptions, this coverage alone won’t be as good as Medicare’s (also referred to as “creditable coverage”). To continue to have prescription drug coverage, you must be enrolled in a Medicare prescription drug plan, like <PDP name>.

What if I paid for drugs before my new coverage starts?
If you filled any covered prescriptions before <effective date>, you might be able to get back part of what the prescriptions cost if you were eligible for Medicare and Medicaid but not enrolled in a Medicare drug plan. Call Medicare’s Limited Income NET program at 1-800-783-1307. TTY users should call 711. You can also visit www.humana.com/pharmacists.

What if I have other prescription drug coverage?
If you now have or are eligible for other types of prescription drug coverage, you may not need to join a Medicare drug plan. You or your dependents could lose your other health or drug coverage completely and not get it back if you join a Medicare drug plan. Read all the materials you get from your insurer or plan provider to learn how joining a Medicare drug plan

<Contract#, alpha-numeric identifier, “CMS Approved/File & Use” [date] (as applicable)>
may affect you or your family’s current coverage. Examples of other types of prescription drug coverage include coverage from an employer or union, TRICARE, the Department of Veterans Affairs, or a Medigap (Medicare Supplement Insurance) policy. Please call your insurer or benefits administrator if you have any questions.

**What if I want to join another plan or I don’t want Medicare prescription drug coverage?**

You are not required to be in our Medicare prescription drug plan. If you want to join a different Medicare prescription drug plan, call that plan to find out how to join.

If you don’t want Medicare prescription drug coverage at all, call <PDP name> at <phone number>. TTY users should call <TTY number>. We are open <insert days/hours of operation and, if different, TTY hours of operation>. You will need to tell us you don’t want Medicare prescription drug coverage. You can also call 1-800-MEDICARE (1-800-633-4227, which is available 24 hours a day, 7 days a week). TTY users should call 1-877-486-2048.

Thank you.
Exhibit 25 - PDP Model Notice to Confirm Facilitated Enrollment

Referenced in section: 40.1.4 (F)

<Member #>
<RxID>
<RxGroup>
<RxBin>
<RxPCN>

Dear < member >

You are getting this letter because Medicare is enrolling you in our <PDP name> and your coverage begins <effective date>. Medicare is also mailing you a green letter about your enrollment. If you want coverage to begin earlier, you must tell us by <last day of month that is two months earlier than effective date>.

[Optional: You can use this letter as proof of your prescription drug coverage when you go to the pharmacy until you get your Member ID card from us.]

What are my costs in this plan?
Because you qualify for extra help with your prescription drug costs, you will pay no more than the following:

- <plan premium less premium assistance for which individual is eligible> per month for your <PDP name> premium,
- <insert applicable deductible> for your yearly prescription drug plan deductible,
- <insert copay amount or 15% coinsurance> when you fill a prescription covered by our plan.

If you believe this is incorrect and you have proof that the extra help amounts should be different, please call <PDP name> at the number below.

What if I have other prescription drug coverage?
If you now have or are eligible for other types of prescription drug coverage, you may not need to join a Medicare drug plan. **You or your dependents could lose your other health or drug coverage completely and not get it back if you join a Medicare drug plan.** Read all the materials you get from your insurer or plan provider to learn how joining a Medicare drug plan may affect you or your family’s current coverage. Examples of other types of prescription drug coverage include coverage from an employer or union, TRICARE, the Department of Veterans Affairs, or a Medigap (Medicare Supplement Insurance) policy. Please call your insurer or benefits administrator if you have any questions.

What if I paid for drugs before my new coverage starts?
If you filled any covered prescriptions before <effective date>, you may be able to get back part of what the prescriptions cost if you were eligible for Medicare and Medicaid but not enrolled in a Medicare drug plan. Call Medicare’s Limited Income NET program at 1-800-783-1307. TTY users should call 711. You can also visit www.humana.com/pharmacists.

<Contract#, alpha-numeric identifier, “CMS Approved/File & Use” [date] (as applicable)>
What if I want to join another plan, or I don’t want Medicare prescription drug coverage?  
You are not required to be in our Medicare prescription drug plan. If you want to join a different 
Medicare prescription drug plan, simply call that plan to find out how to join.

If you don’t want Medicare prescription drug coverage at all, call <PDP name> at <phone 
number>. TTY users should call <TTY number>. We are open <insert days/hours of operation 
and, if different, TTY hours of operation>. You will need to tell us you don’t want Medicare 
prescription drug coverage. You can also call 1-800-MEDICARE (1-800-633-4227, which is 
available 24 hours a day, 7 days a week). TTY users should call 1-877-486-2048.

Thank you.
Exhibit 26 - PDP Acknowledgement of Request to Decline or Opt-Out of Part D Prior to Effective Date

(Referenced in section 40.1.4 (G)

<Date>

Dear <Member>:

As you requested, <PDP name> has processed your request to decline (opt-out of) Medicare prescription drug coverage. Your decision to decline Medicare prescription drug coverage doesn’t affect your enrollment in Medicare Part A or Part B. **If you have drug coverage through Medicaid (Medical Assistance), that program will no longer pay for your prescription drugs.**

Remember, like other insurance, Medicare prescription drug coverage will be there when you need it to help you with drug costs. Even if you don’t take a lot of prescription drugs now, you still should consider joining a Medicare drug plan. As we age, most people need prescription drugs to stay healthy.

[Our records show that you are eligible for extra help with your prescription drug costs, but you must have Medicare prescription drug coverage to get this help.] If you continue to qualify for extra help with your prescription drug costs you may enroll in, or disenroll from, a plan at any time. If you lose this extra help during the year, your opportunity to make a change continues for two months after you are notified that you no longer qualify for extra help.

If you change your mind and decide you would like to join, please contact <PDP name> at <toll-free number> <days and hours of operation>. TTY/TDD users should call <toll-free TTY number>. You can also call 1-800-MEDICARE (1-800-633-4227, which is available 24 hours a day, 7 days a week) or visit www.medicare.gov. TTY users should call 1-877-486-2048

Thank you.
Exhibit 26a - PDP Acknowledgement of Request to Disenroll from PDP and Opt-Out of Part D After Effective Date

(Referenced in section 40.1.4 (G)

<Date>

Dear <Member>:

As you requested, <PDP name> has processed your request to disenroll from (opt-out of) Medicare prescription drug coverage. Your decision to disenroll from Medicare prescription drug coverage doesn’t affect your enrollment in Medicare Part A or Part B. Your disenrollment from <PDP name> is effective <effective date>. After this date, <PDP name> will no longer pay for your prescription drugs. **If you previously had drug coverage through Medicaid (Medical Assistance), that program will no longer pay for your prescription drugs.**

Remember, like other insurance, Medicare prescription drug coverage will be there when you need it to help you with drug costs. Even if you don’t take a lot of prescription drugs now, you still should consider joining a Medicare drug plan. As we age, most people need prescription drugs to stay healthy.

[Our records show that you are eligible for extra help with your prescription drug costs, but you must have Medicare prescription drug coverage to get this help.] If you continue to qualify for extra help with your prescription drug costs you may enroll in, or disenroll from, a plan at any time. If you lose this extra help during the year, your opportunity to make a change continues for two months after you are notified that you no longer qualify for extra help.

If you change your mind and decide you would like to remain in our plan, please contact <PDP name> at <toll-free number> <days and hours of operation>. TTY/TDD users should call <toll-free TTY number>. You can also call 1-800-MEDICARE (1-800-633-4227, which is available 24 hours a day, 7 days a week) or visit www.medicare.gov. TTY users should call 1-877-486-2048

Thank you.
Exhibit 27 – Auto and Facilitated Enrollees Who Permanently Reside in another Region Where the PDP Sponsor Offers another PDP at or below the Low-Income Premium Subsidy Amount for that Region

Referenced in section: 50.2.1.4

<Member #>
<RxID>
<RxGroup>
<RxBin>
<RxPCN>
<Date>

Dear <Member>:

You recently told us that you live in <state>. To make sure that you have Medicare prescription drug coverage where you live, we are enrolling you in <PDP name> that serves <insert states in the new plan’s region>. Your new coverage will begin <effective date>.

If you disagree with the information in this letter or if you have any questions, please call <PDP name> at the phone number provided at the end of this letter.

[Optional: You can use this letter as proof of your prescription drug coverage when you go to the pharmacy until you get your Member ID card from us.]

Because you qualify for extra help with your prescription drug costs, you will pay no more than the following:

- <plan premium less premium assistance for which individual is eligible> per month for your <PDP name> premium,
- <insert applicable deductible> for your yearly prescription drug plan deductible,
- <insert applicable copayments> when you fill a prescription covered by our plan.

If you believe this is incorrect and you have proof that the extra help amounts should be different, please contact <PDP name>.

You aren’t required to be in <PDP name>. If you want to join a different Medicare prescription drug plan, call that plan to find out how to join. You can also call 1-800-MEDICARE (1-800-633-4227, which is open 24 hours a day, 7 days a week) or visit www.medicare.gov on the web to choose and join a plan in your area that meets your needs. TTY users should call 1-877-486-2048.

If you have any questions, please call our <Customer Service, Member Services> department at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>.

Thank you.

<Contract#, alpha-numeric identifier, “CMS Approved/File & Use” [date] (as applicable)>
Exhibit 28 – Auto and Facilitated Enrollees Who Permanently Reside in another Region Where the PDP Sponsor DOES NOT offer another PDP at or below the Low-Income Premium Subsidy Amount for that Region

Referenced in section: 50.2.1.4

<Date>

Dear <Member>:

You recently told us that you live in a place where we don’t provide a Medicare prescription drug plan with premiums fully covered by extra help. You must live in <insert states where current PDP is offered> to be enrolled in <PDP name>. We have asked Medicare to disenroll you from <PDP name> beginning <effective date>.

It is important for you to call 1-800-MEDICARE (1-800-633-4227, which is available 24 hours a day, 7 days a week) to choose and join a plan that serves your state or territory. TTY users should call 1-877-486-2048. If you want to learn about other Medicare prescription drug plans in your area that you can join, call 1-800-MEDICARE or visit www.medicare.gov.

If you disagree with the information in this letter or if you have any questions, please call customer service at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>.

Thank you.
Exhibit 29 - Model Reassignment Confirmation

Referenced in section: 40.1.5 (E)

<Member #>
<RxID>
<RxGroup>
<RxBIN>
<RxPCN

Dear <member >

You are getting this letter because Medicare has enrolled you in <PDP name> for coverage beginning January 1, <following calendar year>. You should have already received a blue letter from Medicare telling you that they were moving you from the drug plan you were originally assigned to because either 1) that plan was leaving the Medicare program on December 31, <current calendar year>, or 2) the cost for that plan was increasing beginning January 1, <following calendar year>.

As of January 1, <following calendar year>, you should begin using <PDP name> network pharmacies to fill your prescriptions. If you use an out-of-network pharmacy, except in an emergency, <PDP name> may not pay for your prescriptions.

[Optional: You can use this letter as proof of your prescription drug coverage when you go to the pharmacy until you get your Member ID card from us.]

Because you qualify for extra help with your prescription drug costs, you will pay no more than the following:

- <insert $0 per month for your <PDP name> premium, [for LIS individuals with 100% premiums subsidy] OR
- <insert applicable amount per month> for your <PDP name> premium, [for LIS individuals with premium subsidy other than 100%],
- <insert applicable deductible> for your yearly prescription drug plan deductible,
- <insert applicable LIS copay/coinsurance amount that will be charged in following calendar year> when you fill a prescription.

If you believe this is incorrect and you have proof that the extra help amounts should be different, please contact customer service.

You aren’t required to be in <PDP name>. If you want to join a different Medicare prescription drug plan, call that plan to find out how to join. If you don’t want Medicare prescription drug coverage at all, call <PDP name> at <phone number>. TTY users should call <TTY number>. We are open <days/times> of operation and, if different, <TTY hours of operation>. You will need to tell us you don’t want Medicare prescription drug coverage.

Thank you.

<Contract#, alpha-numeric identifier, “CMS Approved/File & Use” [date] (as applicable)>
Exhibit 30 - Optional Notice for “Losing Plan” to LIS Beneficiaries Re-Assigned to a Different PDP Sponsor (in lieu of ANOC)

Referenced in section: 40.1.5 (E)

Dear <Member>:

Recently Medicare sent you a blue letter telling you that they will switch you to another Medicare drug plan starting January 1, <following calendar year>. This is because it will cost you more if you stay in <PDP name>.

The letter also said that you can stay in <PDP name> in <following calendar year>. However, if you stay with us, you will pay a higher monthly premium in <following calendar year>. If you want more information to help you decide, please call our <PDP name> <days and hours of operation>, at <customer service toll-free number>. TTY users should call <TTY number> for the hearing impaired. We will send you more information about the following:

- How your monthly premium would change for <following calendar year>
- How your benefits and costs would change for <following calendar year>
- What to do if your drug in <following calendar year> is no longer on the formulary or is more expensive

If you would like this information to help you decide or if you want to stay in <current plan>, call and let us know as soon as possible.

You can also get information about the Medicare Program and Medicare drug plans by visiting www.medicare.gov on the web or by calling 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048. Medicare customer service representatives are available, 24 hours a day, seven days a week, to answer questions about Medicare.

If you do nothing, your membership with us will end on December 31, <current calendar year>. You will get information from your new plan telling you about your benefits and any costs for <following calendar year>.

If you have any questions, please call customer service at <toll-free number><days and hours of operation>. TTY users should call <toll-free TTY number>.

Thank you.
Exhibit 31 - Enrollment Status Update -- For use with Transaction Reply Codes (TRC) from User Interface (UI) changes

[Member #]

<Date>

Dear <Member>:

Your enrollment in <PDP name> has been updated.

[Insert one or more of the following, including sufficient detail, to describe the specific enrollment change:

- You have been enrolled in <PDP name>. Your coverage will start on <start date> and will end on <end date>.  [Insert information about premiums, if applicable, and how to access coverage, etc.].

- Your enrollment in <old PBP name> has been changed to <new PBP name>. Your coverage in <new PBP name> will start on <date>.  [Insert information on premium differences (if any), cost sharing information, and other details the individual will need to ensure past and future coverage is accessible and clear].

- Your enrollment in <PDP name> started on an earlier date. Your coverage will start <date>.  [Include information about premiums and coverage here]

- Your enrollment in <PDP name> has been changed to start on a later date. Your coverage with <PDP name> will start on <date>.  [Insert information about refunding premium, where applicable, and impact to paid claims]

- Your enrollment in <PDP name> ended on <date>. This means you won’t have coverage from <PDP name> after <date>.  [Insert appropriate descriptive information, such as premium owed if the date has moved forward, or premium refunds if the date has moved back, and impact on paid claims or how to submit claims, as applicable].

- Your enrollment in <PDP name> has been cancelled. This means that you don’t have coverage from <PDP name>.  [Insert information about refund of premium, if applicable, and impact to any paid claims].

- [Insert other pertinent and appropriate information regarding the enrollment status update and the resulting impact to the beneficiary as necessary.]

Call <PDP name> at <toll-free number> <days and hours of operation> if you have any questions or want more information. TTY users should call <toll-free TTY number>.

Did you know that people with limited incomes may qualify for extra help to pay for their Medicare prescription drug costs? If you qualify, Medicare could pay for 75% or more of your drug costs including monthly prescription drug premiums, annual deductibles, and co-insurance. Additionally, those who qualify won’t have a coverage gap or a late enrollment penalty. Many people qualify for these savings and don’t even know it. For more information about this extra help, contact your local Social Security office, or call Social Security at 1-800-772-1213. TTY users should call 1-800-325-0778. You can also apply for extra help online at www.socialsecurity.gov/prescriptionhelp. Thank you.
Exhibit 32 - Model Employer/Union Sponsored Prescription Drug Plan Group Enrollment Mechanism Notice

<Date>

Dear (name)

<Name of Employer or Union> is enrolling you in <name of PDP> as your retiree prescription drug plan beginning <effective date>, unless you tell us by <insert date no less than 21 days from the date of notice> that you don’t want to join our plan. <Plan name> is a Medicare Prescription Drug (Part D) plan. This enrollment will automatically cancel your enrollment in a different Medicare Prescription Drug (Part D) plan or a Medicare Advantage plan. Please call us if you think you might be enrolled in a different Medicare Prescription Drug plan or a Medicare Advantage plan.

What do I need to know as a member of <PDP name>?
This mailing includes important information about <PDP name> and the coverage it offers, including a summary of benefits document. Please review this information carefully. If you want to be enrolled in this Medicare prescription drug plan, you don’t have to do anything, and your coverage will start on <effective date>.

Once you are a member of <PDP name>, you have the right to appeal plan decisions about payment or services if you disagree. Read the <insert either Member Handbook or Evidence of Coverage document> from <PDP name> when you get it to know which rules you must follow to receive coverage with this Medicare prescription drug plan.

<PDP Name> is a Medicare drug plan and is in addition to your coverage under Medicare Part A or Part B. Your enrollment in <PDP name> doesn’t affect your coverage under Medicare Part A or Part B. It is your responsibility to inform <PDP name> of any prescription drug coverage that you have or may get in the future. You can be in only one Medicare prescription drug plan at a time. If you are currently in a Medicare prescription drug plan, your enrollment in <PDP name> will end that enrollment. Enrollment in <PDP plan> is generally for the entire year.

By joining this Medicare prescription drug plan, you acknowledge that <PDP Name> will release your information to Medicare and other plans as is necessary for treatment, payment and health care operations. You also acknowledge that <PDP Name> will release your information, including your prescription drug event data, to Medicare, who may release it for research and other purposes which follow all applicable Federal statutes and regulations.

What happens if I don’t join <PDP name>?
You aren’t required to be enrolled in this plan. <insert information about other group sponsored plan options, if there are any>. You can also decide to join a different Medicare drug plan. You can call 1-800-MEDICARE (1-800-633-4227) 24 hours per day, 7 days per week for help in learning how. TTY uses should call 1-877-486-2048. However, if you decide not to be enrolled <insert consequences for opting out of group plan, like that you cannot return, or that other benefits are impacted>.

<Contract#, alpha-numeric identifier, “CMS Approved/File & Use” [date] (as applicable)>
What should I do if I don’t want to join <PDP name>?
To request not to be enrolled by this process <insert clear instruction for opting out, including telephone numbers and days/hours of operation>.

What if I want to leave <PDP name>?
Medicare limits when you can make changes to your coverage. You may leave this plan only at certain times of the year or under certain special circumstances. To request to leave, call <PDP name>.

<PDP name> serves a specific area. If you move out of the area that <PDP Name> serves, you need to notify us so you can disenroll and find a new plan in your area.

Keep in mind that if you leave our plan and don’t have or get other Medicare prescription drug coverage or creditable coverage (as good as Medicare’s), you may have to pay a late enrollment penalty in addition to your premium for Medicare prescription drug coverage in the future.

If you have any questions, please call customer service at <toll-free number><days and hours of operation>. TTY users should call <toll-free TTY number>.

Thank you.
Exhibit 33: PDP Model Notice to Research Potential Out of Area Status

Referenced in section 50.2.1.3

<Date>
<Member ID>

Dear <member name>:

We have recently received information that your address may have changed and that you may not live inside the service area of <plan name>. If you don’t contact us to verify your address, you will be disenrolled from <plan name> effective <disenrollment effective date>.

It is important that you contact us to verify your permanent address. You may use this form and return it to us in the enclosed envelope or you may call our <Customer Service, Member Services> department at <phone number><days and hours of operation>. TTY users should call <TTY number>.

Please note that your permanent address must be inside our service area in order for you to be a member of <plan name>. You may request that we send mail to you at another address outside of our service area. You may also temporarily reside for up to 12 months outside our service area and remain a member of <plan name>. But if you permanently move outside our service area or if you temporarily live outside our service area for more than 12 months in a row, we must disenroll you from <plan name>. You will have an opportunity to enroll in a plan that serves the area where you now live.

Your Permanent Address
Please tell us the permanent address where you live. Don’t use a post office box.

Street: ______________________________________________
City, State, ZIP: ______________________________________________
County: ______________________________________________
Current Phone Number: _________________________________________

Your Temporary Address
If you are currently living somewhere other than your permanent address, please provide the address. Don’t use a post office box. (You may skip this section if you are living at your permanent address.)

Street: ______________________________________________
City, State, ZIP: ______________________________________________
County: ______________________________________________
Current Phone Number: _________________________________________
When did you begin living at this address? __________________________
When do you expect to return to your permanent address? ________________
Your Mailing Address
If the address that you want us to use to send information to you is different than your permanent address, please provide it below. (You may skip this section if your mailing address is the same as your permanent address that you provided.)

Street or P.O. Box: _______________________________________________
City, State, ZIP: _______________________________________________
County: _______________________________________________
Current Phone Number: _________________________________________

If you have moved and haven’t told the Social Security Administration (SSA) about your new address, you may call them at 1-800-772-1213 (TTY 1-800-325-0778) Monday-Friday, 7am to 7pm.

If you have any questions or need help, please call us at the <Customer Service, Member Services> phone number listed above.

Thank you.
Exhibit 34: PDP Model Notice for Disenrollment Due Out of Area Status (No Response to Request for Address Verification)

Referenced in section: 50.2.1.3

<Date>
<Member ID>

Dear <member name>:

On <date of notice requesting address verification> we asked you to contact us so that we could determine whether you had moved out of the [Optional: <Parent Organization Name>] <plan name> service area. As we explained in our earlier letter, in order to be a member of our plan, you must live in the <plan name> service area, although you may be out of the service area temporarily for up to 12 consecutive months.

Our records show that you haven’t responded to our earlier letter. Therefore, you will be disenrolled from <plan name> effective <disenrollment effective date>. Beginning <effective date>, <plan name> won’t cover your prescription drugs.

This letter pertains only to your Medicare Prescription Drug Plan benefits. Your other Medicare benefits aren’t affected by your disenrollment from <PDP name>.

What if I disagree with this decision?
You have the right to ask us to reconsider this decision. You can ask us to reconsider by filing a grievance with us. Look in your <EOC document name> for information about how to file a grievance.

Can I enroll in a new plan?
You may have up to two months to join a new Medicare Prescription Drug Plan that serves the area where you now live. You may call 1-800-MEDICARE (1-800-633-4227) anytime, 24 hours a day, 7 days a week (TTY users should call 1-877-486-2048) for information about plans that may serve your area.

If you don’t enroll in a Medicare Prescription Drug Plan during this special two-month period, you may have to wait to enroll in a new plan. Medicare limits when you can enroll in a new Medicare Prescription Drug Plan or in a Medicare Health Plan (such as an HMO or PPO). From October 15 through December 7 each year, you can enroll in a new Medicare Prescription Drug Plan or Medicare Health Plan for the following year. You may not enroll in a new Plan during other times of the year unless you meet certain special exceptions, such as if you want to join a plan in your area with a 5-star rating or you qualify for extra help in paying for your prescription drug costs.

What happens if I don’t enroll in another Medicare Prescription Drug Plan?
Please remember, if you don’t enroll in another Medicare Prescription Drug Plan (or a Medicare Advantage Plan with prescription drug coverage) or you don’t have or obtain other coverage that is at least as good as Medicare drug coverage (also referred to as “creditable coverage”), you
may have to pay a late enrollment penalty if you enroll in Medicare prescription drug coverage in the future.

**Can I get help paying my premiums and other out-of-pocket costs?**
People with limited incomes may qualify for extra help to pay for their prescription drug costs. If you qualify, Medicare could pay for 75% or more of your drug costs including monthly prescription drug premiums, annual deductibles, and co-insurance. Additionally, those who qualify won’t have a coverage gap or a late enrollment penalty. Many people qualify for these savings and don’t even know it. For more information about this extra help, contact your local Social Security office, or call Social Security at 1-800-772-1213. TTY users should call 1-800-325-0778. You can also apply for extra help online at www.socialsecurity.gov/prescriptionhelp.

If you qualify for extra help with your prescription drug costs you may enroll in, or disenroll from, a plan at any time. If you lose this extra help during the year, your opportunity to make a change continues for two months after you are notified that you no longer qualify for extra help.

**What should I do if I’ve moved?**
If you have moved and haven’t notified Social Security of your new address, you may call them at 1-800-772-1213 (TTY: 1-800-325-0778) Monday-Friday, 7am to 7pm.

**What should I do if I have more questions?**
If you have any questions or need help, please call our <Customer Service, Member Services> department at <phone number> <days and hours of operation>. TTY users should call <TTY number>.

Thank you.
Exhibit 35 – PDP Notice of Disenrollment Due to Out of Area Status (Upon New Address Verification from Member)

Referenced in section: 50.2.1.3

<Date>
<Member ID>

Dear <member name>:

Thank you for informing us of your recent change of permanent address. Your permanent address is now outside the <plan name> service area. In order to be a member of our plan, you must live in the <plan name> service area, although you may be out of the service area temporarily for up to 12 consecutive months. Therefore, you will be disenrolled from <plan name> effective <disenrollment effective date>. Beginning <effective date>, <plan name> won’t cover your prescription drugs.

This letter pertains only to your Medicare Prescription Drug Plan benefits. Your other Medicare benefits aren’t affected by your disenrollment from <PDP name>.

What if I disagree with this decision?
You have the right to ask us to reconsider this decision. You can ask us to reconsider by filing a grievance with us. Look in your <EOC document name> for information about how to file a grievance.

Can I enroll in a new plan?
You may have up to two months to join a new Medicare Prescription Drug Plan that serves the area where you now live. You may call 1-800-MEDICARE (1-800-633-4227) anytime, 24 hours a day, 7 days a week (TTY users should call 1-877-486-2048) for information about plans that may serve your area.

What if I don’t enroll in a new plan right now?
If you don’t enroll in a Medicare Prescription Drug Plan during this special two-month period, you may have to wait to enroll in a new plan. Medicare limits when you can enroll in a new Medicare Prescription Drug Plan or in a Medicare Health Plan (such as an HMO or PPO). From October 15 through December 7 each year, you can enroll in a new Medicare Prescription Drug Plan or Medicare Health Plan for the following year. You may not enroll in a new Plan during other times of the year unless you meet certain special exceptions, such as if you want to join a plan in your area with a 5-star rating or you qualify for extra help in paying for your prescription drug costs.

What happens if I don’t enroll in another Medicare Prescription Drug Plan?
Please remember, if you don’t enroll in another Medicare Prescription Drug Plan (or a Medicare Advantage Plan with prescription drug coverage) or you don’t have or obtain other coverage that is at least as good as Medicare drug coverage (also referred to as “credible coverage”), you may have to pay a late enrollment penalty if you enroll in Medicare prescription drug coverage in the future.
What if my premium was being deducted from my Social Security/Railroad Retirement Board benefit check?
If your Medicare Part D premium is being deducted from your Social Security or Railroad Retirement Board benefit, please allow up to 3 months for us to process a refund. If you haven’t received a refund from Social Security/the Railroad Retirement Board within 3 months of this letter, you should contact 1-800-MEDICARE.

Can I get help paying my premiums and other out-of-pocket costs?
People with limited incomes may qualify for extra help to pay for their prescription drug costs. If you qualify, Medicare could pay for 75% or more of your drug costs including monthly prescription drug premiums, annual deductibles, and co-insurance. Additionally, those who qualify won’t have a coverage gap or a late enrollment penalty. Many people qualify for these savings and don’t even know it. For more information about this extra help, contact your local Social Security office, or call Social Security at 1-800-772-1213. TTY users should call 1-800-325-0778. You can also apply for extra help online at www.socialsecurity.gov/prescriptionhelp.

If you qualify for extra help with your prescription drug costs you may enroll in, or disenroll from, a plan at any time. If you lose this extra help during the year, your opportunity to make a change continues for two months after you are notified that you no longer qualify for extra help.

What should I do if I’ve moved?
If you have moved and have not notified Social Security of your new address, you may call them at 1-800-772-1213 (TTY: 1-800-325-0778) Monday-Friday, 7am to 7pm.

What should I do if I have more questions?
If you have any questions or need help, please call our <Customer Service, Member Services> department at <phone number> <days and hours of operation>. TTY users should call <TTY number>.

Thank you.
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Introduction

Under §1860D-13(b) of the Social Security Act, and 42 CFR §423.46, 423.56(g), Medicare beneficiaries may incur a late enrollment penalty (LEP) if there is a continuous period of 63 days or more at any time after the end of the individual’s Part D initial enrollment period during which the individual was eligible to enroll, but was not enrolled in a Medicare Part D plan and was not covered under any creditable prescription drug coverage. “Creditable prescription drug coverage” is coverage that meets Medicare’s minimum standards since it is expected to pay, on average, at least as much as Medicare’s standard prescription drug coverage.

Creditable prescription drug coverage includes, but is not limited to: some employer-based prescription drug coverage, including the Federal Employees Health Benefits Program; qualified State Pharmaceutical Assistance Programs (SPAPs); military-related coverage (e.g., VA, TRICARE); and certain Medicare supplemental (Medigap) policies. (See 42 C.F.R §423.56(b) for a complete list of types of prescription drug coverage that may be determined to be creditable. As outlined at 42 CFR 423.56(c) and (d), with the exception of Prescription Drug Plan (PDP) Sponsors, Medicare Advantage (MA) Organizations, §1876 Cost-Based Contractors, and PACE organizations offering prescription drug plans, entities that offer prescription drug coverage must make an annual determination of creditable coverage status and provide a disclosure notice to Medicare eligible individuals. Additional information related to creditable coverage requirements for employer and union-sponsored plans and all other entities that sponsor prescription drug coverage may be found at http://www.cms.hhs.gov/CreditableCoverage/.)

In general, Prescription Drug Plan (PDP) Sponsors, Medicare Advantage (MA) Organizations (including special needs plans (SNPs)), 1876 Cost-Based Contractors, and PACE organizations offering prescription drug plans (hereafter referred to as “Part D plan sponsors”) are responsible for determining, at the time of enrollment, whether a beneficiary was previously enrolled in a Medicare prescription drug plan or had other creditable coverage prior to applying to enroll in their plan, and whether there were any lapses in coverage of 63 days or more. Part D plan sponsors inform CMS of these lapses in creditable coverage so that CMS can compute the LEP and inform the sponsor of the LEP amount. The sponsor then bills the beneficiary for the LEP as part of the premium. (For those in premium withhold status, the LEP is deducted (with the premium) from the individual’s Social Security check.) With limited exceptions, as described in this chapter, the Part D LEP remains with the beneficiary for as long as he/she has Medicare prescription drug coverage.

This guidance describes the procedures that Part D plan sponsors are required to use in making creditable coverage period determinations, reporting them to CMS, and collecting the LEP.
10 - PROCESS FOR MAKING A CREDITABLE COVERAGE PERIOD DETERMINATION

The Part D plan sponsor shall make a creditable coverage period determination for their enrollees, unless otherwise noted in §10.3.

10.1 - Determine the Period in Question

The Part D plan sponsor shall determine, at the time of enrollment, whether a beneficiary who enrolls in Medicare drug plan will have or had a break in creditable prescription drug coverage for a continuous period of 63 days or more anytime after they were first eligible to enroll in a Medicare prescription drug plan. The Part D plan sponsor shall first determine the appropriate period in question: (1) following Part D/Retiree Drug Subsidy (RDS) disenrollment as described below; (2) the end of the Part D Initial Enrollment Period (IEP); or (3) end of the subsequent IEP.

10.1.1 - End of Prior Part D/RDS Enrollment

Where there is prior Part D or RDS plan coverage, the Part D plan sponsor does not have to look all the way back to the end of the member’s initial enrollment period. Instead, the Part D plan sponsor shall determine whether the member has any period without creditable prescription drug coverage since the date he/she disenrolled from the prior Part D or RDS plan. The period in question begins on the effective date of the member’s disenrollment from the prior Part D or RDS plan and ends on the day before the beneficiary’s enrollment becomes effective with the current Part D plan sponsor. Plans shall only look at this period when determining if a beneficiary had or will have a continuous period of 63 days or more without creditable prescription drug coverage.

Example:

Mr. Jones enrolled in a Part D plan sponsor, Plan ABC, during his Part D IEP with an enrollment effective date of June 1, 2006. He disenrolled from Plan ABC effective December 31, 2007 and enrolled in another Part D plan, Plan XYZ, a year later, with coverage effective January 1, 2009. Plan XYZ will review the period of January 1, 2008 to December 31, 2008 to determine whether Mr. Jones went at least 63 continuous days without creditable prescription drug coverage.

10.1.2 - End of the Part D Initial Enrollment Period

For individuals who did not have prior Part D plan or RDS enrollment and are not in their subsequent IEP, the period in question begins on the day following the
beneficiary’s Part D IEP and ends on the day before the beneficiary’s enrollment becomes effective with the Part D plan sponsor.

Unless otherwise informed by CMS, a Part D plan sponsor shall assume that the last day of a beneficiary’s IEP is/was:

- May 15, 2006 for a beneficiary who was eligible for Medicare Part D in January 2006; or
- The last day of the 3rd month following the month of initial eligibility for Medicare Part D, for a beneficiary who became/becomes eligible for Part D after January 2006.

**Example:**

*Mrs. Smith’s 65th birthday is April 20, 2006. She is entitled to Medicare Part A and her Part B IEP begins January 1, 2006. Therefore, her IEP for Part D begins on January 1, 2006, and ends on July 31, 2006.*

*Note: Even if Mrs. Smith delayed enrolling in Part B, her IEP for Part D still ended on July 31, 2006 because the Part D IEP is based on entitlement to Medicare Part A and/or enrollment in Part B. As long as a beneficiary resides in a Part D plan service area, the month that he/she initially becomes eligible for Part D is generally the earlier of the first day of the month of entitlement to Medicare Part A and/or enrollment in Part B. These dates are on the beneficiary’s enrollment request.*

If CMS or its designee informs the Part D plan sponsor of a different IEP end date, the Part D plan sponsor shall use this new date in determining uncovered months and shall include documentation of the new IEP end date in the beneficiary’s file.

Refer to the enrollment guidance appropriate to your plan type for more information about the Part D IEP.
10.1.3 - End of the Subsequent Part D IEP

An individual who is entitled to Medicare prior to turning age 65 (e.g., those who were entitled based on disability), will have a new or subsequent Part D IEP when they become entitled to Medicare based on age. If an enrollee attains age 65 while enrolled in a Part D plan and has been paying an LEP, his/her LEP will end on the day before his/her subsequent IEP begins, which is three months prior to the month s/he attains age 65.

The Part D plan sponsor shall have a process in place for identifying members who are attaining age 65 or who have recently attained age 65.

Example
Mrs. Brown was initially eligible for Medicare based on a disability, but never enrolled in a Part D plan. She will turn 65 on May 19 and her new (or subsequent) IEP will begin on February 1 and continue through August 30. If she enrolls in a Part D plan during this subsequent IEP, she will not be subject to an LEP.

Note: If, in this example above, Mrs. Brown was already enrolled in a Part D plan when she attained age 65, her current plan must take appropriate actions to have the LEP removed effective on the date that her IEP begins, which is February 1. See §30.4.3 for more information.

10.2 - Determining Whether There Has Been a Break in Creditable Prescription Drug Coverage

In general, the Part D plan sponsor shall follow the steps described below to determine whether there has been a qualifying break in creditable prescription drug coverage since the end of the Part D IEP, subsequent IEP, or Part D/RDS enrollment.

Step 1. Review the enrollment request and determine the period in question as described in §10.1. The Part D plan sponsor shall use the Beneficiary Eligibility Query (BEQ) or Common UI and other available information to determine whether there is a lapse in creditable prescription drug coverage of 63 continuous days or more since the end of his/her prior Part D/RDS enrollment, IEP, or subsequent IEP. Other information can be information that the Part D sponsor has indicating that the enrollee had creditable prescription drug coverage through another product it offers, e.g., employer coverage, individual coverage, or coverage offered by another plan benefit package (PBP). Also, this can be information that the beneficiary, on his/her own initiative, submitted to the Part D plan sponsor along with his/her enrollment application. (Refer to §20.1 for more information).

If this information shows that there has been no gap of 63 continuous days or more in which the individual did not have creditable prescription drug coverage since the end
of his/her prior Part D/RDS enrollment; or the beneficiary’s IEP (or subsequent IEP) has not ended, the Part D plan sponsor shall determine that there is no break in creditable prescription drug coverage and shall determine that zero (0) is the appropriate number of uncovered months to report to CMS in accordance with §30 Reporting Creditable Coverage Period Determinations to CMS. In this case, the Part D plan sponsor shall not proceed to Step 2. That is, the Part D plan sponsor should not send the attestation documents to the member. Instead, the Part D plan sponsor shall include the appropriate documentation in the member’s file and determine that zero (0) is the appropriate number to report to CMS. The Part D plan sponsor shall report zero uncovered months to CMS in accordance with §30 Reporting Creditable Coverage Period Determinations to CMS.

If a continuous period of 63 days or more have passed since the end of the enrollee’s prior Medicare prescription drug plan enrollment, IEP, or subsequent IEP proceed to Step 2.

**Step 2.** If the BEQ or Common UI indicates that there is a gap of 63 continuous days or more in which the individual did not have creditable prescription drug coverage since the end of his/her prior Part D/RDS enrollment, IEP, or subsequent IEP, the Part D plan sponsor shall determine the number of months that the individual went without such creditable coverage. The Part D plan shall accomplish this by counting the number of full months (number of uncovered months) up to the month of enrollment in its plan. The Part D plan sponsor shall determine the number of months that the individual went without such creditable coverage. The Part D plan shall accomplish this by counting the number of full months (number of uncovered months) up to the month of enrollment in its plan. The Part D plan sponsor shall insert this information in the attestation documents (Exhibits 1A or 1B, 1C, and 1D) in accordance with §20, within 7 calendar days of receipt of the BEQ or Common UI response. The Part D plan sponsor shall instruct the beneficiary to return the form within 30 calendar days of the date on the form.

10. 3 - Exceptions to Making Creditable Coverage Period Determinations

There are specific cases in which Part D plan sponsors shall not proceed with the creditable coverage period determination described in §10.2 above.

10.3.1 - Creditable Coverage Period Determinations for Disenrolled Members

In cases where a beneficiary submits a valid cancellation request to the Part D plan sponsor prior to his/her enrollment effective date the plan should not proceed with a creditable coverage period determination. (See the enrollment guidance appropriate to your plan type for information on valid cancellation requests),

However, if the member disenrolls after coverage is effective and the Part D sponsor has not had an opportunity to assess the LEP, the plan shall continue with a creditable
coverage period determination, report the number of uncovered months to CMS in accordance with §30.2 and, if applicable, notify the member of the LEP amount in accordance with §50 of this chapter.

It is important that the Part D plan sponsor proceeds with its determination because subsequent plans will not look back beyond the end of the beneficiary’s enrollment in the previous plan as described in §10.1.1 Part D/RDS Enrollment) when determining the number of uncovered months.

10.3.2 - Creditable Coverage Period Determinations for Deceased Members

The Part D plan sponsor shall not initiate a determination or continue with a determination already in progress if the member dies before the plan has had an opportunity to report its determination to CMS.

10.3.3 - Creditable Coverage Period Determinations for Low-Income Subsidy (LIS) Eligibles

Pursuant to 42 CFR 423.46(a) and 42 CFR 423.780(e) Medicare beneficiaries who qualify for the low-income subsidy (LIS) may enroll in a Medicare prescription drug plan with no penalty. Therefore, Part D plan sponsors are not to make creditable coverage period determinations for any new enrollee who is LIS eligible at the time he/she makes the enrollment request or at the time the enrollment becomes effective. Additionally, should the enrollee lose his/her LIS status, but remain continuously enrolled in a Part D plan sponsor, the Part D plan sponsor shall not make a creditable coverage period determination following such loss for any period prior to their loss of LIS.

The Part D plan sponsor shall make a creditable coverage period determination, as described in §10.2, only if the individual loses his/her LIS-eligibility, disenrolls from a Part D plan sponsor, incurs a qualifying gap in creditable prescription drug coverage, and is not LIS-eligible at the time of reenrollment or at the time the enrollment is effective in a Medicare prescription drug plan.

10.3.4 - Enrollees in the Program of All-Inclusive Care for the Elderly (PACE)

As stated in the introduction to this Chapter, PACE organizations offering prescription drug plans also are required to make creditable coverage period determinations at the time of enrollment and report any lapses in coverage of 63 days or more to CMS. However, PACE enrollees who are dual-eligible members are not
subject to the LEP as long as they remain enrolled in Part D. Therefore, PACE organizations do not need to make creditable coverage period determinations for dual-eligible members. However, the organization is required to make the creditable coverage period determination in accordance with §10.2 for their Medicare-only enrollees.

In the event that a Medicare-only member becomes eligible for Medicaid while the PACE organization is conducting a creditable coverage period determination, the organization shall suspend its determination. If the organization has already submitted uncovered months to CMS, it shall submit a plan change transaction (73) in order to report zero uncovered months. (Refer to §30, for reporting requirements.)

10.3.5 - Individuals in the U.S. Territories

Beneficiaries in the U.S. territories who are dually eligible (e.g., those in Puerto Rico who are eligible for Medicare and Puerto Rico’s Medicaid plan known as Reforma) are exempt from the LEP in the same manner as those who are LIS-eligible in the States.
20 - ATTESTATION OF CREDITABLE PRESCRIPTION DRUG COVERAGE

The Part D plan sponsor shall solicit information about creditable prescription drug coverage from beneficiaries (or organizations permitted to attest to such coverage on behalf of its beneficiary) where possible gaps in such coverage appear following a response from the BEQ or Common UI.

20.1 - Attestation Documents

As described in §10.2 above, if the BEQ or Common UI indicates that there is a gap of 63 continuous days or more in which the individual did not have creditable prescription drug coverage since the end of either his/her Part D/RDS enrollment, IEP, or subsequent IEP, the Part D plan sponsor shall send the attestation documents to the beneficiary so that the beneficiary can attest to whether he/she had creditable prescription drug coverage for the period in question. When soliciting prior creditable prescription drug, the Part D plan sponsor shall not request the beneficiary to provide proof of such coverage since the beneficiary’s signature on the attestation form (or verbal attestation) affirms that the information he/she has provided is true and correct to the best of his/her knowledge. However, if the beneficiary, on his/her own initiative, provides proof of prior creditable prescription drug coverage, the Part D plan sponsor shall consider that information when determining whether the beneficiary had a qualifying gap in creditable coverage.

The attestation documents (Exhibits 1A, 1B, 1C, 1D, 1E, and 1F) are provided as models and may therefore be modified, subject to CMS review and approval. However, we strongly urge plans to refrain from adding extraneous information to the documents or from putting their own letterhead on the documents, except where indicated on Exhibit 1D.

The marketing codes for these models can be found in HPMS and are located on the Exhibits at the end of this chapter. Plans must use the appropriate marketing codes and can use these models as “file and use.”

20.1.1 - Initial Attestation Documents

The Part D plan sponsor shall fill-in the appropriate blank spaces as required on the following series of attestation documents and mail them within 7 calendar days of receipt of the BEQ or Common UI response as follows:

(1) Exhibit 1A—Beneficiary Cover Letter (HPMS Code 8013), Exhibit 1C—Frequently Asked Questions and Answers (HPMS Code 8014), and Exhibit 1D—Declaration of Prior Prescription Drug Coverage. The Part D plan sponsor shall mail
these exhibits collectively to those beneficiaries who had prior Part D or RDS coverage but incurred a break in creditable prescription drug coverage;

**OR**

(2) Exhibit 1B— *Beneficiary Cover Letter* (HPMS Code 8013), Exhibit 1C— *Frequently Asked Questions and Answers* (HPMS Code 8014), and Exhibit 1D— *Declaration of Prior Prescription Drug Coverage*. The Part D plan sponsor shall mail these exhibits collectively to those beneficiaries who have never enrolled in a Medicare prescription drug plan but may have incurred a break in creditable prescription drug coverage.

The Part D plan sponsor shall instruct beneficiaries to return the *Declaration of Prior Prescription Drug Coverage* form (also called the *attestation form*) within 30 calendar days of the date on the form.

When mailing the attestation documents, the Part D plan sponsor **shall not** include Appendix 14—*LEP Reconsideration Notice* and Appendix 15—*Reconsideration Request Form* (refer to §50 regarding issuance of these two documents). Likewise, the Part D plan sponsor shall not mail the attestation documents with an enrollment form, nor shall the Part D plan sponsor include any question(s) regarding the individual’s creditable prescription drug coverage on the enrollment form, as doing so may lead the beneficiary to believe that his/her enrollment in a Medicare prescription drug plan is contingent upon having prior creditable coverage. However, if the beneficiary, on his/her own initiative, includes creditable prescription drug coverage information and/or documentation with the enrollment form, the Part D plan sponsor shall take that information into account when determining whether there has been a gap in coverage. If the creditable coverage information provided coincides with the potential qualifying gap identified during the specific period in question, the Part D plan sponsor may not need to send the attestation documents.

In cases where a beneficiary provides creditable coverage information without an enrollment request, the Part D plan sponsor shall return the creditable coverage with a notice explaining why the information was returned. The Part D plan sponsor shall use the *Exhibit 8: Model Notice—Return of Creditable Coverage Information Received Without an Accompanying Enrollment Request* or create its own form using the requisite elements shown in the model, subject to CMS’ marketing review procedures.

### 20.1.2 - “Final Notice” Attestation Documents

Exhibits 1E and 1F are optional notices that the Part D plan sponsor may use to follow-up with beneficiaries to remind them that the 30-day deadline is approaching or has passed and no information has been provided. The Part D plan sponsor choosing to use these documents shall use the same return date that was inserted on
the initial attestation forms (See §20.1.1 above) when instructing the beneficiary of the return date deadline. However, the Part D plan sponsor must mail these “Final Notice” attestation documents with a deadline return date that will allow the plan enough time to meet the required timeframe for reporting to CMS. (See §30). Additionally, the Part D plan sponsor must mail one of the following sets of attestation documents outlined below:

(1) For beneficiaries who had prior Part D or RDS coverage but incurred a break in creditable prescription drug coverage --
   • Exhibit 1E—“Final Notice” Beneficiary Cover Letter (HPMS Code 8013)
   • Exhibit 1C—Frequently Asked Questions and Answers (HPMS Code 8014)
   • Exhibit 1D—Declaration of Prior Prescription Drug Coverage.

OR

(2) For beneficiaries who have never enrolled in a Medicare prescription drug plan but may have incurred a break in creditable prescription drug coverage –
   • Exhibit 1F—“Final Notice” Beneficiary Cover Letter (HPMS Code 8013),
   • Exhibit 1C—Frequently Asked Questions and Answers (HPMS Code 8014)
   • Exhibit 1D—Declaration of Prior Prescription Drug Coverage.

20.2 - Telephonic Attestation

Telephonic Attestation is a process that Part D plan sponsors can use to allow beneficiaries to provide creditable coverage information over the telephone rather than relying on the beneficiary to complete and return the form.

In all cases where the Part D plan sponsor provides this option, the Part D plan must still mail either Exhibits 1A or 1B along with 1C, and 1D as described in §20.1.1 above, and shall include on the attestation documents all of the information specific to telephonic attestations, as well as the Part D plan’s mailing information as shown in those exhibits. Part D plan sponsors may not use telephonic attestations in lieu of mailing the initial attestation documents.

When accepting an attestation via telephone, the Part D plan sponsor is not required to record the conversation but shall document the call and ensure that it captures all of the requisite elements of the attestation documents (as shown in Exhibits 1A/1B, 1C and 1D) and amend the beneficiary’s record.

20.3 - Attestations from Third Parties

Part D plan sponsors shall accept and retain creditable coverage information (including attestation documents) from all employer and union groups, as well as State Pharmaceutical Assistance Programs (SPAPs) that attest to their members’
creditable coverage history. The creditable coverage information or attestation documents can include the members’ names and dates of creditable coverage.

CMS refrains from specifying the form and manner of the attestation of coverage and defers to arrangements made between the plan and the employer or union group and SPAP. For example, documentation can include individual attestations signed by one of the entities or one attestation supplemented by a list of affected members.

If an employer, union, or SPAP attests to creditable coverage on behalf of its members, but a member has also provided creditable coverage information (e.g., via a telephonic attestation, or via completed and returned Declaration of Creditable Prescription Drug Coverage form), the Part D plan sponsor shall use the information most favorable to the beneficiary. Thus, the information provided by the employer, union, or SPAP shall supersede the beneficiary’s signed attestation only if it would eliminate or reduce the LEP.
30 - REPORTING CREDITABLE COVERAGE PERIOD DETERMINATIONS TO CMS

After the Part D plan sponsor makes its creditable coverage period determination in accordance with §10.2, it shall report its determination to CMS. Creditable coverage period determinations are reported to CMS in the form of full uncovered months, also referred to as a number of uncovered months (NUNCMO). The NUNCMO reflects the number of full calendar months that a beneficiary incurred during any continuous period of 63 calendar days or more after the end of his/her initial Part D IEP, subsequent Part D IEP, or prior RDS/Part D enrollment in which he/she did not have Medicare prescription drug coverage or other creditable prescription drug coverage.

In general, any period of time determined to be a period of uncovered months for the purposes of the Part D LEP always occurs outside a Part D plan enrollment period. Therefore, the effective date of the “number of uncovered months” data is always equal to a Part D plan enrollment effective date, with two exceptions: 1) when an individual becomes LIS eligible (see §30.4.B); and 2) when an individual has a second or subsequent Part D IEP (see §30.4.D).

30.1 - Reporting a Creditable Coverage Period Determination Using an Enrollment or Plan Change Transaction for New or Current Enrollees

Generally, the Part D plan sponsor may report a creditable coverage period determination to CMS in two ways: 1) on the enrollment transaction (transaction codes 60, 61, 62, and 71); or 2) on a plan change transaction (transaction code 73), provided that it meets the timeframes outlined in this chapter and in the appropriate enrollment guidance for the sponsor’s plan type. In accordance with CMS’ enrollment guidance (§30.3 of Chapter 2 of the Prescription Drug Manual and §40.3 of Chapter 3 of the Medicare Managed Care Manual), the sponsor must submit the enrollment transaction to CMS within 7 calendar days of receipt of a complete enrollment request. Therefore, it is often the case that the sponsor must submit the enrollment transaction before it can complete its creditable coverage period determination. In this situation, the sponsor shall submit an enrollment transaction that shows no uncovered months (in accordance with the process outlined in 30.1.1 below), and then, if necessary, submit a plan change transaction after it makes its determination to add the number of uncovered months, or indicate that there is a gap in coverage. (See §30.1.2 below.)

30.1.1 - Reporting Uncovered Months on the Enrollment Transaction

If the part D plan sponsor is not able to determine whether there is a break in creditable coverage before the deadline for submitting the enrollment transaction to CMS, the sponsor shall report to CMS the beneficiary had creditable coverage by taking the following actions:

(1) Set the creditable coverage flag to “Y”;

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(2) Set “000” (zero) as the NUNCMO; and
(3) Set the enrollment transaction date equal to the enrollment effective date in the plan.

30.1.2 - Submitting Uncovered Months Using a Plan Change (transaction code 73) Transaction

If the sponsor needs to change the number of uncovered months after submitting the enrollment transaction to CMS, Part D plan sponsor shall submit a plan change (73) transaction to reflect the new number of uncovered months as follows:

1) Set the creditable coverage flag to “N”;
2) Set the number value equal to the number of uncovered months; and
3) Set the effective date of the transaction equal to the effective date of enrollment in the plan.

Below is a description the creditable coverage flags “Y” and “N” along with how the Part D plan sponsor must notate the number of uncovered months it reports. Refer to Appendix 1: *Summary of MARx Transactions to Add, Change, or Remove the Number of Uncovered Months for an Enrolled Beneficiary* for a detailed listing of transactions used to report NUNCMOs to CMS.

<table>
<thead>
<tr>
<th>Creditable Coverage Flag</th>
<th>Description</th>
<th>Number of Uncovered Months (NUNCMO)</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Y”</td>
<td>Use if sponsor has not yet completed determination, but enrollment transaction must be sent in order to meet the deadline. This transaction remains unchanged if your subsequent creditable coverage period determination is that the member had creditable prescription drug coverage for the entire period in question. That is, the determination is that there are no uncovered months for the period in question. In this case, you do not need to submit “Y” and “000” a second time via the plan change transaction code 73.</td>
<td>Report zero “000” (leading zeroes or right justified).</td>
</tr>
<tr>
<td>“N”</td>
<td>Use if member did not have creditable prescription drug coverage. That is, the determination is that there are uncovered months for the period in question.</td>
<td>Report a number equal to or greater than 1 (leading zeros, right justified; example“001”)</td>
</tr>
</tbody>
</table>
30.2 - Reporting Creditable Coverage Determinations for Disenrolled Members

The Part D plan sponsor shall report a creditable coverage period determination for a member who has since disenrolled from the Part D plan sponsor in cases that include, but are not limited to, the following:

(1) The Part D plan sponsor did not make or adjust a creditable coverage period determination (see §10.3.1 and §30.4) prior to the effective date of the member’s disenrollment from that plan;

(2) CMS’s Independent Review Entity (IRE) has made a reconsideration decision that requires an adjustment to the number of uncovered months previously reported by the Part D plan sponsor (see §30.4.F); or

(3) The Part D plan sponsor realizes it made an error in making and/or reporting its creditable coverage determination to CMS while the member was enrolled in its plan.

Note: The Part D plan sponsor can make changes to the number of uncovered months for a disenrolled member for any time period up through the last day of the member’s enrollment in the plan.

In order to report NUNCMO information for a member after the effective date of disenrollment, the Part D plan sponsor shall take the following steps:

1) Submit a plan change (73) transaction via a retroactive batch file. The header date of the retroactive file must reflect a date that the member was enrolled in the Part D plan sponsor that is adjusting an existing or reporting a new creditable coverage determination and be in the month/year format (mm/yyyy). You must obtain approval from CMS to submit.

2) Contact the MMA Help Desk to obtain a ticket number to request the submission of a batch retroactive file to report these transactions. CMS Central Office staff will review each ticket and contact the requesting Part D plan sponsor regarding the request.

The Part D plan sponsor submitting the change to the uncovered months will receive a transaction reply code (TRC) on the transaction reply report (TRR) regarding the uncovered months and a recalculated LEP amount on the Low Income Subsidy/Late Enrollment Penalty (LIS/LEP) Report for members in direct bill status and the Monthly Premium Withholding Report/ Data file (MPWRD) for members in premium withhold status. Additionally, the disenrolled member’s subsequent plan(s), including the member’s current plan, will be impacted by this change to the uncovered months. Therefore, the member’s subsequent plan(s) will receive information regarding changes to the uncovered months and recalculated LEP only on the Low Income Subsidy/Late...
Enrollment Penalty (LIS/LEP) Report for members who are in direct bill status and the Monthly Premium Withholding Report/ Data file (MPWRD) for members in premium withhold status.

NOTE: The plan that submits the change to an individual’s uncovered months will be the entity that receives a transaction reply on the TRR. The affected plans will see the change on the Low Income Subsidy/Late Enrollment Penalty (LIS/LEP) for members in direct bill status and on the Monthly Premium Withholding Report/ Data file (MPWRD) for members in premium withhold status.

In cases where the former plan sponsor reports a creditable coverage determination (or an adjustment to a previous determination) that results in the imposition of or increase in the LEP amount, the former plan sponsor shall notify the member of the LEP amount in accordance with §50 of this chapter.

Example:

Mrs. Johnson enrolled in Plan KLM effective January 1, 2008. She disenrolled from Plan KLM with a coverage end date of February 28, 2008 and enrolled in Plan BCD effective March 1, 2008. Plan KLM completed its creditable coverage period determination on March 10, 2008, and determined that Mrs. Smith had 3 uncovered months. Plan KLM contacted the MMA Help Desk and asked to submit a batch retro file that contained a valid plan change (73) transaction changing the number of uncovered months from “000” to “003”, setting the creditable coverage flag to “N,” and using a header date of “012008” (January 2008) or “022008” (February 2008).

Plan KLM received authorization from CMS and submitted the change as directed and received a transaction reply code (TRC) from CMS showing that the change was accepted and another TRC from CMS showing that the LEP amount had changed.

Plan KLM then notified Mrs. Johnson that she owes an LEP. Since Mrs. Johnson is in premium withhold status, her current plan, Plan BCD, received this information on the MPWRD and then notified Mrs. Smith that her plan premium was increased accordingly, as a result of the LEP.

30.3 - Timeframes for Reporting Creditable Coverage Period Determinations to CMS

In all cases where the Part D plan sponsor has queried the BEQ or Common UI, it shall report its creditable coverage period determination to CMS in accordance with the reporting timeframes described in the below subsections. Additionally, in cases where the Part D plan sponsor has mailed the attestation form in accordance with §20, it shall follow up with its beneficiary (via telephone or in writing) to obtain the requested information if such information is not received or is received incomplete.
Beneficiary follow-up shall be done within a period of time that allows the Part D plan sponsor to meet the reporting timeframes as described below.

30.3.1 - Reporting Determinations Based on Information received from BEQ or Common UI

When the Part D plan sponsor queries the BEQ or Common UI and determines, in accordance with §20 Attestation of Creditable Prescription Drug Coverage of this chapter, that it does not need to send the attestation documents to the beneficiary, it shall report its creditable coverage period determination to CMS within 14 calendar days of receiving the information from the BEQ or Common UI in accordance with §§30.1 and 30.2.

30.3.2 - Reporting Determinations Based on Timely and Complete Attestations

If the Part D plan sponsor sends the attestation documents to a beneficiary as described in §20 of this chapter and receives the completed attestation form within the stated timeframe, the Part D plan sponsor shall report its creditable coverage period determination to CMS within 14 calendar days of receiving the creditable coverage information.

The Part D plan sponsor shall consider the attestation form complete if it contains:

1. The signature of the beneficiary, or the signature of the beneficiary’s authorized representative (along with the authorized representative’s name, address, phone number, and his/her relationship to the beneficiary; AND
2. A “√” in one of the boxes indicating that he/she did or did not have prior creditable prescription drug coverage; and
3. Where the box is selected indicating that he/she did have creditable prescription drug coverage, the dates of such coverage is indicated on the corresponding lines.

NOTE: If the Part D plan sponsor receives a timely and complete attestation form (or the creditable coverage information is provided telephonically) after it has submitted an enrollment transaction to CMS on behalf of that beneficiary but before receiving confirmation of that beneficiary’s enrollment from CMS, the Part D plan sponsor shall wait for CMS to confirm the beneficiary’s enrollment before reporting its creditable coverage period determination to CMS. In this case, the Part D plan sponsor shall report its creditable coverage period determination within 14 calendar days of receiving confirmation of that beneficiary’s enrollment.
30.3.3 - Reporting Determinations Based on a Timely, Incomplete Attestation Form

If the Part D plan sponsor receives an incomplete attestation form, the Part D plan sponsor shall follow-up with the beneficiary to obtain the missing information. The Part D plan sponsor shall follow up with the beneficiary via notice (e.g., it may send the “Final Notice” Exhibits 1E or 1F, and 1C, and 1D), telephone, or other method to obtain the missing information. However, it must follow-up with the beneficiary to obtain the missing information.

In the case of an unsigned attestation form, if the Part D plan sponsor chooses to use the telephonic method to follow-up with the beneficiary in order to obtain the missing information, the Part D plan sponsor can accept the beneficiary’s verbal attestation to the information he/she provides. The beneficiary does not need to provide a ‘wet signature’ in such case. Instead, as with all types of missing information, the Part D plan sponsor shall document the telephone call and amend the beneficiary’s record accordingly (see above §20.2 Telephonic Attestation).

The Part D plan sponsor shall report its creditable coverage determination to CMS within 28 calendar days of receipt of the incomplete form.

30.3.4 - Reporting Determinations Based on Missing Attestations

Where the beneficiary fails to return the attestation form (or fails to provide creditable coverage information via telephone) within 30 calendar days of the date on the initial attestation documents mailed to the beneficiary (refer to §20.1 et. al., Attestation Documents), the attestation form is considered “missing.” In such case, the Part D plan sponsor shall follow-up with the member to obtain the missing information or to obtain the actual attestation form.

The Part D plan sponsor may send a follow-up notice or contact the beneficiary via telephone to obtain the beneficiary’s prior creditable prescription drug coverage information. If the Part D plan sponsor receives information about the beneficiary’s prior creditable prescription drug coverage via telephone, it shall document that information in accordance with §20.2 of this chapter. If the Part D plan sponsor chooses to use the model language “Final Notices”—(Exhibits 1E or 1F, and 1C, and 1D)—it must do so in accordance with §20.1.2.

The Part D plan sponsor shall follow-up with the beneficiary within a timeframe that allows the plan to report its creditable coverage period determination within 14 calendar days after the stated deadline on the initial attestation documents. The Part D plan sponsor must report its creditable coverage period determination to CMS within this 14 calendar day timeframe even if it was unable to obtain the requested information from the beneficiary after performing the required follow-up.
30.4 - Reporting Adjustments to Creditable Coverage Period Determinations Previously Reported to CMS

There are circumstances in which a creditable coverage period determination has been made and reported to CMS, but later needs to be adjusted. The reasons for such adjustments include, but are not limited to, the following:

A. Receipt of a beneficiary’s late attestation of creditable coverage;
B. Beneficiary becomes LIS-eligible;
C. Beneficiary loses LIS eligibility;
D. Incurring a subsequent Part D IEP;
E. Corrections due to plan errors; or
F. Decisions rendered by CMS’s Independent Review Entity (IRE);

Where an adjustment to a member’s previously submitted number of uncovered months needs to be made, unless otherwise noted in this Chapter or the enrollment chapters, the Part D plan sponsor shall report the adjustment as soon as it receives information that is the impetus for such change to the previously reported number of uncovered months.

A. Reporting Adjustments Based on Untimely Attestations

(1) The Part D plan sponsor shall accept an attestation form (or permit plan members to provide information about their creditable coverage via telephone in accordance with §20.2, if the plan offers this option) if it is received no more than 60 days past the return deadline stated on the beneficiary’s attestation form. If the plan sponsor has already reported its creditable coverage period determination to CMS, and must adjust the number of uncovered months previously reported, it shall take the following actions: Submit a plan change transaction (73) with the creditable coverage flag set to either:
   a. (Y) if the late attestation indicates that there is no gap in creditable prescription drug coverage and set the number value to zero (“000”);
   OR
   b. (N) if the late attestation indicates that there is still a gap in creditable prescription drug coverage and set the number value to a number greater than zero (e.g., “010” for 10 uncovered months)

(2) Set the date of the transaction equal to the enrollment effective date in the plan.

In cases where the member has already requested a review of the LEP and CMS’s independent review entity (Maximus) has notified the plan of a pending reconsideration request (i.e., Maximus has requested the case file from the plan), the plan must contact Maximus to alert them of the change and provide documentation of the such change. Plans should use the fax number noted on the LEP Reconsideration Case File Request Form to communicate this information to Maximus. If the change
results in the removal of the LEP (i.e., the NUNCMO = zero (0)), Maximus will then dismiss the case because there are no longer uncovered months in dispute. If, however, the change does not eliminate the LEP, Maximus will then proceed with its review of the LEP based on the new information that the plan used to adjust the member’s uncovered months.

If the Part D plan sponsor receives an attestation more than 60 days after the return deadline stated on the member’s attestation form, it shall not make any adjustments to the member’s number of uncovered months it previously reported. Instead, the Part D plan sponsor shall inform the member via telephone or in writing (using the Exhibit 10: Model Notice—Creditable Coverage Information Received After Deadline) that the sponsor is not accepting the form (or verbal attestation) because more than 60 days have passed since the deadline. The Part D plan sponsor shall also inform the member that he/she will be notified in writing (Exhibit 2: Model Notice—Beneficiary Notice of Late Enrollment Penalty) of the amount of any LEP (if such notification has not been provided already) and, that information about requesting a review (using Appendices 14 and 15) of the plan’s decision will be (or has already been) included with the letter.

NOTE: Exhibit 2 and Appendices 14 and 15 shall be mailed to the beneficiary in accordance with §50.1 of this chapter.

B. Reporting Adjustments Due to Low-Income Subsidy Eligibility

Pursuant to 42 CFR §§ 423.46(a) and 423.780(e), individuals who are LIS-eligible are exempt from being assessed an LEP. Therefore, if a beneficiary currently paying an LEP becomes LIS-eligible, the penalty is removed effective with the start of LIS eligibility. In such cases, the plan shall submit a plan change transaction to CMS that resets the NUNCMO to zero (0). Resetting the NUNCMO to zero (0) will also remove the LEP amount. To accomplish this, the Part D plan sponsor shall take the following actions:

1. Submit a plan change transaction (73) with the creditable coverage flag set to “R”;
2. Submit the number value zero “000”; and
3. Submit the effective date equal to the effective date of the individual’s LIS eligibility.

NOTE: Using “R” means to “reset.” The reset action will end an existing period of time subject to an LEP and begin a new period. This means that the NUNCMO (and corresponding LEP amount) will apply up until the reset date, and a new period will begin with zero NUNCMO (and zero LEP amount) effective with the reset date.

Part D plan sponsors are responsible for reviewing the appropriate CMS reports (see §40.2), including other updated information about its members’ LIS status, in order to
ensure that the Part D plan sponsor accurately and timely resets the member’s number of uncovered months.

The Part D plan sponsor shall notify the LIS-eligible member of the removal of the LEP and shall use either Exhibit 5: Model Letter Informing Beneficiary of the Removal of the LEP Due to LIS Eligibility or create its own form using the requisite elements shown in the model, subject to CMS’s marketing review procedures. The Part D plan sponsor shall send this notice within 14 calendar days of receiving information about the member’s LIS status from CMS (see §40.2). For members in direct bill status, the Part D plan sponsor shall issue a refund of any LEP amount paid since the member became LIS eligible in accordance with §60.3 of this chapter.

Example:
Mr. Johnson enrolled in Part D for the first time effective January 1, 2007. His Part D IEP ended on May 15, 2006, and, because he had no other creditable coverage prior to enrolling in Part D, he had 7 uncovered months, and was charged an LEP. He became eligible for LIS effective February 1, 2008, and his plan, Plan RST, was notified of this change through CMS plan reports released during the month of February. Plan RST must submit a plan change transaction (73) with the creditable coverage flag set to “R” and the number of uncovered months value set to “000” with the effective date of February 1, 2008 because this is the effective date of his LIS eligibility.

These actions will reset his NUNCMO to zero, thereby, resetting the LEP amount to zero as well. Therefore, he will no longer be assessed the LEP based on 7 uncovered months effective February 1, 2008.

NOTE: LIS-eligible members are responsible for any unpaid LEP amount owed prior to the effective date of their LIS eligibility; and the Part D plan sponsor shall bill and collect the owed amount in accordance with §40.3 of this chapter.

C. Reporting Adjustments Due to Loss of LIS-Eligibility

If a beneficiary loses his/her LIS-eligibility after enrolling in a Part D plan, the previous number of uncovered months that were reset to zero shall not be reapplied, even if the beneficiary later incurs a break of more than 63 days in creditable prescription drug coverage. Additionally, if the beneficiary disenrolls from the Part D plan, incurs a qualifying break in creditable prescription drug coverage and subsequently re-enrolls in a Part D plan, the previously reset number of uncovered months (i.e., the number of uncovered months that were reset to zero) shall not be counted towards any new number of uncovered months.

Continuing with the example described above, consider the following:

Mr. Johnson incurred an LEP because he enrolled after the end of his Part D IEP, and did not have other creditable prescription drug coverage for the period of May 15, 2006 to December 31, 2006 (a total of 7 uncovered months). Mr. Johnson’s LEP
was removed effective February 1, 2008 because he was eligible for LIS as of that date. Assume Mr. Johnson then disenrolled from Plan RST. His last day of coverage with Plan RST was April 30, 2008. He later enrolled in Plan DEF effective January 1, 2009. Mr. Johnson was not LIS-eligible when he requested enrollment in Plan DEF, and did not have creditable prescription drug coverage for the period May 1, 2008 through December 31, 2008 (a total of 8 months). Accordingly, Plan DEF reported 8 uncovered months to CMS. CMS then reported to the plan the LEP amount for Mr. Johnson based on 8 uncovered months because none of the prior uncovered months (for the period of May 15, 2006 to December 31, 2006) were counted towards Mr. Johnson’s new penalty.

D. Reporting Adjustments Based on Subsequent Part D IEPs

As explained in §10.1.3 of this Chapter, an individual who is eligible for Medicare prior to turning age 65, will have a new (subsequent) Part D IEP based on entitlement to Medicare due to attaining age 65. Any uncovered periods prior to the first day of their subsequent Part D IEP will not be counted towards any future number of uncovered months.

As noted in §10.1.3, The Part D plan sponsor shall have a process in place for identifying members who are attaining age 65 or who have recently attained age 65; and shall notify the member of the removal of the LEP and shall use Exhibit 4: Model Notice—Removal of Late Enrollment Penalty Due to Subsequent IEP or create its own form using the requisite elements shown in the model, subject to CMS’s marketing review procedures. Additionally, for any LEP amount unpaid prior to the member’s subsequent IEP, the Part D plan sponsor shall bill in accordance with §40.3 of this chapter.

Depending on the specific situation, the Part D plan sponsor shall take one of the actions described below to accurately report the NUNCMO to CMS when a beneficiary incurs a subsequent IEP.

1. **Current Plan Members**

For individuals who are currently enrolled in a Medicare prescription drug plan at the start of their subsequent Part D IEP, the LEP ends on the day before the second IEP begins, which is three months prior to the month the individual attains age 65.

**Example:**

*Mrs. Smith is entitled to Medicare due to disability, but did not join a Medicare prescription drug plan when she was first eligible, and has been paying a LEP based on 9 uncovered months. Mrs. Smith turns age 65 on April 3, 2008. Her last day to be assessed an LEP is December 31, 2007, the day before her second or subsequent IEP begins on January 1, 2008.*
The Part D plan sponsor shall take the following steps to reset the NUNCMO to zero (0):

1. Submit a plan change transaction (73) with the creditable coverage flag set to “R”;
2. Submit the number value zero “000”; and
3. Submit the effective date of the transaction equal to the effective date of the first month of the new Part D IEP.

2. New Members Enrolling During their Subsequent IEP

For individuals with prior Part D enrollment, who are currently not enrolled in a D plan, who have previous uncovered months greater than zero (0), and who are enrolling during their subsequent IEP, the Part D plan sponsor shall take the following steps to reset the number of uncovered months to zero (“0”):

1. Submit an enrollment transaction (60, 61, 62, or 71)—not a plan change transaction (73)—with the creditable coverage flag set to “R”;
2. Submit the number value zero “000”; and
3. Submit the effective date of the transaction equal to the effective date of the enrollment

*Example:* 

Mrs. Johnson is currently not enrolled in a Part D plan, but had 12 uncovered months submitted by her previous Medicare prescription drug plan, Plan ABC. Mrs. Johnson was turning 65 on August 3, 2008. Her subsequent IEP was from May 1, 2008 through November 30, 2008. She decided to switch Medicare prescription drug plans during this period and enrolled in Plan XYZ in the month of July. Plan XYZ knew that Mrs. Smith was enrolling during her subsequent IEP and therefore submitted an enrollment transaction (61) with the creditable coverage flag set to “R” along with the number value 000 and the effective date August 1, 2008.

For individuals who are currently enrolled in a Part D plan, the current plan is responsible for resetting the number of uncovered months to zero as of the first day of the subsequent IEP. For this reason, if an enrollment request is received during the subsequent IEP, the plan receiving the new enrollment request should not have to take additional action to reset a prior number of uncovered months value.

3. Members Who Enrolled After Their Subsequent IEP

For individuals who did not enroll in a Medicare prescription drug plan by the end of their subsequent Part D IEP, who are currently not enrolled in a D plan and who have previous uncovered months greater than zero (0), the Part D plan sponsor shall take the steps outlined below to “reset” the first number of uncovered months value and
report any uncovered months incurred after the subsequent IEP so that a second LEP can be imposed:

(1) Submit the appropriate enrollment transaction with the creditable coverage flag set to “Y” and the number of uncovered months value set to “000.”
(2) Submit a plan change transaction (73) with the creditable coverage flag set to “R”; the number value equal to zero “000”; and the effective date of the transaction equal to the end date of the previous Medicare prescription drug plan enrollment; then
(3) After acceptance of the last change transaction, submit an additional plan change (73) transaction with the creditable coverage flag set to “N”; the number value equal to the number of uncovered months; and the effective date of the transaction equal to the current enrollment effective date.

Example:

Mr. Smith was entitled to Medicare based on disability in 2004. He did not enroll in a Medicare prescription drug plan by May 15, 2006. Instead, he enrolled in a Medicare prescription drug plan (Plan QRS) with his enrollment effective January 1, 2007. Following the attestation process, Plan QRS reported 7 uncovered months to CMS. Mr. Smith disenrolled from Plan QRS effective January 1, 2008. Mr. Smith turned age 65 on June 15, 2008. Therefore, his subsequent Part D IEP began March 1, 2008 and ended September 30, 2008. Mr. Smith did not enroll in a plan during his subsequent IEP. He later enrolled in Plan TUV effective January 1, 2009.

Within seven days of receiving Mr. Smith’s enrollment application, plan TUV submitted an enrollment transaction with creditable coverage flag (Y), zero (000) uncovered months, and the effective date 01/01/ 2009. Following the attestation process, Plan TUV determined that Mr. Smith had 3 uncovered months since the end of his subsequent Part D IEP. Plan TUV submitted a plan change transaction (73) with the creditable coverage flag set to “R” to reset Mr. Smith’s prior uncovered months (7) submitted by Plan QRS and submitted the number value (000) with the effective date December 31, 2007. Plan TUV then submitted another plan change transaction (73), set the creditable coverage flag to “N,” and the number of uncovered months’ value of (003), with the enrollment effective date of January 1, 2009. The number of uncovered months now shows that Mr. Smith had 7 uncovered months from 01/01/2007 through 12/31/2007. As of 12/31/2007, this value was reset to 0. As of 01/01/2009, Mr. Smith has a number of uncovered months of 003. The LEP for Mr. Smith is 3% beginning 01/01/2009 and going forward.

E. Reporting Corrections to Creditable Coverage Period Determinations

In the event the Part D plan sponsor discovers it has reported an incorrect number of uncovered months to CMS, the Part D plan sponsor shall submit a plan change (73) transaction in accordance with §30.1.2. In all cases where a correction to the member’s uncovered months are made due to plan error as described in this subsection, the Part D plan sponsor that adjusted the number of uncovered months due to the error it made, shall advise the member of the adjustment within ten (10) calendar days of receiving confirmation from CMS that the transaction was accepted.
The Part D plan sponsor shall use the model notice *Exhibit 6: Model Notice Informing the Beneficiary of LEP Adjustment Due to Plan Error* or create its own form using the requisite elements shown in the model, subject to CMS’s marketing review.

If the member is no longer enrolled in the plan that submitted the number of uncovered months that need to be corrected, the Part D plan sponsor shall follow the instructions for submitting a plan change (73) transaction in accordance with §30.2 of this chapter.

If the change to the number of uncovered months results in the imposition of or increase in the LEP (where the increase is due to reporting additional uncovered months except where the increase is due to a reconsideration), the plan must include the *Appendix 14--LEP Reconsideration Notice* and *Appendix 15—Reconsideration Request Form* with this notice. If, however, such a change results in the elimination or reduction of the LEP, the beneficiary is afforded no new reconsideration rights and the Part D plan sponsor shall not include the *Appendices 14 and 15*.

In cases where the member has already requested a review of the LEP and CMS’s independent review entity (Maximus) has notified the plan of a pending reconsideration request (i.e., Maximus has requested the case file from the plan), the plan must contact Maximus to alert them of the change and provide documentation of the change. Plans should use the fax number noted on the LEP Reconsideration Case File Request Form to communicate this information to Maximus. If the correction results in the removal of the LEP (i.e., the NUNCMO = zero (0)), Maximus will then dismiss the case because there are no longer uncovered months in dispute. If, however, the correction does not eliminate the LEP, Maximus will then proceed with its review of the LEP based on the new information that the plan used to adjust the member’s uncovered months.

Also, in limited, circumstances, there may be a change to the number of uncovered months because of a corresponding change in a member’s enrollment effective date. In such cases, the Part D plan sponsor shall correct the previously reported number of uncovered months by submitting a plan change (73) transaction in accordance with §30.1.2 of this chapter.

**F. Reporting Adjustments Due to Reconsideration Decisions**

As noted in §60, the Part D plan sponsor shall refer to Chapter 18, §80.7.1 *Reconsideration of Late Enrollment Penalty Determinations* of this manual for a detailed explanation of the LEP Reconsideration process.

Reconsideration decisions may uphold, increase, decrease or eliminate the number of uncovered months previously submitted by a Part D plan sponsor. If the member is still enrolled in the Part D plan sponsor that imposed the number of uncovered
months to be adjusted, the Part D plan sponsor shall take the steps outlined below to remove or adjust the number of uncovered months previously reported:

- To remove the LEP, the Part D plan sponsor shall:
  1. Submit a plan change transaction (73) with the creditable coverage flag “Y”;
  2. Set the number value to zero (“000”); and
  3. Set the effective date of the transaction equal to the effective date of the member’s enrollment in the plan.

- To adjust the number of uncovered months to a number other than “0”, the Part D plan sponsor shall:
  1. Submit a plan change transaction (73) with the creditable coverage flag “N”;  
  2. Set the number value equal to the number of uncovered months; and
  3. Set the effective date of the member’s enrollment in the plan.

The Part D plan sponsor shall take the appropriate action and report the revised number of uncovered months to CMS within 14 calendar days of receiving a reconsideration decision from CMS’s IRE.

If the member is no longer enrolled in the Medicare Part D plan sponsor that imposed the number of uncovered months to be adjusted, the Part D plan sponsor shall follow the steps in §30.2 of this chapter.

The Part D plan sponsor that imposed the number of uncovered months to be removed shall notify its member (or former member in cases where the member has disenrolled prior to the outcome of the reconsideration request) of any adjustment to his/her LEP as a result of a reconsideration decision by CMS’s IRE. The Part D plan sponsor shall use Exhibit 7: Model Notice—Confirm Adjustment of Premium Based on Reconsideration of Late Enrollment Penalty or create its own form using the requisite elements shown in the model, subject to CMS’s marketing review procedures. If the Part D plan sponsor that imposed the number of uncovered months collected an LEP based on the previous uncovered months, it shall issue a refund to the member in accordance with §60.3.

NOTE: In cases where the Part D plan sponsor that imposed the number of uncovered months to be removed receives notice of a partially or fully favorable LEP reconsideration on behalf of a deceased member, the Part D plan sponsor shall submit a plan change transaction and send the beneficiary’s estate notification in accordance with this chapter.

30.5 - Reporting Adjustments on Behalf of Current Members for Prior Periods

In general, a member’s current plan can submit changes to his/her number of uncovered months for any time period prior to the member’s enrollment in the plan,
and for any period during which s/he is currently enrolled in the Medicare prescription drug plan using the prospective regular batch file process.

The effective date of the plan change (73) transaction may be retroactive but cannot be prior to June 1, 2006. The effective date on the plan change (73) transaction can be prospective, but not beyond the current payment month plus two months (CPM+2).

When the member’s current plan submits changes to the number of uncovered months, it will receive a transaction reply code (TRC) on the transaction reply report (TRR) regarding the adjustment and a recalculated LEP amount on the LIS/LEP Report for members in direct bill status and the MPWRD for members in premium withhold status. Additionally, when applicable, the member’s previous plan(s) will be impacted by this change to the uncovered months. Therefore, prior plan(s) affected by this change will receive information regarding changes to the uncovered months and recalculated LEP only on the LIS/LEP Report for members who are in direct bill status and the MPWRD for members in premium withhold status.

NOTE: The plan that submits the change to an individual’s uncovered months will be the entity that receives a transaction reply on the TRR. The affected plans will see the change on the Low Income Subsidy/Late Enrollment Penalty (LIS/LEP) for members in direct bill status and on the Monthly Premium Withholding Report/Data file (MPWRD) for members in premium withhold status.

There will be instances when a member will no longer be enrolled in the Medicare prescription drug plan that imposed the number of uncovered months to be adjusted as a result of a reconsideration decision rendered by CMS’s IRE. In this situation, CMS’s IRE will mail a copy of its reconsideration determination letter to the member’s current Part D plan sponsor, as well as the prior plan that imposed the number of uncovered months to be adjusted. The member’s current Medicare prescription drug plan may (but is not required to) adjust the number of uncovered months previously reported by the member’s prior plan. If the plan does report an adjustment to the uncovered months, it must then notify the member, using Exhibit 7: Model Notice—Confirm Adjustment of Premium Based on Reconsideration of Late Enrollment Penalty—of the adjustment and refund any LEP amounts collected, in accordance with §60 of this chapter.

Example:

Mrs. Brown enrolled in Plan CDE effective January 1, 2008. Plan CDE determined that Mrs. Brown had five (5) uncovered months during which she was not enrolled in Part D and did not have other creditable coverage and reported this information to CMS. Plan CDE notified Mrs. Brown of the LEP, advised her of her right to request reconsideration, and collected the LEP owed since January 1, 2008, in accordance with CMS guidance. Mrs. Brown requested CMS’s IRE to review her LEP in a timely manner.
manner. While her request was pending with CMS’s IRE, Mrs. Brown disenrolled from Plan CDE effective March 31, 2008, and enrolled in Plan DEF effective April 1, 2008. CMS’s IRE found that Mrs. Brown did have creditable coverage during the 5 months in question, and issued a favorable decision for Mrs. Brown in April 2008. Plans CDE and DEF received a copy of the decision rendered by CMS’s IRE.

Plan CDE must use the process described in §30.2 of this chapter to submit a batch retro file that contains a Plan Change (73) transaction changing the number of uncovered months from “005” to “000” and the creditable coverage flag from “N” to “Y” and using a header date of “012008” (January 2008), “022008” (February 2008), or “032008” (March 2008). Plan CDE submits the change as directed, and receives a transaction reply code showing that the change was accepted and another one showing that the LEP has also changed. Plan CDE notifies Mrs. Brown that the LEP was removed effective January 1, 2008, and refunds any LEP collected since that time.

Plan DEF receives the information regarding the change to Mrs. Brown’s uncovered months and LEP on the Low Income Subsidy/Late Enrollment Penalty (LIS/LEP) Report since she is in direct bill status. Plan DEF also notifies Mrs. Brown that her plan premium was reduced as a result of the reconsideration decision and refunds any LEP collected since her enrollment in Plan DEF was effective on April 1, 2008.

Although Plan DEF is not required to make the adjustment to Mrs. Brown’s uncovered months (as Plan CDE is required to do so), Plan DEF could have submitted a Plan Change (73) transaction for the entire period in question – from January 1, 2008 up through the current payment month – through the regular batch file process, with the same results.

40 - CMS CALCULATING & REPORTING LEP TO PART D PLAN SPONSORS

40.1 - Calculating the LEP

CMS is the only entity authorized to calculate the beneficiary’s LEP amount. Currently, the LEP is assessed as 1% of the national base beneficiary premium for the coverage year times the total number of uncovered months, regardless of the year(s) in which those months occurred. The LEP amount is rounded to the nearest ten cents.

Note: The national base beneficiary premium used in the calculation of the LEP is not the part D plan sponsor’s premium. It is a national amount that is a function of the national average bid for the year in which the beneficiary is enrolled in a Part D plan sponsor. Therefore, even if there is no change in the number of uncovered months, the LEP may change each year because it is recalculated using the total number of uncovered months and the national base beneficiary premium for that particular year.
Example:
Mr. Jones enrolled in Plan XYZ effective January 1, 2009. Plan XYZ determined that Mr. Jones had a gap in creditable prescription drug coverage following the end of his Part D IEP. Therefore, Plan XYZ reported 5 uncovered months. Although Mr. Jones had uncovered months in 2008, CMS calculated the 5 uncovered months based on the 2009 national base beneficiary premium for the coverage year 2009 which is $30.36 and arrived at the amount of $1,518. CMS rounded this amount to the nearest ten cents and informed Plan XYZ that Mr. Jones’ Part D LEP amount is $1.50.

If the Part D plan sponsor receives a general inquiry about how the LEP is calculated, it shall inform the enrollee of the process by which CMS assesses the LEP, and if applicable, the number of uncovered months the Part D plan sponsor reported to CMS. However, the Part D plan sponsor shall not estimate the LEP and inform the beneficiary of that amount. The Part D plan sponsor shall wait for CMS to notify the Part D plan sponsor of the LEP amount and then inform the beneficiary of that amount using the appropriate notice as explained in §50.

If an inquiry is made about the likelihood of a beneficiary being assessed an LEP, but no enrollment request has been submitted on behalf of that beneficiary, the Part D plan sponsor shall exercise care when explaining the policy, since any explanation, (e.g., including hypothetical scenarios with beneficiary-specific information) may be interpreted by the beneficiary as official creditable coverage period determinations and an actual LEP amount.

### 40.2 - LEP Reports to Plans

According to §50, Part D plan sponsors are required to notify members, in writing, of the imposition of or adjustment to an LEP within 10 calendar days (or unless otherwise noted in this Chapter) of receiving notice of the LEP from CMS. Notification from CMS is in the form of several reports that are summarized in the table below. The 10-day reporting timeframe starts with the first report from CMS that contains the member-specific LEP.

For example, if information is first available in the LIS/LEP Report (for members in direct bill status) or the Monthly Premium Withholding Report Data File (for members in premium withhold status), the Part D plan sponsor has 10 calendar days from the receipt of these reports to notify the member of the LEP.

<table>
<thead>
<tr>
<th>Name of Data File/Report</th>
<th>Availability</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weekly Transaction Reply Report (Weekly TRR) (only includes information about beneficiaries for whom a transaction was submitted during the prior week)</td>
<td>Weekly</td>
</tr>
<tr>
<td>Monthly Transaction Reply Report (Monthly TRR)</td>
<td>Monthly</td>
</tr>
</tbody>
</table>
(only includes information about beneficiaries for whom a transaction was submitted during the prior month)

<table>
<thead>
<tr>
<th>Description</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low-Income Subsidy/Late Enrollment Penalty (LIS/LEP) (direct bill beneficiaries only)</td>
<td>Monthly</td>
</tr>
<tr>
<td>Monthly Premium Withholding Report Data File (MPWRD) (beneficiaries in premium withhold status only)</td>
<td>Monthly</td>
</tr>
</tbody>
</table>

The weekly/monthly TRR will show the LEP amount and number of uncovered months it submitted. However, to determine the members’ total number of uncovered months, i.e., the number of uncovered months submitted by all Part D plan sponsors on which the total LEP amount is based, the Part D plan sponsor can review the Common UI M231—Beneficiary Detail Premium Screen, the M232—Beneficiary Eligibility Screen, and the BEQ Response File.

NOTE: The data files, reports, and information contained in the Common UI and BEQ Response File are described in detail in the Plan Communications Users Guide (PCUG). The Part D plan sponsor shall use the most recent PCUG or updated guidance from CMS to learn of any changes to the location of the LEP.

### 40.3 - Annual Changes in LEP Amounts

At the start of each calendar year, the LEP amount will change based on the change to the national base beneficiary premium. While there is no Transaction Reply Code (TRC) associated with this change, Part D plan sponsors will see the adjustment in the December LIS/LEP Report for January 1st plan payment and the January Monthly Premium Withhold Report for February 1st play payment. These reports will be released in accordance with the reports schedule contained in the Plan Communications User Guide.

Part D plan sponsors shall adjust their bills accordingly to reflect the new amount and include notification of this new amount in their premium bill or via a separate notice. If the Part D plan sponsor chooses to notify its member about this change to his/her LEP, it may use Exhibit 9: Model Notice—Yearly Change to LEP Amount, or create its own.

NOTE: The reconsideration process is not available for adjustments to the LEP based on a change to the national base beneficiary premium. Therefore, the Part D plan sponsor shall not include Appendix 14—LEP Reconsideration Notice and Appendix 15—Reconsideration Request Form with notice of the adjusted LEP.
50 - NOTIFICATION TO BENEFICIARIES OF THE LATE ENROLLMENT PENALTY

50.1 - Notification of LEP Based on a Creditable Coverage Period Determination

This subsection provides the notice requirements the Part D plan sponsor shall follow when a creditable coverage period determination is made in accordance with §10. The Part D plan sponsor shall follow the notice requirements outlined in §30.4 in cases where a creditable coverage period determination has been made and reported to CMS, but later needs to be adjusted.

The Part D plan sponsor that submitted the number of uncovered months which results in an imposition of or increase in the LEP (where the increase is due to reporting additional uncovered months) shall provide the beneficiary a written notice about the LEP within 10 calendar days of receiving notice of the LEP from CMS (as described in subsection §40.2.1 of this chapter) and information about how to request a review of the penalty. The Part D plan sponsor shall mail the member Exhibit 2: Model Notice—Beneficiary Notice of Late Enrollment Penalty, as well as Appendix 14—LEP Reconsideration Notice and Appendix 15—Reconsideration Request Form.

If the Part D plan sponsor creates its own notice, it must use the following requisite elements:

1) Beneficiary’s name;
2) Monthly premium (in dollars and cents) for the current year, and provide what portion of that premium is the LEP;
3) Effective date of the penalty;
4) Basis for LEP in terms of the number of uncovered months reported to CMS; and
5) Information about the beneficiary’s right to request reconsideration (review) of the LEP and the reconsideration filing deadline using the requisite elements described in Appendix 14—LEP Reconsideration Notice and Appendix 15—Reconsideration Request Form located in Chapter 18 of this manual.

Note: The Part D plan sponsor shall only include Appendices 14 and 15 when there is an imposition of or increase to an LEP (where the increase is due to reporting additional uncovered months). The Part D plan sponsor shall not include Appendix 14—LEP Reconsideration Notice and Appendix 15—Reconsideration Request Form when notifying a beneficiary of an adjustment due to a reconsideration decision.
50.2 - Notification of LEP Imposed by Prior Part D Plan Sponsor

This subsection provides the notice requirements for Part D plan sponsors who have members with prior Part D enrollments and an LEP is imposed or adjusted by the member’s prior plan after the member has disenrolled from that plan.

The LEP amount that a member is currently paying (or has previously paid) may change when a member’s prior plan delays making a creditable coverage period determination (see §10.3.1 and §30.2) or adjusts a creditable coverage period determination it previously reported to CMS (see §30.4). As a result, the member’s subsequent plan(s) will be impacted because this will result in a change to the LEP amount the subsequent plan(s) is billing, has billed, or needs to bill. When this occurs, the member’s subsequent plan(s) shall notify the member that it either owes the member a refund or that the member owes the subsequent plan(s) additional payment as a result of adjustment. Unless otherwise noted in this chapter, the subsequent(s) plan shall notify the member of the imposition of or adjustment to the LEP using Exhibit 11: Model Notice – Beneficiary Notification of LEP Adjustment Reported within 10 calendar days of receiving notice from CMS about the beneficiary’s LEP.

The subsequent plan(s) shall notify the member of the adjusted LEP in cases where the new or adjusted creditable coverage period determination removes, reduces, imposes, or increases the LEP. In all cases, however, the subsequent plan(s) shall not include Appendix 14—LEP Reconsideration Notice and Appendix 15—Reconsideration Request Form.

If the subsequent plan(s) creates its own notice, it must use the following requisite elements:

1) Beneficiary’s name;
2) The full LEP amount to be refunded or owed (in dollars and cents). (If the member is currently in a plan affected by the change, it shall include the monthly premium amount and provide what portion of that premium is the LEP);
3) Effective date of the penalty owed or to be refunded;
4) Basis for LEP in terms of the number of uncovered months reported to CMS; and
5) A statement explaining that the plan was notified by CMS regarding the LEP.

The subsequent plan(s) shall bill or refund any LEP in accordance with §60 of this chapter.
50.3 - Notification of Existing LEP

In cases where the member’s subsequent plan(s) is aware of an existing LEP at the time of enrollment, it may also use Exhibit 3: Model Notice—Beneficiary Notice of Existing Late Enrollment Penalty to remind the member that he/she has an existing LEP. However, the Part D plan sponsor is not required to provide additional information about an existing LEP. If the Part D plan sponsor opts to remind a member of an existing LEP using this form it shall not include Appendix 14—LEP Reconsideration Notice and Appendix 15—Reconsideration Request Form as this notification does not trigger the right to request a review of the LEP.

If the subsequent plan(s) creates its own notice, it must use the following requisite elements:

1) Beneficiary’s name;
2) The full LEP amount to be refunded or owed (in dollars and cents). (If the member is currently in a plan affected by the change, it shall include the monthly premium amount and provide what portion of that premium is the LEP);
3) Effective date of the penalty owed or to be refunded;
4) Basis for LEP in terms of the number of uncovered months reported to CMS; and
5) A statement explaining that the plan was notified by CMS regarding the LEP.

50.4 - Notice of LEP When Employer/ Union Sponsors Pays the LEP

In cases where an employer or union sponsors prescription drug coverage for its members through the Part D plan sponsor, and the employer or union elects to pay the LEP on behalf of its members, the Part D plan sponsor shall inform the beneficiary that the employer or union has agreed to pay the LEP on his/her behalf. The Part D plan sponsor shall also inform the beneficiary that, if the coverage is terminated by him/her or by the employer or union sponsoring the Part D plan sponsor, the beneficiary will be responsible for paying the LEP if and when he/she enrolls into another Part D plan sponsor. Exhibit 2: Model Notice—Beneficiary Notice of Late Enrollment Penalty provides model paragraphs that Part D plan sponsors can use to convey this information.
60 - BILLING, COLLECTING, AND REFUNDING THE LEP

60.1 - Billing and Collecting the LEP from Members in Direct Bill Status

In accordance with 42 CFR §§423.286(d)(3) and 423.293(a)(1), the LEP is part of the Part D premium. Therefore, the Part D plan sponsor shall bill and collect it in the same manner it does the non-LEP portion of its member’s premium once it receives information from CMS about the amount in accordance with §40.2 of this chapter. The same is also true for the Part D plan sponsor that has a zero ($0) premium—members enrolled in such plans with LEPs must be billed and must be permitted to pay monthly—42 CFR 423.293(a)(2).

The Part D plan sponsor shall bill and make a reasonable attempt to collect any LEP amounts owed since the beneficiary’s enrollment effective date but no earlier than January 1, 2007. The Part D plan sponsors shall also bill and make a reasonable attempt to collect any unpaid LEP from its former members.

For members that are billed directly for the Part D premium (i.e., members in direct bill status), the Part D plan sponsor shall bill such members for the LEP at the same time it bills for the Part D plan premium. The plan sponsor may choose to issue a separate invoice for the LEP and indicate that it is due at the same time as the non-LEP premium, or the plan sponsor may itemize the LEP amount on the same invoice as the non-LEP premium. Additionally, plans may establish a quarterly or annual billing cycle, but must always afford the member the option of monthly payment. The member must be permitted to actively choose among the various billing cycles a plan may provide.

Due to the time associated with the creditable coverage period determination process, in most cases, plans will initially have to bill members for LEP amounts retroactively. When this occurs, the Part D plan sponsor must bill and collect the retroactive LEP amount and may retroactively bill members for the past-due amount. Note that in all cases, even where the LEP is imposed or adjusted by a member’s prior plan after the member has disenrolled from that plan, the Part D plan sponsor must bill and make a reasonable attempt to collect the LEP. (See §§10.3.1, 30.2, 30.4, and 50 of this chapter).

60.1.2 - Members in Premium Withhold Status

The Part D plan sponsor shall not bill members who are in premium withhold status, but shall notify the member of the LEP amount, in accordance with §50 of this chapter. The Social Security Administration (SSA) will take the necessary actions to collect the LEP amount from the member who has elected the SSA premium withhold
option. SSA accomplishes this by increasing the withhold amount by the amount of the LEP.

60.1.3 - Billing Employer or Union Sponsors

If an employer or union sponsors prescription drug coverage for its members through the Part D plan, the plan sponsor may bill the employer or union directly for any LEP if both parties agree.

60.1.4 - Billing the LEP During the Reconsideration Process

In cases where the member has filed a request for reconsideration, the Part D plan sponsor shall continue to bill (and SSA will continue to withhold) the LEP as part of the premium. The Part D plan sponsor shall not allow its member to forego paying his/her LEP until a decision is rendered by CMS’s IRE.

Unless otherwise authorized by CMS, the Part D plan sponsor shall adjust the amount it bills the member only after the Part D plan sponsor has submitted a plan change (73) transaction to change the number of uncovered months based on the reconsideration decision and CMS has notified the Part D plan sponsor of the new LEP amount. In the event that the IRE determines that no LEP is owed, the sponsor shall promptly cease collection of the LEP and refund any LEP amount paid.

60.2 - Failure to Pay the LEP Portion of the Premium

If the Part D plan sponsor has opted to have a policy of involuntary disenrollment for failure to pay plan premiums (as explained in the enrollment guidance appropriate to your plan type), then it must also disenroll members who fail to pay the LEP portion of their premium. Plans may not selectively enforce this policy. However, the Part D plan sponsor can choose to set a threshold amount for non-payment of premiums before it disenrolls a member who fails to pay.

60.3 - Refunding the LEP

In accordance with §30.4 of this chapter, there are circumstances in which a creditable coverage period determination has been made and reported to CMS, but later needs to be adjusted. In cases where the adjustment reduces or removes the number of uncovered months previously reported, the Part D plan sponsor that imposed the number of uncovered months to be adjusted (as well as any subsequent Part D plan sponsor that billed the member a LEP based on the previously reported number of uncovered months to be adjusted), shall refund (or credit the member’s future bill) any LEP amount paid by the member based on such uncovered months. If
the adjustment to the previously reported number of uncovered months results in a reduction rather than a removal of uncovered months, CMS will also provide the new number of uncovered months.

In cases where an individual has disenrolled from the Part D plan sponsor that imposed the number of uncovered months that was adjusted and is enrolled in another Medicare prescription drug plan, CMS will also notify the member’s current plan of the refund amount and, if applicable, the new number of uncovered months.

Any Part D plan sponsor(s) that collected LEP payments based on the previously reported uncovered months shall notify the member of the LEP refund owed (see §50 of this chapter) and refund the LEP (or apply the amount to a future premium bill) promptly. If the beneficiary’s premium was withheld from his/her Social Security benefits, CMS and SSA will take the necessary action to refund the LEP withheld as part of the premium.

The amount to refund the beneficiary can be found on the LIS/LEP and MPWRD Reports for members in direct bill and premium withhold statuses respectively.

70 - LEP RECONSIDERATION PROCESS

Part D plan sponsors shall refer to Chapter 18, §80.7.1 Reconsideration of Late Enrollment Penalty Determinations of this manual for a detailed explanation of the LEP Reconsideration Process.

80 - INFORMATION RETENTION REQUIREMENTS

In accordance with 42 CFR §423.46(d), Part D plan sponsors are required to retain all information collected concerning creditable coverage period determinations in the same manner as enrollment records. That is, the Part D plan sponsor shall retain creditable coverage period determinations for the current contract period and 10 (ten) prior periods. (See the appropriate CMS enrollment guidance for more information about these requirements). Similarly, the Part D plan sponsor shall also retain copies of any evidence of creditable coverage, including attestation forms, and any information regarding LEP reconsideration decisions.
Appendices
## Appendix 1: Summary of MARx Transactions to Add, Change, or Remove the Number of Uncovered Months for an Enrolled Beneficiary

<table>
<thead>
<tr>
<th>Action</th>
<th>Creditable Coverage Flag Value</th>
<th>Number of Uncovered Months Field Value</th>
<th>Effective Date on Transaction Code 73**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Submit a new number of uncovered months that is greater than 0</td>
<td>N</td>
<td>Number greater than 0</td>
<td>Equal to existing enrollment effective date&lt;br&gt;Note: This information may also be provided on an enrollment transaction (60/61/62/71),</td>
</tr>
<tr>
<td>Change an existing number of uncovered months</td>
<td>N</td>
<td>Revised number greater than 0</td>
<td>Equal to existing enrollment effective date</td>
</tr>
<tr>
<td></td>
<td>Y</td>
<td>0</td>
<td>Equal to existing enrollment effective date</td>
</tr>
<tr>
<td>Reset the existing number of uncovered months to 0 due to another IEP for Part D</td>
<td>R</td>
<td>0</td>
<td>Equal to the effective date of the 1st month of the new IEP for Part D or as otherwise noted in this chapter.</td>
</tr>
<tr>
<td>Reset the existing number of uncovered months to 0 due to an individual becoming LIS eligible.</td>
<td>R</td>
<td>0</td>
<td>Equal to the effective date of the start of LIS eligibility.</td>
</tr>
<tr>
<td>Correct Erroneous Reset action already submitted</td>
<td>U</td>
<td>0</td>
<td>Effective date is equal to the date of the reset “R” transaction. (Page 5 of Fall Memo).</td>
</tr>
<tr>
<td>Submit a new number of uncovered months or change uncovered months for a former member</td>
<td>Insert the correct value as/per the directions above for the desired change</td>
<td>Insert the correct value as/per the directions above for the desired change</td>
<td>Equal to original enrollment effective date&lt;br&gt;You must contact MMA Help Desk to obtain a ticket number to request the submission of a batch retro file to report these transactions.</td>
</tr>
</tbody>
</table>

*For more information about MARx transactions, please consult the October 9, 2007 HPMS Memo re: Announcement of Fall Software Changes and current CMS Plan Communications User Guide.

**For more information about the 73 Transaction, please consult the January 9, 2009 HPMS Memo re: Announcement of Spring 2009 Software Release.
Appendix 2: Creditable Coverage Period Determination/Late Enrollment Penalty Exhibits

<table>
<thead>
<tr>
<th>Exhibit</th>
<th>Notice</th>
<th>Required?</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>1A</td>
<td>Beneficiary Cover Letter for Individuals with Break in Coverage</td>
<td>Yes – only for beneficiaries with prior RDS or Medicare Part D coverage</td>
<td>Within 7 calendar days of receipt of the Beneficiary Eligibility Query response</td>
</tr>
<tr>
<td>1B</td>
<td>Beneficiary Cover Letter for Individuals Newly Enrolled in Medicare Drug Plan</td>
<td>Yes – for beneficiaries new to Medicare Part D coverage</td>
<td>Within 7 calendar days of receipt of the Beneficiary Eligibility Query response</td>
</tr>
<tr>
<td>1C</td>
<td>Frequently Asked Questions and Answers</td>
<td>Yes</td>
<td>As attachment to 1A, 1B, 1E and 1F</td>
</tr>
<tr>
<td>1D</td>
<td>Declaration of Prior Prescription Drug Coverage</td>
<td>Yes</td>
<td>As attachment to 1A, 1B, 1E and 1F</td>
</tr>
<tr>
<td>1E</td>
<td>“Final Notice” Beneficiary Cover Letter for Individuals with Break in Coverage</td>
<td>No</td>
<td>Must be mailed with a deadline return date that will allow plans enough time to meet the plans reporting deadline to CMS</td>
</tr>
<tr>
<td>1F</td>
<td>“Final Notice” Beneficiary Cover Letter for Individuals Newly Enrolled in Medicare Drug Plan</td>
<td>No</td>
<td>Must be mailed with a deadline return date that will allow plans enough time to meet the plans reporting deadline to CMS</td>
</tr>
<tr>
<td>2</td>
<td>Model Notice – Beneficiary Notice of Late Enrollment Penalty</td>
<td>Yes</td>
<td>Within 10 calendar days of receiving first notification from CMS regarding the beneficiary-specific LEP information</td>
</tr>
<tr>
<td>3</td>
<td>Model Notice - Beneficiary Notice of Existing Late Enrollment Penalty</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>4</td>
<td>Model Notice - Removal of Late Enrollment Penalty Due to Subsequent IEP</td>
<td>Yes</td>
<td>Within 10 calendar days of receiving first notification from CMS regarding the beneficiary-specific LEP information</td>
</tr>
<tr>
<td></td>
<td>Model Notice - Removal of the LEP Due to LIS Eligibility</td>
<td>Yes</td>
<td>Within 14 calendar days of receiving information about LIS status from CMS</td>
</tr>
<tr>
<td>---</td>
<td>--------------------------------------------------------</td>
<td>-----</td>
<td>--------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>6</td>
<td>Model Notice – LEP Adjustment Due to Plan Error</td>
<td>Yes</td>
<td>Within 10 calendar days of receiving confirmation from CMS that transaction was accepted</td>
</tr>
<tr>
<td></td>
<td>(to be sent with Appendices 14 and 15 as attachments if error imposes or increases LEP due to reporting additional uncovered months).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Model Notice - Confirm Adjustment of Premium After Reconsideration of Late Enrollment Penalty</td>
<td>Yes</td>
<td>Within 10 calendar days of receiving first notification from CMS regarding the beneficiary-specific LEP information</td>
</tr>
<tr>
<td>8</td>
<td>Model Notice - Return of Creditable Coverage Information Received Without an Accompanying Enrollment Request</td>
<td>Yes</td>
<td>Within 10 calendar days of the plan’s receipt of creditable coverage information from beneficiary</td>
</tr>
<tr>
<td>9</td>
<td>Model Notice - Yearly Change in LEP Amount</td>
<td>No</td>
<td>N/A</td>
</tr>
<tr>
<td>10</td>
<td>Model Notice - Creditable Coverage Information Received After Deadline</td>
<td>Yes, if attestation information is provided more than 60 days past attestation return deadline</td>
<td>Send no earlier than the 61st day following the deadline return date on beneficiary’s attestation form but no later than 10 calendar days following receipt of the late attestation form or creditable coverage information.</td>
</tr>
<tr>
<td>11</td>
<td>Model Notice – Beneficiary Notification of LEP Adjustment Reported</td>
<td>Yes</td>
<td>Within 10 calendar days of receiving notice of the LEP information from CMS</td>
</tr>
<tr>
<td>Appendix 14</td>
<td>Model Notice - Part D Late Enrollment Penalty Reconsideration Notice</td>
<td>Yes</td>
<td>As attachment to 2 and 6</td>
</tr>
<tr>
<td>Appendix 15</td>
<td>Model Notice - Part D Late Enrollment Penalty</td>
<td>Yes</td>
<td>As attachment to 2 and 6</td>
</tr>
<tr>
<td>Reconsideration Request Form</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NOTE: The marketing material code(s) for these models can be found in HPMS. Plans must use the appropriate marketing code(s) and can use these models as “file and use.” The marketing codes are located at the top of each Exhibit.
EXHIBITS

Model Forms & Notices
<Date of Notice>

<Insert Name of Enrollee>
<Insert Enrollee’s Full Mailing Address>
<Insert Enrollee’s ID Number>

<Insert Name of Enrollee>:

You recently enrolled in <insert name of Plan> prescription drug plan and Medicare’s records show that you may owe a late enrollment penalty.

Prior to enrolling in the <insert name of Plan>, it appears that you had a break in prescription drug coverage from <insert first day without creditable prescription drug coverage in month/day/year format> to <insert last day without creditable prescription drug coverage in month/day/year format>. If you did not have prescription drug coverage during this time period that met Medicare’s minimum standards, you will owe a penalty on your monthly premiums. If you did have prescription drug coverage during this time period, you may be able to avoid the penalty by returning the enclosed form.

Please complete the enclosed form and return it immediately to <insert the name of plan and complete mailing address> [insert the following if you offer telephonic attestation: or call us at <insert plan’s toll-free number and toll-free TTY number> to provide us with the information] by <insert the date that is 30 days from the date of this letter in month/day/year format>.

<Contract#, Material ID#, CMS approval date (if applicable)>
If you don’t contact <insert name of plan> by <insert the date that is 30 days from the date of this letter in month/day/year format>, we will assume the above information is correct and you will owe a late enrollment penalty.
Exhibit 1B: Beneficiary Cover Letter for Individuals Newly Enrolled in Medicare Drug Plan (HPMS Code 8013)

<Insert Name of Enrollee>  
<Insert Enrollee’s Full Mailing Address>  
<Insert Enrollee’s ID Number>

<Insert Name of Enrollee>:  

Prior to enrolling in the <insert name of Plan>, it appears that you did not have prescription drug coverage that met Medicare’s minimum standards. If your records show that you did have prescription drug coverage from <insert first day without creditable prescription drug coverage in month/day/year format> to <insert last day without creditable prescription drug coverage in month/day/year format>, you may be able to avoid paying the monthly penalty by returning the enclosed form.

Please complete the enclosed form and return it immediately to <insert the name of plan and complete mailing address> [insert the following if you offer telephonic attestation: or call us at <insert plan’s toll-free number and toll-free TTY number> to provide us with the information] by <insert the date that is 30 days from the date of this letter in month/day/year format>.

If you don’t contact <insert name of plan> by <insert the date that is 30 days from the date of this letter in month/day/year format>, we will assume the above information is correct and you will owe a late enrollment penalty.
Avoid a Penalty Related to Your Medicare Prescription Drug Plan Premium!

If you fail to respond to this notice by *<insert the return date located on the Beneficiary Cover Letter in name of month, day, and four digit year format>*<sup>1</sup>, you will owe a penalty. You may be able to avoid a penalty by completing the attached “Declaration of Prior Prescription Drug Coverage” form or calling your Medicare drug plan directly to provide this information.

**Why am I getting this letter?**

*<Insert name of plan>* has sent you the attached form because it appears that you had a break in prescription drug coverage for 63 days or more and you may owe a penalty. We need you to complete the enclosed form or call us to give more information about your prior drug coverage. This information will help us determine if you had coverage that met Medicare’s minimum standards and can avoid paying the late enrollment penalty.

**What is the Part D late enrollment penalty?**

The late enrollment penalty is an amount added to your monthly Medicare drug plan (Part D) premium for as long as you have Medicare prescription drug coverage. This penalty is required by law and is designed to encourage people to enroll in a Medicare drug plan when they are first eligible or keep other prescription drug coverage that meets Medicare’s minimum standards.

You may owe a late enrollment penalty if you didn’t join a Medicare drug plan when you were first eligible for Medicare Part A and/or Part B, and:

- You didn’t have other prescription drug coverage that met Medicare’s minimum standards; OR

<Contract#, Material ID#, CMS approval date (if applicable)>
• You had a break in coverage of at least 63 days.

**How do I know if my prior prescription drug coverage met Medicare’s minimum standards?**
Most plans that offer prescription drug coverage, like plans from employers or unions, must send their members a notice explaining how their prescription drug coverage compares to Medicare prescription drug coverage. This notice tells you if the prescription drug coverage you had through your prior plan was “creditable prescription drug coverage,” which means that it met Medicare’s minimum standards. If you didn’t get a separate written notice, your plan may have provided this information in its benefits handbook. If you don’t know if the prescription drug coverage you had met this standard, you should contact your prior plan.

**When do I need to respond?**
You must respond by <insert the return date located on the Beneficiary Cover Letter in name of month, day, and four digit year format> to avoid the penalty.

**Where do I return the form?**
**Option 1:** <Delete this heading if you do not offer telephonic attestation and do not include Option 2 below>
Complete the “Declaration of Prior Prescription Drug Coverage” form attached to this sheet and mail it back to your Medicare drug plan at:

<Insert name of plan>

<Insert complete mailing address>

<Insert “Option 2” as shown below, if you offer telephonic attestation>

**Option 2:**
Instead of completing the enclosed form, you can call your Medicare drug plan to provide them with additional information they need.

<Insert name of plan and plan’s toll-free number and toll free TTY number>
What if I have questions?
If you have questions about the information in this form or the late enrollment penalty [or would like to complete this form over the telephone], call your Medicare drug plan.

- *<Insert name of Plan, plan’s toll-free number, and day and hours of operations>*
- *<Insert plan’s TTY toll-free number>*

You may also contact Medicare:
- Visit www.medicare.gov on the web
- Call 1-800-MEDICARE (1-800-633-4227)
- TTY users call 1-877-486-2048.
Exhibit 1D: Declaration of Prior Prescription Drug Coverage (HPMS Code 8015)

**DECLARATION OF PRIOR PRESCRIPTION DRUG COVERAGE**

Date: _______________________
Enrollee Name: ______________________________
Address: ______________________________
Phone: ______________________________

**Medicare Health Insurance Claim #:**
(from red, white and blue Medicare card)

Name of Medicare Prescription Drug Plan: ______________________________

<table>
<thead>
<tr>
<th>Please check all boxes that apply to you.</th>
<th>Dates of Coverage (month/year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ I had creditable* prescription drug coverage from an Employer/Union, including the Federal Employees Health Benefits Program (FEHBP)</td>
<td>From: __________ To: __________</td>
</tr>
<tr>
<td>Name: ________________________________</td>
<td></td>
</tr>
<tr>
<td>☐ I had creditable* prescription drug coverage from Medicaid, State Pharmaceutical Assistance Program (SPAP), or another plan sponsored by my state</td>
<td>From: __________ To: __________</td>
</tr>
<tr>
<td>Name of SPAP: __________________________</td>
<td></td>
</tr>
<tr>
<td>If you are in an SPAP, what state do you live in:</td>
<td></td>
</tr>
<tr>
<td>________________________________________</td>
<td></td>
</tr>
<tr>
<td>☐ I had prescription drug coverage through my VA</td>
<td>From: __________</td>
</tr>
</tbody>
</table>

* “Creditable” means that your prior coverage met Medicare’s minimum standards.

<Contract#, Material ID#, CMS approval date (if applicable)>
<table>
<thead>
<tr>
<th>benefits (veterans, survivor, or dependent benefits)</th>
<th>To: __________</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ I had prescription drug coverage through my TRICARE or other military coverage</td>
<td>From: __________</td>
</tr>
<tr>
<td>□ I had a Medigap (Medicare Supplemental) policy with creditable* prescription drug coverage</td>
<td>From: __________</td>
</tr>
<tr>
<td>□ I had prescription drug coverage through the Indian Health Service, a Tribe or Tribal organization, or an Urban Indian organization (I/T/U)</td>
<td>From: __________</td>
</tr>
<tr>
<td>□ I had prescription drug coverage through PACE (Program of All-Inclusive Care for the Elderly)</td>
<td>From: __________</td>
</tr>
<tr>
<td>□ I had creditable* prescription drug coverage from a different source not listed above. Name of other source: __________________________</td>
<td>From: __________</td>
</tr>
<tr>
<td>□ I have/had extra help from Medicare to pay for my prescription drug coverage.</td>
<td>From: __________</td>
</tr>
<tr>
<td>□ I lived in an area affected by Hurricane Katrina at the time of the hurricane (August 2005) and I joined a Medicare prescription drug plan before December 31, 2006. Name of Parish: __________________________</td>
<td>From: __________</td>
</tr>
<tr>
<td>□ I never had creditable* drug coverage</td>
<td></td>
</tr>
</tbody>
</table>

Please complete this section: “To the best of my knowledge, the information on this form is true and correct. I understand that if I didn’t have creditable coverage and/or don’t give proof of creditable prescription drug coverage if asked, my premium may be higher.

I understand that my signature (or the signature of the person authorized to act on behalf of the individual under the laws of the State where the individual resides) on this document means that I have read and understand the contents of this declaration. If signed by an authorized individual (as described above), this signature certifies that: 1) this person is authorized under State law to complete
this enrollment and 2) documentation of this authority is available upon request by <insert name of plan> by Medicare.”

Signature: _____________________________________
Date: (month/day/year): ____________________________

If you are the representative, you must provide the following information:
Name: _______________________________________
Address: ______________________________________
City: ____________________________ State: __________
Zip: ________
Phone Number: (______) ______- _________
Relationship to Enrollee: _____________________________
<Date of Notice>

<Insert Name of Enrollee>
<Insert Enrollee’s Full Mailing Address>
<Insert Enrollee’s ID Number>

FINAL NOTICE

<Insert Name of Enrollee>:

You recently enrolled in <insert name of Plan> prescription drug plan and Medicare’s records show that you may owe a late enrollment penalty.

Prior to enrolling in the <insert name of Plan>, it appears that you had a break in prescription drug coverage from <insert first day without creditable prescription drug coverage in month/day/year format> to <insert last day without creditable prescription drug coverage in month/day/year format>. If you did not have prescription drug coverage during this time period that met Medicare’s minimum standards, you will owe a penalty on your monthly premiums. If you did have prescription drug coverage during this time period, you may be able to avoid the penalty by returning the enclosed form.

Please complete the enclosed form and return it immediately to <insert the name of plan and complete mailing address> [insert the following if you offer telephonic attestation: or call us at <insert plan’s toll-free number and toll-free TTY number> to provide us with the information] by <insert the same return date that was inserted on the original Beneficiary Cover Letter mailed, in month/day/year format>.

<Contract#, Material ID#, CMS approval date (if applicable)>
If you don’t contact <insert name of plan> by <insert the same return date that was inserted on the original Beneficiary Cover Letter mailed, in month/day/year format>, we will assume the above information is correct and you will owe a late enrollment penalty.
<Insert Name of Enrollee>:

Prior to enrolling in the <insert name of Plan>, it appears that you did not have prescription drug coverage that met Medicare’s minimum standards. If your records show that you did have prescription drug coverage from <insert first day without creditable prescription drug coverage in month/day/year format> to <insert last day without creditable prescription drug coverage in month/day/year format>, you may be able to avoid paying the monthly penalty by returning the enclosed form.

Please complete the enclosed form and return it immediately to <insert the name of plan and complete mailing address> [insert the following if you offer telephonic attestation: or call us at <insert plan’s toll-free number and toll-free TTY number> to provide us with the information] by <insert the same return date that was inserted on the original Beneficiary Cover Letter mailed, in month/day/year format>.

If you don’t contact <insert name of plan> by <insert the same return date that was inserted on the original Beneficiary Cover Letter mailed, in month/day/year format>, we will assume the above information is correct and you will owe a late enrollment penalty.

<Date of Notice>

<Insert Name of Enrollee>
<Insert Enrollee’s Full Mailing Address>
<Insert Enrollee’s ID Number>

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare and Medicaid Services
Exhibit 2: Model Notice - Beneficiary Notice of Late Enrollment Penalty
(HPMS Code 8003)

<Date>

Dear <Insert Name of Enrollee>:

We are writing to tell you that starting <effective date> your new premium will include a late enrollment penalty of <amount of new premium> per month. Your new premium amount includes an additional <LEP amount> each month because you didn’t have Medicare prescription drug coverage or other drug coverage that met Medicare’s minimum standards (credible coverage).

[Insert the following if the beneficiary is enrolling in a Part D plan for the first time:]
According to Medicare’s records, you did not have creditable coverage for <# of uncovered months> from <__date__> to <__date__> after you were first eligible to sign up for Medicare prescription drug coverage.

[OR insert the following if the beneficiary was previously enrolled in a Part D prescription drug plan:]
According to Medicare’s records, you did not have creditable coverage for <# of uncovered months> from <effective date of disenrollment from previous plan> to <the month before the effective date in your plan> following your disenrollment effective date from your last Medicare prescription drug plan.

[Insert the following if the beneficiary’s LEP amount has to be paid retroactively:]
Since you owe an LEP dating back to your effective date of enrollment, we will charge you a lump sum amount of <amount of lump sum owed retroactive to the date of their enrollment in the plan>. After this one time lump sum payment, you will be charged <amount of new premium> per month. [For members in direct-bill status, insert the following language:] Your premium bill will reflect this new premium amount. [For members in premium withhold status, insert the following language:] This lump sum amount will be deducted from your Social Security check. After this, your new
premium amount will also be deducted from your monthly Social Security check.

[Insert the following if employer, union, or State Pharmaceutical Assistance Program is paying the LEP amount on behalf of member:] <Name of employer or union sponsoring the Plan> has agreed to pay <LEP amount>, the amount of your late enrollment penalty, on your behalf. If your coverage is terminated by you or <name of employer or union sponsoring the Plan>, or if <name of employer or union sponsoring the Plan> stops paying your late enrollment penalty, you will be responsible for paying that amount.

If you disagree with your late enrollment penalty, you can ask Medicare to reconsider (review) its decision if certain circumstances apply to you. (For example, you might disagree with the penalty if you had extra help from Medicare to pay for your prescription drug coverage; or if you did not receive notice that clearly explained whether you had creditable coverage). A notice explaining your right to a reconsideration of the late enrollment penalty is included with this letter along with a reconsideration request form. You must submit your reconsideration request within 60 days of the date of this letter to the address listed on the enclosed Part D Late Enrollment Penalty Reconsideration Request Form, or Medicare may not consider your request.

If you have questions about the information in this letter, or if you would like more information about the late enrollment penalty, call <Plan Name> at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>. You can also get information by visiting www.medicare.gov on the web or by calling 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.

Thank you.
Exhibit 3: Model Notice - Beneficiary Notice of Existing Late Enrollment Penalty (HPMS Code 8008)

<Date>

Dear <Insert Name of Enrollee>:

We are writing to tell you that starting <effective date>, your premium will be <amount of premium> per month. This amount is based on an existing late enrollment penalty that you were charged by your previous plan(s) because you did not have Medicare prescription drug coverage or other drug coverage that met Medicare’s minimum standards (creditable coverage) for a total of <insert total # of uncovered months that resulted in the existing LEP> months.

[Insert the following if the beneficiary’s LEP amount has to be paid retroactively:]
Since you owe a late enrollment penalty dating back to your effective date of enrollment, we will charge you a lump sum amount of <amount of lump sum owed retroactive to the date of their enrollment in the plan>. After this one time lump sum payment, you will be charged <amount of premium> per month. [For members in direct-bill status, insert the following language:] Your premium bill will reflect this new premium amount. [For members in premium withhold status, insert the following language:] This lump sum amount will be deducted from your Social Security check. After this, your new premium amount will also be deducted from your monthly Social Security check.

[Insert the following if employer, union, or State Pharmaceutical Assistance Program is paying the LEP amount on behalf of member:]
<Name of employer or union sponsoring the Plan> has agreed to pay <LEP amount>, the amount of your late enrollment penalty, on your behalf. If your coverage is terminated by you or <name of employer or union sponsoring the Plan>, or if <name of employer or union sponsoring the Plan> stops paying your late enrollment penalty, you will be responsible for paying that amount.

If you have questions about the information in this letter, or if you would like more information about the late enrollment penalty, call <Contract#, Material ID#, CMS approval date (if applicable)>
<Plan Name> at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>. You can also get information by visiting www.medicare.gov on the web or by calling 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.

Thank you.
Exhibit 4: Model Notice - Removal of Late Enrollment Penalty Due to Subsequent IEP (HPMS Code 8009)

<Date>

Dear <Insert Name of Enrollee>:

We are writing to inform you that beginning <effective date of new IEP> you will no longer be charged a late enrollment penalty. This means that your monthly premium will be reduced by <insert amount of LEP>. Your new monthly premium will be <insert amount of premium minus LEP>.

You <will no longer> no longer owe a late enrollment penalty because this penalty is removed whenever a beneficiary enters a new Initial Enrollment Period for Part D (Part D IEP). In your case, Medicare’s records show that you <will have> had a new Part D IEP based on turning age 65 that begins/began <insert first month of new IEP> and ends/ended <insert last month of new IEP>. As long as you have Medicare prescription drug coverage or other drug coverage that meets Medicare’s minimum standards (creditable coverage) after the end of this Part D IEP, you will not be charged a late enrollment penalty.

If you have questions about the information in this letter, or if you would like more information about the late enrollment penalty, call <Plan Name> at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>. You can also get information by visiting www.medicare.gov on the web or by calling 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.

Thank you.
Exhibit 5: Model Letter - Informing Beneficiary of the Removal of the LEP Due to LIS Eligibility (HPMS Code 8010)

<Date>

Dear <Insert Name of Enrollee>:

We are writing to inform you that your monthly premium will no longer include a late enrollment penalty amount that you were being charged.

You will no longer be charged a late enrollment penalty because Medicare’s records show that effective <effective date of LIS eligibility> you were receiving extra help from Medicare to pay for your prescription drug coverage. This means that your monthly premium will be reduced by <insert amount of LEP>. Therefore, your new premium amount will be <new premium amount>.

[For members in direct-bill status, insert the following language:] This also means any late enrollment penalty amount that you’ve paid since <effective date of LIS eligibility> [Select method of LEP refund:] will be refunded back to you as soon as possible OR will be applied to reduce your next bill. We will [Select method of LEP refund:] refund you /reduce your next bill by <total LEP amount since the effective date of LIS eligibility>. However, if you owe a late enrollment penalty prior to <effective date of LIS eligibility> you are responsible for paying that amount.

[OR insert the following for members in premium-withhold status:] This also means that any late enrollment penalty amount that you’ve paid since <effective date of LIS eligibility> will be refunded to you by the Social Security Administration. The Social Security Administration will refund you <total LEP amount since the effective date of LIS eligibility> as soon as possible. However, if you owe a late enrollment penalty prior to <effective date of LIS eligibility> you are responsible for paying that amount.

If you have questions about the information in this letter or if you would like more information about the late enrollment penalty, call <Plan Name> at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>. You can also get
information by visiting www.medicare.gov on the web or by calling 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048. Thank you.
Exhibit 6: Model Notice - Informing Beneficiary of LEP Adjustment Due To Plan Error (HPMS Code 8011)

<Date>

Dear < Insert Name of Enrollee >:

We are writing to tell you that starting <effective date>, your new premium will be <amount of new premium> per month. This new amount is due to <insert the reason, e.g., erroneous calculation of number of uncovered months or error in transmitting that information to CMS>.

[Insert the following if the error imposes or increases the amount of the LEP amount:] As a result of this error, the above monthly premium includes a new late enrollment penalty of <new LEP amount>. [Insert the following if the error causes a beneficiary to owe a retroactive amount due to the error:] This also means that you now owe a past due late enrollment penalty of <amount of retroactive LEP amount owed as a result of error>.

[Insert the following if the beneficiary’s LEP amount has to be paid retroactively:] Since you owe a late enrollment penalty dating back to your effective date of enrollment, we will charge you a lump sum amount of <amount of lump sum owed retroactive to the date of their enrollment in the plan>. After this one time lump sum payment, you will be charged <amount of new premium> per month. [For members in direct-bill status, insert the following language:] Your premium bill will reflect this new premium amount. [For members in premium withhold status, insert the following language]: This lump sum amount will be deducted from your Social Security check. After this, your new premium amount will also be deducted from your monthly Social Security check.

[OR insert the following if the error reduces the LEP amount:] Because of this error, your new late enrollment penalty amount has been reduced. Your new late enrollment penalty amount is <new LEP amount>. [For members in direct bill status, insert the following language:] This also means that any late enrollment penalty amount

<Contract#, Material ID#, CMS approval date (if applicable)>
that you’ve paid as a result of this error [Select method of LEP refund:] will be refunded back to you as soon as possible OR will be applied to reduce your next bill. We will [Select method of LEP refund:] refund you /reduce your next bill by <total LEP amount owed to the beneficiary>. [For members in premium-withhold status, insert the following language:] This also means that any late enrollment penalty amount that you’ve paid as a result of this error will be refunded to you by the Social Security Administration. The Social Security Administration will refund you <total LEP amount owed to the beneficiary> as soon as possible.

[Insert the following only if the error resulted in the imposition of or increase in LEP, except where the increase is due to a reconsideration:] If you disagree with your late enrollment penalty, you can ask Medicare to reconsider (review) its decision if certain circumstances apply to you. (For example, you might disagree with the penalty if you got/get extra help from Medicare to pay for your prescription drug coverage or if you did not receive notice that explained whether you had other prescription drug coverage that met Medicare’s minimum standards (credible coverage). A notice explaining your right to a reconsideration of the late enrollment penalty is included with this letter. You must submit your reconsideration request to the address listed on the enclosed Part D Late Enrollment Penalty Reconsideration Request Form within 60 days of the date of this letter, or Medicare may not consider your request.

If you have questions about the information in this letter or if you would like more information about the late enrollment penalty, call <Plan Name> at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>. You can also get information by visiting www.medicare.gov on the web or by calling 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.

Thank you.
Dear <Name of Member>: 

Your Part D late enrollment penalty has changed based on Medicare’s reconsideration (review) of your circumstances, as explained in the decision letter you received from Medicare’s Appeals Contractor dated <insert date>. 

[Insert the following if the beneficiary still owes an LEP; i.e., the LEP reconsideration decision was either PARTIALLY FAVORABLE or UNFAVORABLE:] [For current members:] As a result of Medicare’s reconsideration decision, your premium still includes a late enrollment penalty. Your premium amount is <premium amount> per month effective <effective date>. [For prior members:] As a result of Medicare’s reconsideration decision you still owe a penalty of <penalty amount> per month, effective <effective date>. 

[For current and prior members, insert the following if the beneficiary’s LEP amount has to be paid retroactively:] Since you owe a late enrollment penalty dating back to your effective date of enrollment, we will charge you a lump sum amount of <amount of lump sum owed retroactive to effective date of enrollment>. [For current and prior members in premium withhold status, insert the following language:] This lump sum amount will be deducted from your Social Security check. [For current members in premium withhold status only, insert the following language:] After this one time lump sum payment, your new premium amount of <amount of new premium> will be deducted from your monthly Social Security check. [For current members in direct bill status only, insert the following language:] After this one time lump sum payment, your premium bill will reflect this premium amount of <amount of new premium> per month. 

[OR for current and prior members who no longer owe an LEP; i.e., the LEP reconsideration]
decision was FULLY FAVORABLE, insert the following:] Medicare decided you are not required to pay a late enrollment penalty. Any late enrollment penalty you have already paid [Select method of LEP refund:] will be refunded to you as soon as possible OR [for current members:] will be applied to reduce your next bill. [For prior and current members in direct bill status, insert the following language:] We will refund you <total LEP amount owed to the beneficiary> OR [for current members only select alternative method of LEP refund:] We will apply <total LEP amount owed to the beneficiary> to reduce your next bill. [For prior and current members in premium-withhold status, insert the following language:] This means that any late enrollment penalty amount that you’ve paid as a result of this error will be refunded to you by the Social Security Administration. The Social Security Administration will refund you <total LEP amount owed to the beneficiary> as soon as possible.

If you have questions about the information in this letter or if you would like more information about the late enrollment penalty, call <Plan Name> at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>. You can also get information by visiting www.medicare.gov on the web or by calling 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.

Thank you.
Exhibit 8: Model Notice - Return of Creditable Coverage Information Received Without an Accompanying Enrollment Request (HPMS Code 8005)

<Date>

Dear <Insert Name of Enrollee>:

We received information from you that showed you had other prescription drug coverage that met Medicare’s minimum standards (creditable coverage), but our records don’t show that you have applied to join <Plan Name>. Since we don’t have an application from you to join our plan, we are returning your creditable coverage information to you. If you want to join <Plan Name>, please call us at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>.

Once we receive your application, we will let you know if we will let you know if we think you need to tell us whether you had creditable coverage prior to joining <Plan Name>. Remember, if you don’t keep Medicare prescription drug coverage or other creditable coverage after you are eligible to join a Medicare prescription drug plan, you may have to pay a late enrollment penalty for each month you were eligible to join but didn’t. You will then have to pay the penalty as long as you have Medicare prescription drug coverage.

If you have questions about the information in this letter or if you would like more information about the late enrollment penalty, call <Plan Name> at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>. You can also get information by visiting www.medicare.gov on the web or by calling 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.

Thank you.
Exhibit 9: Model Notice - Yearly Change to LEP Amount (HPMS Code 8012)

<Date>

Dear < Insert Name of Enrollee >:

We are writing to tell you that starting <January 1, yyyy>, your new premium will be <amount of new premium> per month.

This new amount is a change to your current late enrollment penalty amount based on the annual change to the National Base Beneficiary Premium. This means that each year that the National Base Beneficiary Premium changes, so will the amount of your late enrollment penalty.

If you have questions about the information in this letter or if you would like more information about the how the national base beneficiary premium affects the late enrollment penalty, call <Plan Name> at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>. You can also get information by visiting www.medicare.gov on the web or by calling 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.

Thank you.
Exhibit 10: Model Notice - Creditable Coverage Information Received After Deadline (HPMS Code 2055)

< Date >

Dear < Insert Name of Enrollee >

On <insert the date located on the Beneficiary Cover Letter for Individuals with Break in Coverage (HPMS Code 8013)>, we sent a letter asking you to complete a form that would tell us about any prescription drug coverage you had that met Medicare’s minimum standards. We sent this request to you because Medicare records show that you have a break in prescription drug coverage from <insert first day without creditable prescription drug coverage in month/day/year format> to <insert the day before enrollment in your plan in month/day/year format>. That letter told you that the deadline for providing us with any information about creditable coverage you had during this period was <insert return date from final notice>.

[If the beneficiary returned the attestation form, include the following sentence: On <insert date plan received attestation form>, we received your attestation form.] [Or, if you offer telephonic attestation and the beneficiary attempted to provide telephonic attestation, insert the following sentence: On <insert date the beneficiary provided (or attempted to provide) telephonic attestation> you attempted to provide this information over the telephone.] However, we received this information more than 60 days after the deadline that we gave you to respond to our request. Therefore, we did not consider this information when we reported to Medicare the number of months you went without creditable coverage.

We <insert one of the following: [have already sent] [will send]> a letter to you explaining the amount of your late enrollment penalty and a notice of your right to ask Medicare to reconsider (review) its penalty decision if certain circumstances apply to you. If you ask Medicare to review its decision, follow the instructions in the notice entitled “YOUR RIGHT TO ASK MEDICARE TO REVIEW YOUR MEDICARE PART D LATE ENROLLMENT PENALTY.”

<Contract#, Material ID#, CMS approval date (if applicable)>
include the following sentence: If you ask Medicare’s Appeals Contractor to review your case, you should include a copy of the information we are returning to you.

If you have any questions, please call <insert name of plan> at <insert plan’s toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>. You can also get information by visiting www.medicare.gov on the web or by calling 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.
Exhibit 11: Model Notice - Beneficiary Notice of Late Enrollment Penalty Adjustment Reported (HPMS Code 2056)

<Date>

Dear <Insert Name of Enrollee>:

[Insert the following paragraph if the reporting of uncovered months imposes or increases an LEP and the member is currently enrolled in your plan]:

We are writing to tell you that Medicare informed us that your previous plan reported that you did not have prescription drug coverage that met Medicare’s minimum standards for at least 63 days. As a result of this, starting <effective date of enrollment>, your new premium will be <amount of new premium> per month. Your new premium amount includes an additional <LEP amount>. [Insert the following if the new LEP causes a beneficiary to owe a retroactive amount in your plan:] This also means that you owe a previous late enrollment penalty dating back to your effective date of enrollment. [Insert the following if the member is in direct bill status]: Therefore, we will charge you a lump sum amount of <amount of lump sum owed retroactive to the date of their enrollment in the plan>. [Insert the following if the member is in premium withhold status]: This lump sum amount will be deducted from your Social Security check.

[OR insert the following paragraph if the reporting of uncovered months imposes or increases an LEP and the member is no longer enrolled in your plan]:

We are writing to tell you that Medicare informed us that your previous plan reported that you did not have prescription drug coverage that met Medicare’s minimum standards for at least 63 days. As a result of this, we should have charged you [Insert the appropriate language]: a/an additional late enrollment penalty amount of <total LEP amount owed. [Insert the following if the individual is in direct bill status]: Please send your payment to following address:

<Insert Name of Plan and full mailing address where plan should remit payment>

<Contract#, Material ID#, CMS approval date (if applicable)>
[Insert the following if the individual is in premium withhold status]:
This amount will be deducted from your Social Security check.

[Or insert the following paragraph if the reporting of uncovered months reduces or removes an LEP and the member is currently enrolled in your plan]:
We are writing to tell you that your late enrollment penalty has been [Insert the appropriate language]: reduced OR removed based on a change to what your former plan reported to Medicare. Your new premium amount is <insert total premium amount>. This amount [Insert the appropriate language] no longer includes a late enrollment penalty OR includes a reduced late enrollment penalty amount of <new LEP amount>. [For members in direct bill status, insert the following language:] This also means that any late enrollment penalty amount that you paid, while in our plan, [Select method of LEP refund:] will be refunded back to you as soon as possible OR will be applied to reduce your next bill. We will [Select method of LEP refund:] refund you /reduce your next bill by <total LEP amount owed to the beneficiary>. [For members in premium-withhold status, insert the following language:] This also means that any late enrollment penalty amount that you paid, while in our plan, will be refunded to you by the Social Security Administration. The Social Security Administration will refund you <total LEP amount owed to the beneficiary> as soon as possible.

[Or insert the following paragraph if the reporting of uncovered months reduces or removes an LEP and the member is no longer enrolled in your plan]:
We are writing to tell you that Medicare informed us that [Insert the appropriate language]: you should not have been assessed a late enrollment penalty OR you should have paid a reduced late enrollment penalty while you were enrolled in our plan. This decision was based on information reported to Medicare by your previous plan. [For members in direct bill status, insert the following language:] Therefore, we will refund you <total LEP amount owed to the beneficiary> as soon as possible [For members in premium-withhold status, insert the following language:] Therefore, this means that the Social Security Administration will refund you <total LEP amount owed to the beneficiary> as soon as possible.
[Include the below paragraph with the appropriate paragraph you selected above]:
We did not make this decision. Therefore, if you have questions about what your previous plan reported to Medicare, you should contact your previous plan. If you have questions about other information contained in this letter, or would like more information about the late enrollment penalty, you can call <Plan Name> at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>. You can also get information by visiting www.medicare.gov on the web or by calling 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048.

Thank you.
CMS is pleased to release updated Chapter 5 of the Medicare Prescription Drug Benefit Manual (Benefits and Beneficiary Protections). The revisions to Chapter 5 reflect changes previously released in the final regulations published in the Federal Register on April 15, 2010 and 2011 and in the Calendar Year 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter released on April 4, 2011.

Specifically, CMS:

- Added the definitions of “Applicable beneficiary,” “Applicable drug,” “Coverage Gap,” and “Non-applicable drugs” to the definition section.
- Updated the description of Standard Prescription Drug Coverage and Alternative Prescription Drug Coverage to address coinsurance in the coverage gap.
- Clarified existing policy with respect to “Free first fill programs” by specifying that, for a new prescription, such programs must apply to both a beneficiary switch from a brand-name medication.
- Stipulated in the section Enhanced Alternative Gap Coverage that sponsors will no longer indicate their level of gap coverage in the Plan Benefit Package (PBP) software, but rather, CMS will quantify each plan’s gap coverage and assign appropriate descriptions.
- Clarified existing policy in the section Restrictions on the Offering of Enhanced Alternative Coverage by MA Organizations to ensure that MA organizations offer at least one option for Part D coverage for supplemental premium at the cost of basic prescription drug coverage and announcing that two questions have been added to the PBP to help ensure this requirement is being met.
- Added a new section Coverage Gap Coinsurance.
- Clarified and updated existing policy regarding dispensing fees to reflect the long-term care dispensing requirements effective January 1, 2013.
- Updated the section Ensuring Meaningful Differences in Approved Bids to reflect that CMS will only approve a bid submitted by a sponsor if its plan benefit package or cost structure is meaningfully different from other plan offerings by the sponsor in the same service area with respect to key characteristics.
• Updated the section Meaningful Differences in Basic Prescription Drug Coverage Options to state that CMS believes that sponsors should only submit one basic offering for a stand-alone prescription drug plan in a service area.
• Updated the section Meaningful Differences in Enhanced Alternative Coverage Options to state that CMS will announce its meaningful differences evaluation methodology via the annual payment notice and call letter.
• Updated the section Transition Period for Sponsors or Parent Organizations with New Acquisitions to reflect a 2 year transition period.
• Updated the section Consolidated Renewal Plan to cover consolidation of two enhanced alternative plans.
• Updated the section PDP Plan Benefit Package (PBP) Renewal and Crosswalk Guidance to include a section Consolidated Plans under a Parent Organization.
• Added a new section Low Enrollment Plans.
• Added a new section Manufacturer Drug Discount Program.
• Updated the sections Costs that Count as Incurred Costs, Costs that do not Count as Incurred Costs, Summary of TrOOP-Eligible and TrOOP-Ineligible Payers, and Pharmacy Waiver/Reduction of Cost-Sharing and Applicability, by addressing discounts paid by manufacturers as part of the Medicare Coverage gap Discount program, costs paid by the Indian Health Service or an Indian tribe or organization, and costs paid by AIDS Drug Assistance Program.
• Clarified the section on Mail-Order Pharmacy Access to state that a pharmacy that makes some, but not all, deliveries by common carrier is not a mail order pharmacy.
• Clarified the section Level Playing Field Between Mail-Order and Retail Pharmacies by stating that the alternative retail/mail order pharmacy rate shall not cause the standard terms and conditions offered to similarly situated pharmacies to vary with respect to the any willing provider pharmacy provisions.
• Revised the section Out-of-Network Pharmacy Access to add an option for sponsors to create an out-of-network benefit structure.
• Clarified the section Public Disclosure of Pharmaceutical Prices for Equivalent Drugs to state that CMS may modify the timing requirement for informing enrollees of any differential between the price of a covered part D drug to an enrollee and the price of the lowest priced generic version if the requirement becomes impracticable to administer.
• Added an Electronic Transactions Standards section to address unique BIN/PCN provisions and Prescriber Identifiers.
• Updated Appendix 1: Adequate Access to Network Home Infusion Pharmacies by State/Territory and Contract Type with 2011 data.

The manual revisions are available at

http://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp

Any questions regarding this manual chapter may be directed to Lisa Thorpe via e-mail at Lisa.Thorpe@cms.hhs.gov.
Prescription Drug Benefit Manual

Chapter 5: Benefits and Beneficiary Protections

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(Rev. 14, 09-30-11)

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(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

10.1 - Introduction  
(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

This chapter deals with Part D sponsor requirements with regard to Part D benefits and a number of beneficiary protections for Part D enrollees, including:

- The establishment of prescription drug plan (PDP) service areas;
- Access standards with regard to covered Part D drugs;
- Disclosure to beneficiaries of pricing information for generic versions of covered Part D drugs; and
- Privacy, confidentiality, and accuracy of PDP sponsors’ enrollee records.

Except where specifically noted, these requirements apply to all Part D sponsors, including PDPs, MA-PD plans, and cost plans offering Part D coverage. Other requirements related to beneficiary protections are contained in other chapters of the Prescription Drug Benefit Manual, which can be accessed at: http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage

10.2 - Definition of Terms  
(Rev. 14, Issued: 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Unless otherwise stated in this chapter, the following definitions apply:

**Actual cost**: The negotiated price for a covered Part D drug when the drug is purchased at a network pharmacy, and the usual and customary price when a beneficiary purchases the drug at an out-of-network pharmacy consistent with 42 CFR 423.124(a).

**Applicable beneficiary**: Means an individual who, on the date of dispensing a covered Part D drug—
(1) Is enrolled in a prescription drug plan or an MA-PD plan;
(2) Is not enrolled in a qualified retiree prescription drug plan;
(3) Is not entitled to an income-related subsidy under section 1860D-14(a) of the Act;
(4) Has reached or exceeded the initial coverage limit under section 1860D-2(b)(3) of the Act during the year;
(5) Has not incurred costs for covered Part D drugs in the year equal to the annual out-of-pocket threshold specified in section 1860D-2(b)(4)(B) of the Act; and
(6) Has a claim that—
   (i) Is within the coverage gap;
   (ii) Straddles the initial coverage period and the coverage gap;
   (iii) Straddles the coverage gap and the annual out-of-pocket threshold; or
(iv) Spans the coverage gap from the initial coverage period and exceeds the annual out-of-pocket threshold.

Applicable drug: Means a Part D drug that is--
(1)(i) Approved under a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA); or
(ii) In the case of a biological product, licensed under section 351 of the Public Health Service Act (other than a product licensed under subsection (k) of such section 351); and
(2)(i) If the PDP sponsor of the prescription drug plan or the MA organization offering the MA-PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in;
(ii) If the PDP sponsor of the prescription drug plan or the MA organization offering the MA-PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in; or
(iii) Is provided to a particular applicable beneficiary through an exception or appeal for that particular applicable beneficiary.

Bioequivalent: The meaning given such term in section 505(j)(8) of the Food, Drug, and Cosmetic Act.

Catastrophic coverage: The Part D benefit phase above the annual out-of-pocket threshold described at 42 CFR 423.104(d)(5)(iii) (and in section 20.3.1).

Contracted pharmacy network: Licensed pharmacies, including retail, mail-order, and institutional pharmacies, under contract with a Part D sponsor to provide covered Part D drugs at negotiated prices to Part D enrollees.

Coverage gap: Means the period in prescription drug coverage that occurs between the initial coverage limit and the out-of-pocket threshold. For purposes of applying the initial coverage limit, Part D sponsors must apply their plan specific initial coverage limit under basic alternative, enhanced alternative or actuarially equivalent Part D benefit designs.

Employer/Union-Only Group Waiver Plan: For the purpose of this section, Medicare-approved prescription drug plans that qualify for waivers or modifications to their plan offerings consistent with Pub. 100-16, Medicare Managed Care Manual, Chapter 9, Section 10 and Pub. 100-18, Medicare Prescription Drug Benefit Manual, Chapter 12, Section 10.

Generic drug: A drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(j)) is approved.

Government-funded health program: Any program established, maintained, or funded, in whole or in part, by the Government of the United States, by the government of any State or political subdivision of a State, or by any agency or instrumentality of any of the foregoing, which uses public funds, in whole or in part, to provide to, or pay on behalf of, an individual the cost of Part D drugs, including any of the following: (1) An approved State child health plan under title XXI of the Act providing benefits for child health assistance that meets the requirements of section 2103 of the Act; (2) The Medicaid program under title XIX of the Act or a waiver under section 1115 of the Act; (3) The veterans' health care program under Chapter 17 of title 38 of the United
States Code; (4) The Indian Health Service program under the Indian Health Care Improvement Act under Chapter 18 of title 25 of the United States Code; and (5) Any other government-funded program whose principal activity is the direct provision of health care to persons.

Group health plan: For purposes of applying the definition of incurred costs in 42 CFR 423.100, has the meaning given such term in 29 U.S.C. 1167(1), but specifically excludes a personal health savings vehicle.

Insurance: A health plan that provides, or pays the cost of Part D drugs, including, but not limited to, any of the following: (1) health insurance coverage (as defined in 42 U.S.C. 300gg-91(b)(1)); (2) a Medicare Advantage (MA) plan (as described under section 1851(a)(2) of the Act); and (3) a PACE organization (as defined under sections 1894(a)(3) and 1934(a)(13) of the Act). This definition specifically excludes a personal health savings vehicle.

I/T/U pharmacy: A pharmacy operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization, all of which are defined in section 4 of the Indian Health Care Improvement Act, 25 U.S.C. 1603.

Long-term care (LTC) facility: A skilled nursing facility as defined in section 1819(a) of the Act, or a medical institution or nursing facility for which payment is made for an institutionalized individual under section 1902(q)(1)(B) of the Act.

Long-term care pharmacy: A pharmacy owned by or under contract with a long-term care facility to provide prescription drugs to the facility’s residents.

Long-term care network pharmacy: A long-term care pharmacy that is a network pharmacy.


Network pharmacy: A licensed pharmacy that is under contract with a Part D sponsor to provide covered Part D drugs at negotiated prices to its Part D plan enrollees.

Non-preferred pharmacy: A network pharmacy that offers covered Part D drugs at negotiated prices to Part D enrollees at higher cost-sharing levels than apply at a preferred pharmacy.

Non-applicable drugs: Covered Part D drugs that are not applicable drugs as defined in this section. This includes generic drugs.

Or otherwise: Through a government-funded health program.

Out-of-network (OON) pharmacy: A licensed pharmacy that is not under contract with a Part D sponsor to provide negotiated prices to Part D plan enrollees.

Parent organization: An organization that holds at least the majority of the voting stock in a legal entity that holds a Medicare Prescription Drug Plan (PDP) sponsor contract or a Medicare Advantage (MA) Organization contract.

Part D drug: A drug described in chapter 6, section 10, of this manual.
Person: A natural person, corporation, mutual company, unincorporated association, partnership, joint venture, limited liability company, trust, estate, foundation, not-for-profit corporation, unincorporated organization, government or governmental subdivision or agency.

Personal health savings vehicle: A vehicle through which individuals can set aside their own funds to pay for health care expenses, including covered Part D drugs, on a tax free basis including any of the following: (1) a Health Savings Account (as defined under section 220 of the Internal Revenue Code); (2) a Flexible Spending Account (as defined in section 106(c)(2) of the Internal Revenue Code) offered in conjunction with a cafeteria plan under section 125 of the Internal Revenue Code; and (3) an Archer Medical Savings Account (as defined under section 223 of the Internal Revenue Code). This definition specifically excludes a Health Reimbursement Arrangement (as described under Internal Revenue Ruling 2002-41 and Internal Revenue Notice 2002-45).

Plan allowance: The amount Part D plans that offer coverage, other than defined standard coverage, may use to determine their payment and Part D enrollees’ cost-sharing for covered Part D drugs purchased at an out-of-network pharmacy or in a physician’s office in accordance with the requirements of 42 CFR 423.124(b).

Plan Benefit Package (PBP): A set of benefits for a defined MA or PDP service area. The PBP is submitted by PDP sponsors and MA organizations to CMS for benefit analysis, marketing and beneficiary communication purposes.

Preferred drug: A covered Part D drug on a Part D sponsor's formulary for which beneficiary cost-sharing is lower than for a non-preferred drug on the sponsor’s formulary.

Preferred multiple source drug: A drug that is both a preferred drug and a multiple source drug, meaning that one version of that drug is placed on the sponsor’s formulary with lower cost sharing than for a non-preferred drug.

Preferred pharmacy: A network pharmacy that offers covered Part D drugs at negotiated prices to Part D enrollees at lower levels of cost-sharing than apply at a non-preferred pharmacy under its pharmacy network contract with a Part D sponsor.

Retail pharmacy: Any licensed pharmacy that is not a mail order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy.

Rural: A five-digit ZIP Code in which the population density is less than 1,000 individuals per square mile.

Suburban: A five-digit ZIP Code in which the population density is between 1,000 and 3,000 individuals per square mile.

Supplemental drugs: Drugs that would be covered Part D drugs but for the fact that they are specifically excluded as Part D drugs under 42 CFR 423.100, and as described in section 20.1 of chapter 6. However, because such drugs must have otherwise qualified as covered Part D drugs
(as defined in section 10.2 of chapter 6) in order to be covered as a supplemental benefit, and because only prescription drugs are included in the definition of a Part D drug, over-the-counter drugs cannot be supplemental drugs, as discussed in section 10.10 of chapter 6. Supplemental drugs may be included as a supplemental benefit under enhanced alternative coverage, as described in section 20.4.2 of this chapter.

**Therapeutically equivalent:** Drugs that are rated as therapeutic equivalents under the Food and Drug Administration’s most recent publication of “Approved Drug Products with Therapeutic Equivalence Evaluations.”

**Third party payment arrangement:** Any contractual or similar arrangement under which a person has a legal obligation to pay for covered Part D drugs.

**Urban:** A five-digit ZIP Code in which the population density is greater than 3,000 individuals per square mile.

**Usual and customary (U&C) price:** The price that an out-of-network pharmacy or a physician’s office charges a customer who does not have any form of prescription drug coverage for a covered Part D drug.

### 20 - Requirements Related to Qualified Prescription Drug Coverage
(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

#### 20.1 - General
(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

A Part D sponsor must provide enrollees with qualified prescription drug coverage. Qualified prescription drug coverage, which consists of the either of the following options, may be provided directly by the Part D sponsor or through arrangements with other entities:

1. Standard prescription drug coverage (as described in section 20.3), which includes both defined standard coverage (as described in section 20.3.1) and actuarially equivalent standard coverage (as described in section 20.3.2).

2. Alternative prescription drug coverage (as described in section 20.4), which includes both basic alternative coverage (as described in section 20.4.1) and enhanced alternative coverage (as described in section 20.4.2).

For purposes of ensuring that Part D enrollees have a variety of different benefit options in a particular service area, CMS also makes a distinction between qualified prescription drug coverage that is basic prescription drug coverage and qualified prescription drug coverage that provides supplemental benefits (as described in section 20.4.2). Basic prescription drug coverage consists of any of the following:

1. Defined standard coverage, as described in section 20.3.1;

2. Actuarially equivalent standard coverage, as described in section 20.3.2; or
As described in section 20.4.2, plans may offer an additional type of qualified prescription drug coverage – enhanced alternative coverage – that includes both: (1) basic prescription drug coverage, as described above, and (2) supplemental benefits. Table 1 summarizes the difference between qualified prescription drug coverage and basic prescription drug coverage.

### Table 1
Qualified and Basic Prescription Drug Coverage

<table>
<thead>
<tr>
<th>Types of Coverage that May be Included</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Qualified Prescription Drug Coverage</strong></td>
</tr>
<tr>
<td>• Defined Standard Coverage</td>
</tr>
<tr>
<td>• Actuarially Equivalent Standard Coverage</td>
</tr>
<tr>
<td>• Basic Alternative Coverage</td>
</tr>
<tr>
<td>• Enhanced Alternative Coverage</td>
</tr>
<tr>
<td><strong>Basic Prescription Drug Coverage</strong></td>
</tr>
<tr>
<td>• Defined Standard Coverage</td>
</tr>
<tr>
<td>• Actuarially Equivalent Standard Coverage</td>
</tr>
<tr>
<td>• Basic Alternative Coverage</td>
</tr>
</tbody>
</table>

### 20.2 - Availability of Prescription Drug Plans
(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

A PDP sponsor must offer its prescription drug plans to all Part D eligible beneficiaries residing in those plans’ service areas (refer to section 40 for more information about PDP service areas). Unlike an MA-PD sponsor, a PDP is not eligible for a capacity limit as described in 42 CFR 422.60(b).

### 20.3 - Standard Prescription Drug Coverage
(Rev. 14, Issued: 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Standard prescription drug coverage includes two distinct types of coverage: (1) defined standard coverage; and (2) actuarially equivalent standard coverage. Both types of standard prescription drug coverage consist of coverage of covered Part D drugs subject to an annual deductible; 25 percent coinsurance (or an actuarially equivalent structure) up to an initial coverage limit; coinsurance equal to the gap coinsurance percentages (or an actuarially equivalent amount) during the coverage gap; and catastrophic coverage after an individual incurs out-of-pocket expenses above the annual out-of-pocket threshold. Both defined standard coverage and actuarially equivalent standard coverage include access to negotiated prices, as described in section 20.5.

### 20.3.1 - Defined Standard Coverage
(Rev. 14, Issued: 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)
Defined standard coverage consists of coverage of covered Part D drugs subject to:

- An annual deductible.
- Twenty-five percent coinsurance for actual costs above the annual deductible but at or below an initial coverage limit.
- **Coinsurance that is equal to the costs of non-applicable and applicable (brand) drugs during the coverage gap multiplied by the gap coinsurance percentages described in section 20.5.**
- Catastrophic coverage with nominal cost-sharing for the remainder of the coverage year once an enrollee’s costs exceed the annual out-of-pocket threshold.

The annual deductible, initial coverage limit, out-of-pocket threshold, and beneficiary cost-sharing after the annual out-of-pocket threshold is met are adjusted annually. As provided in 42 CFR 423.104(d)(5)(iv), these amounts will be adjusted relative to the previous year’s amounts by the annual percentage increase in average per capita aggregate expenditures for Part D drugs for the 12-month period ending in July of the previous year. The updated benefit parameters for 2012 include an adjustment for any variations between the projected and actual amounts from the prior period. For more information about the methodologies used to update the 2012 benefit parameters, refer to:


**20.3.2 - Actuarially Equivalent Standard Coverage**  

Part D sponsors may also offer actuarially equivalent standard coverage, under which they would substitute certain cost-sharing requirements in defined standard coverage (including tiered structures tied to plan formularies or preferred pharmacies in a plan’s network, as described in section 50.9) for:

1. Costs above the annual deductible and up to the initial coverage limit, provided that those alternative cost-sharing requirements are actuarially equivalent to the average expected coinsurance of 25 percent for costs above the annual deductible and up to the initial coverage limit under defined standard coverage; and/or

2. **Costs for coinsurance during the coverage gap, provided that those alternative cost-sharing requirements are actuarially equivalent to the average expected coinsurance (that is equal to the costs of non-applicable and applicable drugs multiplied by the gap coinsurance percentages described in section 20.5) under defined standard coverage; and/or**

3. Costs in the catastrophic portion of the benefit, provided that those alternative cost-sharing requirements are actuarially equivalent to the average expected cost-sharing
under defined standard coverage described in the applicable annual Rate Announcement/Call Letter found at www.cms.gov/PrescriptionDrugCovContra/01_Overview.asp.

Cost-sharing arrangements under actuarially equivalent standard coverage could include reducing cost-sharing to $0 for generic or preferred covered Part D drugs, as long as the cost-sharing structure is actuarially equivalent to an average expected coinsurance of 25 percent for costs above the annual deductible and up to the initial coverage limit and/or to an average expected cost-sharing in the catastrophic portion of the benefit equivalent to the cost-sharing described in the applicable annual Rate Announcement/Call Letter found at www.cms.gov/PrescriptionDrugCovContra/01_Overview.asp. Any such cost-sharing arrangements will be reviewed, along with the rest of a plan’s benefit design, to ensure that they do not discriminate against certain Part D eligible individuals.

20.4 - Alternative Prescription Drug Coverage
(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Alternative prescription drug coverage includes two distinct types of coverage: (1) basic alternative coverage; and (2) enhanced alternative coverage. Both basic alternative coverage and enhanced alternative coverage include access to negotiated prices, as described in section 20.6. In modifying the standard prescription drug coverage design to offer alternative prescription drug coverage, Part D sponsors must use defined standard coverage (and not actuarially equivalent standard coverage) as a fixed point of comparison. In order to receive approval to offer an alternative prescription drug benefit design, a Part D sponsor must:

1. Include a deductible that is no greater than the deductible offered under defined standard coverage.

2. Provide coverage above the annual out-of-pocket threshold that is at least as generous as that provided under defined standard coverage. In other words, Part D sponsors may, at their option, reduce cost-sharing below that required under defined standard coverage.

3. Ensure that the beneficiary premium is at least equal to the beneficiary premium under defined standard coverage.

4. Ensure that, for individuals whose total spending exceeds the initial coverage limit under standard prescription drug coverage, the average Part D sponsor payout is at least equal to that under defined standard coverage.

5. Ensure that the actuarial value of the total or gross coverage is at least equal to that under defined standard coverage.

Sponsors have flexibility to establish benefit designs within the aforementioned parameters that include the following features, which may be particularly useful for increasing utilization of generic drugs. All cost-sharing arrangements will be reviewed, along with the rest of a sponsor’s benefit design, to ensure that they do not discriminate against certain Part D eligible individuals.
• **Brand-only deductible:** Sponsors may lower or eliminate cost sharing for generics in the deductible period. Sponsors may not, however, increase the deductible for brands above the defined standard benefit’s annual deductible amount in order to compensate for decreasing the cost-sharing for generics before the deductible is met. Sponsors electing a brand-only deductible should note that beneficiary and plan paid amounts for generic drugs will accrue to total drug costs but not toward the brand-only deductible.

“**Free first fill**” program: Sponsors may establish programs whereby enrollees are offered an incentive in the form of a cost-sharing reduction if 1) with respect to a new prescription, the enrollee chooses a generic version of, or a preferred brand-name therapeutic alternative to, a medication, over a brand-name drug, and 2) with respect to a refill, the enrollee switches from a brand-name to the generic version of, or a preferred brand-name therapeutic alternative to, a medication. The goal of such incentive programs is to minimize drug spend and maximize compliance with plan formularies. A sponsor that elects this benefit design must identify these drugs in the Free First Fill supplemental formulary flat file.

### 20.4.1 - Basic Alternative Coverage
(Rev. 14, Issued: 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Basic alternative coverage is alternative prescription drug coverage that is actuarially equivalent to defined standard prescription drug coverage, as described in section 20.3.1. Within the parameters for alternative prescription drug coverage described in section 20.4, a Part D sponsor offering a basic alternative prescription drug benefit design could combine features such as the following to maintain an actuarial value of coverage equal to defined standard prescription drug coverage:

- A reduction in the deductible;
- Changes in cost-sharing (e.g., benefit designs that use tiered copayments or coinsurance) in an actuarially equivalent manner to the 25 percent cost-sharing above the deductible and below the initial coverage limit under defined standard coverage and in an actuarially equivalent manner to the gap coverage coinsurance (that is equal to the costs of non-applicable and applicable drugs multiplied by the gap coinsurance percentages described in section 20.5) during the coverage gap; and
- A modification of the initial coverage limit

### 20.4.2 - Enhanced Alternative Coverage
(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

#### 20.4.2.1 - General
(Rev. 14, Issued: 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Enhanced alternative coverage refers to alternative prescription drug coverage whose value exceeds that of defined standard coverage. This is only possible if a Part D sponsor offers supplemental benefits in addition to its basic prescription drug benefit. In other words, enhanced
alternative coverage includes both: (1) basic prescription drug coverage, as described in section 20.1; and (2) supplemental benefits.

Supplemental benefits consist of:

- Reductions in cost-sharing in the coverage gap such that enrollees are liable for less than the coinsurance in the gap for defined standard coverage, and the actuarial value of the benefit provided is increased above the actuarial value of basic prescription drug coverage.

- Reductions in cost-sharing that increase the actuarial value of the benefits provided above the actuarial value of basic prescription drug coverage – for example: (1) a reduction in the deductible; (2) a reduction in the coinsurance percentage or copayments applicable to covered Part D drugs obtained between the annual deductible and the initial coverage limit and/or above the annual out-of-pocket threshold; and/or (3) an increase in the initial coverage limit; and/or

- Supplemental drugs.

**20.4.2.2 - Enhanced Alternative Gap Coverage**

*(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)*

As part of an enhanced alternative benefit design, Part D sponsors may include coverage of a subset of drugs throughout the coverage gap. Sponsors may elect to provide additional coverage for:

1. An entire drug tier;
2. A subset of a drug tier, or
3. A capped dollar amount of drugs within a tier or across the entire benefit (limited gap coverage).

CMS will review the breadth of drugs covered through the gap, be it: (1) an entire drug tier; (2) a subset of a drug tier, or (3) a capped dollar amount of drugs, to ensure that the coverage is sufficient to be labeled either gap coverage or limited gap coverage. CMS reserves the right to label coverage of a subset of all formulary drugs through the gap as something less than gap coverage or limited gap coverage. For example, coverage of only insulin through the coverage gap would not be sufficient to be labeled gap coverage.

In CY 2010, sponsors were required to identify their gap coverage offerings for both generic and brand drugs in the plan benefit package (PBP) software using CMS-defined standardized thresholds for the terms “all,” “many,” “some,” “few,” or “none.” These thresholds represented the proportion of unique Health Plan Management System (HPMS) formulary drug entities (i.e., unique clinical drug component and dosage form) that are covered through the gap for drugs described on the formulary as generic and for drugs described as brand (as specified by the drug type label). Beginning in CY 2011, for 2012 bids, sponsors will no longer indicate their level of gap coverage in the PBP. CMS will quantify each plan’s gap coverage based upon the percentage of formulary drugs (brand, or generic above the standard coverage) covered through
the gap and then will assign appropriate descriptions. The gap coverage level descriptions will reflect additional coverage above the mandated coverage gap coinsurance of non-applicable drugs. Supplemental (excluded) drugs will not be factored into the determination of gap coverage. For example, if a plan covers both generic Part D and supplemental drugs, only the generic drugs as defined in this chapter, will be used in calculating the percentage of formulary drugs covered through the gap. CMS will provide a report in HPMS describing the CMS-assigned gap coverage levels. Gap coverage descriptions for drugs will be communicated to beneficiaries through the SB, other marketing materials, and information dissemination materials.

20.4.3 - Restrictions on the Offering of Enhanced Alternative Coverage by PDP Sponsors
(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

A PDP sponsor is not permitted to offer a plan that provides enhanced alternative coverage in a particular service area unless it also offers a plan that provides only basic prescription drug coverage, as described in section 20.1, in that same area. This requirement ensures that PDP sponsors offer at least one option for Part D coverage for a premium at the cost of basic prescription drug coverage. For purposes of meeting this requirement, a PDP sponsor is considered to be a PDP parent organization.

20.4.4 - Restrictions on the Offering of Enhanced Alternative Coverage by MA Organizations
(Rev. 14, Issued: 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

An MA organization may not offer an MA coordinated care plan, as defined in 42 CFR 422.4, in a service area unless that plan, or another MA plan offered by the same organization in the same service area, includes required prescription drug coverage for the entire service area. MA plans, by definition, would include private fee-for-service (PFFS) plans. For purposes of meeting this requirement, an MA organization is considered to be an MA parent organization.

Required prescription drug coverage consists of either: (1) basic prescription drug coverage (as described in section 20.1 of this manual), or (2) enhanced alternative coverage, provided there is no MA monthly supplemental beneficiary premium for the drug coverage applied under the plan. Such enhanced alternative coverage could be provided without a monthly supplemental beneficiary premium only if a plan applied a credit of rebate dollars available under the plan’s Part C bid against the otherwise applicable premium. Rebate dollars represent the dollars available for supplemental (and other) benefits when an MA plan’s risk-adjusted Part C bid is under the risk-adjusted Part C monthly benchmark amount. This requirement ensures that MA organizations offer at least one option for Part D coverage for Part D supplemental premium at the cost of basic prescription drug coverage. Of note, Special Needs Plans (SNPs) cannot satisfy this requirement for non-SNPs in the same service area.

If an MA parent organization does not offer basic prescription drug coverage through a basic plan type (defined standard, actuarial equivalent or basic alternative) in a given service area, to the extent that an MA-PD plan chooses to provide enhanced alternative coverage with no additional premium through the application of rebate dollars, such enhanced alternative coverage
would constitute required coverage for the purposes of meeting the requirement that an MA organization offer a plan that includes required prescription drug coverage.

In order to help ensure that this requirement is being met, CMS has added two questions in the PBP software for enhanced alternative plans. Sponsors must indicate that they either have another basic (defined standard, actuarially equivalent or basic alternative) Part D plan or that the enhanced alternative plan being submitted meets this requirement because the sponsor has brought down the supplemental Part D premium to zero using the MA rebate dollars.

20.4.5 - Restrictions on the Offering of Enhanced Alternative Coverage by Cost Plan Sponsors  
(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

A cost plan sponsor that elects to offer Part D coverage may do so only if such coverage is provided as an optional supplemental benefit (under 42 CFR 417.440(b)(2)(ii)) and if the coverage it offers consists of qualified prescription drug coverage. However, a cost plan sponsor may instead elect to offer prescription drug coverage that is not qualified prescription drug coverage, and the requirements of Part D would not apply to this coverage. However, a cost plan sponsor may not offer both a Part D and a non-Part D drug benefit as enrollee options under the same contract.

A cost plan sponsor that elects to offer qualified prescription drug coverage under Part D may offer enhanced alternative coverage as an optional supplemental benefit (under 42 CFR 417.440(b)(2)(ii)), but only if the cost plan sponsor also offers basic prescription drug coverage as an optional supplemental benefit.

If offered by a cost plan sponsor, an enrollee in the cost plan may elect to receive qualified prescription drug coverage under the cost plan and, if so, whether to receive basic prescription drug coverage or, if offered by the cost plan, enhanced alternative coverage. Individuals enrolling in a Part D plan that is offered as an optional supplemental benefit by a cost plan sponsor may do so according to the requirements for enrollment in a PDP contained in chapter 2. As described in section 10 of chapter 2, such an individual must be a member of the cost plan at the time of the effective date of enrollment in the cost plan’s optional supplemental Part D benefit. Individuals enrolled in a cost plan who do not elect Part D coverage offered by the cost plan sponsor may elect Part D coverage offered by a PDP sponsor.

20.5 - Coverage Gap Coinsurance  
(Rev. 14, Issued: 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Under section 1101(b)(3) of the Health Care and Education Reconciliation Act of 2010 (HCERA), which amended section 3301 of the Patient Protections and Affordable Care Act (PPACA), additional coverage of Part D drugs will be phased into the Part D benefit between 2011 and 2020, so that by 2020 the standard prescription drug benefit will cover 75 percent of the cost of non-applicable drugs in the gap and 25 percent of the cost of applicable (brand) drugs for applicable beneficiaries. Section 1860D-2(b)(2) of the Act was amended to add new paragraphs (C)(i) and (ii) that provide gap coinsurance percentages for future years under the
standard prescription drug benefit. The gap coinsurance percentage for covered Part D drugs that are non-applicable is equal to the following:

<table>
<thead>
<tr>
<th>Year</th>
<th>Coinsurance Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>93 percent</td>
</tr>
<tr>
<td>2012 through 2019</td>
<td>Previous year coinsurance percentage decreased by 7 percentage points</td>
</tr>
<tr>
<td>2020 and thereafter</td>
<td>25 percent</td>
</tr>
</tbody>
</table>

For applicable (i.e., brand) drugs, the gap coinsurance percentage does not get applied until contract year 2013. The gap coinsurance for applicable (brand) drugs is equal to the following:

<table>
<thead>
<tr>
<th>Year</th>
<th>Coinsurance Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013 through 2014</td>
<td>97.5 percent</td>
</tr>
<tr>
<td>2015 through 2016</td>
<td>95 percent</td>
</tr>
<tr>
<td>2017</td>
<td>90 percent</td>
</tr>
<tr>
<td>2018</td>
<td>85 percent</td>
</tr>
<tr>
<td>2019</td>
<td>80 percent</td>
</tr>
<tr>
<td>2020 and thereafter</td>
<td>75 percent</td>
</tr>
</tbody>
</table>

Part D sponsors offering basic Part D plans will include, as part of the bid, the coverage gap coinsurance for all non-applicable drugs on the plan’s formulary, or an actuarially equivalent amount using processes and methods specified under section 1860D-11(c) of the Act. The coverage gap coinsurance applies only to applicable beneficiaries who:

1) Are enrolled in a prescription drug plan or an MA-PD plan;

2) Are not enrolled in a qualified retiree prescription drug plan;

3) Are not entitled to the Federal subsidy for low-income individuals under section 1860D-14(a) and in Chapter 13 of this Manual;

4) Have reached or exceeded the initial coverage limit;

5) Have not incurred costs for covered Part D drugs in the year equal to the annual out-of-pocket threshold; and

6) Have a claim that –

   • Is within the coverage gap;
   • Straddles the initial coverage period and the coverage gap;
   • Straddles the coverage gap and the annual out-of-pocket threshold; or
   • Spans the coverage gap from the initial coverage period and exceeds the annual out-of-pocket threshold.
For alternative plans, the coverage gap begins for the purpose of applying the coverage gap coinsurance based on the plan’s initial coverage limit (approved as part of the bid) and ends at the point a beneficiary reaches the catastrophic threshold.

20.6 - Negotiated Prices  
(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Part D sponsors must provide enrollees with access to negotiated prices for covered Part D drugs as part of their qualified prescription drug coverage. This access to negotiated prices must be provided even when no benefits are otherwise payable on behalf of an enrollee due to the application of a deductible or other cost-sharing. Negotiated prices will take into account negotiated price concessions for covered Part D drugs that are passed through to enrollees at the point of sale, such as:

- Discounts;
- Direct or indirect subsidies;
- Rebates; and
- Other direct or indirect remunerations

In addition, negotiated prices must include any applicable dispensing fees (discussed in section 20.7).

Although negotiated prices do not have to be made available for drugs that are not covered Part D drugs, they must be made available throughout the benefit – including in any phase of the benefit, such as the deductible, in which an enrollee is responsible for 100 percent cost-sharing – for all covered Part D drugs. Part D sponsors must ensure that their payment systems are set up to charge beneficiaries the lesser of a drug’s negotiated price or applicable copayment amount in all phases of the benefit.

Example: A beneficiary’s drug is on a $10 cost-sharing tier. However, the negotiated price of the drug is $4. The beneficiary never pays more than $4.

In addition, uniform negotiated prices must be available to plan enrollees for a particular covered Part D drug when purchased from the same pharmacy. In other words, the negotiated price for a particular covered Part D drug purchased at a particular pharmacy must always be the same regardless of what phase of the Part D benefit an enrollee is in. (To the extent that the negotiated price fluctuates based on fluctuations in Average Wholesale Price (AWP), the actual cost to the beneficiary may vary from purchase to purchase; however the negotiated rate, absent any contractual changes in the reimbursement rate between the pharmacy and the Part D sponsor, will remain constant for that drug.)

20.7 - Dispensing Fees  
(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

As discussed in section 20.6, negotiated prices must include any applicable dispensing fees. Provided that Part D sponsors include only those activities allowed under CMS’ definition of dispensing fees in the dispensing fees negotiated with network pharmacies and offer standard
contracting terms and conditions to all similarly situated pharmacies, in accordance with section 50.8.1, CMS notes that Part D sponsors have the flexibility to vary the actual dispensing fee paid to pharmacies. For example, Part D sponsors may need to increase the dispensing fees paid to rural or long-term care pharmacies in order to obtain their participation in networks and meet the pharmacy access standards. Table 2 below provides a summary of the costs that may be included in dispensing fees, as well as those that may not.

### Table 2
Costs that May and May Not Be Included in Dispensing Fees

<table>
<thead>
<tr>
<th>Costs That May be Included in Dispensing Fees</th>
<th>Costs that are incurred at the point of sale and pay for costs in excess of the ingredient cost of a covered Part D drug each time a covered Part D drug is dispensed.</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Pharmacy costs associated with ensuring that possession of the appropriate covered Part D drug is transferred to a Part D enrollee. These pharmacy costs include, but are not limited to:</td>
<td>• The salaries of pharmacists and other pharmacy workers;</td>
</tr>
<tr>
<td>o Any reasonable costs associated with a pharmacist's time in checking the computer for information about an individual’s coverage;</td>
<td>o Performing quality assurance activities consistent with 42 CFR 423.153(c)(2);</td>
</tr>
<tr>
<td>o Measurement or mixing of the covered Part D drug, including any labor costs associated with mixing a compounded product that contains at least one Part D drug component, as detailed in section 10.4 of chapter 6;</td>
<td>o Filling the container;</td>
</tr>
<tr>
<td>o Physically providing the completed prescription to the Part D enrollee;</td>
<td>o Delivery;</td>
</tr>
<tr>
<td>o Special packaging, e.g., assistive technology packaging; and</td>
<td>o Overhead associated with maintaining the facility and equipment necessary to operate the pharmacy, including costs associated with the acquisition and maintenance of</td>
</tr>
<tr>
<td>o Overhead associated with maintaining the facility and equipment necessary to operate the pharmacy, including</td>
<td></td>
</tr>
</tbody>
</table>
Reasonable pharmacy costs that are appropriate for the typical beneficiary in that pharmacy setting, for example:

- Costs associated with postal or freight shipping (to include air courier) to beneficiaries located in remote and frontier areas with limited or no access to roads. While the typical beneficiary served by a retail pharmacy in most areas of the country would not require postage, freight or other transport costs for delivery of drugs, CMS believes that it is reasonable to assume that the typical beneficiary in remote and frontier areas with limited or no access to roads would require delivery of drugs via postal or freight shipping (to include air courier). Because such a circumstance constitutes a distinct pharmacy setting, CMS believes that the costs associated with postal or freight shipping (to include air courier) to such remotely located beneficiaries would constitute reasonable costs that could be reimbursed as part of the dispensing fee negotiated between a Part D sponsor and a contracted network pharmacy.

- Costs associated with special packaging and delivery for residents of non-LTC facilities (e.g., assisted living facilities and other forms of congregate residential settings) with the same level of care need as residents of LTC facilities. It is reasonable to assume that the typical enrollee residing in a non-LTC facility setting who meets the same level of care need as a beneficiary in an LTC facility would require the provision of dispensing related services such as unit-dose packaging and home delivery that are provided by LTC pharmacies to the residents of LTC facilities. For this reason, CMS believes that non-LTC facilities in which individuals meeting an institutionalized level of care need constitute a distinct pharmacy setting, and one in which specialized services such as specialized packaging and home delivery would be appropriate for Part D sponsors to reimburse LTC pharmacies via the dispensing fee. However, CMS notes that it would not be appropriate for Part D sponsors to reimburse LTC pharmacies for these specialized services for individuals who do not meet an institutionalized level of care need.

- With respect to LTC pharmacies, dispensing fees should take into consideration any incremental costs associated
with any increased number of dispensing events in a billing cycle due to the dispensing methodology used to minimize the dispensing of unused drugs.

- Costs associated with data collection on unused Part D drugs and restocking fees associated with return for credit and reuse in LTC pharmacies when return for credit and reuse is permitted under State law and is allowed under the contract between the Part D sponsors and the pharmacy.

| Costs That May Not be Included in Dispensing Fees |• Administrative costs incurred by the Part D sponsor in the operation of the Part D benefit, including systems costs for interfacing with pharmacies. |
|• Supplies, equipment, and services associated with administration of covered Part D drugs, including those associated with home infusion therapy of covered Part D drugs or with vaccine administration. With the exception of costs associated with vaccine administration, these costs may also not be paid by Part D sponsors through a separate fee or additional compensation to home infusion pharmacies and other providers. Other than medication therapy management programs, medical or clinical services may not be included in administrative fees. In addition, professional services, including those associated with home infusion, may not be included in supplemental Part D benefits. The costs associated with supplies, equipment, and services for home infusion therapy of covered Part D drugs must be paid by either the enrollee or another payer. |
|• Reasonable pharmacy costs that are not appropriate for the typical beneficiary in that pharmacy setting, for example: |
| o Home delivery by retail pharmacies, since the typical retail customer does not require home delivery. While it would be appropriate for Part D sponsors to reimburse LTC, mail-order, and home infusion pharmacies for home delivery costs via the dispensing fee, this would not be the case for retail pharmacies, where the term “delivery” would be limited to the transfer of a covered Part D drug from the pharmacist to the patient at the point of sale. |
| o Costs associated with delivery of drugs from manufacturers |

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1 The administration of a Part D-covered vaccine is included in the definition of a “Part D drug,” effective January 1, 2008. Consequently, the Part D program covers vaccine administration costs associated with Part D vaccines. For more information, refer to section 10.14 of [chapter 6](#).
20.8 - Ensuring Meaningful Differences in Approved Bids  
(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

20.8.1 - General  
(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

CMS ensures that plan offerings by Part D sponsors represent meaningful differences to beneficiaries with respect to benefit packages and plan cost structures. Specifically, §423.272(b)(3)(i) stipulates that CMS will only approve a bid submitted by a Part D sponsor if its plan benefit package or plan cost structure was substantially different from those of other plan offerings by the sponsor in the service area with respect to key characteristics such as premiums, cost-sharing, formulary structure, or benefits offered. Section 423.265(b)(2) also requires that Part D sponsors may submit multiple bids in the same area only if the offerings are substantially different from each other.

While CMS supports the concept of a wide variety of prescription drug coverage choices for Medicare beneficiaries, CMS believes it is necessary to ensure that those choices represent meaningfully different options in order to simplify beneficiaries’ enrollment decision making process. Ensuring that, within each service area, PDP sponsors offer only plan options that are meaningfully different will maximize opportunities for beneficiaries to select the most appropriate plan for their needs and reduce beneficiary confusion with respect to choices offered by the same Part D sponsor.

To determine whether there are meaningful differences amongst plans offered by the same sponsor, CMS will evaluate and compare plan offerings in a service area by evaluating plan-specific benefit data (e.g., cost sharing, formulary, and benefits) for each offering. CMS will provide additional information regarding our meaningfully different bid evaluation processes in our annual payment notice and call letter prior to the date of plan bid submissions.

20.8.2 - Meaningful Differences in Basic Prescription Drug Coverage Options  
(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

To determine whether there are meaningful differences between basic prescription drug coverage options (which includes defined standard, actuarially equivalent standard, and basic alternative benefit designs) offered by the same PDP sponsor in a region, CMS’ analysis focuses on whether there are significant differences in proposed beneficiary out-of-pocket costs and/or formularies. It is important to note that, even though a sponsor may submit different formularies for different Part D offerings, all submitted formularies must be sufficiently robust to pass CMS’ rigorous formulary reviews and checks and be determined not to discourage enrollment by certain types of beneficiaries. Based on CMS’ experience and given statutory actuarial equivalency requirements, CMS does not expect that – absent substantial differences in approved formularies – PDP sponsors can demonstrate meaningful differences between plans offering basic prescription drug coverage. Therefore, CMS believes sponsors should submit only one basic offering (where basic offering includes defined standard, actuarial equivalent and basic alternative drug benefit types) for a stand-alone prescription drug plan in a service area.
20.8.3 - Meaningful Differences in Enhanced Alternative Coverage Options
(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

When evaluating for differentiation among an organization’s plan offerings, CMS will scrutinize enhanced benefit designs that add little or no additional value to its basic offering. CMS has found that it is difficult for beneficiaries to distinguish between plan offerings of the same sponsor when cost-sharing and premiums are similar between the enhanced and basic drug plan offering. CMS recognizes that sponsors may have purposefully established plan benefit designs to address different utilization patterns among sub-groups of beneficiaries and in order to segment risk. However, CMS is concerned that some “low-additional-value” enhanced offerings are not understood by beneficiaries in terms of expected value and may not be meaningfully different from the basic offering.

CMS will evaluate enhanced plans to identify those enhanced plan offerings with meaningful increases in value over basic plan offerings. CMS will announce its meaningful differences evaluation methodology and expectations for plan sponsors via the annual payment notice and call letter. To prepare for negotiations with CMS, Part D sponsors should consult the annual payment notice and call letter when preparing multiple plan bids for the upcoming plan year.

CMS will request that PDP sponsors with plan benefit packages that are not substantially different from each other either withdraw or enhance a bid in order to ensure that all offerings are, in fact, meaningfully different. It is CMS’ experience, based on this analysis that PDP sponsors typically must offer substantive coverage in the coverage gap as a supplemental benefit in order to demonstrate that one enhanced alternative plan design is meaningfully different from another.

20.8.4 - Transition Period for Sponsors or Parent Organizations with New Acquisitions
(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

PDP sponsors or parent organizations with new acquisitions on or after June 7, 2010, will be afforded a period of 2 years to transition their plan offerings to meet the goal of ensuring that the Part D sponsor’s offerings are substantially different from one another. PDP sponsors that have completed a new acquisition will be expected to submit to CMS a plan that details how the 2 year transition will take place.

Example: A PDP sponsor (or its parent organization) completing an acquisition of another PDP sponsor in November 2010 would not be subject to requirements for offering substantially different bids until the 2013 contract year (that is, bids would be due in June 2011 for the 2012 program year; transition would occur during 2011 and 2012; and the Part D sponsor or parent would need to ensure that in June 2012, when it submits its bids for program year 2013, all of its bids are for substantially different plans).

20.9 - PDP Plan Benefit Package (PBP) Renewal and Crosswalk Guidance
(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)
The PDP regions are defined by CMS and consist of one or more entire states (refer to Appendix 2 of this chapter for a map of the 34 PDP regions). Each of a PDP sponsor’s PBPs must be offered in at least one entire region. A Part D sponsor’s PBP cannot be offered in only part of a region. Note that PDP bidding rules require PDP sponsors to submit bids for PBPs that cover only one PDP region at a time. Therefore, HPMS only allows a PDP sponsor’s PBPs to cover one region at a time (e.g., a PDP sponsor offering a “national” PDP would, for purposes of bidding, be said to be offering 34 plans – one in each PDP region – and would submit 34 PBPs).

A PDP sponsor may expand the service area of its offerings by submitting additional bids in the PDP regions the sponsor expects to enter in the following contract year, provided the sponsor submits a PDP Service Area Expansion (SAE) application and CMS approves that application and then approves the sponsor’s submitted bids for the new region or regions.

Conversely, a PDP sponsor may reduce its service area by electing not to submit bids for those regions from which it expects to withdraw. A PDP sponsor must notify CMS in writing of its intent to non-renew by the first Monday in June pursuant to 42 CFR 423.507(a)(2)(i). However, even absent written notification to CMS, a PDP sponsor’s failure to submit a timely bid to CMS constitutes a voluntary non-renewal by the sponsor. (Note that PDP sponsors reducing their service areas must provide notice of their action to affected beneficiaries consistent with Chapter 3, PDP Eligibility, Enrollment, and Disenrollment Guidance of this manual and CMS non-renewal and service area reduction guidance.)

There are six renewal options for PBPs offered by current PDP sponsors: (1) new plan; (2) renewal plan; (3) consolidated renewal plan; (4) renewal plan with a service area expansion (applicable only to “800 series” employer/union-only group waiver plans, or EGWPs); (5) terminated plan (non-renewal); and (6) consolidated plans under a parent organization.

20.9.1 - New Plan
(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

A PDP sponsor may create a new PBP for the following contract year with no link to a PBP it offers in the current contract year. In this situation, beneficiaries electing to enroll in the new PBP must complete enrollment requests, and the PDP sponsor must submit enrollment transactions to the MARx system. No beneficiary notice is required in this case.

20.9.2 - Renewal Plan
(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

A PDP sponsor may retain a current PBP for the following contract year. In order for currently enrolled beneficiaries to remain in the renewed PBP, the sponsor must retain the same PBP identification number for the following contract year. Current enrollees are not required to make an enrollment election to remain enrolled in the renewal PBP, and the sponsor will not submit enrollment transactions for existing members. Current enrollees of a renewed PBP must receive a standard Annual Notice of Change (ANOC) (described in chapter 2 of this manual) which will include any changes to the renewing plan. Based on their review of the ANOC, beneficiaries may elect another plan offered by either the same or another PDP sponsor or MA organization during the Annual Coordinated Election Period.
When renewing a PBP, it is permissible to make the following benefit design changes: (1) from a basic benefit design (meaning a defined standard, actuarially equivalent standard, or basic alternative benefit design) to another basic benefit design; or (2) from an enhanced alternative benefit design to a basic benefit design. As a general matter, CMS will not permit renewal of a PBP through the HPMS Plan Crosswalk when it involves moving enrollees from a basic benefit design to an enhanced alternative benefit design, since enrollees previously not subject to a supplemental premium under a basic benefit design will have to pay a combined basic and supplemental premium under an enhanced alternative benefit design that may be higher than a basic premium.

20.9.3 -Consolidated Renewal Plan  
(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

PDP sponsors are permitted to combine two or more PBPs offered in the current contract year into a single renewal plan so that all enrollees in the combined plans are offered the same benefits under one PBP in the following contract year. When consolidating two existing PBPs into a single renewal PBP, it is permissible for the single renewal PBP to result in a change from:

1. a basic benefit design (meaning a defined standard, actuarially equivalent standard, or basic alternative benefit design) to another basic benefit design;

2. an enhanced alternative benefit design to a basic benefit design; or

3. an enhanced alternative benefit design to another enhanced alternative benefit design.

Again, as a general matter, CMS will not permit consolidation of two existing PBPs into a single renewal PBP through the HPMS Plan Crosswalk when it involves a change from a basic benefit design to an enhanced alternative benefit design, since enrollees previously not subject to a supplemental premium under a basic benefit design will have to pay a combined basic and supplemental premium under an enhanced alternative benefit design that may be higher than a basic premium.

PDP sponsors combining two or more PBPs into a single renewal PBP must designate which of the consolidating plans will be retained in the following contract year after consolidation; that is, the sponsor’s designated renewal plan ID must remain the same in order for CMS to consolidate the beneficiary’s election by moving him or her into the designated renewal plan ID. This is particularly important with respect to minimizing beneficiary confusion when a plan consolidation affects a large number of enrollees. Enrollees of a plan or plans being consolidated into a single renewal plan will not be required to take any enrollment action, and the sponsor will not submit enrollment transactions for existing members, though it may need to submit updated 4Rx data (described in chapter 14 of this manual) for the enrollees affected by the consolidation to CMS. The PDP sponsor will be responsible for sending a standard ANOC to any enrollees whose current plans are being consolidated into a renewal plan. Based on their review of the ANOC, beneficiaries whose enrollment has been consolidated into a renewal PBP may then elect another plan offered by either the same or another PDP sponsor or MA organization during the Annual Coordinated Election Period.
20.9.4 - Renewal Plan with a Service Area Expansion (800 Series EGWPs only)
(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

A PDP sponsor offering an 800 series EGWP PBP in the current contract year may expand its EGWP service area to include additional PDP regions for the following contract year. In order for currently enrolled beneficiaries to remain in the renewed PBP, the sponsor must retain the same PBP identification number for the following contract year. Current enrollees are not required to make an enrollment election to remain enrolled in the renewal PBP, and the sponsor will not submit enrollment transactions for existing members. New enrollees must complete an enrollment election. Current enrollees of a renewed 800-series PBP must receive a standard ANOC notifying them of any changes to the renewing plan.

20.9.5 - Terminated Plan (Non-Renewal)
(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

A PDP sponsor may elect to terminate a current PBP for the following contract year. In this situation, the sponsor will not submit disenrollment requests for affected enrollees. To the extent that affected enrollees elect to enroll in a PBP offered by the current or another PBP sponsor, they must complete an enrollment request, and the enrolling sponsor must submit enrollment transactions so that those individuals are enrolled in the PBP they have selected. Enrollees of terminated PBPs will be sent a termination notice and will receive a written description of options for obtaining prescription drug coverage in their service area. For more information about non-renewal processes and beneficiary notification requirements, refer to the annual summer HPMS memo providing non-renewal and service area reduction guidance.

20.9.6 - Consolidated Plans Under a Parent Organization
(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

For purposes of ensuring compliance with transition requirements following an acquisition or merger under CMS’ meaningful differences policy, or to make plan transitions following a novation, a plan sponsor may elect to combine two or more entire PBPs offered under different contracts (the contracts may be offered by the same legal entity or represent different legal entities). PDP sponsors cannot complete this renewal option in the HPMS Plan Crosswalk. A PDP sponsor must complete and submit a request to CMS in accordance with its annual renewal/non-renewal guidance.

Current enrollees of a plan or plans being consolidated across contracts in this manner will not be required to take any enrollment action, and the sponsor will not submit enrollment transactions for those current members, although it may need to submit updated 4Rx data to CMS for the current enrollees affected by the consolidation. New enrollees must complete enrollment requests, and the sponsor will submit enrollment transactions to CMS for those new enrollees. Current enrollees of a consolidated renewal plan must receive a special notification along with a standard ANOC.

20.10 - Low-Enrollment Plans
(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)
CMS will use its authority under section 1857(c)(2)(B) of the Act, as incorporated by reference for Part D at section 1860D-12(b)(3)(B) and codified in 42 CFR §423.507(b)(1)(iii), to non-renew plans at the benefit-package level that do not have sufficient number of enrollees after a specified length of time to establish that they are viable plan options, because, as a general matter, continuing low enrollment plans is not consistent with the effective and efficient administration of the Medicare program. Consistent with that authority, CMS will be scrutinizing low-enrollment plans during the bid review period and alerting sponsors of low-enrollment plans that CMS expects them to withdraw or consolidate prior to submitting bids for the next calendar year. Before CMS would take any action to non-renew a plan pursuant to 42 CFR §423.507(b)(1)(iii), CMS would take into account all relevant factors.

CMS’ scrutiny of low-enrollment plans will not apply to employer stand-alone Part D plans. At this time, a waiver of the minimum enrollment requirements at 42 CFR 423.512(a) (minimum enrollment requirements) for sponsors of employer group applies.

20.11 - Manufacturer Drug Discount Program
(Rev. 14, Issued: 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Beginning January 1, 2011, discounts were available to applicable Medicare beneficiaries receiving applicable drugs while in the coverage gap. Generally, the discount on each applicable drug is 50% of the negotiated price (excluding dispensing fee). An applicable drug is covered under Part D only if the manufacturer has signed agreement with CMS to provide the discount on coverage gap claims for all of its applicable drugs and remains compliant with the terms of the agreement (assuming all other coverage criteria are met). Part D sponsors provide the discounts for applicable drugs in the coverage gap at the point-of-sale. A CMS contractor will coordinate the collection of discount payments from manufacturers and payment to Part D sponsors.

For additional details regarding the policies, and administration of, the Manufacturer Drug Discount program as it evolves, Part D sponsors should consult HPMS.

30 - Incurred/“True Out-of-Pocket” (TrOOP) Costs
(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

Not all enrollee out-of-pocket expenditures are considered incurred (or “true-out-of-pocket,” or TrOOP, expenditures) for purposes of applicability toward beneficiary spending against the annual out-of-pocket threshold described in section 20.3.1. Sections 30.1 and 30.2 provide further detail on whether certain expenditures are TrOOP-eligible or not, and Table 3 provides a summary of those discussions.

30.1 - Costs that Count as Incurred Costs
(Rev. 14, Issued: 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Costs are considered incurred costs and can be added to an enrollee’s TrOOP balance if all of the following conditions are met:
1. Costs are incurred against any annual deductible, any applicable cost-sharing for costs above the deductible and up to the initial coverage limit, and any applicable cost-sharing for costs above the initial coverage limit and up to the annual out-of-pocket threshold.

2. Costs are incurred with respect to covered Part D drugs that are either included in a PDP or MA-PD plan’s formulary or treated as being included in a plan’s formulary as a result of a coverage determination, redetermination, or appeal under chapter 18.

3. Costs are:
   - Incurred by the enrollee;
   - Incurred by another person (including charities, if they are not otherwise excluded as TrOOP-eligible payers as provided in section 30.2) on behalf of the enrollee other than costs reimbursed by a group health plan, insurance or otherwise (including a government-funded health program), or another third party payment arrangement;
   - Paid by Medicare on behalf of a low-income individual under the Part D subsidy provisions described in 42 CFR 423.782;
   - Discounts paid by manufacturers as part of the Medicare Coverage Gap Discount program;
   - Paid on behalf of the enrollee under a qualified State Pharmaceutical Assistance Program (SPAP) described in 42 CFR 423.454.
   - Paid by the Indian Health Service (IHS), an Indian tribe or tribal organization, or an urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act); and
   - Paid by AIDS Drug Assistant Program (ADAP) under Part B of title XXVI of the Public Health Service Act.

4. Costs are incurred at a network pharmacy or an out-of-network (OON) pharmacy, consistent with the sponsor’s out-of-network access policy (refer to section 60 for more information on out-of-network access requirements).

Following are examples of costs considered incurred costs for purposes of TrOOP calculations:

**Example 1:** Any differential charged to a beneficiary between a network retail pharmacy’s contracted rate and a network mail-order pharmacy’s contracted rate for an extended (for example, 90-day) supply of a covered Part D drug purchased at a retail pharmacy, as described in section 50.10.

**Example 2:** For a covered Part D drug obtained OON consistent with the sponsor’s OON policy, any differential charged to the beneficiary between an OON pharmacy’s usual and
customary price for the covered Part D drug and the plan allowance for that covered Part D drug.

**Example 3:** As provided in section 50.4.2 of chapter 14, costs incurred by enrollees by using a discounted cash price, and not their Part D benefit, provided the purchase is for a covered Part D drug; the purchase is made at a network pharmacy; the discounted cash price is lower than the negotiated price offered by the enrollee’s Part D plan; the enrollee is in any applicable deductible or coverage gap phase of his or her benefit; and the enrollee submits appropriate documentation to his or her Part D plan to be credited for the purchase.

**Example 4:** Covered Part D drug cost-sharing waived or reduced by a pharmacy that is not a group health plan, insurance, government-funded health program, or party to a third party payment arrangement with an obligation to pay for covered Part D drugs, as described in section 30.4.

**30.2 - Costs that Do Not Count as Incurred Costs**

*(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)*

The following are not considered incurred costs and cannot be added to an enrollee’s TrOOP balance:

1. Costs for non-formulary Part D drugs unless treated by the Part D sponsor as being included in the sponsor’s formulary as a result of a coverage determination, redetermination, or appeal as described in chapter 18.

2. Costs for non-Part D drugs, as described in section 20.1 of chapter 6.

3. Costs paid for covered Part D drugs obtained out-of-network when OON access is not consistent with the OON access policy (refer to section 60 for more information on OON access requirements).

4. Costs that are paid for or for which an enrollee is reimbursed by insurance or otherwise, including a government-funded health program.²

5. Costs that are paid for or for which an enrollee is reimbursed by a group health plan.

6. Costs that are paid for or for which an enrollee is reimbursed by another third party payment arrangement.

7. Covered Part D drug cost-sharing waived or reduced by a pharmacy that is also a TrOOP-ineligible payer, as described in section 30.4.

² If an entity providing for or paying the cost of drugs receives a government grant none of which is used to pay for drugs (for example, a low-income housing grant), such an entity is not considered a government-funded health program. If an entity pays for Part D drugs using a mix of private and public funds, the entity is considered a government-funded health program, and all its drug spending is excluded from TrOOP.
Table 3  
Costs that Do and Do Not Count Toward TrOOP Expenditures

<table>
<thead>
<tr>
<th>Costs that Count Toward Incurred / TrOOP Expenditures</th>
<th>1. Costs that are incurred against any annual deductible, any applicable cost-sharing for costs above the deductible and up to the initial coverage limit, and any applicable cost-sharing for costs above the initial coverage limit and up to the annual out-of-pocket threshold; AND</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Costs that are incurred with respect to covered Part D drugs that are either included in a prescription drug plan or MA-PD plan’s formulary or treated as being included in a plan’s formulary as a result of a coverage determination, redetermination, or appeal under chapter 18; AND</td>
<td></td>
</tr>
<tr>
<td>3. Costs that are:</td>
<td></td>
</tr>
<tr>
<td>o Incurred by the enrollee;</td>
<td></td>
</tr>
<tr>
<td>o Incurred by another person on behalf of the enrollee other than costs reimbursed by a group health plan, insurance or otherwise (including a government-funded health program), or another third party payment arrangement;</td>
<td></td>
</tr>
<tr>
<td>o Paid by Medicare on behalf of a low-income individual under the Part D subsidy provisions described in 42 CFR 423.782;</td>
<td></td>
</tr>
<tr>
<td>o <em>Discount paid by a manufacturer as part of the Medicare Coverage Gap Discount program</em>;</td>
<td></td>
</tr>
<tr>
<td>o Paid on behalf of the enrollee under a qualified State Pharmaceutical Assistance Program (SPAP) described in 42 CFR 423.454;</td>
<td></td>
</tr>
<tr>
<td>o <em>Paid by the Indian Health Service (IHS), an Indian tribe or tribal organization, or an urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act)</em>; or</td>
<td></td>
</tr>
</tbody>
</table>
| Costs that Do Not Count Toward Incurred / TrOOP Expenditures | 1. Costs incurred for non-formulary Part D drugs unless treated by a sponsor as being included in the sponsor’s formulary as a result of a coverage determination, redetermination, or appeal.  
2. Costs incurred for non-Part D drugs.  
3. Costs paid for covered Part D drugs obtained OON when such OON access is inconsistent with the sponsor’s OON access policy.  
4. Costs paid for or reimbursed by insurance.  
5. Costs paid for or reimbursed by a government-funded health program.  
6. Costs paid for or reimbursed by a group health plan.  
7. Costs paid for or reimbursed by another third party payment arrangement.  
8. Covered Part D drug cost-sharing waived or reduced by a pharmacy that is also a TrOOP-ineligible payer, as described in section 30.4. |

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### 30.3 - Summary of TrOOP-Eligible and TrOOP-Ineligible Payers

*Rev. 14, Issued: 09-30-11, Effective: 09-30-11, Implementation: 09-30-11*

Part D enrollees may have coverage or receive assistance from any of a number of entities that wrap around the benefits available under Part D. As described in sections 30.1 and 30.2 above, this wrap-around assistance or coverage may or may not count as incurred costs. Table 4 below provides plans with information about whether specific entities are “TrOOP-included,” meaning that their wrap-around assistance counts as an incurred cost, or “TrOOP-excluded,” meaning that their wrap-around assistance does not count as an incurred cost.
### Table 4
Examples of TrOOP-Excluded and TrOOP-Included Entities

<table>
<thead>
<tr>
<th>TrOOP-Excluded Entities</th>
<th>TrOOP-Included Entities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicaid (even when using State-only funds)</td>
<td>State Pharmaceutical Assistance Programs (SPAPs)</td>
</tr>
<tr>
<td>Medicaid 1115 demonstrations</td>
<td>Most charities (unless established, maintained, or otherwise controlled by an employer or union)</td>
</tr>
<tr>
<td>State Children’s Health Insurance Program (SCHIP)</td>
<td><strong>Indian Health Service (IHS), an Indian tribe or tribal organization, or an urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act)</strong></td>
</tr>
<tr>
<td>Federally Qualified Health Centers (FQHCs), Rural Health Clinics, and any safety-net facilities including public hospital systems, community hospitals, and local health departments that are considered “government-funded health programs”</td>
<td><strong>AIDS Drug Assistance Program (ADAP) under Part B of title XXVI of the Public Health Service Act</strong></td>
</tr>
<tr>
<td>Patient assistance programs (PAPs) operating outside the Part D benefit</td>
<td>Health savings accounts (HSAs)</td>
</tr>
<tr>
<td>TRICARE</td>
<td>Flexible spending accounts (FSAs)</td>
</tr>
<tr>
<td>Federal Employee Health Benefits Program (FEHBP) plans</td>
<td>Medical savings accounts (MSAs)</td>
</tr>
<tr>
<td>Black Lung Funds</td>
<td></td>
</tr>
<tr>
<td>State programs that do not meet the definition of a qualified SPAP in 42 CFR 423.464.</td>
<td></td>
</tr>
<tr>
<td>Health reimbursement arrangements (HRAs)</td>
<td></td>
</tr>
</tbody>
</table>

The term “incurred costs” is only defined with respect to the annual out-of-pocket threshold. Therefore, any coverage that supplements the benefits available under basic prescription drug coverage may be counted toward any applicable deductible even though such drug coverage is excluded from the definition of incurred costs for purposes of TrOOP accounting.
Pharmacies are permitted to waive or reduce Part D cost-sharing amounts, provided they do so in an unadvertised, non-routine manner after determining that the beneficiary is financially needy or after failing to collect the cost-sharing amount despite reasonable efforts. In addition, a pharmacy may waive or reduce a beneficiary's Part D cost-sharing for beneficiaries eligible for the low-income subsidy, provided the pharmacy has not advertised that the waivers or reductions of cost-sharing are available. In other words, for low-income subsidy recipients only, pharmacies may provide routine waivers or reductions of cost-sharing amounts and need not ascertain financial need. However, the pharmacies will not be eligible for safe harbor protection if they advertise in any way the availability of waivers or cost reductions.

Waivers or reductions of Part D cost-sharing by pharmacies will generally count toward TrOOP, as will payments made by AIDS Drug Assistance Program (ADAP) under Part B of Title XXVI of the Public Health Service Act, as well as payments made by the Indian Health Service (IHS), an Indian tribe or tribal organizations, or an urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act). However, in all other instances, to the extent that the party paying for cost-sharing on behalf of a Part D enrollee is a group health plan, insurance, government-funded health program, or party to a third party payment arrangement with an obligation to pay for covered Part D drugs, that party’s payment will not count toward TrOOP.

Payments made for beneficiary cost-sharing by any entity – including a safety-net pharmacy – that has an obligation to pay for covered Part D drugs on behalf of Part D enrollees, or which voluntarily elects to use public funds, in whole or in part, for that purpose, will not count toward that beneficiary’s TrOOP expenditures. Safety-net pharmacies typically include Federal, State, and locally supported community health centers or clinics – many of which are deemed FQHCs – public hospital systems, and local health departments. In some communities, they also include mission-driven teaching hospitals, community hospitals, and ambulatory care clinics. Rural health clinics (RHCs), small rural hospitals, critical access hospitals, clinics that receive Ryan White HIV/AIDS grant funding, and nurse managed clinics are also key components of the safety-net. An estimated 12,000 safety-net providers participate in the Health Resources and Services Administration’s (HRSA) 340B Drug Pricing Program, which allows them to purchase their prescription drugs at significantly discounted prices. Participation in the 340B Drug Pricing Program can enable safety-net pharmacies to provide prescriptions to their patients at lower-than-market prices.

Disproportionate Share Hospitals (DSH) may also be TrOOP-excluded entities. Receipt of Medicaid or Medicare DSH payments by a hospital does not, in and of itself, render a DSH facility (and any Part D network pharmacy it owns or operates) a “government-funded health program.” CMS views Medicare and Medicaid DSH funds essentially as adjustments to the Medicare and Medicaid reimbursements these facilities already receive for covered services. However, any program that is operated or funded, in whole or in part, by any government agency, and which uses public funds in whole or in part, to provide to (or pay on behalf of an individual) the costs of Part D drugs is a government-funded health program even if it pays these costs using a mix of private and public funds. An entity that receives DSH funds and uses non-
DSH government funding streams to provide to or pay on behalf of an individual the costs of Part D drugs will meet CMS’ definition of a government-funded health program, and any reduction or waiver of Part D cost-sharing that it offers will not count toward a Part D enrollee’s TrOOP balance.

Similarly, participation in the 340B Drug Pricing Program does not in and of itself render a safety-net pharmacy a government-funded health program. However, as with DSH facilities, any use of government funding streams to provide to or pay on behalf of an individual the costs of Part D drugs will render a safety-net pharmacy a government-funded health program such that any reduction or waiver of Part D cost-sharing that it offers will not count toward a Part D enrollee’s TrOOP balance.

However, if an entity can demonstrate to a Part D sponsor that it uses only non-public funds to pay for the cost of Part D drugs, that sponsor may allow for cost-sharing waivers or reductions in cost-sharing paid for by that entity’s pharmacies to count toward TrOOP. Part D sponsors remain ultimately accountable for correctly tracking their enrollees’ TrOOP expenditures.

If, on the other hand, a pharmacy funds Part D cost-sharing waivers using a mix of private and public funds, the pharmacy is considered a government-funded health program, and all its drug spending is excluded from TrOOP. If a pharmacy is a government-funded health program or other TrOOP-ineligible payer and waives or reduces any applicable Part D enrollee cost-sharing after payment of a claim by the Part D sponsor, that claim must be flagged so that any applicable beneficiary cost-sharing that is waived or reduced by the pharmacy is not added to a beneficiary’s TrOOP balance. Currently, there does not exist any capability under the National Council for Prescription Drug Programs (NCPDP) 5.1 transaction set for pharmacies to indicate a pharmacy’s waiver or reduction of any applicable beneficiary cost-sharing so that such subsidies are not applied to the beneficiary’s TrOOP balance. CMS recommends that Part D sponsors set up manual processes with safety-net pharmacies in their networks in order to accurately maintain beneficiary TrOOP balances.

40 - Prescription Drug Plan Service Areas
(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Prescription drug plan regions are areas in which a contracting PDP sponsor must provide access to covered Part D drugs. The service area for a PDP, with the exception of a fallback plan, consists of one or more PDP regions. A PDP sponsor may offer a PDP in more than one region – including in all PDP regions – so long as coverage is provided in all those regions in their entirety. However, the PDP sponsor must submit separate bids for its coverage in each region of its service area.

There are currently 34 PDP regions and 26 MA regions (refer to Appendix 2 and Appendix 3, respectively, for maps of these PDP and MA regions). Each of the five U.S. Territories – American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, and the Virgin Islands – constitutes an additional PDP region. While these regional boundaries are currently in effect, CMS may revise both the PDP and MA regions in future years.
50 - Access to Covered Part D Drugs  
(Rev. 8, Issued: 12-18-09, Effective/Implementation: 01-01-10)

Part D sponsors must establish a pharmacy network sufficient to ensure access to covered Part D drugs for their enrollees. As detailed below, Part D sponsors must demonstrate that they provide: (1) convenient access to retail pharmacies for all enrollees; (2) adequate access to home infusion pharmacies for all enrollees; (3) convenient access to LTC pharmacies for enrollees residing in LTC facilities; and (4) convenient access to I/T/U pharmacies for American Indian/Alaska Native (AI/AN) enrollees. Except as indicated in section 50.3 for limited access drugs, covered Part D drugs must be accessible to enrollees through network pharmacies through all phases of the Part D benefit.

Sponsors or their pharmacy benefits manager (PBM) should maintain a contracting log documenting their efforts to provide standard terms and conditions to prospective network pharmacies as well as any contracting negotiations between the sponsor or PBM and prospective network pharmacies. This contracting log will help CMS in its efforts to ensure compliance with pharmacy access requirements, including the any willing pharmacy requirement described in section 50.8.1.

After their initial pharmacy access submissions are approved, Part D sponsors must notify their CMS account manager of any substantive change in their pharmacy network that may impact their ability to maintain a Part D pharmacy network that meets CMS’ requirements. Substantive changes to a pharmacy network include, but are not limited to:

- An inability to meet the convenient access standard for retail pharmacies, as described in section 50.1;

- An inability to provide adequate access to home infusion drugs to enrollees within 24 hours of discharge from an acute setting, as described in section 50.4;

- An inability to provide an enrollee residing in an LTC facility convenient access to a network LTC pharmacy that serves the LTC facility, as described in section 50.5.1; or

- Not offering Part D contracts to all I/T/U pharmacies in a Part D sponsor’s service area in order to provide convenient access for AI/AN enrollees, as described in section 50.6.

Part D sponsors will be required to provide CMS with data on an annual basis that will allow CMS to determine whether their retail, home infusion, and LTC pharmacy networks continue to meet CMS’ pharmacy access standards. For more information about these reporting requirements, refer to:
http://www.cms.hhs.gov/PrescriptionDrugCovContra/08_RxContracting_ReportingOversight.aspx#TopOfPage

A Part D sponsor must notify CMS when it changes PBMs to manage its pharmacy network mid-year. Specifically, the sponsor must:
• Notify their CMS account manager at least 60 days prior to the effective date of the new contract or the date the new PBM would begin providing services to beneficiaries, whichever is earlier. In instances of a contractual change occurring within less than 60 days, then the Part D sponsor must notify their account manager within 5 days of signing the new contract.

• Ensure the change includes an internal transition period, as any decision to change PBMs during the last quarter of the contract year may cause disruption to beneficiary access and services.

• Make preparations to submit appropriate documentation, upon request, to CMS Central Office at any time after the date the contract takes effect (targeted audit). Such documentation may include but not be limited to:
  o Executed PBM contract
  o Retail pharmacy contract template
  o Mail order pharmacy contract template
  o Home infusion pharmacy contract template
  o LTC pharmacy contract template
  o I/T/U pharmacy contract template
  o Up-to-date Part D pharmacy network listings
  o Up-to-date Part D geo-access reports

50.1 - Retail Pharmacy Access
(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

Part D sponsors must secure the participation in their pharmacy networks of a sufficient number of pharmacies that dispense drugs directly to patients (other than by mail order) to ensure convenient access to covered Part D drugs by Part D plan enrollees. CMS convenient access rules require Part D sponsors to establish pharmacy networks in which:

• In urban areas, at least 90 percent of Medicare beneficiaries in the Part D sponsor’s service area, on average, live within 2 miles of a retail pharmacy participating in the sponsor’s network;

• In suburban areas, at least 90 percent of Medicare beneficiaries in the Part D sponsor’s service areas, on average, live within 5 miles of a retail pharmacy participating in the sponsor’s network; and

• In rural areas, at least 70 percent of Medicare beneficiaries in the Part D sponsor’s service area, on average, live within 15 miles of a retail pharmacy participating in the sponsor’s network.

The convenient access standards will be applied to different types of Part D sponsors as follows:
- **Regional MA-PD and PDP sponsors:** Must meet or exceed the convenient access standards across urban, suburban, and rural areas, respectively, in each State in which they operate. To the extent that a regional MA-PD or PDP sponsor operates in a multi-region or national service area, it will be required to meet the convenient access standards in each State in that multi-region or national service area; the sponsor may not meet the convenient access standards by applying those standards across the entire multi-State geographic area it services.

- **Local-MA-PD sponsors:** Must meet or exceed the convenient access standards across urban, suburban, and rural areas, respectively, in each service area (including multi-county service areas) in which they operate.

- **Cost plans:** Must meet or exceed the convenient access standards across urban, suburban, and rural areas, respectively, in each geographic area in which they operate.

Part D sponsors may count I/T/U pharmacies and pharmacies operated by FQHCs and RHCs toward the standards for convenient access to retail pharmacies detailed above. However, CMS will review Part D sponsors’ pharmacy network submissions to ensure that inclusion of I/T/U, FQHC, and RHC pharmacies in contracted pharmacy networks does not substitute for the inclusion in Part D plan networks of retail pharmacies.

CMS is aware that there may be some areas of the country in which meeting the rural access standard, in particular, will be impossible or impracticable given the lack of pharmacy infrastructure. CMS will consider modifications to the rural access standard in cases in which Part D sponsors can demonstrate that meeting the standard is impossible or impracticable given a lack of infrastructure.

### 50.2 - Mail-Order Pharmacy Access


The inclusion of mail-order pharmacies in Part D plan networks is optional. However, network mail-order pharmacies will not count toward meeting the retail pharmacy access requirements specified in section 50.1. Since network inclusion of mail-order pharmacies is optional, sponsors may designate a subset of formulary drugs (e.g., particular tiers or “maintenance drugs” only) for availability via network mail-order pharmacies. As described in section 50.10, to the extent that a Part D plan offers benefits, including extended supplies of drugs (e.g., 90-day supplies), through network mail-order pharmacies, the plan must ensure that enrollees have reasonable access to the same benefits at network retail pharmacies. **CMS recognizes that some pharmacies may utilize common carriers in order to meet the needs of their patients, such as Part D enrollees residing in LTC facilities or in remote areas. A pharmacy that makes some, but not predominantly all, deliveries by common carrier is not a mail order pharmacy.**

### 50.3 - Limited Access Drugs and “Specialty” Pharmacies

*(Rev. 8, Issued: 12-18-09, Effective/Implementation: 01-01-10)*

Part D sponsors may not limit access to certain Part D drugs to "specialty" pharmacies within their Part D network in such a manner that contravenes the convenient access protections...
described in section 50.1. In other words, limited access to a Part D drug may not be based solely on the placement of a Part D drug in a specialty or high-cost tier because this tier placement alone is not indicative of any special requirements associated with such drug.

Part D sponsors may only restrict access to Part D drugs to a subset of their network pharmacies for the following reasons:

1. The FDA has restricted distribution of the drug to certain facilities or physicians; or
2. Appropriate dispensing of the Part D drug requires extraordinary special handling, provider coordination, or patient education that cannot be met by a network pharmacy.

Additional education or counseling alone does not qualify a drug for limited distribution within the overall pharmacy network.

Part D sponsors may specify, on a drug-by-drug basis, reasonable requirements for network pharmacies to ensure appropriate handling and dispensing of a particular Part D drug that requires special attention. These drug-by-drug requirements should only apply to special handling and dispensing that may be required for a particular “specialty” drug and not to reimbursement or other standard contracting terms and conditions. Offering pharmacies unreasonably low reimbursement rates for certain “specialty” drugs may not be used to subvert the convenient access standards. In other words, Part D sponsors must offer reasonable and relevant reimbursement terms for all Part D drugs as required by 42 CFR 423.505(b)(18).

In addition, Part D sponsors may not require network pharmacies to qualify as a “specialty” pharmacy in order to dispense any drug that requires special attention if the network pharmacy is capable of appropriately dispensing the particular Part D drug or drugs in question. The convenient access standards dictate that “specialty” pharmacies be used to supplement network pharmacy access when necessary and not otherwise restrict it.

If a Part D sponsor finds it necessary to restrict access to a Part D drug for either of the two reasons listed above, it must indicate this on the formulary information page in the Formulary Submission module, as well as identifying these drugs in the formulary flat file. Additionally, Part D sponsors must be prepared to provide CMS with documentation substantiating the limited access drug criteria.

50.4 - Home Infusion Pharmacy Access

(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

In order to meet the requirements for adequate access to home infusion pharmacies, Part D sponsors must deliver home infusion drugs to enrollees within 24 hours of discharge from an acute setting, unless the next required dose, as prescribed, is required to be administered later than 24 hours after discharge. To ensure Part D sponsors can provide such access, as part of their initial pharmacy access submissions, and through Part D annual reporting requirements (Information Collection Requirements (ICF) OMB 0938-0992), each Part D sponsor must provide a list of all contracted home infusion pharmacies licensed/legally able to serve in all State(s) and/or territories in the service area under each CMS pending contract number. The
pharmacy list must be submitted using the CMS template, which includes NCPDP/National Provider Identifier, pharmacy name, address, and all States and/or territories licensed in/legally able to serve.

CMS conducts an outlier analysis using these home infusion pharmacy network submissions to evaluate the robustness of home infusion pharmacy networks of all active Part D sponsors. As part of the Part D application, initial applicants to the Part D drug benefit program must demonstrate access through submission of their home infusion pharmacy networks, which must be no less robust than these outlier levels for their pending service area(s) as identified in Appendix I. CMS will evaluate access for existing sponsors through a modified outlier approach which looks at both the number of pharmacies relative to the established outlier level combined with evidence that the existing sponsor is meeting the 24 hour delivery standard for its enrollees.

Network robustness is assessed within contract types (e.g., PDP, Regional Prospective Payment Organization or RPPO, and MA-PD). Outliers are those contracts that are in the lowest 25th percentile in terms of the number of contracted home infusion pharmacies within a given state. In other words, 75 percent of all similarly-situated Part D sponsors have a more robust home infusion pharmacy network than the outliers in the lowest 25th percentile. For organizations whose service area comprises an entire state, Appendix 1 provides the minimum number of home infusion pharmacies required to surpass the 2010 Reporting Requirement and 2011 Part D Application outlier level. Organizations operating in a service area smaller than an entire state may use the provided ratios of the number of home infusion pharmacies to the number of beneficiaries in the state and apply it to the number of beneficiaries in the organization’s service area to calculate the minimum required number of home infusion pharmacies for that particular service area.

CMS does not expect Part D sponsors to provide or pay for supplies, equipment, or the professional services needed for home infusion therapy. Part D sponsors’ contracted network pharmacies must be able to:

- Deliver home infused drugs in a form that can be easily administered in a clinically appropriate fashion;

- Provide infusible Part D drugs for both short-term acute care and long-term chronic care therapies;

- Ensure that the professional services and ancillary supplies necessary for the provision of home infusion therapy are in place before dispensing home infusion drugs, consistent with the quality assurance requirement for Part D sponsors described in 42 CFR 423.153(c); and

- Provide covered home infusion drugs within 24 hours of discharge from an acute setting, unless the next required dose, as prescribed, is required to be administered later than 24 hours after discharge.

While Part D sponsors remain ultimately responsible for complying with all Part D requirements, they are also permitted to delegate their responsibilities to plan contractors, such as network pharmacies. Part D sponsors may contractually delegate the responsibility for ensuring timely delivery of home infusion drugs to their network pharmacies provided they meet the
requirements of 42 CFR 423.505(i) regarding relationships with pharmacies or other providers, related entities, contractors, subcontractors, and first tier and downstream entities.

50.5 - Long-Term Care (LTC) Pharmacy Access
(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

As described in section 50.5.1, Part D sponsors must demonstrate that their contracted pharmacy network provides convenient access to LTC pharmacies for enrollees who reside in an LTC facility. Part D sponsors must offer standard LTC pharmacy network contracts to all LTC pharmacies operating in their service area that request such contracts. These standard contracting terms and conditions must include the performance and service criteria for LTC pharmacies specified in section 50.5.2 below.

50.5.1 - Convenient Access to LTC Pharmacies
(Rev. 8, Issued: 12-18-09, Effective/Implementation: 01-01-10)

Part D sponsors will be required to offer a contract to any pharmacy willing to participate in its LTC pharmacy network so long as the pharmacy is capable of meeting the performance and service criteria in section 50.5.2 (and relevant State laws governing the practice of pharmacy in the LTC setting), as well as any other standard terms and conditions established by the Part D sponsor for its network LTC pharmacies (NLTCPs). Once a Part D sponsor has negotiated an agreement with an LTC pharmacy, the LTC pharmacy becomes an NLTCP and is eligible to serve the sponsor’s enrollees who reside in LTC facilities.

CMS expects that each LTC facility will select one or possibly more than one eligible NLTCP to provide Medicare drug benefits to its residents. A facility can continue to contract exclusively with a single LTC pharmacy if it chooses; however, the features to promote competition described above will likely give each facility access to a broader range of potential LTC pharmacies than was the case before the implementation of the Part D benefit. An NLTCP that serves a particular LTC facility must provide the same services, as delineated in its contract with a Part D sponsor, to all of that sponsor’s enrollees who reside in that LTC facility.

Part D sponsors may not rely on OON access to meet the LTC convenient access standard. All of a Part D sponsor’s enrollees who reside in an LTC facility must be able to routinely receive their Part D benefits through the plan’s network of LTC pharmacies in order for a Part D sponsor to be in compliance with CMS’ LTC convenient access standard.

In addition, Part D sponsors may not rely upon beneficiary special enrollment periods (SEPs) to circumvent the LTC convenient access requirement. Although individuals moving into, residing in, or moving out of an institution are entitled to an SEP, and dually eligible individuals are entitled to an ongoing SEP for as long as they are eligible for Medicaid benefits, it is not acceptable for Part D sponsors to rely on this beneficiary option in lieu of contracting with a sufficient number of pharmacies to ensure that a beneficiary can remain in his or her current plan for as long he or she resides in an LTC facility in the Part D sponsor’s service area. Ultimately, all beneficiaries – including those who reside in LTC facilities – should have available to them the full array of plans operating in their area.
Part D sponsors must demonstrate that they have a network of contracted LTC pharmacies that provide convenient access to LTC pharmacies for enrollees who reside in LTC facilities. In order to demonstrate convenient access to LTC pharmacies, Part D sponsors must include, as part of their initial pharmacy access submissions, a list of all contracted LTC pharmacies. In addition, Part D sponsors are required to submit an updated list of all contracted LTC pharmacies as part of the annual Part D reporting requirements developed in accordance with 42 CFR 423.514 and OMB 0938-0992.

CMS will evaluate whether Part D sponsors provide convenient access to LTC pharmacies through analysis of these submissions. Specifically, CMS will use these lists to verify that Part D sponsors have contracts in place with LTC pharmacies that serve the LTC facilities where their beneficiaries reside. Part D sponsors should have processes in place to ensure beneficiaries residing in LTC facilities are being served by an LTC network pharmacy.

CMS expects LTC pharmacy contracting activity will be ongoing as Part D sponsors continue to identify LTC facilities and LTC pharmacies, and as they examine their auto-enrollment assignments and incoming enrollments. To the extent that a beneficiary is enrolled in a Part D sponsor’s plan that does not have a contract with an LTC pharmacy that can serve the LTC facility in which he or she resides, the appropriate action for a Part D sponsor to take is to contract with the facility’s contracted LTC pharmacy or – if that pharmacy will not sign a contract – with another LTC pharmacy that can serve that facility. In some cases, a retroactive contract may be necessary.

50.5.2 - Performance and Service Criteria for Network Long-Term Care Pharmacies (NLTCPs)
(Rev. 8, Issued: 12-18-09, Effective/Implementation: 01-01-10)

In order to participate in Part D sponsor LTC pharmacy networks, a pharmacy must be capable of meeting certain minimum performance and service criteria (and relevant State laws governing the practice of pharmacy in the LTC setting), as well as any other standard terms and conditions established by the Part D sponsor for its network pharmacies. The following minimum performance and service criteria for pharmacies providing LTC services are based on widely used best practices in the market. These performance and service criteria must be incorporated into an addendum to a Part D sponsor’s standard network contract for those pharmacies that would like to be designated NLTCPs.

1. **Comprehensive Inventory and Inventory Capacity** – NLTCPs must provide a comprehensive inventory of plan formulary drugs commonly used in the long-term care setting. In addition, NLTCPs must provide a secured area for physical storage of drugs, with necessary added security as required by Federal and State law for controlled substances. This is not to be interpreted as requiring the pharmacy to have inventory or security measures outside of the normal business setting.

2. **Pharmacy Operations and Prescription Orders** – NLTCPs must provide services of a dispensing pharmacist to meet the requirements of pharmacy practice for dispensing prescription drugs to LTC residents, including but not limited to the performance of drug utilization review (DUR). In addition, the NLTCP pharmacist must conduct DUR to
routinely screen for allergies and drug interactions, to identify potential adverse drug reactions, to identify inappropriate drug usage in the LTC population, and to promote cost effective therapy in the LTC setting. The NLTCP must also be equipped with pharmacy software and systems sufficient to meet the needs of prescription drug ordering and distribution to an LTC facility. Further, the NLTCP must provide written copies of the NLTCP’s pharmacy procedures manual and said manual must be available at each LTC facility nurses’ unit. NLTCPs are also required to provide ongoing in-service training to assure that LTC facility staff are proficient in the NLTCP’s processes for ordering and receiving of medications. NLTCPs must be responsible for return for destruction and/or disposal of unused medications following discontinuance, transfer, discharge, or death as permitted by State Boards of Pharmacy. Controlled substances and out of date substances must be disposed of within State and Federal guidelines.

3. **Special Packaging** – NLTCPs must have the capacity to provide specific drugs in units of use packaging, bingo cards, cassettes, unit dose or other special packaging commonly required by LTC facilities. NLTCPs must have access to, or arrangements with, a vendor to furnish supplies and equipment including but not limited to labels, auxiliary labels, and packing machines for furnishing drugs in such special packaging required by the LTC setting.

4. **IV Medications** – NLTCPs must have the capacity to provide IV medications to the LTC resident as ordered by a qualified medical professional. NLTCPs must have access to specialized facilities for the preparation of IV prescriptions (clean room). Additionally, NLTCPs must have access to or arrangements with a vendor to furnish special equipment and supplies as well as IV trained pharmacists and technicians as required to safely provide IV medications.

5. **Compounding/Alternative Forms of Drug Composition** – NLTCPs must be capable of providing specialized drug delivery formulations as required for some LTC residents. Specifically, residents unable to swallow or ingest medications through normal routes may require tablets split or crushed or provided in suspensions or gel forms, to facilitate effective drug delivery.

6. **Pharmacist On-call Service** – NLTCPs must provide on-call, 24-hour-per-day/7-day-a-week service with a qualified pharmacist available for handling calls after hours and to provide medication dispensing available for emergencies, holidays and after hours of normal operations.

7. **Delivery Service** – NLTCPs must provide for delivery of medications to the LTC facility up to 7 days each week (up to 3 times per day) and in-between regularly scheduled visits. Emergency delivery service must be available 24 hours a day, 7 days a week. Specific delivery arrangements will be determined through an agreement between the NLTCP and the LTC facility. NLTCPs must provide safe and secure exchange systems for delivery of medication to the LTC facility. In addition, NLTCPs must provide medication cassettes, or other standard delivery systems, that may be exchanged on a routine basis for automatic restocking. The NLTCP delivery of medication to carts is a part of routine “dispensing.”
8. **Emergency Boxes** – NLTCPs must provide “emergency” supply of medications as required by the facility in compliance with State requirements.

9. **Emergency Log Books** – NLTCPs must provide a system for logging and charging medication used from emergency/first dose stock. Further, the pharmacy must maintain a comprehensive record of a resident’s medication order and drug administration.

10. **Miscellaneous Reports, Forms and Prescription Ordering Supplies** – NLTCPs must provide reports, forms and prescription ordering supplies necessary for the delivery of quality pharmacy care in the LTC setting. Such reports, forms and prescription ordering supplies may include, but will not necessarily be limited to, provider order forms, monthly management reports to assist the LTC facility in managing orders, medication administration records, treatment administration records, interim order forms for new prescription orders, and boxes/folders for order storage and reconciliation in the facility.

To qualify as an LTC pharmacy for a Part D sponsor’s LTC pharmacy network, a pharmacy must currently have the capacity – either by itself or through subcontracts with other entities – to meet all these performance and service criteria, even if an LTC facility that pharmacy serves does not need a particular service subsumed under those performance and service criteria. Pharmacies subcontracting with other entities to meet the performance and service criteria must ensure that they comply with all relevant Part D requirements, including all performance and service criteria for the provision of LTC pharmacy services. However, it will ultimately be up to LTC facilities and their contracted LTC pharmacy(ies) to determine which of these specific items or services a nursing facility needs. In other words, an LTC pharmacy must be capable of meeting all the aforementioned performance and service criteria at the time it contracts with a Part D sponsor, but it will not be required to provide all those services to LTC facilities if those facilities do not have a need for those certain services.

These performance and service criteria are not intended to be exclusive or exhaustive. Rather, they are intended to be minimum requirements for becoming an NLTCP. While payment terms for LTC pharmaceutical and dispensing services are subject to negotiations between the Part D sponsor and its NLTCPs, CMS notes that payment to LTC pharmacies under Part D may only cover drug ingredient costs and dispensing fees as defined in section 20.6. Specialized services provided in the administration of drugs after they are dispensed and delivered from the LTC pharmacy are specifically not covered by the Part D benefit.

### 50.5.3 - Other LTC Contracting Terms and Conditions and Uniformity of Benefits

(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

Outside of the minimum performance and service criteria, Part D sponsors and pharmacies may propose a number of contracting terms and conditions. With rare exceptions, CMS does not generally involve itself in determining whether standard contracting terms and conditions are “reasonable and relevant,” since these are fact-specific questions that are best left between negotiating parties. Thus, for example, CMS generally does not opine on contracting terms and conditions associated with compensation, billing, and business practices provided such terms and conditions are consistent with explicit Part D statutory and regulatory requirements.
LTC pharmacies may propose other terms and conditions in their negotiations with Part D sponsors as additional beneficiary protections. Such additional terms and conditions may be problematic because they explicitly conflict with statutory and/or regulatory requirements for the Part D program. Some of these proposed contracting terms and conditions not only conflict with CMS rules, but could even be harmful to beneficiaries. Following are several examples of such terms and conditions. While these examples are not exhaustive – and others may exist with similar effects – ultimately, all contracting terms and conditions must comply with Part D rules and requirements in order to protect the interests of beneficiaries and safeguard the integrity of the Medicare prescription drug program.

**Example 1:** Requirements for a longer transition period than the plan has provided for in its transition process submission to CMS.

As described in section 30.4.4.2 of chapter 6, all plans must offer a temporary supply of non-formulary drugs of at least 31 days with multiple refills during a 90-day transition period in the LTC setting. Some pharmacies may wish to extend that transition period to up to 180 days. However, given uniform benefits requirements under the statute and CMS’ regulations, plans cannot agree to a differential transition policy for some of their LTC enrollees. Transition policies must be applied uniformly to all similarly situated enrollees. Moreover, extending a transition period for some plan enrollees has cost implications for plans that may ultimately drive up costs to both beneficiaries and the Medicare program.

**Example 2:** Waivers of prior authorization or other utilization management edits for LTC facility residents.

Plans must determine whether a particular drug is a Part D drug and, in addition, must establish cost-effect utilization management programs. Waivers of prior authorization management edits or other utilization management edits for some plan enrollees run counter to these program requirements. In addition, given uniform benefits requirements under the statute and CMS’ regulations, plans cannot apply prior authorization or other utilization management edits differentially to a subset of their LTC enrollees.

**Example 3:** Waivers of certain DUR requirements for LTC facility residents.

Plans must optimize drug regimens, which requires an up-front and thorough review of enrollee drug files in order to ensure their safety (e.g., by preventing drug-drug interactions). In addition – and as stated above – uniform benefits requirements under the statute and CMS’ regulations mean that plans cannot apply DUR edits differentially to a subset of their LTC enrollees. All plan benefits must be applied uniformly to all similarly situated enrollees.

Part D sponsors may be out of compliance with uniform benefits requirements to the extent that they agree to particular contracting terms and conditions that have the net result of creating a non-uniform benefit for plan enrollees residing in LTC facilities serviced by network LTC pharmacies whose contracts with Part D sponsors may not include these same provisions. Plan benefits must also be applied uniformly across all enrollees (both those who reside in the

...
community and those residing in LTC facilities) when there is no justification for applying different rules to enrollees residing in LTC facilities. However, there are instances in which it is appropriate or legally required under CMS’ Part D guidance for Part D sponsors to establish standards that differentiate between enrollees residing in LTC facilities and ambulatory patients.

For example, it is perfectly acceptable for Part D sponsors to adopt alternative standards applicable only in the LTC setting when clinically justified, legally required, or otherwise justified based on characteristics unique to beneficiaries residing in LTC facilities, such as extended transition periods for enrollees residing in LTC facilities or prior authorization or other utilization management requirements (for example, those that distinguish between Part B and Part D covered drugs given that some drugs covered for use in the home under Part B are not covered by Part B in LTC settings). However, Part D sponsors cannot agree to differential benefits which would result in a non-uniform benefit among enrollees in LTC facilities, such as an extended transition period, certain utilization management edits, or different drug utilization review protocols that are limited to those LTC enrollees who obtain their Part D drugs from a specific LTC pharmacy. Plan benefits must be applied uniformly to all similarly situated enrollees, meaning that all enrollees residing in LTC facilities must be subject to the same rules.

50.5.4 - Access to LTC Pharmacies for Enrollees Residing in Institutions for Mental Disease (IMDs), Intermediate Care Facilities for the Mentally Retarded (ICFs/MR), and LTC Hospitals

To the extent that an ICF/MR or IMD designated by a State as an institution has, as an inpatient, any institutionalized individuals – which means any full benefit dual eligible individual for whom payment is made under Medicaid throughout a month, as provided in section 1902(q)(1)(B) of the Act – it falls within CMS’ regulatory definition of the term “LTC facility.” There exists a statutory Federal financial participation exclusion under Medicaid affecting residents of IMDs between the ages of 22 and 64. However, the IMD exception to the definition of “medical assistance” under section 1902(q)(1)(B) of the Act does not apply to individuals who are age 65 and older. Thus, all elderly full-benefit dual eligibles who are inpatients in an IMD designated by the State as an institution for a full month are considered institutionalized individuals for that month. Long-term care hospitals are also medical institutions and are considered LTC facilities if they have as inpatients any institutionalized individuals.

CMS also clarifies that as medical institutions, hospitals (including long-term care hospitals) that receive payments under section 1902(q)(1)(B) of the Act can meet the definition of an LTC facility. As discussed in section 20.2.1 of chapter 6, to the extent that inpatients in these hospitals exhaust their Part A inpatient days benefit, and payment is no longer available under Part A or Part B for drugs that would otherwise meet the definition of a Part D drug, such drugs are Part D drugs.

This means that Part D sponsors must ensure that they provide convenient access to network LTC pharmacies for:

- All of their enrollees residing in a long-term care hospital or in an IMD or ICF/MR designated by the State as an institution, and in which any institutionalized individuals
reside (although living in an institution that does not meet the definition of an LTC facility does not preclude an individual from enrolling in Part D).

- All of their enrollees who are inpatients in a hospital that is a “medical institution” under 1902(q)(1)(B) of the Act – and therefore would meet the Part D definition of an LTC facility – and whose Part A benefits have been exhausted.

Part D sponsors will not be compliant with CMS’ LTC convenient access standard if they do not provide access to covered Part D drugs via an LTC pharmacy in their network for all of their enrollees who reside in LTC facilities.

Many ICFs/MR, IMDs, and LTC hospitals utilize in-house pharmacies and, particularly in the case of ICFs/MR and IMDs, such pharmacies are State run and operated. In some States, licensing laws preclude facilities from obtaining prescription drugs and LTC services for their residents from anyone but the facility’s in-house pharmacy. States may not be able to agree to certain standard clauses in some LTC standard contracts because of constitutional and legal restraints on States. Part D sponsors should be prepared to readily negotiate with States to address these issues. To the extent that Part D sponsor contracting efforts involve communication with State run and operated pharmacies, CMS encourages Part D sponsors to coordinate their efforts through a single point of contact at the State level. Refer to the following Web site for lists of State contacts for IMDs and ICFs/MR:
http://www.cms.hhs.gov/PrescriptionDrugCovContra/11_PartDContacts.asp#TopOfPage

50.5.5 - Post-Consumption Billing
(Rev. 14, Issued: 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

CMS interprets the term “post-consumption” billing as billing that is performed after a drug is dispensed and consumed by an enrollee, usually at the end of the month or the beginning of the next month. While post-consumption billing is not typical in retail pharmacy, certain LTC pharmacies utilize post-consumption billing procedures. A significant advantage of this type of billing is reduction in waste because only those drugs actually consumed by an individual are billed. Post-consumption billing arrangements are permissible under the Part D program and should be accommodated by sponsors, assuming they are managed in a manner that is compatible with all other Part D requirements (i.e., for a formulary drug used for a medically accepted indication) and in a manner that provides for an accurate calculation of TrOOP expenditures (for example, via a single claim, Point-of-Sale transaction, HIPAA compliant format (i.e., v. NCPDP 5.1 or v. D.0)).

Network pharmacies are responsible for verifying that drugs dispensed to the beneficiary are covered under the beneficiary’s Part D plan. Because network pharmacies utilizing post-consumption billing will not submit the first claim to a Part D plan until after the drug has been dispensed, the pharmacy must employ another mechanism for verifying coverage in advance of dispensing.

50.6 - I/T/U Pharmacy Access
(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)
To the extent that any I/T/U pharmacies are present in their service areas, Part D sponsors must demonstrate that their contracted pharmacy network provides convenient access to I/T/U pharmacies. Part D sponsors must offer standard pharmacy network contracts to all I/T/U pharmacies operating in their service area. These standard contracting terms and conditions must conform to a model addendum developed by CMS, in collaboration with various stakeholders, that accounts for the operational differences between I/T/U and retail pharmacies. Upon request, sponsors must provide CMS with documentation to demonstrate that they have offered all I/T/U pharmacies in their service area a conforming contract; such documentation may be proof of FAX or U.S. postage or other carrier’s receipt of delivery. Refer to the following Web site for a copy of the model I/T/U pharmacy contracting addendum:

http://www.cms.hhs.gov/PrescriptionDrugCovContra/10_RxContracting_SpecialGuidance.asp#TopOfPage

In order to demonstrate convenient access to I/T/U pharmacies, Part D sponsors must include, as part of their initial pharmacy access submissions, a list of all I/T/U pharmacies in their service areas. This information must be submitted at the county level and CMS-designated contract level and include contracting status with each of the I/T/U pharmacies listed. CMS will review this list to ensure that sponsors are providing convenient access to I/T/U pharmacies in their service areas.

50.7 - Waiver of Pharmacy Access Requirements
(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

As detailed below, CMS will waive pharmacy access standards under two circumstances: (1) for MA-PD plans and cost plans offering Part D coverage that operate and own their own pharmacies, provided they demonstrate convenient access using an alternative standard; and (2) for private fee-for-service (PFFS) plans offering Part D coverage that provide coverage for drugs purchased from all pharmacies, regardless of whether they are network pharmacies and do not charge additional cost-sharing to beneficiaries for obtaining their drugs at a non-network pharmacy.

50.7.1 - Waiver of Retail Pharmacy Access Requirements for MA-PD Plans and Cost Plans with Plan-Owned and Operated Pharmacies
(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

MA-PD plans or cost plans that provide access (other than via mail order) to qualified prescription drug coverage through retail pharmacies owned and operated by the MA organization that offers the plan or the cost plan will not be required to meet the retail pharmacy access standards in section 50.1. However, in order for the pharmacy access standards to be waived, the MA-PD plan or cost plan in question must have a pharmacy network that, per CMS’ determination, provides comparable pharmacy access to its enrollees as provided under 42 CFR 422.112 or 42 CFR 417.416(e), as appropriate.

This waiver is automatically granted when the MA-PD plan or cost plan provides Part D drugs predominately through plan-owned and operated retail pharmacies (i.e., more than 50 percent of prescriptions are provided through owned and operated retail pharmacies). While this waiver of the convenient retail access standards is automatically granted to plans that meet this criteria,
MA-PD and cost plans using this waiver must initially submit information to CMS about the number of prescriptions filled at plan-owned retail pharmacies and at contracted pharmacies, and the percentage of prescriptions provided through plan-owned retail pharmacies during the last complete year prior to the contract year when the waiver applies. Part D sponsors that have been granted this waiver will be required to provide CMS with data on an annual basis on prescriptions filled at plan-owned and operated retail pharmacies. For more information about these reporting requirements, refer to: http://www.cms.hhs.gov/PrescriptionDrugCovContra/08_RxContracting_ReportingOversight.asp#TopOfPage

50.7.2 - Waiver of Pharmacy Access Requirements for Private Fee-for-Service Plans
(Rev. 14, Issued: 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Private fee-for-service (PFFS) plans offering Part D coverage will not be subject to the pharmacy access requirements in sections 50.1, 50.4, 50.5, and 50.6, provided they:

- Provide coverage for drugs purchased from all pharmacies, regardless of whether they are network pharmacies; and
- Do not charge additional cost-sharing to beneficiaries for obtaining their drugs at a non-network pharmacy.

Given these two provisions, PFFS plans offering Part D coverage must provide access to pharmacies in one of the following ways:

1. PFFS plans offering Part D coverage that meet the retail pharmacy convenient access standards described in section 50.1, the home infusion pharmacy adequate access standard described in section 50.4, the long-term care pharmacy convenient access standard described in section 50.5, and the I/T/U pharmacy convenient access standard described in section 50.6 will only have to provide access to non-network pharmacies consistent with CMS’ out-of-network access policy as described in section 60. In other words, they will be treated in the same way as all other Part D plans vis-à-vis the access requirements in sections 50.1, 50.4, 50.5, and 50.6.

2. PFFS plans offering Part D coverage will not have to meet the retail pharmacy convenient access standards described in section 50.1, the home infusion adequate access standard described in section 50.4, the long-term care pharmacy convenient access standard described in section 50.5, and the I/T/U pharmacy convenient access standard described in section 50.6– either because they do not contract with any network of pharmacies, or because they contract with a limited network that does not meet the relevant regulatory access requirements – if they provide access to covered Part D drugs at all pharmacies without charging beneficiaries any additional cost-sharing (relative to the cost-sharing applicable at any network pharmacies the plan may have). Access at non-network pharmacies would be provided by reimbursing the pharmacy its usual and customary (U&C) price, minus any applicable beneficiary cost-sharing.
In effect, PFFS plans offering Part D coverage have the following options:

- Create a network that meets CMS’ regulatory access standards and limits access to out-of-network providers consistent with CMS’ regulatory provisions regarding out-of-network access;

- Create a network that does not meet CMS’ regulatory access standards and provides access to all non-network pharmacies by not charging additional cost-sharing for drugs obtained at non-network pharmacies; or

- Not create a network at all but provide access to all pharmacies at the same cost-sharing.

PFFS sponsors choosing to have either no contracted pharmacy network or a limited pharmacy network that does not meet CMS’ pharmacy access requirements must ensure that their enrollees are able to access their benefits at all non-network pharmacies without paying any more cost-sharing than they would under their approved Part D benefit structure.

When accessing their drugs at non-network pharmacies in non-emergent situations, enrollees of PFFS plans that have received waivers of the pharmacy access standards will pay only their required cost-sharing at the point of sale. Moreover, such claims should be adjudicated electronically whenever pharmacies support electronic billing. In other words, PFFS sponsors with pharmacy access waivers should not routinely rely on billing practices that require an enrollee to pay U&C price upfront and then submit a paper claim to the sponsor for reimbursement.

CMS notes that sponsors are required to accurately track TrOOP and gross covered drug spend amounts in order to correctly position an enrollee in the benefit. As indicated in chapter 14 of this manual, plans are required to process claims in real-time and track TrOOP in real-time. Consistent with those requirements, sponsors – including PFFS sponsors – receiving waivers of the pharmacy access standards – must establish policies and procedures appropriately restricting the use of paper claims only to situations in which online claims processing is not available at the point of sale in order to promote accurate TrOOP accounting, to minimize administrative costs to Part D sponsors and the Medicare program, as well as opportunities for fraudulent duplicate claims reimbursement. Therefore, PFFS sponsors choosing to obtain a waiver rather than meet CMS’ pharmacy access requirements must arrange for automated, online billing at non-network pharmacies (similar to the way in which CMS’s point-of-sale contractor has allowed for online billing by non-contracted pharmacies).

50.8 - Pharmacy Network Contracting Requirements
(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

In establishing its contracted pharmacy network, a Part D sponsor must meet certain requirements with respect to any willing pharmacy and insurance risk, as described in sections 50.8.1 and 50.8.2 below.
50.8.1 - Any Willing Pharmacy Requirement  
(Rev. 8, Issued: 12-18-09, Effective/Implementation: 01-01-10)

“Any willing pharmacy” refers to the requirement that Part D sponsors permit the participation in their Part D plan networks of any pharmacy – including non-retail pharmacies such as mail-order pharmacies – that is willing to accept the sponsor’s standard contracting terms and conditions. These standard contracting terms and conditions must be reasonable and relevant. However, whether a Part D sponsor has permitted a pharmacy an opportunity to participate in its network, or whether a pharmacy can meet or has met contract terms in compliance with the law and CMS’ regulations at 42 CFR 423.120(a)(8)(i) are fact-specific questions that are generally best left between the parties.

It is unlikely that a Part D sponsor could establish a network using a uniform set of terms and conditions throughout a service area because it will likely need to modify contracting terms and conditions to ensure access to certain pharmacies – for example, rural and long-term care pharmacies. Standard terms and conditions, particularly for reimbursement terms, may vary to accommodate geographic areas or types of pharmacies, and that this is acceptable, provided that all similarly situated pharmacies are offered the same standard terms and conditions. Thus, for example, provided a Part D sponsor offers all mail-order pharmacies in a particular area with the same standard terms and conditions, it may offer separate standard terms and conditions to mail-order pharmacies than it does to retail pharmacies. With standard terms and conditions as a “floor” of minimum requirements that all similarly situated pharmacies must abide by, Part D sponsors may modify some of their standard terms and conditions to encourage participation by particular pharmacies.

The any willing pharmacy requirement is waived for certain MA-PD plans or cost plans that provide access (other than via mail order) to qualified prescription drug coverage through retail pharmacies owned and operated by the MA organization that offers the plan or the cost plan. In order to obtain this waiver of the any willing pharmacy requirement, an MA organization or cost plan sponsor must generally demonstrate at the plan level that at least 98 percent of enrollee prescriptions have been filled through pharmacies that are owned and operated by the plan sponsor in order to be granted the waiver.

Some pharmacies, particularly independent pharmacies, work with agents or Pharmacy Services Administration Organizations (PSAO) for purposes of negotiating and/or signing contracts with Part D sponsors. Such agents negotiate and/or sign contracts with health plans and PBMs on behalf of participating pharmacies to streamline the contracting process. To the extent that such agents are authorized to act on behalf of a participating pharmacy for purposes of negotiating and/or signing pharmacy network contracts, there is no distinction between a pharmacy and its agent for purposes of the any willing pharmacy requirement. In other words, the any willing pharmacy requirement at 42 CFR 423.120(b)(8)(i) extends to an agent authorized to negotiate and/or sign contacts on behalf of a pharmacy, as long as it is in compliance with all Federal and State laws. A Part D sponsor will be in violation of this requirement if it refuses to offer a standard contract to an agent acting on behalf of a participating pharmacy for purposes of negotiating and/or signing contracts. However, Part D sponsors that currently have independent contracts with pharmacies belonging to a PSAO are only required to offer standard terms and
conditions to those pharmacies under the PSAO with no preexisting contract with the Part D sponsor.

50.8.2 - Insurance Risk
(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

A Part D sponsor may not require a network pharmacy to accept insurance risk as a condition of participation in its pharmacy network. Insurance risk in relation to a network pharmacy refers to risk of the type commonly assumed only by insurers licensed by a State, but not including payment variations designed to reflect performance-based measures of activities within the control of a pharmacy, such as formulary compliance and generic drug substitutions, or elements potentially in the control of the pharmacy (for example, labor costs, and productivity).

More specifically, subcapitation of pharmacies is not allowed in Part D sponsor administration of the Part D benefit. If the only contract Part D sponsors offered a pharmacy were a capitated arrangement, this practice would equate to requiring a pharmacy to accept risk. Second, and more importantly, subcapitated arrangements are inconsistent with the four payment mechanisms CMS is required to use to pay plans. Part D plans must be able to report costs to CMS that distinguish beneficiary liabilities (e.g., for TrOOP accounting and accumulation); low-income cost-sharing subsidy payments made at the individual beneficiary level by plans to pharmacies; costs that are considered supplemental benefits at the individual beneficiary level (supplemental drugs and supplemental cost-sharing); and allocation of plan costs above and below the out-of-pocket threshold at the individual beneficiary level and that subject the plan to different levels of risk-sharing depending on which phase of the drug benefit the beneficiary is in. If the plan's providers do not process and submit meaningful claims, this data is not available to compute these payment streams as mandated by law. Finally, subcapitated payments to certain pharmacies (e.g., home infusion, long-term care, and other non-retail pharmacies) could include payment for services (e.g., clinical professional services and extensive fees for administering drugs to patients) that are not allowed under the Part D benefit.

50.9 - Differential Cost-Sharing for Preferred Pharmacies
(Rev. 8, Issued: 12-18-09, Effective/Implementation: 01-01-10)

Despite the “any willing pharmacy” requirement (discussed in section 50.8.1), Part D sponsors – with the exception of those offering defined standard coverage, since cost-sharing cannot be altered under defined standard coverage – are permitted to reduce cost-sharing differentially for network pharmacies. In other words, Part D sponsors may vary cost-sharing not only based on type of covered Part D drug or formulary tier, but also on a particular pharmacy’s status within their pharmacy network (i.e., Part D sponsors may establish distinctions between “preferred” and “non-preferred” pharmacies within their pharmacy networks).

While these within-network distinctions are allowed, such tiered cost-sharing arrangements must in no way increase CMS payments to Part D sponsors. Therefore, tiered cost-sharing arrangements based on within-network distinctions can only be included in Part D sponsors’ benefits subject to the same actuarial tests that apply to formulary-based tiered cost-sharing structures. Thus, a reduction in cost sharing for preferred pharmacies in a Part D sponsor
network could be offered through higher cost sharing for non-preferred pharmacies (or as alternative prescription drug coverage).

In other words, sponsors cannot designate certain network pharmacies as preferred without designating its other network pharmacies as non-preferred. A pharmacy can only be designated as preferred if it offers enrollees a lower level of cost-sharing than a non-preferred pharmacy. This means that the differences in cost-sharing must be based on the designated cost-sharing levels, and not on the actual cost to the enrollee, as illustrated in the examples below.

**Example 1**: A sponsor with a benefit design based on coinsurance could offer 20% coinsurance at preferred pharmacies and 25% coinsurance at non-preferred pharmacies.

**Example 2**: A sponsor with a benefit design based on copayments could offer a $20 copayment at preferred pharmacies and a $25 copayment at non-preferred pharmacies.

CMS will permit plans to refer to non-preferred pharmacies as “other network pharmacies” instead of “non-preferred pharmacies” in their marketing materials and other beneficiary communications.

Differential cost-sharing in the context of preferred and non-preferred pharmacies does not raise the cost-sharing obligation of low-income subsidy eligible enrollees above the levels specified in 42 CFR 423.782.

A Part D sponsor may not establish a differential between cost-sharing at preferred versus non-preferred pharmacies that is so significant as to discourage enrollees in certain areas (rural areas or inner cities, for example) from enrolling in that Part D plan – even if it otherwise meets the retail access standards detailed in section 50.1. A pharmacy network that effectively limits access in portions of a Part D sponsor’s service areas in this manner would be discriminatory and disallowed as provided in 42 CFR 423.272.

**50.10 - Level Playing Field Between Mail-Order and Retail Pharmacies**

*Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11*

Part D sponsors that include mail-order pharmacies in their networks must permit enrollees to receive benefits, which may include an extended supply of covered Part D drugs (for example, a 90-day supply), through a network retail pharmacy rather than a network mail-order pharmacy, if they so choose. However, a sponsor may require that enrollees choosing to receive benefits, including an extended day supply of covered Part D drugs, at a network retail pharmacy rather than a network mail-order pharmacy be responsible for any higher cost-sharing associated with obtaining those benefits at a network retail pharmacy.

If a sponsor does choose to charge the beneficiary the higher cost-sharing associated with obtaining the drug through a retail pharmacy, any increase in cost sharing must be limited to the “differential in charge” to the sponsor in terms of any difference between higher contract rates at a network retail pharmacy as opposed to a network mail-order pharmacy for that benefit. Sponsors may therefore require an enrollee to pay higher cost-sharing up to an amount equal to the mail-order cost-sharing plus any differential in contracted rates between retail and mail-
order, but plans may charge beneficiaries a lower cost sharing at retail if they so choose. This differential in charge-based cost-sharing should be viewed as a ceiling on cost-sharing and not a floor. In addition, Part D sponsors must ensure that the availability of benefits (including extended day supplies) at retail rather than mail-order pharmacies does not increase costs to the government. Enrollee cost-sharing for an extended-day supply at retail must never exceed what the enrollee would have paid at the same retail pharmacy had the enrollee had his or her prescription filled in multiple 1 month supply increments at retail pharmacy rates.

Sponsors electing to offer extended supplies of covered Part D drugs must make available to retail pharmacies, on request, an “Extended Supply Addendum” to their standard contracting terms and conditions for retail pharmacies. The addendum may allow retail pharmacies to offer an extended supply of drugs to any enrollee at the same negotiated price, reimbursement rate (including dispensing fee, if any), and cost-sharing as their network mail-order pharmacy or pharmacies. CMS refers to this rate as the network mail-order pharmacy rate.

Alternatively, Part D sponsors electing to offer extended supplies of covered Part D drugs may through their addendum allow retail pharmacies to dispense an extended supply of drugs for a higher contracted reimbursement rate (including dispensing fee, if any) than their network mail-order pharmacy rate. At the sponsor’s election, any differential in charge between the network mail-order pharmacy rate and the higher contracted reimbursement rate for the extended supply dispensed at the retail pharmacy may be reflected in higher cost-sharing paid by the beneficiary. CMS refers to this rate as the alternative retail/mail-order pharmacy rate. Any such higher contracted reimbursement rate shall not increase costs to the government and in no event shall the standard terms and conditions offered to similarly situated pharmacies with respect to CMS’ any willing pharmacy provisions vary.

Below are two examples of contracting scenarios designed to illustrate the calculation of a “difference in charge.”

**Example 1: Network Mail Order Pharmacy Rate**

Suppose that a network pharmacy’s contracted retail rate is AWP-12% plus a $2 dispensing fee, and the plan’s retail cost-sharing requires 25% to be paid by the beneficiary. Further suppose that the plan’s contracted mail-order rate is AWP-22%, with no dispensing fee and that the plan’s mail-order cost sharing requires 20% to be paid by the beneficiary. If the sponsor offers a 90-day supply at network mail-order pharmacies, any retail pharmacy must be allowed to fill a 90-day prescription under the same terms and conditions as the mail-order pharmacy provided it agrees to accept the network mail-order pharmacy rate for that 90-day prescription – AWP – 22% (no dispensing fee) with 20% cost sharing paid by the beneficiary.

<table>
<thead>
<tr>
<th>AWP = $100</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retail Rate</td>
</tr>
<tr>
<td>AWP – 12%</td>
</tr>
<tr>
<td>Dispensing Fee</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>
Example 2: Alternative Retail / Mail Order Pharmacy Rate

A Part D sponsor may establish an alternative retail/mail-order pharmacy rate for an extended supply for retail pharmacies that cannot or will not match the network mail-order pharmacy rate for the extended supply prescription. Suppose under this scenario, the retail pharmacy could not match the network mail-order pharmacy rate for a 90-day prescription (see example 1), but would accept an alternative retail/mail-order pharmacy rate of AWP -19% (plus $2.00 dispensing fee). In this case, the sponsor could allow a retail pharmacy to fill the 90-day prescription at the alternative retail/mail-order pharmacy rate. The sponsor also may charge the beneficiary the difference in charge between the network mail-order pharmacy rate for that 90-day prescription and the alternative retail/mail-order pharmacy rate for a 90-day prescription. In this example, the retail pharmacy would be reimbursed AWP -19% plus $2.00 and the beneficiary would have to pay 3% of AWP plus $2.00, which would be added to the 20% cost sharing calculated on AWP – 22%. (As stated earlier, this difference in charge-based cost-sharing would be a ceiling, but not a floor – in other words, the cost-sharing paid at retail could not exceed the amount described in the previous sentence, but it could be lower than such amount.)

<table>
<thead>
<tr>
<th>AWP = $100</th>
<th>Alternative Retail / Mail Order Pharmacy Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Network Mail Order Rate</td>
<td>AWP – 22%</td>
</tr>
<tr>
<td>Dispensing Fee</td>
<td>$0</td>
</tr>
<tr>
<td>Total</td>
<td>$78</td>
</tr>
<tr>
<td>Beneficiary cost sharing paid to pharmacy (20%)</td>
<td>$15.60</td>
</tr>
<tr>
<td>Difference in charge</td>
<td>$5</td>
</tr>
<tr>
<td>Total beneficiary payment to pharmacy</td>
<td>$20.60</td>
</tr>
<tr>
<td>Plan payment to pharmacy</td>
<td>$62.40</td>
</tr>
</tbody>
</table>

NOTE: These examples are not intended to provide guidance on specific prices or contract rates that plans should or should not consider in contracting with pharmacies.

Part D sponsors offering benefits, including extended-day supplies of covered Part D drugs, at network mail-order pharmacies must offer retail pharmacies a reasonable opportunity to provide those same benefits. Part D plans must therefore contract with a sufficient number of network retail pharmacies so as to ensure that enrollees have reasonable access to the same extended day
supply benefits at retail that are available at mail-order. CMS will review the adequacy of initial pharmacy network submissions and may require that plans address any network access issues as part of this review. CMS may conduct additional reviews of a Part D sponsor’s pharmacy network and may require remedial action by Part D sponsors based upon such factors as enrollee complaints that their access to benefits at network retail pharmacies is being unreasonably denied. Part D sponsors will be required to provide CMS with data on an annual basis on the number of retail pharmacies in their networks contracted to provide extended day supply benefits. For more information about these reporting requirements, refer to: 
http://www.cms.hhs.gov/PrescriptionDrugCovContra/08_RxContracting_ReportingOversight.asp#TopOfPage

50.11 - Use of Identification Card for Accessing Negotiated Prices
(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

Part D sponsors must issue (and reissue, as appropriate) a card or other technology for enrollees to use in accessing negotiated prices for covered Part D drugs. CMS has developed standards related to a standardized format for a plan identification card for this purpose. These standards were developed after consultation with the NCPDP and are summarized in our Marketing Guidelines, which can be accessed at: 
http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage

50.12 - Pharmacy Access During a Federal Disaster or Other Public Health Emergency Declaration
(Rev. 8, Issued: 12-18-09, Effective/Implementation: 01-01-10)

If a Presidential major disaster or emergency declaration is issued or the Secretary declares a public health emergency, and the underlying circumstances are reasonably expected to result in a disruption in access to covered Part D drugs, CMS expects sponsors to lift their “refill-too-soon” edits. Part D sponsors may exercise some operational discretion as to how these edits are lifted during a disaster or emergency as long as access to Part D drugs is provided at the point-of-sale. For instance, Part D sponsors could implement an edit that is readily resolvable at the point-of-sale through the use of a pharmacist override code. CMS also expects Part D sponsors to allow an affected enrollee to obtain the maximum extended day supply, if requested and available at the time of refill.

CMS expects that Part D sponsors will continue to lift these edits until the termination of a public health emergency or the end of a declared disaster or emergency. In the case of a public health emergency, it terminates when it no longer exists or upon the expiration of the 90-day period beginning from the initial declaration, whichever occurs first. For major disasters declared by the President, Part D sponsors should pay particular attention to the closure of disaster incident periods listed in the Disaster Federal Register Notice section on Federal Emergency Management Agency’s (FEMA’s) Web site 
http://www.fema.gov/news/disasters.fema, noting that in circumstances in which the incident period has not officially closed 30 days from the initial Presidential declaration. Part D sponsors may consider extending the implementation of the edits but are not required to do so. However, if sponsors choose to remove the edits, they need to work closely with enrollees who indicate that they are still displaced or otherwise impacted by the disaster or emergency.
In the absence of a Presidential major disaster or emergency declaration or a public health emergency, Part D sponsors may consider lifting the edits -- for instance, in advance of an impending disaster -- if they determine it is appropriate to do so to ensure pharmacy access. However, at all times, and especially in disaster and/or public health emergency situations, Part D sponsors must ensure, consistent with this chapter, that their enrollees have adequate access to covered Part D drugs dispensed at out-of-network pharmacies when those enrollees cannot reasonably be expected to obtain covered Part D drugs at a network pharmacy, and when such access is not routine.

50.13 - Drug Shortages
(Rev. 8, Issued: 12-18-09, Effective/Implementation: 01-01-10)

This section describes the expectations of Part D sponsors when shortages impact the offering of drug products on plan formularies. By “shortages”, CMS is referring to those drug products that have been identified on the FDA Drug Shortage Webpage: http://www.fda.gov/Drugs/DrugSafety/DrugShortages/default.htm

When establishing policies and procedures to address shortages, Part D sponsors should not adopt a one-size-fits-all approach. Drug shortages may occur for differing reasons and impact Part D sponsor application of its formulary in different ways. Therefore, when a drug shortage occurs, Part D sponsors should begin by considering the type of drug involved, condition(s) being treated by the drug, expected length of the drug shortage, and which enrollees are impacted. Based on this information, Part D sponsors can work with their enrollees and providers to find appropriate therapeutic alternatives. The Part D sponsor will need to evaluate the availability (or unavailability) of therapeutically equivalent drug products. Different scenarios to be addressed include:

- A single-source formulary brand drug product is temporarily unavailable—no therapeutically equivalent products are available;

- A multiple-source formulary brand drug product is temporarily unavailable—only therapeutically equivalent generic products are available;

- A multiple-source formulary generic drug product is temporarily unavailable (all makers)—only therapeutically equivalent brand product is available; or

- A multiple-source formulary drug product is temporarily unavailable—no brand or generic therapeutically equivalent product is available.

In order to minimize unnecessary changes in therapy resulting from temporary shortages of multiple-source formulary drug products, CMS expects Part D sponsors to provide access to therapeutically equivalent non-formulary drug products, or therapeutically equivalent formulary drug products that otherwise require prior authorization or step therapy, for those enrollees currently taking the drug product subject to a shortage. When applicable, Part D sponsors should allow pharmacies to utilize a value of “8” in field 408-D8 (Dispense as Written/Product Selection Code) of the NCPDP v5.1 Telecommunication Standard to specify that an equivalent
brand product is being dispensed due to the unavailability of any generic formulary products. The Part D sponsor is not required to charge the same cost-sharing that applies to the unavailable formulary product and may charge the applicable non-formulary or brand cost-sharing that would otherwise apply to the substituted therapeutically equivalent product.

Under these circumstances, CMS does not consider access to therapeutically equivalent non-formulary drug products, or therapeutically equivalent formulary drug products that otherwise require prior authorization or step therapy, to be formulary exceptions and, therefore, access to such drug products may be limited to the duration of the shortage. In the event that the shortage becomes a market withdrawal, Part D sponsors must follow notice requirements consistent with 42 CFR 423.120(b)(5) if the Part D sponsor intends to discontinue coverage of the therapeutically equivalent product. This policy does not preclude a beneficiary from seeking a non-formulary or tiering exception to obtain access to a non-formulary drug product or formulary drug product otherwise requiring prior authorization or step therapy.

50.14 - Waivers for Plans in the Territories
(Rev. 8, Issued: 12-18-09, Effective/Implementation: 01-01-10)

To ensure access to coverage in the territories, section 1860D-42(a) of the Act grants CMS the authority to waive access requirements to secure access to qualified prescription drug coverage for Part D eligible individuals residing in the territories. The regulations for the MMA under 42CFR 423.859(c) allow access to coverage in the territories to be waived or modified either through an Applicant’s request or at CMS’ own determination. Under that authority, CMS has waived the convenient access requirements for a plan’s Part D contracted retail, home infusion and long-term care network in the Pacific territories.

60 - Out-of-Network Access
(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

60.1 - Out-of-Network Pharmacy Access
(Rev. 14, Issued: 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Part D sponsors must ensure that their enrollees have adequate access to covered Part D drugs dispensed at OON pharmacies when those enrollees cannot reasonably be expected to obtain covered Part D drugs at a network pharmacy, and when such access is not routine. The coverage rules applicable to covered Part D drugs dispensed at OON pharmacies may generally mirror those applicable to covered Part D drugs dispensed at network pharmacies, to the extent that the OON pharmacy has the ability to effectuate those coverage rules. However, Part D sponsors must develop policies and procedures governing reasonable rules for appropriately limiting OON access (for example, quantity limits, purchase of maintenance medications via mail-order for extended out-of-area travel, or plan notification or authorization processes). Following are various scenarios under which CMS would expect that OON pharmacy access be guaranteed to enrollees.

Example 1: An enrollee is traveling outside his or her Part D plan’s service area; runs out of or loses his or her covered Part D drug(s) or becomes ill and needs a covered Part D drug; and cannot access a network pharmacy.
Example 2: An enrollee cannot obtain a covered Part D drug in a timely manner within his or her service area because, for example, there is no network pharmacy within a reasonable driving distance that provides 24-hour-a-day/7-day-per-week service.

Example 3: An enrollee must fill a prescription for a covered Part D drug in a timely manner, and that particular covered Part D drug (for example, an orphan drug or other specialty pharmaceutical typically shipped directly from manufacturers or special vendors) is not regularly stocked at accessible network retail or mail-order pharmacies.

Example 4: An enrollee is provided covered Part D drugs dispensed by an OON institution-based pharmacy while he or she is a patient in an emergency department, provider-based clinic, outpatient surgery, or other outpatient setting, and as a result cannot get his or her medications filled at a network pharmacy.

Example 5: During any Federal disaster declaration or other public health emergency declaration in which Part D enrollees are evacuated or otherwise displaced from their place of residence and cannot reasonably be expected to obtain covered Part D drugs at a network pharmacy. In addition, in circumstances in which normal distribution channels are unavailable, Part D sponsors are expected to liberally apply their OON policies to facilitate access to medications.

If a Part D sponsor offers coverage other than defined standard coverage, it may require enrollees to not only be responsible for any cost-sharing, including a deductible, that would have otherwise applied if a covered Part D drug had been purchased at a network pharmacy, but also any differential between an OON pharmacy’s (or provider’s) U&C price and the plan allowance.

Given the cost-sharing requirements for defined standard coverage, under which the cost-sharing between the deductible and initial coverage limit must always be 25 percent of the actual cost of a drug at the point of sale (see section 20.3.1), Part D sponsors offering defined standard coverage may not charge enrollees the OON differential described above. Instead, Part D sponsors offering defined standard coverage must simply require their enrollees to pay any deductible or cost-sharing, relative to the OON pharmacy’s (or provider’s) U&C price. The Part D sponsor will pay the difference between the OON pharmacy’s (or provider’s) U&C price and the enrollee’s cost-sharing.

In either case, enrollees will likely be required to pay more for a covered Part D drug purchased OON than one purchased at a network pharmacy. However, as explained in section 30.1, any OON differential that an enrollee is required to pay for purchases made consistent with a Part D sponsor’s OON access policy will count toward his or her TrOOP balance. CMS will pay the OON differential, as applicable, for appropriate OON purchases of covered Part D drugs for individuals receiving the low-income subsidy.

Sponsors may not routinely allow more than a month’s supply of medication to be dispensed at an OON pharmacy. In creating their out-of-network benefit structure, sponsors may choose one of the following options:
• The plan’s network cost-sharing;

• The plan’s network cost-sharing plus the differential between the OON billed charge and their network allowable charge (applicable to all benefit structures except defined standard prescription drug coverage);

• The plan’s network cost-sharing with a limited days supply (this limited days supply must be greater than or equal to 10 days); or

• The plan’s network cost-sharing plus the differential between the OON billed charge and network allowable, with a limited days supply.

Plans may override the 1 month limit on a case-by-case basis when warranted by extraordinary circumstances.

CMS expects that enrollees obtaining covered Part D drugs at an OON pharmacy consistent with a Part D sponsor’s OON access policy may be required to pay the OON pharmacy’s U&C price at the point-of-sale, submit a paper claim to the sponsor, and wait for reimbursement from the sponsor as described above.

60.2 - Access to Vaccines
(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

Part D vaccines may be dispensed and administered in different settings (e.g., by pharmacists in pharmacies, by physicians in physician offices) depending on factors such as State laws regarding the administration of vaccines and product administration complexity. While access to Part D vaccines via a network pharmacy is likely the best method for improving enrollees’ access to Part D vaccines, Part D sponsors must ensure that enrollees have adequate access to Part D vaccines in physician offices when those Part D vaccines are appropriately dispensed and administered in physician offices. Such access is considered OON access because sponsor networks are defined as pharmacy networks only.

CMS recognizes, however, that the process of upfront payment by an enrollee and subsequent reimbursement by his or her Part D plan described for OON purchases in section 60.1 may be less feasible in the case of enrollees who require OON access to a vaccine in a physician’s office. As new vaccines come on the market with indications for use in the Medicare population, network Part D vaccine access will become more critical. To address this issue, CMS offers a range of in-network and facilitated OON approaches, described in sections 60.2.1 and 60.2.2 below, for improving access to Part D vaccines appropriately administered and dispensed by a physician without requiring upfront beneficiary payment and subsequent reimbursement by Part D sponsors. Part D sponsors are not limited to these approaches and are encouraged to pursue the implementation of any cost-effective, real-time billing option at the time of vaccine administration. Additionally, Part D sponsors may consider adopting alternative approaches, depending upon the vaccine and its respective cost, storage requirements, and complexity of administration. Sponsors electing to implement one or more of the options discussed below must still meet their obligation to generally provide OON access when appropriate – including through upfront payment by an enrollee and subsequent reimbursement by his or her Part D plan.
The administration of a Part D-covered vaccine is included in the definition of a “Part D drug,” effective January 1, 2008. Consequently, the Part D program covers vaccine administration costs associated with Part D vaccines. For more information, refer to section 10.14 of chapter 6.

60.2.1 - In Network Vaccine Distribution Approaches
(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

While CMS is in no way limiting Part D sponsors to any specific approach to ensuring access to Part D vaccines, CMS believes that an in-network, real time solution is the best method to improve vaccine access. In addition to the in-network options listed below, Part D sponsors could reduce the burden of copayment collection by establishing a benefit design with zero cost-sharing on vaccines.

1. In Network Retail Pharmacy Access

Enrollees could obtain a prescription from the physician and bring it to their local network retail pharmacy for filling. In some States, it might be possible for the vaccine administration to be provided by the pharmacist. Forty-eight States currently allow pharmacists to provide some type of vaccinations. Where it is safe to dispense these vaccines in the pharmacy, Part D sponsors could explore utilization of their network pharmacists as a provider of adult Medicare Part D vaccines. Pediatric vaccines should continue to be provided by physicians, however.

2. In Network Pharmacy Distribution

A Part D sponsor’s network pharmacy could provide vaccines directly to physician offices. Under this scenario, the physician could call or fax in a prescription, or the beneficiary could mail a prescription for the vaccine to the pharmacy. The pharmacy would fill the prescription for the vaccine, deliver or ship to the physician’s office, and bill the Part D sponsor for the vaccine. This model resembles the competitive acquisition program being implemented by Medicare Part B in that the drug is shipped to the physician but the physician never purchases or is reimbursed for the drug.

60.2.2 - Facilitated OON Access Approaches
(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

While the following options are OON arrangements between physicians and Part D sponsors, CMS expects that these and similar options will reduce the need for up-front beneficiary payment by facilitating other forms of payment arrangements between physicians and Part D sponsors, increasing access beyond the current regulatory OON requirements and avoiding the incurring of significant OON costs by beneficiaries or CMS as part of the low-income subsidy.

1. Model Vaccine Notice for Physicians (Paper Claim Enhancement)

Under this option, Part D sponsors would provide all enrollees with a vaccine-specific notice that the enrollees could bring to their physicians. This notice would provide information
necessary for a physician to contact the enrollee’s Part D plan to receive authorization of coverage for a particular vaccine, reimbursement rates, enrollee cost-sharing to be collected by the physician, and billing instructions. If the Part D sponsor authorizes payment, the physician would then bill the Part D sponsor using the physician standard claim form or ASC X12 electronic format (which Part D sponsors must accept) and would receive payment directly from the Part D sponsor. Alternatively, physicians could access this information directly by calling the sponsor’s prior authorization line.

2. Web-Assisted Electronic Physician Billing

Using a commercially-developed Web-based system based on the real-time NCPDP standard, physicians could electronically request OON reimbursement from Part D sponsors on behalf of beneficiaries for vaccines dispensed and administered in the physician’s office. The physician would agree to accept Part D sponsor payment as payment in full as a condition of using the system.

60.3 - Vaccine Administration
(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

60.3.1 - Vaccine Administration Cost-Sharing Considerations
(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

Since the vaccine administration fee is a component of a vaccine’s negotiated price, any cost-sharing applied to a vaccine should be applied relative to the negotiated price of the vaccine and its related component costs. If a sponsor structures its vaccine cost-sharing as coinsurance, including 100 percent cost-sharing in any applicable deductible or coverage gap, the coinsurance should be applied relative to the entire negotiated price (including the vaccine administration fee). Similarly, if a sponsor structures its vaccine cost-sharing as a copayment, the copayment should be applied relative to the entire negotiated price. In other words, a sponsor should not charge separate copayments for the vaccine ingredient cost and its related component costs, respectively (i.e., the vaccine administration fee and dispensing fee, if applicable), since CMS views the vaccine and its administration as intrinsically linked. Similarly, low income subsidy eligible individuals with copayments set by statute (see section 1860D-14(a)(1)(D) of the Social Security Act) will pay only one copayment for a vaccine and all related charges. Thus, for example, a low income subsidy eligible individual entitled to $1.05/$3.10 copayments in 2008 would pay only $3.10 for both the vaccine and its administration (and any applicable dispensing fee) even if the components are billed separately.³

³ In cases involving defined standard coverage and out-of-network vaccine administration, cost-sharing for a vaccine is based on the usual and customary price for both the vaccine ingredient cost and vaccine administration fee. This is because, given the cost-sharing requirements for defined standard coverage – under which the cost-sharing between the deductible and initial coverage limit must always be 25 percent of the actual cost of a drug at the point of sale – Part D sponsors offering defined standard coverage may not charge enrollees any out-of-network differential. However, sponsors offering other benefit designs (e.g., actuarially equivalent standard coverage, basic alternative coverage, or enhanced alternative coverage), may require enrollees being administered a vaccine out-of-network (e.g., in a physician’s office) to be responsible for any cost-sharing that would have otherwise applied had the drug been purchased at a network pharmacy, and also any differential between the provider’s usual and customary
60.3.2 - Separate Billing of the Vaccine and Vaccine Administration
(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

Although CMS prefers that all Part D vaccines be billed on one claim for both the vaccine and its administration, CMS recognizes there are circumstances that might require vaccine administration to be billed and reimbursed separately from the vaccine. For example, a Part D vaccine might have very specific storage conditions that would impede most physicians’ offices from maintaining a ready inventory for their patients. It might be more efficient for the physician to have a pharmacy dispense and deliver the vaccine for administration. The pharmacy will submit the vaccine ingredient cost and dispensing fee to the Part D sponsor for reimbursement and the physician will bill the beneficiary for the administration. Part D sponsors should establish processes necessary to separately reimburse the pharmacy for the vaccine ingredient cost/dispensing fee and the beneficiary for physician’s administration charge.

CMS has concerns about separate billing of Part D vaccines and vaccine administration fees because it provides an opportunity for both inappropriate and duplicate billing of administration fees. Separate billing is more challenging for Part D sponsors to process and track, and there is greater potential for programmatic fraud and abuse when the vaccine and its administration are not linked at time of reimbursement. Consequently, CMS strongly encourages Part D sponsors to link billing of a vaccine and its administration wherever possible. Where this is not possible, and separate billing occurs, CMS expects Part D sponsors to closely scrutinize the separate claims to ensure the beneficiary has received reimbursement for both elements and that the sponsor has neither over- nor underpaid for both the vaccine and the vaccine administration fee. CMS plans on monitoring Part D sponsors to ensure that when separate billing does occur, there is a reasonable correlation of prescription drug event (PDE) records for vaccines dispensed to PDE records for vaccine administration.

60.3.3 - Claims Processing Considerations
(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

Part D sponsors will implement a process that helps ensure compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) vaccine billing requirements. Under the Tax Relief and Healthcare Act of 2006 (TRHCA), a “covered Part D drug” is defined to include the vaccine and the administration of the vaccine. For purposes of billing for vaccines, Part D vaccine administration therefore is unique. As defined by statute, the “drug” incorporates both the vaccine and its administration. Consequently, billing of the Part D drug vaccine must be conducted using the NCPDP 5.1 standard for both the vaccine and its administration. When the administration is performed by the pharmacy or facilitated by the pharmacy through an established relationship with physician or immunizer, the administration will be included in one standardized field in the billing transaction as part of the vaccine prescription request to the Part D sponsor.\(^4\) In other words, the pharmacy should submit the vaccine and its administration, if price for the vaccine and vaccine administration fee and the plan allowance for the vaccine and vaccine administration (see section 60.1).

\(^4\) Relative to the establishment of relationships between pharmacies and immunizers, the parties must ensure that such arrangements do not violate the physician self-referral (“Stark”)
they are involved with the administration, as a single claim and not as two separate claims. NCPDP has issued formal guidance regarding the standardized field to be used for vaccine administration in the billing transaction.

When administration is billed separately from the dispensing of the vaccine, Part D sponsors or their subcontracted PBM should review existing claims for the presence of a vaccine charge. Should no vaccine charge be present in their claims history, the Part D sponsor should work with the beneficiary to ensure the beneficiary did not forget to submit a paper receipt for the vaccine and that appropriate reimbursement has been paid. For example, a sponsor could generate a letter to an enrollee whenever it receives a claim for a vaccine but does not receive a claim for vaccine administration within a certain time period.

A new, unique vaccine administration field has been added to the PDE elements for Part D sponsor submission of vaccine administration. This specific vaccine administration field allows a one-to-one claim to PDE relationship. For instance, if a sponsor receives a single claim from a network pharmacy inclusive of the vaccine and its administration it will need to attribute the vaccine ingredient cost, dispensing fee (if applicable), and administration to the appropriate fields of the PDE for submission to CMS. If separate billing by a pharmacy for the dispensing of the vaccine and by a physician for its administration occurs, the sponsor will submit one PDE based on the pharmacy claim inclusive of the vaccine and dispensing fee and a separate PDE based on the out-of-network claim from the beneficiary inclusive of the vaccine administration costs attributable to physician’s administration. For this second separate PDE, the vaccine ingredient National Drug Code (NDC) would still be identified, but the vaccine ingredient cost and dispensing fee would be set to zero dollars. The format will be published on www.csscoperations.com.

60.3.4 - Vaccine Administration Access
(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

Part D sponsors will allow any provider so authorized by State law to administer a Part D vaccine. Where it is safe to dispense and administer vaccines in a pharmacy, sponsors could explore utilization of their network pharmacists as providers of adult Medicare Part D vaccines (pediatric vaccines should continue to be provided by physicians). Out-of-network vaccines administered in a physician’s office or by other non-network providers may be covered under the out-of-network access rules detailed in section 60.2, where a Part D enrollee may self-pay for the vaccine cost and its administration and submit a paper claim for reimbursement to his or her Part D sponsor.

70 - Public Disclosure of Pharmaceutical Prices for Equivalent Drugs
(Rev. 14, Issued: 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Part D sponsors must ensure that their network pharmacies inform enrollees of any differential between the price of a covered Part D drug to an enrollee and the price of the lowest priced generic version of that drug that is an AB-rated alternative, therapeutically equivalent and prohibition (section 1877 of the Act), the Federal anti-kickback statute (section 1128B(b) of the Act), or any other applicable Federal or State law or regulation.
bioequivalent, on the plan’s formulary, and available at that pharmacy. This information must be provided:

- At the time the plan enrollee purchases the drug, if the enrollee purchases that drug at a pharmacy; or
- At the time of delivery of that drug, in the case of drugs purchased by mail order.

*CMS may modify the timing requirement (i.e., at the time of purchase or delivery) when CMS determines the requirement to be impossible or impracticable to administer.*

However, disclosure of this information will not be necessary if the particular covered Part D drug purchased by an enrollee was the lowest-priced generic version of that drug available at a particular pharmacy.

The requirement that information on lowest-priced generic drug equivalents be provided to enrollees for covered Part D drugs purchased by Part D plan enrollees is not applicable when those covered Part D drugs are purchased at:

- Any pharmacy, when the individual is enrolled in an MA private fee-for-service plan that offers qualified prescription drug coverage and provides plan enrollees with access to covered Part D drugs dispensed at all pharmacies, without regard to whether they are contracted network pharmacies, and does not charge additional cost-sharing for access to covered Part D drugs dispensed at all pharmacies;
- Out-of-network pharmacies;
- I/T/U network pharmacies;
- Network pharmacies located in any of the U.S. territories (American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, and the Virgin Islands); and
- A long-term care pharmacy.

80 - Privacy, Confidentiality, and Accuracy of Enrollee Records
(Rev. 1, Issued: 07-03-08, Effective: 07-03-08, Implementation: 07-03-08)

To the extent that a PDP offered by a PDP sponsor maintains medical records or other health information regarding Part D enrollees, the PDP sponsor must meet the same requirements regarding confidentiality and accuracy of enrollee records as MA organizations offering MA plans must currently meet under 42 CFR 422.118. These requirements do not apply to PACE organizations and cost plans offering qualified prescription drug coverage, since these plans are subject to similar requirements under 42 CFR 460.200(e) and 460.210, and 42 CFR 417.486, respectively.

Specifically, PDP sponsors must:
• Abide by all Federal and State laws regarding confidentiality and disclosure of medical records or other health and enrollment information, including the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and the privacy rule promulgated under HIPAA;

• Ensure that medical information is released only in accordance with applicable Federal and State law;

• Maintain the records and information in an accurate and timely manner; and

• Ensure timely access by enrollees to records and information pertaining to them.

PDP sponsors are covered entities under the HIPAA Privacy Rule because they meet the definition of “health plan” at 45 CFR 160.103. The Department of Health and Human Services Office for Civil Rights (OCR) is responsible for administering and enforcing the HIPAA Privacy Rule. OCR has authority to investigate complaints, to conduct compliance reviews, and to impose civil money penalties for HIPAA Privacy Rule violations. Thus, any violations by a PDP sponsor for its obligations under the Privacy Rule as a covered entity are subject to such enforcement by OCR. OCR maintains a Web site with frequently asked questions and other compliance guidance at: http://hhs.gov/ocr/hipaa

Part D sponsors, including both PDP sponsors and MA organizations, must effectively secure all beneficiary information, whether in paper or electronic format. This includes ensuring that data files are not saved on public or private computers when accessing corporate e-mail through the Internet, ensuring staff are properly trained to safeguard information, and ensuring electronic systems are properly programmed for beneficiary mailings to avoid inadvertent disclosures of individually identifiable health information. All sponsors should either perform an internal risk assessment or engage an industry-recognized security expert to conduct an external risk assessment of the organization to identify and address security vulnerabilities. Weaknesses or gaps in Part D sponsors’ security programs should be quickly remedied. Sponsors should annually train staff on responsibilities and consequences of failing to secure sensitive beneficiary information. Compliance with the HIPAA Security and Privacy rules must be documented and kept current in response to environmental or operational changes affecting the security and privacy of the electronic protected health information. In addition to HIPAA requirements, sponsors should notify CMS immediately upon discovery of any security breach compromising beneficiary personally identifiable information.

90 - Electronic Transaction Standards
(Rev. 14, Issued: 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

When processing Part D claims, a Part D sponsor or its intermediary must comply with the electronic transaction standards established by 45 CFR 162.1102, which sets forth the HIPAA administrative simplification standards for health care claims.

A Part D sponsor must also require its network pharmacies to submit claims to the Part D sponsor or its intermediary whenever the card described in section 50.11 is presented or on file
at the pharmacy unless the enrollee expressly requests that a particular claim not be submitted to the Part D sponsor or its intermediary.

90.1 - Unique Benefit Identification Number (BIN)/Processor Control Number (PCN) Provisions
(Rev. 14, Issued: 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

For Part D claims with a dispensing date of January 1, 2012 and later, and submitted in, National Council for Prescription Drug Programs (NCPDP) version D.O format, a Part D sponsor must assign and exclusively use a unique:

- Part D cardholder identification number (RxID) for each Medicare Part D enrollee to clearly identify Medicare Part D beneficiaries (other fields such as person code may not be used to differentiate enrollees), and
- Part D BIN or RxBIN and Part D processor control number (RxPCN) combination in its Medicare Part D line of business, unless non-exclusive use is expressly allowed by CMS and industry standard coding.5

Part D sponsors that do not support industry standard coding may only process Part D-covered drug claims under the Part D unique BIN/PCN and must reject all other claims. (See section 90.1.2 below). The intent of the unique BIN/PCN provisions is to ensure: (1) that pharmacies can routinely identify situations in which they are billing a Part D claim; and (2) that payers secondary to Part D can properly coordinate benefits on Part D claims. These goals cannot reliably be met if Part D claims cannot be distinguished from other types of pharmacy claims through unique routing and beneficiary identifiers.

Industry standard coding provides a mechanism whereby, in limited circumstances, both non-Part D Drugs and Part D drugs not covered by the plan be submitted to and processed under a Part D BIN/PCN. The industry standard coding requires Part D plans to clearly indicate on the paid response whether the drug is a non-Part D Drug covered by a Part D plan benefit structure or a Part D drug not covered by the Part D plan but processed under the Part D BIN/PCN.

It should be noted that in order to use Part D routing identifiers, an organization must sponsor a Part D plan. Thus, stand-alone Medicare Advantage plans should not use Part D routing identifiers.

With respect to which level of the sponsor’s or the sponsor’s subcontractor’s organization the unique routing identifier (“BIN” or “BIN/PCN” combination) should be assigned, the BIN or BIN/PCN combination should uniquely identify the Part D line of business and correspond to a payer sheet applicable solely to Part D processing requirements. This means that the BIN or BIN/PCN combination must be exclusively used for Part D claims processing, and must be supported by a payer sheet, regardless of whether the routing identifiers uniquely identify the

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5 E.g., NCPDP Recommendations for Effective 4Rx Usage in Medicare Part D Processing, Version 1.0, July 2011, NCPDP.
processor, the sponsor’s parent organization, or a subset of the sponsor’s business. Thus, one
BIN or BIN/PCN combination could represent multiple sponsors, as long as only Part D claims
are submitted to and processed under that identifier.

90.1.1 - Alternate Identifiers/Crosswalking/Mapping
(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Sponsors may not utilize the unique Part D identifiers “behind the scenes” in adjudicating
claims while providing different 4Rx data (the BIN, PCN, Group, and Cardholder ID identifiers)
to CMS through the MARx system enrollment-related transaction and on PDEs. The 4Rx data
submitted to CMS following enrollment, which supports the online real-time eligibility queries
(“E1 transactions”), must be the same data that pharmacies submit on claims and that the
processor uses to adjudicate claims and prepare PDEs. This way, the plan sponsor, its claims
processor, the pharmacy, the TrOOP facilitator, and any subsequent payers that wrap around
the Part D benefit can all accurately identify and manage Part D claims.

As of January 1, 2012, CMS does not permit the use of alternate identifiers on the inbound claim
that are subsequently crosswalked or otherwise mapped to the identifiers on record with CMS
and/or then converted into PDEs. When alternate identifiers have previously been utilized prior
to the implementation of this policy change, there may be initial disruption the first time a
pharmacy claim is submitted using the old identifiers, and it will be denied. However, the
correct identifiers should be readily available through the use of an E1 query or claim reject
responses processes as defined by industry standard. Once the proper identifiers have been
submitted, subsequent claims should not reject for invalid BIN/PCN/Group or Member ID.

CMS recognizes that some plans and processors do not use all 4 data elements of 4Rx
(BIN/PCN/GROUP/Cardholder ID) or may only use a portion of the characters for matching
purposes and as such expects that sponsors consult the industry standard on how to
communicate to CMS when certain data elements or values within a data element are not used.

90.1.2 - Sponsors that do not Support Industry Standard Coding to Distinguish
non-Part D-Covered Drugs
(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

If a sponsor does not support industry standard coding as described above in this section, the
sponsors must not use the Part D BIN or RxBIN and Part D processor control number (RxPCN)
for the following type claims:

• Part B Claims

The Part D routing identifiers cannot be used to process Part B claims at point of sale when
the sponsor is a Medicare Advantage Organization or an MA-PD. Processing a Part B
claim as if it were a Part D claim will cause the pharmacy to pass the Part B claim to any
secondary payer or subsequent payers that coordinate benefits with Part D. This may result
in these other payers providing benefits that they are not authorized to provide.

• Co-Administration of Part D and Secondary Payer Benefits
Unique Part D routing identifiers may only be used to process co-administered primary Part D and secondary payer benefits, such as when a sponsor contracts with both CMS for primary Medicare Part D benefits and with an SPAP for secondary coverage, as long as the sponsor is reasonably certain that no other payers are liable to coordinate benefits on Part D claims. (In the absence of independent knowledge of any such other payers, the sponsor may rely upon the CMS Coordination of Benefits (COB) files for this information). In this situation, the pharmacy would correctly treat the claim as a Part D claim, and no subsequent payer would be at risk of inappropriate coordination of benefits. However, the sponsor takes on additional risk in segregating and reporting the components of the one transaction properly to the two respective payers, as well as ensuring that the transaction is HIPAA compliant.

- **Discount Card Transactions**

The unique Part D routing numbers cannot be used to process discount card or other transactions that extend Part D negotiated prices to non-covered drugs (Part D or otherwise). Such use could lead pharmacies to misidentify such claims and apply Part D rules, terms and conditions to non-Part D claims.

90.2 - **Prescriber Identifiers**
(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Sponsors must report on PDE records one of the following four prescriber identifiers:

- NPI,
- DEA number
- UPIN
- State license number

Beginning January 1, 2012, sponsors must ensure these identifiers are active and valid.

Sponsors may not reject a pharmacy claim solely on the basis of an invalid prescriber identifier in order to not impede Medicare beneficiary access to needed medications unless the issue can be resolved at point of sale. In other words, sponsors may not reject a pharmacy claim at point of sale without prompt follow-up to ensure that the claim has been resubmitted with a corrected and valid prescriber identifier, or new information has been otherwise received to correct the sponsor’s information. If this is not possible, pharmacies can fill prescriptions and sponsors can pay the associated drug claims with an unvalidated prescriber ID at the point of sale. However, sponsors are then responsible for verifying and reporting a valid prescriber ID on the PDE record, and, whichever type of identifier is reported on the PDE, the identifier must be valid. Therefore, if an active and valid prescriber ID is not included on the Part D claim, either the sponsor, or the pharmacy if in accordance with the contractual terms of the network pharmacy agreement, must follow up retrospectively to acquire a valid ID of one of the four acceptable types before the PDE is submitted to CMS.
Follow-up may require review of the prescription, contact with the prescriber, use of the multiple sources of state and federal data on providers, or the purchase of prescriber ID validation services from a commercial vendor. Among the available state and federal sources are individual state licensing board data on licensing and sanctions, Drug Enforcement Agency registrant files, the Social Security Administration death file, OIG and state Medicaid program excluded provider lists, and the CMS National Plan & Provider Enumeration System (NPPES) database. Periodically updated files are available from these databases, in some cases directly from these agencies, or otherwise through the Department of Commerce’s National Technical Information Service (NTIS). In addition to these resources, CMS understands that multiple commercial firms compile databases and offer services for validation of prescriber identifiers, so an alternative approach would be for sponsors to purchase prescriber identifier validation services from commercial vendors who already have access to these sources of data and are currently providing these services to pharmacy, health plan, and pharmaceutical manufacturer clients. Thus, sponsors have the option to either build their own systems or contract with commercial vendors for prescriber ID validation services.

Although the requirement for validation of prescriber identifiers is imposed on Part D sponsors, CMS expects that network pharmacies may either contractually agree to provide some of these services themselves, or will fully support any retrospective review of the prescription and other records necessary to identify the prescriber and obtain a valid identifier. Contractual negotiations between sponsors/their agents and network pharmacies should address the terms and conditions as to responsibilities for these processes and any penalties for failure to perform. However, any requirement for a pharmacy to acquire and utilize its own automated validation capability should be a result of mutual agreement between the parties, since such a requirement may be impractical for many smaller pharmacy organizations. Also, CMS would expect that pharmacies will have the opportunity to correct any invalid data before payment for a claim is reversed whether or not the applicable contract delegates any sponsor duties.

90.2.1 - Foreign Prescribers
(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Certain border states permit prescriptions from foreign (e.g., non-U.S. or U.S. territory licensed) prescribers under their applicable pharmacy laws.

The only exception to the guidance in section 90.2 of this manual is that the identifier of a foreign prescriber cannot practically be validated. Therefore, sponsors should use the license number assigned by the foreign jurisdiction and report it on the PDE without validation against any official database, if the Part D claim was submitted in a state that recognizes prescriptions from foreign-located prescribers. By license number, CMS means the one assigned by an appropriate licensing board in the foreign jurisdiction in which the prescriber practices/resides on the claim with the State license qualifier.

90.2.2 - Beneficiary Requests for Reimbursement
(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Beginning 2012, a valid prescriber identifier must be reported on the PDE record of non-standard format claims, such as requests for reimbursement (“paper” claims) submitted by
Medicare beneficiaries. Sponsors may require members to furnish the prescriber’s name and address or phone number, or the pharmacy information, to assist the sponsor in obtaining the prescriber ID. Once the prescriber or pharmacy contact information is acquired, the sponsor must process the request for reimbursement and the sponsor, or the pharmacy (if doing so is in accordance with its contract terms), must follow up retrospectively to acquire a valid ID. Follow-up may entail a review of the prescription, prescriber contact, use of state or federal data on providers, or purchase of prescriber ID validation services from a commercial vendor.

Payment to the beneficiary cannot be made dependent upon the sponsor’s acquisition of the prescriber ID, itself. Sponsors may withhold reimbursement to the beneficiary only if there is a reason to suspect fraud or if there are coverage issues. In the absence of fraud, if the sponsor is unable to retrospectively acquire a valid prescriber ID, the sponsor may not seek recovery of the Part D payment from the beneficiary.

90.2.3 - National Provider Identifiers (NPIs)
(Rev. 14, Issued: 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

CMS will begin validating the format of all prescriber identifiers on PDEs that are coded as an NPI and will exclude from payment reconciliation PDEs with invalid NPIs. CMS will also be assessing each sponsor’s performance regarding NPI use and validity and will be notifying plan sponsors of their performance level. While section 90.2 of this manual has specifically addressed prescriber identifiers, CMS reminds both Medicare Advantage organizations and Part D sponsors that they are also required to obtain valid provider NPIs on claims. NPIs may be deactivated for reasons such as provider death or fraud related to identity theft and other forms of fraud. The NPPES database is updated monthly to reflect these changes. Therefore, in addition to verifying the reported NPI is valid, sponsors must also periodically confirm the identifiers are active. In those instances when the NPI is found to have been deactivated, sponsors must follow up with the provider to determine the reason for the deactivation.

90.2.4 - Controlled Substances
(Rev. 14, Issued: 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

In 2012, sponsors are required to confirm the validity of DEA numbers on Schedule II-V drug claims or map NPIs on these claims to the prescriber’s DEA numbers. In addition, sponsors will be required to confirm that the controlled substance prescribed is consistent with the prescriber’s DEA Schedule registration. As noted in section 90.2 of this manual, sources of state and federal data on providers are available to support sponsor efforts in this regard in addition to prescriber identifier validation services from commercial vendors. Sponsors should understand that this requirement supports (and does not supersede or alter) existing pharmacy obligations relative to DEA registrants under the Controlled Substances Act and DEA rules.
Appendix 1: Adequate Access to Network Home Infusion Pharmacies by State/Territory and Contract Type
(Rev. 14, Issued: 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

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<th>PDP &amp; RPPO</th>
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**NOTE:** Number of pharmacies listed above is based on the Beneficiary Data Count File (release date January 4, 2011) used for the CY2011 Reporting Requirements & CY2012 Part D Applications. The number of pharmacies needed to meet adequate access may change annually based on beneficiary counts.
Appendix 2: PDP Regions
(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Note: Each territory is its own PDP region.
Appendix 3: MA Regions
(Rev. 14, Issued; 09-30-11, Effective: 09-30-11, Implementation: 09-30-11)

Note: An MA region is one color. A difference in shading indicates that there are multiple PDP regions nested within the MA region. No change indicates that the MA and PDP regions are the same. For example, Wisconsin and Illinois are in one MA region; they are each a separate PDP region. Each territory is its own PDP region.
### Transmittals Issued for this Chapter

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# Medicare Prescription Drug Benefit Manual

## Chapter 6 – Part D Drugs and Formulary Requirements

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(Rev. 10, 02-19-10)

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Appendix B - Part D Drugs/Supplemental Drugs Summary Table
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Part D drugs are defined in Title XVIII of the Social Security Act (the Act) and in the regulations (42 CFR 423.100). Part D sponsors are responsible for making appropriate coverage determinations and ensuring that covered Part D drugs meet the requirements in this section.

10.1 - General

Subject to the exclusions specified in section 20 of this chapter, a Part D drug means a drug that may be dispensed only upon a prescription, is being used for a medically-accepted indication as defined by section 1927(k)(6) of the Act, and is one of the following:

- A drug that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act;
- A biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act;
- Insulin described in section 1927(k)(2)(C) of the Act;
- Medical supplies associated with the delivery of insulin;
- A vaccine licensed under section 351 of the Public Health Service Act and its administration.

CMS considers it best practice for Part D sponsors to consider the proper listing of a drug product with the FDA as a prerequisite for making a Part D drug coverage determination. The FDA is unable to provide regulatory status determinations through their regular processes if a drug product is not properly listed. Therefore, Part D sponsors should begin the drug coverage determination process by confirming that a prescription drug product national drug code (NDC) is properly listed with the FDA.

CMS interprets “dispensed only upon a prescription” as meaning a drug that is recognized by the Food and Drug Administration as a prescribed drug requiring “Rx only” on its label per section 503(b)(4) of the Federal Food Drug and Cosmetic (FD&C)Act.

Additionally, Part D sponsors must recognize a physician’s authority to delegate prescribing where authorized by State law. Generally, in retail pharmacy, standing orders and protocols are methods used by physicians to delegate and define their prescribing authority to non-physician providers such as pharmacists. Standing orders are typically pre-approved documents for a specific drug or vaccine, contain a set of required clinical criteria and permit administration of the drug without physician examination, as long as the required clinical criteria are met. A protocol is similar to a standing order but is generally broader in scope and may include multiple drugs and extensive clinical criteria. When these and other recognized delegation tools are used in accordance with Federal and State laws, the Part D requirement of “upon a prescription” will be satisfied.
10.2 - Covered Part D Drug  
(Rev. 2; Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

A covered Part D drug is a Part D drug that is included in a Part D sponsor’s formulary, or treated as being included in a Part D plan’s formulary as a result of a coverage determination or appeal under 42 CFR 423.566, 423.580, and 423.600, 423.610, 423.620 and 423.630, and obtained at a network pharmacy or an out-of-network pharmacy in accordance with 42 CFR 423.124.

10.3 - Commercially Available Combination Products  
(Rev. 2; Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Commercially available combination prescription drug products that contain at least one Part D drug component are Part D drugs when used for a “medically-accepted” indication, unless CMS makes the determination that such product, as a whole, belongs in one of the categories of drugs excluded from coverage under Part D. If CMS has not provided guidance to exclude a specific combination product, such combination product, so long as it contains at least one Part D drug component, should be considered a Part D drug (unless it is excluded from coverage under Part D for another reason).

10.4 - Extemporaneous Compounds  
(Rev. 2; Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Compounded prescription drug products can contain: (1) all Part D drug product components; (2) some Part D drug product components; or (3) no Part D drug product components. Only costs associated with those components that satisfy the definition of a Part D drug are allowable costs under Part D because the compounded products as a whole do not satisfy the definition of a Part D drug.

The labor costs associated with mixing a compounded product that contains at least one Part D drug component can be included in the dispensing fee (as defined in 42 CFR 423.100).

For compounds containing all generic products, the generic cost-sharing should be applied. If a compound contains any brand name products, the Part D sponsor may apply the higher brand name cost-sharing to the entire compound.

10.5 - Medical Supplies Associated with the Delivery of Insulin  
(Rev. 2; Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Medical supplies directly associated with delivering insulin to the body, including syringes, needles, alcohol swabs, gauze, and insulin injection delivery devices not otherwise covered under Medicare Part B, such as insulin pens, pen supplies, and needle-free syringes, can satisfy the definition of a Part D drug. However, test strips, lancets and needle disposal systems are not considered medical supplies directly associated with the delivery of insulin for purposes of coverage under Part D.
Insulin syringes equipped with a safe needle device, in their entirety (syringe and device), are also Part D drugs and should be managed like any other Part D drug the sponsor places on its formulary. Part D sponsors must make safety enabled insulin syringes available on their formularies for all of their institutionalized beneficiaries.

10.6 - Medically-Accepted Indication
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Section 1860D-2(e)(1)(B) of the Act limits “medically-accepted indication,” by reference to section 1927(k)(6) of the Act, to any use of a covered Part D drug which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act. The compendia are:

I. American Hospital Formulary Service Drug Information,
II. DRUGDEX Information System, and
III. United States Pharmacopeia-Drug Information (or its successor publications).

Part D sponsors are responsible for ensuring that covered Part D drugs are prescribed for “medically-accepted indications.” Part D sponsors may rely on utilization management policies and procedures to make such determinations but pharmacists are not required to contact each prescriber to verify whether a prescription is being used for other than a medically-accepted indication.

“Medically-accepted indication” refers to the diagnosis or condition for which a drug is being prescribed, not the dose being prescribed for such indication. Part D sponsors may have dose limitations based on FDA labeling, but an enrollee may request (and be granted) an exception to a dose restriction through the formulary exception process based on medical necessity criteria.

Additionally a Part D drug must be used for a medically-accepted indication that facilitates the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (except for Part D vaccines). Consequently, if a drug works on medical equipment or devices and is not used for a medically-accepted indication of therapeutic value on the body, it cannot satisfy the definition of a Part D drug. For example, a heparin flush is not used to treat a patient for a medically-accepted indication, but rather to dissolve possible blood clots around an infusion line. Therefore, heparin’s use in this instance is not therapeutic but is, instead, necessary to make durable medical equipment work. It would therefore not be a Part D drug when used in a heparin flush.

10.6.1 - Retrospective Determination of a Medically-Accepted Indication
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

1 CMS is considering whether to establish a process for identifying successor publications for purposes of Section 1927(g)(1)(B)(i) and will provide further notification of any decision to establish such a process.
Part D sponsors may retrospectively identify and confirm – either as part of their retrospective review programs required under 42 CFR 423.153, or incident to another utilization management review – that a dispensed drug was not prescribed for a medically-accepted indication for a particular individual (see the example below, in which this occurred because a dosage issue resulted in the case being flagged).

Example: An individual receives a prescription and takes a drug within a common dosing regimen (i.e., one tablet daily). Several months later, that individual’s physician writes a new prescription for an increased dosage of that drug. The second prescription triggers a quantity limit (for example, based on safety limits) and, as a result, the individual’s physician submits evidence to support an exception to the quantity limit. Based on that evidence, the Part D sponsor makes a determination that the drug was not prescribed for a medically-accepted indication.

When it was not reasonable to expect a Part D sponsor to require prior authorization to ensure a drug is being used for an accepted medical indication, CMS would not expect the sponsor to recover payments made to pharmacies or attempt to obtain reimbursement from enrollees. However, Part D sponsors must send notice of coverage determination decisions to affected enrollees (i.e., those for whom a coverage determination is made based on lack of evidence of a medically-accepted indication) in accordance with the rules provided in 42 CFR 423.566 through 423.576. Such notification must include the following information:

- The name of the affected covered Part D drug,
- The reason why the Part D sponsor is no longer covering the drug for the member,
- Alternative drugs on the Part D sponsor’s formulary, and expected cost-sharing for those drugs, and
- The enrollee’s right to a redetermination.

CMS expects a Part D sponsor to consider the enrollee’s health situation, and continue to cover the drug to the extent it determines that doing so is necessary to avoid risk to the enrollee’s health while providing for a transition to another form of treatment.

10.7 - Drug Purchased in Another Country
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Part D sponsors must exclude Part D drugs from qualified prescription drug coverage if they are not used and sold in the United States. In addition, Part D sponsors may only pay for drugs that satisfy the definition of Part D drug. In general, such definition requires FDA approval for sale in the United States. Therefore, even if the manufacturer has FDA approval for a drug, the version produced for foreign markets usually does not meet all of the requirements of the U.S. approval, and thus it is considered to be unapproved.

10.8 - Drugs Used to Treat Opioid Dependence
Part D sponsors must include coverage for Part D drugs, either by formulary inclusion or via an exception, when medically necessary for the treatment of opioid dependence. Coverage is not limited to single entity products such as Subutex®, but must include combination products when medically necessary (e.g., Suboxone®). For any new enrollees, CMS requires sponsors to have a transition policy to prevent any unintended interruptions in pharmacologic treatment with Part D drugs during their transition into the benefit. This transition policy, along with CMS’ non-formulary exceptions/appeals requirements, should ensure that all Medicare enrollees have timely access to their medically necessary Part D drug therapies for opioid dependence.

A Part D drug is defined, in part, as “a drug that may be dispensed only upon a prescription.” Consequently, methadone is not a Part D drug when used for treatment of opioid dependence because it cannot be dispensed for this purpose upon a prescription at a retail pharmacy. (NOTE: Methadone is a Part D drug when indicated for pain). State Medicaid Programs may continue to include the costs of methadone in their bundled payment to qualified drug treatment clinics or hospitals that dispense methadone for opioid dependence.

10.9 - DESI Drugs

For a drug to be available for reimbursement by a Part D sponsor it must meet the definition of a Part D drug. Section 1860D–2(e)(1) of the Social Security Act (the Act) generally defines a Part D drug to include those drugs that may be dispensed only upon a prescription and that meet the requirements of section 1927(k)(2) of the Act. Section 1927(k)(2) generally requires that the drug be approved by the FDA or otherwise described under sections 1927(k)(2)(A)(ii) or (A)(iii) of the Act. These provisions address those drugs affected by the Drug Amendments of 1962 (amending the Federal Food, Drug & Cosmetic Act), which require that a new drug be proven effective, as well as safe. FDA’s Drug Efficacy Study Implementation (DESI) evaluates the effectiveness of those drugs that had been previously approved on safety grounds alone. FDA indicates that these drugs, and those identical, related, and similar to them, may continue to be marketed until the administrative proceedings evaluating their effectiveness have been concluded, at which point continued marketing is permitted only if a new drug application (NDA) or abbreviated new drug application (ANDA) is approved. The vast majority of the DESI proceedings have been concluded, but a few are still pending.

The definition of a Part D drug does not include less than effective (LTE) DESI drugs or those identical, related or similar drugs to the LTE DESI drug. As FDA continues to undertake reviews under the DESI program and announces results of its hearings, CMS would expect Part D sponsors to adjust their formularies accordingly, as they should with any other applicable FDA drug product announcement. If a sponsor discovers the presence of any LTE DESIs on its formulary based on an FDA announcement or otherwise, it should remove these drugs from the formularies on accordance with section 30.3.2
10.10 - Over-the-Counter Products (OTCs)
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

The definition of a Part D drug does not include OTCs. Therefore, Part D sponsors cannot cover OTCs under their basic prescription drug benefit or as a supplemental benefit under enhanced alternative coverage. However, CMS will allow Part D sponsors the option to provide OTCs as part of their administrative costs structure. Refer to chapter 7, section 60, of this manual for further discussion of this option.

When an existing formulary product switches to an OTC status during the contract year, any existing inventory of the previous legend product (manufactured under the legend New Drug Application (NDA) and possessing the legend National Drug Code (NDC) number) will continue to satisfy the Part D drug definition. Given the potential for beneficiaries requiring conversion to other therapeutically equivalent legend products, CMS strongly recommends immediate notification of affected enrollees using the notification criteria outlined in section 30.3.4. CMS will direct sponsors to remove the converted legend product from their formulary at the next formulary submission window after the OTC product becomes available.

Providing the OTC product at no cost to beneficiaries, as outlined in chapter 7, section 60, of this manual, will not satisfy CMS’ formulary requirements and Part D sponsors may need to add additional drugs when the OTC is removed from its formulary. However, adjudication of the legend product may continue as long as the market holds residual inventory.

10.11 - Common Home Infusion Drugs
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

CMS has identified a list of acute care drugs that are most commonly utilized in the home infusion setting. The use of these drugs or drug classes often results in an earlier hospital discharge and reduced healthcare costs. Rapid access to these agents is imperative for these health care transitions. It is CMS’ expectation that Part D sponsors will not implement policies that could potentially delay or restrict beneficiary access to these important agents. In general, should prior authorization or other utilization management edits apply to any of these agents, CMS would expect that Part D sponsors handle these in an expedited manner in order to facilitate hospital discharge in appropriate time frames. In addition, it is CMS’ expectation that Part D sponsors ensure appropriate beneficiary access to these drugs or drug classes via formulary inclusion. See Appendix A for a list of commonly utilized home infusion drugs.

10.12 - Bundling of Home Infusion Drugs Under a Part C Supplemental Benefit
(Rev. 10, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

2 If, based on an FDA announcement, a Part D sponsor recognizes and removes a non-Part D drug from its formulary, CMS expects that Part D sponsors will provide 60 days of advance notice of the formulary removal.
Part D sponsors that offer Medicare Advantage (MA) prescription drug plans may choose to provide Part D home infusion drugs as part of a bundled service as a mandatory supplemental benefit under Part C, provided the sponsor consistently applies the option (i.e., in a given contract year, the plan either always covers a particular home infusion drug as part of a bundled service under Part C, or always covers a particular home infusion drug under Part D). Given uniform benefits requirements, sponsors electing this option must also ensure that the bundled service is available to all enrollees of any MA-PD or cost plan in which it chooses to provide Part D home infusion drugs as a mandatory supplemental benefit under Part C. In addition, plans electing this option must ensure that the bundle of services (which includes both infusion drugs and the services and supplies associated with infusion drugs) is available to all plan enrollees -- including those residing in long-term care facilities -- as a mandatory supplemental benefit under Part C.

Interested Part D sponsors must appropriately assign these costs to the Part C component of their bids to account for these bundled drugs. They must also provide, through the Formulary Submission module, a file that clearly identifies the Part D home infusion drugs that will be offered as part of a mandatory supplemental benefit under Part C for the following contract year. CMS will review sponsors’ home infusion drug files as part of our formulary review process to ensure that only home infusion drugs are included as part of the Part C supplemental benefit.

Effective with contract year 2010, CMS waives the definition of a Part D drug at 42 CFR 423.100 with respect to Part D drugs covered as part of a bundled benefit under a Part C supplemental benefit. Waiver of the definition of a Part D drug will improve benefit coordination of home infusion therapy between Parts C and D, particularly since the services and supplies necessary for home infusion are never covered under Part D but would be provided as part of a bundle of service under a Part C mandatory supplemental benefit. However, this waiver is conditioned on the application of zero cost sharing for the bundle of home infusion services provided under a Part C supplemental benefit. Thus, sponsors will not qualify for the waiver and, in turn, will not qualify to cover Part D home infusion drugs as part of a bundle of services under a Part C supplemental benefit without indicating on their Plan Benefit Packages (PBPs) that the applicable cost sharing for this bundle of services is $0.

In addition, the requirement that Part D sponsors’ formularies include at least two Part D drugs that are not therapeutically equivalent and bioequivalent in each category and class of covered Part D drugs – except where a particular category or class includes only one Part D drug – at 42 CFR 423.120(b)(2)(i) is waived for Part D sponsors for applicable formulary categories or classes when Part D home infusion drugs are provided as part of a bundled service as a mandatory supplemental benefit under Part C. Waiver of the requirement at 42 CFR 423.120(b)(2)(i) will allow Part D sponsors choosing to provide Part D home infusion drugs as a part of bundled service under a Part C mandatory supplemental benefit to improve benefit coordination of home infusion therapy between Part C and Part D. This improved benefit coordination promotes continuity of care and cost avoidance of more expensive institutional care by facilitating continuous access to home infusion drugs, as well as the costs of administration and supplies associated with that therapy.
Part D sponsors choosing to provide Part D home infusion drugs as part of a bundled service must indicate on their marketed formularies that certain drugs may be covered under the sponsor’s medical, rather than its prescription, benefit. For more information, consult the model formulary available at: http://www.cms.hhs.gov/PrescriptionDrugCovContra/PartDMMM/list.asp#TopOfPage.

10.13 - Inhaler Supplies
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

The definition of a Part D drug includes a drug that is described in section 1927(k)(2)(A)(i) of the Social Security Act. This section specifically defines a “covered outpatient drug” as one that is approved for safety and effectiveness as a prescription drug under section 505 of the Federal Food, Drug, and Cosmetic Act, which requires submission by the manufacturer of an NDA or ANDA.

In general, only those accessories for meter dose inhalers (MDIs), Dry Powder Inhalers (DPIs), or Nasal Spray Inhalers (NS) that are included on the NDA or ANDA, listed on the package insert, and specifically packaged with the drug product itself are eligible to meet the definition of a Part D drug. If the accessories (i.e., actuator, chamber) are sold separately or are not included on the drug product’s NDA or ANDA, they would not meet the definition of a Part D drug.

10.14 - Vaccine Administration
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Beginning on January 1, 2008, the Part D program will cover vaccine administration costs associated with Part D vaccines. CMS interprets this statutory requirement to mean that the Part D vaccine administration costs are a component of the negotiated price for a Part D-covered vaccine. In other words, the negotiated price for a Part D vaccine will be comprised of the vaccine ingredient cost, a dispensing fee (if applicable), and a vaccine administration fee. This interpretation recognizes the intrinsic linkage that exists between the vaccine and its corresponding administration, since a beneficiary would never purchase a vaccine without the expectation that it would be administered.

In general, CMS believes that Part D vaccines, including the associated administration costs, should be billed on one claim for both in- and out-of-network situations. For example, if an in-network pharmacy dispenses and administers the vaccine in accordance with State law, the pharmacy would process a single claim to the Part D sponsor and collect from the enrollee any applicable cost-sharing on the vaccine and its administration. Alternatively, if a vaccine is administered out-of-network in a physician’s office, the physician would provide the vaccine and its administration and then bill the beneficiary for the entire charge, including all components. The beneficiary would, in turn, submit a paper claim to the Part D sponsor for reimbursement for both the vaccine ingredient cost and administration fee.

10.14.1 - Elements of Vaccine Administration
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)
Vaccine administration fees should be subject to negotiations between Part D sponsors and pharmacies. CMS expects that sponsors will take into consideration the elements reflected in existing Part B vaccine administration fees when establishing their own vaccine administration fees. For example, Part B considers the immunizing professional’s time in physically delivering the vaccine to a beneficiary, the resources encompassing the supplies (syringe, gauze, band-aid, alcohol prep pad, etc.), the indirect costs of the office, and professional liability.

10.14.2 - Establishment of Multiple Vaccine Administration Fees
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Part D sponsors will have the discretion to implement either a single vaccine administration fee for all vaccines or multiple administration fees based on type of vaccine, variance in provider type, and product administration complexity. CMS plans to retrospectively review vaccine administration fees to look for outliers and potentially discriminatory practices that would impact beneficiary access to Part D vaccines.

10.14.3 - Other Vaccine Administration Considerations
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Part D sponsors may implement drug utilization management tools to determine if a vaccine is necessary; however, in the absence of any information showing previous immunization (i.e., claims data), the Part D sponsor should make payment available for a vaccine and its administration consistent with Advisory Committee on Immunization Practices (ACIP) recommendations.

20 - Part D Exclusions
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

20.1 - Excluded Categories
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Part D drugs do not include drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1927(d)(2) of the Act, except for smoking cessation agents.

Excluded:

- Agents when used for anorexia, weight loss, or weight gain (even if used for a non-cosmetic purpose (i.e., morbid obesity)).

- Agents when used to promote fertility.

- Agents when used for cosmetic purposes or hair growth.

- Agents when used for the symptomatic relief of cough and colds.
• Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

• Nonprescription drugs.

• Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

• Barbiturates.

• Benzodiazepines.

• Agents when used for the treatment of sexual or erectile dysfunction (ED). ED drugs will meet the definition of a Part D drug when prescribed for medically-accepted indications approved by the FDA other than sexual or erectile dysfunction (such as pulmonary hypertension). However, ED drugs will not meet the definition of a Part D drug when used off-label, even when the off label use is listed in one of the compendia found in section 1927(g)(1)(B)(i) of the Act: American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information (or its successor publications), and DRUGDEX Information System.

Not Excluded:

• Prescription drug products that otherwise satisfy the definition of a Part D drug are Part D drugs when used for AIDS wasting and cachexia due to a chronic disease, if these conditions are medically-accepted indications as defined by section 1927(k)(6) of the Act for the particular Part D drug. Specifically, CMS does not consider such prescription drug products being used to treat AIDS wasting and cachexia due to a chronic disease as either agents used for weight gain or agents used for cosmetic purposes.

• Part D drugs indicated for the treatment of psoriasis, acne, rosacea, or vitiligo are not considered cosmetic.

• Vitamin D analogs such as calcitriol, doxercalciferol, paricalcitol and dihydrotachysterol, when used for a medically-accepted indication as defined by section 1927(k)(6) of the Act, are not excluded because CMS interprets the exclusion of prescription vitamin D products as being limited to products consisting of ergocalciferol (vitamin D2) and/or cholecalciferol (vitamin D3).

• Prescription-only smoking cessation products.

• Prescription Niacin Products (Niaspan, Niacor).

• Cough and cold medications are eligible to meet the definition of a Part D drug in clinically relevant situations other than those of symptomatic relief of cough and colds.
For example, when cough medications are used for a medically-accepted indication that treats a cough produced by a medical condition unrelated to symptomatic cough and cold. In such circumstances, such as the treatment of cough to alleviate bronchospasm in asthma, CMS does not consider these cough medications as excluded drugs.

See Appendix B for further clarification of Part D coverage or non-coverage of specific products/drugs/drug categories.

20.2 - Drugs Covered Under Medicare Part A or B
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Part D specifies that a drug prescribed to a Part D eligible individual cannot be considered a covered Part D drug if payment for such drug “...is available (or would be available but for the application of a deductible) under part A or B for that individual.” CMS interprets this to mean that if payment could be available under Part A or Part B to the individual for such drug, then it will not be covered under Part D. Consequently, drugs covered under Parts A and B are considered available (and excluded from Part D) if a beneficiary chooses not to pay premiums or if a beneficiary has enrolled in Part B but that coverage has not yet taken effect.

See Appendix C for further explanation and clarification of specific issues regarding coverage under Medicare Part B.

20.2.1 - Exhausted Part A Benefits
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

The issue of applicability of Part D coverage has also arisen in the context of inpatients in acute care hospital settings (including long-term care (LTC) hospitals, which are certified as acute care hospitals) who have exhausted their Part A inpatient stay benefit, but who require and continue to receive a level of care that qualifies them for a Part A inpatient stay.

Drugs provided in an inpatient setting to an individual who has exhausted his or her lifetime inpatient hospital benefit under Part A are not drugs that could be covered under Part A for that individual. Unlike a beneficiary who, for example, chooses not to buy into Part B, there is no way for an individual who has exhausted his or her Part A inpatient stay benefit to obtain coverage under Part A for his or her drugs; therefore, Part D coverage may be available to a Part D enrollee who has exhausted his or her Part A inpatient stay benefit and who remains in that inpatient setting (provided the drug would otherwise be covered under Part D). See chapter 5, section 50.5.4, regarding sponsor contracting requirements when a beneficiary has exhausted inpatient Part A benefit days.

20.2.2 - Part D Sponsor Due Diligence in Prior Authorization of Part B Versus Part D Coverage Determination
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Part D sponsors may rely upon physician information included with the prescription, such as diagnosis information (e.g., to determine whether the prescription is related to a Medicare...
covered transplant) or location of administration (e.g., to determine if the prescription is being dispensed for a beneficiary in a nursing home) to the same extent they rely on similar information acquired through documentation from physicians on prior authorization forms. Assuming the indication on the script is sufficient to make the coverage determination, there is no need in such cases to require additional information to be obtained from the physician.

To the extent that the Part D sponsor requires its contracted pharmacies to report the information provided on the prescription to assist in the determination of Part B versus Part D coverage, the sponsor may rely on the pharmacist’s report of appropriate information to make the coverage determination under Part D. For example, for cases in which prednisone is prescribed for a condition other than immunosuppression secondary to a Medicare-covered transplant, and this is indicated on the prescription, a sponsor may cover the drug under Part D without seeking further information from the prescribing physician.

This clarification should not be construed to indicate that a Part D sponsor may not impose prior authorization or other procedures to ensure appropriate coverage under the Medicare drug benefit. The Part D sponsor is ultimately responsible for making the initial Part D coverage determination. However, CMS believes that the sponsor will have met appropriate due diligence standards without further contacting a physician if necessary and sufficient information is provided on the prescription, and the contracted pharmacy is able to communicate this information to the sponsor in order to make the coverage determination.

CMS encourages industry trade collaboration with Part D sponsors to streamline Part B vs. Part D coverage determinations. For instance, CMS has received comments recommending that as Part D sponsors learn of a beneficiary’s transplant status they record this in an electronic database which could be shared with subsequently enrolled Part D sponsors minimizing data collection and speeding appropriate coverage determinations. CMS also encourages further utilization of locator codes in claims for long term care beneficiaries who are ineligible for Part B drugs under the durable medical equipment benefit based on their place of residence.

20.3 - Coverage of Supplemental Drugs Under Enhanced Alternative Coverage
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

A Part D sponsor may include coverage of drugs that would meet the definition of a Part D drug but for the application of section 20.1 (these are known as “supplemental drugs,” as provided in section 10.2 of chapter 5 of this manual) as a supplemental benefit under enhanced alternative coverage.

20.4 - Application of General Exclusion Provisions
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

In accordance with section 1860D-2(e)(3) of the Act, a Part D sponsor may exclude from qualified prescription drug coverage any Part D drug:
• For which payment would not be made if items and services are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (except for Part D vaccines); or

• Which is not prescribed in accordance with the Part D sponsor.

Such exclusions are coverage determinations subject to reconsideration and appeal.

Unlike other Part D drugs that may be excluded when not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, Part D vaccines may only be excluded when their administration is not reasonable and necessary for the prevention of illness.

30 - Formulary Requirements
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

A Part D sponsor that uses a formulary under its qualified prescription drug coverage must meet requirements for the following:

• Pharmacy and Therapeutics committee;
• Provision of an adequate formulary;
• Transition process;
• Limitation on changes in therapeutic classification;
• Provision of notice regarding formulary changes;
• Limitation of formulary changes prior to beginning of contract year;
• Provider and patient education; and
• Formulary changes during the contract year.

30.1 - Pharmacy and Therapeutics (P&T) Committee
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

A Part D sponsor’s formulary must be developed and reviewed by a P&T committee that meets specific requirements with respect to:

• Membership;
• Conflict of interest;
• P&T member disclosure to CMS;
• Meeting administration;
• Formulary management;
• Formulary exceptions; and
• P&T committee role.
30.1.1 - Membership
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Part D sponsors’ P&T committee membership must satisfy the following requirements:

- P&T committee members must come from various clinical specialties that adequately represent the needs of sponsors’ enrollees.
- A majority of the P&T committee members must be practicing physicians, practicing pharmacists or both.
- At least one P&T committee practicing pharmacist and one practicing physician must be an expert in the care of elderly or disabled persons.
- At least one P&T committee practicing pharmacist and one practicing physician must be independent and free of conflict with respect to the Part D sponsor and pharmaceutical manufacturers. Such P&T committee members may have certain non-employee relationships with pharmaceutical manufacturers (for example consulting, advisory, or research relationships) and still be considered independent and free of conflict provided those relationships do not constitute significant sources of income and they do not otherwise have a conflict of interest that would compromise their independence. In addition, panel providers in a staff model HMO may be considered independent and free of conflict to the extent that any remuneration received from a Part D sponsor is limited to his or her clinical responsibilities for the care of plan enrollees.

30.1.2 - Conflict of Interest
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

P&T committee members should sign a conflict of interest statement revealing economic or other relationships with entities affected by drug coverage decisions that could influence committee decisions.

30.1.3 - P&T Committee Member Disclosure to CMS
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

In the event the Part D sponsor has entered into a confidential agreement such that the Pharmacy Benefits Manager (PBM) will not disclose its P&T committee membership to the Part D sponsor, then it is the Part D sponsor’s responsibility to notify CMS that this information will be submitted by the sponsor’s PBM. Moreover, the Part D sponsor must ensure that the PBM notifies CMS of the P&T committee membership. The Part D sponsor maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract and the sponsor must ensure that the PBM notifies the sponsor that this information has been successfully submitted to CMS.

30.1.4 - Meeting Administration
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)
The Part D sponsor’s P&T committee should meet on a regular basis, but no less than quarterly. P&T committee decisions regarding formulary development or revision must be documented in writing.

### 30.1.5 - Formulary Management
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Part D sponsor’s P&T committee will consider the following:

- The P&T committee must review for clinical appropriateness the practices and policies for formulary management activities, such as prior authorizations, step therapies, quantity limitations, generic substitutions and other drug utilization activities that affect access. P&T committee recommendations regarding these activities are advisory only and not binding on the Part D sponsor.

- Formulary management decisions must be based on scientific evidence, and may also be based on pharmacoeconomic considerations that achieve appropriate, safe and cost effective drug therapy.

- The P&T committees will be required to establish and document procedures to ensure appropriate drug review and inclusion. This includes documentation of decisions regarding formulary development and revision and utilization management activities (42 CFR 423.120(b)(1)(viii)). P&T committee recommendations regarding which Part D drugs are placed on a sponsor’s formulary are binding on the Part D sponsor.

- Clinical decisions by the P&T committee should be based on scientific evidence and standards of practice, including peer reviewed medical literature, well-established clinical practice guidelines and pharmacoeconomic studies, as well as other sources of appropriate information.

- Drugs’ therapeutic advantages in terms of safety and efficacy must be considered when selecting formulary drugs and placing them on formulary tiers.

- The P&T committee will make a reasonable effort to review a new FDA approved drug product (or new FDA approved indication) within 90 days and will make a decision on each new FDA approved drug product (or new FDA approved indication) within 180 days of its release onto the market, or a clinical justification will be provided if this timeframe is not met.

- The P&T committee will evaluate and analyze treatment protocols and procedures related to the sponsor’s formulary at least annually.

- The P&T committee will approve inclusion or exclusion of the therapeutic classes in the formulary on an annual basis.
- Part D sponsors that change PBMs mid-year are required to continue the existing formulary. Decisions regarding formulary inclusion made by the previous PBM’s P&T committee are binding on the assuming PBM. CMS will not approve negative formulary change requests for the purpose of aligning an existing formulary with that of a new PBM.

### 30.1.6 - Formulary Exceptions

P&T committees must review for clinical appropriateness protocols and procedures for the timely use of and access to both formulary and non-formulary drug products. Part D coverage determinations and appeals information can be found in chapter 18 of this manual.

### 30.1.7 - P&T Committee Role in Transition

(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

At a minimum, a sponsor’s transition process, the minimum requirements of which are detailed in section 30.4, will address procedures for medical review of non formulary drug requests and, when appropriate, a process for switching new Part D sponsor enrollees to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination. CMS will look to transition process submissions for assurances that a sponsor’s P&T committee will review and provide recommendations regarding the procedures for medical review of non-formulary drug requests. P&T committee involvement will help ensure that transition decisions appropriately address situations involving enrollees stabilized on drugs that are not on the sponsor’s formulary (or that are on the formulary but require prior authorization or step therapy under a sponsor's utilization management requirements) and which are known to have risks associated with any changes in the prescribed regimen.

### 30.2 - Provision of an Adequate Formulary

(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

CMS encourages Part D sponsors to submit formularies similar to those in widespread use today. CMS will check the formulary to ensure inclusion of a range of drugs in a broad distribution of therapeutic categories and classes, in order to satisfy the Medicare Modernization Act (MMA) requirement that a sponsor’s categorization system does not substantially discourage enrollment by any group of beneficiaries. CMS will consider the specific drugs, tiering and utilization management strategies employed in each formulary. CMS will identify outliers from common benefit management practices for further evaluation. Sponsors may be asked to provide written clinical justification for unusual benefit features that are identified as outliers.

### 30.2.1 - Formulary Categories and Classes

(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Part D formularies must include drug categories and classes that cover all disease states. CMS will evaluate the sufficiency of a Part D sponsor’s formulary categories and classes in conjunction with the formulary drug list to ensure that the formulary provides access to an acceptable range of Part D drug choices.
Part D sponsors that utilize a classification system that is consistent with the United States Pharmacopedia (USP) classification system, available at www.usp.org, will qualify for a safe harbor, meaning that CMS will approve their formulary classification system. For sponsors that choose to adopt an alternative to USP’s classification structure, CMS will check the sponsor’s proposed classification system to determine if it is similar to USP or other commonly used classification systems, such as the American Hospital Formulary Service (AHFS) Pharmacologic-Therapeutic Classification (information available at www.ashp.org/ahfs).

Each category or class must include at least two drugs (unless only one drug is available for a particular category or class, or only two drugs are available but one drug is clinically superior to the other for a particular category or class), regardless of the classification system that is utilized. The two drug minimum requirement must be met through the provision of two chemically distinct drugs. In other words, Part D sponsors will not meet this requirement by including only two dosage forms or strengths of the same drug, or a brand name drug and its generic equivalent.

Aside from the inclusion of two drugs in each category or class, multiple strengths and dosage forms should also be available for each covered drug. This should encompass dosage forms used commonly in LTC facilities and home infusion.

CMS may require more than two drugs for particular categories or classes if additional drugs present unique and important therapeutic advantages in terms of safety and efficacy, and their absence from the sponsor’s formulary would substantially discourage enrollment by beneficiaries with certain disease states.

30.2.1.1 - Application of Existing or New Drugs into the Current Version of the USP Model Guidelines
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

For those formularies that utilize the USP Model Guidelines classification structure, there are several methods to accommodate new Part D drugs that come on to the market during the contract year. These methods may also be utilized to accommodate existing Part D drugs that cannot be classified under the USP Model Guidelines. CMS expects one of the four options listed below to be used for the above mentioned situations.

1. Addition of a Part D drug into an existing USP category or class. In the event that a new Part D drug is approved and is to be added to the formulary, the newly approved Part D drug may fit into the current classification system. For instance, if a new protease inhibitor is approved, this drug would be added to the formulary in the USP Antivirals category, under the Anti-HIV Agents, Protease Inhibitors class.

2. Placement of a Part D drug into an “Other” class. In the current USP Model Guidelines, USP listed an “Other” class under various categories. Should a new Part D drug receive approval that can not be placed into an existing class, and the particular USP category contains an “Other” class, the new drug may be placed into the “Other” class.
3. Addition of a new class under an existing category. If a new Part D drug is approved that does not fit into an existing class, but is appropriate for a particular category, then a new class may be displayed under an existing category. This method would also apply to formularies that utilize AHFS or another classification structure.

4. Miscellaneous Therapeutic Agents. If an existing or newly approved Part D drug does not fit into any existing category, a “Miscellaneous Therapeutic Agents” category may be displayed on the formulary.

30.2.2 - Formulary Benefit Management Tools
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

CMS will look to existing best practices to check that Part D sponsors’ use of prior authorization, step therapy, and quantity limits is consistent with such practices. CMS will look to current industry standards as well as appropriate guidelines that might be found from expert organizations and to the use of such standards in existing drug sponsors that are widely used by seniors and people with disabilities. CMS will ensure that sponsors’ use of such tools is consistent with best practices. CMS will also compare formularies among the applicants to analyze the comparative use of practices such as prior authorization, step therapy, and quantity limits. Part D sponsors should be consistent with the FDA approved label when applying prior authorization to assess beneficiaries’ eligibility for coverage. In cases where a sponsor may fall outside of best practices, the sponsor will be asked to provide a reasonable justification for its practices.

CMS’ expectation is that formulary benefit management tools will be used in Part D formularies consistent with the way they are applied in existing formulary systems.

30.2.2.1 - Formulary Submission of “Safety-Related” Utilization Management Edits
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

CMS continues to require Part D sponsors to submit utilization management requirements, such as prior authorization, step therapy and quantity limits not based upon the FDA’s maximum daily dose limits, as part of their Health Plan Management System (HPMS) formulary submission. See chapter 7 of this manual for more information on drug utilization management tools.

CMS does not require Part D sponsors to submit all point-of-sale (POS) safety related edits as part of their HPMS formulary submission. Specifically, CMS does not require Part D sponsors to submit those POS safety edits implemented to satisfy the concurrent drug utilization review requirements set forth in 42 CFR 423.150(c)(2). These edits are typically applied at the point-of-sale or point-of-distribution and assist the pharmacist in identifying and/or preventing inappropriate drug therapy. These utilization review edits include the following:

- Screening for potential drug therapy problems due to therapeutic duplication;
- Age/gender-related contraindications;
- Over-utilization and underutilization (e.g., early refill);
- Drug-drug interactions;
- Incorrect drug dosage or duration of drug therapy; and
- Drug-allergy contraindications

30.2.3 - Long-term Care Accessibility
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Part D sponsors will be required to provide medically necessary prescription drug treatments for enrollees in the general Medicare population, as well as those enrollees who reside in LTC facilities. For example, it is CMS’ expectation that sponsors provide coverage of dosage forms of drugs that are widely utilized in the LTC setting, such as unit dose products and liquid, chewable, and parenteral preparations. Further, while nebulized solutions may not be required on all formularies, CMS would expect sponsors to also cover these dosage forms under circumstances in which Part B coverage is not available. When determining days supplies for residents in LTC facilities, Part D sponsors should follow industry best practices and allow for at least 31 days per fill.

30.2.4 - Specialty Tiers
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

42 CFR 423.578(a)(7) allows Part D sponsors to exempt a formulary tier, in which it places very high cost and unique items, from tiered cost-sharing exceptions. In order to ensure that a Part D sponsor does not substantially discourage enrollment by specific patient populations reliant upon these medications, CMS will only approve specialty tiers within formularies and benefit designs that comply with the following:

- Only one tier is designated a specialty tier exempt from cost-sharing exceptions.
- Cost-sharing associated with the specialty tier is limited to 25% after the deductible and before the initial coverage limit (or an actuarially equivalent for sponsors with decreased or no deductible under alternative prescription drug coverage designs).
- Only Part D drugs with sponsor negotiated prices that exceed the dollar-per-month amount established by CMS in the annual Call Letter may be placed in the specialty tier. CMS will apply an upfront evaluation across all plans for drugs that exceed the dollar-per-month threshold and are intended for inclusion in the specialty tier.
- If not all drugs (including all strengths) within a category or class meet the criteria for inclusion in the specialty tier, the sponsor must ensure that placement of the remaining drugs among the other tiers of the formulary does not substantially discourage enrollment.

Part D sponsors will need to evaluate the negotiated prices at the drug product strength, package size, and formulation level in order to determine appropriate inclusion of the drug in the Part D
plan’s specialty tier. If a Part D drug product is available in multiple strengths, package sizes and formulations, CMS will only allow inclusion on the specialty tier of those strengths, package sizes and formulations that would reasonably exceed the dollar-per-month threshold. As a result, Part D sponsors should be prepared to locate smaller package sizes, strengths, and formulations of the very same drug on a tier other than the specialty tier if the smaller size cannot satisfy the monthly dollar threshold.

Part D sponsors must evaluate the long acting nature of some drug formulations and calculate the monthly cost across the drug's full duration of action. For example, if the specialty tier threshold was $600 dollars, a long acting formulation with a plan negotiated price of $900 dollars that lasts for 3 months would not be eligible for the plan's specialty tier since the monthly cost is only $300 dollars.

30.2.5 - Protected Classes
(Rev. 10, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

Part D sponsor formularies must include all or substantially all drugs in the immunosuppressant (for prophylaxis of organ transplant rejection), antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes. CMS instituted this policy because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in certain Part D plans, as well as to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations.

Formularies must include substantially all drugs in these six categories that are FDA approved by the last CMS specified HPMS formulary upload date for the upcoming contract year. New drugs or newly approved uses for drugs within the six classes that come onto the market after the CMS specified formulary upload date will be subject to an expedited P&T committee review. The expedited review process requires P&T committees to make a decision within 90 days, rather than the normal 180-day requirement. At the end of the 90 day period, these drugs must be added to Part D plan formularies.

“Substantially all” in this context means that all drugs and unique dosage forms in these categories are expected to be included in sponsor formularies, with the following exceptions:

- multi-source brands of the identical molecular structure;
- extended release products when the immediate-release product is included;
- products that have the same active ingredient or moiety; and
- dosage forms that do not provide a unique route of administration (e.g., tablets and capsules versus tablets and transdermals);

Part D sponsors may not implement prior authorization or step therapy requirements that are intended to steer beneficiaries to preferred alternatives within these classes for enrollees who are currently taking a drug. This prohibition applies to those beneficiaries already enrolled in the plan as well as new enrollees who were actively taking drugs in any of the six classes of clinical concern prior to enrollment into the plan. If a sponsor cannot determine at the point of sale that
an enrollee is not currently taking a drug (e.g., new enrollee filling a prescription for the first time), sponsors shall treat such enrollees as currently taking the drug.

For HIV/AIDS drugs, utilization management tools such as prior authorization and step therapy are generally not employed in widely used, best practice formulary models. Part D sponsors may conduct consultations with physicians regarding treatment options and outcomes in all cases.

Part D sponsors may apply prior authorization to establish appropriate payment under Part B or Part D, even if the beneficiary is currently taking the drug. In Part B versus Part D situations, CMS expects Part D sponsors will work aggressively to eliminate any interruptions of current therapy.

30.2.6 - Submission of Multiple Formularies
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

CMS recognizes that sponsors may wish to submit more than one formulary in order to offer enhanced access to Part D drugs. CMS has the responsibility to ensure that there are meaningful differences between multiple formulary submissions from one organization to reduce confusion amongst beneficiaries. CMS may request that sponsors withdraw a formulary in which no meaningful differences can be demonstrated.

30.2.7 - Formulary Performance and Content Review
(Rev. 10, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

Regardless of the classification system chosen, CMS will review and approve drug lists that are consistent with best practice formularies currently in widespread use today. The current formulary requirements are subject to change and/or revision.

CMS requires formulary drug lists to pass the following checks:

- CMS will review formularies to ensure representation of USP formulary key drug types on all Part D formularies. Part D sponsors whose formularies are identified as outliers will be contacted and their formularies will require re-evaluation.

- CMS will review tier placement to ensure that the formulary does not substantially discourage enrollment of certain beneficiaries. When developing their formulary tier structure, sponsors should utilize standard industry practices. Tier 1 should be considered the lowest cost-sharing tier available to beneficiaries. Any and all subsequent tiers within the formulary structure will be higher cost-sharing tiers in ascending order. For example, drugs in Tier 3 will have a higher cost-share for beneficiaries than drugs in Tier 2. Best practices in existing formularies and preferred drug lists generally place drugs in a less preferable position only when drugs that are therapeutically similar (i.e., drugs that provide similar treatment outcomes) are in more preferable positions on the formulary. The CMS review will focus on identifying drug categories that may substantially discourage enrollment of certain beneficiaries by placing drugs in non-preferred tiers in the absence of commonly used therapeutically similar drugs in more preferred positions.
CMS will analyze formularies to determine whether appropriate access is afforded to drugs or drug classes addressed in widely accepted treatment guidelines which are indicative of general best practice. Examples of these may include asthma, diabetes, chronic stable angina, atrial fibrillation, heart failure, thrombosis, lipid disorders, hypertension, chronic obstructive pulmonary disease, dementia, depression, bipolar disorder, schizophrenia, benign prostatic hyperplasia, osteoporosis, migraine, gastroesophageal reflux disease, epilepsy, Parkinson’s disease, end stage renal disease, hepatitis, tuberculosis, community acquired pneumonia, rheumatoid arthritis, multiple sclerosis and HIV. Part D sponsors should be aware of treatment guidelines impacting those enrollees residing in LTC facilities, such as CDC’s annual Morbidity and Mortality Weekly Report (MMWR) on prevention and control of influenza. This list of conditions does not represent an exhaustive list, but merely serves as another check in the review process.

CMS will analyze the availability and tier position of the most commonly prescribed drug classes for the Medicare population (Appendix D). This list is derived from Part D claims data. The drugs identified will be expanded to the class level and used in the formulary review process. CMS understands that sponsors will not provide identical coverage of these drug classes, and CMS’ review will focus on ensuring that sponsors present a balanced formulary. These drug classes will cover common diseases and conditions, and will allow CMS to ensure that sponsors are covering the most widely used medications, or therapeutically similar medications, for the most common conditions.

CMS will review all Part D sponsors’ formularies to ensure they contain all commercially available vaccines (unless excluded due to available reimbursement under Part B, e.g., influenza or pneumococcal vaccines). Sponsors will only be allowed to use drug utilization management tools to:

- Assess the necessity of vaccines that are less commonly administered in the Medicare population, such as anthrax and yellow fever vaccines;
- Facilitate use of vaccines in line with Advisory Committee on Immunization Practices (ACIP) recommendations; and
- Evaluate potential reimbursement of those vaccines that could be covered under Part B when directly related to the treatment of an injury or direct exposure to a disease or condition (e.g., tetanus).

All formularies will be evaluated using the criteria above in this section. Outliers for each area of review will be further evaluated by CMS to determine whether the outlier is deemed potentially discriminatory. Examples of this may include a lack of appropriate drug classes to treat certain diseases, a lack of sufficient drugs in a therapeutic class, inappropriate tier placement that would discriminate against a group of beneficiaries, or missing drugs that would
cause discrimination. If any of the outliers appear to create problems of access, sponsors will have the opportunity to present reasonable clinical justifications.

30.2.8 - Formulary Submission Timeline
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Part D sponsors that fail to meet formulary submission and re-submission deadlines during the formulary approval process may face a CMS determination that CMS cannot approve their Part D bids. For most Part D sponsors, a failure to obtain bid approvals will result in the termination of their Part D sponsor or MA organization contracts effective at the end of the existing contract year. In the case of an initial Part D sponsor or MA organization contract applicant, CMS would decline to enter into a contract with the organization.

All Part D sponsors that fail to meet CMS established formulary timelines will be precluded from entering into a contract with CMS. Such a determination would be made on the basis that the organization had failed to submit a bid which CMS could approve, a determination that would not be subject to a request for appeal under Subpart N of 42 CFR 423 (for Part D sponsors) and 42 CFR 422 (for MA organizations).

30.3 - Formulary Changes
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

The removal of any drug, whether a Part D drug or a supplemental drug offered as a supplemental benefit under an enhanced alternative benefit design, is subject to the formulary change guidance contained in the following sections.

30.3.1 - Limitation on Changes in Therapeutic Classification
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Except as CMS may permit to account for new therapeutic uses and newly approved Part D drugs, a Part D sponsor may not change formulary categories and classes after the last CMS specified HPMS formulary upload date for the upcoming contract year.

30.3.2 - Limitation of Formulary Changes Prior to Beginning of Contract Year
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Except when the Food and Drug Administration deems a Part D drug unsafe or a manufacturer removes a Part D drug from the market, a Part D sponsor may not remove a covered Part D drug from its formulary, or make any change in preferred or tiered cost-sharing status of a covered Part D drug, between the beginning of the annual coordinated election period described in section 42 CFR 423.38(b) and 60 days after the beginning of the contract year associated with the annual coordinated election period.

30.3.3 - Midyear Formulary Changes
Both industry best practices and the best interests of Medicare beneficiaries call for limited formulary changes during the contract year. CMS believes that formulary stability is extremely important so that enrollees maintain access to the benefit they chose during enrollment as represented to them by the sponsor. However, prescription drug therapies are constantly evolving, and new drug availability, medical knowledge, and opportunities for improving safety and quality in prescription drug use at a low cost will inevitably occur over the course of the year. As recognized in the statute and regulations, these new developments may require formulary changes during the year in order to provide high-quality, low-cost prescription drug coverage.

30.3.3.1 - Policy Regarding Formulary Changes

The following is CMS’ policy regarding formulary changes:

- Part D sponsors may expand formularies by adding drugs to their formularies, reducing copayments or coinsurance by placing a drug on a lower cost-sharing tier, or deleting utilization management requirements at any time during the year.

- Formulary Maintenance Changes: After March 1, Part D sponsors may make maintenance changes to their formulary, such as replacing brand name with new generic drugs or modifying formularies as a result of new information on drug safety or effectiveness.

- Non-maintenance (Other) Formulary Changes: Part D sponsors may only remove Part D drugs from their formulary, move covered Part D drugs to a less preferred tier status, or add utilization management requirements. For these additional types of formulary changes approved by CMS, Part D sponsors should make such formulary changes only if enrollees currently taking the affected drug are exempt from the formulary change for the remainder of the contract year.

CMS must approve any changes to a Part D sponsor’s formulary; however, Part D sponsors are not required to obtain CMS approval for drugs that have been withdrawn from the market by either the FDA or a product manufacturer.

30.3.3.2 - Formulary Maintenance Changes

In order to promote best practices and protect the interests of Medicare beneficiaries, CMS will generally give positive consideration to the following types of formulary changes:

- Removal or placement in a less preferred tier of a brand name drug upon the availability and addition of an A-rated generic or multi-source brand name equivalent, at a lower tier or cost to the beneficiary.
- Removal of a non-Part D drug inadvertently included on the formulary.
- Addition of utilization management tools based upon a new FDA “black box” warning.
- Removal of a drug based upon a new FDA market withdrawal notice.
- Removal of a drug based on long term shortage and market availability (described in chapter 5, section 50.13).
- Removal or placement in a less preferred tier based upon new clinical guidelines or information recognized by CMS (e.g., CDC’s recommendation against using older antivirals for treatment and prophylaxis of the flu).
- The addition of utilization management when necessary to effectuate other approved formulary changes (e.g., prior authorization on a brand name drug when generic is now available on formulary at a lower cost), to help determine B vs. D coverage (subject to CMS guidance on least burdensome ways to make this determination), or to promote safe utilization of a Part D drug based upon new clinical guidelines or information.

Part D sponsors will need to provide a justification when submitting formulary maintenance change requests, but they may assume that change requests based upon these justifications are approved if they do not hear from CMS within 30 days of submission.

30.3.3.3 - Non-maintenance (Other) Formulary Changes
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Experience with formulary management indicates that the vast majority of formulary changes are “maintenance” changes that would generally be approved by CMS. CMS will review additional types of non-maintenance formulary change requests and their corresponding justification. Part D sponsors should make such formulary changes only if enrollees currently taking the affected drug are exempt from the formulary change for the remainder of the contract year. These additional types of change requests include, but are not limited to:

- Changing preferred or non-preferred formulary drugs, adding utilization management, or increasing cost sharing on preferred drugs (unrelated to the reasons stated above);
- Removing dosage forms; or
- Exchanging therapeutic alternatives (either by formulary addition/removal or tier exchanges).

If CMS disapproves a formulary change request, the justification for disapproval will generally be based on one of the following:
• The reasonableness and/or necessity for the proposed change in the context of preventing any appearance of “bait and switch” in the formulary. Medicare beneficiaries select Part D sponsors, in part, based on the formulary that is marketed during annual open enrollment and, therefore, have a legitimate expectation that they will have continuing access to coverage of the Part D drugs they are using throughout the contract year. This beneficiary expectation will be balanced against the sponsor’s desire to practice good formulary management in order to provide a low-cost, high-quality prescription drug benefit that continues to effectively meet the needs of beneficiaries. Part D sponsors may avoid any appearance of a “bait and switch” concern by exempting enrollees who are currently using the affected drugs from the formulary change for the remainder of the contract year.

• The proposed change on its face in the context of substantially discouraging enrollment by certain beneficiary groups.

• The impact of the proposed change on the formulary as a whole to ensure the formulary continues to satisfy the minimum formulary requirements established by CMS.

Because these additional types of change requests will require more extensive review by CMS, Part D sponsors must not implement such changes until they receive explicit notification of approval from CMS and must not issue any beneficiary notices of such forthcoming changes prior to receiving explicit and affirmative CMS approval.

30.3.4 - Provision of Notice Regarding Formulary Changes
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Part D sponsors must provide notice of formulary changes as outlined in the following sections. Additionally, for formulary maintenance changes (described in section 30.3.2), CMS will not require Part D sponsors to wait for approval before sending notice of a proposed formulary change to required parties. For these changes, a Part D sponsor may choose to provide notice to CMS and other required parties at the same time. Part D sponsors will provide notice to CMS via the HPMS system, which will also require plans to specify the intended effective date. Although sponsors may provide notice to all required parties prior to receiving CMS approval, sponsors might prefer to wait so that they do not risk sending notice of a change that is subsequently disapproved by CMS. For formulary non-maintenance or “other” changes (described in section 30.3.3.3), Part D sponsors must not issue any beneficiary notices until CMS has explicitly approved the non-maintenance change.

30.3.4.1 - Beneficiary Notice Requirements
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Prior to removing a covered Part D drug from its formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug, a Part D sponsor must either:

• Provide direct written notice to affected enrollees at least 60 days prior to the date the change becomes effective; or
At the time an affected enrollee requests a refill of the Part D drug, provide such enrollee with a 60 day supply of the Part D drug under the same terms as previously allowed and written notice of the formulary change.

If a beneficiary is not “affected” by a formulary change (in other words, exempted from a formulary change), notice is not required.

The written notice must contain the following information:

- The name of the affected covered Part D drug;
- Whether the Part D sponsor is removing the covered Part D drug or changing its preferred or tiered cost-sharing status;
- The reason why the Part D sponsor is removing such covered Part D drug from the formulary, or changing its preferred or tiered cost-sharing status;
- Alternative drugs in the same therapeutic category or class or cost-sharing tier and expected cost-sharing for those drugs; and
- The means by which enrollees may obtain a coverage determination under 42 CFR 423.566 or exception under 42 CFR 423.578.

As an alternative to providing written notice, Part D sponsors may provide such notice electronically if, and only if, an enrollee affirmatively elects to receive such notice electronically.

30.3.4.2 - Notice for Other Entities
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Prior to removing a covered Part D drug from its formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug, a Part D sponsor must provide at least 60 days notice to CMS, State Pharmaceutical Assistance Programs (as defined in 42 CFR 423.454), entities providing other prescription drug coverage (as described in 42 CFR 423.464(f)(1), authorized prescribers, network pharmacies, and pharmacists prior to the date such change becomes effective.

To the extent possible, sponsors may elect to provide State Pharmaceutical Assistance Programs, entities providing other prescription drug coverage (as described in 42 CFR 423.464(f)(1), authorized prescribers, network pharmacies, and pharmacists an annual notice providing information on the sponsor’s formulary change policy (i.e., length of notice, methods of communication with beneficiaries, and any electronic notices providers may receive at the point-of-sale regarding formulary status) and the sponsor’s Web site where these entities can verify the formulary status of particular drugs.

30.3.4.3 - Provision of Notice Regarding Safety-Related Formulary Changes
Part D sponsors may immediately remove from their formularies covered Part D drugs deemed unsafe by the Food and Drug Administration or removed from the market by their manufacturer without meeting the advance notice requirements specified in this section. However, Part D sponsors must provide retrospective notice of any such formulary changes to affected enrollees, CMS, State Pharmaceutical Assistance Programs (as defined in 42 CFR 423.454), entities providing other prescription drug coverage (as described in 42 CFR 423.464(f)(1), authorized prescribers, network pharmacies, and pharmacists consistent with the requirements set forth in this section. CMS expects that this retrospective notice will occur as soon as possible to inform enrolled beneficiaries of potential safety concerns surrounding medications they are taking, especially those beneficiaries who may have a 90 day supply and will not interact with the pharmacy for an extended period.

In instances where there has been an announcement of a market withdrawal, but the withdrawal has not yet taken place, Part D sponsors may opt to either remove the drug immediately with a retrospective notice to “affected enrollees” or provide an advance notice. CMS expects Part D sponsors to consider all pertinent information available from the FDA related to the withdrawal.

30.3.4.4 - Notice Requirements for Pending Formulary Changes
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

When a Part D sponsor notifies CMS of a formulary change in HPMS, the change is assigned a prospective effective date. During the period of time between when a Part D sponsor has notified CMS of a prospective change and the actual effective date of that change, Part D sponsors must ensure appropriate beneficiary protections are implemented should a beneficiary who has not been notified of the change present with a new prescription for the drug whose formulary status is changing.

For maintenance changes outlined in section 30.3.3.2, the Part D sponsor must implement the beneficiary notice requirements contained in section 30.3.4.1 (i.e., 60 days of advance written notice before implementing the change for the individual). For example, assume on March 1st, a Part D sponsor notifies CMS via HPMS that it is removing a brand name drug from its formulary due to the availability of a new generic. The sponsor indicates the effective date for this formulary change will be May 1st. If a beneficiary were to present on April 1st with a new prescription for the brand name drug pending removal, the Part D sponsor would provide written notice of the change and not implement the change until June 1st, in order to provide the full 60 days of advance notice to that beneficiary.

A Part D sponsor may elect to provide written notice to all of its enrollees of a pending formulary maintenance change in lieu of notifying only the “affected enrollees.” Such an approach would satisfy the beneficiary notice requirements in section 30.3.4.1 because all enrollees, including “affected enrollees” would receive advance notice of a formulary change. In addition, it would preclude the plan from needing to extend the formulary change effective date for those enrollees who present with a new prescription for the drug between the date when a Part D sponsor notifies CMS of a prospective change and the actual effective date of that change.
However, Part D sponsors are still required to provide advance written notice of a formulary change and a 60 day-supply of the drug whose formulary status is changing to those beneficiaries who enroll in the plan after the initial advance formulary change notice, as described above.

For non-maintenance changes outlined in section 30.3.3.3, the Part D sponsors must not implement the formulary change for a beneficiary who presents with a new prescription for a pending formulary drug. In accordance with our non-maintenance formulary change policy, enrollees currently taking the affected drug must be exempt from the formulary change for the remainder of the contract year. For example, assume on March 1st, a Part D sponsor notifies CMS via HPMS it is removing a drug from its formulary with no replacement. CMS approves the change. The sponsor indicates the effective date for this formulary change will be May 1st. If a beneficiary were to present on April 1st with a new prescription for the drug pending removal, the Part D sponsor would not implement this change for the beneficiary for the remainder of the contract year.

30.3.5 - Formulary Change Notice in Advance of Upcoming Contract Year
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Enrollees must receive an annual notice of change (ANOC) by October 31st prior to the upcoming contract year. The ANOC is intended to outline benefit changes for the upcoming year including changes in cost-sharing and drug tier structures. Because the upcoming year’s formulary is viewed as a new formulary, Part D sponsors are not required to identify specific drug changes impacting enrollees in their explanation of benefits, or provide a 60-day notice of changes for the upcoming year’s formulary. However, enrollees must receive a comprehensive or abridged formulary with the ANOC, which will provide enrollees with at least 60 days to review the new formulary to determine if their medications are covered and whether the cost-sharing for their covered medications will change in the upcoming contract year.

30.4 - Transition
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

A Part D sponsor must provide for an appropriate transition process for new enrollees prescribed Part D drugs that are not on its formulary. The transition policy must satisfy the requirements in the following sections.

30.4.1 - Transition Requirements
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

A Part D sponsor’s transition process is necessary with respect to: (1) the transition of new enrollees into prescription drug plans following the annual coordinated election period; (2) the transition of newly eligible Medicare beneficiaries from other coverage; (3) the transition of individuals who switch from one plan to another after the start of the contract year; (4) enrollees residing in LTC facilities; and (5) in some cases, current enrollees affected by formulary changes from one contract year to the next. In addition, sponsors should consider how to expedite transitions to formulary drugs for enrollees who change treatment settings due to changes in level of care.
Transition process requirements will be applicable to non-formulary drugs, meaning both: (1) Part D drugs that are not on a sponsor’s formulary, and (2) Part D drugs that are on a sponsor’s formulary but require prior authorization or step therapy under a plan's utilization management rules, since a formulary drug whose access is restricted via utilization management requirements is essentially equivalent to a non-formulary Part D drug to the extent that the relevant utilization management requirements are not met for a particular enrollee.

A Part D sponsor’s transition process must address situations in which an individual first presents at a participating pharmacy with a prescription for a drug that is not on the formulary, unaware of what is covered by the plan or of the sponsor’s exceptions process for providing access to Part D drugs that are not covered. This may be particularly true for full-benefit dual eligible beneficiaries who are auto-enrolled in a plan and do not make an affirmative choice based on review of a plan’s benefit relative to their existing medication needs. Part D sponsors must have systems capabilities that allow them to provide a one time, temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor’s formulary but require prior authorization or step therapy under a sponsor’s utilization management rules) in order to accommodate the immediate needs of an enrollee, as well as to allow the sponsor and/or the enrollee sufficient time to work out with the prescriber an appropriate switch to a therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons.

30.4.2 - General Transition Process
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Part D sponsors must ensure that they have provided their enrollees who have used a transition benefit with the appropriate assistance and information necessary to enable them to better understand the purpose of the transition. Steps that sponsors should consider to ensure a meaningful transition include:

- Analyzing claims data to determine which enrollees require information about their transition supply.

- Contacting those enrollees to ensure they have the necessary information to enable them to switch to a formulary product or as an alternative to pursue necessary prior authorizations or formulary exceptions.

- Increasing call center capacity, including pharmacy help lines, to respond to an anticipated increase in call volume from affected enrollees regarding the sponsor’s transition process.

- Making arrangements to continue to provide necessary drugs to an enrollee by extending the transition period, on a case-by-case basis, if the enrollee’s exception request or appeal has not been processed by the end of the minimum transition period.

30.4.3 - New Prescriptions Versus Ongoing Drug Therapy
CMS is aware that it may be difficult for Part D sponsors to distinguish between new prescriptions for non-formulary Part D drugs and refills for ongoing drug therapy involving non-formulary Part D drugs. For example, some new enrollees may need to switch pharmacies when they enroll in a new Part D plan (or when they enroll in Part D for the first time) and, depending on State law, their prescriptions may not transfer from pharmacy to pharmacy. In other words, some enrollees may need to present at their new network pharmacy with a new prescription for use at that pharmacy, even if that prescription is for ongoing drug therapy. CMS recognizes that it may be difficult for sponsors to distinguish between ongoing drug therapy and a brand-new prescription for a non-formulary Part D drug. Although Part D sponsors may attempt to follow up with prescribing physicians and pharmacies to ascertain the status of a prescription presented during the transition period, CMS clarifies that if a sponsor is unable to make this distinction at the point of sale, it will be required to apply all transition process standards to a new prescription for a non-formulary Part D drug. In other words, a brand-new prescription for a non-formulary drug will not be treated any differently than an ongoing prescription for a non-formulary drug when a distinction cannot be made at the point of sale.

30.4.4 - Transition Timeframes and Temporary Fills
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Within the first 90 days of coverage under a new plan, plans must provide a temporary fill when the beneficiary requests a refill of a non-formulary drug (including Part D drugs that are on a plan’s formulary but require prior authorization or step therapy under a plan’s utilization management rules). This 90 day timeframe applies to retail, home infusion, long-term care and mail-order pharmacies. CMS believes it makes sense to both limit and define the amount of time during which a transition process is applicable to new enrollees. Thus, plans will be required to provide a temporary supply fill anytime during the first 90 days of a beneficiary’s enrollment in a plan. Since certain enrollees may join a plan at any time during the year, this requirement will apply beginning on an enrollee’s first effective date of coverage, and not only to the first 90 days of the contract year. This 90 day timeframe assists those beneficiaries transitioning from other prescription drug coverage who obtained extended (e.g., 90-day) supplies of maintenance drugs prior to the last effective date of their previous coverage.

30.4.4.1 - Timeframe and Transition Fills in the Outpatient Setting
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

In the outpatient setting, the one-time, temporary supply of non-formulary Part D drugs – including Part D drugs that are on a sponsor’s formulary but require prior authorization or step therapy under a sponsor’s utilization management rules – must be for at least 30 days of medication, unless the prescription is written by a prescriber for less than 30 days. Part D sponsors should note that, outside the long-term care setting, such a temporary fill may be a one-time fill only.

30.4.4.2 - Timeframe and Transition Fills in the Long Term Care Setting
(Rev. 10, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)
The temporary supply of non-formulary Part D drugs – including Part D drugs that are on a Part D sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules – for a new enrollee in an LTC facility may be for up to 31 days (unless the prescription is written for less than 31 days). CMS is requiring up to a 31-day transition supply given that many LTC pharmacies and facilities dispense medications in 31-day increments. However, unlike in the outpatient setting, sponsors must honor multiple fills of non-formulary Part D drugs, including Part D drugs that are on a sponsor’s formulary but require prior authorization or step therapy under a sponsor’s utilization management rules, as necessary during the entire length of the 90-day transition period.

*Beginning with contract year 2010, CMS is permitting Part D sponsors the option of sending required transition fill notices to network long term care pharmacies. In addition to sending enrollees residing in LTC facilities a model transition notice via U.S. mail within 3 business days of the transition fill, Part D sponsors may elect to send the beneficiary transition notice to the LTC pharmacy serving the beneficiary’s LTC facility. The LTC pharmacy must then ensure delivery of the notice to the beneficiary within 3 business days of the fill.*

**Part D sponsors electing this option must update their existing transition policy to specifically address that:**

1. *The sponsor maintains documentation of the LTC pharmacies’ willingness to be delegated transition notice responsibilities; and*

2. *The sponsor maintains a fully functional electronic communication process with the LTC pharmacy once a transition fill has occurred (within 3 business days).*

3. *The LTC pharmacy will maintain a process that demonstrates notice has been provided to the beneficiary (or his/her representative) within the 3-day period.*

*This option must be in place prior to the start of the 2010 contract year; otherwise, the Part D sponsor must continue to provide notice directly to the beneficiary (or his/her designated representative) via U.S. mail.*

**30.4.4.3 - Transition Extension**  
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

A Part D sponsor may need to make arrangements to continue to provide necessary drugs to an enrollee via an extension of the transition period, on a case-by-case basis, to the extent that his or her exception request or appeal has not been processed by the end of the minimum transition period. It is vital that sponsors give affected enrollees clear guidance regarding how to proceed after a temporary fill is provided, so that an appropriate and meaningful transition can be effectuated by the end of the transition period. Until that transition is actually made, however, either through a switch to an appropriate formulary drug, or a decision is made regarding an exception request, continuation of drug coverage is necessary, other than for drugs not covered under Part D.
30.4.5 - Transition Across Contract Years  
(Rev. 10, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

After enrollees receive their ANOC on October 31st of a given year, CMS expects sponsors to select one of the following two options for effectuating an appropriate and meaningful transition for enrollees whose drugs are no longer on the formulary. These transition requirements apply both to drugs that are removed from a sponsor’s formulary from one contract year to the next, as well as to formulary drugs that remain on formulary but to which a new prior utilization or step therapy restriction is added from one contract year to the next:

- **Provide a transition process for current enrollees consistent with the transition process required for new enrollees.** In order to prevent coverage gaps, sponsors choosing this option are expected to provide a temporary supply of the requested prescription drug (where not medically contraindicated) and provide enrollees with notice that they must either switch to a drug on the sponsor’s formulary or get an exception to continue taking the requested drug; or

- **Effectuate a transition for current enrollees prior to the start of the new contract year.** In effectuating this transition, sponsors must aggressively work to (1) prospectively transition current enrollees to a therapeutically equivalent formulary alternative; and (2) complete requests for formulary and tiering exceptions to the new formulary prior to the start of the contract year. If a sponsor approves such an exception request pursuant to chapter 18 of this manual, the sponsor shall authorize payment prior to January 1 of the new contract year. If, however, sponsors have not successfully transitioned affected enrollees to a therapeutically equivalent formulary alternative or processed an exception request by January 1 they will be expected to provide a transition supply beginning January 1 and until such time as they have effectuated a meaningful transition.

Part D sponsors that can identify objective information demonstrating that a meaningful transition has occurred (such as the processing of an exception request and/or evidence of a new prescription claim for a formulary alternative processed in the month of December) do not have to provide access to a transition supply in the new contract year for that beneficiary. However, lacking such objective evidence, the sponsor is expected to provide a transition supply in the new contract year and provide the corresponding transition notice.

Part D sponsors must extend their transition policies across contract years should a beneficiary enroll into a plan with an effective enrollment date of either November 1 or December 1 and need access to a transition supply. For example, if a beneficiary enrolls effective December 1, in a plan whose transition policy affords a 90-day transition period for LTC enrollees and that beneficiary requires a transition supply in mid-December, the sponsor must offer a full 90-day transition period beginning December 1 (including a one-time, 30-day transition supply) and extending into the following contract year. In addition, sponsors must send beneficiaries with a November 1 or December 1 effective enrollment date an ANOC as soon as practicable after the effective enrollment date. This ANOC will serve as advance notice of any formulary or benefit changes in the following contract year.
30.4.6 - Emergency Supply for Current Enrollees  
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

Since, as a matter of general practice, LTC facility residents must receive their medications as ordered without delay, Part D sponsors must cover an emergency supply of non-formulary Part D drugs for LTC facility residents as part of their transition process. During the first 90 days after a beneficiary's enrollment, he or she will receive a transition supply. However, to the extent that an enrollee in an LTC setting is outside his or her 90-day transition period, the sponsor must still provide an emergency supply of non-formulary Part D drugs – including Part D drugs that are on a sponsor's formulary that would otherwise require prior authorization or step therapy under a sponsor's utilization management rules – while an exception or prior authorization is requested. These emergency supplies of non-formulary Part D drugs – including Part D drugs that are on a sponsor’s formulary but require prior authorization or step therapy under a sponsor’s utilization management rules – must be for at least 31 days of medication, unless the prescription is written by a prescriber for less than 31 days.

30.4.7 - Level of Care Changes  
(Rev. 10, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

In addition to circumstances impacting new enrollees who may enter a plan with a medication list that contains non-formulary Part D drugs, other circumstances exist in which unplanned transitions for current enrollees could arise and in which prescribed drug regimens may not be on sponsor formularies. These circumstances usually involve level of care changes in which a beneficiary is changing from one treatment setting to another. For example, beneficiaries who enter LTC facilities from hospitals are sometimes accompanied by a discharge list of medications from the hospital formulary with very short term planning taken into account (often under 8 hours). Similar situations may exist, for example, for beneficiaries who are discharged from a hospital to a home; for beneficiaries who end their skilled nursing facility Medicare Part A stay (where payments include all pharmacy charges) and who need to revert to their Part D plan formulary; for beneficiaries who give up hospice status to revert to standard Medicare Part A and B benefits; for beneficiaries who end an LTC facility stay and return to the community; and for beneficiaries who are discharged from psychiatric hospitals with drug regimens that are highly individualized.

For these unplanned transitions, beneficiaries and providers must clearly avail themselves of sponsor exceptions and appeals processes. CMS has streamlined the grievance, coverage determination, and appeals process requirements in order to ensure that beneficiaries receive quick determinations regarding the medications they need. In all cases, CMS makes it clear that a Part D sponsor is required to make coverage determinations and redeterminations as expeditiously as the enrollee’s health condition requires.

*Effective transition of care at time of discharge to home is a major concern in LTC. Ensuring appropriate medication reconciliation in the community is a safety issue, and requires pre-discharge planning. This optimally involves prescriptions being written and transmitted to the patients’ families in the week before discharge, to assure that the medications are obtained in*
advance of community discharge, to prevent a gap in care. The billing date may appear to overlap the skilled nursing home stay, but the medications, which may be dispensed by either the LTC or a retail pharmacy, are to be used in the home setting. While Part A does provide reimbursement for “a limited supply” to facilitate beneficiary discharge, beneficiaries must be permitted to have a full outpatient supply available to continue therapy once this limited supply is exhausted. This is particularly true for beneficiaries using mail-order pharmacy, home infusion therapy, or residing in rural areas where obtaining a continuing supply of drugs may involve certain delays. The current standard of care promotes caregivers receiving outpatient Part D prescriptions in advance of discharge from a Part A stay.

When an enrollee is admitted to or discharged from an LTC facility, he or she will not have access to the remainder of the previously dispensed prescription (through no fault of his or her own) and, therefore, sponsors must allow the enrollee to access a refill upon admission or discharge. An early refill edit is a utilization management tool used to promote compliance and to prevent waste. An early refill edit cannot be used to limit appropriate and necessary access to an enrollee's Part D benefit. For example, if a patient gets a prescription for 30 tablets for a 30 day supply (i.e., 1 tablet daily), but the prescriber changes the dose to 2 tablets daily after only 10 days, it would be inappropriate for a sponsor to deny as "too soon" a claim for a new prescription with the new dosage because the enrollee will not have enough medication to last until the originally scheduled refill date.

However, even with these protections, there may exist some period of time in which beneficiaries with level of care changes have a temporary gap in coverage while an exception is processed. For this reason, CMS strongly encourages Part D sponsors to incorporate processes in their transition plans that allow for transition supplies to be provided to current enrollees with level of care changes.

30.4.8 - Edits for Transition Fills
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

A Part D sponsor must ensure that a new enrollee is able to leave a pharmacy with a temporary supply of non-formulary Part D drugs without unnecessary delays. Part D sponsors may only apply certain drug utilization management edits during a beneficiary’s transition period. Drug utilization management edits that are appropriate during a beneficiary’s transition period include the following:

- Edits to help determine Part B vs. Part D coverage;
- Edits to prevent coverage of non-part D drugs (i.e., excluded drugs); and
- Edits to promote safe utilization of a Part D drug (e.g., quantity limits based on FDA maximum recommended daily dose; early refill edits).

While Part D sponsors may implement step therapy or prior authorization edits during transition, they may do so only if such edits are resolved at the point of sale. For example, if a prescriber writes a prescription for 5mg tablets at 2 tablets daily, Part D sponsors might have dose optimization edits in place to require the prescription to be changed to 10mg tablets, 1 tablet
daily. However, during transition, Part D sponsors would need to allow pharmacies to override this edit if the prescriber will not authorize the change at point of sale. In other words, the beneficiary should leave the pharmacy with sufficient quantity of medication (either 5mg or 10mg tablets) to last the plan allowable days supply, unless the prescriber originally wrote for a lesser days supply. If the dose optimization edit (or any other step therapy/prior authorization edit) is overridden at point of sale for transition purposes only, but not permanently, the beneficiary must be so notified so that he or she can begin the exception process if necessary. As part of their transition process submissions to CMS, sponsors should describe any edits on transition drugs and their process for resolving those edits at the point of sale.

CMS notes that although Part D sponsors may implement quantity limits for safety purposes or drug utilization edits that are based on approved product labeling during a beneficiary’s transition period, to the extent that the prescription is dispensed for less than the written amount due to a plan edit, sponsors must provide refills for that transition supply (at least a 30-day supply in an outpatient setting and a 31-day supply with multiple refills in an LTC setting). For example, if a beneficiary presents at a retail pharmacy with a prescription for 1 tablet per day for 30 days and a plan has a quantity limit edit in place that limits the days supply to 14 per prescription for safety purposes, the beneficiary would receive a 14-day supply (consistent with the safety edit). At the conclusion of the 14-day supply, the beneficiary should be entitled to another 14-day supply while he/she continues to pursue an exception with the Part D plan, or a switch to a therapeutic alternative that is on the plan’s formulary.

Irrespective of transition, all of these edits are subject to exceptions and appeals. For example, if a quantity limit edit (based on maximum recommended daily dose) results in the dispensing of a quantity that is less than indicated on the prescription and is less than the plan allowable days supply (as determined by the prescribed daily dose), Part D sponsors must ensure that beneficiaries are made aware of this quantity limit and that an exception is required to obtain a greater quantity. Part D sponsors must expeditiously process such exception requests so that beneficiaries will not experience unintended interruptions in medically necessary Part D drug therapies and/or will not inappropriately pay additional cost-sharing associated with multiple fills of lesser quantities when the originally prescribed doses of Part D drugs are medically necessary.

A Part D sponsor does retain the authority to deny access to quantities or doses during transition (i.e., where clearly articulated safety limits established by the FDA or based upon the same peer reviewed medical literature or well-established clinical practice guidelines used by the P&T committee in formulary management have been exceeded). Prior to implementing such a denial, a Part D sponsor should ensure and track that both: (1) an initial transition supply has been provided up to the maximum limit, and (2) the sponsor has assisted the beneficiary or physician in filing an exception or that an exception has been processed.

30.4.9 - Cost-sharing Considerations
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

A Part D sponsor may charge cost-sharing for a temporary supply of drugs provided under its transition process. Cost-sharing for transition supplies for low-income subsidy (LIS) eligibles can never exceed the statutory maximum copayment amounts. For non-LIS enrollees, a sponsor
must charge cost-sharing based on one of its approved drug cost-sharing tiers (if the sponsor has a tiered benefit design), and this cost-sharing must be consistent with cost-sharing that the sponsor would charge for non-formulary drugs approved under a coverage exception.

30.4.10 - Transition Notices
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

A successful transition process is contingent upon informing enrollees and their caretakers about their options for ensuring that enrollees’ medical needs are safely accommodated within a Part D sponsor’s formulary. An enrollee who receives a temporary supply of a non-formulary Part D drug at a network pharmacy might simply assume that, by virtue of filling his or her prescription, that the plan will cover that drug for the remainder of the contract year. For this reason, sponsors must provide enrollees with appropriate notice regarding their transition process within a reasonable amount of time after providing a temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor’s formulary but require prior authorization or step therapy under a sponsor’s utilization management rules).

Part D sponsors will be required to send a written notice, via U.S. First Class mail, to each enrollee who receives a transition fill. This standard is consistent with CMS’ requirement that other beneficiary communications, including formulary change notices and explanations of benefits, be sent via U.S. First Class mail. In addition, this notice must be sent to each affected enrollee within 3 business days of the temporary fill. CMS believes this turnaround is necessary in order to provide an affected enrollee with sufficient time -- especially in light of CMS’ 30-day transition fill policy in the outpatient setting -- to work with his or her prescriber to switch to a therapeutically equivalent drug that is on the plan’s formulary or to process an exceptions request.

The notice must include the following elements:

- That the transition supply provided is temporary and may not be refilled unless a formulary exception is approved;
- That the enrollee should work with the sponsor as well as his or her health care provider to identify appropriate therapeutic alternatives that are on the sponsor’s formulary and that will likely reduce his or her costs;
- That the member has the right to request a formulary exception, the timeframes for processing the exception, and the member's right to request an appeal if the sponsor issues an unfavorable decision; and
- The sponsor’s procedures for requesting a formulary exception.

CMS provides Part D sponsors with a model letter that they may submit to CMS under the file and use certification process. CMS expects that sponsors will make prior authorization or exception request forms available upon request to both enrollees and prescribing physicians and via a variety of mechanisms -- including by mail, fax, email, and on sponsor Web sites. To the
extent that sponsors have the capacity, CMS encourages them to provide any prior authorization or exception request forms a beneficiary will need to effectuate a transition with the transition notice.

In addition, CMS strongly encourages point-of-sale notification of enrollees about transition supplies by pharmacists. CMS has worked with the pharmacy and drug benefit industry, including the National Council for Prescription Drug Programs (NCPDP), to incorporate a work-around process for using structured payment coding in the message field of billing transaction responses indicating that a particular fill is a transition supply. This process is consistent with the current NCPDP 5.1 standard. For more information about Standardized Claims Messaging see chapter 14, section 50.5.

30.4.11 - Public Notice of Transition Process
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

As a general matter, CMS believes Part D sponsors must make general information about their transition processes available to beneficiaries in a manner similar to information provided on formularies and benefit design. It is likely that individuals will base their decision on which prescription drug best meets their needs on a variety of factors. Having information about a sponsor’s transition process in plan enrollment materials and Web sites, as well as on the Medicare Prescription Drug Plan Finder, may reassure beneficiaries that there will be procedures in place to assist them in switching to therapeutic alternatives or in obtaining a formulary exception where appropriate. It will also serve to educate advocates and other interested third parties – for example, State Medicaid agencies – about sponsor transition processes. CMS will make plan transition process information available via a required link from the Medicare Prescription Drug Plan Finder to individual sponsor Web sites.

30.5 - Provider and Patient Education
(Rev. 2, Issued: 07-18-08; Effective/Implementation Date: 07-18-08)

A Part D sponsor must establish policies and procedures to educate and inform health care providers and enrollees concerning its formulary. See the marketing guidelines on CMS’ Web site at http://www.cms.hhs.gov/PrescriptionDrugCovContra/07_RxContracting_Marketing.asp#TopOfPage for more information on acceptable formulary marketing methods.
# Chapter 6 - Appendix A
## Common Acute Care Home Infusion Drugs

(This is a tool to assist plans in recognizing common Home Infusion drugs. It does not represent an exhaustive list of such drugs).

<table>
<thead>
<tr>
<th>Category</th>
<th>Common Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>5-HYDROXYTRYPTAMINE 3 (5-HT3) ANTAGONISTS</strong></td>
<td>ECHINOCANDIN ANTIFUNGALS</td>
</tr>
<tr>
<td><strong>AMINO ACIDS</strong></td>
<td>ELECTROLYTES</td>
</tr>
<tr>
<td><strong>AMINO DERIVATIVE PENICILLINS</strong></td>
<td>ERYTHROPOIETINS</td>
</tr>
<tr>
<td><strong>AMINOGLYCOSIDES</strong></td>
<td>EXTENDED SPECTRUM PENICILLINS</td>
</tr>
<tr>
<td><strong>AZOLE ANTIFUNGALS</strong></td>
<td>GLUCOCORTICOID-SYSTEMIC</td>
</tr>
<tr>
<td><strong>BETA-LACTAM, OTHER</strong></td>
<td>GLYCOPEPTIDE ANTIBACTERIALS</td>
</tr>
<tr>
<td><strong>CEPHALOSPORIN ANTIBACTERIALS, 1ST GENERATION</strong></td>
<td>H1 BLOCKING AGENTS, SEDATING</td>
</tr>
<tr>
<td><strong>CEPHALOSPORIN ANTIBACTERIALS, 2ND GENERATION</strong></td>
<td>HEPARIN</td>
</tr>
<tr>
<td><strong>CEPHALOSPORIN ANTIBACTERIALS, 3RD GENERATION</strong></td>
<td>LACTATED RINGERS</td>
</tr>
<tr>
<td><strong>CEPHALOSPORIN ANTIBACTERIALS, 4TH GENERATION</strong></td>
<td>LINCOMYCIN ANTIBACTERIALS</td>
</tr>
<tr>
<td><strong>COLISTIMETHATE</strong></td>
<td>LIPIDS</td>
</tr>
<tr>
<td><strong>COLONY STIMULATING FACTORS</strong></td>
<td>LOOP DIURETICS</td>
</tr>
<tr>
<td><strong>DEXTROSE 10%/NAACL 0.45%</strong></td>
<td>LOW MOLECULAR WEIGHT HEPARINS</td>
</tr>
<tr>
<td><strong>DEXTROSE 10%</strong></td>
<td>MACROLIDES</td>
</tr>
<tr>
<td><strong>DEXTROSE 10% / NAACL 0.2%</strong></td>
<td>MISCELLANEOUS ANTIBACTERIALS</td>
</tr>
<tr>
<td><strong>DEXTROSE 2.5%</strong></td>
<td>NATURAL PENICILLINS</td>
</tr>
<tr>
<td><strong>DEXTROSE 2.5% / LACTATED RINGERS</strong></td>
<td>OPIOID ANALGESICS, LONG-ACTING</td>
</tr>
<tr>
<td><strong>DEXTROSE 2.5% / NAACL 0.45%</strong></td>
<td>OPIOID ANALGESICS, SHORT-ACTING</td>
</tr>
<tr>
<td><strong>DEXTROSE 5%</strong></td>
<td>OXAZOLIDINONE ANTIBACTERIALS</td>
</tr>
<tr>
<td><strong>DEXTROSE 5% / LACTATED RINGERS</strong></td>
<td>PENICILLINASE-RESISTANT PENICILLINS</td>
</tr>
<tr>
<td><strong>DEXTROSE 5%/NAACL 0.2%</strong></td>
<td>POTASSIUM CHLORIDE</td>
</tr>
<tr>
<td><strong>DEXTROSE 5%/NAACL 0.225%</strong></td>
<td>PROTON PUMP INHIBITORS</td>
</tr>
<tr>
<td><strong>DEXTROSE 5%/NAACL 0.33%</strong></td>
<td>QUINOLONES</td>
</tr>
<tr>
<td><strong>DEXTROSE 5%/NAACL 0.45%</strong></td>
<td>SODIUM CHLORIDE SOLUTION</td>
</tr>
<tr>
<td><strong>DEXTROSE 5%/NAACL 0.9%</strong></td>
<td>SULFONAMIDES</td>
</tr>
<tr>
<td><strong>TETRACYCLINES</strong></td>
<td></td>
</tr>
</tbody>
</table>
This table provides Part D coverage clarifications for specific products/drugs/drug categories in accordance with statutory and regulatory requirements for Part D drugs. This is not an exhaustive list but only addresses those products/drugs/drug categories that have been the subject of frequently asked questions. Specific products not identified in this table should always be evaluated against the statutory and regulatory definition of a “Part D drug” before drawing conclusions from this table. This table does not address Part B versus Part D coverage questions.

<table>
<thead>
<tr>
<th>Product/Drug/Drug Category (Listing is NOT all-inclusive)</th>
<th>May be covered under basic Part D benefit (when used for “medically accepted indication”(^3) and not covered under Medicare Parts A or B)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agents when used for anorexia, weight loss, or weight gain</td>
<td>No</td>
<td>Prescription drug products being used to treat AIDS wasting and cachexia are not considered agents used for weight gain or agents used for cosmetic purposes, and therefore such products are NOT excluded under such exclusion categories.</td>
</tr>
<tr>
<td>Agents when used for cosmetic purposes or hair growth</td>
<td>No</td>
<td>Treatments indicated for psoriasis, acne, rosacea, or vitiligo are NOT considered cosmetic.</td>
</tr>
<tr>
<td>Agents when used for symptomatic relief of cough and colds</td>
<td>No</td>
<td>Cough and cold medications are eligible to meet the definition of a Part D drug in clinically relevant situations other than those of symptomatic relief of cough and colds. For example, when cough medications are used for a medically accepted indication that treats a cough produced by a medical condition unrelated to symptomatic cough and cold, CMS does not consider these cough medications as excluded drugs [such as the treatment of cough to alleviate bronchospasm in asthma].</td>
</tr>
</tbody>
</table>

\(^3\) Medically Accepted Indication for purposes of Part D is an FDA labeled indication or an indication supported by citation in either the American Hospital Formulary System (AHFS), USP-DI (or its successor publications), or Drugdex.
<table>
<thead>
<tr>
<th>Product/Drug/Drug Category (Listing is NOT all-inclusive)</th>
<th>May be covered under basic Part D benefit (when used for “medically accepted indication” and not covered under Medicare Parts A or B)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antihistamine/Decongestant Combinations (RX)</td>
<td>Yes, except when being used for symptomatic relief of cough and cold</td>
<td></td>
</tr>
<tr>
<td>Barbiturates</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Blood glucose testing strips</td>
<td>No</td>
<td>NOT directly associated with injection of insulin</td>
</tr>
<tr>
<td>Electrolytes/Replenishers:</td>
<td>*Potassium Iodide products are excluded from Part D as Iodine products (minerals) because they are not used for potassium supplementation.</td>
<td></td>
</tr>
<tr>
<td>*Potassium</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Sodium</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calcium</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Magnesium</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Erectile (ED) Dysfunction Drugs</td>
<td>No</td>
<td>Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration. In addition, ED drugs will meet the definition of a Part D drug when prescribed for medically accepted indications approved by the FDA other than sexual or erectile dysfunction such as pulmonary hypertension. However, ED drugs will not meet the definition of a Part D drug when used off-label, even if the off label use is listed in one of the compendia found in section 1927(g)(1)(B)(i) of the Act.</td>
</tr>
<tr>
<td>Extemporaneous Compounds, including sterile compounding of IV’s and total parenteral nutrition</td>
<td>Yes, but only costs for Part D drug components may be billed under Part D</td>
<td>Dispensing fee may include labor costs associated with mixing a compounded drug product that contains at least one Part D drug component</td>
</tr>
<tr>
<td>Fioricet® (Bultalbital, APAP)</td>
<td>No</td>
<td>Part D drug components used solely as vehicles in a compound may be covered under Part D (e.g., D5W, Normal Saline)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Potassium Iodide products are excluded from Part D as Iodine products (minerals) because they are not used for potassium supplementation.
<table>
<thead>
<tr>
<th>Product/Drug/Drug Category (Listing is NOT all-inclusive)</th>
<th>May be covered under basic Part D benefit (when used for “medically accepted indication” and not covered under Medicare Parts A or B)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caffeine)</td>
<td></td>
<td>Product Policy Section 10.3</td>
</tr>
<tr>
<td>Fioricet® with Codeine</td>
<td>Yes</td>
<td>See Commercially Available Combination Product Policy Section 10.3</td>
</tr>
<tr>
<td>Fiorinal® (Butalbital, ASA, Caffeine)</td>
<td>No</td>
<td>See Commercially Available Combination Product Policy Section 10.3</td>
</tr>
<tr>
<td>Fiorinal® with Codeine</td>
<td>Yes</td>
<td>See Commercially Available Combination Product Policy Section 10.3</td>
</tr>
<tr>
<td>Fosamax plus D</td>
<td>Yes</td>
<td>See Commercially Available Combination Product Policy Section 10.3</td>
</tr>
<tr>
<td>Heparin/Saline Flushes</td>
<td>No</td>
<td>See Section 10.6.</td>
</tr>
<tr>
<td>Injectable or IV Iron products such as Iron Dextran, Iron Sucrose and Sodium ferric gluconate</td>
<td>No</td>
<td>Prescription vitamin/mineral product</td>
</tr>
<tr>
<td>Insulin</td>
<td>Yes</td>
<td>Syringes are NOT covered for injection of other Part D drugs</td>
</tr>
<tr>
<td>Insulin syringes</td>
<td>Yes</td>
<td>Syringes are NOT covered for injection of other Part D drugs</td>
</tr>
<tr>
<td>IV Solutions for hydration therapy</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Klonopin® (Clonazepam)</td>
<td>No</td>
<td>Benzodiazepine</td>
</tr>
<tr>
<td>Lancets</td>
<td>No</td>
<td>NOT directly associated with injection of insulin</td>
</tr>
<tr>
<td>Less-than-effective DESI Drugs (and those drugs identical, related or similar)</td>
<td>No</td>
<td>See Section 10.9</td>
</tr>
<tr>
<td>Leucovorin Calcium</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Librax®</td>
<td>No</td>
<td>Less-than-effective DESI drug</td>
</tr>
<tr>
<td>Limbitrol® (Amitriptyline/chlordiazepoxide)</td>
<td>Yes</td>
<td>See Commercially Available Combination Product Policy Section 10.3</td>
</tr>
<tr>
<td>Megestrol Acetate and Growth Hormone when used for AIDS</td>
<td>Yes</td>
<td>Prescription drug products that otherwise satisfy the definition of Part D drug are</td>
</tr>
<tr>
<td>Product/Drug/Drug Category (Listing is NOT all-inclusive)</td>
<td>May be covered under basic Part D benefit (when used for “medically accepted indication” and not covered under Medicare Parts A or B)</td>
<td>Comments</td>
</tr>
<tr>
<td>----------------------------------------------------------</td>
<td>------------------------------------------------------------------------------------------------</td>
<td>----------</td>
</tr>
<tr>
<td>wasting and cachexia</td>
<td></td>
<td>Part D drugs when used for AIDS wasting and cachexia if these conditions are &quot;medically accepted&quot; indications, as defined by section 1927(k)(6) of the Social Security Act (SSA), for the particular Part D drug. Specifically, CMS does not consider such prescription drug products being used to treat AIDS wasting and cachexia as either agents used for weight gain or agents used for cosmetic purposes, and therefore such products cannot be excluded from the Medicare Prescription Drug Benefit by reference to section 1927(d)(2) of the SSA.</td>
</tr>
<tr>
<td>Methadone</td>
<td>Yes, except when indicated for the treatment of opioid dependence</td>
<td>A Part D drug is partially defined as “a drug that may be dispensed only upon a prescription”. . . . Consequently, Methadone is not a Part D drug when used for treatment of opioid dependence because it cannot be dispensed for this purpose upon a prescription at a retail pharmacy.</td>
</tr>
<tr>
<td>Primidone (Mysoline®)</td>
<td>Yes</td>
<td>NOT considered a barbiturate</td>
</tr>
<tr>
<td>Nonprescription/Over-the-counter (OTC) drugs&lt;sup&gt;4&lt;/sup&gt;</td>
<td>No, except insulin and supplies associated with the injection of insulin</td>
<td>Supplies associated with the injection of insulin include syringes, alcohol wipes, insulin pens and pen needles, gauze, and alcohol</td>
</tr>
<tr>
<td>Omacor®</td>
<td>Yes</td>
<td>Barbiturate</td>
</tr>
<tr>
<td>Phenobarbital</td>
<td>No</td>
<td>Prescription vitamin/mineral product</td>
</tr>
<tr>
<td>PhosLo®</td>
<td>Yes</td>
<td>Barbiturate</td>
</tr>
<tr>
<td>Polysaccharide Iron Complex</td>
<td>No</td>
<td>Prescription vitamin/mineral product</td>
</tr>
</tbody>
</table>

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<sup>4</sup> Part D plans may include OTC drugs in step therapy protocols as part of their cost effective drug utilization management program. However, OTC drugs included in these step therapy protocols are considered administrative costs, not Part D drugs.
<table>
<thead>
<tr>
<th>Product/Drug/Drug Category (Listing is NOT all-inclusive)</th>
<th>May be covered under basic Part D benefit (when used for “medically accepted indication” and not covered under Medicare Parts A or B)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescription niacin products</td>
<td>Yes</td>
<td>Prescription niacin products are approved by the Food and Drug Administration as safe and effective drugs, are used therapeutically for the treatment of dyslipidemia, and do not serve as nutritional supplements or address a vitamin deficiency. These products are used at dosages much higher than appropriate for nutritional supplementation. For these reasons, CMS has concluded that these products should not be considered prescription vitamins for purposes of Part D coverage, and therefore, are not universally excluded from coverage under the Medicare prescription drug program.</td>
</tr>
<tr>
<td>Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td><strong>Examples:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B vitamins (Folic Acid, Cyanocobalamin)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitamin K (phytonadione)</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Vitamin D (ergocalciferol and cholecalciferol)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Zinc (sulfate, acetate)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iron</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iodine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multivitamin additives for parenteral nutrition</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoking cessation drugs (OTC)</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Smoking cessation drugs (RX)</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Sterile Saline/water for Irrigation</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Suboxone®, Subutex®</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Vitamin D Analogs (Calcitriol, doxercalciferol, paricalcitol, and dihydrotachysterol)</td>
<td>Yes</td>
<td>NOT considered prescription vitamins</td>
</tr>
</tbody>
</table>
Chapter 6 – Appendix C - Summary of Coverage Policy

MEDICARE PART B VERSUS PART D COVERAGE ISSUES

This document is not a statement or promise of coverage, but rather a high level summary of when something may be covered under Parts A, B or D, if all other coverage requirements are met. Appropriate coverage policies and guidance must be consulted for final coverage determinations.

Introduction

This document provides an overview of outpatient prescription drug coverage policies under Medicare. Beneficiaries who are inpatients of hospitals or skilled nursing facilities (SNF) during covered stays may receive drugs as part of their treatment. Typically, the payment for drugs is bundled into the Medicare Part A payments made to these types of facilities. Under the hospice benefit, beneficiaries receive drugs that are medically necessary for symptom control or for pain relief. In general, references are seen to five major categories of Medicare Part B drug spending: 1. drugs billed by physicians and typically provided in physicians offices (such as chemotherapy drugs); 2. drugs billed by pharmacy suppliers and administered through durable medical equipment (DME), such as respiratory drugs given through a nebulizer; 3. drugs billed by pharmacy suppliers and self-administered by the patient (such as immunosuppressive drugs and some oral anti-cancer drugs); 4. separately billable drugs provided in hospital outpatient departments; and 5. separately billable End Stage Renal Disease (ESRD) drugs such as erythropoietin (EPO). Regional differences in Part B coverage policies for drugs can occur in the absence of a national coverage decision. A drug for which coverage is available under Part A or Part B, as it is being “prescribed and dispensed or administered” with respect to the individual, is excluded from the definition of a Part D drug and, therefore, cannot be included in Part D basic coverage.

Medicare Part A and Part B Covered Drugs

Part A/B Covered Drugs Set by Statute

Traditional Medicare (Part A/B) does not cover most outpatient prescription drugs. Medicare bundled payments made to hospitals and skilled nursing facilities generally cover all drugs provided during a stay. Medicare also makes payments to physicians for drugs or biologicals that are not usually self-administered. This means that coverage is usually limited to drugs or biologicals administered by infusion or injection. However, if the injection is generally self-administered (e.g., Imitrex), it is not covered.

5 If these drugs are provided as part of a Medicare Part A covered inpatient hospital or skilled nursing facility stay, they are generally bundled in the Medicare Part A payment to the facility. The exception with regard to inpatient hospital services is clotting factor which is paid separately. For covered SNF stays certain high cost chemotherapy drugs are billed separately along with preventive injections (e.g. flu shots). If a beneficiary does not have Part A coverage, if Part A coverage for the stay has run out or if a stay is non-covered, hospitals and SNFs can be paid for most categories of Part B covered drugs.
Despite the general limitation on coverage for outpatient drugs under Part B, the law specifically authorizes coverage for the following:

- **Durable Medical Equipment (DME) Supply Drugs.** These are drugs that require administration by the use of a piece of covered DME (e.g., a nebulizer, external or implantable pump). The statute does not explicitly cover DME drugs; they are covered as a supply necessary for the DME to perform its function. The largest Medicare expenditures for drugs furnished as a DME supply are for inhalation drugs, which are administered in the home through the use of a nebulizer (e.g., albuterol sulfate, ipratropium bromide). The other category of drugs Medicare covers as a DME supply are drugs for which administration with an infusion pump in the home is medically necessary (e.g. some chemotherapeutic agents).

- **Immunosuppressive Drugs.** Drugs used in immunosuppressive therapy (such as cyclosporine) for a beneficiary who has received a Medicare covered organ transplant.

- **Hemophilia clotting factors.** Hemophilia clotting factors for hemophilia patients competent to use such factors to control bleeding without medical supervision, and items related to the administration of such factors.

- **Oral Anti-Cancer Drugs.** Drugs taken orally during cancer chemotherapy provided they have the same active ingredients and are used for the same indications as chemotherapy drugs that would be covered if they were not self-administered and were administered as incident to a physician’s professional service.

- **Oral Anti-emetic Drugs.** Oral anti-nausea drugs used as part of an anti-cancer chemotherapeutic regimen as a full therapeutic replacement for an intravenous anti-emetic drug within 48 hours of chemotherapy administration.

- **Pneumococcal vaccine.** The vaccine and its administration to a beneficiary if ordered by a physician.

- **Hepatitis B vaccine.** The vaccine and its administration to a beneficiary who is at high or intermediate risk of contracting hepatitis B.\(^6\)

- **Influenza vaccine.** The vaccine and its administration when furnished in compliance with any applicable state law. The beneficiary may receive the vaccine upon request without a physician’s order and without physician supervision.

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\(^6\) High risk groups currently identified include: individuals with ESRD; individuals with hemophilia who received Factor VIII or IX concentrates; clients of institutions for individuals for the mentally handicapped; persons who live in the same household as a hepatitis B Virus (HBV) carrier; homosexual men; illicit injectable drug abusers. Intermediate risk groups include: staff in institutions for the mentally handicapped and workers in health care professions who have frequent contact with blood or blood-derived body fluids during routine work.
• Antigens. These are prepared by a physician (usually an allergist) for a specific patient. The physician or physician’s nurse generally administers them in the physician’s office. In some cases the physician prepares antigens and furnishes them to a patient who has been taught to self-administer them at home.

• Erythropoietin (EPO). EPO for the treatment of anemia for persons with chronic renal failure who are on dialysis.

• Parenteral Nutrition. Parenteral nutrients are covered under the prosthetic benefit. They are available to beneficiaries who cannot absorb nutrition through their intestinal tract. Parenteral nutrition is administered intravenously and is regulated as a drug by the FDA.

• Intravenous Immune Globulin Provide in the Home. The Medicare Modernization Act created a benefit for the provision of intravenous immune globulin (IVIG) for beneficiaries with a diagnosis of primary immune deficiency disease. Coverage is provided if a physician determines that the administration of IVIG in the patient’s home is medically appropriate. Payment is limited to that for the IVIG itself and does not cover items and services related to administration of the product.

Part B Covered Drugs in the Context of a Professional Service

Drugs furnished “Incident To” a Physician’s Service. These are injectable or intravenous drugs that are administered predominantly by a physician or under a physician’s direct supervision as “incident to” a physician’s professional service. The statute limits coverage to drugs that are not usually self-administered.\(^7\) In order to meet all the general requirements for coverage under the “incident-to” provision, an FDA approved drug or biological must:

• Be of a form that is not usually self-administered (as determined by the A/B Contractor);
• Must be furnished by a physician; and
• Must be administered by the physician, or by auxiliary personnel employed by the physician and under the physician’s personal supervision.

The charge, if any, for the drug or biological must be included in the physician’s bill and the cost of the drug or biological must represent an expense to the physician. Drugs and biologicals furnished by other health professionals may also meet these requirements.

Drugs furnished by a Medicare Advantage Organization “Incident To” a Physician’s Service. If a drug could be covered under Part B when furnished by a physician who incurred an expense in procuring the drug, it could also be covered under Part B in the case of a Medicare Advantage (MA) plan physician when the MA organization has incurred the expense of procuring the drug, and the drug is administered to an enrollee in the MA plan. Under Pub. 100-02, Medicare Benefit Policy Manual, chapter 15, section 60.1, drugs can be covered as “incident to”

\(^7\) If a drug is not self-administered by more than 50 percent of Medicare beneficiaries, it is considered “not usually self-administered”.
physicians’ services if they “represent an expense to the physician or legal entity billing for the services or supplies.” Applying this principle to the case of a not-usually self-administered drug administered by an MA plan physician to an MA plan enrollee, if the MA organization supplies the drug to the plan physician, it is the “legal entity billing” for the drug, since it is the entity that receives payment from Medicare that includes the cost of such a drug. Consequently, if the MA organization supplies the drug to the network provider, the MA organization should account for the drug under its A/B benefits. If a network pharmacy supplies the drug directly to the beneficiary, the drug must be accounted for under its Part D benefits.

Separately Billable ESRD Drugs. Most drugs furnished by dialysis facilities are separately billable. The largest Medicare expenditures for such drugs are for erythropoietin (EPO) which is covered for dialysis beneficiaries when it is furnished by independent and hospital-based ESRD facilities, as well as when it is furnished by physicians.

Separately billable drugs provided in Hospital Outpatient Departments. Medicare continues to pay separately for drugs, biologicals and radiopharmaceuticals whose median cost per administration exceeds an amount (or threshold amount) determined by CMS, while packaging the cost of drugs, biologicals, and radiopharmaceuticals whose median cost per administration is less than an amount (or threshold amount) determined by CMS into the procedures with which they are billed.

Drugs covered as Supplies or - “Integral to a Procedure.” Some drugs are covered as supplies that are an integral part of a procedure which is a diagnostic or therapeutic service, including radiopharmaceuticals (both diagnostic and therapeutic) and low osmolar contrast media. Other examples of drugs covered under the “integral to a procedure” provision include eye drops administered before cataract surgery.

Blood. Medicare does make separate payment for blood and blood products and these products are regulated as biological agents by the FDA.

Drugs furnished as a part of a service in these provider settings. 1. Drugs packaged under the Hospital Outpatient Prospective Payment System (OPPS); 2. Drugs furnished by ESRD facilities and included in Medicare’s ESRD composite rate; 3. Osteoporosis drugs provided by home health agencies under certain conditions; 4. Drugs furnished by critical access hospitals’ (CAH) outpatient departments; 5. Drugs furnished by a rural health clinic (RHC); 6. Drugs furnished by federally qualified health centers (FQHC); 7. Drugs furnished by community mental health centers (CMHC); 8. Drugs furnished by ambulances; 9. Separately billable drugs provided in comprehensive outpatient rehabilitation facilities (CORF).

**Part D Covered Drugs**

**Definition of a Part D Covered Drug**

A Part D covered drug is available only by prescription, approved by the Food and Drug Administration (FDA) (or is a drug described under section 1927(k)(2)(A)(ii) or (iii) of the Act), used and sold in the United States, and used for a medically accepted indication (as defined in
section 1927(k)(6) of the Act). A covered Part D drug includes prescription drugs, biological products, insulin as described in specified paragraphs of section 1927(k) of the Act, vaccines licensed under section 351 of the Public Health Service Act and for vaccine administration on or after January 1, 2008, its administration. The definition also includes medical supplies directly associated with delivering insulin to the body, including syringes, needles, alcohol swabs, gauze, and insulin injection delivery devices not otherwise covered under Medicare Part B, such as insulin pens, pen supplies, and needle-free syringes, can satisfy the definition of a Part D drug. CMS defines those medical supplies to include syringes, needles, alcohol swabs, gauze, and those supplies directly associated with delivering insulin into the body.

**Part D Supplementary (Excluded) Drugs**

The definition of a covered Part D drug excludes any drug for which as prescribed and dispensed or administered to an individual, payments would be available under Parts A or B of Medicare for that individual, even though a deductible may apply.

In addition, the definition of a covered Part D drug specifically excludes drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under section 1927(d)(2) of the Act, with the exception of smoking cessation agents. The drugs or classes of drugs that may currently be otherwise restricted under Medicaid include:

- Agents when used for anorexia, weight loss, or weight gain (even if used for a non-cosmetic purpose (i.e., morbid obesity)).
- Agents when used to promote fertility.
- Agents when used for cosmetic purposes or hair growth.
- Agents when used for the symptomatic relief of cough and colds.
- Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.
- Nonprescription drugs.
- Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.
- Barbiturates.
- Benzodiazepines.
- Agents when used for the treatment of sexual or erectile dysfunction (ED). ED drugs will meet the definition of a Part D drug when prescribed for medically-accepted indications approved by the FDA other than sexual or erectile dysfunction such as pulmonary hypertension. However, ED drugs will not meet the definition of a Part D drug when used off-label, even when the off label use is listed in one of the compendia found in section 1927(g)(1)(B)(i) of the Act: American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information (or its successor publications), and DRUGDEX Information System. ED drugs meet the definition of a Part D drug only when used for FDA-approved indications.
While these drugs or uses are excluded from basic Part D coverage, Part D sponsors can generally include them as part of supplemental benefits, provided they otherwise meet the definition of a Part D drug. Because over-the-counter (OTC) drugs do not otherwise meet the definition of a Part D drug, they may not be included as part of supplemental benefits; however, under certain conditions as part of a plan utilization management program, OTC drugs can be provided at no cost to enrollees. The cost of these drugs to the Part D sponsor would be treated as administrative costs under such programs.

**Other Resources**

1. Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15. “Covered Medical and Other Health Services”. Section 110
2. Pub. 100-02, Medicare Benefit Policy Manual Chapter 15. “Covered Medical and Other Health Services” Section 50.2.
Chapter 6 – Appendix C - Summary of Coverage Policy

ATTACHMENT I

Part B Drugs and Part D Coverage Chart

Drugs are covered under Part B in a variety of settings and under a variety of payment methodologies.

- Some drugs are paid on a cost basis or are part of a prospective payment, including: drugs packaged under the outpatient prospective payment system (OPPS); drugs furnished by End-Stage Renal Disease (ESRD) facilities and included in Medicare’s ESRD composite rate; osteoporosis drugs provided by home health agencies under certain conditions; and drugs furnished by: critical access hospitals’ outpatient departments (CAHs); rural health clinics (RHCs); federally qualified health centers (FQHCs); community mental health centers (CMHCs); and ambulances.

- In addition, there are 13 categories of drugs for which separate payment is made under Part B\(^8\), including: drugs furnished “incident to” a physician’s service; separately billable ESRD drugs; separately billable drugs provided in hospital outpatient departments; durable medical equipment (DME) supply drugs; drugs covered as supplies; drugs used in immunosuppressive therapy; blood clotting factors; certain vaccines; antigens; parenteral nutrition; certain oral drugs used in cancer treatment; separately billable drugs provided in comprehensive outpatient rehabilitation facilities (CORFs); and intravenous immune globulin provide in the home.\(^9\)

The following chart groups the various categories of Part B coverage according to the extent to which they present some ambiguity for billing entities and/or Part D sponsors with regard to whether coverage should be under Part B or Part D. This ambiguity has different implications for stand alone Part D sponsors and for Medicare Advantage-Prescription Drug (MA-PD) Plans (including PACE plans and Section 1876 Cost plans which are treated similarly to MA-PDs). For stand alone Part D sponsors, the sponsor needs to determine whether it should make any payment. For MA-PDs, the MA organization needs to determine whether a payment should be assigned to its Part D spending or to its spending for Part B services.

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\(^8\) If these drugs are provided as part of a Medicare Part A covered inpatient hospital or skilled nursing facility stay, they are generally bundled into the Medicare Part A payment to the facility. The exception with regard to inpatient hospital services is clotting factor which is paid separately. For covered SNF stays certain high cost chemotherapy drugs are billed separately along with preventive injections (e.g., flu shots). If a beneficiary does not have Part A coverage, if Part A coverage for the stay has run out or if a stay is non-covered, hospitals and SNFs can be paid for most categories of Part B covered drugs.

\(^9\) Medicare does make separate payment for blood and blood products under Part A and Part B. Although these products are regulated as biologicals by FDA, they are not administered in a context that would not be covered under Part A or Part B. Therefore, generally these products are not Part D drugs. As a result, they are not included in this discussion.
A. Situations in which a billing entity would have to decide whether for a given drug to bill Part B or Part D based on characteristics of beneficiary or medical use of the drug.

<table>
<thead>
<tr>
<th>Relationship between Part B and Part D Coverage</th>
<th>Categories of Separately Billable Part B Drugs</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The same drug dispensed by a pharmacy may be covered under Part B or Part D depending on the characteristics of the beneficiary.</td>
<td>Drugs used in immunosuppressive therapy for a transplant covered under Medicare.</td>
<td>Pharmacists would bill Part B or the individual’s Part D plan based on information received from the individual or the Part D plan. Part B would be billed if the individual had a Medicare-covered transplant; otherwise, the Part D plan would be billed. (Part D plan eligibility systems could contain a marker for members who had a Medicare covered transplant. This information could come from a question included on the Part D sponsor’s enrollment or coordination of benefit (COB) survey form.)</td>
</tr>
</tbody>
</table>

In determining whether to pay for an immunosuppressive drug under Part D, it would not be appropriate for a Part D sponsor to institute a general policy of requiring a Part B claim rejection, as a substitute for maintaining information on transplant status and paying claims based on that information. Such a policy would be disruptive to beneficiaries and pharmacies and would unnecessarily increase Part B contractor costs. Instead a prior authorization requirement would be appropriate. |

| 2. The same drug provided by an infusion/DME supplier may be covered under Part B or Part D depending on the characteristics of the beneficiary or method of administration. | a. Parenteral nutrition or intradialytic parenteral nutrition (IDPN) (for individuals with a non-functioning digestive tract). | The supplier would need to know whether the therapy was being provided because of a non-functioning digestive tract. If so, Part B would be billed. Otherwise this would be a Part D drug. |

It would not be appropriate for Part D sponsors to routinely require a rejection of a claim under Part B before processing a Part D claim. Such a policy would be disruptive to beneficiaries and pharmacies and would unnecessarily increase Part B contractor costs. However, if a Part D sponsor had evidence |
indicating that a particular claim for parenteral nutrition should be covered under Part B, it would be reasonable to require a rejection by Part B before processing in this case.

| b. Infusible DME supply drugs | In general, the supplier would bill Part B if the drug was administered using an infusion pump and bill the Part D plan for infusion using other methods (e.g., IV push). While professional services and supplies related to the administration of the infused drug are not payable under Part D, some coverage may be available under Part A or B home health benefits, under Medicaid, or from secondary commercial health benefits.

As a rule, drugs infused using an implantable pump would be covered under Part B. Drugs infused in the home using an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare DME MAC. In the case of a beneficiary in a hospital, or a SNF bed, (1) who does not have Part A coverage, (2) whose Part A coverage for the stay has run out or (3) whose stay is non-covered -- infusible DME supply drugs are not covered under Part B because the law limits coverage under Part B’s DME benefit to those items that are furnished for use in a patient’s home, and specifies that a hospital or SNF cannot be considered the beneficiary’s “home” for this purpose. In this case, coverage for the drugs would be available under Part D. (see Attachment II, INFUSION DRUGS, Question 3 for other facilities which cannot be considered a beneficiary’s “home” for DME purposes.)

The fact that coverage is available for a particular drug under Part B with the use of an infusion pump does not mean that coverage under Part D using some other method of administration automatically can be denied. There is no Part B coverage in the home for infusion drugs administered without an
### 3. The same drug dispensed by a pharmacy may be covered under Part B or Part D depending on how the drug is used in treatment and the medical condition for which the drug is being prescribed.

<table>
<thead>
<tr>
<th>c. Intravenous immune globulin (IVIG) provided in the home for individual with diagnosis of primary immune deficiency disease</th>
<th>The supplier would bill Part B if the diagnosis is primary immune deficiency disease. IVIG provided in the home for other diagnoses would be a Part D benefit. As discussed above, it would not be appropriate, as a general rule, for Part D sponsors to require a rejection of a claim under Part B before processing a Part D claim. Prior authorization programs could be used to ensure medical necessity in accordance with the Part D sponsor’s policy.</th>
</tr>
</thead>
</table>

| a. Certain oral chemotherapy agents used in cancer treatment for which there is an infusible version of the drug. | Pharmacists would need to determine the reason for treatment. If related to cancer treatment, Part B would be billed; otherwise, the Part D plan should be billed. To the extent that a Part B-covered oral anti-cancer drug has no other medically accepted indication besides cancer treatment, Part D sponsors should not include these drugs on their formularies because of Part B coverage. For the drugs that have other medically accepted indications, prior authorization programs or other mechanisms to obtain diagnostic information could be used to ensure appropriate payment. |

| b. Oral anti-emetics used in cancer treatment as a full replacement for intravenous treatment. | 2. Pharmacists would need to determine the reason for treatment. If both related to cancer treatment and a full replacement for intravenous administration within 48 hours of cancer treatment, Part B would be billed; otherwise, the Part D plan should be billed. |

### infusion pump (e.g., IV push).

There is also no Part B coverage in the home for infusion drugs administered with an infusion pump unless the drug is specifically covered under the local coverage policy of the applicable Medicare DME MAC. Therefore, determinations about Part D sponsor payment for these other methods of administration and for drugs administered with an infusion pump but not covered by the local DME MAC policy should be based on the question of whether the drug is on the sponsor’s formulary.
billed. **NOTE:** In order to receive Part B payment, CMS currently requires that the prescribing physician indicate on the prescription that the oral anti-emetic is being used “as a full therapeutic replacement for an intravenous anti-emetic drug as part of a cancer chemotherapeutic regimen.”

If based on a prior authorization program or other mechanism to obtain diagnostic information, a Part D sponsor determined that a) a Part B-covered oral anti-emetic was being billed, and b) the drug was being furnished in the context of cancer treatment for use within 48 hours of cancer treatment, the Part D sponsor should deny payment. Such drugs dispensed for use after the 48-hour period, or any oral anti-emetic prescribed for conditions other than the effects of cancer treatment, would be Part D drugs.

4) The same vaccine may be covered under Part B or Part D depending on the characteristics of the beneficiary.

- Hepatitis B vaccine for individuals at high or intermediate risk.

Physicians would need to determine the level of risk of the individual. If the individual is at high or intermediate risk, Part B would be billed. For all other individuals, prior authorization programs could be used to ensure appropriate level of risk.

### B. Situation where the form of the drug determines where it is covered.

<table>
<thead>
<tr>
<th>Relationship between Part B and Part D Coverage</th>
<th>Categories of Separately Billable Part B Drugs</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>The same drug provided by a <strong>DME supplier</strong> or a <strong>pharmacy</strong> may be covered under Part B or Part D depending on its form (i.e., for use in nebulizer or in metered dose inhaler)</td>
<td>Inhalation DME supply drugs</td>
<td>Certain inhalation drugs are generally covered under Part B when used with a nebulizer in the home. These drugs would not be covered under Part D for use with a nebulizer. However, if these drugs were delivered with a metered dose inhaler or other non-nebulized administration, they would be Part D drugs.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>In the case of a beneficiary in a hospital, or a SNF bed, (1) who does not have Part A coverage, (2) whose Part A coverage for the stay has run out or (3) whose stay is non-covered --</td>
</tr>
</tbody>
</table>
inhalation DME supply drugs are not covered under Part B because the law limits coverage under Part B’s DME benefit to those items that are furnished for use in a patient’s home, and specifies that a hospital or SNF cannot be considered the beneficiary’s “home” for this purpose. In this case, coverage for the drugs would be available under Part D. (See Attachment II, **INFUSION DRUGS**, Question 3 for other facilities which cannot be considered a beneficiary’s “home” for DME purposes.)

### C. Situations where Part B coverage is in the context of another service.

<table>
<thead>
<tr>
<th>Relationship between Part B and Part D Coverage</th>
<th>Categories of Separately Billable Part B Drugs</th>
<th>Comments</th>
</tr>
</thead>
</table>
| The same drug dispensed by a pharmacy is covered under Part B if provided as part of a service in a provider setting, physician’s office or home. | 1. Drugs furnished “incident to” a physician service  
2. Separately billable ESRD drugs  
3. Separately billable drugs in HOPDs  
4. Separately billable drugs in CORFs  
5. Drugs packaged under the OPPS  
6. Drugs furnished by ESRD facilities and included in Medicare’s ESRD composite rate  
7. Osteoporosis drugs provided by home health agencies under certain conditions | Generally, if a beneficiary presents at a pharmacy with a script it would be a Part D drug. The availability of Part B coverage in a provider setting or physician’s office should not result in a refusal of coverage under Part D for drugs dispensed by a pharmacy. This is the case because coverage is not available under Part B as the drug is being “prescribed and dispensed or administered” with respect to the individual. Thus, for example, while Part B covers certain injectables provided “incident to” a physician services, injectables dispensed by a pharmacy are not being “furnished” by a physician and would be Part D drugs. Part D sponsors should deny claims submitted by members for Part B-covered injectables if they are administered in a physician office from a physician’s supply. Part D sponsors can subject injectables and infusables that would be covered under Part B as “incident to” a physician service, to a prior authorization program. To the extent that the sponsor determines based on medical literature that there exist serious... |
8. Drugs furnished by CAHs outpatient departments  
9. Drugs furnished by RHCs  
10. Drugs furnished by FQHCs  
11. Drugs furnished by CMHCs  
12. Drugs furnished by ambulances.  
safety concerns such that it would go against accepted medical practice for a particular injectable or infusible to be dispensed directly to an enrollee, the claim can be denied as not "reasonable."
Safety-based reasonableness determinations will need to be made on a case-by-case basis, since circumstances will vary. In general, however, there are very few instances when an injectable or infusible drug could not be reasonably dispensed directly to the patient.

D. Completely unambiguous situations.

<table>
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<th>Relationship between Part B and Part D Coverage</th>
<th>Categories of Separately Billable Part B Drugs</th>
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<tr>
<td>1) Unique drugs never dispensed by a pharmacy.</td>
<td>Non-DME drugs covered as supplies (including radiopharmaceuticals (both diagnostic and therapeutic) and low osmolar contrast media.)</td>
<td>This category of drugs is those used for diagnostic or therapeutic purposes in a provider or physician office setting. CMS would assume that these drugs are not dispensed by pharmacies.</td>
</tr>
</tbody>
</table>
| 2) Drugs that **would not** be covered under Part D because of Part B coverage. | 1. Blood clotting factors  
2. Antigens  
Pneumococcal and influenza vaccines | These categories would not be a Part D benefit and should not be included on a Part D sponsor’s formulary. |
EXCLUSIONS RELATED TO MEDICARE COVERAGE UNDER PART A OR PART B

Question 1 – Should Part D sponsors deny claims for drugs covered under Part A or Part B of Medicare?

Answer 1 – Drugs, or uses of drugs, for which coverage is available under Part A or Part B are excluded from the definition of a Part D drug and, therefore, cannot be included in Part D basic coverage. Unlike the list of supplementary drugs, these drugs, or uses of drugs, cannot be included in supplemental coverage.

There are two important considerations in determining whether a claim to Part D can be denied based on the availability of coverage under Part A or Part B of Medicare.

- First, the exclusion from the definition of a Part D drug for drugs covered under Parts A or B is based on whether coverage is available under Part A or Part B for the drug as it is being “prescribed and dispensed or administered” with respect to the individual. Thus, the same drug may be covered under different circumstances under both programs and coverage generally cannot be determined based solely on the drug itself. Since most Part B drug coverage is available in a provider setting or physician’s office rather than as drugs dispensed by pharmacists, there are very limited situations when a drug claim submitted by a pharmacy should be denied based on the availability of coverage under Part A or Part B.

- Second, to the extent a drug could be covered under part B as prescribed and dispensed or administered, Part D sponsors should view coverage as “available” under Part B regardless of whether or not an individual is actually enrolled in Part B.

Question 2 – Can a Part D sponsor require that coverage be denied under Part A or Part B before making payment under Part D?

Answer 2 – Generally, no. In limited instances, prior authorization programs may be necessary to determine whether the diagnosis of the individual or the particular use of a drug is consistent with Part D coverage, but it would not be appropriate to routinely require a denial from Part A or Part B before making payment in lieu of prior authorization. Such a policy would be disruptive to beneficiaries and pharmacies and would unnecessarily increase Part B contractor costs.

Question 3 - What happens if a Part D sponsor makes payment for a drug and later determines that the drug was covered under Part B as prescribed and dispensed or administered?
**Answer 3** - If the drug as prescribed and dispensed or administered was covered under Part B on that day, the payment by the Part D sponsor would have been in error and it should seek recovery from the billing entity, which should bill Part B instead.

**Question 4** - In the case of a newly approved drug that may be covered under one of the Part B benefit categories, can a Part D sponsor defer a coverage decision until Part B makes a decision?

**Answer 4** - No. Once a drug is approved by the FDA it is a Part D drug. While it is not automatically a covered Part D drug, that is, it may not be included on a Part D sponsor’s formulary, a member could request coverage on an exception basis.

For Medicare Part B coverage, a determination has to be made as to whether the approved drug fits in a benefit category (e.g., a drug covered as a supply of an external infusion pump used at home). In the vast majority of cases these determinations are delegated to the individual contractors. If a drug has a Medicare Part B benefit category and the drug is being “prescribed and dispensed or administered” as covered under Part B, the drug is no longer a Part D drug.

**Question 5** - How will Part D sponsors determine whether a drug is covered under Part B?

**Answer 5** - First, it is important to keep in mind that in most cases Part B drug coverage should not impact payment decisions by Part D sponsors since Part B coverage is generally in a provider setting or physician’s office rather than for drugs dispensed at a pharmacy.

Payment for a particular drug can be denied only if there is Part B coverage as the drug is prescribed and dispensed or administered. The fact that a claim is received for a drug that is sometimes covered by Part B is not a basis for denial since the Part D sponsor would have to determine whether the drug is being prescribed and dispensed or administered on the basis under which Part B coverage is available. This will generally involve interaction between the Part D sponsor and the Medicare Part B contractor with jurisdiction in that geographic area for that drug.

With regard to new drugs, as decisions are made nationally or by individual A/B contractors, this information will be available on the CMS and contractor Web sites.

**INFUSION DRUGS**

**Question 1** - Since Part B covers infusion drugs in the home, can a Part D sponsor reject any claim for home infusion?

**Answer 1** – No. Part B coverage is generally limited to a number of drugs that require the use of an infusion pump in the home. Any agents administered in the home via IV drip or push injection would be covered under Part D. This could include the same drugs that are covered under Part B when furnished through the use of an infusion pump.
Question 2 – Does Part B cover drugs that require an external infusion pump in the case of a beneficiary in a hospital or SNF bed who does not have Part A coverage, whose Part A coverage for the stay has run out or whose stay is non-covered?

Answer 2 – No, drugs that require an external infusion pump are not covered under Part B under those circumstances because the law limits coverage under Part B’s DME benefit to those items that are furnished for use in a patient’s home, and specifies that a hospital or SNF cannot be considered the beneficiary’s “home” for this purpose.

Question 3 - What other facilities cannot be considered the beneficiary’s “home” under the law for purposes of receiving the Medicare DME benefit?

Answer 3 – In addition to a hospital, a SNF or a distinct part SNF, the following facilities cannot be considered a home for purposes of receiving the Medicare DME benefit:

- a nursing home that is dually-certified as both a Medicare SNF and a Medicaid nursing facility (NF);
- a Medicaid-only NF that primarily furnishes skilled care;
- a non-participating nursing home (i.e., neither Medicare or Medicaid) that provides primarily skilled care; and
- an institution which has a distinct part SNF and which also primarily furnishes skilled care.

Question 4 - If the infusion services are furnished in an outpatient provider setting, can a Part D sponsor deny a claim?

Answer 4 – Yes. If a physician office or hospital outpatient department bill for infusion administered in those settings, the claim should always be denied because of coverage in those settings under Part B.

Question 5 – Since Part B covers intravenous immune globulin (IVIG) provided in the home, should a Part D sponsor deny claims for this drug?

Answer 5 – It depends. Part B coverage for IVIG in the home is for individuals whose diagnosis is primary immune deficiency disease. Part D would provide coverage for IVIG in the home for all other medically accepted indications. Prior authorization requirements could be used to ensure appropriate payment in accordance with the Part D sponsor’s medical necessity criteria. It would not be appropriate to routinely require a rejection of a claim under Part B before processing a Part D claim. Such a policy would be disruptive to beneficiaries and pharmacies and would unnecessarily increase Part B contractor costs.

Question 6 – Since Part B covers parenteral nutrition under certain circumstances, should Part D sponsors deny these claims?

Answer 6 – It depends. Part B coverage for parenteral nutrition is limited to individuals with a non-functioning digestive tract. So if parenteral nutrition is being provided based on this
condition, the claim should be denied. For all other medically accepted indications, coverage would be under Part D. Prior authorization programs could be used to ensure appropriate payment. As a general policy, it would not be appropriate to require a rejection of a claim under Part B before processing a Part D claim. However, if a Part D sponsor had a reasonable basis for assuming that a particular claim would be covered under Part B, it could require a rejection by Part B before processing.

**ORAL ANTI-CANCER DRUGS**

**Question 1** - With regard to oral anti-neoplastics, we understand that if they have an IV form, they are covered under Part B. It is our thinking then, that we could exclude those that are used solely for cancer under this premise since they would be covered under Part B.

**Answer 1** – Yes. Part D sponsors should not include on their formularies the oral anti-cancer agents covered by Part B whose only medically accepted indication is as an anti-cancer agent. They should always deny claims for these drugs. For the drugs that have other medically accepted indications, Part D sponsors should deny claims for these drugs when used for cancer treatment but when these drugs are used for other indications they would be Part D drugs. The use of the drug could be determined through a prior authorization program.

**ORAL ANTI-EMETICS**

**Question 1** - Do pharmacies bill oral anti-emetics under Part B or Part D?

**Answer 1** - It depends. Before billing either Part B or Part D, pharmacists would need to determine the reason for treatment. If it is related to cancer treatment and is a full replacement for intravenous administration within 48 hours of cancer treatment, Part B would be billed; otherwise, Part D should be billed.\(^\text{10}\) In order to receive Part B payment, CMS currently requires that the prescribing physician indicate on the prescription that the oral anti-emetic is being used “as a full therapeutic replacement for an intravenous anti-emetic drug as part of a cancer chemotherapeutic regimen.”

If (based on a prior authorization program) a Part D sponsor determines that a Part B-covered oral anti-emetic drug is being billed, and that the drug is being furnished in the context of cancer treatment for use within 48 hours of such treatment, the Part D sponsor should deny payment since coverage is available under Part B. Such drugs dispensed for use after the 48-hour period, or any oral anti-emetic prescribed for conditions other than treatment of the effects of cancer treatment, would be Part D drugs.

**IMMUNOSUPPRESSANTS**

**Question 1** - Do pharmacies bill oral immunosuppressants under Part B or Part D?

\(^{10}\) There may be some local A/B contractor variance regarding the 48 hour interval for the oral anti-emetics granisetron and dolasetron. Part D sponsors should contact their local A/B contractor for more information regarding these drugs.
Answer 1 - It depends. Pharmacists would bill Part B or the individual’s Part D plan based on information received from the individual or sources substantiating the patient’s transplant. Part B would be billed if the individual had a Medicare covered transplant; otherwise, the Part D plan would be billed.

INJECTABLES

Question 1 - Can claims submitted by pharmacies for injectable drugs be denied based on Part B coverage in a physician office “incident to” a physician service?

Answer 1 – No. The exclusion from the definition of a Part D drug of drugs covered under Parts A or B is based on whether coverage is available under Part A or Part B for the drug as it is being “prescribed and dispensed or administered” with respect to the individual. Thus, the same drug may be covered under different circumstances under both programs. As a result, coverage cannot generally be determined based solely on the drug itself.

The fact that an injectable is covered under Part B in a physician’s office or hospital outpatient department or other provider setting does not mean that these drugs should be excluded from the Part D sponsor’s formularies, or that a Part D sponsor can deny a claim from a pharmacy based on availability of Part B coverage in a physician’s office. If, however, a member submits an out-of-network claim for an injectable drug administered in-office from a physician’s supply, and this drug is covered in that setting by the Part B contractor for that area, such a claim should be denied by the Part D sponsor based on Part B coverage. (Of course, an MA-PD plan would not deny such a claim, but rather pay it under the A/B benefit.)

Question 2 - An injectable drug that a Medicare contractor considers to be usually not self-administrable (e.g., injectable chemotherapy drugs) can only be covered under Part B as “incident to” a physician service if it is obtained by a physician and administered as part of a physician service. Can Part D sponsors require prior authorization for these medications when dispensed by a pharmacy? If the sponsor determines that the drug will be administered in a physician office, can the sponsor deny the claim because the practice of the patient taking the drug to the physician’s office for administration is unsafe and because coverage is available under Part B if the physician obtained and administered the drug?

Answer 2 - Part D sponsors determine the scope of their own prior authorization programs subject to CMS review to ensure that such programs have a sound medical basis and do not discriminate against beneficiaries with certain medical conditions.

To the extent that a sponsor’s prior authorization program applies to injectables and infusables that would be covered under Part B as “incident to” a physician’s service, and the sponsor determines based on medical literature that there exist serious safety concerns such that it would go against accepted medical practice for a particular injectable or infusible to be dispensed directly to a member, the claim can be denied as not "reasonable." Thus, the dispensing of that particular drug to that member may be excluded by the Part D sponsor under Section
1862(a)(1)(A) of the Social Security Act as applied to Part D under 1860D-2(e)(3)(A) of the Act. This same safety concern would not exist, however, if the claim for the drug was being submitted by an infusion supplier.

Safety-based reasonableness determinations will need to be made on a case-by-case basis, since circumstances will vary. In general, there are very few instances when an injectable or infusible drug could not be reasonably dispensed directly to the patient. All drugs are in some sense hazardous. This is not a unique characteristic of injectables and infusables.

Some situations that would present safety concerns in dispensing directly to a patient who is transporting the drug to a physician’s office for administration include:

- The drug itself presents a bona fide public safety hazard (e.g., highly radioactive substance or an environmentally hazardous chemotherapeutic agent) that requires chain of custody handling to ensure use of appropriate equipment (i.e., safety hood) or persons of special qualifications.

- The drug requires special handling to preserve biologic activity and the patient is incapable or unwilling to do so. (For instance, a vaccine that must be kept frozen could be a problem if the patient had to transport it a long distance in summer heat.)

- The patient presents a high risk of diversion or inappropriate use. (For instance, giving a heroin addict a vial of morphine.)

- The patient has demonstrated unreliability, aversion, or unwillingness in transporting drugs to his doctor’s office. (For instance, with respect to dispensing injectable psychiatric meds.)

In the absence of a serious safety concern based on the individual situation, however, there is no basis for denying a prescription presented at a pharmacy based on the availability of Part B coverage in another setting (e.g., physician office).

Finally, it is CMS’ understanding that the practice of “brown-bagging” drugs is opposed by medical societies. CMS continues to urge them to reinforce this message with their members.

**Question 3 – Most Medicare Advantage plans treat most non-self-injectables as a medical benefit. Do they have to treat them as a Part D benefit?**

**Answer 3** - If an injectable drug is covered under Part B in a provider or physician office setting, it will continue to be covered under Part B in those settings. If an injectable drug is not covered in a provider setting (e.g., determined by the contractor to be usually self-administered), then it will need to be covered under Part D. In addition, claims for non-Part-B-covered injectables whether usually self-administered or not, when dispensed and submitted by pharmacists could be covered under Part D. However, Part D plans could establish medical necessity criteria for limiting coverage of injectable drugs in physician offices.
Question 4 - What are Part D sponsors to do if their region includes multiple A/B contractor areas and these contractors have differing policies with regard to injectable drugs?

Answer 4 – A Part D sponsor will have to modify its coverage based on the variation in Part B coverage across contractor areas within its region. That is, assume that there are two contractor areas within a Part D sponsor’s region, Contractor A and Contractor B. Further assume that Contractor A covers injectable X when furnished in a physician office but Contractor B does not. As a result of this difference in Part B coverage, injectable X is a Part D drug when furnished in a physician office for members residing in Contractor B’s area, but not in Contractor A’s area. In either area, injectable X would be covered under Part D if dispensed by a pharmacy.

For MA-PD plans, rules for selecting local coverage determinations apply. That is, if a local MA plan’s service area includes more than one contractor area, the plan may seek approval from CMS to apply uniformly to all of the plan’s enrollees local coverage policies that are the most beneficial to enrollees. Regional MA plans can select a set of local coverage policies to apply uniformly to their enrollees without CMS pre-approval. In either case, if the selected contractor covers injectable X, the MA-PD would treat injectable X as a basic A/B benefit. If the selected contractor does not cover injectable X, the MA-PD would treat it as a Part D drug.

Question 5 – What about new injectable drugs?

Answer 5 - As new injectables are approved by FDA, Part B contractors or CMS would continue to make coverage decisions regarding drugs provided incident to a physician’s service based on whether the drug is “not usually self-administered.” Injectables not covered under Part B as incident to a physician’s service would become Part D drugs. However, there is no requirement for Part D sponsors to provide coverage of non-Part-B-covered drugs in the physician office setting if the drugs can be safely self-administered and there is no medical necessity for administration in that setting.

INHALATION DRUGS

Question 1 - Can claims submitted by a pharmacy for inhalation drugs delivered through metered-dose inhalers be denied based on Part B coverage of inhalation drugs used with a nebulizer?

Answer 1– No. Since there currently is no coverage under Part B for inhalation drugs delivered through metered-dose inhalers and dispensed by a pharmacy, these drugs would be covered under Part D.

Question 2 – Does Part B cover inhalation drugs used with a nebulizer in the case of a beneficiary in a hospital or SNF bed who does not have Part A coverage, whose Part A coverage for the stay has run out or whose stay is non-covered?

Answer 2 – No, inhalation drugs used with a nebulizer are not covered under Part B under those circumstances because the law limits coverage under Part B’s DME benefit to those items that
are furnished for use in a patient’s home, and specifies that a hospital or SNF cannot be considered the beneficiary’s “home” for this purpose. (See list above (INFUSION DRUGS, Question 3) for other facilities which cannot be considered a beneficiary’s “home” for DME purposes.

**VACCINES**

**Question 1 – Are all vaccines be covered under Part D?**

**Answer 1** – No. There are a number of vaccines that remain covered under Part B. For instance, pneumococcal and influenza vaccines are not covered under Part D because of Part B coverage. Hepatitis B vaccine is covered under Part B for individuals at high or intermediate risk; for all other individuals, it would be covered under a Part D benefit. Part B also covers certain vaccines reasonable and necessary for the treatment of an illness or injury. All other currently available vaccines and all future preventative vaccines could be covered under Part D.

**Question 2- If a Part D sponsor determines through a prior authorization program that a hepatitis B vaccine is going to be administered by a physician can the Part D sponsor deny the claim based on Part B coverage in the setting?**

**Answer 2** – No. Since the Part B benefit for hepatitis B vaccine is separate from the “incident to” benefit, the determination about whether it is a Part D drug depends solely on characteristics of the beneficiary. However, if the Part D sponsor determines based on Medicare Part B guidelines that the individual is at high or medium risk for hepatitis B, the claim should be denied. For all other individuals, the vaccine would be a “Part D drug”.

**Question 3 - Medicare Part B covers hepatitis B vaccine for high and intermediate risk groups if ordered by a doctor of medicine or osteopathy, how are these groups defined?**

**Answer 3** – The high risk groups for whom vaccination is covered include:

- Individuals with End stage renal disease (ESRD);
- Individuals with hemophilia who received Factor VIII or IX concentrates;
- Clients of institutions for individuals for the mentally handicapped;
- Persons who live in the same household as a hepatitis B Virus (HBV) carrier;
- Homosexual men; and
- Illicit injectable drug abusers

Intermediate risk groups include:

- Staff in institutions for the mentally handicapped; and
- Workers in health care professions who have frequent contact with blood or blood-derived body fluids during routine work.

**ANTIGENS**
Question 1 – If a pharmacy submits a claim for antigens should a Part D sponsor make payment?

Answer 1 – No. Antigens are covered only under Part B.

**BLOOD CLOTTING FACTORS**

Question 1 – If a pharmacy submits a claim for blood clotting factors should a Part D sponsor make payment?

Answer 1 – No. Blood clotting factors are covered under Part A and Part B.
# Chapter 6 – Appendix C - Summary of Coverage Policy

## ATTACHMENT III

### Web sites for Part B Coverage Information

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# Chapter 6 - Appendix D

*(Rev. 10, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)*

The Most Commonly Prescribed Drug Classes for the Medicare Population

<p>| 3- HYDROXY- 3- METHYLGLUTARYL COENZYME A (HMG COA) REDUCTASE INHIBITORS | HORMONAL AGENTS, STIMULANT/REPLACEMENT/MODIFYING (THYROID) |
| 5 ALPHA- REDUCTASE INHIBITORS | INSULIN, INTERMEDIATE-ACTING |
| ADENOSINE DIPHOSPHATE P2Y12 INHIBITORS | INSULIN, LONG-ACTING |
| ALPHA 1- ADRENERGIC BLOCKING AGENTS | INSULIN, SHORT-ACTING |
| ALPHA- ADRENERGIC AGONISTS | LAXATIVES |
| ALPHA-ADRENERGIC AGONISTS, OPHTHALMIC | LEUKOTRIENE RECEPTOR ANTAGONISTS |
| ANGIOTENSIN II RECEPTOR ANTAGONISTS | LINCOMYCIN ANTIBACTERIALS |
| ANGIOTENSIN- CONVERTING ENZYME (ACE) INHIBITORS | LOCAL ANESTHETICS |
| ANTI- INFLAMMATORIES, INHALED CORTICOSTEROIDS | LOOP DIURETICS |
| ANTIARRHYTHMICS - CLASS IAI/II/III/IV | LTC DRUGS- AMINO DERIVATIVE PENICILLINS (CHEWABLE) |
| ANTICHOLINERGICS | LTC DRUGS- AMINO DERIVATIVE PENICILLINS (ORAL LIQUID) |
| ANTICOAGULANTS | LTC DRUGS- ANTIEMETICS (SUPPOSITORY) |
| ANTIDEPRESSANTS, OTHER | LTC DRUGS- BRONCHODILATORS, SYMPATHOMIMETIC (SHORT-ACTING SOLUTION) |
| ANTIEMETICS | LTC DRUGS- HISTAMINE2 (H2) BLOCKING AGENTS (ORAL LIQUID) |
| ANTIHERPETIC AGENTS | LTC DRUGS- LOOP DIURETICS (ORAL LIQUID) |
| ANTISPASMODICS, GASTROINTESTINAL | LTC DRUGS- MACROLIDES (ORAL LIQUID) |
| ANTISPASMODICS, URINARY | LTC DRUGS- NONSTEROIDAL ANTI-INFLAMMATORY DRUGS (ORAL LIQUID) |
| ANTISPASTICITY AGENTS | MACROLIDES |
| ANXIOLYTICS | MISCELLANEOUS ANTIBACTERIALS |
| ATYPICALS | NICOTINIC ACID |
| AZOLE ANTIFUNGALS, ORAL | NITROFURAN ANTIBACTERIALS |
| BETA- ADRENERGIC BLOCKING AGENTS WITH VASODILATING PROPERTIES | NONSELECTIVE BETA-ADRENERGIC BLOCKING AGENTS |
| BETA- ADRENERGIC BLOCKING AGENTS, OPHTHALMIC | NONSTERoidal ANTI-INFLAMMATORY DRUGS |
| BETA- LACTAM, PENICILLINS | OPHTHALMIC AMINOGLYCOSIDES |
| BIGUANIDES | OPHTHALMIC ANTI-ALLERGY AGENTS |</p>
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Prescription Drug Benefit Manual
Chapter 7 – Medication Therapy Management and Quality Improvement Program

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Appendix A – Chapter 7 Related Web Sites
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(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)

10.1 - Introduction  
(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)

Title 42 CFR Part 423, Subpart D, establishes the requirements Part D sponsors must meet with regard to cost control and quality improvement under the Social Security Act (the Act). This chapter is divided into five main areas:

- Section 20 – Quality Assurance Requirements
- Section 30 – Medication Therapy Management Program (MTMP)
- Section 40 – Consumer Satisfaction Surveys
- Section 50 – Electronic Prescription Program (E-prescribing)
- Section 60 – Drug Utilization Management Section

10.2 - Definition of Terms  
(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

For the purposes of this chapter the following definitions apply:

Dispenser—means a person or other legal entity licensed, registered, or otherwise permitted by the jurisdiction in which the person practices or the entity is located to provide drug products for human use by prescription in the course of professional practice.

Electronic media—means electronic storage media including memory devices in computers (hard drives), and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card; or transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the Internet (wide open), extranet (using Internet technology to link a business with information only accessible to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media, because the information being exchanged did not exist in electronic form before the transmission.

[NOTE: Computer-generated fax transmissions start with data that is in an electronic form, and thus qualify as transmissions using electronic media. Absent the current exemption in 42 CFR 423.160(a)(3) to a particular Part D standard (the “NCPDP SCRIPT 8.1” standard), such transmissions could not meet the Part D e-prescribing standards (because they cannot be transmitted using NCPDP SCRIPT 8.1). The exemption was allowed due to fears that the imposition of final e-prescribing standards would drive computer-generated faxers to revert to paper.]
E-prescribing—means the transmission using electronic media, of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or health plan, either directly or through an intermediary, including an e-prescribing network. E-prescribing includes, but is not limited to, two-way transmissions between the point of care and the dispenser.

Electronic prescription drug program—means a program that provides for e-prescribing for covered Part D drugs prescribed for Part D eligible individuals.

Immediate need – For Part D complaints, an “immediate” complaint is defined as a life-threatening complaint that is related to the beneficiary’s need for medication when the beneficiary has 2 or less days of medication remaining.

Prescriber—means a physician, dentist, or other person licensed, registered, or otherwise permitted by the U.S. or the jurisdiction in which he or she practices, to issue prescriptions for drugs for human use.

Prescription-related information—means information regarding eligibility for drug benefits, medication history, or related health or drug information for Part D eligible individuals.

Urgent need – For Part D complaints, an “urgent” complaint is defined as a complaint that is related to the beneficiary’s need for medication when the beneficiary has 3 to 14 days of medication remaining.

20 – Quality Assurance Requirements
(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)

20.1 – General Rule
(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)

Each Part D plan sponsor must establish quality assurance (QA) measures and systems to reduce medication errors and adverse drug interactions and improve medication use. The Part D sponsor’s comprehensive quality assurances system will ensure enrollees receive access to high quality prescription drug coverage. As a result, the Part D sponsor’s QA measures and systems minimally include:

1. Representation that the Part D sponsor requires network providers to comply with minimum standards for pharmacy practice as established by the States.
2. Concurrent drug utilization review (DUR) systems, policies and procedures.
3. Retrospective DUR systems, policies and procedures.
4. Internal medication error identification and reduction systems.
5. Provision of information to CMS regarding the plan sponsor’s QA measures and systems, according to CMS-specified guidelines.

Furthermore, Part D sponsors must establish and maintain an electronic prescription drug program that is consistent with uniform e-prescribing standards that are adopted under 1860D-4(e)(3) of the Act (see section 50 of this manual chapter for a description of the current e-prescribing standards). Prescribers, dispensers and plans must utilize the final e-prescribing standards when transmitting prescription and prescription-related information using electronic media for Part D covered drugs for Part D eligible individuals. While e-prescribing is voluntary for physicians (and other prescribers) and pharmacies (and other dispensers), if these persons or entities e-prescribe covered Part D drugs for Part D eligible individuals, they must comply with the adopted standards.

E-prescribing (addressed in section 50 of this chapter), although not required as an element of the sponsor’s quality assurance system, has demonstrated value in preventing medication errors by permitting each prescription to be checked electronically for dosage, interactions with other medications, and therapeutic duplication at the point-of-care, thereby improving overall medication use. Therefore, CMS recommends Part D sponsors incorporate their electronic prescription drug program within their quality assurance system.

20.2 – Compliance With State Standards
(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)

Part D sponsors are required in 42 CFR 423.153(c)(1) to ensure their existing quality assurance system includes representation that network providers comply with minimum standards for pharmacy practice. While CMS believes that current pharmacy practice standards established by the States provide applicable minimum standards for all pharmacy practice settings, CMS encourages sponsors and network pharmacies to establish and agree upon additional quality assurance standards as necessary.

20.3 – Concurrent Drug Utilization Review (DUR)
(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

A Part D sponsor must have concurrent DUR systems, policies, and procedures designed to ensure that a review of the prescribed drug therapy is performed before each prescription is dispensed to an enrollee in a sponsor’s Part D plan, typically at the point-of-sale or point of distribution.

The Part D sponsor’s concurrent DUR program must include, but is not limited to, the following checks each time a prescription is dispensed:

- Screening for potential drug therapy problems due to therapeutic duplication
- Age/gender-related contraindications
- Over-utilization and under-utilization
- Drug-drug interactions
- Incorrect drug dosage or duration of drug therapy
- Drug-allergy contraindications
- Clinical abuse/misuse

*Part D sponsors should maintain written concurrent DUR policies and procedures that explain the level of the DUR checks (i.e., whether they are imposed at the pharmacy and/or plan level), systems logic for establishing the edits, thresholds used to trigger the edits, and accompanying pharmacy messaging. These policies should detail how the aforementioned elements were established (e.g., thresholds used are based upon relevant clinical and drug information references), validated and revised. Sponsors’ DUR policies should also address pharmacy requested overrides and detail how pharmacy override requests are evaluated and approved. Moreover, sponsors’ policies should explain how trends in override requests (both approved and unapproved) are monitored and considered in ongoing formulary management.

Part D sponsors should be able to demonstrate how information obtained from their DUR program is used in their overall quality assurance system and improves their enrollees’ quality of care.

**20.4 – Retrospective Drug Utilization Review (RDUR)**  
(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

A Part D sponsor must have retrospective drug utilization review systems, policies, and procedures designed to ensure ongoing periodic examination of claims data and other records, through computerized drug claims processing and information retrieval systems, in order to identify patterns of inappropriate or medically unnecessary care among enrollees in a sponsor’s Part D plan, or associated with specific drugs or groups of drugs.

*Part D sponsors should maintain a written retrospective DUR policy that establishes clear objectives and identifies the relevant claims data proposed for review, the evaluation period, the criteria used in the evaluation, and the proposed interventions. The policy should also include a periodic assessment that determines the success of the proposed objectives, interventions, findings, and outcomes.*

*Part D sponsors should be innovative in improving the quality of care provided to enrollees through application of DUR. For example, Part D sponsors may want to apply retrospective DUR upon FDA issuance of a new drug safety warning to ensure enrollees and/or physicians are aware of alternative therapies. Alternatively, Part D sponsors may consider application of retrospective DUR for purposes of ensuring appropriate Part B versus Part D payment by working to obtain additional information after point-of-sale adjudication.*

It is vitally important, upon notification or discovery of an allegation of fraud, abuse or suspected pattern of inappropriate drug utilization, the Part D sponsor reviews the case with the utmost concern to eliminate obvious billing or claims processing errors and, if necessary, direct the case
to the appropriate authorities (i.e., Medic or local law enforcement). In such a case, Part D sponsors would provide prescriber and beneficiary education as appropriate. For instance, if a potential drug problem is discovered, intervention letters would be sent to all providers who ordered a drug relevant to the identified problem. An intervention might consist of an informational letter to the prescriber, a response form for the prescriber to complete, along with a pre-addressed return envelope, and a patient drug profile. Part D sponsors should not implement programs that decrease beneficiaries’ access to their Part D benefit. This includes any sort of a “lock-in” program that limits beneficiaries to utilizing only a single pharmacy.

20.5 – Medication Error Identification and Reduction (MEIR)  
(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

While CMS currently does not require external medication error reporting, CMS does require sponsors to implement internal MEIR systems as described in 42 CFR 423.153(c)(4).

The Part D sponsor’s internal MEIR process should be fully documented and identify what types of medication errors will be collected internally. For example, Part D sponsors may receive calls or letters from enrollees containing a broad range of issues, including medication errors. Other operational functions may also receive and report medication errors, such as the sponsor’s exceptions and appeals group, the clinical division involved in processing prior authorization forms, or the electronic prescribing group involved in resolving issues with the implementation of new e-prescribing standards. As a result, appropriate sponsor staff should be trained to identify potential reportable medication errors and understand how to evaluate resolve, document, and, if necessary, report to the appropriate authority (i.e., FDA, DEA).

As a component of the sponsor’s error reduction program, a periodic evaluation of the medication errors should be completed looking for trends and patterns that require the sponsor’s attention and resolution. Additionally, when appropriate, reported medication errors should be shared and discussed with downstream contractors to ensure that corrective actions are implemented and future errors are prevented.

The National Coordinating Council for Medication Error Reporting and Prevention’s definition of “medication error,” which the Food & Drug Administration proposed during rulemaking but never formally adopted, can serve as a guide for internal medication error identification and reduction systems. Plans may exercise the discretion to define medication error either more narrowly or more broadly than the description below. CMS expects plans to consider their internal control systems, current monitoring program and, ultimately, what is in the best interest of their enrollees, in preventing medication errors.

“[A]ny preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice; healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.’” (See 68 FR 12501 (March 14, 2003)).
20.6 – Medwatch Reporting
(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)

The Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety, efficacy, and security of marketed medical products, such as drugs and medical devices (including OTCs and dietary supplements). In order to perform ongoing safety surveillance of medical products, the FDA relies on the voluntary reporting of serious adverse events, product quality problems and product use errors. FDA MedWatch enables healthcare professionals and consumers to report serious problems that they suspect are associated with the drugs and medical devices they prescribe, dispense, or use. Healthcare professionals and consumers may report adverse events and product problems to MedWatch by calling 1800-FDA-1088, by submitting the MedWatch 3500 form by mail or fax, or by going online to the FDA Web page. CMS encourages Part D sponsors to educate prescribers and pharmacy providers about the importance of reporting adverse events, product problems and product use errors, as well as how to utilize the FDA Medwatch reporting mechanisms. A broader discussion on Medwatch reporting, including downloadable Medwatch forms, is available at the FDA MedWatch Web page (see Appendix A).

20.7 – CMS Performance Measures
(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

CMS believes that utilization of specific performance measures help ensure Medicare beneficiaries receive the highest quality prescription drug coverage and services. Publicly available measures encourage Part D sponsors to improve the quality of services and to maximize their ratings in an effort to attract new enrollees through the competitive nature of the Part D program. To facilitate this process, CMS continuously reviews various data sources to refine and identify new performance measures. CMS generally relies upon data received from internal CMS systems, the complaints tracking module (CTM), the Medicare Prescription Drug Plan Finder Tool, Appeals Data, and Call Center statistics. As well, CMS also integrates information into the measures from the Medicare Part D Reporting Requirements (see Appendix A).

After a comprehensive analysis of these various data streams, CMS has identified several key Part D performance areas CMS believes are the basis for evaluating prescription drug coverage across the Part D program. Some of these areas include customer service, complaints, appeals, data systems, member satisfaction, and drug pricing. While these measures are broad, elements of each can be integrated together to ensure beneficiaries receive superior services. For instance, independent review entity (IRE) data are used in conjunction with information from CTM and the sponsors’ self reported appeals information to assess whether plan enrollees are obtaining access to the Part D drugs they need to sustain or improve their health. Star ratings are assigned and displayed on plan finder. While CMS investigates and audits those plans with lower than average ratings, beneficiaries will likely migrate to those plans with the highest ratings and highest quality prescription drug coverage. Plans with sustained low performance may be subject to compliance actions.
The development of performance measures is a particularly dynamic process based upon the availability of new information. As continuing analyses are completed and show promise in improving the quality of drug coverage, additional measures will be incorporated to the existing inventory of measures.

In addition to the plan ratings displayed on plan finder, CMS will post information on operational and clinical measures on the CMS Web site http://www.cms.hhs.gov. These data include selected measures that are not ready for Medicare Options Compare (MOC) or the Medicare Prescription Drug Plan Finder (MPDPF), that are in development, are duplicative, or are limited by a small sample size. In contrast to the Plan Ratings available on the MOC or MPDPF on http://www.medicare.gov, information about sponsors’ performance on these measures are displayed without any assignment of star ratings.

CMS provides preview periods for Part D sponsors’ review of individual contract data and ratings as part of the performance measures. Sponsors are required to review and notify CMS of any data inaccuracies during these periods, as well as submit any questions or issues identified by the sponsors’ preview.

Finally, CMS is committed to working with external stakeholders, such as the Pharmacy Quality Alliance, to establish industry wide strategies for measuring and reporting data that will help consumers make informed choices and appropriate healthcare decisions.

20.8 – Information for Quality Improvement Organizations (QIOs)
(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)

CMS expects that the QIOs will work with providers, practitioners, and Part D sponsors to improve the quality of beneficiaries’ medication therapies. The QIOs’ goal is to improve quality of care, not to assign blame. They can assist each of these players to design systems to facilitate the delivery of quality care. Similarly, CMS expects that Part D sponsors, as well as providers and practitioners, will be able to request technical assistance from QIOs to improve their MTMPs.

The QIOs are required to offer providers, practitioners, and Part D sponsors quality improvement assistance pertaining to health care services, including those related to prescription drug therapy, in accordance with contracts established with the Secretary.

Pursuant to section 1154(a)(14) of the Social Security Act, QIOs are required to review enrollees’ written complaints about the quality of services they have received under the Medicare program, as specified within the Social Security Act. For any Part D quality of care complaint submitted to a QIO, the Part D sponsor should cooperate with the QIO in resolving the complaint. Upon completion of the investigation and resolution of the complaint with the Part D sponsor, the QIO will notify the beneficiary of the final disposition.

Information collected, acquired, or generated by a QIO in the performance of its responsibilities under 42 CFR 423.162 is subject to the confidentiality provisions of 42 CFR 480.
30 – Medication Therapy Management Program (MTMP)
(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)

30.1 – General Rule
(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

A Part D sponsor must have established an MTMP that—

- Is designed to ensure that covered Part D drugs prescribed to targeted beneficiaries, as described in section 30.2, are appropriately used to optimize therapeutic outcomes through improved medication use;

- Is designed to reduce the risk of adverse events, including adverse drug interactions, for targeted beneficiaries;

- May be furnished by a pharmacist or other qualified provider; and

- May distinguish between services in ambulatory and institutional settings. While services and interventions may vary across setting, the criteria for identifying targeted beneficiaries eligible for MTMP cannot.

Until 2009, CMS did not identify specific medication therapy management (MTM) requirements beyond those contained in the Social Security Act. In large part this was due to the fact there was insufficient industry experience and no widely accepted standard practices for MTMPs. However, given the experience garnered from the first few years of the Part D program, CMS determined it necessary to provide more specific Part D MTMP instructions for enrollment methods, targeting procedures, and MTM services. In the 2010 Call Letter, CMS included policy guidance regarding the implementation of MTMPs. This policy guidance reflects common practices among Part D MTMPs that were derived from CMS’ extensive review of MTMP applications, plan-reported data, exploratory research on MTM, informal interviews with Part D sponsors, and other relevant literature and data.

Sponsors are expected to analyze and evaluate their MTM programs and make changes to continuously improve their programs.

MTMP requirements do not apply to MA Private Fee for Service (MA-PFFS) organizations. However, considering MA-PFFS organizations have an equal responsibility to provide quality Part D products, CMS encourages MA-PFFS organizations to establish an MTM program to improve the quality of care furnished to Medicare beneficiaries.

The MTMP Web site (see Appendix 1) contains more information related to Part D MTMP reporting requirements.

30.2 – Targeted Beneficiaries
(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)
Part D sponsors are expected to target beneficiaries who:

1. Have multiple chronic diseases;
   - In defining multiple chronic diseases, sponsors cannot require more than three chronic diseases as the minimum number of multiple chronic diseases and sponsors must target at least four of the following seven core chronic conditions:
     1. Hypertension;
     2. Heart Failure;
     3. Diabetes;
     4. Dyslipidemia;
     5. Respiratory Disease (such as asthma, chronic obstructive pulmonary disease (COPD), or chronic lung disorders);
     6. Bone Disease-arthritis (such as osteoporosis, osteoarthritis, or rheumatoid arthritis);
     7. Mental Health (such as depression, schizophrenia, bipolar disorder, or chronic and disabling disorders).

2. Are taking multiple Part D drugs; and
   - In defining multiple Part D drugs, sponsors cannot require more than 8 Part D drugs as the minimum number of multiple covered Part D drugs. Sponsors may set this minimum threshold at any number equal to or between two and eight.

3. Are likely to incur annual costs for covered Part D drugs that exceed a predetermined level as specified by the Secretary.
   - For CY 2010 the cost threshold will be $3000, and sponsors’ targeting criteria should be adjusted accordingly.

Sponsors are required to target beneficiaries for enrollment at least quarterly during the year to allow more Medicare beneficiaries to have access to the MTM program earlier in the year. For example, daily, weekly, monthly, or quarterly targeting frequencies would meet this requirement. However, CMS also expects Part D sponsors to promote continuity of care by performing an end-of-year analysis that identifies current MTM program participants who will continue to meet the eligibility criteria for the next program year for the same plan. This targeting could be done to auto-enroll eligible beneficiaries in the plan’s MTM program early in the next program year in order to provide MTM interventions with less interruption.
Additionally, sponsors are required to enroll targeted beneficiaries into MTM programs using only an opt-out method. A beneficiary that meets the targeting criteria would be auto-enrolled and considered to be enrolled unless he/she declines enrollment. The enrolled beneficiaries may refuse or decline individual services without having to disenroll from the program. This requirement will allow Medicare beneficiaries to have more access to MTM services and increase member compliance and enrollment into these programs. Part D sponsors are reminded that if an enrollee chooses to opt-out of the plan’s MTM program, they must continue to apply their existing drug utilization management program to ensure the beneficiary receives high quality prescription drug coverage.

Although plans decide how potential providers of MTM services are informed of MTM qualified beneficiaries, CMS envisions that the most common method for identifying targeted beneficiaries to individuals responsible for providing the services (e.g., pharmacists), will be system edits, computerized notices that appear on the pharmacists’ computer when a beneficiary fills a prescription. CMS expects that sponsors and pharmacists will coordinate these edits as part of the terms and conditions of their contracts. Therefore, Part D sponsors need to develop appropriate mechanisms for identifying and notifying targeted beneficiaries who are eligible for MTM services.

Should an enrollee desire to permanently opt-out of the plan’s MTM program, the plan should honor the request and not re-target the beneficiary in future contract years; however, if the enrollee actively seeks enrollment into the MTMP at a later time, perhaps due to a level of care change, the plan must allow the enrollee to participate as long as he or she meet the necessary MTMP requirements.

Although participation in MTMPs is voluntary for beneficiaries, CMS hopes they will participate to improve their therapeutic outcomes. Beneficiaries must not be denied access to prescription drugs based upon failure to participate in MTMPs.

**30.3 – MTM services**
*Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10*

At a minimum, Part D sponsors are expected to offer MTM services that include the following:

1. **Offer a comprehensive medication review (CMR) by a pharmacist or other qualified provider at least annually to all targeted beneficiaries enrolled in the MTM program.** A CMR is a review of a beneficiary’s medications, including prescription, over-the-counter (OTC) medications, herbal therapies and dietary supplements, that is intended to aid in assessing medication therapy and optimizing patient outcomes. While initial preparations to assess medication use and identify medication-related problems before the patient interaction may be conducted ‘behind the scenes’, they are only a piece of the overall comprehensive medication review. CMS recognizes the importance of offering an interactive, person-to-person consultation with the beneficiary for a complete assessment of the beneficiary’s needs to improve medication use or outcomes. This includes three components:
a. Review of medications to assess medication use and identify medication-related problems. This may be conducted person-to-person or ‘behind the scenes’ by a qualified provider and/or using computerized, clinical algorithms.

b. Offering to provide to each targeted beneficiary enrolled in the MTM program an interactive, person-to-person consultation performed by a qualified provider. This real-time interaction may be face-to-face or through other interactive methods such as the telephone. This interaction may include further assessment of the beneficiary’s medication history and use (could enable sponsors to collect information from the beneficiary, such as OTC medications or supplements, that is outside of the claims data they have access to), health status, clinical information, adverse events, or other issues that could affect medication use or outcomes.

c. Implementation of a systematic process to summarize the interactive consultation and provide an individualized written “take-away” to the beneficiary such as a personal medication record, reconciled medication list, action plan, recommendations for monitoring, education, or self-management, etc.

2. For ongoing monitoring, perform targeted medication reviews for all beneficiaries enrolled in the MTM program, no less often than quarterly, to assess medication use since the CMR, monitor whether any unresolved issues need attention, new drug therapy problems have arisen, or if the beneficiary has experienced a transition in care. Part D sponsors must assess the findings of these reviews to determine if a follow-up intervention is necessary and if the intervention is warranted for the beneficiary and/or prescriber. These assessments could be person-to-person and/or system generated. The follow-up interventions should be interactive, if possible, but may be delivered via U.S. mail or other means.

3. Offer interventions targeted to prescribers to resolve medication-related problems or other opportunities to optimize the targeted beneficiary’s medication use. These interactions may be passive (e.g., faxed, mailed) or interactive when determined necessary.

For targeted beneficiaries enrolled in the MTM program that are in an LTC setting, sponsors are not required to offer the interactive CMR component, but still must perform quarterly medication reviews and offer interventions targeted to the beneficiaries’ prescribers.

While all targeted beneficiaries should be offered a CMR, the beneficiaries may refuse the CMR or individual services. Even if a beneficiary declines the CMR, sponsors should conduct quarterly targeted medication reviews for all targeted beneficiaries and offer interventions to the prescriber.

CMS expects that sponsors will have procedures in place to drive participation and follow-up with beneficiaries that do not respond to initial offers for MTM services. In addition, sponsors
are expected to consider using more than one approach when possible to reach all eligible patients who may wish to receive MTM services.

30.4 – **Use of Experts**  
*(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)*

MTMPs should be developed in cooperation with licensed and practicing pharmacists and physicians. Part D sponsors are expected to comply with State licensure requirements for pharmacy practice and ensure that network providers, where appropriate, are licensed accordingly.

30.5 – **Considerations in MTMP Fees**  
*(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)*

A Part D sponsor must—

- Describe in its application how it takes into account the resources used and time required to implement the MTMP it chooses to adopt in establishing fees for pharmacists or others providing MTMP services for covered Part D drugs under a Part D plan.

- Disclose to CMS, upon request, the amount of the management and the portion paid for MTMP services to pharmacists and others upon request. Reports of these amounts are protected under the confidentiality provisions of section 1927(b)(3)(D) of the Act.

Individual plans determine fees associated with providing MTMPs, which may include services offered by pharmacists or other providers. Part D sponsors will have the flexibility to establish their own fees, but must take into account the time and resources associated with implementing the MTMP. CMS will require potential Part D sponsors to explain, as part of their application, how their fees account for the time and resources associated with their medication therapy management program.

CMS considers MTMP services provided to targeted beneficiaries as an administrative cost (included in the plan bid), incident to appropriate drug therapy, and not an additional benefit.

30.6 – **MTMP Application**  
*(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)*

Each Part D sponsor is required to incorporate an MTMP into its plans’ benefit structure. Annually, all Part D sponsors, including renewing sponsors and new applicants, must submit an MTMP description to CMS for review and approval. A CMS-approved MTMP is one of several required elements in the development of sponsors’ bids for a contract year.

MA Private Fee for Service (MA-PFFS) organizations, as described in 42 CFR 422.4 (a)(3), are not required to have an MTMP. However, given that MA-PFFS organizations have an equal responsibility to provide a quality Part D product, CMS encourages MA-PFFS organizations to establish MTMPs to improve quality for their enrollees and to submit their program to CMS for
review. [NOTE: MTMPs offered by MA-PFFS organizations should meet the same standards as other Part D MTMPs.]

The MTMP submission should be submitted through the Health Plan Management System (HPMS) in the MTMP module. This interface was established to enable Part D sponsors to enter, edit, and submit their MTMP descriptions within HPMS at the contract level. The submitted MTMP descriptions should be as detailed as possible and an MTMP submission template is provided as a guide to facilitate the submission process. This memorandum is updated annually and posted on the MTMP Web page (see Appendix A).

CMS will communicate with each sponsor regarding the status of their MTMP review (including if the MTMP requires resubmission to correct deficiencies or if the MTMP meets all of the minimum requirements for the contract year). Communications will be sent via email to the HPMS MTMP Main Contact and Medicare Compliance Officer. Sponsors should ensure that their contact information is up-to-date in HPMS under the Contract Management section.

If a Part D sponsor needs to submit an MTMP outside of the initial submission upload and resubmission processes, it should email a request to have the submission gate opened to partd_mtm@cms.hhs.gov. The following represents information that sponsors are required to submit as part of their MTMP applications.

**Information that MUST be included with the MTMP Application**

- **Criteria #1: Multiple Chronic Diseases**
  - Provide the minimum number of chronic diseases a beneficiary must have to meet this criterion. (NOTE: the definition of multiple is any number of two or more)
  - Provide the specific name of each chronic disease that applies or if any chronic disease applies.
  - Example 1: A beneficiary must have any two or more chronic diseases.
  - Example 2: A beneficiary must have two or more chronic diseases. The following chronic diseases will be targeted: Respiratory Disease-asthma, Respiratory Disease-COPD, Bone Disease-arthritis-rheumatoid arthritis, dyslipidemia, Mental Health-depression, autoimmune disorders, HIV/AIDS.

- **Criteria #2: Multiple Covered Part D Drugs**
  - Provide the minimum number of covered Part D drugs that a beneficiary must have filled to meet this criterion. (NOTE: the definition of multiple is any number of two or more)
  - Provide the type of covered Part D drugs that applies (i.e., any Part D drug, chronic/ maintenance drugs, disease-specific, specific Part D drug classes).
• Example 1: A beneficiary must have filled any five or more distinct covered Part D drugs.

• Example 2: A beneficiary must have filled any two or more distinct covered Part D chronic/maintenance drugs.

• Criteria #3: Are likely to incur annual costs for covered Part D drugs that exceed a predetermined level as specified by the Secretary.

  • Provide a detailed description of the analytical procedure used to determine if a beneficiary is likely to incur annual costs in excess of a predetermined level as specified by the Secretary for all covered Part D drugs.

  • Example 1: Provide the monthly or quarterly dollar threshold per beneficiary for covered Part D drugs (the specific threshold should be provided).

  • Example 2: Describe the predictive model used to identify beneficiaries who are likely to incur this annual cost.

• Procedure and frequency of identifying beneficiaries

  • Provide the frequency of identifying beneficiaries which is required to be no less frequently than quarterly. For example, daily, weekly, monthly or quarterly targeting frequencies should meet this requirement.

  • Describe the data evaluated for targeting eligible beneficiaries. Examples include drug claims, medical claims, lab data, etc.

• Methods of enrollment and disenrollment. Sponsors are required to enroll targeted beneficiaries using an opt-out model.

• Type, frequency and recipient of interventions.

  • Provide the recipient of MTM interventions. This will automatically default to beneficiary and prescriber. Other recipients may also be provided.

  • Provide the specific beneficiary interventions:

    • This will automatically default to review of medications, interactive, person-to-person consultation, and individualized, written summary of the interactive consultation.

    • Selections must be provided for the delivery method(s) for the interactive consultation and the type(s) of written takeaways.
• Targeted medication reviews at least quarterly will also be an automatic default.

• Additionally, other beneficiary interventions may be provided.

  o Provide the specific prescriber interventions:

    • This will automatically default to prescriber interventions to resolve medication-related problems or optimize therapy.

    • Selections must be provided for the delivery method(s) for the prescriber consultation.

    • Additionally, other prescriber interventions may be provided.

  o Provide a detailed description of how your program will provide the MTM interventions for both beneficiaries and prescribers, including the annual comprehensive medication review for the beneficiary, which includes a review of medications, interactive, person-to-person consultation, and an individualized, written summary of interactive consultation, and quarterly targeted medication reviews.

• Resources and who will provide MTM services.

  o Provide the type of personnel that will be providing the MTM services such as in-house staff or the type of outside personnel.

  o Provide the type of qualified provider such as pharmacist, physician, or registered nurse.

• How fees will be established for MTM if using outside personnel. If establishing fees for pharmacists or others, provide the amount of fee respective to MTM management and the fee paid for the provider of the MTM.

  o Provide if fees are covered as part of the services of the global Pharmacy Benefits Manager (PBM) or vendor contract (without being priced out separately) or if fees are priced out separately.

  o If the fees are priced out separately and the plan is charged a fee by the PBM or vendor within the contract, then a description of the specific fees needs to be reported.

    • Provide the specific fee(s), billing method(s) such as per minute or per service. A description of these fees may also be included.

• Methods of documenting and measuring outcomes.
30.7 – MTMP Approval Considerations
(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

During the MTMP approval process, CMS reviews the MTMP submission to ensure Part D sponsors meet the following expectations:

- Beneficiaries will not be disenrolled from the MTMP program if they no longer meet one or more of the MTMP eligibility criteria as defined above, and will remain in the MTMP program for the remainder of the calendar year;

- The MTMP will serve and provide interventions for enrollees who meet all three of the required criteria, as defined above, regardless of setting (e.g., ambulatory, long term care, etc.);

- The MTMP will not include discriminatory exclusion criteria. If an enrollee meets all three of the required criteria as described by the plan, the enrollee should be eligible for MTM intervention;

- The plan will put into place safeguards against discrimination based on the nature of its MTM interventions (i.e., TTY if phone-based, Braille if mail-based, etc.).

- The plan will consider the provision of the other prescription drug quality improvement interventions to beneficiaries who do not meet all three of the required MTMP criteria as described by the plan, however, these cannot be considered for MTM reimbursement by CMS.

- Plans will promote continuity of care by performing an end-of-year analysis that identifies current MTM program participants who will continue to meet the eligibility criteria for the next program year for the same plan.

- Plans will have procedures in place to drive participation and follow-up with beneficiaries that do not respond to initial offers for MTM services.

- Plans will consider using more than one approach when possible to reach all eligible patients who may wish to receive MTM services.

- Plans will analyze and evaluate their MTMP and make changes to continuously improve their programs.

An MTMP is based on the contract year. The plan's bid should take into account MTM costs for the applicable contract year, as MTMPs can change from year to year. As mentioned above, it is CMS’ expectation that once enrolled in the MTMP, beneficiaries will not be disenrolled if they no longer meet one or more of the MTMP eligibility criteria as defined by the plan and will
remain enrolled in the MTMP program for the remainder of the calendar/contract year. This expectation, however, would not apply across contract years.

**30.8 – Mid-Year MTMP Changes**
*(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)*

*Once an MTMP is approved by CMS during the Annual Review, limited changes to the Part D sponsors’ MTMP may be allowed in accordance with CMS policy. To promote evolving MTM best practices and to serve the best interests of the Medicare beneficiary, CMS allows certain mid-year changes to Part D sponsors’ approved MTMPs during three Update Cycle windows: March 1-March 10, June 1-June 10, and September 1-September 10. All proposed MTMP changes must be submitted to CMS for review and approval prior to the implementation of requested changes.*

CMS has a four part policy regarding MTMP changes during the program year or prior to the start of the upcoming program year.

1. Part D sponsors may make positive changes to the plan-designed eligibility criteria for multiple chronic diseases, multiple covered Part D drugs, or analytical procedures used to determine if a beneficiary is likely to incur annual costs in excess of a predetermined level as specified by the Secretary. These changes would make eligibility for the MTMP more inclusive and could increase the number of beneficiaries eligible to receive Part D MTM services. Positive changes may include:
   - Decreasing the minimum number of multiple chronic diseases.
   - Expanding the list of specific chronic diseases that apply.
   - Decreasing the minimum number of multiple covered Part D drugs.
   - Expanding the list of specific covered Part D drugs, or types of drugs, that apply.

2. Part D sponsors may make program enhancements or maintenance changes, including changes to:
   - *Frequency of* identification of potential enrollees to increase or promote ease of beneficiary participation.
   - Expand the levels of intervention or services provided to participating targeted beneficiaries.
   - Methods of documenting and measuring outcomes.

3. Part D sponsors may make changes to the following:
   - The provider of MTM services.
Any fee schedules established for pharmacists and other MTM providers if using outside personnel. CMS will request that Part D sponsors disclose the newly established fees for outside personnel.

4. Part D sponsors may not make any negative changes to their MTMP. While the following list is not exhaustive, potentially negative changes include those that:

- Promote discriminatory or exclusionary practices.
- Decrease the number of enrollees eligible for MTM services.
- Lower quality or robustness of MTM services.

MTMP requests for changes during the program year may be submitted to CMS during any of the three Update Cycle windows: March 1-March 10, June 1-June 10, and September 1-September 10. Requests for changes to an approved MTMP that would be effective for an upcoming program year should be submitted to CMS during the September 1-September 10 update cycle window.

The MTMP change request should be submitted through the HPMS in the MTMP submission module under “Plan Formularies.” This interface was established to enable Part D sponsors to enter, edit, and submit their MTMP descriptions within HPMS at the contract level. The ‘MTMP Change Request Form’ is now integrated within the enter/edit function of the MTMP submission module for the Update Cycles. The MTMP submission gates to enter/edit the MTMP will automatically be open during the Update Cycle windows. For any submissions made in the Update Cycles due to updates, required resubmissions, and contract exceptions, a sponsor is required to enter information in the Change Request Form Description field(s) to justify the change on the Enter/Edit pages and check the attestation, “I attest that the following change(s) do not impact approved MTM marketing materials or such marketing materials will be submitted and approved by CMS as necessary prior to implementation of the change” on the Verify Submission page.

Part D sponsors will receive an email correspondence regarding the approval of the MTMP change request. Part D plans must not implement changes until they receive explicit notification of approval from CMS, and must not include any changes in marketing material until receiving explicit and affirmative CMS approval. Depending upon the number of submitted requests, plans should expect a response within 30 days. A memo containing information and additional instruction related to Part D MTMP change requests is posted at MTMP Web page, see Appendix A.

30.9 – MTMP Reporting
(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

Part D sponsors will be required to provide CMS with data on a semiannual basis that will allow CMS to determine whether plan MTMPs comply with the standards outlined in this chapter.
Consistent with CMS's 2010 Part D reporting requirements, Part D sponsors must measure and report, at the beneficiary level, the number of CMRs, the number of targeted medication reviews, number of prescriber interventions, and the change(s) in therapy directly resulting from the MTM interventions.

For more information about these reporting requirements, see Appendix A for the MTMP Web page.

30.10 – Claims Processing for MTM Services
(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

For MTM claims processing, covered entities should use the American Standards Committee (ASC) X12 837P Version 4010/4010A1. CMS articulated in its January 28, 2005 Final Rule on the Medicare Prescription Drug Benefit that CMS viewed MTM as a clinical service (70 FR 4194, 4231). Therefore, claims for MTM would be considered professional health care claims rather than retail pharmacy drug claims. Pursuant to the Health Insurance Portability and Accountability Act (HIPAA) of 1996, the ASC X12 837P was adopted as the transaction standard for professional health care claims. Therefore, similar to physician clinical services, if MTM providers bill Part D sponsors electronically for MTM services, such billing claims must be transmitted using the ASC X12 837 P Version 4010/4010A1. Part D sponsors are not precluded from using the NCPDP 5.1 system edits as a method to identify targeted beneficiaries, or provide applicable information at the point of service to pharmacists or other MTM providers responsible for providing the MTM services, but the health care claim must be transmitted using the ASC X12 837P.

While CMS adheres to its foregoing interpretation of the regulations requiring that MTM retail pharmacy services be reported using the X12 837P standard, CMS recognizes that a reasonable argument could be advanced in response to the Department of Health and Human Services (HHS) seeking to enforce this regulation, contending that the regulations could be read to instead direct the use of the NCPDP, Version 5.1 standard for such services. CMS further realizes that notice and comment rulemaking, which HHS anticipates initiating in the near future, will very likely resolve the apparent ambiguity of these regulatory provisions. In light of the foregoing planned rulemaking and the uncertain outcome of any enforcement action, CMS elects not to take enforcement action against those covered entities that continue to use the NCPDP, Version 5.1 standard for this transaction.

40 – Consumer Satisfaction Surveys
(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)

40.1 – General Rule
(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)

Section 1860D-4(d) of the Act specifies that consumer satisfaction surveys be conducted for Part D in a manner similar to how they are conducted for MA plans. Accordingly, CMS will use the Consumer Assessment of Healthcare Providers and System (CAHPS®) Survey process established for Part C at 42 CFR 422.152(b).
The CAHPS® survey is conducted annually to assess the experiences of beneficiaries with the services they receive from their health plan. The CAHPS® survey is designed to provide information in a timely manner to Medicare beneficiaries in order to facilitate their plan choice which is normally made during the fall of the year. The survey is also used by CMS and MA organizations as a tool in assessing and benchmarking plan performance. Survey respondents are comprised of a randomly selected sample of plan enrollees who were members of a plan for at least 6 months.

The Medicare CAHPS® survey includes questions about prescription drug benefits in order to assess Medicare beneficiaries’ experiences with Medicare prescription drug coverage. For Medicare Advantage plans, the questions relevant to Part D are asked only of those Medicare Advantage enrollees with prescription drug coverage, whereas stand-alone Part D plan enrollees are sent a separate survey. CAHPS® questions focus on beneficiaries’ experience with getting needed information about their prescription drug plan and with getting the prescription drugs they need.

The results of the Medicare CAHPS® survey are compiled annually and disseminated to all Part D sponsors in January of each year. For purposes of display on the Medicare Prescription Drug Plan Finder, elements of the CAHPS® survey are compared to a national average and assigned star ratings depending on their item or composite average. During annual enrollment, beneficiaries can review the star ratings as part of their overall decision making process about drug coverage for the upcoming contract year.

40.2 – Part D Sponsor Follow-up Responsibilities
(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)

Specific responsibilities for plan follow-up based upon survey results from CAPH'S®, once developed, will be described here.

50 – Electronic Prescription Program (E-prescribing)
(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)

50.1 – General Rule
(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)

Section 101 of the MMA added section 1860D-4(e) to the Act to require that prescriptions and certain other information for covered Part D drugs prescribed for Part D eligible individuals that are transmitted electronically be transmitted in accordance with designated uniform standards. 42 CFR 423.160(a) requires Part D sponsors to establish and maintain an electronic prescription drug program that complies with those designated uniform standards when transmitting prescriptions and prescription-related information using electronic media.

To satisfy these requirements, CMS expects Part D sponsors to have all the necessary contracts and systems in place should prescribers desire to electronically transmit prescriptions for their Medicare eligible patients. This includes ensuring that network pharmacies can receive
electronic prescriptions (with allowance for exceptions when it is impractical or otherwise could jeopardize beneficiary access) in accordance with the adopted standards.

In order to monitor the uptake of electronic prescribing in the Part D program, CMS needs to collect prescription level data that demonstrates the frequency of electronic prescribing. CMS believes the most effective method for gathering this data is use of the Prescription Origin Code via the NCPDP 5.1 optional field 419 DJ. CMS expects to add a new optional field to the Prescription Drug Event (PDE) record that will capture the Prescription Origin Code, and CMS strongly recommends that Part D sponsors work with their network pharmacies to voluntarily begin using the 419 DJ field.

Part D plans will also be responsible for complying with future e-prescribing standards that are adopted as part of the industry standard or regulatory process. The final e-prescribing standards that have been adopted thus far establish a framework from which a robust, interoperable e-prescribing environment can develop and grow. CMS expects significant activity in this area given the rapid development of e-prescribing and its ability to improve quality of care for Part D eligible Medicare beneficiaries. Part D sponsors should familiarize themselves with the CMS e-prescribing Web site (see Appendix A) and remain current with all the e-prescribing requirements, standards and exemptions.

Except to the extent that the Drug Enforcement Agency (DEA) states otherwise, these e-prescribing rules do not apply to controlled drugs, even though such drugs may satisfy the definition of a Part D drug. Controlled drug substances remain under the jurisdiction of the DEA under the Controlled Substances Act. HHS and the DEA are working together to address the intersection of these regulations to ensure reliable standards are implemented across all prescribing environments.

50.2 – State Law Preemption
(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)

Section 1860D-4(e)(5) of the Act preempts State laws and regulations that are either contrary to the Federal standards or that restrict the ability to carry out (that is, stand as an obstacle to), the electronic prescription drug program requirements, and that also pertain to the electronic transmission of prescriptions or certain information regarding Part D drugs for Part D eligible individuals. CMS has identified several categories of State laws that are preempted in whole, or in part. These categories are intended to be examples and do not constitute an exhaustive list. Those categories of State laws that are preempted include:


2. State laws that prohibit the transmission of electronic prescriptions through intermediaries, such as networks and switches or pharmacy benefit managers (PBMs), or that prohibit access to such prescriptions by plans or their agents or other duly authorized third parties.
3. State laws that require certain language to be used, such as dispense as written, to indicate whether generic drugs may or may not be substituted, insofar as such language is not consistent with the adopted standard.

4. State laws that require handwritten signatures or other handwriting on prescriptions.

50.3 – Standards for E-Prescribing  
(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

Part D sponsors are required to establish electronic prescription drug programs to provide for electronic transmission of certain information to the prescribing provider and the dispensing pharmacy and pharmacist. There is no requirement that prescribers or dispensers implement e-prescribing. However, prescribers and dispensers who electronically transmit prescription and certain other prescription-related information for Medicare Part D covered drugs prescribed for Medicare Part D eligible individuals are required to comply with any applicable final standards that are in effect.

Part D sponsors should ensure that their pharmacy contracts require compliance with the Part D e-prescribing standards whenever the network pharmacy electronically receives or transmits prescriptions or prescription-related information about Part D covered drugs that are prescribed to Part D eligible individuals. Although Part D sponsors are not required to pay for standard e-prescribing transactions between prescribers and network pharmacies, such e-prescribing transaction costs incurred by their network pharmacies are legitimate Part D overhead costs that should be a consideration in setting network dispensing fees.

The Medicare Modernization Act (MMA) required the identification of potential e-prescribing standards, which the Secretary would recognize as “initial uniform standards.” These standards would generally be subject to pilot testing prior to the promulgation of final uniform standards. This general requirement was to be waived, however, in instances in which there was “adequate industry experience” with an initial standard.

The Secretary recognized a number of initial standards. Three met the requirements for adequate industry experience. The “E-Prescribing and the Prescription Drug Program” final rule, which was published in the Federal Register on November 7, 2005, (70 FR 67568) adopted these “foundation e-prescribing standards.” CMS refers to them as "foundation standards" because they were the first set of final standards adopted for the Part D e-prescribing program. As subsequently amended (see, 73 FR 18918) the foundation standards are as follows:

1. Prescription standards.

On or after April 1, 2009, The National Council for the Prescription Drug Programs (NCPDP)Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1, (Version 8.1) October 2005, to provide for the communication of a prescription or prescription-related information between prescribers and dispensers, for the following:
○ Get message transaction.
○ Status response transaction.
○ Error response transaction.
○ New prescription transaction.
○ Prescription change request transaction.
○ Prescription change response transaction.
○ Refill prescription request transaction.
○ Refill prescription response transaction.
○ Verification transaction.
○ Password change transaction.
○ Cancel prescription request transaction.
○ Cancel prescription response transaction.

2. Eligibility standards.

○ For transmitting eligibility inquiries and responses between prescribers and Part D sponsors—


○ For transmitting eligibility inquiries and responses between dispensers and Part D sponsors—


Six other initial standards were pilot tested. Based upon the evaluation of the pilot project and public comments CMS issued the Standards for E-Prescribing Under Medicare Part D final rule (73 FR 18918) adopting four additional e-prescribing standards with which Part D sponsors’ e-prescribing programs must also comply. These four standards are:

1. Medication History

○ To provide for the communication of Part D medication history information among Medicare Part D sponsors, prescribers, and dispensers—
2. **Prescription Fill Status Notification (RxFill)**

   - To provide for the communication of prescription fill status between prescribers and dispensers—


3. **Formulary and Benefits**

   - For transmitting formulary and benefits information between prescribers and Part D sponsors—


   This standard includes five separate files for providing formulary or benefit information to the prescriber:

   - Formulary Status List
   - Formulary Alternatives List
   - Benefit Coverage List
   - Benefit Copay List
   - Drug Classification List

   *Part D sponsors must be capable of sending all of these files electronically using the adopted standard if such information is requested, including all conditional fields for all these files if such information is requested by prescribers.*

4. **Provider Identifier**

   - To identify an individual health care provider to Part D sponsors, prescribers and dispensers, in electronically transmitted prescriptions or prescription-related materials for Part D covered drugs for Part D eligible individuals—

   *The National Provider Identifier (NPI), as defined at 45 CFR 162.406.*

   *In order to monitor the uptake of e-prescribing in the Part D program, Part D sponsors are required to obtain the Prescription Origin Code via the NCPDP Telecommunication Standard 5.1 optional field 419 DJ and report this code on their prescription drug event (PDE) submissions. A corresponding Prescription Origin Code field has been added to the PDE record file layout and PDE return file layout at field number 41.*
CMS requires the Prescription Origin Code (using alphanumeric values 1-4) only on PDEs for new prescriptions submitted in Standard format (currently Standard format is NCPDP Telecommunication Standard 5.1). The Prescription Origin Code will remain optional for all PDEs for refills submitted in the Standard format and for all PDEs submitted in the Non-Standard Format. Further, the Part D sponsor has the options to report “blank” for PDEs for refills and Non-Standard format PDEs.

50.4 – Exemptions
(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)

The November 7, 2005, foundation standards final rule (70 FR 67568) implemented specific exemptions for certain entities potentially involved in e-prescribing. These exemptions continue to change as improvements are realized in the e-prescribing environment. Part D sponsors should remain aware of these exemptions and work with their network pharmacies as necessary.

1. Entities may use either Health Level 7 (HL7) messages or the NCPDP SCRIPT Standard to transmit prescriptions or prescription-related information internally when the sender and the recipient are part of the same legal entity. If an entity sends prescriptions outside the entity (for example, from an HMO to a non-HMO pharmacy), it must use the adopted NCPDP SCRIPT Standard or other applicable adopted standards. Any pharmacy within an entity must be able to receive electronic prescription transmittals for Medicare beneficiaries from outside the entity using the adopted NCPDP SCRIPT Standard.

   This exemption does not supersede any HIPAA requirement that may require the use of a HIPAA transaction standard within an organization. For further information on the HIPAA transaction standards, refer to 45 CFR 162, or the NCPDP or ASC Web sites at www.ncpdp.org or www.x12.org respectively.

2. Entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider (such as a nursing facility) that, in turn, forwards the prescription to a dispenser, are exempt from the requirements to use the NCPDP SCRIPT Standard in transmitting such prescriptions or prescription-related information.

3. Entities transmitting prescriptions or prescription-related information by means of computer-generated facsimile are exempt from the requirement to use the NCPDP SCRIPT Standard in transmitting such prescriptions or prescription-related information.

4. In accordance with section 1860D-4(e)(5) of the Act, the standards specified in 42 CFR 423.160(b) supersede any State law or regulation that—

   o Is contrary to the standards or restricts the ability to carry out Part D of Title XVIII of the Act; and
Pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered Part D drugs under Part D of Title XVIII of the Act.

50.5 – Promotion of Electronic Prescribing by MA-PD Plans
(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)

An MA organization offering an MA-PD plan may provide for a separate or differential payment to a participating physician that prescribes covered Part D drugs in accordance with the electronic prescription standards established in the Federal regulations at 42 CFR 423.160(b). Any payments must be in compliance with applicable Federal and State laws related to fraud and abuse, including the physician self-referral prohibition (section 1877 of the Act), and the Federal anti-kickback statute (section 1128B (b) of the Act), and incentives must not inappropriately influence physician prescribing patterns.

60 – Drug Utilization Management Program
(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)

60.1 – General Rule
(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)

A Part D sponsor must establish a reasonable and appropriate drug utilization management program that—

- Maintains policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications;
- Provides CMS with information concerning the procedures and performance of its drug utilization management program, according to guidelines specified by CMS; and,
- Includes incentives to reduce costs when medically appropriate.

Common utilization management tools include formularies, prior authorization requirements, and promotion of lower cost generics. Part D sponsors will be required to submit their utilization management tools to CMS for approval as a component of the sponsor’s formulary. Further information on formulary benefit management tools, including CMS expectations on criteria, can be found in Chapter 6 of the Medicare Prescription Drug Benefit Manual.

60.2 – Over-the-Counter Drugs as Part of Utilization Management Programs
(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

Over-the-counter drugs (OTCs), many of which (e.g., Prilosec OTC® and Zyrtec®) were available by prescription when first marketed, may offer significantly less expensive alternatives to branded prescription medications. The MMA does not allow Medicare plans to include OTCs as part of their drug benefit or supplemental coverage. However, CMS allows Part D sponsors the option to provide OTCs as part of their administrative cost structure. Consequently, for those
Part D sponsors who elect to do so, OTCs are a component of the plan premium and result in OTCs provided to the enrollee without any direct cost-sharing at the point of sale. Furthermore, if Part D sponsors elect to provide OTCs they must do so for the full duration of the contract year and cannot limit OTCs to certain benefit phases.

Part D sponsors may offer OTCs either as (1) part of general drug utilization management or (2) as part of a step therapy protocol. To ensure safe and effective use of OTCs, Part D sponsors will submit an OTC drug file, along with their HPMS formulary submission, identifying which OTCs will be provided. Upon bid approval, Part D sponsors are prohibited from removing OTCs from their plan offering for the full contract year. Enhancements of OTC offerings (i.e., additional OTC step 1 drugs or providing recently converted OTCs as part of general drug utilization management) are permitted mid-year.

If a Part D sponsor includes OTCs as a part of its general drug utilization management strategy, the sponsor may only require prior authorization or otherwise limit dispensing of formulary alternatives if such limitation is readily resolvable at the point of sale. Should beneficiaries decide that they do not want to take advantage of the zero cost OTCs, they must be provided access to the prescription product or formulary alternative the physician has prescribed for them. Conversely, if OTCs are offered as part of an approved step therapy protocol, the step therapy edit is not required to be resolvable at point of sale; however, Part D sponsors must be able to disclose the protocol requirements to beneficiaries or their representatives in accordance with section 60.4 of this chapter.

Part D sponsors choosing to include OTC products should be prepared to appropriately educate their enrollees on the difference between OTCs provided as part of the administrative costs component of the plan benefit, as opposed to covered Part D drugs. Although beneficiaries will enjoy no direct cost-sharing on these OTCs, they will not have the same beneficiary protections, such as coverage determinations or temporary fills, required to ensure appropriate access to Part D drugs. (This does not affect enrollees’ ability to pursue an exception or appeal of a step-therapy requirement where the plan requires the enrollee to use an OTC agent prior to covering a Part D drug. The enrollee could pursue an exception or appeal in order to directly access the prescription drug without trying the OTC drug first.)

60.3 – Exception for Private Fee-for-Service MA Plans
(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)

A private fee-for-service (PFFS) MA plan, as described in 42 CFR 422.4(a)(3), that offers qualified prescription drug coverage, is exempt from the requirement to establish a drug utilization management program. If a PFFS MA plan elects to implement a drug utilization management program, they must comply with all of the requirements contained in this chapter.

60.4 – Drug Utilization Management Disclosure Requirements
(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

Part D sponsors must provide current and prospective enrollees (or their physician or authorized representative) with information regarding specific prior authorization criteria and other
utilization management requirements (i.e., step therapy and quantity limits). This information must be made available on a timely basis so that beneficiaries can make informed enrollment decisions and so that physicians can access information that will help avoid delays at the pharmacy and potential interruptions in drug therapy.

Instructions at 42 CFR 423.128(c)(1)(v) and (c)(2) require Part D sponsors to provide Part D eligible beneficiaries information about their formulary and utilization management procedures. Similarly, 42 CFR 423.128(d) requires Part D sponsors to provide current and prospective beneficiaries “specific information” such as specific prior authorization requirements, “on a timely basis” through a toll-free customer service call center. Accordingly, Part D sponsors must explain their utilization management requirements and criteria through their customer service call centers. To ensure that such requests are addressed in a timely manner, if the customer service representative is unable to adequately address or answer the enrollee’s (or his/her authorized representative’s) or physician’s questions, sponsors must expedite the call to their pharmacy technical help call center where further detail can be provided on the drug and utilization management criteria in question.

60.5 – Website Posting Requirements
(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

Part D sponsors must post their approved PA criteria (including PA criteria applied to supplemental drugs provided by enhanced alternative plans), quantity limit restrictions and step therapy requirements on plan Web sites. Given the uniformity that results from utilization of a standardized HPMS submission form during formulary review, CMS believes that Web page posting of this information will augment the Part D sponsor’s ability to rapidly provide this information, improve transparency and allow Part D plan comparison during enrollment. Part D sponsors will need to ensure that all approved utilization management (UM) criteria are posted on Part D sponsor Web sites in the formulary section by November 15 each year. CMS expects Part D sponsors to make these criteria available for beneficiary viewing either from a link when the drug identified with UM is displayed or from a general link on the formulary page. Part D sponsors will be expected to display all of the UM criteria content contained within the CMS approved HPMS files without modification. Minor grammatical changes will be permitted for display purposes in cases where abbreviations or grammatical errors occurred due to HPMS file character limitations.

60.6 – Revision of Utilization Management Criteria Requirements
(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)

Part D sponsors must not change existing utilization management criteria (i.e., prior authorization, step therapy, or quantity limits) to make them more restrictive or limiting without direct CMS approval. During the contract year, a Part D sponsor should not need significant revision of its approved criteria. For instance, submitted PA criteria should already have been evaluated for clinical accuracy, since in accordance with 42 CFR 423.120(b)(vi), the sponsor’s Pharmacy and Therapeutics Committee has completed a thorough review of proposed PA criteria prior to submission of the formulary to CMS. Furthermore, during the annual enrollment period, beneficiaries may view plan prior authorization criteria as a component of making informed
decisions. To permit changes after the annual enrollment period could undermine beneficiaries’ enrollment decisions and anticipated drug coverage. As a result, it is CMS’ expectation that Part D sponsors will not update their utilization management criteria except under extraordinary circumstances, such as when new drug safety-related information becomes available during the contract year (e.g., FDA release of a new Black Box warning).

In the event that a Part D sponsor needs to make its utilization management criteria more restrictive, the sponsor will be required to submit the proposed changes to CMS in advance. CMS will address each request in order of receipt and will generally only permit criteria changes to incorporate new safety information. Conversely, Part D sponsors are not required to receive CMS approval in order to make their existing utilization management criteria less restrictive. For example, when sponsors are modifying their criteria to indicate coverage for new medically-accepted indications or removing certain diagnostic criteria, the sponsors are not required to notify CMS of such mid-year changes. However, even though there is no notice requirement, sponsors must still submit the appropriate updated utilization management criteria document reflecting the formulary enhancements during the next available HPMS formulary upload window.

### 70 - Part D Complaints Processing
(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)

#### 70.1 – General Rule
(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

In accordance with 42 CFR 423.564, Part D sponsors must provide meaningful procedures for timely hearing and resolving enrollee grievances. Chapter 18 of this manual (see Appendix A for Web site) defines a grievance as any complaint or dispute other than one that involves a coverage determination or a low-income subsidy or late enrollment penalty determination, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Part D sponsor, regardless of whether remedial action is requested. A grievance may also include a complaint that a Part D plan sponsor refused to expedite a coverage determination or redetermination. Grievances may include complaints regarding the timeliness, appropriateness, access to, and/or setting of a provided item. CMS recommends that plans record and monitor grievances separately from Complaints Tracking Module (CTM) complaints as part of their Part D reporting requirements. Upon receiving a complaint, a Part D sponsor must promptly review the submitted case and notify the enrollee of its decision as expeditiously as the case requires based upon the enrollee’s health status. To facilitate and streamline this process CMS has developed the CTM system for tracking and processing complaints received from beneficiaries and providers specifically related to the Part D Medicare Prescription Drug Program. CTM may be populated by a number of sources, including CMS contractor at 1800Medicare, CMS staff or Part D sponsors. Given the time sensitive nature of many of the submitted complaints, Part D sponsors should continuously access, view, respond and resolve the Part D complaints(s) submitted to their organization in CTM.

Additionally, CMS recognizes that Part D sponsors are the primary resource Medicare beneficiaries rely upon for the prompt resolution of their inquiries. CMS expects each Part D
sponsor to educate their members to ensure that beneficiaries call the sponsor’s call center directly with any Part D related complaints.

70.2 – Timeframes for Complaints Processing

(Rev. 11, Issued: 02-19-10, Effective/Implementation Date: 03-01-10)

All Part D sponsors are accountable for the prompt resolution of CMS recorded complaints in the CTM. As a result, Part D sponsors will resolve any complaints designated as “immediate need” (see section 10.2 Definition of Terms) within 2 calendar days of receipt into CTM. Complaints categorized as “urgent need” should be resolved within 7 calendar days of receipt; and complaints without an immediate or urgent designation should be resolved within 30 days of receipt.12

Part D sponsors are required to have at least 95% of cases designated as “immediate need” resolved within 2 calendar days of receipt. For a given month, CMS will calculate the proportion of “immediate need” complaints that remain unresolved at the end of each month. The analysis will exclude those complaints that can be identified as not attributable to the sponsor, such as SSA premium withhold, retroactive disenrollment, enrollment exception, and facilitated enrollment complaints.

Should a Part D sponsor not meet the 95% of cases designated as “immediate need” resolved within 2 calendar days of receipt threshold, CMS will consider those organizations out of compliance with one or more Part D requirements, including but not limited to requirements related to enrollment; coverage determinations, appeals, and formulary exceptions; and claims processing. In that instance, CMS may conduct a targeted audit of the Part D sponsor. Where audit findings indicate that the sponsor is not meeting Part D requirements, CMS may demand the sponsor develop and complete a formal corrective action plan to rectify the deficiencies indicated by the audit. If there is significant non-compliance, CMS may impose intermediate sanctions (i.e., suspend marketing and enrollment activities or withhold CMS payments). If the non-compliance presents potential harm to beneficiaries, CMS may also pursue civil monetary penalties against the organization.

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1 CMS reserves the right to classify any complaint as “Immediate Need” or “Urgent” if it doesn’t meet the standard guidelines for these types of complaints (such as access to care or lack of medications) should the complaint be egregious in nature. An egregious complaint would mean that there is potential for harm or hardship to the beneficiary.

2 The resolution time period begins on the initial assignment/reassignment date into CTM. Friday complaints are loaded into CTM on Saturday; weekend complaints are loaded into CTM on Monday.
Appendix A – Chapter 7 Related Web Sites
(Rev. 3, Issued: 09-05-08, Effective: 09-01-08, Implementation: 09-01-08)

CMS e-prescribing Web site
www.cms.hhs.gov/eprescribing

CMS Medication Therapy Management Program Web site
http://www.cms.hhs.gov/PrescriptionDrugCovContra/082_MTM.asp#TopOfPage

CMS Reporting Requirements Web site
http://www.cms.hhs.gov/PrescriptionDrugCovContra/08_RxContracting_ReportingOv
gight.asp

FDA Medwatch Reporting
http://www.fda.gov/medwatch
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Appendix B: Laws and Regulations to Consider in Standards of Conduct and/or Training
These compliance program guidelines reflect the Centers for Medicare and Medicaid Services (CMS) interpretation of the Compliance Program requirements and related provisions for Medicare Advantage Organizations (MAO) and Medicare Prescription Drug Plans (PDP) (Chapter 42 of the Code of Federal Regulations, Parts 422 and 423, hereinafter collectively referred to as “Parts C & D”). This chapter is designed to assist sponsors to establish and maintain an effective compliance program.

These compliance program guidelines apply fully to the prescription drug benefit programs of sections 1833 and 1876 Cost Plans. In addition, these compliance program guidelines apply to the prescription drug benefit programs of Program of All-Inclusive Care for the Elderly (PACE) plans only with respect to those portions of this chapter that pertain to Elements 6 and 7, which are embodied in 42 C.F.R. 423 §§504(b)(4)(vi)(F) and (G) respectively. These compliance program guidelines do not apply to the PACE plans or to sections 1833 and 1876 Cost Plans that do not have a prescription drug benefit program. However, given the Office of Inspector General (OIG) guidance promoting compliance programs for all sponsors, the CMS strongly encourages sponsors to voluntarily develop and implement effective compliance programs.

This guidance is subject to change as policy, technology and Medicare business practices continue to evolve.

Each sponsor must implement an effective compliance program that meets the regulatory requirements set forth at 42 C.F.R. §§422.503(b)(4)(vi) and 423.504(b)(4)(vi). Sponsors should apply the principles outlined in these guidelines to all relevant decisions, situations, communications and developments. Any new rule-making or interpretive guidance (e.g., annual call letter or Health Plan Management System (HPMS) guidance memoranda) may update the guidance provided in this document. Sponsors may also wish to consult the resources listed in the Appendices, which provide additional information on some topics addressed in this chapter.

In this chapter, the word “must” is used to reflect requirements created by statute or regulation. The word “should” is used to indicate expectations created by this guidance. Recommendations are noted as “best practices.”

Chapter 9 previously addressed the prevention of fraud, waste and abuse (FWA) by only Part D sponsors. In contrast, this chapter provides interpretive rules and guidance to help all sponsors to establish and maintain an effective compliance
program to prevent, detect, and correct FWA and Medicare program noncompliance

These guidelines, published in both Pub. 100-18, Medicare Prescription Drug Benefit Manual, chapter 9 and in Pub. 100-16, Medicare Managed Care Manual, chapter 21, are identical and allow organizations offering both Medicare Advantage (MA) and Prescription Drug Plans (PDP) to reference one document for guidance.

20 – Definitions
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

The following definitions apply for purposes of these guidelines only:

Abuse includes actions that may, directly or indirectly, result in: unnecessary costs to the Medicare Program, improper payment, payment for services that fail to meet professionally recognized standards of care, or services that are medically unnecessary. Abuse involves payment for items or services when there is no legal entitlement to that payment and the provider has not knowingly and/or intentionally misrepresented facts to obtain payment. Abuse cannot be differentiated categorically from fraud, because the distinction between “fraud” and “abuse” depends on specific facts and circumstances, intent and prior knowledge, and available evidence, among other factors.

Act refers to the Social Security Act.

Appeal (Part C Plan): Any of the procedures that deal with the review of adverse organization determinations on the health care services an enrollee believes he or she is entitled to receive, including delay in providing, arranging for, or approving the health care services (such that a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for a service as defined in 42 C.F.R. § 422.566(b). These procedures include reconsideration by the MA Plan and, if necessary, an independent review entity, hearings before Administrative Law Judges (ALJs), review by the Medicare Appeals Council (MAC), and judicial review.

Appeal (Part D Plan): Any of the procedures that deal with the review of adverse coverage determinations made by the Part D plan sponsor on the benefits under a Part D plan the enrollee believes he or she is entitled to receive, including a delay in providing or approving the drug coverage (when a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for the drug coverage, as defined in 42 C.F.R. §423.566(b). These procedures include redeterminations by the Part D plan sponsor, reconsiderations by the independent
review entity (IRE), Administrative Law Judge (ALJ) hearings, reviews by the Medicare Appeals Council (MAC), and judicial reviews.

Audit is a formal review of compliance with a particular set of standards (e.g., policies and procedures, laws and regulations) used as base measures.

Cost Plan is a Health Maintenance Organization (HMO) or Competitive Medical Plan (CMP) with a cost-reimbursement contract under section 1876(h) of the Act (See 42 C.F.R. §417.1, §423.4). Cost Plan sponsors may contract to offer prescription drug benefits under the Part D program. (See, 42 C.F.R. §423.4.)

Data Analysis is a tool for identifying coverage and payment errors, and other indicators of potential FWA and noncompliance.

Deemed Provider or Supplier means a provider or supplier that has been accredited by a national accreditation program (approved by CMS) as demonstrating compliance with certain conditions.

DHHS is the Department of Health and Human Services. CMS is the agency within DHHS that administers the Medicare program.

DOJ is the Department of Justice.

Downstream Entity is any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the MA benefit or Part D benefit, below the level of the arrangement between an MAO or applicant or a Part D plan sponsor or applicant and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services. (See, 42 C.F.R. §, 423.501).

Employee(s) refers to those persons employed by the sponsor or a First Tier, Downstream or Related Entity (FDR) who provide health or administrative services for an enrollee.

Enrollee means a Medicare beneficiary who is enrolled in a sponsor’s Medicare Part C or Part D plan.

External Audit means an audit of the sponsor or its FDRs conducted by outside auditors, not employed by or affiliated with, and independent of, the sponsor.

FDR means First Tier, Downstream or Related Entity.

First Tier Entity is any party that enters into a written arrangement, acceptable to CMS, with an MAO or Part D plan sponsor or applicant to provide administrative services or health care services to a Medicare eligible individual under the MA program or Part D program. (See, 42 C.F.R. § 423.501).

Fraud is knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any health care benefit program or to obtain (by means of false or fraudulent pretenses, representations, or promises) any of the money or property owned by, or under the custody or control of, any health care benefit program. 18 U.S.C. § 1347.

FWA means fraud, waste and abuse.

Governing Body means that group of individuals at the highest level of governance of the sponsor, such as the Board of Directors or the Board of Trustees, who formulate policy and direct and control the sponsor in the best interest of the organization and its enrollees. As used in this chapter, governing body does not include C-level management such as the Chief Executive Officer, Chief Operations Officer, Chief Financial Officer, etc., unless persons in those management positions also serve as directors or trustees or otherwise at the highest level of governance of the sponsor.

GSA means General Services Administration.

Internal Audit means an audit of the sponsor or its FDRs conducted by auditors who are employed by or affiliated with the sponsor.

Medicare is the health insurance program for the following:

- People 65 or older,
- People under 65 with certain disabilities, or
- People of any age with End-Stage Renal Disease (ESRD) (permanent kidney failure requiring dialysis or a kidney transplant).

Monitoring Activities are regular reviews performed as part of normal operations to confirm ongoing compliance and to ensure that corrective actions are undertaken and effective.

NBI MEDIC means National Benefit Integrity Medicare Drug Integrity Contractor (MEDIC), an organization that CMS has contracted with to perform specific program integrity functions for Parts C and D under the Medicare Integrity Program. The NBI MEDIC’s primary role is to identify potential FWA in Medicare Parts C and D.
OIG is the Office of the Inspector General within DHHS. The Inspector General is responsible for audits, evaluations, investigations, and law enforcement efforts relating to DHHS programs and operations, including the Medicare program.

Pharmacy Benefit Manager (PBM) is an entity that provides pharmacy benefit management services, which may include contracting with a network of pharmacies; establishing payment levels for network pharmacies; negotiating rebate arrangements; developing and managing formularies, preferred drug lists, and prior authorization programs; performing drug utilization review; and operating disease management programs. Some sponsors perform these functions in-house and do not use an outside entity as their PBM. Many PBMs also operate mail order pharmacies or have arrangements to include prescription availability through mail order pharmacies. A PBM is often a first tier entity for the provision of Part D benefits.

PDP means Prescription Drug Plan.

Related Entity means any entity that is related to an MAO or Part D sponsor by common ownership or control and

1. Performs some of the MAO or Part D plan sponsor’s management functions under contract or delegation;

2. Furnishes services to Medicare enrollees under an oral or written agreement; or

3. Leases real property or sells materials to the MAO or Part D plan sponsor at a cost of more than $2,500 during a contract period. (See, 42 C.F.R. §423.501).

Special Investigations Unit (SIU) is an internal investigation unit responsible for conducting investigations of potential FWA.

Sponsor refers to the entities described in the Introduction to these guidelines.

TrOOP (True Out of Pocket) Costs are costs that an enrollee must incur on Part D covered drugs to reach catastrophic coverage. (These incurred costs are defined in regulation at §423.100 and Pub. 100-18, Medicare Prescription Drug Benefit Manual, chapter 5, section 30). In general, payments counting toward TrOOP include payments by enrollee, family member or friend, Qualified State Pharmacy Assistance Program (SPAP), Medicare’s Extra Help (low income subsidy), a charity, manufacturers participating in the Medicare coverage gap discount program, Indian Health Service, AIDS Drug Assistance Programs, or a personal health savings vehicle (flexible spending account, health savings account, medical savings account). Payments that do NOT count toward TrOOP include Part D premiums and coverage by other insurances, group health plans, government programs (non-
SPAP), workers’ compensation, Part D plans’ supplemental or enhanced benefits, or other third parties, drugs purchased outside the United States, and over-the-counter drugs and vitamins.

Waste is the overutilization of services, or other practices that, directly or indirectly, result in unnecessary costs to the Medicare program. Waste is generally not considered to be caused by criminally negligent actions but rather the misuse of resources.

30 – Overview of Mandatory Compliance Program
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

Section 1860D-4(c)(1)(D) of the Act, 42 C.F.R. §§ 422.503(b)(4)(vi), 423.504(b)(4)(vi)

All sponsors are required to adopt and implement an effective compliance program, which must include measures to prevent, detect and correct Part C or D program noncompliance as well as FWA.

The compliance program must, at a minimum, include the following core requirements:

1. Written Policies, Procedures and Standards of Conduct;
2. Compliance Officer, Compliance Committee and High Level Oversight;
3. Effective Training and Education;
4. Effective Lines of Communication;
5. Well Publicized Disciplinary Standards;
6. Effective System for Routine Monitoring and Identification of Compliance Risks; and

In order to be effective, a sponsor’s compliance program must be fully implemented, and should be tailored to each sponsor’s unique organization, operations and circumstances.

A compliance program will not be effective unless sponsors devote adequate resources to the program. Adequate resources include those that are sufficient to do the following:

1. Promote and enforce its Standards of Conduct
2. Promote and enforce its compliance program;
3. Effectively train and educate its governing body members, employees and FDRs;
4. Effectively establish lines of communication within itself and between itself and its FDRs;
5. Oversee FDR compliance with Medicare Part C and D requirements;
6. Establish and implement an effective system for routine auditing and monitoring; and
7. Identify and promptly respond to risks and findings.

CMS will consider a sponsor’s size, structure, business model, activities, the extent of its delegation of responsibilities to other entities, the breadth of its operation, and the risks it faces in evaluating whether adequate resources have been devoted to the compliance program.

40 – Sponsor Accountability for and Oversight of FDRs
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi), 422.504(i), 423.504(b)(4)(vi), 423.505(i)

Sponsors may enter into contracts with FDRs to provide administrative or health care services for enrollees on behalf of the sponsor. Sponsors may not delegate compliance program administrative functions (e.g., compliance officer, compliance committee, compliance reporting to senior management, etc.) to entities other than its parent organization or corporate affiliate; however, sponsors may use FDRs for compliance activities such as monitoring, auditing, and training.

The sponsor maintains the ultimate responsibility for fulfilling the terms and conditions of its contract with CMS, and for meeting the Medicare program requirements. Therefore, CMS may hold the sponsor accountable for the failure of its FDRs to comply with Medicare program requirements.

Medicare program requirements apply to FDRs to whom the sponsor has delegated administrative or health care service functions relating to the sponsor’s Medicare Parts C and D contracts. These requirements do not apply to persons and entities whose administrative contracts with the sponsor do not relate to the sponsor’s Medicare functions, for example, a contract between a sponsor and a real estate broker in connection with the rental of office space.

Below are examples of functions that relate to the sponsor’s Medicare Parts C and D contracts:

- Sales and marketing;
• Utilization management;
• Quality improvement;
• Applications processing;
• Enrollment, disenrollment, membership functions;
• Claims administration, processing and coverage adjudication;
• Appeals and grievances;
• Licensing and credentialing;
• Pharmacy benefit management;
• Hotline operations;
• Customer service;
• Bid preparation;
• Outbound enrollment verification;
• Provider network management;
• Processing of pharmacy claims at the point of sale;
• Negotiation with prescription drug manufacturers and others for rebates, discounts or other price concessions on prescription drugs;
• Administration and tracking of enrollees’ drug benefits, including TrOOP balance processing;
• Coordination with other benefit programs such as Medicaid, state pharmaceutical assistance or other insurance programs;
• Entities that generate claims data; and
• Health care services.
First tier and related entities may contract with downstream entities to fulfill their contractual obligations to the sponsors. A field marketing organization (first tier entity) may contract with a smaller brokerage firm (downstream entity) to sell the sponsors’ Medicare Parts C and D products. That smaller brokerage firm may further contract with individual sales agents (downstream entities) to perform the day-to-day sales work. A related entity may also be either a first tier entity or a downstream entity.

It is critical that sponsors correctly identify those entities with which they contract that qualify as FDRs. Sponsors are required to comply with CMS requirements for FDRs. Unless it is very clear that an entity is or is not an FDR, the determination of
FDR status requires an analysis of all of the circumstances. Sponsors should have clearly defined processes and criteria to evaluate and categorize all vendors with which they contract. Below are some factors to consider in determining whether an entity is an FDR:

- The function to be performed by the delegated entity;

- Whether the function is something the sponsor is required to do or to provide under its contract with CMS, the applicable federal regulations or CMS guidance;

- To what extent the function directly impacts enrollees;

- To what extent the delegated entity has interaction with enrollees, either orally or in writing;

- Whether the delegated entity has access to beneficiary information or personal health information;

- Whether the delegated entity has decision-making authority (e.g., enrollment vendor deciding time frames) or whether the entity strictly takes direction from the sponsor;

- The extent to which the function places the delegated entity in a position to commit health care fraud, waste or abuse; and

- The risk that the entity could harm enrollees or otherwise violate Medicare program requirements or commit FWA.

The method by which the analysis is performed is left to the discretion of the sponsor. Some sponsors use a multi-functional committee, consisting of members from the compliance and legal departments as well as the business owner of the FDR function, to make the determination.

The sponsor’s compliance officer, working with the sponsor’s compliance committee, must develop procedures to promote and ensure that all FDRs are in compliance with all applicable laws, rules and regulations with respect to Medicare Parts C and D delegated responsibilities. The sponsor must have a system in place to monitor FDRs. Sponsors are free to choose the method for monitoring their FDRs’ compliance with Medicare program requirements. Sponsors must be able to demonstrate that their method of monitoring is effective. It is a best practice to use metrics to assist in observing compliance performance and operational trends.

For more information on requirements for contracts with FDRs, see Pub. 100-16, Medicare Managed Care Manual, chapter 11, §110.
50 – Elements of an Effective Compliance Program
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi), 423.504(b)(4)(vi)

This section discusses the seven elements of an effective compliance program, as set forth in the applicable Federal regulations governing Parts C and D.

50.1 – Element I: Written Policies, Procedures and Standards of Conduct
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(A), 423.504(b)(4)(vi)(A)

Sponsors must have written policies, procedures and standards of conduct that –

1. Articulate the sponsor’s commitment to comply with all applicable Federal and State standards;

2. Describe compliance expectations as embodied in the Standards of Conduct;

3. Implement the operation of the compliance program;

4. Provide guidance to employees and others on dealing with suspected, detected or reported compliance issues;

5. Identify how to communicate compliance issues to appropriate compliance personnel;

6. Describe how suspected, detected or reported compliance issues are investigated and resolved by the sponsor; and

7. Include a policy of non-intimidation and non-retaliation for good faith participation in the compliance program, including, but not limited to, reporting potential issues, investigating issues, conducting self-evaluations, audits and remedial actions, and reporting to appropriate officials.

The requirements that are discussed in this section must be included as part of the compliance program but may be stated either in policies and procedures or in Standards of Conduct. They may, but need not, appear in both documents.
50.1.1 – Standards of Conduct
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
42 C.F.R. §§ 422.503(b)(4)(vi)(A), 423.504(b)(4)(vi)(A)

Standards of Conduct, also known in some organizations as the “Code of Conduct” or by other similar names, state the overarching principles and values by which the company operates, and define the underlying framework for the compliance policies and procedures. Standards of Conduct should describe the sponsor’s expectations that all employees conduct themselves in an ethical manner; that issues of noncompliance and potential FWA are reported through appropriate mechanisms; and that reported issues will be addressed and corrected.

The Standards of Conduct may be stated in a separate Medicare-specific stand-alone document or within the corporate Code of Conduct. Sponsors should update the Standards of Conduct to incorporate changes in applicable laws, regulations, and other program requirements, such as those listed in Appendix B.

Standards of Conduct communicate to employees and FDRs that compliance is everyone’s responsibility from the top to the bottom of the organization. For that reason, and because Standards of Conduct are the most fundamental statement of the sponsor’s governing principles, Standards of Conduct should be approved by the sponsor’s full governing body.

It is a best practice of some sponsors to include a resolution of the full governing body stating the sponsor’s commitment to compliant, lawful and ethical conduct. This communicates to employees and FDRs that compliance and ethics are valued and important to those at the highest levels of authority in the company.

50.1.2 – Policies and Procedures
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
42 C.F.R. §§ 422.503(b)(4)(vi)(A), 423.504(b)(4)(vi)(A)

Compliance policies and/or procedures are detailed and specific, and describe the operation of the compliance program. Compliance policies may address issues such as sponsors’ compliance reporting structure, compliance and FWA training requirements, the operation of the hotline or other reporting mechanisms, and how suspected, detected or reported compliance and potential FWA issues are
investigated and addressed and remediated. Sponsors should update the policies and procedures to incorporate changes in applicable laws, regulations, and other program requirements.

50.1.3 – Distribution of Compliance Policies and Procedures and Standards of Conduct
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(A), 423.504(b)(4)(vi)(A)

In order to be effective, compliance policies and procedures and Standards of Conduct must be distributed to employees who support the sponsor’s Medicare business. Distribution must occur within 90 days of hire, when there are updates to the policies, and annually thereafter. Sponsors may choose their distribution method. Some examples are furnishing hard copies at the time of hire and electronic copies thereafter, emailing an electronic copy, or posting on the company intranet. The sponsors should have a method to demonstrate that the Standards of Conduct and policies and procedures were distributed to employees.

The Standards of Conduct should be written in a format that is easy to read and comprehend. Sponsors should consider translating Standards of Conduct and policies and procedures into other languages as necessary.

In order to communicate the sponsor’s compliance expectations for FDRs, sponsors should ensure that Standards of Conduct and policies and procedures are distributed to FDRs’ employees. Sponsors may make their Standards of Conduct and policies and procedures available to their FDRs. Alternatively, the sponsor may ensure that the FDR has comparable policies and procedures and Standards of Conduct of their own.

The sponsors should have a method to demonstrate that Standards of Conduct and policies and procedures were distributed to FDRs’ employees. Sponsors or the FDR may make the policies available through methods such as a fax blast, placement on an FDR portal, in contract materials, etc. A best practice is to include appropriate contract provisions in the FDR contract, coupled with periodic monitoring of a sample of FDRs based on risk assessment, including a review of the FDRs’ compliance policies and procedures and Standards of Conduct.

50.2 – Element II: Compliance Officer, Compliance Committee and High Level Oversight
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
The sponsor must designate a compliance officer and a compliance committee who report directly and are accountable to the sponsor’s chief executive or other senior management.

1. The compliance officer, vested with the day-to-day operations of the compliance program, must be an employee of the sponsor, parent organization or corporate affiliate. The compliance officer may not be an employee of an FDR.

2. The compliance officer and the compliance committee must periodically report directly to the sponsor’s governing body on the activities and status of the compliance program, including issues identified, investigated, and resolved by the compliance program.

3. The sponsor’s governing body must be knowledgeable about the content and operation of the compliance program and must exercise reasonable oversight with respect to the implementation and effectiveness of the compliance program.

50.2.1 – Compliance Officer

The compliance officer position should be full-time. The sponsor is not required to have a separate compliance officer (“Medicare Compliance Officer”) dedicated only to its Medicare Parts C and D business, although CMS strongly recommends a dedicated Medicare compliance officer. Sponsors must assess the scope of the existing compliance officer’s responsibilities, the size of the organization, and the organization’s resources when determining whether a single compliance officer can effectively implement the Medicare compliance program and the sponsor’s commercial or other governmental business.

The compliance officer must be an employee of the sponsor (preferred) or of its parent company or corporate affiliate. Sponsors may not delegate the compliance officer position or compliance program functions to first tier or downstream entities. When the compliance officer is not employed by the sponsor itself, but by the sponsor’s parent company or corporate affiliate, the sponsor must ensure that
the compliance officer has detailed involvement in and familiarity with the sponsor's operational and compliance activities.

The sponsor must ensure that reports from the compliance officer reach the sponsor’s senior-most leader (typically the CEO or President). The direct reporting relationship between the compliance officer and the senior-most leadership refers to the direct reporting of information, not necessarily to a supervisory reporting relationship. This can be accomplished through a dotted line or matrix reporting.

The compliance officer must have express authority to provide unfiltered, in-person reports to the sponsor’s senior-most leader. The compliance officer’s reports should not be routed to the CEO or President through operational management such as the COO, CFO, GC (General Counsel) or other executives responsible for operational areas. For example, the compliance officer’s report to the CEO should not be filtered through the CFO. However, the compliance officer’s reports may be relayed to the sponsor’s senior-most leader through divisional Presidents. For example, the compliance officer may report directly to the President of the division that houses the Medicare program, who then reports to the CEO of the sponsor on the status and activities of the Medicare compliance program.

The compliance officer’s reports to the sponsor’s governing body must be made through the compliance infrastructure. The compliance officer must have express authority to provide unfiltered, in-person reports to the sponsor’s governing body at his/her discretion.

The Medicare compliance officer may report compliance issues directly to the corporate compliance officer and/or the compliance committee, who then provide compliance reports directly to the sponsor’s governing body. The compliance officer, in his/her discretion, need not await approval of the sponsor’s governing body to implement needed compliance actions and activities, provided that those actions and activities, as appropriate, are reported to the governing body or governing body committee at its next scheduled meeting. It is a best practice for sponsors who have both a corporate compliance officer and a Medicare compliance officer to allow the Medicare compliance officer to regularly attend meetings of the sponsor’s governing body and to make in-person reports to the sponsor’s governing body. A related best practice is to allow the compliance officer to meet in Executive Session with the governing body.

The compliance officer should be independent. The compliance officer should not serve in both compliance and operational areas (e.g., where the compliance officer is also the CFO, COO or GC). This leads to self-policing in the operational area(s) in which he/she serves, which is a conflict of interest.

Because the compliance officer must be free to raise compliance issues without fear of retaliation, it is a best practice to require governing body approval before the compliance officer can be terminated from employment.
The compliance officer is responsible for the implementation of the compliance program. The compliance officer defines the program structure, educational requirements, reporting, and complaint mechanisms, response and correction procedures, and compliance expectations of all personnel and FDRs.

The compliance officer should have training and/or experience working with MA, MA-PD or PDP programs and, with regulatory authorities. It is a best practice for the compliance officer to be a member of senior management.

Duties of the compliance officer may include, but are not limited to:

- Ensuring that Medicare compliance reports are provided regularly to the sponsor’s corporate compliance officer (if any), governing body, CEO, and compliance committee. Reports should include the status of the sponsor’s Medicare compliance program implementation, the identification and resolution of suspected, detected or reported instances of noncompliance, and the sponsor’s compliance oversight and audit activities;

- Being aware of daily business activity by interacting with the operational units of the sponsor;

- Creating and coordinating, by appropriate delegation, if desired, educational training programs to ensure that the sponsor’s officers, governing body, managers, employees, FDRs, and other individuals working in the Medicare program are knowledgeable about the sponsor’s compliance program, its written Standards of Conduct, compliance policies and procedures, and all applicable statutory and regulatory requirements;

- Developing and implementing methods and programs that encourage managers and employees to report Medicare program noncompliance and potential FWA without fear of retaliation;

- Maintaining the compliance reporting mechanism and closely coordinating with the internal audit department and the SIU, where applicable;

- Responding to reports of potential FWA, including the coordination of internal investigations with the SIU or internal audit department and the development of appropriate corrective or disciplinary actions, if necessary. To that end, the compliance officer should have the flexibility to design and coordinate internal investigations;

- Ensuring that the DHHS OIG and Government Services Administration (“GSA”) exclusion lists have been checked with respect to all employees, governing body members, and FDRs monthly and coordinating any resulting
personnel issues with the sponsor’s Human Resources, Security, Legal or other departments as appropriate;

- Maintaining documentation for each report of potential noncompliance or potential FWA received from any source, through any reporting method (e.g., hotline, mail, or in-person);

- Overseeing the development and monitoring of the implementation of corrective action plans;

- Coordinating potential fraud investigations/referrals with the SIU, where applicable, and the appropriate NBI MEDIC. This includes facilitating any documentation or procedural requests that the NBI MEDIC makes of the sponsor.

Similarly, the compliance officer should collaborate with other sponsors, State Medicaid programs, Medicaid Fraud Control Units (MCFUs), commercial payers, and other organizations, where appropriate, when a potential FWA issue is discovered that involves multiple parties; and

- The compliance officer should have the authority to:
  - Interview or delegate the responsibility to interview the sponsor’s employees and other relevant individuals regarding compliance issues;
  - Review company contracts and other documents pertinent to the Medicare program;
  - Review or delegate the responsibility to review the submission of data to CMS to ensure that it is accurate and in compliance with CMS reporting requirements;
  - Independently seek advice from legal counsel;
  - Report potential FWA to CMS, its designee or law enforcement;
  - Conduct and/or direct audits and investigations of any FDRs;
  - Conduct and/or direct audits of any area or function involved with Medicare Parts C or D plans; and
  - Recommend policy, procedure, and process changes.

50.2.2– Compliance Committee
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
Sponsors must have a compliance committee in place that oversees the Medicare compliance program. The sponsor need not have a separate Medicare compliance committee, as long as the committee addresses Medicare compliance issues. In many organizations, the compliance committee is chaired by the compliance officer. The compliance committee serves to advise the compliance officer. The compliance committee is accountable to, and must provide regular compliance reports to, the sponsor’s senior-most leader and governing body. Reports on the status of the compliance program are usually reported through the chairperson of the committee.

Duties of the compliance committee may include, but are not limited to:

- Meeting at least on a quarterly basis, or more frequently as necessary to enable reasonable oversight of the compliance program;

- Developing strategies to promote compliance and the detection of any potential violations;

- Reviewing and approving compliance and FWA training, and ensuring that training and education are effective and appropriately completed;

- Assisting with the creation and implementation of the compliance risk assessment and of the compliance monitoring and auditing work plan;

- Assisting in the creation, implementation and monitoring of effective corrective actions;

- Developing innovative ways to implement appropriate corrective and preventative action;

- Reviewing effectiveness of the system of internal controls designed to ensure compliance with Medicare regulations in daily operations;

- Supporting the compliance officer’s needs for sufficient staff and resources to carry out his/her duties;

- Ensuring that the sponsor has appropriate, up-to-date compliance policies and procedures;

- Ensuring that the sponsor has a system for employees and FDRs to ask compliance questions and report potential instances of Medicare program
- Ensuring that the sponsor has a method for enrollees to report potential FWA.
- Reviewing and addressing reports of monitoring and auditing of areas in which the sponsor is at risk for program noncompliance or potential FWA and ensuring that corrective action plans are implemented and monitored for effectiveness; and
- Providing regular and ad hoc reports on the status of compliance with recommendations to the sponsor’s governing body.

The compliance committee should include individuals with a variety of backgrounds, and reflect the size and scope of the sponsor. Members of the compliance committee should have decision-making authority in their respective areas of expertise. Sponsors should include members of senior management (e.g., CFO, COO), as well as auditors, pharmacists, registered nurses, and nationally certified pharmacy technicians on the compliance committee (to the extent that their organization has those positions on staff). Other committee members might include personnel experienced in legal issues, statistical analysts, and staff/managers from various departments within the organization who understand the vulnerabilities within their respective areas of expertise.

50.2.3 – Governing Body
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(B), 423.504(b)(4)(vi)(B)

The sponsor’s governing body (e.g., Board of Directors or Board of Trustees) must exercise reasonable oversight with respect to the implementation and effectiveness of the sponsor’s compliance program. The governing body of the organization that contracted with CMS or its parent company may oversee the Medicare compliance program. When compliance issues are presented to the sponsor’s governing body, it should make further inquiry and take appropriate action to ensure the issues are resolved.

The sponsor’s governing body may delegate compliance program oversight to a specific committee of the governing body (e.g., Board Audit Committee or Board compliance committee), but the governing body as a whole remains accountable for reviewing the status of the compliance program. The scope of the delegation from
the full governing body to the governing body committee must be clear in the committee’s charter and reporting.

The governing body must receive training and education as to the structure and operation of the compliance program. The governing body should be knowledgeable about compliance risks and strategies, should understand the measurements of outcome, and should be able to gauge effectiveness of the compliance program.

Reasonable oversight by the governing body (assisted by a committee, if desired) includes, but is not limited to:

- Approving the Standards of Conduct (this should be performed by the full governing body and not a committee);
- Understanding the compliance program structure;
- Remaining informed about the compliance program outcomes, including results of internal and external audits;
- Remaining informed about governmental compliance enforcement activity such as Notices of Non-Compliance, Warning Letters and/or more formal sanctions;
- Receiving regularly scheduled, periodic updates from the compliance officer and compliance committee; and
- Reviewing the results of performance and effectiveness assessments of the compliance program.

The following are examples of activities in which the governing body, or a governing body committee, may wish to have involvement. Alternatively, the governing body may delegate some or all of these activities to senior management or to the compliance committee:

- Development, implementation and annual review of compliance policies and procedures;
- Approval of compliance policies and procedures;
- Review and approval of compliance and FWA training;
- Review and approval of compliance risk assessment;
- Review of internal and external audit work plans and audit results;
• Review and approval of corrective action plans resulting from audits;

• Review and approval of appointment of the compliance officer;

• Review and approval of performance goals for the compliance officer;

• Evaluation of the senior management team’s commitment to ethics and the compliance program; and

• Review of dashboards, scorecards, self-assessment tools, etc., that reveal compliance issues.

The governing body should collect and review measurable evidence that the compliance program is detecting and correcting Medicare program noncompliance on a timely basis. It is a best practice for the governing body to be provided with data showing that the program has reduced the risks of program noncompliance and FWA. Some indicators of an effective compliance program are:

• Use of quantitative measurement tools (e.g., scorecards, dashboard reports, key performance indicators) to report, and track and compare over time, compliance with key Medicare Parts C and D operations such as enrollment, appeals and grievances, prescription drug benefit administration;

• Use of monitoring to track and review open/closed corrective action plans, FDR compliance, Notices of Non-Compliance, warning letters, CMS sanctions, marketing material approval rates, training completion/pass rates, etc.;

• Implementation of new or updated Medicare requirements (e.g., tracking HPMS memo from receipt to implementation) including monitoring or auditing and quality control measures to confirm appropriate and timely implementation;

• Increase or decrease in number and/or severity of complaints from employees, FDRs, providers, beneficiaries through customer service calls or the Complaint Tracking Module (CTM), marketing misrepresentations, Parts A and B issues, etc.;

• Timely response to reported noncompliance and potential FWA, and effective resolution (i.e., non-recurring issues);

• Consistent, timely and appropriate disciplinary action; and

• Detection of noncompliance and FWA issues through monitoring and auditing:
Whether root cause was determined and corrective action appropriately and timely implemented and tested for effectiveness;

Detection of FWA trends and schemes via daily claims reviews, outlier reports, pharmacy audits, etc.; and

Actions taken in response to compliance reports submitted by FDRs.

The sponsor should ensure that CMS is able to validate, through review of governing body meeting minutes or other documentation, the active engagement of the governing body in the oversight of the Medicare compliance program. A governing body that is appropriately engaged asks questions, requires follow-up on issues and takes action when necessary.

50.2.4 – Senior Management Involvement in Compliance Program
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(B), 423.504(b)(4)(vi)(B)

An effective compliance program cannot be achieved unless the CEO (or senior-most leader) and other senior management, as appropriate, are engaged in the compliance program. The CEO and senior management must recognize the importance of the compliance program in the sponsor’s success.

In situations where the contract holder engages in multiple lines of business (e.g., commercial, Medicare, etc.), with each line of business having its own CEO, the senior-most leader of the contract holder must be engaged in compliance program oversight.

The CEO and senior management should ensure that the compliance officer is integrated into the organization and is given the credibility, authority and resources necessary to operate a robust and effective compliance program. The CEO must receive periodic reports from the compliance officer of risk areas facing the organization, the strategies being implemented to address them and the results of those strategies. The CEO must also be advised of all governmental compliance enforcement activity, from Notices of Non-compliance to formal enforcement actions.

50.3 – Element III: Effective Training and Education
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
The sponsor must establish, implement and provide effective training and education for its employees, including the CEO, senior administrators or managers, and for the governing body members, and FDRs.

The training and education must occur at least annually and be made a part of the orientation for new employees, including the chief executive and senior administrators or managers, governing body members, and FDRs.

FDRs who have met the FWA certification requirements through enrollment into the Medicare program or accreditation as a Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) are deemed to have met the training and educational requirements for fraud, waste, and abuse.

Effectiveness of Training and Education

Effectiveness of training, education, compliance policies and procedures, and Standards of Conduct will be apparent through sponsor’s compliance with all Medicare program requirements. Sponsors must ensure that employees are aware of the Medicare requirements related to their job function.

50.3.1 – General Compliance Training
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

The sponsor’s employees (including temporary workers and volunteers), and governing body members, must, at a minimum, receive general compliance training within 90 days of initial hiring, and annually thereafter. The following are examples of how sponsors may satisfy the general compliance training requirements:

- Classroom training;
- Online training modules; or
- Attestations that employees have read and received the sponsor’s Standards of Conduct and/or compliance policies and procedures.

Sponsors must be able to demonstrate that their employees have fulfilled these training requirements. Examples of proof of training may include copies of sign-in sheets, employee attestations and electronic certifications from the employees taking and completing the training.
Sponsors must ensure that general compliance information is communicated to their FDRs. The sponsor’s compliance expectations can be communicated through distribution of the sponsor’s Standards of Conduct and/or compliance policies and procedures to FDRs’ employees. Distribution may be accomplished through Provider Guides, Business Associate Agreements or Participation Manuals, etc.

Sponsors should review and update, if necessary, the general compliance training whenever there are material changes in regulations, policy or guidance, and at least annually.

The following are examples of topics the general compliance training program should communicate:

- A description of the compliance program, including a review of compliance policies and procedures, the Standards of Conduct, and the sponsor’s commitment to business ethics and compliance with all Medicare program requirements;

- An overview of how to ask compliance questions, request compliance clarification or report suspected or detected noncompliance. Training should emphasize confidentiality, anonymity, and non-retaliation for compliance related questions or reports of suspected or detected noncompliance or potential FWA;

- The requirement to report to the sponsor actual or suspected Medicare program noncompliance or potential FWA;

- Examples of reportable noncompliance that an employee might observe;

- A review of the disciplinary guidelines for non-compliant or fraudulent behavior. The guidelines will communicate how such behavior can result in mandatory retraining and may result in disciplinary action, including possible termination when such behavior is serious or repeated or when knowledge of a possible violation is not reported;

- Attendance and participation in compliance and FWA training programs as a condition of continued employment and a criterion to be included in employee evaluations;

- A review of policies related to contracting with the government, such as the laws addressing gifts and gratuities for Government employees;

- A review of potential conflicts of interest and the sponsor’s system for disclosure of conflicts of interest;
• An overview of HIPAA/HITECH, the CMS Data Use Agreement (if applicable), and the importance of maintaining the confidentiality of personal health information;
• An overview of the monitoring and auditing process; and
• A review of the laws that govern employee conduct in the Medicare program.

See Appendix B for other examples of laws and regulations that may be discussed in training.

50.3.2 – Fraud, Waste, and Abuse Training
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(C), 423.504(b)(4)(vi)(C)

The sponsor’s employees (including temporary workers and volunteers), and governing body members, as well as FDRs’ employees who have involvement in the administration or delivery of Parts C and D benefits must, at a minimum, receive FWA training within 90 days of initial hiring (or contracting in the case of FDRs), and annually thereafter. Additional, specialized or refresher training may be provided on issues posing FWA risks based on the individual’s job function (e.g., pharmacist, statistician, customer service, etc.). Training may be provided:

• upon appointment to a new job function;
• when requirements change;
• when employees are found to be noncompliant;
• as a corrective action to address a noncompliance issue; and
• when an employee works in an area implicated in past FWA.

Sponsors may choose to tailor the training in response to circumstances surrounding potential FWA and specific functions performed by FDRs.

Sponsors must be able to demonstrate that their employees and FDRs have fulfilled these training requirements as applicable. Examples of proof of training may include copies of sign-in sheets, employee attestations and electronic certifications from the employees taking and completing the training.

Sponsors must provide the FWA training directly to their FDRs or provide appropriate FWA training materials to their FDRs.
To reduce the potential burden on FDRs, CMS has developed and provided a standardized FWA training and education module. The module is available through the CMS Medicare Learning Network (MLN) at http://www.cms.gov/MLNProducts. Using CMS’ training module is optional and a sponsor may use another method. However, this training meets CMS’ FWA training requirements so sponsors should accept FDRs’ use of this FWA training option. For details on accessing the FWA training and education on the MLN website, see the May 8, 2012, HPMS memo regarding Fraud, Waste and Abuse Training and Education Guidance.

Topics that should be addressed in FWA training include, but are not limited to the following:

- Laws and regulations related to MA and Part D FWA (i.e., False Claims Act, Anti-Kickback statute, HIPAA/HITECH, etc.);
- Obligations of FDRs to have appropriate policies and procedures to address FWA;
- Processes for sponsors and FDR employees to report suspected FWA to the sponsor (or, as to FDR employees, either to the sponsor directly or to their employers who then must report it to the sponsor);
- Protections for sponsor and FDR employees who report suspected FWA; and
- Types of FWA that can occur in the settings in which sponsor and FDR employees work.

Sponsors are accountable for maintaining records for a period of 10 years of the time, attendance, topic, certificates of completion (if applicable), and test scores of any tests administered to their employees, and must require FDRs to maintain records of the training of the FDRs’ employees.

FDRs who have met the FWA certification requirements through enrollment into Parts A or B of the Medicare program or through accreditation as a supplier of DMEPOS are deemed to have met the FWA training and education requirements. No additional documentation beyond the documentation necessary for proper credentialing is required to establish that an employee or FDR or employee of an FDR is deemed. In the case of chains, such as chain pharmacies, each individual location must be enrolled into Medicare Part A or B to be deemed. See examples of such entities in Pub. 100-16, Medicare Managed Care Manual, chapter 6 §70.

50.4 – Element IV: Effective Lines of Communication
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
The sponsor must establish and implement effective lines of communication, ensuring confidentiality between the compliance officer, members of the compliance committee, the sponsor’s employees, managers and governing body, and the sponsor’s FDRs. Such lines of communication must be accessible to all and allow compliance issues to be reported including a method for anonymous and confidential good faith reporting of potential compliance issues as they are identified.

50.4.1 – Effective Lines of Communication Among the Compliance Officer, Compliance Committee, Employees, Governing Body, and FDRs

Sponsors must have an effective way to communicate information from the compliance officer to others. Such information should include the compliance officer’s name, office location and contact information; laws, regulations and guidance for sponsors and FDRs, such as statutory, regulatory, and sub-regulatory changes (e.g., HPMS memos); and changes to policies and procedures and Standards of Conduct.

Methods to communicate information may include physical postings of information, e-mail distributions, internal websites, and individual and group meetings with the compliance officer. The dissemination of information from the compliance officer must be made within a reasonable time and to all appropriate parties.

50.4.2 – Communication and Reporting Mechanisms

The sponsor’s written Standards of Conduct and/or policies and procedures must require all employees, members of the governing body, and FDRs to report
compliance concerns and suspected or actual violations related to the Medicare program to the sponsor.

Sponsors must have a system in place to receive, record, respond to and track compliance questions or reports of suspected or detected noncompliance or potential FWA from employees, members of the governing body, enrollees and FDRs and their employees. Reporting systems must maintain confidentiality (to the greatest extent possible), allow anonymity if desired (e.g., through telephone hotlines or mail drops), and emphasize the sponsor’s / FDR’s policy of non-intimidation and non-retaliation for good faith reporting of compliance concerns and participation in the compliance program. FDRs that partner with multiple sponsors may train their employees on the FDR’s reporting processes including emphasis that reports must be made to the appropriate sponsor.

Sponsors must adopt, widely publicize, and enforce a no-tolerance policy for retaliation or retribution against any employee or FDR who in good faith reports suspected FWA. Employees and FDRs must be notified that they are protected from retaliation for False Claims Act complaints, as well as any other applicable anti-retaliation protections.

The methods available for reporting compliance or FWA concerns and the non-retaliation policy must be publicized throughout the sponsor’s or FDR’s facilities. This information can be publicized, for example, through the use of posters, table tents, mouse pads, key cards and other prominent displays. General compliance training should include the reporting requirements and the available methods for reporting.

Sponsors must make the reporting mechanisms user friendly, easy to access and navigate, and available 24 hours a day for employees, members of the governing body, and FDRs. It is a best practice for sponsors to establish more than one type of reporting mechanism to account for the different ways in which people prefer to communicate or feel comfortable communicating.

When a suspected compliance issue is reported, it is a best practice for sponsors to provide the complainant with information regarding expectations of a timely response, confidentiality, non-retaliation and progress reports.

50.4.3 – Enrollee Communications and Education
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(D), 423.504(b)(4)(vi)(D)
Sponsors must educate their enrollees about identification and reporting of potential FWA. Education methods may include flyers, letters, pamphlets that can be included in mailings to enrollees (such as enrollment packages, Explanation of Benefits (“EOB”), and information published on sponsor websites (especially on enrollee links), etc.

50.5 – Element V: Well-Publicized Disciplinary Standards
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(E), 423.504(b)(4)(vi)(E)

Sponsors must have well-publicized disciplinary standards through the implementation of procedures which encourage good faith participation in the compliance program by all affected individuals. These standards must include policies that:

1. Articulate expectations for reporting compliance issues and assist in their resolution;

2. Identify noncompliance or unethical behavior; and

3. Provide for timely, consistent, and effective enforcement of the standards when noncompliance or unethical behavior is determined.

50.5.1 – Disciplinary Standards
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(E), 423.504(b)(4)(vi)(E)

Sponsors must establish and implement disciplinary policies and procedures that reflect clear and specific disciplinary standards. The disciplinary policies must describe the sponsor’s expectations for the reporting of compliance issues including noncompliant, unethical or illegal behavior, that employees participate in required training, and the expectations for assisting in the resolution of reported compliance issues. In addition, the disciplinary policies must identify noncompliant, unethical or illegal behavior, through examples of violative conduct that employees might encounter in their jobs. Further, the policies must provide for timely, consistent and effective enforcement of the standards when noncompliant or unethical behavior is found. Finally, the disciplinary action must be appropriate to the seriousness of the violation.
50.5.2 – Methods to Publicize Disciplinary Standards
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(E), 423.504(b)(4)(vi)(E)

To encourage good faith participation in the compliance program, sponsors must publicize disciplinary standards for employees and FDRs. The standards should include the duty and expectation to report issues or concerns. The following are examples of the types of publication mechanisms that could be used:

- Newsletters;
- Regular presentations at department staff meetings;
- Communications with FDRs;
- General compliance training;
- Intranet site;
- Posters prominently displayed throughout employee work and break areas; and
- Cafeteria table tents.

50.5.3 – Enforcing Disciplinary Standards
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(E), 423.504(b)(4)(vi)(E)

Sponsors must be able to demonstrate to CMS that disciplinary standards are enforced in a timely, consistent and effective manner. Records must be maintained for a period of 10 years for all compliance violation disciplinary actions, capturing the date the violation was reported, a description of the violation, date of investigation, summary of findings, disciplinary action taken and the date it was taken. Sponsors should periodically review these records of discipline to ensure that disciplinary actions are appropriate to the seriousness of the violation, fairly and consistently administered and imposed within a reasonable timeframe. Sponsors may consider including compliance as a measure on an individual's annual performance review. In addition, a best practice followed by some sponsors is to publish de-identified disciplinary action in employee publications, such as a newsletter, in order to demonstrate to employees that disciplinary action is imposed for violations.
50.6 – Element VI: Effective System for Routine Monitoring, Auditing and Identification of Compliance Risks
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(E), 423.504(b)(4)(vi)(E)

Sponsors must establish and implement an effective system for routine monitoring and identification of compliance risks. The system should include internal monitoring and audits and, as appropriate, external audits, to evaluate the sponsor’s, including FDRs’, compliance with CMS requirements and the overall effectiveness of the compliance program.

50.6.1 – Routine Monitoring and Auditing
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

Sponsors must undertake monitoring and auditing to test and confirm compliance with Medicare regulations, sub-regulatory guidance, contractual agreements, and all applicable Federal and State laws, as well as internal policies and procedures to protect against Medicare program noncompliance and potential FWA.

Monitoring activities are regular reviews performed as part of normal operations to confirm ongoing compliance and to ensure that corrective actions are undertaken and effective. An audit is a formal review of compliance with a particular set of standards (e.g., policies and procedures, laws and regulations) used as base measures.

Sponsors must develop a monitoring and auditing work plan that addresses the risks associated with the Medicare Parts C and D benefits. The compliance officer and compliance committee are key participants in this process.

Sponsors must have a system of ongoing monitoring and auditing that is reflective of its size, organization, risks and resources to assess performance in, at a minimum, areas identified as being at risk. The monitoring and auditing work plan must be coordinated, overseen and/or executed by the compliance officer, assisted if desired by the compliance department staff and/or the compliance committee. The compliance officer may coordinate with the audit department, if any, in connection with these activities. The compliance officer must receive regular reports from the
audit department or from those who are conducting the audits regarding the results of auditing and monitoring and the status and effectiveness of corrective actions taken. It is the responsibility of the compliance officer or his/her designee to provide updates on monitoring and auditing results to the compliance committee, the CEO, senior leadership and the sponsor’s governing body. In addition, for specific work coordinated with the audit department, the compliance officer and Chief Audit Executive may share the responsibility to provide updates on monitoring and auditing results to the compliance committee, the CEO, senior leadership and the sponsor’s governing body.

50.6.2 – Development of a System to Identify Compliance Risks
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)
Sponsors must establish and implement policies and procedures to conduct a formal baseline assessment of the sponsor’s major compliance and FWA risk areas, such as through a risk assessment. The sponsor’s assessment must take into account all Medicare business operational areas. Each operational area must be assessed for the types and levels of risks the area presents to the Medicare program and to the sponsor. Factors that sponsors may consider in determining the risks associated with each area include, but are not limited to:

- Size of department;
- Complexity of work;
- Amount of training that has taken place;
- Past compliance issues; and
- Budget.

Areas of particular concern for Medicare Parts C and D sponsors include, but are not limited to, marketing and enrollment violations, agent/broker misrepresentation, selective marketing, enrollment/disenrollment noncompliance, credentialing, quality assessment, appeals and grievance procedures, benefit/formulary administration, transition policy, protected classes policy, utilization management, accuracy of claims processing, detection of potentially fraudulent claims, and FDR oversight and monitoring.

Risks identified by the risk assessment must be ranked to determine which risk areas will have the greatest impact on the sponsor, and the sponsor must prioritize the monitoring and auditing strategy accordingly. Risks change and evolve with changes in the law, regulations, CMS requirements and operational matters. Therefore, there must be ongoing review of potential risks of noncompliance and FWA and a periodic re-evaluation of the accuracy of the sponsor’s baseline
assessments. Risk areas identified through CMS audits and oversight, as well as through the sponsor’s own monitoring, audits and investigations are priority risks. The results of the risk assessment inform the development of the monitoring and audit work plan.

50.6.3 – Development of the Monitoring and Auditing Work Plan
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

Once the risk assessment has been completed, a monitoring and auditing work plan must be developed. The compliance officer may coordinate with each department to develop a monitoring and auditing work plan based upon the results of the risk assessment. The work plan may include:

- The audits to be performed;
- Audit schedules, including start and end dates
- Announced or unannounced audits;
- Audit methodology;
- Necessary resources;
- Types of Audit: desk or onsite;
- Person(s) responsible;
- Final audit report due date to compliance officer; and
- Follow up activities from findings.

Sponsors must include in their work plans a process for responding to all monitoring and auditing results and for conducting follow-up reviews of areas found to be non-compliant to determine if the implemented corrective actions have fully addressed the underlying problems.

Corrective action and follow-up should be led or overseen by the compliance officer and assisted, if desired, by the compliance department staff, and include actions such as reporting findings to CMS or to the NBI MEDICs, if necessary.

50.6.4 – Audit Schedule and Methodology
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)
The work plan must include a schedule that lists all of the monitoring and auditing activities for the calendar year. Sponsors may want to organize the schedule by month or quarter.

Sponsors must audit their operational areas and those of their first tier entities. It is a best practice for sponsors to use a combination of desk and on-site audits, including, as appropriate and as permitted by contractual agreements, unannounced audits or “spot checks” when developing the work plan. On-site audits provide the auditor an opportunity to assess the on-site operations, interview staff, and gain a better understanding of the performance of the area under review.

Sponsors should prepare a standard audit report that includes items such as:

- Audit Objectives;
- Scope and Methodology;
- Findings:
  - Condition;
  - Criteria;
  - Cause;
  - Effect; and
- Recommendations

In developing the types of audits to include in the work plan sponsors must:

- Determine which risk areas will most likely affect the sponsor, and prioritize the monitoring and audit strategy accordingly;
- Utilize appropriate methods in:
  - Selecting sponsor facilities, pharmacies, providers, claims, and other areas for audit;
  - Determining appropriate sample size;
  - Extrapolating audit findings using statistically valid methods that comply with generally accepted auditing standards to the full universe; and
  - Applying targeted or stratified sampling methods driven by data mining and complaint monitoring;
- Use special targeted techniques based on aberrant behavior;
• Assess compliance with internal processes and procedures;

• Examine the performance of the compliance program, including a review of training, reporting mechanisms (e.g., hotline log), investigation files, OIG/GSA exclusion list screenings, evidence of employee receipt of Standards of Conduct and conflict of interest disclosures/attestations, and sampling for evidence in support of attestations, if the sponsor uses attestations to monitor compliance; and

• Conduct follow up review by auditing, monitoring or otherwise of areas previously found non-compliant to determine if the implemented corrective actions have fully addressed the underlying problem.

50.6.5 – Audit of the Sponsor’s Operations and Compliance Program
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

The compliance officer and compliance committee must ensure the implementation of an audit function appropriate to the sponsor’s size, scope and structure. The audit function may be performed by a separate audit department or may be performed by the compliance department. Staff dedicated to the audit function will be responsible for monitoring and auditing the sponsor’s operational areas to ensure compliance with Medicare regulations. Adequate resources must be devoted to the audit function considering factors such as size and scope of the sponsor’s Medicare Part C and D programs, its compliance history, current compliance risks, and the amount of resources necessary to meet the goals of its annual work plan.

Participants in the audit function must be knowledgeable about CMS operational requirements for the areas under review. Auditors may include, as needed, pharmacists, nurses, physicians, certified public accountants, fraud investigators, SIU staff, compliance staff with operational backgrounds and other highly skilled staff. These specific roles need not reside within the audit department or compliance department. Rather, they may reside in other departments provided their services are accessible to perform the necessary audit responsibilities.

Sponsors must ensure that auditors are independent and do not engage in self-policing. Operations staff may assist in audit activities provided the assistance is compatible with the independence of the audit function. For example, operations staff may gather data for samples requested by the auditor and may provide other types of information to auditors. Sponsors must ensure that audit staff have access to the relevant personnel, information, records and areas of operation under review, including the operational areas at the plan and FDR level.
Sponsors must audit the effectiveness of the compliance program and the results must be shared with the governing body. Audits of the compliance program should occur at least annually. In order to avoid self-policing, sponsors who exclusively use compliance department staff, including the compliance officer, for their auditing function should train employees who are not part of the compliance department to perform the audit, or outsource the audit to external auditors.

While the compliance department staff may not conduct the formal audit of the effectiveness of the compliance program, it may administer less formal measures of compliance program effectiveness, such as a self-assessment tool or dashboard or scorecard in support of the compliance program effectiveness audit.

50.6.6 – Monitoring and Auditing FDRs
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

Sponsors are responsible for the lawful and compliant administration of the Medicare Parts C and D benefits under their contracts with CMS, regardless of whether the sponsor has delegated some of that responsibility to FDRs. The sponsor must develop a strategy to monitor and audit its first tier entities to ensure that they are in compliance with all applicable laws and regulations, and to ensure that the first tier entities are monitoring the compliance of the entities with which they contract (the sponsors’ “downstream” entities). Sponsors must also monitor any related entities to ensure those entities are compliant with all applicable laws and regulations.

Sponsors must include in their work plan the number of first tier entities that will be audited each year and how the entities will be identified for auditing. It is a best practice for sponsors to conduct a number of on-site audits.

Sponsors must conduct specific monitoring of first tier entities to ensure they fulfill the compliance program requirements. When a sponsor has a large number of first tier entities, making it impractical and/or cost prohibitive to monitor or audit all first tier entities for all compliance program requirements, the sponsor may perform a risk assessment to identify its highest risk first tier entities, then select a reasonable number of first tier entities to audit from the highest risk groups. Monitoring of first tier entities for compliance program requirements must include an evaluation to confirm that the first tier entities are applying appropriate compliance program requirements to downstream entities with which the first tier contracts.
When FDRs perform their own audits, it is a best practice for sponsors to obtain a summary of the audit work plan and audit results that relate to the services the FDR performs. Examples of reports that sponsors should receive and review as part of their FDR monitoring and auditing efforts include, but are not limited to:

- **Payment Reports** that detail the amount paid by both the sponsor and the enrollee; in addition, payment reports identifying the provider, the enrollee and a description of the drug (including dosage and amount) or service provided. These reports should be used to identify over and under payments, duplicate payments, timely payments, and pricing aberrances, and to help verify correct pricing;

- **Drug Utilization Reports** that identify the number of prescriptions filled by a particular enrollee and in particular, numbers of prescriptions filled for suspect classes of drugs, such as narcotics, to identify possible therapeutic abuse or illegal activity by an enrollee. Enrollees with an abnormal number of prescriptions or prescription patterns for certain drugs should be identified in reports. Likewise, Drug Utilization Management reports from FDRs may be a useful tool in identifying FWA;

- **Provider Utilization Reports** that identify the number and types of visits and services submitted for payment to identify possible spikes and/or irregularities such as a provider submitting claims for services that would not normally be performed by the provider’s specialty;

- **Prescribing and Referral Patterns by Physician Reports** that identify the number of prescriptions and referrals written by a particular provider and typically focus on a class or particular type of drug, such as narcotics, or a specific type of DME, such as scooters. These reports should be generated to identify possible prescriber and referral/provider, pharmacy fraud and DME fraud; and

- **Geographic ZIP Reports** that identify possible doctor shopping schemes or script mills by comparing the geographic location (ZIP code) of the patient to the location of the provider that wrote the prescription and should include the location of the dispensing pharmacy. These reports should generate information on those enrollees who obtain multiple prescriptions from providers located more than the normal distance traveled for care (for example, 30 miles). “Normal distance” should take into account where the enrollee resides (i.e., enrollees in rural areas would typically have longer trips to a doctor or pharmacy than enrollees living in urban areas).

When corrective action is needed, sponsors must ensure that corrective actions are taken by the entity. Although first tier entities may perform their own internal auditing, the sponsor remains obligated to perform its own auditing of first tier entities.
Sponsors should track and document compliance efforts. In addition to formal audits and monitoring, it is a best practice for sponsors to regularly track and document compliance using dashboards, scorecards, self-assessment tools that the sponsor creates or purchases, and other mechanisms that show the extent to which operational areas and FDRs are meeting compliance goals. Compliance of operational areas should be tracked by management and publicized to employees. Issues of noncompliance identified in dashboards, scorecards and self-assessment tools, etc., should be shared with senior management. Sponsors should consider including compliance performance as a measure for staff, management, and FDR evaluations.

This section provides guidance regarding sponsors’ implementation of FWA safeguards to identify excluded providers and entities. Medicare payment may not be made for items or services furnished or prescribed by an excluded provider or entity. Sponsors shall not use federal funds to pay for services, equipment or drugs prescribed or provided by a provider, supplier, employee or FDR excluded by the DHHS OIG or GSA.

Sponsors must review the DHHS OIG List of Excluded Individuals and Entities (LEIE list) and the GSA Excluded Parties Lists System (EPLS) prior to the hiring or contracting of any new employee, temporary employee, volunteer, consultant, governing body member, or FDR, and monthly thereafter, to ensure that none of these persons or entities are excluded or become excluded from participation in federal programs. Monthly screening is essential to prevent inappropriate payment to providers, pharmacies, and other entities that have been added to exclusions lists since the last time the list was checked. After entities are initially screened against the entire LEIE and EPLS at the time of hire or contracting, sponsors need only
review the LEIE supplement file provided each month, which lists the entities added to the list that month, and review the EPLS updates provided during the specified monthly time frame.

OIG’s LEIE includes all health care providers and suppliers that are excluded from participation in federal health care programs, including those health care providers and suppliers that might also be on the EPLS. In addition to health care providers (that are also included on the OIG LEIE) the EPLS includes non-health care contractors.

Links to instructions for accessing this information are available in Appendix A: Resources.

50.6.9 – Use of Data Analysis for Fraud, Waste and Abuse Prevention and Detection
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

Sponsors must perform effective monitoring in order to prevent and detect FWA. Sponsors may accomplish this through the use of data analysis. Data analysis should include the comparison of claim information against other data (e.g., provider, drug or medical service provided, diagnoses or beneficiaries) to identify unusual patterns suggesting potential errors and/or potential fraud and abuse. Data analysis should factor in the particular prescribing and dispensing practices of providers who serve a particular population (e.g., long term care providers, assisted living facilities, etc.). Use of data analysis may include monitoring pharmacy and medical billing to detect unusual patterns. Sponsors may invest in data analysis software applications that give them the ability to analyze large amounts of data to detect FWA both internally and externally. Data analysis should:

- Establish baseline data to enable the sponsor to recognize unusual trends, changes in drug utilization over time, physician referral or prescription patterns, and plan formulary composition over time;

- Analyze claims data to identify potential errors, inaccurate TrOOP accounting, and provider billing practices and services that pose the greatest risk for potential FWA to the Medicare program;

- Identify items or services that are being over utilized;

- Identify problem areas within the plan such as enrollment, finance, or data submission;
• Identify problem areas at the FDR (e.g., PBM, pharmacies, pharmacists, physicians, other health care providers and suppliers); and

• Use findings to determine where there is a need for a change in policy.

Sponsors should develop indicators that will be used to identify norms, abnormalities, and individual variables that describe statistically significant time-series trends. Examples include:

- Standard deviations from the mean;
- Percent above the mean or median; and
- Percent increase in charges, number of visits/services from one period to another.

Sponsors should routinely generate and review reports on pharmacy billing, medical claims, etc., based upon the data analysis performed to identify pharmacies and other FDRs that require further review.

50.6.10 – Special Investigation Units (SIUs)
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F)

An effective program to control FWA includes policies and procedures to identify and address FWA at both the sponsor and FDR levels in the delivery of Parts C and D benefits. An SIU is an internal investigation unit, often separate from the compliance department, responsible for conducting surveillance, interviews, and other methods of investigation relating to potential FWA. Depending upon the size of and resources available within the organization, sponsors must either establish a specific SIU or ensure that responsibilities generally conducted by an SIU are conducted by the compliance department. Sponsors are not expected to perform law enforcement activities and may refer all matters indicative of FWA to the NBI MEDIC or law enforcement.

SIU responsibilities should include:

- Reducing or eliminating Medicare Parts C and D benefit costs due to FWA;

- Reducing or eliminating fraudulent or abusive claims paid for with federal dollars;

- Preventing illegal activities;
• Identifying enrollees with overutilization issues;

• Identifying and recommending providers for exclusion, including those who have defrauded or abused the system to the NBI MEDIC and/or law enforcement;

• Referring suspected, detected or reported cases of illegal drug activity, including drug diversion, to the NBI MEDIC and/or law enforcement and conducting case development and support activities for NBI MEDIC and law enforcement investigations; and

• Assisting law enforcement by providing information needed to develop successful prosecutions.

SIUs must be accessible through multiple channels such as via phone, email, Internet message submission, and mail. Sponsors must ensure that suspicions of FWA can be reported anonymously to the SIU.

Sponsors must ensure that the SIU and compliance department communicate and coordinate closely to ensure that the Medicare Parts C and D benefits are protected from fraudulent, abusive and wasteful schemes throughout the administration and delivery of benefits, both at the sponsor and FDR levels.

50.6.11 – Auditing by CMS or its Designee
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(F), 423.504(b)(4)(vi)(F), 422.504(e)(2), 423.505(e)(2)

CMS has the discretionary authority to perform audits under 42 C.F.R. 44 422.504(e)(2) and 423.505(e)(2), which specify the right to audit, evaluate, or inspect any books, contracts, medical records, patient care documentation, and other records of sponsors or FDRs that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable under the contract or as the Secretary of Health and Human Services may deem necessary to enforce the contract.

Sponsors must allow access to any auditor acting on behalf of the federal government or CMS to conduct an on-site audit. On-site audits require a thorough review of required documentation. Such reviews include any information needed to determine compliance with the Medicare Parts C and D regulations and contracts, such as copies of prescriptions, invoices, provider and pharmacy licenses, claims records, signature logs, records documenting delivery status by postal carrier, long-term care delivery notice to nursing staff, other forms of documentation of
medication delivery, purchase records, contracts, rebate and discount agreements, as well as interviews of the staff. The interviews gauge whether control activities are practiced as dictated by the company's policy and applicable Parts C and D requirements are being followed. On-site audits are based on sampling or results of desk audits. In most cases, CMS or its designee will provide reasonable notice to the sponsor of the time and content of the audit.

The OIG has independent authority to conduct audits and evaluations necessary to ensure accurate and correct payment and to otherwise oversee Medicare reimbursement.

Sponsors and FDRs must provide records to CMS or its designee. Sponsors should cooperate in allowing access as requested. Failure to do so may result in a referral of the sponsor and/or FDR to law enforcement and/or implementation of other corrective actions, including intermediate sanctioning in line with 42 C.F.R. Subpart O. MEDICs and other contractors tasked to conduct audits by CMS, as well as contractors trained by CMS and engaged by sponsors to conduct CMS data validation audits, are acting on behalf of the federal government and are not required to sign the sponsor’s confidentiality statement prior to the start of an on-site audit. Sponsors and FDRs are required to cooperate with CMS and CMS’ contractors, such as the NBI MEDICs. This cooperation includes providing CMS and/or the NBI MEDICs or other contractors access to all requested records associated in any manner with the Parts C or D program.

When CMS or its designee (e.g., the NBI MEDIC) requests information that will be used for an audit, CMS or its designee will notify the sponsor of an appropriate time period within which to provide the requested information.

50.7 – Element VII: Procedures and System for Prompt Response to Compliance Issues
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)


Sponsors must establish and implement procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensuring ongoing compliance with CMS requirements.

1. If the sponsor discovers evidence of misconduct related to payment or delivery of items or services under the contract, it must conduct a timely, reasonable inquiry into that conduct.
2. The sponsor must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible individuals) in response to the potential violation referenced above.

3. The sponsor should have procedures to voluntarily self-report potential fraud or misconduct related to the Medicare program to CMS or its designee (such as the NBI MEDIC).

50.7.1 – Conducting a Timely and Reasonable Inquiry of Detected Offenses

(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)


Sponsors must conduct a timely and well-documented reasonable inquiry into any compliance incident or issue involving potential Medicare program noncompliance or potential FWA.

Program noncompliance and FWA may occur at the level of the sponsor or its FDRs. It may be discovered through a hotline, a website, an enrollee complaint, during routine monitoring or self evaluation, an audit, or by regulatory authorities. Regardless of how the noncompliance or FWA is identified, sponsors must initiate a reasonable inquiry as quickly as possible, but not later than 2 weeks after the date the potential noncompliance or potential FWA incident was identified.

A reasonable inquiry includes a preliminary investigation of the matter by the compliance officer or a delegated member of his/her staff and/or the sponsor’s SIU. If the issue appears to involve potential fraud or abuse and the sponsor does not have either the time or the resources to investigate the potential fraud or abuse in a timely manner, it should refer the matter to the NBI MEDIC within 30 days of the date the potential fraud or abuse is identified so that the potentially fraudulent or abusive activity does not continue.

Sponsors are responsible for monitoring for FWA and Medicare program noncompliance within their organizations. When serious noncompliance or waste occurs, CMS strongly encourages sponsors to refer the matter to CMS. When potential fraudulent or abusive activity is identified, CMS strongly encourages sponsors to refer the matter to the appropriate MEDIC (currently, the NBI MEDIC).
50.7.2 – Corrective Actions
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)


Sponsors must undertake appropriate corrective actions in response to potential noncompliance or potential FWA.

Corrective actions must be designed to correct the underlying problem that results in program violations and to prevent future noncompliance. A root cause analysis determines what caused or allowed the FWA, problem or deficiency to occur. A corrective action must be tailored to address the particular FWA, problem or deficiency identified, and must include timeframes for specific achievements.

The sponsor must ensure that FDRs have corrected their deficiencies. When developing corrective actions for FWA or program noncompliance by an FDR, the elements of the corrective action should be detailed in writing and include ramifications if the FDR fails to implement the corrective action satisfactorily. Also, the sponsor / FDR contract should include language that details the ramifications of failing to maintain compliance or engaging in FWA, such as contract termination.

In order to ensure that the FDR has implemented the corrective action, sponsors should conduct independent audits or review the FDR’s monitoring or audit reports. Sponsors must continue to monitor corrective actions after their implementation to ensure that they are effective.

The elements of the corrective action that address noncompliance or FWA committed by the sponsor’s employee(s) or FDRs must be documented, and include ramifications should the sponsor’s employee(s) or its FDRs fail to satisfactorily implement the corrective action. The sponsor must enforce effective correction through disciplinary measures, including employment or contract termination, if warranted.

Thorough documentation must be maintained of all deficiencies identified and corrective actions taken.

50.7.3 – Procedures for Self-Reporting Potential FWA and Significant Non Compliance
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
Self-reporting of FWA and Medicare program noncompliance is voluntary. CMS nonetheless strongly encourages self-reporting as an important practice in maintaining an effective compliance program. Sponsors should self-report potential FWA discovered at the plan level, and potential fraud and abuse by FDRs, as well as significant waste and significant incidents of Medicare program noncompliance.

Where sponsors notify the MEDICs of potential FWA in accordance with the guidelines described below, the MEDICs will refer potential FWA to law enforcement when appropriate. Issues that are referred to the NBI MEDIC and are determined not to be potential FWA will be returned to the sponsor to be addressed.

Sponsors are required to investigate potential FWA activity to make a determination whether potential FWA has occurred. Sponsors must conclude investigations of potential FWA within a reasonable time period after the activity is discovered. If after conducting a reasonable inquiry, the sponsor (e.g., the compliance officer or SIU) determines that potential FWA related to the Medicare Parts C or D programs has occurred, the matter should be referred to the NBI MEDIC promptly. Sponsors should also refer potential FWA at the FDR levels to the NBI MEDIC so that the NBI MEDIC can help identify and address any scams or schemes.

Sponsors should also consider reporting potentially fraudulent conduct to government authorities such as the Office of Inspector General (through the OIG’s Provider Self-Disclosure Protocol) or the Department of Justice. All health care providers doing business with Medicare that want to disclose violations of law are eligible to disclose fraudulent conduct under the Provider Self-Disclosure Protocol. The Protocol offers a detailed step-by-step explanation of how a provider should proceed in reporting and assessing the extent of potential fraud and how the OIG will go about verifying irregularities.

Where a sponsor discovers an incident of significant Medicare program noncompliance, the sponsor should report the incident to CMS as soon as possible after its discovery. This will enable CMS to provide guidance to the sponsor on mitigation of the harm caused by the incident of noncompliance. While no bright line definition exists as to what is a “significant” or “serious” incident that should be reported, sponsors should err on the side of over-reporting rather than under-reporting.

Self-reporting offers sponsors the opportunity to minimize the potential cost and disruption of a full scale audit and investigation, to negotiate a fair monetary settlement, and to potentially avoid an OIG permissive exclusion preventing the entity from doing business with Federal health care programs.
50.7.4 – NBI MEDIC

Medicare Drug Integrity Contractors (MEDIC) are organizations that CMS contracts with to perform specific program integrity functions for Parts C and D under the Medicare Integrity Program. The MEDIC’s primary role is to identify potential fraud and abuse in Medicare Part C and Part D. There is currently one National Benefit Integrity (NBI) MEDIC.

NBI MEDICs will investigate referrals from sponsors, develop the investigations, and make referrals to appropriate law enforcement agencies or other outside entities when necessary. The NBI MEDIC will keep the sponsor apprised of the development and status of the investigation. If the NBI MEDIC determines a referral to be a matter related to noncompliance or mere error rather than fraud or abuse, the matter will be returned to CMS and/or the sponsor for appropriate follow-up.

Sponsors should refer cases involving potential fraud or abuse that meet any of the following criteria to the NBI MEDIC:

- Suspected, detected or reported criminal, civil, or administrative law violations;
- Allegations that extend beyond the Parts C and D plans, involving multiple health plans, multiple states, or widespread schemes;
- Allegations involving known patterns of fraud;
- Pattern of fraud or abuse threatening the life or well being of beneficiaries; and
- Scheme with large financial risk to the Medicare Program or beneficiaries.

50.7.5 – Referrals to the NBI MEDIC

Sponsors should refer cases involving potential fraud or abuse that meet any of the following criteria to the NBI MEDIC:

- Suspected, detected or reported criminal, civil, or administrative law violations;
- Allegations that extend beyond the Parts C and D plans, involving multiple health plans, multiple states, or widespread schemes;
- Allegations involving known patterns of fraud;
- Pattern of fraud or abuse threatening the life or well being of beneficiaries; and
- Scheme with large financial risk to the Medicare Program or beneficiaries.
Each sponsor referral to the NBI MEDIC should contain specifics that will allow an investigator to follow-up on a case including basic identifying information and contacts as well as a description of the allegations.

If available, a referral should include:

- **Name of:**
  - compliance officer or SIU investigator, and
  - Organization;

- **Contact information for follow up;**

- **Summary of the Issue:**
  - Include the basic who, what, when, where, how, and why; and
  - Any potential legal violations;

- **Specific Statutes and Allegations:**
  - List civil, criminal, and administrative code or rule violations, state and federal; and
  - Provide detailed description of the allegations or pattern of fraud, waste, or abuse;

- **Incidents and Issues:**
  - List incidents and issues related to the allegations;

- **Background information:**
  - Contact information for the complainant, the perpetrator or subject of the investigation, and beneficiaries, pharmacies, providers, or other entities involved; and
  - Additional background information that may assist investigators, such as names and contact information of informants, relators, witnesses, websites, geographic locations, corporate relationships, networks;

- **Perspectives of Interested Parties:**
  - Perspective of Plan, CMS, enrollee;

- **Data:**
  - Existing and potential data sources;
  - Graphs and trending;
Maps; and

Financial impact estimates; and

• Recommendations in Pursuing the Case:
  o Next steps, special considerations, cautions.

Call the NBI MEDIC at 1-877-7SafeRX (1-877-772-3379).

For referral forms, go to:

The NBI MEDIC may request additional information in order to fully investigate and resolve the matter. The sponsor shall furnish additionally requested information within 30 days, unless the NBI MEDIC specifies otherwise. In instances where the MEDIC requires information in less than 30 days, all parties involved will be notified as soon as possible. Sponsors should provide updates to the NBI MEDIC when new information regarding the matter is identified.

50.7.6 – Responding to CMS-Issued Fraud Alerts
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)


CMS issues alerts to Part D sponsors concerning fraud schemes identified by law enforcement officials. Typically, these alerts describe alleged activities involving pharmacies practicing drug diversion or prescribers participating in illegal remuneration schemes. Sponsors may take action (including denying or reversing claims) in instances where the sponsor’s own analysis of its claims activity indicates that fraud may be occurring. A sponsor’s decision to deny or reverse claims should be made on a claim-specific basis.

When a Fraud Alert is received, the sponsor should review its contractual agreements with the identified parties. It would be appropriate for the sponsor to consider terminating the contract(s) with the identified parties if law enforcement has issued indictments against particular parties and the terms of the sponsor’s contract(s) authorizes contract termination in those circumstances.

Sponsors are also obligated to review their past paid claims from entities identified in a fraud alert. With the issuance of a fraud alert, CMS has placed sponsors on notice (see 42 CFR 423.505(k)(3)) that they should review claims involving identified providers. To meet the “best knowledge, information, and belief” standard of certification, sponsors should make their best efforts to, identify claims that may be
or may have been part of an alleged fraud scheme and remove them from their sets of prescription drug event data submissions.

50.7.7 – Identifying Providers with a History of Complaints
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

42 C.F.R. §§ 422.503(b)(4)(vi)(G), 423.504(b)(4)(vi)(G), 422.504(d)-(e)
Sponsors should maintain files for a period of 10 years on both in-network and out-of-network providers who have been the subject of complaints, investigations, violations, and prosecutions. This includes enrollee complaints, NBI MEDIC investigations, OIG and/or DOJ investigations, US Attorney prosecution, and any other civil, criminal, or administrative action for violations of Federal health care program requirements. Sponsors should also maintain files that contain documented warnings (i.e., fraud alerts) and educational contacts, the results of previous investigations, and copies of complaints resulting in investigations. Sponsors must comply with requests by law enforcement, CMS and CMS’ designee regarding monitoring of providers within the sponsor’s network that CMS has identified as potentially abusive or fraudulent.
Appendix A: Resources
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

For more information on topics discussed in this chapter, including developing and implementing effective compliance and fraud and abuse plans, see:

Government Resources:

1. National Benefit Integrity MEDIC:

2. Stop Medicare Fraud:
   http://www.stopmedicarefraud.gov

3. The Patient Protection and Affordable Care Act:

4. Compliance Guidance for Medicare+Choice Organizations:
   http://oig.hhs.gov/fraud/docs/complianceguidance/111599.pdf

5. Office of the Inspector General, Compliance Program Guidance for the Healthcare Industry:

6. Federal Sentencing Guidelines:
   http://www.ussc.gov/Guidelines

7. Fraud Alerts, Bulletins and Other Guidance from the OIG:
   http://oig.hhs.gov/compliance/alerts/index.asp

8. False Claims Act:

9. Health Insurance Portability and Accountability Act (HIPAA):
   http://aspe.hhs.gov/admnsimp/pl104191.htm

10. Anti-Kickback Statute (see section 1128B(b)):
    http://www.ssa.gov/OP_Home/ssact/title11/1128B.htm#f

    https://www.cms.gov/PhysicianSelfReferral/
12. TRICARE Fraud & Abuse:  
http://www.tricare.osd.mil/fraud

Other Resources:

1. Health Care Administrators Association (HCAA):  
http://www.hcaa.org /

2. Heath Care Compliance Association (HCCA):  
http://www.hcca-info.org

3. Society of Corporate Compliance and Ethics (SCCE):  
http://www.corporatecompliance.org

http://www.healthlawyers.org

5. National Health Care Anti-Fraud Association (NHCAA):  
http://www.nhcaa.org

6. Institute for Health Care Improvement (IHI):  
http://ihi.org

http://oig.hhs.gov/fraud/docs/complianceguidance/CorporateResponsibilityFinal%209-4-07.pdf

Links to OIG and GSA Exclusions Databases

- OIG LISTSERV via the OIG Website: http://exclusions.oig.hhs.gov/

- General Services Administration (GSA) database of excluded individuals/entities:  https://www.epls.gov/
Appendix B: Laws and Regulations to Consider in Standards of Conduct and/or Training
(Chapter 9 - Rev. 15, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)
(Chapter 21 - Rev. 109, Issued: 07-27-12, Effective: 07-20-12; Implementation: 07-20-12)

- Title XVIII of the Social Security Act
- Medicare regulations governing Parts C and D found at 42 C.F.R. §§ 422 and 423 respectively
- Patient Protection and Affordable Care Act (Pub. L. No. 111-148, 124 Stat. 119)
- Health Insurance Portability and Accountability Act (HIPAA) (Public Law 104-191)
- Anti-Kickback Statute (42 U.S.C. § 1320a-7b(b))
- The Beneficiary Inducement Statute (42 U.S.C. § 1320a-7a(a)(5))
- Civil monetary penalties of the Social Security Act (42 U.S.C. § 1395w-27 (g))
- Physician Self-Referral (“Stark”) Statute (42 U.S.C. § 1395nn)
- Fraud and Abuse, Privacy and Security Provisions of the Health Insurance Portability and Accountability Act, as modified by HITECH Act
- Prohibitions against employing or contracting with persons or entities that have been excluded from doing business with the Federal Government (42 U.S.C. §1395w-27(g)(1)(G)
- Fraud Enforcement and Recovery Act of 2009
- All sub-regulatory guidance produced by CMS and HHS such as manuals, training materials, HPMS memos, and guides
## Transmittals Issued for this Chapter

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<td>Chapter 9, Compliance Program Guidelines</td>
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SUBJECT: Chapter 12-Employer/Union Sponsored Group Health Plans

I. SUMMARY OF CHANGES: Initial release of Chapter 12 of the Medicare Prescription Drug Benefit Manual into the CMS Manual System. Normally, red italic font identifies new material. However, because this release is a new chapter, normal text font is used for the initial release. New material in subsequent releases will be identified in red, italic font.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: November 7, 2008
IMPLEMENTATION DATE: November 7, 2008

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously posted to http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage or http://www.cms.hhs.gov/manuals/ and disseminated via the Health Plan Management System (HPMS). However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.


II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED)

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III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

IV. ATTACHMENTS:

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*Unless otherwise specified, the effective date is the date of service.
Prescription Drug Benefit Manual
Chapter 12 – Employer/Union Sponsored Group Health Plans

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10 - Introduction
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

10.1 - Application of CMS Employer Group Waiver Authority
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

CMS has statutory authority to waive or modify requirements that hinder the design of, the offering of, or the enrollment in, employer/union sponsored standalone prescription drug plans (PDPs). This statutory authority, set forth in section 1860D-22(b) of the Social Security Act (the “Act”), provides:

(b) Application of MA Waiver Authority. – The provisions of section 1857(i) shall apply with respect to prescription drug plans in relation to employment-based retiree health coverage in a manner similar to the manner in which they apply to an MA plan in relation to employers, including authorizing the establishment of separate premium amounts for enrollees in a prescription drug plan by reason of such coverage and limitations on enrollment to part D eligible individuals enrolled in such coverage.¹

Under this specific statutory authority, in order to facilitate the offering of PDPs to employer/union group health plan sponsors, CMS may grant waivers and/or modifications to PDP sponsors. When exercising its discretion to grant these waivers or modifications, each waiver or modification will be conditioned upon the PDP sponsor meeting a set of defined circumstances and complying with a set of conditions. PDP sponsors offering employer group plans must comply with all Part D requirements unless those requirements have been specifically waived or modified.

Waivers/modifications may be granted to PDP sponsors offering “individual” PDPs or PDP sponsors offering customized employer group PDPs offered exclusively to employer/union group health plan sponsors. Individual PDPs are open to both individual Medicare beneficiaries and employer/union sponsored group health plans’ Part D eligible beneficiaries. Customized employer group PDPs offered exclusively to employer/union group health plan sponsors include: (1) plans offered by PDP sponsors to employers/ unions (these plans are hereinafter referred to as “800 series” plans because their plan benefit packages are enumerated in the CMS Health Plan Management System (HPMS) with identifiers in the 800s to distinguish them from individual plans offered by PDP sponsors); and (2) plans offered by employers/unions that directly contract with CMS (hereinafter referred to as “Direct Contract” plans). These “800 series” and Direct Contract PDPs are referred to collectively as employer/union-only group waiver plans (“EGWPs”).

Note that CMS’ employer group waiver authority only applies to the Part D portion of the coverage provided by Cost Plans, not Parts A and B. Thus, Cost Plans may only use the Part

¹ Section 1857(i) of the Act, which applies to Medicare Advantage Organizations, provides as follows: To facilitate the offering of [Medicare Advantage] plans under contracts between [Medicare Advantage] organizations and employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) to furnish benefits to the entity’s employees, former employees (or combination thereof) or members or former members (or combination thereof) of the labor organizations, the Secretary may waive or modify requirements that hinder the design of, the offering of, or the enrollment in such [Medicare Advantage] plans.
D waiver authority to offer Part D EGWPs as an optional supplemental benefit. Therefore, Cost Plans with supplemental Part D benefits will only qualify for the employer/union group health plan waivers applicable to Part D. See Pub. 100-16, Medicare Managed Care Manual, Chapter 17 (Cost Based Payment), Subchapter F (Benefits and Beneficiary Protections), Section 60.

10.2 - Employer/Union Group Health Plan Sponsorship of Employer/Union-Only Group Waiver Plans (EGWPs)
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

As stated above, all EGWPs must restrict enrollment to employer/union group health plan Part D eligible retirees and/or their Part D eligible spouses and dependents (hereinafter referred to as “Part D eligibles”). The final benefit packages of “800 series” EGWPs are typically developed through private contractual negotiations between the PDP sponsor and employer/union group health plan sponsors of employment-based retiree coverage.

CMS has issued specific guidance waiving or modifying a number of Part D requirements that apply to these two kinds of PDPs which are detailed below. However, Direct Contract and “800 series” EGWPs must comply with all Part D requirements unless those requirements have been specifically waived or modified.

10.3 - Employer/Union Group Health Plan Sponsorship of Individual PDPs
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

As stated above, in addition to EGWPs, employer/union group health plan sponsors may choose to enroll their Part D eligibles in individual PDPs. These PDPs do not qualify for all of the employer/union group health plan waivers outlined below in this chapter. Those waivers that apply to employer/union group sponsorship of individual PDPs will be specifically identified below (e.g., group enrollment/disenrollment process, special enrollment periods (SEPs), and the annual open enrollment period waiver).

10.4 - Identification of Employer/Union Sponsored Group Health Plan Enrollees
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

The EGHP (Employer Group Health Plan) Flag field must be set to “Y” when submitting enrollment transactions for any beneficiary who is a Part D eligible retiree of an employer/union sponsored group health plan (this includes Direct Contract and “800 series” enrollments and employer/union group health plan sponsored enrollments in individual PDPs). This flag should be set to “Y” for all enrollment transaction codes (including 60, 61, 71 and 72 transactions). This designation is especially important when employer/union group health plan Part D eligibles are enrolled in individual PDPs to differentiate them from individual beneficiaries. For more details, see Medicare Advantage and Prescription Drug Plans - Plan Communications User Guide and Appendices.
10.5 - Private Reinsurance Arrangements with Employer/Union Group Health Plan Sponsors

(Pv.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

PDP sponsors must meet Part D state licensure and financial solvency requirements under 42 CFR 423.401. With regard to these requirements, all PDP sponsors are permitted to obtain reinsurance or make other arrangements for the cost of coverage provided to any enrollee (including arrangements with employers/unions) to the extent that the PDP sponsor is at risk for providing the coverage. See 42 CFR 423.401(b). Similarly, Part D requirements do not prohibit PDP sponsors offering “800 series” or individual PDPs to employer and union group health plan sponsors from entering into these kinds of reinsurance arrangements with self-insured (i.e., self-funded) employers/unions.\(^2\) Notwithstanding these arrangements, the PDP sponsor retains the responsibility for meeting all Part D requirements.

10.6 - Employer/Union-Only Group Waiver Plans and COBRA

(Pv.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

The Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) requires employer group health plans with at least 20 employees to offer continuation coverage to plan enrollees who experience a COBRA qualifying event such as termination of employment, death of the participant or a divorce. COBRA requirements apply to active employee plans and retiree plans. Employer/union sponsored group Medicare plans that meet the definition of “group health plan,” as that term is defined at section 5000(b)(1) of the Internal Revenue Code, may be subject to COBRA requirements.

The standard Part D benefits are not subject to COBRA continuation of coverage requirements. Employer/Union sponsors, however, may be required by COBRA to offer continuation of coverage for supplemental benefits that are financed outside of Medicare to beneficiaries in their plans that experience a COBRA qualifying event. For example, if an employer offered additional drugs that were integrated into a customized EGWP (Direct Contract or “800 series” plan) for the employer/union sponsored PDP but was solely paid for by employer premiums, the employer/union sponsor may be required to offer continuation of coverage only for the additional drugs when a beneficiary enrolled in the plan experiences a COBRA qualifying event.

However, there is nothing in either the Medicare law or the COBRA law that prohibits an employer/union sponsor from electing to provide continuation of coverage for the entire employer sponsored group plan (the Medicare benefits along with the non-Medicare supplemental benefits). In doing so, however, an employer/union sponsor must adhere to Medicare requirements. These include the following requirements:

1 (1) When a PDP sponsor offering an employer/union sponsored group plan receives notification that an individual is no longer eligible for the employer/union group sponsored

\(^2\) Similarly, employer group plans may enter into administrative services only (ASO) arrangements with PDP sponsors whereby the entity provides certain administrative services to a self-funded employer group plan, such as claims adjudication and enrollment services.
plan because a COBRA qualifying event has occurred, it must follow the termination procedures documented in Pub. 100-18, chapter 3, section 40.6, which only allows prospective termination. Terminations can be effective only at the end of a calendar month; and

(2) Although COBRA permits a group health plan to charge up to 102% of the applicable premium for continuation of coverage, an employer/union sponsor that offers COBRA coverage can charge no more than 100% of the premium for the Medicare portion of the benefits offered (Medicare will continue to pay its portion of the cost). If an employer/union sponsor can segregate the premium for the non-Medicare supplemental benefits offered, it can charge up to 102% of the portion of the premium that is attributable to the non-Medicare supplemental benefits.

Since employer/union sponsors in some instances have up to 44 days after a qualifying event to provide a notice to an enrollee of a right to elect continuation of coverage, and an enrollee has up to 60 days after receiving the notice to elect continuation of coverage, an enrollee may make the election to continue this coverage after the effective date of termination. Under COBRA law, an enrollee who elects continuation of coverage is entitled to have coverage reinstated retroactively back to the date of the termination of coverage. For employer/union sponsors that wish to reinstate beneficiaries who elect continuation of coverage back to the effective date of termination, PDP sponsors offering such plans should submit such reinstatements using Transaction Code 60 where possible and/or by submission to the CMS retroactive adjustment contractor when necessary.

10.7 - EGWP Application Procedures
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Entities that seek to offer a Part D EGWP must enter into a contract with CMS. An applicant must meet certain requirements before CMS can consider entering into a contract with the entity. In addition, an applicant must have an acceptable bid before it may enter into a contract to offer a Part D EGWP (for bidding instructions see section 20.9 below). Information on the application process can be found at http://www.cms.hhs.gov/EmpGrpWaivers/01_Overview.asp.

20 - Approved Employer/Union Sponsored Group Health Plan Waivers
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Set forth below is a list of waivers or modifications approved for PDP sponsors offering employer/union sponsored group health plans. As noted above, as a condition of CMS granting the particular waiver or modification, PDP sponsors must demonstrate that they meet the criteria established by CMS as outlined in the specific waiver. For each waiver, CMS has noted whether the waiver/modification applies to “800 Series” PDPs, Direct Contract PDPs, or employer/union sponsored group health plan enrollments in individual PDPs. Each of these waivers/modifications will automatically apply to those PDP sponsors approved to offer EGWPs or individual plans that satisfy the applicable criteria; thus, they do not need to be granted on an individual basis. However, some waivers may be restricted to particular kinds of entities and/or a particular set of circumstances as noted below.
In addition to the waivers that have been granted, PDP sponsors have the ability to request additional waivers or modifications of Part D requirements on a case-by-case basis. If a waiver or modification is granted, it will apply to all similarly situated entities. Details on how to request additional waivers or modifications can be found in Appendix IV.

20.1 - Enrollment in Employer/Union Sponsored PDPs
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

20.1.1 - Enrollment Eligibility
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

“Employment-Based” Group Health Plan Requirement

Employer/union group health plan enrollment in EGWPs and individual PDPs is only available to beneficiaries who are Part D eligibles of an employer/union sponsored group health plan. Thus, a beneficiary’s enrollment in one of these PDPs must be based on receiving “employment-based” retiree health coverage from an employer/union group health plan sponsor that has entered into a contractual arrangement with a PDP sponsor to provide coverage or that has contracted directly with CMS to provide coverage for its Part D eligibles. Membership in a State Pharmaceutical Assistance Program (SPAP) would not make an individual eligible for enrollment into these types of plans. Similarly, coverage obtained through a professional or other type of group association would not make a beneficiary eligible for these kinds of plans, except to the extent that the coverage obtained through the association can properly be characterized as “employment-based” group health plan coverage.

Retiree Status Requirement

In accordance with the waiver authority set forth in section 1860D-22(b) of the Act, employer-sponsored enrollments in individual PDPs and EGWPs may only be offered to Part D eligible retirees (and Part D eligible spouses and dependents of these retirees). PDP sponsors may not enroll Part D eligible current (i.e., active) employees (or their Part D eligible spouses and dependents) in employer/union sponsored individual PDPs or EGWPs. (NOTE: Medicare Advantage Organizations are subject to a different statutory waiver authority under section 1857(i) of the Act, which allows these entities to enroll both current (i.e., active) employees and retirees (and their spouses and dependents) of an employer/union group health plan sponsor in individual MA plans and “800 series” and Direct Contract MA plans, provided such individuals are eligible for Medicare Parts A and B. However, when enrolling active employees into these employer/union group sponsored MA plans, MA Organizations must comply with all applicable Medicare program requirements including the

3 “Employment-based retiree health coverage” means health insurance or other coverage of health care costs for Part D eligible individuals (or for such individuals and their spouses or dependents) based on their status as retired participants. The term “group health plan” includes such a plan as defined in section 607(1) of the Employee Retirement Income Security Act of 1974 and also includes federal and state governmental plans, collectively bargained plans, and church plans. See Section 1860D-22(c) of the Act. See also, 42 CFR 423.454 (“Employer-sponsored group prescription drug plan means prescription drug coverage offered to retirees who are Part D eligible individuals under employment-based retiree health coverage (as defined in §423.882) approved by CMS as a prescription drug plan.”)
Medicare Secondary Payer (MSP) requirements and must ensure that employers are not allowed to enroll actives in a Medicare plan offered by MA Organizations in a manner contrary to MSP rules (see Pub. 100-16, chapter 9, section 20.1.1).

Restricted Enrollment Requirement

In general, PDP sponsors have to accept all Medicare-eligible beneficiaries who reside in their service area as set forth in 42 CFR 423.104(b). EGWPs are not subject to this requirement. Instead, under the CMS eligibility rules for these kinds of plans, EGWPs must restrict enrollment solely to those Medicare eligible individuals who are also eligible for the employer/union sponsor’s employment-based retiree health coverage. See Section 1860D-22(b) of the Act. Note that, aside from having Medicare eligibility, the employer/union sponsor’s eligibility rules exclusively govern a beneficiary’s enrollment entitlement in these plans. Under the employer/union sponsor’s eligibility requirements, for example, Medicare eligible spouses and dependents of participants in the employer/union sponsor’s plan may be permitted to enroll in these EGWPs based on the employer/union sponsor’s eligibility rules regardless of whether or not the participant is Medicare eligible.

Employer/Union Group Health Plan Part D Eligibles Must Permanently Reside In The Service Area of the PDP As Defined By The PDP sponsor Within HPMS

In addition to the above eligibility requirements, the eligibility requirements set forth in Pub. 100-18, chapter 3, section 10 apply to all employer/union group health plan sponsored individual PDP and EGWP enrollments in the same manner applicable to individual enrollments in individual PDPs. Therefore, in order for a beneficiary to be eligible to enroll in an employer-sponsored individual PDP or EGWP, he/she must permanently reside in the defined service area of the individual PDP or EGWP. See also Pub. 100-18, chapter 3, section 40.2 (Required Involuntary Disenrollment).

PDP sponsors offering EGWPs are eligible for extended geographic service areas for these plans under waivers issued by CMS. See section 20.2 of this chapter. Therefore, PDP sponsors offering EGWPs should ensure that their EGWP defined service area includes all geographic areas in which employer/union sponsored group health plan Part D eligibles may reside (e.g., national service area) during the contract year. No mid-year service area expansions will be permitted.

20.1.2 - Minimum Enrollment Requirements

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

In general, PDPs must meet minimum enrollment standards as set forth in 42 CFR 423.512(a). These minimum enrollment requirements do not apply to EGWPs.

20.1.3 - Annual Open Enrollment Periods

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

CMS has waived the requirement to comply with the Medicare annual coordinated election period described in 42 CFR 423.38(b) for employer/union group health plans sponsored enrollments in EGWPs or individual PDPs. Thus, employer/union group sponsored
enrollments in EGWPs or individual PDPs may have different annual open enrollment periods. However, such plans must accept valid requests for disenrollment at any time.

20.1.4 - Group Enrollment/Disenrollment
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

All PDP sponsors may group enroll/disenroll employer/union sponsored group health plan Part D eligibles. This waiver applies to both EGWPs and individual PDPs offered to employer/union group health plan Part D eligibles. The group enrollment/disenrollment procedures are outlined in Pub. 100-18, chapter 3, sections 30.1.6 and 40.6.1.

20.1.5 - Special Enrollment Periods (SEPs)
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Employer/union members enrolled in EGWPs and individual PDPs are eligible for special enrollment periods (SEPs). These SEPs apply to employer-sponsored enrollments in an individual PDP or an EGWP. The employer/union sponsor’s eligibility rules would determine when the SEP may be used. These SEPs also apply to beneficiaries disenrolling from an employer-sponsored EGWP or individual PDP in order to enroll in an individual PDP not sponsored by an employer/union. These SEP procedures are outlined in Pub. 100-18, chapter 3, section 20.3.8.

20.1.6 - Transaction Reply Code (TRC) 127 Procedures When Transitioning Employer/Union Group Health Plans from the Retiree Drug Subsidy (RDS) to Employer/Union Sponsored Individual PDPs or EGWPs
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Pub. 100-18, chapter 3, section 10.4 requires a PDP sponsor to follow certain procedures when the entity receives a Transaction Reply Code (TRC) 127 after submitting an electronic enrollment transaction to CMS. TRC 127 indicates that the beneficiary is being claimed for the Retiree Drug Subsidy (RDS) by a particular employer/union during the same period of time identified in the Part D enrollment request. An employer/union group health plan sponsor cannot claim the RDS for a beneficiary simultaneously enrolled in a PDP. In accordance with CMS instructions, before effectuating the enrollment request, a PDP that receives TRC 127 is required to contact the beneficiary to prevent inadvertent Part D enrollments and potential loss of employer/union coverage caused by the required notification to the employer/union of the beneficiary’s enrollment in Part D.

Where the PDP sponsor is working directly with an employer/union group health plan sponsor to enroll its Part D eligibles into an individual PDP or EGWP and receives TRC 127 for these Part D eligibles, the notification procedures identified above are not needed to protect these beneficiaries from possible loss of that employer/union group health plan coverage. Accordingly, the PDP sponsor in this situation is not required to provide each beneficiary with the notification letter or other contact specified in CMS enrollment guidance. The PDP sponsor can immediately resubmit the enrollment with the proper employer subsidy override flag. PDP sponsors should maintain records to support the use of this alternate process for these Part D eligibles.
Note that, in some rare instances, the employer/union group health plan Part D eligible may have other drug coverage through another employer/union group health plan sponsor receiving the RDS (i.e., as a spouse or dependent of a retired participant). In these instances, the employer/union group health plan Part D eligible may potentially lose this other coverage upon enrollment in Part D. CMS strongly recommends that the PDP sponsor work closely with employer/union group health plan sponsors to communicate about this possibility, identify affected Part D eligibles (if possible) prior to enrollment into the PDP, and properly communicate with all Part D eligibles about their opt-out rights in accordance with the CMS group enrollment notification procedures.

20.1.7 - Beneficiary Enrollment Notification Requirements
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

In general, the notice requirements contained in Appendix 1 (Summary of Notice Requirements) of chapter 3 of this manual apply to all employer/union group health plan sponsored enrollments in individual PDPs or EGWPs, with the following clarifications:

- Each of the model beneficiary notices which are applicable to employer/union sponsored group health plans can be customized to the extent the modifications will more clearly and accurately reflect the employer group plan being offered by each individual employer/union group health plan sponsor (in accordance with the waivers/modifications set forth in section 20.3.2.1.1 of this chapter).

- The PDP sponsor retains the ultimate responsibility for the proper and timely dissemination of the notices. However, the PDP sponsor and the employer/union group health plan sponsor can enter into an agreement where the employer/union group health plan sponsor agrees to disseminate particular notices to its Part D eligibles on behalf of the PDP sponsor.

Note that certain notices contained in Appendix 1 are not applicable to employer/union group health plan sponsored enrollments in individual PDPs or EGWPs, as identified below:

- Exhibit 5a – Model Notice to Potential Auto-Enrollee with RDS
- Exhibit 13a – PDP Model Notice for Auto-Enrollments Provided by CMS with Recent Deceased Code
- Exhibit 24 – Confirmation of Auto-enrollment
- Exhibit 25 – Confirmation of Facilitated Enrollment
- Exhibit 27 – Auto and Facilitated Enrollees Who Permanently Reside in Another Region Where the PDP sponsor Offers Another PDP at or Below the Low-Income Premium Subsidy Amount for that Region
- Exhibit 28 – Auto and Facilitated Enrollees Who Permanently Reside in Another Region Where the PDP sponsor Does Not Offer Another PDP at or Below the Low-Income Premium Subsidy Amount for that Region
- Exhibit 29 – Reassignment Confirmation
Exhibit 30 – Optional Notice for “Losing Plan” to LIS Beneficiaries Re-Assigned to a Different PDP sponsor (in lieu of ANOC)

20.1.8 – Permitting Employer/Union Sponsors to Enroll Beneficiaries in Both an “800 series” Local MA-Only Coordinated Care Plan and an “800 Series” Standalone PDP (Waiver Effective Beginning Contract Year 2009)

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Subject to certain exceptions, a Part D eligible person who is enrolled in a Medicare Advantage (MA) plan may not be simultaneously enrolled in a stand-alone PDP. See Section 1860D-1(a)(1)(B)(ii) of the Act, and 42 CFR 423.30(b). Beginning in 2009, CMS has granted a modification of a previously issued 2007 waiver policy which will permit all employer/union sponsors to enroll beneficiaries in both an EGWP (i.e., “800 series”) local coordinated care MA-Only plan and an “800 series” standalone PDP.

Beginning with the 2007 contract year, CMS granted a limited waiver for certain public employers to simultaneously enroll their Part D eligibles in an “800 series” local coordinated care MA-Only plan and an “800 series” standalone PDP under certain limited circumstances (see Pub. 100-16, chapter 9, section 20.1.10). In order to be eligible for the waiver, the public employer was required to have a longstanding, pre-existing partnership with separate vendors. Also, the vendors were required to have been working closely with the employer to provide coordinated care and disease management services between the medical and prescription drug portions of the benefit similar to the kind of coordination that would be offered if the employer purchased the medical coverage and drug coverage from a single MA-PD vendor.

Beginning with the 2009 contract year, all employer/union group health plan sponsors will be allowed to enroll their Part D eligibles in both an “800 series” local coordinated care MA-Only plan (i.e., HMO, HMO/POS, Local PPO) and an “800 series” standalone PDP. Like the previous waiver, as a condition of this expanded waiver, CMS will require the separate medical and prescription drug vendors to work closely together with the employer/union sponsor to provide coordinated care and disease management services between the MA and PD portions of the benefit. This coordination is similar to the kind that would be offered if the employer/union purchased the medical coverage and the drug coverage from a single local MA-PD vendor.

20.2 - Service Areas

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

20.2.1 - “800 series” EGWP Service Areas (Elimination of the “Nexus Test” Beginning in Contract Year 2008)

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

For contract years 2006 and 2007, CMS employer group waiver policy required PDP sponsors to offer plans to individual Medicare beneficiaries as a condition of being able to offer “800 series” plans associated with the same contract. Also, if the PDP offered individual coverage in the PDP region where the most substantial portion of an employer’s employees reside, PDP sponsors were permitted to extend their “800 series” plan service area and enroll an
employer/union sponsor’s retirees that resided outside of the individual plan service area. (This service area extension policy is commonly known as the “nexus test”).

Beginning with the 2008 contract year, PDP sponsors offering prescription drug plans are not required to offer these plans to individual beneficiaries as a condition of offering associated “800 series” plans. This change includes the elimination of the “nexus test.” The changes described above will apply to entities renewing “800 series” plan benefit packages in 2008, as well as to entities offering “800 series” plans for the first time in 2008.

Notwithstanding these changes, entities offering these plans will continue to have to meet all CMS requirements that are not otherwise waived or modified, including the requirement to be licensed as a risk bearing entity eligible to offer health insurance or health benefits. For entities that choose to only offer “800 series” plans for a particular PDP sponsor contract, this requirement will be met if the entity is licensed in at least one state.

For more details on the service area waiver policies (including the “nexus test” policy) that applied to EGWPs in contract years 2006 and 2007, see Appendix I below.

20.2.2 - Direct Contract EGWP Service Areas
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

In general, PDP sponsors can only cover beneficiaries in the service areas in which they operate. However under CMS waiver authority, for employers/ unions which directly contract with CMS to sponsor their own PDP, coverage can extend to all of their Part D eligibles, regardless of whether they reside in one or more other PDP regions in the nation. However, in order to meet the enrollment eligibility requirements described in Pub. 100-18, chapter 3, section 10, which includes the requirement that the beneficiary must permanently reside in the EGWP-specific service area, all Direct Contract PDPs should ensure their defined service area includes all geographic areas in which their plan Part D eligibles may reside (e.g., national service area).

20.3 - Marketing and Dissemination
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

20.3.1 - Prior Review and Approval of Marketing Materials and Enrollment Forms
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Direct Contract and “800 series” Plans

CMS has waived the prior review and approval requirements for marketing materials and enrollment forms contained in 42 CFR 423.2262, 423.2264, 423.2266, and 423.2268 for all EGWPs. These include all “800 series” plans as well as Direct Contract plans. This waiver applies to all marketing materials, including the marketing materials requirements contained in the Medicare Marketing Guidelines.
Note that as a result of this waiver, Direct Contract plans and PDP sponsors offering “800 series” EGWPs or employer-sponsored individual PDPs are not subject to the annual restriction against communicating to Medicare eligible beneficiaries before October 1st. Rather, CMS strongly encourages employer/union sponsors and entities offering these plans to employers/unions to begin the communication process early with these beneficiaries and to continue to communicate about their benefits as frequently as possible prior to their particular annual open enrollment period (which may differ from Medicare’s annual coordinated election period). More specifically, employers/unions and/or entities that offer employer-sponsored “800 series” or individual plans to employers/unions should be prepared to direct beneficiaries to available resources and should explain their coverage and how it works with Medicare.

**Employer/Union Group Plan Sponsored Individual PDPs**

Note that the waiver of prior review and approval requirements for marketing materials and enrollment forms contained in 42 CFR 423.2262, 423.2264, 423.2266, and 423.2268 will also apply to a PDP sponsor that elects to use the waiver outlined in section 20.3.2.1.1 below which allows PDP sponsors to customize dissemination materials. More specifically, the waiver will apply to those PDP sponsors that elect to customize dissemination materials for a particular employer/union group health plan sponsor that offers coverage to its Part D eligibles using an individual PDP (e.g., individual PDP paired with a non-Medicare supplemental drug coverage designed to “wrap around” or enhance the individual PDP).

**20.3.2 - Timing and Content of Employer/Union Sponsored Group Health Plan Dissemination Materials**

*(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)*

**20.3.2.1 - Employer/Union Sponsored Group Plans Subject to Medicare Dissemination Requirements**

*(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)*

In general, dissemination materials for employer/union sponsored enrollees in Direct Contract plans, “800 series” plans or individual PDPs are subject to all applicable Medicare dissemination regulatory requirements (42 CFR 423.128) and sub-regulatory guidance (including any requirements related to the timing and content of these materials) unless waived or modified as outlined below. This also includes all of the dissemination requirements contained in the Medicare Marketing Guidelines unless those requirements have been explicitly waived or modified.

**20.3.2.1.1 - Customizing Medicare Dissemination Materials and Enrollment Forms**

*(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)*

In order to meet the requirements of 42 CFR 423.128(a)(2), which require a Part D sponsor to disclose information about the plan in a clear, accurate and standardized form, PDP sponsors should provide customized dissemination materials to “800 series” and Direct Contract PDP enrollees to reflect the modified/supplemental benefits being provided to that particular
employer/union group health plan enrollees, if any. More specifically, CMS has waived any rules that would otherwise prohibit these entities from offering customized dissemination materials to the extent those customized materials will more clearly and accurately describe the benefits available to employer/union group Part D eligibles (for example, when the supplemental coverage is taken into account). Note that this waiver also allows customization of dissemination materials for employer-sponsored enrollments in individual PDPs (e.g., where an employer/union group health plan sponsors coverage to its retirees using an individual PDP and a non-Medicare supplemental plan designed to “wrap around” or enhance the individual PDP or where the employer/union sponsor is subsidizing or paying premium amounts for its Part D eligibles enrolled in an individual PDP).

With regard to premium amounts (including premium amounts for low-income premium subsidy eligible individuals) that are required to be accurately reflected on any customized beneficiary dissemination materials (e.g., Evidence of Coverage, LIS Rider), PDP sponsors should ensure these materials accurately reflect the actual premium amount the beneficiary pays when the supplemental coverage, if any, and any corresponding employer/union premium subsidization (or subsidization by CMS in the case of low-income premium subsidy eligible beneficiaries) is taken into account. Alternatively, if accurate premium information concerning the amount the beneficiary actually pays is not available to the PDP sponsor, the PDP sponsor may substitute language in lieu of providing actual premium amounts (e.g., “For information concerning the actual premiums you will pay, please contact [insert employer/union group health plan sponsor name] or your employer group benefits plan administrator.”)

As provided in section 20.3.1 above, all customized employer/union group health plan materials are not required to be submitted for review and approval by CMS prior to use. Customized materials must not be submitted through HPMS.

Also, beginning with contract year 2009, PDP sponsors are no longer required to submit informational copies of these dissemination materials to CMS at the time of use (for details on the previous waiver policies in effect for contract years 2006 through 2008 requiring informational copies of employer/union group health plan dissemination materials to be submitted to CMS, see Appendix II). However, as a condition of CMS providing these particular waivers or modifications, CMS reserves the right to request and review these materials in the event of beneficiary complaints or for any other reason it determines to ensure the information accurately and adequately informs Medicare beneficiaries about their rights and obligations under the plan.

PDP sponsors also will be required to retain these dissemination materials and provide access to these written materials to CMS (or its designees) in accordance with 42 CFR 423.504(d) and 423.505(d) and (e). If the materials for multiple employer/union sponsors are identical except for employer group sponsor identifier information, CMS will not require a PDP sponsor to retain materials for each employer group (i.e., retention of one “template” version of dissemination materials used for particular employer groups is permissible).
20.3.2.1.2 - Timing for Issuance of Employer/Union Sponsored Group Plan Medicare Dissemination Materials

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Employer sponsored “800 series” plans, Direct Contract plans or individual PDPs that are subject to Medicare marketing and dissemination requirements are also subject to any applicable timing requirements for issuance of these materials. However, CMS has waived or modified applicable timing requirements in certain circumstances. These include those circumstances where a particular employer/union sponsor has an open enrollment period that differs from Medicare’s Annual Coordinated Election Period (ACEP). In this situation, the timing for issuance of any dissemination materials that are based on the ACEP should be based instead on the employer/union sponsor’s open enrollment period. For example, for contract year 2008, in accordance with applicable timing requirements for these materials, if an employer/union sponsor’s open enrollment period began on December 1, 2007, the ANOC and Summary of Benefits (SB), LIS Rider and Formulary must have been received by beneficiaries no later than November 16, 2007 (15 days before the beginning of the employer/union group health plan’s open enrollment period). Beginning in 2009, a combined Annual Notice of Change/Evidence of Coverage (ANOC/EOC), LIS rider, and Formulary are required to be received by beneficiaries no later than 15 days before the beginning of the ACEP. Therefore, for contract year 2009, if an employer/union sponsor’s open enrollment period begins on December 1, 2008, these documents must be received by beneficiaries no later than November 16, 2008 (15 days before the beginning of the employer/union group health plan’s open enrollment period). The timing for other dissemination materials that may be based on the start of the Medicare plan (i.e., calendar) year should be appropriately based on the employer/union sponsor’s plan year. If the employer/union sponsor does not have an open enrollment period, then dissemination materials that are based on the ACEP must be received by beneficiaries no later than 15 days before the beginning of the plan year.

20.3.2.2 - Plans with Employer/Union Sponsors Eligible for Waiver of Medicare Dissemination Requirements (“Alternative Dissemination Standards Waiver”)

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

CMS has waived the specific dissemination requirements of 42 CFR 423.128 for employer/union group health plan beneficiaries when the employer/union sponsor is subject to alternative dissemination requirements (e.g., those required by the Employee Retirement Income Security Act of 1974 (“ERISA”)), and the employer/union sponsor complies with such alternative requirements. However, these alternative dissemination materials (including summary plan descriptions and all other beneficiary communications that provide descriptions of the Medicare benefit offerings) must be provided by the Direct Contract PDP or the PDP sponsor offering the “800 series” plan or employer-sponsored individual PDP to beneficiaries on a timely basis.
Similarly, for an employer/union sponsor plan eligible for the alternative dissemination standards waiver referenced above in section 20.3.2.1.2, a PDP sponsor that offers “800 series” plans to these employer/union sponsors must retain copies of these alternative dissemination materials or, alternatively, the information that would be necessary to satisfy its reporting and disclosure obligations under 42 CFR 423.514(d). 42 CFR 423.514(d) provides that entities must furnish, upon request, the information that any employees’ health benefits plan needs to fulfill its reporting and disclosure obligations under ERISA.

However, as a condition of CMS providing these particular waivers or modifications, CMS reserves the right to request and review these materials in the event of beneficiary complaints or for any other reason it determines to ensure the information accurately and adequately informs Medicare beneficiaries about their rights and obligations under the plan. PDP sponsors also will be required to retain these dissemination materials and provide access to these written materials to CMS (or its designees) in accordance with 42 CFR 423.504(d) and 423.505(d) and (e).

20.3.3 - Identification Card (ID) Card Requirements
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Direct Contract PDPs and PDP sponsors that offer “800 series” plans may provide enrollees with one combination member Identification (ID) card which incorporates the medical, Part D, and employer sponsored non-Medicare supplemental medical and/or drug benefits. However, entities must comply with all other CMS ID card requirements, including the requirements contained in the Medicare Marketing Guidelines. Note that this same waiver applies when a PDP sponsor elects to use the waiver outlined in section 20.3.2.1.1 above to customize dissemination materials for a particular employer/union sponsor that offers coverage to its retirees using an individual Medicare plan paired with a non-Medicare supplemental plan designed to “wrap around” or enhance the individual Medicare plan.

Note that it is also permissible to include the name and/or logo of the employer/union sponsor on the ID card. This activity is not considered “co-branding”.

20.3.4 - “Doing Business As” (DBA) Requirements
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

PDPs that offer “800 series” plans may use different names for “doing business as” purposes. However, for HPMS purposes only, these entities will be restricted to entering one “doing business as” name.

20.3.5 - Agent and Broker Licensure and Training Requirements
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

All agents and brokers (employed and contracted) selling “800 series” plans to employer/union group plan sponsors on behalf of a PDP sponsor must be licensed to sell these products as required by state law. However, representatives of a PDP sponsor or those representatives of employer/union group plan sponsors or others acting on their behalf (e.g., their employees, benefit consultants, third party administrators) who conduct educational, enrollment or informational events for retirees of employer/union sponsors are not required to
be licensed for these purposes as these activities would not constitute marketing or sales activities.

To ensure that employer/union group sponsors are receiving accurate and reliable information to make informed decisions on behalf of its retirees, it is critical that health plan representatives such as agents and brokers (employed and contracted) performing these marketing and sales activities are knowledgeable about the products they are selling, including “800 series” plans. CMS expects that PDP sponsors will ensure that brokers and agents are knowledgeable about the products they are selling by requiring they are trained on Medicare rules and regulations, as well as on plan details specific to the plan products being sold. However, the broker/agent testing requirements at 42 CFR 423.2274(c) do not apply under these circumstances.

Note that beginning with the 2007 contract year, the marketing and dissemination guidance contained in this chapter (section 20.3) supersedes the EGWP Marketing and Disclosure/Dissemination guidance located in Pub. 100-18, Chapter 2, section 13 (released on July 25, 2006).

20.4 - Premium Requirements
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Waiver of Uniform Premium Requirement

The uniform premium requirement (see 42 CFR §423.286(a)) has been waived for entities offering “800 series” plans under certain circumstances. Under this waiver of the uniform premium requirement, entities offering “800 series” plans serving multiple regions or the nation will be allowed to vary premium and cost sharing between defined market areas within the same employer/union sponsored group plan. This waiver is contingent on the requirement that the market areas (geographic areas) within the employer sponsored group plan with premium variation are based on objective market information demonstrating verifiable differences in drug costs between these market areas. The PDP sponsor must have documentation validating the drug cost variation in these market areas comprising the plan. PDP sponsors will be required to retain all of these documents and must provide access to this documentation for inspection or audit by CMS (or its designee) in accordance with the requirements of 42 CFR 423.504(d) and 423.505(d) and (e).

Premium Subsidization by Employer/Union Group Health Plan Sponsors

Under its waiver authority, CMS will allow the employer/union sponsoring the PDP flexibility in determining how much of a plan enrollee’s Part D monthly beneficiary premium it will subsidize, subject to the conditions set forth below.

First, an employer/union sponsor can subsidize different amounts for different classes of enrollees in a plan provided such classes are reasonable and based on objective business criteria, such as years of service, date of retirement, business location, job category, and nature of compensation (e.g., salaried vs. hourly). Different classes cannot be based on eligibility for the Part D Low-Income Subsidy. Second, the premium cannot vary for individuals within a given class of enrollees. Third, with regard to the Part D premium, an
employer/union cannot charge an enrollee for prescription drug coverage provided under the PDP more than the sum of his or her monthly beneficiary premium attributable to basic prescription drug coverage and 100% of the monthly beneficiary premium attributable to his or her non-Medicare Part D benefits (if any). The employer/union must pass through any direct subsidy payments received from CMS to reduce the amount that the beneficiary pays (or in those instances where the subscriber to or participant in the employer/union-only plan pays premiums on behalf of a Medicare eligible spouse or dependent, the amount the subscriber or participant pays).

As a condition of CMS providing these particular waivers, PDP sponsors that offer “800 series” PDPs to employers/unions will be required to obtain in writing from such employers/unions their agreement that they will satisfy the requirements of this waiver with respect to the premiums charged to their participants. Also, PDP sponsors will be required to retain these agreements with employers/unions and provide access to these written agreements to CMS (or its designees) in accordance with 42 CFR 423.504(d) and 423.505(d) and (e).

Charging Different Premiums to Different Employer/Union Group Health Plan Sponsors

In addition to the flexibilities outlined above for employers/unions to subsidize different amounts of an enrollee’s premium contribution, “800 series” PDPs have the flexibility to negotiate with and vary the premium charged to particular employer/union group health plan sponsors. This includes the ability to “experience rate” “800 series” employer/union group health plan sponsors in determining these premiums.

20.5 - Premium Withhold
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

PDP sponsors must permit their enrollees, at their option, to pay their premium through deductions from their Social Security checks, Railroad Retirement checks, or Federal annuity. When employers/unions also contribute to the beneficiary’s premium, in whole or in part, it is not feasible for both PDP sponsors and CMS to factor in the employer/union sponsor’s contribution and adjust the amount of the premium that should be deducted from the beneficiary’s Social Security or other check.

Because of these operational obstacles, as a condition of sponsoring an EGWP, CMS has waived the requirement that PDP sponsors offering “800 series” and Direct Contract EGWPs must provide beneficiaries the option to pay their premium through withholding. Thus, the premium withhold option will not be available for enrollees in EGWPs. PDP sponsors offering these plans will be required to bill the beneficiary and/or the employer/union directly. This waiver is not applicable to employer-sponsored enrollments in individual PDPs (employer-sponsored group beneficiaries enrolled in these PDPs will have the option to pay premiums through withholding).

20.6 - Providing Information to CMS about Part D
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

CMS has waived the requirements contained in 42 CFR 423.48 for all EGWPs. These regulatory provisions require plans to report certain information annually to CMS to enable it
to provide current and potential beneficiaries the information they need to make informed
decisions concerning their available choices for Part D coverage. This would include
information to be included in the CMS “Medicare and You” publications and on the CMS
Web site (e.g., “Medicare Prescription Drug Plan Finder”). Since these kinds of employer-
sponsored PDPs are not available for general enrollment, these requirements do not apply and
are therefore waived.

20.7 - Requirement for Part D Sponsor to Provide Specific Information via
an Internet Web site

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

To the extent a PDP sponsor has a Web site or provides information through the Internet, 42
CFR 423.128(d)(2) requires them to provide certain Part D information on an Internet Web
site (e.g., current formulary, notice regarding the removal or change in the preferred or tiered
cost sharing status of a Part D drug on its formulary, etc.).

CMS has waived the requirements of 42 CFR 423.128(d)(2) for all “800 series” plans. PDP
sponsors will not be required to provide any information concerning these EGWPs on the
PDP sponsor’s Internet Web site. Since these kinds of employer-sponsored PDPs are not
available for general enrollment, these requirements do not apply and are therefore waived.

20.8 - Access to Covered Part D Drugs

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

PDPs cannot limit coverage to only mail order prescription drugs and must meet specific
standards in 42 CFR 423.120(a)(1) regarding the assembling of broad networks of retail
pharmacies to provide convenient access to beneficiaries. While waivers of the mail order-
only prohibition will not be granted, CMS also recognizes different circumstances
surrounding employer/union group health plan coverage as compared to other PDPs. For
example, an employer/union arrangement may have only a small number of Part D eligibles
concentrated in a local area within a large region. Employers/unions also have an interest in
ensuring their Part D eligibles have adequate pharmacy access.

To facilitate the offering of such plans and maximize flexibility, CMS has waived the specific
Part D retail pharmacy access standards contained in 423.120(a)(1) for “800 series” and Direct
Contract EGWPs as long as the PDP sponsor attests that its networks are and will continue to
be sufficient to meet the needs of its Part D eligibles, including situations involving
emergency access. However, CMS may review the adequacy of the pharmacy networks and
potentially require expanded access in the event of beneficiary complaints or for other reasons
in order to ensure that the plan’s network is sufficient to meet the needs of its enrollee
population.

Note that other than the waiver of the retail pharmacy access requirements described above,
no other waivers or modifications of the Part D pharmacy access requirements have been
granted for EGWPs. Thus, all PDP sponsors offering EGWPs must adhere to all other CMS
pharmacy access requirements (e.g., the requirements for long term care, home infusion, and
I/T/U pharmacy access). See 42 CFR 423.120(a) and chapter 5, section 50, of this manual.
20.9 - Submission of Part D EGWP Bids and Requirements Concerning Providing EGWP Supplemental Coverage  
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Note that beginning with the 2008 contract year, PDP sponsors are no longer required to submit Part D EGWP bids. PDP sponsors are still required to take certain actions with the PBP software. See Appendix III for detailed bidding instructions for Part D EGWPs. For the 2006 and 2007 contract years, PDP sponsors submitted Part D bids for “800 series” and Direct Contract EGWPs in a manner similar to the flexible method offered to Medicare Advantage Organizations offering “800 series” plans in the past. Under this approach, CMS required PDP sponsors to submit bids for EGWPs only for the standardized Part D coverage. Entities were not required to submit separate bids for each employer/union benefit design variation.

For “800 series” EGWPs, any supplemental (i.e., additional non-Medicare Part D) prescription drug coverage is provided separately pursuant to a private agreement between the PDP sponsor and the employer/union sponsor. However, any EGWP supplemental coverage offered cannot reduce the value of the basic standardized Part D benefit design. For example, supplemental coverage cannot impose a cap that would preclude employer group health plan Part D eligibles from realizing the full value of coverage under the standard Part D benefit. To assure that the actuarial equivalence of the standard Part D benefit design is maintained, CMS requires all PDP sponsors offering EGWPs to ensure that the total employer/union sponsored plan (including adjusting for any supplemental coverage) provides at least the standard Part D coverage, including a deductible no higher than that of defined standard Part D (for 2008 - $275), and catastrophic coverage after the true out-of-pocket limit (for 2008 - $4,050) is met.

Beginning in 2006, no employer/union Part D EGWP bids were included in the calculation of the Part D national average monthly bid amount or in the low-income regional benchmark premium amounts.

20.10 - Part D EGWP Cost Sharing  
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

In general, a PDP offered to individual Medicare beneficiaries can offer actuarially equivalent standard, basic alternative or enhanced alternative prescription drug coverage (i.e., coverage that differs from defined standard prescription drug coverage) if certain actuarial equivalence standards are met. For example, 42 CFR 423.104(e)(5) requires that the coverage be designed to provide for the payment of costs incurred for covered Part D drugs equal to the initial coverage limit defined in 42 CFR 423.104(d)(3) ($2,510 in 2008) that is equal to or greater than what a PDP offering defined standard prescription drug coverage would pay between such limit and the deductible at section 42 CFR 423.104(d)(1) ($275 in 2008). (Throughout that range, defined standard prescription drug coverage covers on average 75 percent of the costs and beneficiaries pay on average 25 percent.) See Pub. 100-18, chapter 5, sections 20.3.2, 20.4.1 and 20.4.2, for more information.

Employer/union group health plan coverage has often differed from the defined standard benefit design in Part D. For example, many arrangements offer lower deductibles or provide coverage for claims incurred in the Part D coverage gap. By contrast, within the deductible
and the initial coverage limit range, these designs may provide somewhat less coverage than
defined standard prescription drug coverage under Part D. Therefore, to provide beneficiaries
with more choices and enable employer/union group health plans to continue offering Part D eligibles their familiar coverage, CMS has waived the 42 CFR 423.104(e)(5) prong of the actuarial equivalence test for EGWPs offered exclusively to employer/union group health plan Part D eligibles. Absent this waiver, this provision requires defined standard coverage for costs incurred between the deductible and initial coverage limit.

However, this guidance is not intended to waive other actuarial equivalence standards in 42 CFR 423.104(e), including (but not limited to) the requirement in 42 CFR 423.104(e)(3) that the total or gross value of the coverage be at least equal to the total or gross value of defined standard coverage and the requirement in 42 CFR 423.104(e)(2) regarding catastrophic reinsurance coverage. Thus, for example, an EGWP that requires beneficiary coinsurance that on average is greater than 25 percent may still satisfy actuarial equivalence by instead offering a lower deductible, or by providing coverage above the initial coverage limit, if the gross value coverage standard, the catastrophic coverage, and other requirements are satisfied.

20.11 - CMS EGWP Part D Payment
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

20.11.1 - Direct Subsidy
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

The Part D risk adjusted direct subsidy payment for all EGWPs will be based on the national average monthly bid amount and the national base beneficiary premium (not on bids amounts as for plans offered to individual Medicare beneficiaries).

20.11.2 - Reinsurance Subsidies
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

In addition, CMS will modify the way catastrophic reinsurance is paid for all EGWPs. CMS will not make a prospective payment for reinsurance, and instead will include all EGWPs in the normal Part D reinsurance reconciliation at year end. Since no prospective payments will have been made during the year, the year-end process will result in the full reinsurance payment being paid to the plan. Since most employers/unions will be providing enhanced drug coverage through supplemental arrangements (which raises the threshold for catastrophic coverage), the reinsurance payments to these PDP sponsors are expected to be small as a result of the application of the True Out of Pocket Costs (TrOOP) rule. See chapter 5, section 30 (Incurred / “True Out-of-Pocket” (TrOOP) Costs), of this manual.

20.11.3 - Low-Income Subsidies
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Information concerning low-income subsidy requirements as they relate to EGWPs is set forth in section 20.12.
Risk corridor payments assist PDP sponsors entering a new market without any experience in mitigating any losses or gains by sharing these losses or gains with Medicare. Risk corridor payments are not available for EGWPs.

The following table summarizes the differences in payment between EGWPs and plans offered to individual Medicare beneficiaries.
### Part D EGWP Payments

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<tr>
<th>Plan Types</th>
<th>Direct Subsidy</th>
<th>Low-Income Premium Subsidy and Cost Sharing Amounts</th>
<th>Reinsurance</th>
<th>Risk-Sharing</th>
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<td>42 CFR 423.329(a)(1)</td>
<td>42 CFR 423.780 42 CFR 423.329(c)</td>
<td>42 CFR 423.329(c)</td>
<td>42 CFR 423.336</td>
</tr>
</tbody>
</table>

#### Part D Calendar Year Plans
- The national average monthly bid amount is multiplied by the individual’s risk score. This amount is then reduced by the rounded base beneficiary premium ($27.90 for 2008).
- Payment methodology is the same as for plans offered to individual Medicare beneficiaries, except that the rounded base beneficiary premium ($27.90 for 2008), will be used in the low-income premium subsidy regional benchmark comparison.
- Note that beginning in 2008, because of the elimination of the requirement to submit Part D EGWP bids, Low-Income Cost Sharing (LICS) amounts will be paid retrospectively at year-end reconciliation (rather than prospectively as in 2006 and 2007). See section 20.12.2 below.
- Reinsurance is paid retrospectively at year-end reconciliation (rather than being paid prospectively).

#### Part D Non-Calendar Year Plans
- Same as above (payments are on calendar year basis; plan may be administered on non-calendar year basis)
- Same as above
- No reinsurance payments

### 20.12 - Low-Income Subsidies

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

For each beneficiary entitled to the low-income subsidy (LIS), CMS pays the beneficiary’s premium (up to the plan’s low-income premium subsidy amount) and cost sharing obligations minus the beneficiary’s cost-sharing responsibilities under the LIS rules. However, for EGWPs there are a number of important additional requirements that must be adhered to concerning both the low-income premium subsidy and the low-income cost-sharing subsidy as set forth below.
20.12.1 - Premium Subsidy  
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Low-Income Premium Subsidy Pass Through Requirements

PDP sponsors offering EGWPs are required to comply with the same low-income premium subsidy amount requirements that apply to PDP sponsors offering plans to individual Medicare beneficiaries. See 42 CFR 423.800(b). Thus, EGWP Part D sponsors are responsible for identifying employer/union group health plan LIS Part D eligibles and passing through the low-income premium subsidy amount payments made by CMS on behalf of these Part D eligibles to reduce their premium contributions.

Premiums charged (to the beneficiary and/or the employer/union) for a particular “800 series” PDP plan benefit package can vary between different employer/union group health plan sponsors and also among a particular employer group health plan’s Part D eligibles based on legitimate criteria such as years of service. See section 20.4 of this chapter. CMS does not take into account these variations in premiums because CMS does not receive information on these variations during the annual Part D bidding process. Even though premium amounts may vary among and between employer/union group health plan enrollees as described above, the LIS premium subsidy amounts paid by CMS to all EGWPs for all enrollees of a particular “800 series” or Direct Contract plan benefit package do not vary.

As a condition of receiving the waivers and modifications described above, CMS requires that all PDP sponsors offering EGWPs ensure that any low-income premium subsidy amount paid on behalf of an LIS beneficiary accrues first to the benefit of the LIS-eligible employer/union group health plan Part D eligible. Specifically, the low-income premium subsidy must first be used to reduce any portion of the monthly beneficiary premium paid by the Part D eligible (or in those instances where the subscriber to or participant in the employer/union plan pays premiums on behalf of a low-income eligible spouse or dependent, the amount the subscriber or participant pays), with any remaining portion of the premium subsidy amount then applied toward the portion of any monthly premium paid for by the employer/union. However, if the sum of the enrollee’s monthly premium (or the subscriber’s/participant’s monthly premium, if applicable) and the employer/union sponsor’s monthly premiums (i.e., total monthly premium) is less than the monthly low-income premium subsidy amount, any portion of the low-income premium subsidy amount above the total monthly premium must be returned directly to CMS.

Similarly, if there is no monthly premium charged to the beneficiary (or subscriber/participant, if applicable) or employer/union, the entire low-income premium subsidy amount must be returned directly to CMS and cannot be retained by the PDP sponsor, the employer/union, or the employer/union group Part D eligible (or the subscriber/participant, if applicable). If low-income premium subsidy amounts need to be returned to CMS for any employer/union group sponsor enrollees that meet the above criteria,
PDP sponsors are required to immediately contact their CMS account manager for instructions on how to return these amounts.

As stated in section 10.5, PDP sponsors may enter into reinsurance or administrative services arrangements with self-insured (i.e., self-funded) employers/unions. Therefore, instead of paying an insurance premium to the PDP sponsor, the employer/union group typically pays an administrative fee to the PDP sponsor. In these kinds of arrangements, in order to properly administer the low-income premium subsidy requirements outlined above, the PDP sponsor must develop an “illustrative premium.” The “illustrative premium” is equal to the premium the employer/union group plan sponsor would have paid if they had purchased an equivalent product offered by the PDP sponsor. The same rules outlined above would be applied using the illustrative premium in the place of actual premium. The PDP sponsor will be required to develop and apply an “illustrative premium” for each self-insured or self-funded employer/union group plan sponsor.

Note that if the low-income premium subsidy amount for which an enrollee is eligible is less than the portion of the monthly beneficiary premium paid by the Part D eligible (or subscriber/participant, if applicable), then the employer/union should communicate to the Part D eligible (or subscriber/participant) the financial consequences of the low-income subsidy eligible individual enrolling in the employer/union sponsored group health plan as compared to enrolling in another PDP with a monthly beneficiary premium equal to or below the low-income premium subsidy amount.

### Ability to Refund Low-Income Premium Subsidy Amounts

In accordance with 42 CFR 423.800, where the PDP sponsor offering the EGWP directly bills the employer/union sponsor’s Part D eligibles for their premium contributions, the Part D sponsor is required to reduce up-front the premiums charged to reflect the low-income premium subsidy payments paid to the PDP sponsor by CMS on behalf of these individuals.

If, however, the PDP sponsor does not or cannot directly bill an employer/union group health plan’s Part D eligibles, CMS will waive this up-front reduction requirement and permit the PDP sponsor to directly refund the amount of the low-income premium subsidy to the LIS beneficiary. This refund must meet the above requirements concerning beneficiary premium contributions; specifically, that the amount of the refund not exceed the amount of the monthly premium contribution by the Part D eligible (or subscriber/participant, if applicable) and/or the employer/union sponsor. In addition, the PDP sponsor must refund these amounts to the beneficiary within a reasonable time period. However, under no circumstances may this time period exceed 45 days from the date that the PDP sponsor receives from CMS the low-income premium subsidy amount payment for the low-income subsidy eligible enrollee.

Alternatively, the PDP sponsor and the employer/union may agree that the employer/union will be responsible for reducing up-front the premium contribution required for its Part D eligibles that are eligible for the Low-Income Subsidy. In those instances where the employer/union is not able to reduce up-front the premiums paid by the enrollee (or subscriber/participant, if applicable), the PDP sponsor and the employer/union may agree that the employer/union shall directly refund to the Part D eligible (or subscriber/participant, if applicable) the amount of the low-income premium subsidy up to the monthly premium.
contribution previously collected from the Part D eligible (or subscriber/participant, if applicable). The employer/union is required to complete the refund on behalf of the PDP sponsor within 45 days of the date the PDP sponsor receives from CMS the low-income premium subsidy amount payment for the low-income subsidy eligible enrollee.

Note that in some cases the LIS beneficiary may not be the subscriber to or participant in an employer/union sponsored group health plan, but the spouse or dependent of the subscriber/participant. In these instances, where the PDP sponsor or employer/union refunds low-income premium subsidy amounts to LIS enrollees, it may refund such amounts directly to the employer/union group health plan subscriber/participant on behalf of a spouse or dependent who is an LIS-eligible beneficiary.

Requirement to Retain and Provide Documents

As a condition of receiving the waivers and modifications described above and to support the PDP sponsor’s compliance with the low-income pass-through requirements, CMS requires that all PDP sponsors offering EGWPs retain documents and/or working papers that support their adherence to these requirements. These include documents evidencing that low-income premium subsidy amounts were properly passed through or refunded by either the PDP sponsor or the employer/union group plan sponsor and documents or working papers evidencing the calculation of “illustrative premium” for each self-insured/self-funded employer/union group plan sponsor. Also, PDP sponsors will be required to retain all of these documents and must provide access to this documentation for inspection or audit by CMS (or its designee) in accordance with the requirements of § 42 CFR 423.504(d) and 423.505(d) and (e).

Requirement to Obtain and Provide Written Agreements With Employer/Union Group Plan Sponsors

As a condition of receiving the waivers and modifications described above, CMS also requires that all PDP sponsors offering EGWPs enter into written agreements with employers/unions which require the employer/union to comply with the above requirements and to retain and provide documents upon request to the PDP sponsor evidencing the employer/union group plan sponsor’s adherence to such requirements. This includes the requirement that any low-income premium subsidy amount paid to the employer/union sponsor on behalf an LIS beneficiary is first used to reduce any portion of the monthly PDP premium paid for by the Part D eligible (or subscriber/participant, if applicable). Also, if the employer/union assumes responsibility for either reducing up-front LIS beneficiaries’ monthly premiums or refunding to LIS beneficiaries their monthly premium contributions, the PDP sponsor shall ensure that its written agreement with the employer/union also reflects the employer/union sponsor’s assumption of these duties consistent with the above requirements (including a provision requiring that any refunds to an LIS beneficiary be completed within 45 days of the date the PDP sponsor receives the low-income premium subsidy amount payment for that beneficiary from CMS). PDP sponsors will be required to retain all of these written agreements with employers/unions and must provide access to these written agreements for inspection or audit by CMS (or its designee) in accordance with § 42 CFR 423.504(d) and 423.505(d) and (e).

CMS Payment of LIS Premium Amounts to All EGWPs
Beginning in 2007, HPMS included a new table that provides all Part D sponsors with the monthly payments they are receiving to subsidize their low-income enrollees’ premiums. These same payment amounts are reflected in the electronically generated reports received by all PDP sponsors on a regular basis from CMS. HPMS will continue to have a separate table providing the low-income premiums that beneficiaries pay in the plans. However, HPMS will no longer display the low-income premiums for EGWP enrollees in this table. These amounts will be reflected as “N/A” for all EGWPs because, as stated above, the premiums for beneficiaries enrolled in these plans can vary, and CMS does not collect this information.

Note that beginning in 2007, the following rounding rules were used in determining EGWP LIS premium payment amounts: the base beneficiary premium ($27.35) was rounded to the nearest $.10 ($27.40) and was used as the Direct Contract or “800 series” plan premium. See 42 CFR 423.780(b)(1). The rounded base beneficiary premium was compared to the un-rounded low-income benchmark premium amount for the PDP region. If the low-income benchmark premium amount was less than the rounded base beneficiary premium, the low-income benchmark premium amount was rounded to the nearest $.10 to derive the low-income premium subsidy amount.

20.12.2 - Cost-Sharing Subsidy
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Benefits provided to EGWP enrollees cannot vary based on the Part D eligible’s LIS eligibility. In addition, for an LIS Part D eligible enrollee in an EGWP, CMS will subsidize only those cost-sharing obligations actually imposed on the Part D eligible under the plan, which includes any supplemental prescription drug coverage offered by the employer/union group health plan sponsor, with the supplemental coverage primary to the LIS program.

For example, an “800 series” PDP that provides benefits exclusively to employer X’s Part D eligibles has a $100 deductible. For expenses incurred by a full subsidy eligible individual, CMS’ payments to the plan will be determined based on that $100 deductible (minus any minimal co-pays an individual is responsible for under 42 CFR 423.782(a)). CMS payments will not be based on the plan having a $265 deductible (as reflected in Part D defined standard prescription drug coverage).

As noted above, beginning with the 2008 contract year, PDP sponsors are no longer required to submit Part D EGWP bids. As a result, beginning in 2008, CMS will not pay interim prospective LIS cost sharing amounts to EGWPs because these amounts are directly derived from Part D bids. Instead, as a condition of the waiver of the requirements to submit a Part D bid, CMS will make LICS payments during the normal year-end reconciliation process.

20.13 - Non-Calendar Year EGWPs
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Many employers, particularly public employers, determine benefits and enroll individuals in plan years that differ from the calendar year. Many of these plan years are mandated by state laws, federal law or union contracts.
CMS has granted a waiver to permit PDP sponsors offering EGWPs to establish non-calendar year plan benefit packages in HPMS in order to allow employer groups to determine benefits (including deductibles, out-of-pocket limits, etc.) on a non-calendar year basis. However, for these non-calendar year plan benefit packages, most submissions to CMS, along with CMS payments, will be determined on a calendar year basis in a process similar to the process historically used for “800 series” MA plans.

Non-calendar year EGWPs will be subject to the following rules:

- All required submissions to CMS, including applications and formularies for such plans, must be submitted at the same time as calendar-year EGWPs.

- With regard to Part D coverage, the plan must be actuarially equivalent to defined standard coverage for the portion of its plan year that falls in a given calendar year. A plan will meet this standard if it is actuarially equivalent for the calendar year in which the plan year starts and no design change is made for the remainder of the plan year. In no event can a plan increase during the plan year the out-of-pocket limit at which catastrophic coverage begins.

- Medicare direct subsidy payments will be based on the national average monthly bid amount for the calendar year for which the direct subsidy is being paid.

- Part D LIS payments and reconciliations will be determined based on the calendar year for which the payments are made.

- Prescription Drug Event (PDE) data will be reported to CMS on a plan year (i.e., non-calendar year) basis. Reconciliation, however, will be done on a calendar year basis.

- Certain benefits parameters (e.g., premium, cost sharing amounts) may be administered on a non-calendar plan year basis; however, other items such as formulary, deductible, gross covered drug spend and TrOOP may be administered on a calendar year basis.

- Like all other EGWPs, CMS will allow Part D eligibles of an employer/union sponsored group PDP that operates on a non-calendar year basis to disenroll from such plan and enroll in another plan through a special enrollment period (SEP) (see section 20.1.5).

Reinsurance and Risk Sharing Payments Not Available

With regard to Part D coverage, catastrophic reinsurance payments and risk corridor payments will not be made available to non-calendar year EGWPs (risk corridor payments are also not paid to calendar year EGWPs). However, the waiver of catastrophic reinsurance payments does not change the requirement for such plans to provide catastrophic coverage comparable to the standard benefit, though eligibility for such catastrophic coverage under the plan can be determined on a plan year basis.

Administration of Non-Calendar Year Plans
With regard to TrOOP and gross covered drug cost balance transfer requirements under the current TrOOP balance transfer process, two TrOOP and gross covered drug cost accumulations are necessary for Part D EGWPs. Plans must report TrOOP and gross covered drug cost balance transfers to a new plan of record as a calendar year accumulation when a beneficiary switches plans mid-year. However, plans will also be required to track TrOOP and gross covered drug costs on a non-calendar plan year basis in order to properly administer the non-calendar year benefit. If a beneficiary joins a non-calendar year plan during the middle of the plan year, any TrOOP and gross covered drug cost accumulation for costs incurred under a different plan between the beginning of the non-calendar plan year and the effective date of enrollment in the plan and within the same calendar year must carry over with the beneficiary. (Refer to the discussion of non-calendar year plans and sample scenarios in the guidance on automated TrOOP balance transfer dated October 20, 2008.) Explanation of Benefit (EOB) beneficiary dissemination materials must reflect the benefit design and TrOOP and gross covered drug cost accumulation coinciding with the non-calendar plan benefit year. Note that once the new Financial Reporting Transaction process is implemented, non-calendar year EGWPs will no longer need to track TrOOP and gross covered drug cost accumulations on a separate, calendar year track since this new method of TrOOP balance transfer will involve tracking these amounts on a month-by-month basis.

Note that if an employer/union group sponsor’s year starts mid-calendar year and ends on December 31st, renewing on January 1 of the subsequent year, the EGWP is not considered a non-calendar year plan. Also, PDP sponsors are not allowed to extend an employer/union only group health plan year longer than 12 months. The PDP sponsor must offer the EGWP for a portion of the contract year which ends on December 31st and renews on January 1st of the subsequent year.

20.14 - Part D Formularies

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

PDP sponsors will not be required to submit to CMS every formulary variation offered to Part D eligibles enrolled in EGWPs. Rather, PDP sponsors are permitted to submit a base formulary for use with its employer/union sponsored group health plans. After submission and approval of a base formulary, PDP sponsors may enhance the formulary (add new drugs or make positive changes to cost sharing) without having to resubmit the formulary for review and approval by CMS. These formularies may not be modified to remove any drugs from the list, or to add any restrictions or limitations unless these modifications or removals are otherwise consistent with CMS requirements.

20.14.1 - Formularies for Non-Calendar Year Plans

(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

CMS allows PDP sponsors to offer prescription drug benefits on a calendar year and on a non-calendar year basis (if PDP sponsors are approved to offer non-calendar year Part D EGWP plan benefit packages). Negative formulary change requests for non-calendar year Part D EGWPs are required to follow the same review and approval process as calendar year plans. Thus, the time frame for non-calendar year Part D EGWPs to make negative changes is the same as calendar year plans.
Non-calendar year Part D EGWPs may elect to convert to the conditionally approved formulary for the next calendar year on January 1st. PDP sponsors offering non-calendar year EGWPs that choose this option must provide appropriate beneficiary notice as specified in 423.120(b)(5). Alternatively, PDP sponsors offering non-calendar year Part D EGWPs whose plan start date occurs after conditional approval of the formulary for the following calendar year (CY) may elect to use that formulary for the entire non-calendar plan year. Any further changes for the rest of the non-calendar year would have to be consistent with the process for updating CY 2008 formularies and requesting negative formulary changes as described in the HPMS memorandum, Updating CY 2008 Formularies, November 28, 2007.

The following example illustrates the above-stated policy. A non-calendar year Part D EGWP with a start date of October 1, 2008, could either:

- Use its CY 2008 conditionally approved formulary throughout the employer/union sponsor’s plan year (October 1, 2008 – September 30, 2009) and make no negative changes;

- Use its CY 2008 conditionally approved formulary from October 1, 2008 – December 31, 2008 and its CY 2009 conditionally approved formulary from January 1, 2009 – September 30, 2009) and request negative changes through July 31, 2009, in accordance with the above-stated policy; or

- Use its CY 2009 conditionally approved formulary throughout the employer/union sponsor’s plan year (October 1, 2008 – September 30, 2009) and request negative changes through July 31, 2009, in accordance with the above-stated policy.

20.15 - Beneficiary Customer Service Call Center Requirements
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

CMS has granted a waiver of the Part D beneficiary customer service call center hour requirements for all Direct Contract and “800 series” EGWPs offered by PDP sponsors. See Addendum 2 - Customer Service Call Center Requirements of the Medicare Marketing Guidelines (as revised 7/25/06). These entities will be allowed to operate beneficiary customer service call center hours for their employer/union group health plan only enrollees that differ from the Part D requirements for plans offered to individual beneficiaries. These entities must ensure that a sufficient mechanism is available to respond to beneficiary inquiries and must provide customer service call center services to these Part D eligibles during normal business hours. However, CMS may review the adequacy of these call center hours and potentially require expanded beneficiary customer service call center hours in the event of beneficiary complaints or for other reasons in order to ensure that the entity’s customer service call center hours are sufficient to meet the needs of its enrollee population. Also, CMS has granted a waiver of the Part D call center performance requirements for all Direct Contract and “800 series” EGWPs.
20.16 - Waivers Only Applicable to Direct Contract EGWP
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

20.16.1 - Governmental Entities
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

In general, in accordance with section 1860D-41(a)(13) of the Act, governmental entities are not permitted to be PDP sponsors. However, CMS waived this prohibition for governmental entities, such as for state retirement funds and municipal or local government plans, applying to sponsor a Direct Contract EGWP for their retirees.

20.16.2 - State Licensure
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

In general, a Part D sponsor must be organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers coverage (42 CFR 423.401(a)(1) and 42 CFR 423.504(b)(2)). However, an employer/union Direct Contract EGWP applying to become a PDP solely for purposes of providing prescription drug coverage to its retirees will not have to meet the state licensing requirements set forth in 42 CFR 423.401(a)(1) and 42 CFR 423.504(b)(2) as a condition of being a Medicare prescription drug plan sponsor. CMS waived the licensure requirement for employer/union Direct Contract EGWPs that provide coverage to their own retirees. However, as a condition of this waiver, CMS requires that these entities meet certain financial solvency standards (see section 20.16.3).

20.16.3 - Financial Solvency
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

The financial solvency requirements for employer/union Direct Contract EGWPs are set forth in Appendix I of the 2009 Solicitation for Applications for New Employer/Union Direct Contract Prescription Drug Plans (PDP) Sponsors, dated January 24, 2008. CMS requires that the entity demonstrate that its fiscal soundness is commensurate with its financial risk and that through other means, the entity can assure that claims for benefits paid for by CMS and beneficiaries will be covered. In all cases, CMS will require that the employer/union sponsor’s contracts and sub-contracts contain beneficiary hold harmless provisions as described in Appendix I and in other CMS guidance. The employer/union may request waivers/modifications of the requirements in Appendix I by completing Appendix III (“HPMS Technical Plan Bidding Instructions for Organizations Offering Part D Employer/Union-Only Group Waiver Plans in Contract Year 2009”). CMS may, at its discretion, approve requests for such waivers/modifications on a case-by-case basis.
20.16.4 - Bonding and Insurance  
(Rcv.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

An employer/union Direct Contract EGWP must meet the bonding and insurance standards described in 42 CFR 423.504(b)(4)(iv)-(v). However, CMS may, on a case-by-case basis, provide flexibility to an employer/union directly contracting with CMS as a Part D sponsor by waiving these requirements upon a demonstration that different federal or state legal standards (such as ERISA bonding requirements) are satisfied.

20.16.5 - Management and Operations  
(Rcv.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

In general, an entity seeking to contract with CMS as a Part D sponsor must have administrative and management arrangements that demonstrate the following pursuant to 42 CFR 423.504(b)(4)(i)-(iii): policy-making bodies exercising oversight and control to ensure that management actions are in the best interest of the organization and its enrollees; appropriate personnel and systems relating to prescription drug services, administration and management; and an executive manager whose appointment and removal are under the control of the policy-making body.

An employer/union Direct Contract EGWP may be subject to other potentially different standards governing its management and operations, such as fiduciary requirements under the Employee Retirement Income Security Act of 1974 (“ERISA”), state law standards, and certain oversight standards created under the Sarbanes-Oxley Act. To reflect these issues and avoid imposing additional (and potentially conflicting) government oversight that may hinder employers/unions from considering Part D direct contracts with CMS, the requirements of 42 CFR 423.504(b)(4)(i)-(iii), as noted above, are waived if the employer/union (or to the extent applicable, the business associate with which it contracts for prescription drug benefit services) is subject to ERISA fiduciary requirements or similar state or federal law standards. However, such entities (or their business associates) are not relieved from the record retention standards applicable to other Part D sponsors set forth in 42 CFR 423.505(d).

20.16.6 - Reporting Requirements  
(Rcv.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

In general, PDP sponsors must report certain information to CMS, to their enrollees, and to the general public (such as the cost of their operations and financial statements) under 42 CFR 423.514(a). To avoid imposing additional and possibly conflicting public disclosure obligations that would hinder the offering of employer/union sponsored group health plans, CMS will modify these reporting requirements for Direct Contract EGWPs to allow information be reported to enrollees and to the general public to the extent required by other law (including ERISA or securities laws), or by contract.
Appendix I  
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

“800 series” EGWP Service Area Waiver Applicable for Contract Years 2006 and 2007 (superseded by subsequent Contract Year employer group waivers):

“800 series” EGWP Service Areas (The “Nexus Test”)

A PDP sponsor is permitted to offer an EGWP to employers/unions in a given PDP region of the country if the sponsor - either itself or through subcontractors or other partners - provides PDP coverage to Part D eligible individuals in that region. Through its waiver authority, however, CMS will permit PDP sponsors of EGWPs to expand coverage to an employer/union sponsor’s Part D eligibles residing in other regions through contracts and other arrangements provided that the most substantial portion of the employer/union sponsor’s employees live in a region where the PDP is offering plans to individual Medicare beneficiaries. This requirement is known as the “nexus test”.

Example 1: An employer has 600,000 employees, of whom 400,000 live in California and 200,000 live in Florida. A PDP sponsor that serves the non-group market in California (or that contracts or partners with an entity serving the non-group market in California) can offer a PDP sponsored by the employer that not only serves the employer’s California retirees, but also those retirees in Florida or any other state in the nation.

Example 2: An employer has 100,000 employees, of whom 45,000 live in New York, with the remainder spread out in smaller numbers among 20 other states. A PDP sponsor that serves the non-group market in New York (or that contracts or partners with an entity serving the non-group market in New York) can offer a PDP sponsored by the employer that not only serves the employer’s New York retirees, but also the retirees residing in the other 20 states where they reside.

A PDP sponsor that does not meet the most substantial portion test described above for a given employer/union may provide retiree-only PDP coverage for the retirees in any region where the PDP provides PDP coverage to individuals.

The foregoing service area rules are summarized in this table:

<table>
<thead>
<tr>
<th>Region (Service Area) for Individual Medicare Beneficiary Coverage</th>
<th>Largest Region (Service Area) for Employer/Union Retiree Group Coverage</th>
</tr>
</thead>
<tbody>
<tr>
<td>No coverage offered to individual Medicare beneficiaries.</td>
<td>Employer/union sponsored PDP coverage prohibited.</td>
</tr>
<tr>
<td></td>
<td>However, other MMA options are available for nationwide coverage, including the 28% retiree drug subsidy for qualifying retiree prescription drug plans. (Entities can offer prescription drug coverage that qualifies for</td>
</tr>
<tr>
<td>Region where most substantial portion of employees (or for union funds, participants) reside.</td>
<td>Nationwide</td>
</tr>
<tr>
<td>Region other than where most substantial portion of employees (or for union funds, participants) reside.</td>
<td>Limited to that same region where it provides coverage to individual Medicare beneficiaries.</td>
</tr>
</tbody>
</table>
Appendix II
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Instructions for Providing Copies of Dissemination Materials to CMS for Contract Years 2006-2008

What Materials to Send

For contract years 2006, 2007 and 2008, all Direct Contract PDPs and PDPs that offer “800 series” plans must provide copies of all dissemination materials to the CMS Central Office at the time of use. If the materials for multiple employer/union sponsors are identical except for sponsor identifier information, CMS will not require duplicate submissions of such materials (i.e., submission of one “template” version is permissible). Note that these same requirements to provide copies of customized dissemination materials at the time of use will apply to PDP sponsors that elect to utilize the waiver outlined in section 20.3.2.1.1 above on behalf of employers/unions that sponsor an individual PDP (e.g., use an individual Medicare plan paired with a non-Medicare supplemental plan designed to “wrap around” or enhance the individual Medicare plan to provide coverage to retirees).

For an employer/union sponsor plan eligible for the alternative dissemination standards waiver referenced above in section 20.3.2.2, a PDP Sponsor that offers “800 series” plans to these employer/union sponsors may provide copies to CMS of the alternative dissemination materials or, alternatively, the information that would be necessary to satisfy its reporting and disclosure obligations under 42 CFR 423.514(d). 42 CFR 423.514(d) provides that entities must furnish, upon request, the information that any employees’ health benefits plan needs to fulfill its reporting and disclosure obligations under ERISA. All information intended to satisfy 423.514(d) must be provided to CMS prior to November 1st.

How to Send the Materials

All marketing and dissemination materials must be sent to CMS via e-mail (in Microsoft Word or PDF format) to the following e-mail address: EGWPdisclosure@cms.hhs.gov. If the materials are subject to Medicare standards, include in the subject line of the e-mail “Medicare Dissemination Materials for Contract #xxxxx”. If the materials are subject to alternative dissemination standards in accordance with the waiver outlined in section 20.3.2.2 above, include in the subject line of the e-mail “Alternative Dissemination Materials for Contract #xxxxx”. For all materials, also provide in the body of the e-mail the type of document being submitted (e.g., Summary Plan Description, Information Required to Satisfy 42 CFR 423.514(d), etc.) and contact information (a contact name, phone number and e-mail address) if there are questions concerning the materials.

Materials must not be submitted through HPMS for any Direct Contract or “800 series” plan. Employer group plan sponsored materials also must not be submitted through HPMS when a PDP sponsor elects to use the waiver outlined in section 20.3.2.1.1 above to customize dissemination materials for a particular employer/union sponsor that offers coverage to its retirees using an individual Medicare plan paired with a non-Medicare supplemental plan designed to “wrap around” or enhance the individual Medicare plan.
Appendix III  
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

HPMS Technical Plan Bidding Instructions for Organizations Offering Part D Employer/Union-Only Group Waiver Plans in Contract Year 2009

Starting in contract year (CY) 2008, Part D entities that offer employer/union-only group waiver plans (EGWPs) were no longer required to complete Part D Bid Pricing Tool (BPT) submissions. See 2008 Employer Group Waiver Policy – Elimination of the Requirement for Entities Offering EGWPs to Submit Part D Bids, February 28, 2007. This waiver policy has been extended to CY 2009. As noted in the memo, this waiver policy applies to all MA, PDP, and 1876 Cost organizations offering Part D EGWPs (i.e., “800 series” EGWPs) as well as to employers/unions that directly contract with CMS to offer Part D benefits to their retirees (i.e., “Direct Contract” EGWPs).

NOTE: CMS’ employer group waiver authority applies only to Part D, not to Parts A or B of the Cost Plan. Thus, section 1876 Cost Plan sponsors may only offer “800 series” Part D coverage as an optional supplemental benefit and may not offer customized “800 series” A/B benefits.

CMS has also modified the corresponding Plan Benefit Package (PBP) submission requirement for all EGWPs offering Part D.

The following table outlines the HPMS PBP and BPT submission requirements for each type of Part D EGWP for the 2009 contract year:

<table>
<thead>
<tr>
<th>PBP Section/BPT</th>
<th>MA-PD “800 series” EGWP and Direct Contract MA-PD EGWP</th>
<th>PDP and 1876 Cost “800 series” EGWP and Direct Contract PDP EGWP</th>
</tr>
</thead>
<tbody>
<tr>
<td>PBP Section A</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>PBP Sections B, C, and D</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>PBP Rx Section</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>MA BPT</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>PD BPT</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

Plans that fall under column A will download and install the 2009 PBP software, create their 2009 plans, and download their plan-specific data into the software, per the usual process. Column A plans will complete sections A, B, C, and D of the 2009 PBP software, but the Rx Section of the PBP will be disabled. Column A plans will also complete the MA BPT.

Plans that fall under column B will download and install the 2009 PBP software, create their 2009 plans, and download their plan-specific data into the software, per the usual process. While no actual data entry is required in Section A of the PBP for PDP plan types, plans are still required to open Section A, review the plan information, and exit Section A with validation.
All plans outlined in column A and B are required to upload their plans into HPMS, per the usual process. In addition, these plans are still required to meet all applicable pre-upload submission requirements to upload plans into HPMS.

**NOTE:** Plans that fall under column B are required to complete the upload process as a mechanism for establishing their official set of plan IDs for the 2009 contract year in HPMS.
Appendix IV
(Rev.6, Issued: 11-07-08, Effective/Implementation: 11-07-08)

Instructions for MA Organizations and PDP Sponsors Requesting Additional Waiver/Modification of Requirements.

MA organizations and PDP sponsors may submit individual waiver/modification requests at any time to CMS. The Applicant should submit these additional waiver/modification requests to their Account Manager.

These requests must be identified as requests for additional waivers/modifications and must fully address the following items:

- Specific provisions of existing statutory, regulatory, and/or CMS policy requirement(s) the entity is requesting to be waived/modified (identify the specific requirement (e.g., “42 CFR 422.66,” or “Pub. 100-16, Medicare Managed Care Manual chapter 2, section 40.4,”) and whether you are requesting a waiver or a modification of these requirements);

- How the particular requirements hinder the design of, the offering of, or the enrollment in, the employer-sponsored group plan;

- Detailed description of the waiver/modification requested including how the waiver/modification will remedy the impediment (i.e., hindrance) to the design of, the offering of, or the enrollment in, the employer-sponsored group plan;

- Other details specific to the particular waiver/modification that would assist CMS in the evaluation of the request; and

- Contact information (contract number, name, position, phone, fax and email address) of the person who is available to answer inquiries about the waiver/modification request.
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      40.1.2 - Effective Date of Initial Determinations
      40.1.3 - Changes in Subsidy Level Within Established Span
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Note: This chapter is subject to change to both periodic and annual updates, and currently reflects CY 2011 guidance.
10 - Introduction
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

This chapter establishes the Part D sponsor requirements and limitations for payments made by and on behalf of low-income Medicare beneficiaries who enroll in a Part D plan. The Medicare Prescription Drug Benefit, which went into effect January 1, 2006, provides extra help with prescription drug costs for eligible individuals whose income and resources are limited. This help takes the form of subsidies paid by the Federal government to the Part D sponsor. The low-income subsidy (LIS) provides assistance to certain low-income individuals to supplement the premium and cost-sharing (including deductibles and cost-sharing during the coverage gap) associated with the Part D benefit.

Except where specifically noted, these requirements apply to all Part D sponsors offering Part D coverage. Other requirements related to beneficiary protections are contained in other chapters of Pub. 100-18, Medicare Prescription Drug Benefit Manual, which can be accessed at: http://www.cms.hhs.gov/manuals/downloads/Pub100_18.pdf.

20 - Definitions
(Rev. 13, Issued: 07-29-11, Effective Date: 01-01-11; Implementation Date: 01-01-11)

Unless otherwise stated in this chapter, the following definitions apply:

**Annual out-of-pocket threshold:** The point in the Part D benefit when a beneficiary enters the catastrophic coverage phase. Detailed description is found in chapter 5, section 20.3.1 of this manual. For years subsequent to 2006, it is the annual out-of-pocket threshold for 2006 ($3600) increased by the annual percentage increase specified at 42 CFR 423.104(d)(5)(iii). See Appendix A for the current calendar year annual out-of-pocket threshold.

**Applicant:** The Part D eligible individual applying for the low-income subsidy with either the Social Security Administration (SSA) or the State Medicaid agency.

**Basic prescription drug coverage:** Refer to chapter 5, section 20.1 of this manual for the description of this term.

**Best Available Evidence:** Documentation used by the Part D sponsor to support a favorable change to a low-income subsidy eligible beneficiary’s LIS status.

**Copayment Amounts:** Applicable calendar year copayment/coinsurance amounts provided in Appendix A for full subsidy and partial subsidy eligible individuals.

**Coverage Gap:** The Part D benefit phase above the initial coverage limit and at or below the annual out-of-pocket threshold described at 42 CFR 423.104(d)(4) (and in chapter 5, section 20.3.1 of this manual).
Covered Part D drugs: Refer to chapter 6, section 10.2 of this manual for the description of this term.

Deductible Amounts: Applicable deductible amounts provided in Appendix A for partial subsidy eligible individuals.

Deemed Eligible Individual: An individual who is deemed as meeting the eligibility requirements for full subsidy eligible individuals if the individual is entitled to Medicare and:

- A full benefit dual eligible individual (eligible for full Medicaid benefits);
- A recipient of Supplemental Security Income (SSI) benefits; or
- Eligible for full Medicaid benefits, and/or the Medicare Savings Program as a Qualified Medicare Beneficiary (QMB), Specified Low Income Medicare Beneficiary (SLMB), or Qualifying Individual (QI) under a State’s Medicaid plan.

A full description is found at section 40.2 of this chapter.

Dual Status: Entitlement to Medicare and concurrent eligibility for a Title XIX benefit (i.e., Medicaid or a Medicare Savings Program).

Extra Help: The low-income subsidy (LIS) or subsidy.

Family Size: Includes the applicant, the spouse, if any, living in the same household and the number of individuals, if any, related to the applicant(s) living in the same household, and dependent on the applicant or the applicant’s spouse for at least one-half of their financial support.

Federal Poverty Level (FPL): The income standard for poverty that is updated annually by the U.S. Department of Health and Human Services and generally used as the basis for determining the low-income subsidy level. For more information regarding specific FPLs, see section 40.1.1 of this chapter.

Full Benefit Dual Eligible Individual: An individual who is entitled to Medicare and is eligible for comprehensive Medicaid benefits and meets the requirements of the definition at 42 CFR 423.772.

Full Subsidy: The amount of reductions to a full subsidy eligible individual’s costs under a Part D plan, including:

- 100% subsidy of the monthly premium for basic prescription drug coverage up to the regional low-income premium subsidy amount;
- Elimination of the annual deductible;
• Reduced cost-sharing if the copayment under the basic or enhanced portion of the plan's benefit package is more than the applicable LIS copayment amounts provided in Appendix A for Part D covered drugs (further explained in section 60.4);
• Elimination of the coverage gap;
• Elimination of cost-sharing above the annual out-of-pocket threshold; and,
• Waiver of late enrollment penalty.

A full description is found at 30.1 of this chapter.

Full Subsidy Eligible Individual:

• A subsidy eligible individual whose income is below 135 percent of the FPL applicable to the individual’s family size and whose resources do not exceed the resources described in 42 CFR 423.773(b)(2)(ii). For current year resource limits see https://secure.ssa.gov/apps10/poms.nsf/lnx/0603030025; and
• An individual deemed eligible as a full subsidy eligible individual.

Generic: A drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(j)) is approved.

Income: Money received in cash or in-kind by the applicant or a spouse who is living with the applicant that can be used to meet their needs for food and shelter. This definition includes the income of the applicant and spouse who is living in the same household, if any, regardless of whether the spouse is also an applicant. Effective January 1, 2010, income for support and maintenance in kind is not counted as income to the applicant.

Individual Receiving Home and Community-Based Services: A full-benefit dual eligible individual who is receiving services under a home and community-based waiver authorized for a State under section 1115 or subsection (c) or (d) of section 1915 of the Social Security Act or under a State plan amendment under subsection (i) of such section or if such services are provided through enrollment in a Medicaid managed care organization with a contract under section 1903(m) or under section 1932 of the Social Security Act.

Institutionalized Individual: A full-benefit dual eligible individual who is an inpatient in a medical institution or nursing facility for which payment is made under Medicaid throughout a calendar month, as defined in section 1902(q)(1)(B) of the Social Security Act.

Low-Income Subsidy (LIS) Individual’s Premium Amount: The premium paid by the low-income subsidy beneficiary for basic prescription drug coverage after the premium subsidy amount is applied.
**MA-PD plan:** A plan offered by a Medicare Advantage (MA) organization that provides qualified prescription drug coverage.

**Medicare Savings Program (MSP):** For purposes of the Medicare Part D full subsidy eligibility, the Qualified Medicare Beneficiary (QMB) benefit, the Specified Low Income Medicare Beneficiary (SLMB) benefit, or the Qualifying Individual (QI) benefit under title XIX of the Social Security Act.

**Multiple source or multi-source drug:** A drug defined in section 1927(k)(7)(A)(i) of the Social Security Act.

**Part D sponsor:** A prescription drug plan (PDP) sponsor, MA organization offering an MA-PD plan, a Program for All-inclusive Care for the Elderly (PACE) organization offering a PACE plan including qualified prescription drug coverage, and a cost plan offering qualified prescription drug coverage.

**Partial Subsidy:** Partial reductions in a beneficiary’s costs imposed under a Part D plan, including:

- Reduction to the deductible when the deductible is greater than the maximum deductible amounts for partial subsidy eligible individuals (See Appendix A);

- 25% to 100% subsidy of the monthly premium for basic prescription drug coverage up to the regional low-income premium subsidy amount;

- Reduction to 15% coinsurance per prescription for covered Part D drugs, up to the annual out-of-pocket threshold, and copayments of not more than the maximum copayments for Partial subsidy eligible individuals above the annual out-of-pocket threshold (See Appendix A);

- Elimination of the coverage gap; and,

- Waiver of late enrollment penalty (LEP).

**Partial subsidy eligible individual:** Referred to as other low-income subsidy eligible individuals at 42 CFR 423.773, or a subsidy eligible individual who has:

- Income less than 150% of the Federal Poverty Level (FPL) applicable to the individual’s family size; and

- Resources that do not exceed the amounts described in section 30.2 of this chapter (see [https://secure.ssa.gov/apps10/poms.nsf/lnx/0603030025](https://secure.ssa.gov/apps10/poms.nsf/lnx/0603030025) for the current year resource limitations).
**Personal representative:** For purposes of this chapter, (1) an individual who is authorized to act on behalf of the applicant; (2) if the applicant is incapacitated; or incompetent, someone acting responsibly on their behalf; or (3) an individual of the applicant’s choice who is requested by the applicant to act as his or her representative in the application process.

**Preferred drug:** A covered Part D drug on a Part D sponsor’s formulary for which beneficiary cost-sharing is lower than for a non-preferred drug on the sponsor’s formulary.

**Preferred multiple source drugs:** A drug that is both a preferred drug and a multiple source drug, meaning that one version of that drug is placed on the sponsor’s formulary with lower cost sharing than for a non-preferred drug.

**Prescription Drug Plan (PDP):** Prescription drug coverage that is approved under 42 CFR 423.272 and that is offered by a PDP sponsor that has a contract with CMS.

**Reference Month:** The month in the previous calendar year as identified by CMS for the calculation of the low-income benchmark premium amount. See 423.780(b)(2), 422.258(c)(1).

**Resources:** With the exception of the value of the individual’s life insurance policy, the liquid resources of an LIS applicant (and, if married, his or her spouse who is living in the same household), such as checking and savings accounts, stocks, bonds, and other resources that can be readily converted to cash within 20 days, that are not excluded from resources in section 1613 of the Act, and real estate that is not the applicant’s primary residence or the land on which the primary residence is located. Effective January 1, 2010, the value of any life insurance policy is not counted as a resource to the applicant.

**Regional low-income premium subsidy amount:** The greater of the PDP region’s low-income benchmark premium amount or the lowest monthly beneficiary premium for a PDP that offers basic prescription drug coverage in the PDP region as defined in section 50.2.1.

**State:** Each of the 50 States and the District of Columbia.

**Subsidy:** The low-income subsidy.

**Supplemental drugs:** Drugs that would be covered Part D drugs but for the fact that they are specifically excluded as Part D drugs under 42 CFR 423.100, and as described in chapter 6, section 20.1 of this manual. Because such drugs must have otherwise qualified as covered Part D drugs (as defined in chapter 6, section 10.2 of this manual) in order to be covered as a supplemental benefit, and because only prescription drugs are included in the definition of a Part D drug, over-the-counter drugs cannot be supplemental drugs, as discussed in chapter 6, section 10.10. Supplemental drugs may be included as a supplemental benefit under enhanced alternative coverage, as described in chapter 5, section 20.4.2 of this manual.
Transaction Reply Report (TRR): A report that CMS provides to Part D sponsors containing details of the rejected and accepted enrollment transactions that CMS has processed for a Part D sponsor’s contract(s) over a specified time period. There are two types of TRRs: the Weekly TRR that covers the processing week (typically Sunday through Saturday) and the Monthly TRR that covers the payment processing month.

TrOOP or True Out-Of-Pocket costs – See chapter 5, section 30 of this manual for the description of this term.

30 - Eligibility Requirements
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

This section describes the requirements for Medicare beneficiaries with limited income and resources to qualify for the Part D LIS. Specifically, it discusses eligibility for the two categories of the LIS: the full subsidy and the partial subsidy.

The LIS described in this chapter is limited to Medicare beneficiaries who reside in the 50 States and the District of Columbia. U.S. Territories receive a Federal grant to operate their own programs to assist dual Medicare/Medicaid beneficiaries with the costs of the Part D benefit. Discussion of the U.S. Territories enhanced allotment program is described in section 90 of this chapter.

Individuals who receive prescription drug coverage through plans other than Part D plans, including those for whom employers are claiming a retiree drug subsidy, do not receive the benefits of the LIS. Low-income individuals must be enrolled in a Part D plan to have their premium, deductible, coverage gap, and cost-sharing subsidized by the low-income subsidy.

30.1 - Full Subsidy Eligible Individuals
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

An individual can qualify for the full subsidy in two ways. First, an individual qualifies if he or she applies and is determined to have:

1. An annual income below 135 percent of the FPL as applicable to the individual’s family size; and

2. Resources that do not exceed the resource limitations specified at https://secure.ssa.gov/apps10/poms.nsf/lnx/0603030025 for the plan year. For subsequent years, the amount of resources allowed for the previous year will be increased by the annual percentage increase set forth by the U.S. consumer price index (all items, U.S. cities). The annual percentage increase will be determined by September of the previous year and will be rounded to the nearest multiple of $10. The nearest multiple will be rounded up if it is equal to or greater than $5 and rounded down if it is less than $5.
The following individuals are deemed automatically eligible for the full subsidy based on their qualification for other Federal programs:

1. Full-benefit dual eligible individuals;

2. Recipients of Supplemental Security Income (SSI) benefits under title XVI of the Act or;

3. Individuals eligible for Medicare Savings Programs as a Qualified Medicare Beneficiary (QMB), Specified Low Income Medicare Beneficiary (SLMB), or a Qualifying Individual (QI) under a State’s plan.

**30.2 - Partial Subsidy Eligible Individuals**  
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

An individual is eligible for the partial subsidy if she/he applies and is determined to have:

1. An annual income below 150 percent of the FPL as applicable to the individual’s family size; and

2. Resources that do not exceed the resource limitations at [https://secure.ssa.gov/apps10/poms.nsf/lnx/0603030025](https://secure.ssa.gov/apps10/poms.nsf/lnx/0603030025) (including the assets and resources of the individual’s spouse). For subsequent years, the amount of resources allowed for the previous year is increased by the annual percentage increase set forth by the U.S. consumer price index (all items, U.S. cities). The annual percentage increase is determined by September of the previous year and will be rounded to the nearest multiple of $10. The nearest multiple will be rounded up if it is equal to or greater than $5 and rounded down if it is less than $5.

**40 - Eligibility Determinations, Redeterminations, and Applications**  
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

This section describes the process for determining eligibility for the full or partial subsidy, and for deeming eligibility for the full subsidy. “Determining” is the term used to describe the process in which an individual must apply and be found eligible in order to qualify for the full subsidy. “Deeming” is the term that is used to describe the process in which an individual automatically qualifies for the full subsidy without applying, by virtue of having applied and been found qualified for certain other Federal programs. An individual's LIS status cannot begin earlier than his or her Part D eligibility.

For details on the eligibility determination processes discussed in the following sections, see 20 CFR Part 418 and the SSA Program Operations Manual System [POMS], available at [http://policy.ssa.gov/poms.nsf/aboutpoms](http://policy.ssa.gov/poms.nsf/aboutpoms), under Health Insurance (HI) 030.

**40.1 - Eligibility Through Application**  
(Rev. 13, Issued: 07-29-11, Effective Date: 01-01-11; Implementation Date: 01-01-11)
This section describes the process for those who must apply and be determined eligible in order to qualify for the LIS.

A beneficiary who believes he or she may be eligible for the LIS (but is not deemed eligible by virtue of being Medicaid, MSP, or SSI-eligible) may apply for the subsidy through the Social Security Administration (SSA) or by requesting a State determination at his or her State Medicaid agency. The agency (SSA or State Medicaid agency) that makes the subsidy decision is responsible for on-going case activity, including notices, redeterminations of subsidy eligibility, and appeals. If an application is filed with the State Medicaid agency, that agency is responsible for screening the applicant for eligibility for a Medicare Saving Program (MSP) and offering to enroll any applicant who qualifies. If a State Medicaid agency determines LIS eligibility, the applicant would be subject to state reporting requirements, which might result in different timeframes for reduction or termination of eligibility than under the process administered by SSA.

The Affordable Care Act created a special rule for widows and widowers regarding eligibility for the low-income subsidy. This provision requires that, beginning January 1, 2011, the surviving spouse of a subsidy-eligible couple receive an extension of the effective period for a determination or redetermination through the date that is 1 year after the date on which the next redetermination after the death of a spouse would have occurred. Subsequently, the subsidy eligible widow/widower is to be determined or redetermined, as appropriate, for the subsidy on the same basis as other subsidy-eligible beneficiaries. States must, therefore, adjust their redetermination schedule when the death of a spouse is reported.

Eligibility determinations made by SSA are made in accordance with requirements set forth by the Commissioner of Social Security (see 42 CFR § 423.774). State Medicaid agencies, at the request of the applicant, must make subsidy eligibility determinations using the same financial rules used by SSA but apply the case processing standards (including time frames for making decisions and notifying applicants) that the State uses for its Medicaid cases. State LIS applications are available at the State Medicaid agencies. The Guidance to States on the Low-Income Subsidy (available at http://www.cms.hhs.gov/States/03_lowincomesubsidy.asp) provides policies and procedures for State LIS determinations. In order for LIS subsidy applications under this section to be considered complete, applicants (or personal representatives applying on the individual’s behalf) are required to:

1. Complete all required elements of the application;
2. Provide any requested statements from financial institutions to support information in the application; and
3. Certify, under penalty of perjury or similar sanction for false statements, as to the accuracy of the information provided on the application form.
SSA verifies most information through data matches with existing SSA, Internal Revenue Service and other government files. The agency (SSA or State Medicaid agency) that makes the subsidy decision may request additional documentation if there are discrepancies between the data matches and the attestations on the application. If the individual, or his or her personal representative, files an application with the State or SSA seeking subsidy eligibility for any portion of an eligibility period covered by an earlier application, the later application is void if the individual has received a subsidy approval on that earlier application from the State or SSA.

SSA and the states notify CMS of individuals whom they have determined to be eligible for the LIS and CMS in turn provides the subsidy information, including effective date and level of subsidy, to the Part D plan in which the beneficiary enrolls. (For details on how CMS communicates LIS eligibility to Part D sponsors, see section 70 of this chapter.)

It is important to remember that the low-income subsidy provides no benefit if the beneficiary is not enrolled in a Part D plan. LIS-eligible beneficiaries have a continuous Special Enrollment Period and may enroll at any time by:

- Calling 1-800-MEDICARE;
- Filing a request with the On-Line Enrollment Center at www.medicare.gov; or
- Calling the Part D sponsor directly.

40.1.1 - Financial Standards for Low-Income Subsidy (LIS) Applications
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

To qualify for the Part D low-income subsidy, Medicare beneficiaries must have resources and income no greater than the resource and income limits established by the Medicare Modernization Act (MMA). The financial standards applicable to LIS applications are those in effect on the date of application. When determining whether a beneficiary qualifies for LIS, $1,500 in resources per person (applicant and spouse) are excluded from consideration if the beneficiary indicates that they expect to use some of their resources for burial expenses.

CMS is required by law to update the Part D income and resource limits each year. Resource limits for the next calendar year are updated based on the September Consumer Price Index (CPI) Resource limits (see https://secure.ssa.gov/apps10/poms.nsf/lnx/0603030025 for the current year resource limits). Early each year, the U.S. Department of Health and Human Services updates that income level equivalent to 100% of the Federal Poverty Level (FPL) for that same calendar year (see http://aspe.hhs.gov/-poverty/). CMS calculates the corresponding FPL (income) levels necessary for qualifying for the LIS benefit, i.e., 135%, 140%, 145% and 150%, and notifies Part D sponsors of the updated levels via an HPMS memo by the end of January or early February. The new poverty guidelines are retroactive to January 1 of that year.

40.1.2 - Effective Date of Initial Determinations
(Rev. 13, Issued: 07-29-11, Effective Date: 01-01-11; Implementation Date: 01-01-11)
An individual who applies and is determined eligible for the LIS is eligible effective the first day of the month in which the individual submitted an application (but no earlier than January 1, 2006). In most cases, LIS applicant status is effective retroactively. The majority of new LIS applicants are already entitled to Medicare when they apply for LIS. For individuals who are entitled to Medicare at the point in time they submit an application, their LIS effective date will be retroactive to the first day of the month the application was filed. If a beneficiary is already enrolled in a Part D plan, the Part D sponsor must take steps to ensure that the beneficiary is made whole with respect to any premium or cost-sharing the member has paid that should have been covered by the subsidy (see section 70 for details on Part D sponsor obligations). This applies to both current and former members.

For individuals who are not yet entitled to Medicare, the LIS effective date is the first day of the month in which their Medicare Part D eligibility starts. Note that the beneficiary must be enrolled in a Part D plan in order to benefit from the subsidy.

Example 1: An individual who is already Medicare eligible applies at SSA for the LIS on April 22, 2011. SSA makes a determination on May 19, 2011, that the person qualifies for the subsidy. Their LIS is effective retroactive to April 1, 2011.

Example 2: An individual who is not yet Medicare eligible applies at SSA for the LIS on April 22, 2011. SSA makes a determination on May 19, 2011, that the person qualifies for the subsidy. The person’s Medicare eligibility starts June 1, 2011, so the subsidy effective date is also June 1, 2011.

Initial LIS determinations are made for a period not to exceed 12 months. Thereafter, if the individual is found ineligible, the subsequent end date would be established by the agency that made the decision. The end date is always the last day of a calendar month but may occur in any month of the year, depending on the requirements of the agency (either the State or SSA) making the decision. On-going LIS eligibility will appear in the Medicare Beneficiary Database (MBD) as a span without an end date.

40.1.3 - Changes in Subsidy Level Within Established Span
(Rev. 13, Issued: 07-29-11, Effective Date: 01-01-11; Implementation Date: 01-01-11)

For cases in which eligibility is established through application with SSA, report of a subsidy-changing event will trigger a redetermination of subsidy eligibility during the calendar year. This can result in changes to the individual’s deductible, premium subsidy, cost-sharing subsidy, or even termination of their LIS. Subsidy changing events are:

- Marriage;
- Divorce;
- Death of spouse;
- Separation;
• Reunion after separation; and
• Annulment.

When SSA receives a report of a subsidy-changing event, the beneficiary is mailed a redetermination form to complete and return within 90 days. Any change (i.e., increase, decrease, or termination) in the level of the subsidy indicated by the completed redetermination form will take effect as of the first day of the month following the month of the initial report of the change.

The Affordable Care Act created a special rule for widows and widowers regarding eligibility for the subsidy. This provision requires that, beginning January 1, 2011, the surviving spouse of a subsidy-eligible couple receive an extension of the effective period for a determination or redetermination through the date that is 1 year after the date on which the next redetermination after the death of a spouse would have occurred. Subsequently, the subsidy-eligible widow/widower is to be determined or redetermined, as appropriate, for the subsidy on the same basis as other subsidy eligible beneficiaries.

Example: An individual who is subsidy-eligible reports to SSA on April 10, 2011, that her husband died on March 25, 2011. SSA mails a 1026-SCE (subsidy changing event) form to the widow.

• If the report data would increase the subsidy or provide a more favorable resources level, the change will be effective the month following the month of the report. In the above example, the change would be effective May 1, 2011.

• If the report data result in no change, SSA will not send the widow a redetermination form in the following year unless the widow belongs to a category of individuals that is designated for frequent review.

• If the report data would decrease the subsidy, or provide a less favorable resources level, SSA will not add the widow to the August redetermination selection for 2011, but rather will add her to the August redetermination selection in the next year (2012), with any change being effective January 1, 2013.

Part D sponsors are obligated to make the beneficiary whole with respect to overpaid premiums and cost-sharing or to collect any underpaid premiums and cost-sharing due from the beneficiary as discussed in section 70.3 of this chapter. This applies to both former and current members.

40.1.4 - Deeming After Eligibility Through Application
(Rev. 13, Issued: 07-29-11, Effective Date: 01-01-11; Implementation Date: 01-01-11)

If, after establishing LIS eligibility through application, an individual is reported by his or her State Medicaid agency as Medicaid or MSP-eligible, or by SSA as SSI-eligible, deemed status is established for the individual. When this occurs, the LIS determination is
terminated. The deemed status prevails over the application status and provides a subsidy benefit that is at least as good as the subsidy established through application.

Example: Beneficiary applies for the LIS with SSA on October 9, 2010, and is approved for a partial subsidy, effective October 1, 2010. In March, 2011, he is reported by his State as being eligible for Medicaid effective March 1, 2011. His eligibility as an LIS applicant for a partial subsidy is terminated effective February 29, 2011. His deemed status (and thus qualification for full subsidy) is effective March 1, 2011 through December 31, 2011.

When an individual who was previously approved for the subsidy through application is deemed for a short period (less than 1 year), SSA will restore its subsidy determination when deeming ceases if the subsidy eligibility was determined or redetermined in the last 2 years.

Refer to section 70.3 regarding the Part D sponsor’s obligation to make the member whole with respect to overpaid premiums and cost-sharing or to recoup any underpaid premiums and cost-sharing due from the beneficiary. This applies to both former and current members.

40.1.5 - Determining Agency Notification to Applicant
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

Individuals who applied for LIS will be notified of the results of the eligibility determination, redetermination, or impact of subsidy-changing events by the agency (SSA or State Medicaid agency) that made the initial LIS determination.

40.1.6 - Redetermination Process
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

The agency (SSA or State Medicaid agency) that makes the subsidy decision is responsible for on-going case activity, including redeterminations of LIS eligibility. CMS and the Part D sponsor may not be notified of an appeal decision until after the effective date in case of an appeal.

40.1.7 - Appeals
(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

When an individual disagrees with a determination of his or her subsidy eligibility, subsidy level, or subsidy termination, the individual may appeal the decision with either SSA or the State Medicaid agency, whichever agency made the initial determination. Beneficiary information regarding the appeals process for subsidy determinations are further described in the determination letter sent by SSA or the Medicaid agency. Instructions regarding SSA appeals within the SSA Program Operations Manual System are found at: https://secure.ssa.gov/apps10/poms.nsf/lnx/0603040000!opendocument.
40.2 - Eligibility Through Deeming  
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08) 

This section describes how individuals are deemed automatically eligible for the full subsidy. Individuals are never deemed eligible for the partial subsidy.

40.2.1 - Source Data  
(Rev. 13, Issued: 07-29-11, Effective Date: 01-01-11; Implementation Date: 01-01-11) 

CMS deems individuals automatically eligible for the full subsidy, based on data from State Medicaid Agencies and the Social Security Administration.

SSA sends a monthly file of SSI-eligible beneficiaries to CMS.

Similarly, the State Medicaid agencies submit MMA files to CMS that identify beneficiaries who are:

- Eligible for full Medicaid benefits (full benefit dual eligible), or
- Eligible for a Medicare Savings Program (QMB, SLMB, or QI).

Data from States are also submitted to CMS in two additional ways:

1. From CMS’ Contractor for the Limited Income NET Program (LI NET) the contractor provides immediate coverage at point of sale for subsidy eligible individuals who are not enrolled in a Part D plan. The eligibility verification contractor checks State eligibility data to confirm the individuals are full benefit or partial dual eligible individuals, and submits those data to CMS for the purpose of subsidy deeming).

2. From Part D sponsor-submitted data indicating best available evidence (BAE), which documents the individual’s LIS eligibility (see section 70.5).

An individual needs to be reported eligible by SSA or the State for only 1 month in a calendar year to be deemed eligible from that month through the end of the year.

Example: An individual is reported by her State as Medicaid-eligible in March, 2011. She will be deemed eligible from March 1, 2011 through December 31, 2011.

40.2.2 - Effective Date of Initial Deemed Status  
(Rev. 13, Issued: 07-29-11, Effective Date: 01-01-11; Implementation Date: 01-01-11) 

CMS deems individuals automatically eligible for LIS effective as of the first day of the month that the individual attains the qualifying status (i.e., when a Medicare beneficiary becomes eligible for Medicaid, QMB, SLMB, QI, or SSI). The end date is, at a minimum, through the end of the calendar year. Individuals who are deemed LIS eligible for any
month during the period of July through December of a year are deemed eligible through the end of the following calendar year.

Once a beneficiary becomes deemed eligible through the end of a given calendar year, he/she remains deemed even if he/she is no longer reported by his or her Medicaid agency as a full benefit dual eligible individual or partial dual eligible individual, or by SSA as an SSI recipient, due to loss of eligibility.

In most cases, LIS deemed status is effective retroactively. The majority of newly deemed individuals are already entitled to Medicare and apply for Medicaid/QMB/SLMB/QI/SSI. When eligibility for these programs is retroactive, eligibility for LIS deemed status is also retroactive. If a beneficiary is already enrolled in a Part D plan, Part D sponsors must take steps to ensure that the beneficiary is made whole with respect to any premiums and cost-sharing the member has paid that should have been covered by the subsidy (see section 70 of this chapter for details on Part D sponsor obligations). This applies to current and former members.

Example 1: An individual becomes a full-benefit dual eligible individual effective March 1, 2011. The effective date of deemed status is March 1, 2011 through December 31, 2011.

Example 2: A Medicare individual becomes SSI eligible effective October 1, 2011. The effective date of deemed status is October 1, 2011 through December 31, 2012.

For individuals who are initially entitled to Medicaid or SSI-only, and are about to become entitled to Medicare, States and SSA attempt to submit the data for these individuals prior to the start of their Medicare eligibility to help ensure that LIS deemed status is established the first day of their Medicare entitlement.

40.2.3 - Changes to Subsidy Status Within the Established Deemed Span
(Rev. 13, Issued: 07-29-11, Effective Date: 01-01-11; Implementation Date: 01-01-11)

Within a given calendar year, an individual’s deemed status may change based on data received from States or SSA subsequent to the initial deeming process. CMS uses any such data from States or SSA to determine whether the beneficiary may qualify for a lower copayment obligation. Thus, CMS changes an individual’s deemed status mid-year only when such a change qualifies the beneficiary for a lower copayment obligation. The other benefits of their LIS full subsidy – premium subsidy and elimination of deductible and coverage gap – remain unchanged.

Example 1: An individual is deemed for the $2.50/$6.30 copayment level for January 1 through December 31, 2011. Data are subsequently received indicating the individual now qualifies for the $1.10/$3.30 level effective March 1, 2011. For the period of March 1, 2011 through December 31, 2011, the individual is now deemed for the copayment level of $1.10/$3.30.
Example 2: Effective January 1, 2011, an individual is reported as a full dual with income below 100% FPL and is assigned a copayment level of $1.10/$3.30. From August, 2011 onward, the individual is reported as QMB-only (who normally qualify for a level of $2.50/$6.30 in 2010). The individual’s copayment level will remain $1.10/$3.30 through December 31, 2011.

The following example reflects an individual whose copayment level changed effective during the period of July through December of the calendar year.

Example: An individual is initially deemed eligible for the $1.10/$3.30 copayment level for April 1, 2010 through December 31, 2010. Data are subsequently received indicating the individual qualifies for $0 copayment effective November 1, 2010. The individual is deemed at this new copayment level from November 1, 2010 through December 31, 2011.

40.2.4 - CMS Notices to Deemed Individuals
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

CMS provides notices to each individual when they are initially deemed eligible for the LIS informing them that they are full subsidy eligible individuals and that they automatically qualify for the LIS. See section 40.2.6 for information on CMS’ notices to beneficiaries pursuant to the annual “re-deeming” process.

40.2.5 - Redetermination of Deemed Status (“Redeeming”)
(Rev. 13, Issued: 07-29-11, Effective Date: 01-01-11; Implementation Date: 01-01-11)

In July of each year CMS initiates its “re-deeming” process, and runs its re-deeming process daily thereafter. During the re-deeming process, CMS identifies individuals who qualify in the current year and who will continue to be automatically deemed for the full subsidy in the next calendar year. Individuals who are eligible for Medicaid/QMB/SLMB/QI at any point during the period of July through December of the current year qualify to be re-deemed for the following calendar year, as do SSI recipients who are eligible in any month from July through December of the current year.

Example 1: An individual is initially deemed for January 1, 2010 through December 31, 2010, with a $0 copayment, based on State data indicating the person is an institutionalized, full benefit dual eligible individual. The individual appears on a State MMA file as institutionalized for July 2010. The individual is re-deemed for January 1, 2011 through December 31, 2011 with the $0 copayment.

Example 2: An individual is initially deemed for January 1, 2010 through December 31, 2010, as a full benefit dual eligible individual with copayments of $1.10/$3.30, based on State data indicating that the individual’s income is less than 100% of the Federal Poverty Level. Beginning in October 2010, the State reports the individual as a full benefit dual eligible individual and institutionalized. The
individual’s copayments are reduced to $0 effective October 1, 2010 through December 31, 2011.

Example 3: An individual is initially deemed for January 1, 2010 through December 31, 2010 as a full benefit dual eligible individual with copayments of $1.10/$3.30, based on State data that the individual’s income is less than 100% of the Federal Poverty Level. No State data is submitted for the individual from July 2010 through December 2010. Therefore, the individual loses deemed status on December 31, 2010. In February 2011, the State resumes reporting the individual, but as a Medicare Savings Program (MSP) recipient, effective November 2010. Based on the MSP status, the individual’s copayments will be $2.50/$6.30 effective January 1, 2011. The copayment levels ($1.10/$3.30) for November through December 2010 are not affected because, for the deemed population, only favorable changes occur mid-year.

The re-deemed date will appear in plans’ weekly transaction reply reports (TRRs) in July. Since 95% of the re-deemed population is re-deemed in July, Part D sponsors should expect to see large numbers of re-deemed records on their weekly TRRs that month. TRC 121 identifies individuals who have been re-deemed. (See Appendix E.)

For individuals who do not qualify automatically for the next year, their LIS deemed status ends on December 31 of the current year. However, the Part D sponsor should encourage the individual to apply for the LIS, since they may re-qualify for the LIS through the application process.

Example 1: An individual loses deemed status and on October 15, applies with SSA to reestablish LIS eligibility for the next year. The application is approved and the individual's subsidy eligibility continues into the next calendar year.

Example 2: An individual loses deemed status and on January 5 of the next year applies with SSA to reestablish LIS eligibility. If the Part D plan offers a grace period for individuals who have proof of application for LIS, collection of premiums and cost sharing may be delayed, pending a decision on the application. The application is approved and the individual’s subsidy eligibility is retroactively effective January 1 and continues through the end of the calendar year.

Example 3: An individual loses deemed status but does not apply with SSA to reestablish LIS eligibility until February 5 of the next year. The application is approved and LIS eligibility is retroactively effective February 1, creating a 1-month gap between the prior year’s benefit that ended on December 31 and the newly approved benefit.

40.2.6 - CMS Notification to Beneficiaries Losing Deemed Status or Having a Copay Change
(Rev. 13, Issued: 07-29-11, Effective Date: 01-01-11; Implementation Date: 01-01-11)
In September of each year, CMS sends a gray notice to beneficiaries who will lose deemed status effective the next calendar year. This notice includes an SSA subsidy application, along with a postage-paid return envelope. Also in September of each year, CMS sends Part D sponsors and State Medicaid agencies files of members who received the notice of loss of deemed status. This file is informational only and should be used for outreach to the affected beneficiaries. Plan sponsors should not update their systems until the December loss-of-subsidy file is received.

In October, CMS sends an orange notice to individuals who will continue to qualify automatically for the LIS in the next calendar year but will have a change in their copayment level triggered by a change in their Medicaid eligibility. CMS does not send a special file to Part D sponsors, but sponsors are encouraged to use the weekly TRR to identify those enrollees whose copayment level is changing in the following year.

**40.2.7 - Appeals**  
*(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)*

If a Part D enrolled beneficiary disagrees with the level of premium subsidy, or cost-sharing subsidy, the beneficiary should follow the appeals procedures of the agency (SSA or State Medicaid Agency) that provided the data on which deemed status is based.

**40.2.8 - Grace Period for Those Losing Deemed Status**  
*(Rev. 13, Issued: 07-29-11, Effective Date: 01-01-11; Implementation Date: 01-01-11)*

Part D sponsors may choose to offer up to a 3-month grace period for the collection of premiums and cost-sharing to individuals who have lost their LIS deemed status and are able to demonstrate that they have applied for the LIS, provided this option is offered to all such individuals. If, after the expiration of the grace period, the member still does not appear to be LIS eligible according to the CMS’ records or has not submitted BAE documentation to the Part D sponsor, sponsors must attempt to recoup unpaid premiums and cost-sharing amounts consistent with guidance provided in section 70.3 of this chapter. See section 70.2 of this chapter for details on the model notice.

Sponsors must confirm, either verbally or in writing that an individual has applied for LIS prior to invoking the grace period. In other words, the grace period may not be applied automatically to all individuals losing LIS; instead, sponsors may apply the grace period only if an LIS application has been submitted. For example, for calendar year 2011, sponsors could send a letter to affected members instructing them to call the sponsor if they are interested in the grace period. Any communication with the members should advise them of the potential for retroactive liability for higher premiums and cost sharing as of January 1, 2011. The communication should also include information regarding the special enrollment period for loss of deemed status and the need to take action by March 31, 2011, if they do not regain LIS status and wish to change plans. Sponsors should submit these notices or scripts to CMS for review and approval according to Medicare marketing guidelines (see chapter 3).
50 - Premium Subsidy
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

Individuals who qualify for the LIS will be eligible for a premium subsidy, which may or may not cover their plan’s entire Part D premium for basic prescription drug coverage. The premium subsidy will vary based upon the subsidy level for which the beneficiary qualifies. Additional discussion regarding how plan premiums attributable to basic prescription drug coverage are determined in the bidding process will be addressed in Chapter 10 - Bidding and Premiums, which is currently being developed.

50.1 - Calculation of the Low-Income Subsidy Individual’s Premium Amount
(Rev. 13, Issued: 07-29-11, Effective Date: 01-01-11; Implementation Date: 01-01-11)

The LIS individual’s premium amount is the monthly premium attributable to basic prescription drug coverage after the premium subsidy, as calculated in accordance with sections 50.2 and 50.3 below. The premium subsidy is rounded to the nearest 10 cents before the premium subsidy is applied to the individual’s monthly premium attributable to basic prescription drug coverage. Any supplemental, enhanced, or MA premiums are then added to come to the final premium amount.

Under section 3303 of the Affordable Care Act, starting in 2011 a Part D sponsor may volunteer to waive the portion of the monthly adjusted basic beneficiary premium that is a de minimis amount above the LIS benchmark for a subsidy eligible individual. The de minimis amount is determined and announced by CMS each year. The de minimis amount for 2011 is $2.00. LIS individuals who enroll in plans that volunteer to waive the de minimis premium amount will be charged a monthly beneficiary premium for basic prescription drug coverage that is equal to the premium subsidy amount.

50.2 - Calculation and Payment of the Premium Subsidy Amount for Full Subsidy Eligible Individuals
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

Full subsidy eligible individuals are entitled to a premium subsidy equal to 100 percent of the premium subsidy amount. The calculated premium subsidy amount is equal to the lesser of the plan’s premium for basic prescription drug coverage or the regional low-income premium subsidy amount calculated in section 50.2.1.

50.2.1 - Calculation of the Regional Low-Income Premium Subsidy Amount
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

The regional low-income premium subsidy amount is the greater of the PDP region’s low-income benchmark premium amount or the lowest monthly beneficiary premium for a PDP
that offers basic prescription drug coverage in the PDP region. CMS performs this “greater of” test before it releases the regional low-income premium subsidy amounts for the PDP region.

The low-income benchmark premium amount for a PDP region is a weighted average of the premium amounts described in section 50.2.2. The weight for each PDP and MA-PD plans is equal to a percentage, the numerator being equal to the number of Part D low-income subsidy eligible individuals enrolled in the plan in the reference month and the denominator equal to the total number of Part D low-income subsidy eligible individuals enrolled in all PDP and MA-PD plans (but not including PACE, private fee-for-service plans or 1876 cost plans) in a PDP region in the reference month.

More information regarding the calculation of the regional low-income subsidy amount and low-income benchmark premium amount will be discussed in Chapter 10 (Bidding and Premiums), which is currently being developed.

**50.2.2 - Premiums Used to Calculate the Low-Income Benchmark Premium Amount**

*(Rev. 13, Issued: 07-29-11, Effective Date: 01-01-11; Implementation Date: 01-01-11)*

The premium amounts used to calculate the low-income benchmark premium amount include:

Basic PDP - the monthly beneficiary premium.

Enhanced PDP - the portion of the monthly beneficiary premiums attributable to basic prescription drug coverage.

MA-PD - the monthly prescription drug beneficiary premium (as defined under section 1854(b)(2)(B) of the Social Security Act).

Note that the MA monthly premium for basic prescription drug coverage that is used in this calculation was net of Parts A and B rebates for 2006-2009. *Beginning in 2010*, the weighted average premium amounts described above are calculated using the Part D premiums for MA-PD plans before they have been reduced by any applicable MA A/B rebates. *This change in calculation was initially implemented under the “Medicare Demonstration to Revise the Part D Low-Income Benchmark Calculation,” as approved on August 11, 2009. It was later codified in the Affordable Care Act.* The calculation does not include bids submitted by MA private fee-for-service plans, PACE programs under section 1894 of the Act, “800 series” plans, and contracts under reasonable cost reimbursement contracts under section 1876(h) of the Act (“Cost Plans”).

**50.3 - Calculation of the Premium Subsidy for Partial Subsidy Eligible Individuals - Sliding Scale Premium**

*(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)*
Partial subsidy eligible individuals will be eligible for a premium subsidy based upon a linear sliding scale ranging from 100 percent to 25 percent of the premium subsidy amount as specified in section 50.2 and based upon the following chart:

<table>
<thead>
<tr>
<th>FPL &amp; Assets</th>
<th>Percentage of Premium Subsidy Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Income up to 135% FPL, and with assets that do not exceed the calendar year resource limits* for individuals or couples.</td>
<td>100%</td>
</tr>
<tr>
<td>Income above 135% FPL but at or below 140% FPL, and with assets that do not exceed the calendar year resource limits for individuals or couples.</td>
<td>75%</td>
</tr>
<tr>
<td>Income above 140% FPL but at or below 145% FPL, and with assets that do not exceed the calendar year resource limits for individuals or couples.</td>
<td>50%</td>
</tr>
<tr>
<td>Income above 145% FPL but below 150% FPL, and with assets that do not exceed the calendar year resource limits for individuals or couples.</td>
<td>25%</td>
</tr>
</tbody>
</table>

*See [https://secure.ssa.gov/apps10/poms.nsf/lnx/0603030025](https://secure.ssa.gov/apps10/poms.nsf/lnx/0603030025) for the calendar year resource limits.

50.4 - Waiver of Late Enrollment Penalty  
(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

Depending upon when a beneficiary enrolls in a plan, s/he may be subject to late enrollment penalties. However, low-income subsidy eligible individuals are not subject to a late enrollment penalty as of the effective date of LIS eligibility. As long as these individuals stay continuously enrolled in a PDP or MA-PD, they will not be assessed an LEP, even if they lose their LIS eligibility. If LIS individuals disenroll and do not have creditable coverage for a continuous period of 63 days or longer, they will incur an LEP upon re-enrollment into a Part D plan if they are not LIS eligible; however, their uncovered months prior to LIS eligibility will not be a factor in the calculation of their LEP. Chapter 4 of this manual describes the late enrollment penalty in detail and how plans should administer this policy.

60 - Cost-Sharing Subsidy  
(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

The following section describes the application of the cost-sharing subsidy to full subsidy eligible and partial subsidy eligible individuals. The specific cost-sharing and deductible amounts are specifically referenced in Appendix A of this chapter.
60.1 - Full Subsidy Eligible Individuals
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

60.1.1 - Application to Deductible
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

Full subsidy eligible individuals as defined in section 30.1 are entitled to a full subsidy for the elimination of the Part D plan's annual deductible. Therefore, full subsidy eligible individuals will not be subject to any deductible under a Part D plan's basic prescription drug coverage. Refer to chapter 5 of this manual for a description of a Part D plan's deductible.

60.1.2 - Application to Cost-Sharing
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

Full subsidy eligible individuals will receive a reduction in cost-sharing for all covered Part D drugs under the PDP or MA-PD plan to the copayment amounts for full subsidy eligible individuals as provided in Appendix A.

The copayment amounts for full benefit dual eligible individuals with income at or below 100% of the FPL are increased annually by the annual percentage increase in the Consumer Price Index, All Urban Consumers (all item, U.S. city average) as of September of the previous year and rounded to the nearest multiple of 5 cents or 10 cents respectively.

The copayment amounts for non-institutionalized full subsidy eligible individuals with income above 100% of the FPL are increased annually by the annual percentage increase in average per capita aggregate expenditures for covered Part D drugs in the United States for Part D eligible individuals as of July of the prior year and rounded to the nearest multiple of 5 cents.

60.2 - Full Benefit Dual Eligible Individuals Who are Institutionalized or Receiving Home and Community-Based Services (HCBS)
(Rev. 13, Issued: 07-29-11, Effective Date: 01-01-11; Implementation Date: 01-01-11)

This section describes the elimination of cost sharing for full benefit dual eligible individuals who are either institutionalized or receiving home and community-based services (HCBS).

60.2.1 - Institutionalized Individuals
(Rev. 13, Issued: 07-29-11, Effective Date: 01-01-11; Implementation Date: 01-01-11)

Institutionalized full benefit dual eligible individuals will not pay any cost-sharing (deductibles or copayments) towards the costs of their covered Part D drugs. For the purpose of this section, those individuals who are an inpatient in a medical institution or
nursing facility for which payment is made under Medicaid throughout a month, as defined under section 1902(q)(1)(B) of the Act, are considered institutionalized.

Specifically, a full benefit dual eligible beneficiary must be an inpatient in a medical institution or nursing facility in order to receive the zero cost-sharing exemption. The definition of medical institution and nursing facility are defined in regulation under Medicaid. The term “medical institution” for this portion of the Medicaid statute is further defined in Medicaid regulation at section 42 CFR 435.10. These definitions do not include: assisted living facilities, residential care homes and boarding homes.

The Medicaid definition also provides that a person is not considered institutionalized until the person is an inpatient in a medical institution or nursing facility for which payments are made under Medicaid throughout a month. (See section 1902(q)(1)(B) of the Act). This being the case, a full benefit dual eligible individual who enters a nursing home or medical institution does not qualify for the zero copayment immediately.

Example: If a full benefit dual eligible person enters an institution in the middle of January, the individual will not be eligible for zero copayment in January, as he/she was not in the institution for that full calendar month. If the beneficiary stays at least until the end of February, and Medicaid has paid for the beneficiary’s stay in the institution for the entire month of February, the “Medicaid payment throughout a month” requirement would be met for February. The individual will be deemed eligible for the zero copayment from February 1 through the end of the calendar year.

Institutional status is not interrupted by transfers between medical institutions or by bed hold days. Institutional status is only interrupted by a discharge to a community setting such as the home or an assisted living facility. However, even though the beneficiary may be discharged to a community setting, the individual remains deemed for zero co-pay throughout the remainder of the calendar year.

Not all beneficiaries who receive Medicaid and who are residents of nursing facilities or medical institutions are eligible for the zero cost-sharing. Beneficiaries with Medicaid coverage of premiums and/or cost sharing only (i.e., Medicare Savings Program beneficiaries), and who are not entitled to the entire Medicaid benefit, will not be eligible for the zero cost-sharing. It is likely, however, the majority of these beneficiaries will eventually “spend-down” to the full benefit dual eligible status when they enter a nursing facility and eventually receive the zero cost-sharing.

The State, as the Medicaid payer, reports to CMS the full benefit dual eligible individuals and the institutionalized individuals in their State. CMS in turn reports this information to the Part D sponsor. The Part D sponsor uses this information to set the beneficiary’s copayments to zero. In the example above, the State will acknowledge the beneficiary’s institutionalized status in either late February or early March when the facility bills the state for the beneficiary’s stay. The State must then report this individual to CMS. Given the time lags inherent in the reporting, the Part D sponsor may not receive this information.
from CMS until April or May. In the interim, however, a Part D sponsor must accept and use BAE (see section 70.5 on BAE policy) to substantiate the beneficiary’s correct LIS cost-sharing level and correct the cost-sharing level in its own systems.

In a month in which co-pays are charged to the resident, these costs are the resident’s liability. Under Medicaid, these costs are treated as a deduction from income when calculating the individual’s contribution to the cost of institutional care, as are other medical and remedial services that remain the individual’s responsibility. This deduction reduces the amount of income the resident is considered to have available to contribute toward the facility rate, and allows the resident to retain an amount necessary to satisfy the copayment liability. Because the income available to contribute toward the facility rate is less, the State payment under Medicaid to the facility will increase by the amount of the deduction. By contrast, the personal needs allowance (PNA) is a separate deduction for incidental or personal expenses, and is not for medical expenses such as co-pays. If the individual has insufficient income to cover the full cost of the co-pays in a given month, the difference may be carried over to the following month(s) until the liability is satisfied.

60.2.2 - Individuals Receiving HCBS
(Rev. 13, Issued: 07-29-11, Effective Date: 01-01-11; Implementation Date: 01-01-11)

The Affordable Care Act extended the elimination of cost sharing to individuals who would be an institutionalized individual (or couple) as described in 60.2.1 of this chapter, if the full benefit dual eligible individual was not receiving HCBS under title XIX of the Act. The effective date of this change will be no earlier than January 1, 2012. Plans will receive an indicator of “3” to the institutional indicator on the daily TRR when a beneficiary begins receiving HCBS under Medicaid.

60.3 - Partial Subsidy Eligible Individuals
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

60.3.1 - Application to Deductible
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

Partial subsidy eligible individuals will be subject to a reduction in the annual deductible to the deductible amount specified in Appendix A for the current calendar year, unless the Part D plan benefit package has a deductible that is less than the deductible amount.

The deductible amount increases each year by the annual percentage increase in average per capita aggregate expenditures for Part D drugs in the United States for Part D eligible individuals, rounded to the nearest multiple of $1. If a plan’s benefit package contains a deductible that is less than the deductible amount, the full deductible under the plan's benefit package is applied to the partial subsidy eligible individual’s covered Part D prescription drug costs.

60.3.2 - Application to Cost-Sharing
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)
Partial subsidy eligible individuals will be subject to a reduction in cost-sharing to 15% coinsurance after any deductible described in section 60.3.1 has been met. If the Part D plan charges cost-sharing that is less than 15% coinsurance, no further reduction is taken.

60.4 - Administration of Cost-Sharing Subsidy
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

60.4.1 - Application to Generic and Multiple-Source Drugs
(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

When imposing cost sharing on low-income subsidy eligible individuals, sponsors are required to apply specific copayments for generic drugs as defined by regulation and in section 10 of this chapter. Specifically, 42 CFR 423.4 defines generic drugs as those drug products for which there is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(j)). For purposes of Part D, what determines whether a drug is a generic drug is the type of application on file for that drug product with the Food and Drug Administration (FDA). If a drug product approval is based upon an abbreviated new drug application (ANDA), that drug is therefore a generic drug.

This definition applies regardless of whether the brand-name drug is no longer manufactured and there is only one remaining ANDA-approved drug product on the market, whether the sponsor’s formulary includes the drug on its generic cost-sharing tier or on a higher tier, or how a particular drug product is identified by the major drug listing services. Consequently, when sponsors by statute are required to apply specific copayments for generic drugs (that is, for generic drugs obtained by low-income subsidy eligible enrollees and enrollees with spending above the out-of-pocket threshold), they must ensure that the appropriate cost-sharing is applied to the generic drug as defined under CMS regulations and reflected in this manual.

For example, in accordance with 42 CFR 423.782(a)(2)(iii)(A), in 2010, non-institutionalized full-benefit dual eligible individuals with incomes that do not exceed 100 percent of the Federal poverty level for their family size will pay no more than $1.10 for generic drugs. Consequently, the sponsor must ensure that these individuals pay no more than a $1.10 copayment for generic drugs, that is, all those drug products approved under an ANDA, even if a Part D sponsor places such a drug product in its preferred cost-sharing tier rather than its generic cost-sharing tier.

A multiple-source drug includes the branded product when the same drug is also available as a generic. A prescription may be filled with the generic version of a drug, or the pharmacy may choose to dispense a branded, multiple-source drug because the pharmacy purchased the branded, multiple-source drug at a better price. Under this scenario, the beneficiary pays the lower copayment for the generic/preferred multiple-source copayment (provided in Appendix A) regardless of whether they received the generic or branded multiple-source drug. Alternatively, the plan may have identified a specific branded multiple-source drug as a preferred product to be used whenever a generic could be
dispensed and, therefore, the beneficiary would pay the lower cost sharing in this instance, as well. However, if the pharmacy is required to dispense a branded multiple-source drug (for instance, if a physician requires dispense as written), and that drug is not cheaper for the pharmacy nor identified by the plan as a preferred multiple-source drug, the beneficiary would be required to pay the higher copayment.

60.4.2 - Application to Days Supply
(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

Part D sponsors must apply the equivalent of one copayment for LIS eligible beneficiaries to each pharmacy transaction irrespective of days supply. For example, in 2010, a full subsidy eligible individual with incomes over 100% of the FPL who uses mail order to purchase his/her prescription medications may not be charged more than $2.50 for a 90 day supply of a generic or preferred multiple source drug and more than $6.30 for a 90 day supply of any other drug. This same policy applies to fills during the catastrophic coverage period as explained in chapter 5.

60.4.3 - Application of Cost Sharing Subsidy When Individual Chooses Enhanced Alternative Coverage
(Rev. 13, Issued: 07-29-11, Effective Date: 01-01-11; Implementation Date: 01-01-11)

Although the cost-sharing subsidy only applies to basic prescription drug coverage, it applies equally to beneficiaries enrolled in both basic and enhanced alternative plans. When a Part D sponsor provides enhanced alternative coverage, thus reducing the cost sharing on a covered Part D drug, the cost-sharing subsidy applies to the beneficiary liability after the plan's supplemental benefit is applied. Supplemental benefits provided under the plan are always applied before beneficiary liability and low-income subsidy (LICS) amounts are calculated. Therefore, the plan should determine the cost-sharing due under the enhanced alternative coverage after the supplemental benefit is provided, then apply the LICS amount to further reduce the LIS beneficiary’s cost-sharing liability.

For example, the beneficiary qualifies for full subsidy benefits in 2011 and is only required to pay a maximum of $3.30 per prescription. The cost of the drug is $100. Under the plan’s basic benefit package, the cost sharing for a non-LIS beneficiary would be 25% of $100, or $25. Since the beneficiary qualifies for LIS, the Part D sponsor would receive $21.70 in LICS payments ($25-$3.30) under the basic benefit package. Under the enhanced alternative plan, the cost sharing is supplemented by the plan an additional $10 resulting in the cost share of $15. The Part D sponsor would receive $11.70 in LICS for the LIS beneficiary ($15-$3.30).

The LIS only applies to covered Part D drugs. For supplemental drugs covered by a Part D plan, the LIS beneficiary pays the same amount of cost-sharing as any other beneficiary under their benefit package.

60.4.4 - Application of Lesser of Cost Sharing Amounts Test
(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)
Since the cost sharing subsidy is a reduction in beneficiary liability at the point-of-sale (POS), Part D sponsors must perform a calculation that compares the amount due from a non-low income subsidy (non-LIS) individual under the plan, to the statutory cost sharing provisions described in Appendix A. For each dispensing event, the Part D sponsor must compare the amount of cost-sharing due from a non-LIS beneficiary under the plan’s benefit package to the maximum cost-sharing and deductible amounts due from a low-income subsidy eligible beneficiary. The low-income subsidy beneficiary should be charged the lesser of the two amounts. The calculation of the cost-sharing subsidy to be advanced to the Part D sponsor for these situations will be explained further in Chapter 11 - Payments.

60.4.5 - Cost Sharing When Claims for LIS Individuals Cross Multiple Benefit Phases
(Rev. 13, Issued: 07-29-11, Effective Date: 01-01-11; Implementation Date: 01-01-11)

When a claim crosses multiple phases of the prescription drug benefit that all have co-payments, Part D sponsors must charge beneficiaries only one co-payment per prescription. Part D sponsors are specifically required to charge all beneficiaries the co-payment applicable to the phase of the benefit in which the claim began. For example, a beneficiary is enrolled in an enhanced alternative plan that has a generic co-payment of $5 in the initial coverage period and a generic co-payment of $15 in the coverage gap. If the beneficiary purchases a generic drug and that purchase moves the beneficiary from the initial coverage period to the coverage gap phase of their prescription drug benefit, the plan must charge the beneficiary a $5 co-payment because the claim started in the initial coverage period. Note that this policy does not apply to claims that cross multiple benefit phases in which any of the benefit phases have coinsurance.

If a claim crosses multiple benefit phases in which any of the benefit phases have coinsurance, the beneficiary is responsible for the applicable cost sharing in each phase that the claim crosses. However starting in 2008 for LIS beneficiaries, when a claim crosses from the coverage gap to the catastrophic phase of the benefit, Part D sponsors are required to charge the cost sharing applicable to the portion of the claim below the out-of-pocket threshold only. For example, a partial subsidy LIS beneficiary is enrolled in a defined standard plan in 2008 and has $4,035 in true out-of-pocket costs (TrOOP). If the beneficiary purchases a covered Part D brand drug that has a total cost of $150, the plan must charge the beneficiary $2.25 in coinsurance (15%) for the $15 in gross covered drug cost applicable to the coverage gap phase. The plan would not charge the LIS beneficiary the additional $5.60 co-payment for the portion of the drug cost applicable to the catastrophic phase.

70 - Part D Sponsor Responsibilities When Administering the Low-Income Subsidy
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)
Part D sponsors are responsible for charging LIS beneficiaries the correct premium, deductible, copayments and/or coinsurance for the correct effective dates. To do so, Part D sponsors must update their systems appropriately based on CMS file notifications, as well as establish procedures to react promptly to evidence indicating that beneficiaries should have a more advantageous cost-sharing than indicated by CMS data. Sponsors are responsible for notifying members when they become LIS eligible, when their LIS levels change, and when their LIS eligibility terminates. Since LIS changes are frequently effective retroactively, sponsors must establish procedures to reimburse current and former members for cost-sharing (including deductible and copayments) and premiums paid before notification of LIS eligibility. The following subsections describe these requirements in detail, as well as the LIS notification requirements that are the responsibility of the Part D sponsor.

70.1 - Establishing Low-Income Subsidy Status
(Rev. 13, Issued: 07-29-11, Effective Date: 01-01-11; Implementation Date: 01-01-11)

In order to establish the correct premium, cost sharing and deductible levels with the correct effective dates for current, prior, and prospective enrollees, Part D sponsors should refer to the Weekly/Monthly Transaction Reply Report (TRR). Part D sponsors will receive data indicating new or modified LIS eligibility status for former, current, and prospective members of their Part D plan via the weekly TRR. Full replacement LIS profiles are represented by an ensemble composed of one or more of TRCs 121, 194, and 223. Each profile returns LIS period start and end dates, premium subsidy percentage, copayment level, enrollee type flag, and LIS source code. The enrollee type flag identifies a beneficiary as being a prior, current, or prospective enrollee. The LIS source code identifies whether the LIS period is the result of CMS deeming or SSA approval.

In addition, twice each year, CMS issues special files related to Part D sponsors’ LIS members. These are the September and December versions of the Loss of Subsidy file. The September file informs sponsors who in their plan is getting CMS’ “undeemed” letter, and is to be used for outreach purposes. However, the December file is the definitive file of those losing LIS status, and is to be used to update sponsors’ systems and to identify to whom they should send the LIS termination notice. CMS will send guidance notifying Part D Sponsors of the specific dates of these special files and reminding them of their purpose. For more information on these files’ purpose, see section 40.2.6; for additional details and technical specifications, see the appendices of the Plan Communications User Guide (PCUG) http://www.cms.hhs.gov/MMAHelp/ for the Loss of Subsidy Data File (section E18).

70.2 - Member Notifications
(Rev. 13, Issued: 07-29-11, Effective Date: 01-01-11; Implementation Date: 01-01-11)

Part D sponsors are required to notify members when they initially become LIS-eligible; when their LIS levels change; and when their LIS eligibility terminates. In addition, certain notifications are required pursuant to the BAE policy (see section 70.5). The descriptions below explain the different LIS notifications, when Part D sponsors must mail
these notifications to their member beneficiaries and where the current year model notifications are located in this chapter’s appendices:

- **LIS Rider - Part D Sponsors must send the LIS Rider at least once a year to their members at the same time as the combined Evidence of Coverage (EOC) and Annual Notice of Change (ANOC). Part D sponsors must also send an LIS rider at other times of the year if an enrollee becomes newly LIS eligible, or experiences a change in the level of LIS for which he/she qualifies (for terminations of LIS, use notices below). The LIS rider must be sent within 30 days of receiving systems' notification from CMS for changes effective in the current calendar year. “Notification” means any of the sources identified in Appendix E. When notifications are received starting July that an individual is re-deemed for LIS for the following calendar year, the LIS Rider conveying the following year’s status need not be sent until the combined ANOC/EOC. If a sponsor did not send the LIS Rider with a beneficiary’s EOC/ANOC (because no notification had been received before that mailing), but notification is subsequently received, the sponsor must send an LIS rider within 30 days of the notification.

- **Notice for Beneficiaries Whose Low-income Subsidy is Terminated (Appendix B) –** Part D sponsors must send this notice **within 30 days of notification** to affected members when the member’s LIS terminates. Part D sponsors should use this notice when CMS sends data terminating LIS via the TRR. This notice contains variable language for deemed beneficiaries and LIS applicants. For deemed individuals the beneficiary is directed to apply to the SSA in order to be determined if he/she is eligible for LIS.

- **Notice of Removal of LIS Period(s) – (Appendix C) –** Part D sponsors are responsible for collecting any underpaid cost sharing or premiums when a beneficiary is retroactively found not eligible, or qualifies at a less generous cost sharing level per section 70.3.1. Sponsors should make reasonable attempts to notify affected members **within 30 days of notification** to advise them of their retroactive liability for higher premiums and cost sharing, when LIS eligibility is removed. This notification should also include information regarding the special enrollment period for loss of LIS status if they wish to change plans.

- **Notice of Error in Premiums and Cost Sharing (Appendix D) –** Part D sponsors must send this notice **within 30 days of notification** when they grant an optional grace period per section 40.2.8 for those losing deemed status, and for an individual who does not regain LIS eligibility within the grace period.

### 70.3 - Sponsor Requirements When Retroactive Changes to Subsidy Levels Occur
(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)
As noted in section 40, the effective date of LIS eligibility is often retroactive for those newly eligible for LIS. The retroactive date may extend to the previous calendar year, and may affect former members. The Part D sponsor offering the Part D plan must reimburse all LIS eligible individuals, as well as other payers of prescription drug coverage paying cost-sharing or premiums on behalf of such individuals, if the beneficiary is found retroactively eligible for the LIS.

Example: A beneficiary is enrolled in a plan effective January 1, 2010, and has been paying the appropriate cost-sharing associated with his/her benefit package. In May, the Part D sponsor is notified by CMS that the individual is eligible for LIS, retroactive to March 1, 2010. The Part D sponsor reimburses the beneficiary accordingly and revises the prescription drug event (PDE) to reflect the availability of the subsidy to the individual.

70.3.1 - Refunds and Recoupments of Cost-Sharing and Premiums
(Rev: 13, Issued: 07-29-11, Effective Date: 01-01-11; Implementation Date: 01-01-11)

CMS regulations at 42 CRF 423.800(c) require the Part D sponsor to reimburse subsidy-eligible individuals, and any organizations paying cost sharing on behalf of such individuals (e.g., State Pharmaceutical Assistance Programs (SPAPs)), any excess premium or cost sharing paid by such individual or organization. This includes the refunding of cost sharing amounts that were paid during the period of LIS retroactive coverage. The intent of this provision is to direct the Part D sponsor to make reasonable efforts to determine the party that should be reimbursed for excess cost sharing before making reimbursement. That is, when a retroactive change to an individual’s LIS level occurs, the sponsor must determine the excess cost-sharing and premium amounts and reimburse the beneficiary, or other party who paid on the beneficiary’s behalf, automatically; i.e., without a direct request for reimbursement. It should be noted that this policy cannot apply in situations where both the LIS status change and the Part D enrollment are retroactive, as the sponsor will not have the paid claims information for the retroactive period and will therefore still require documentation from the beneficiary or other payer to handle the refund.

CMS expects that sponsors will develop standard operating procedures (SOPs) to address the research and determination of liability for cost sharing reimbursements, and will not adopt a “one size fits all” approach, such as always cutting checks directly to the beneficiary. Part D sponsors should consider such variables as institutionalized status or the presence of secondary payers reported on the Coordination of Benefit (COB) files in their SOPs. Moreover, any direct request for reimbursement with appropriate evidence of payment should be handled expeditiously.

When implementing retroactive subsidy level changes for a full-benefit dual eligible individual who meets the definition of an institutionalized individual but is incorrectly charged cost-sharing, sponsors should not automatically reimburse beneficiaries residing in long-term care (LTC) facilities. In such situations, it is unlikely that LTC pharmacies have collected the applicable cost-sharing from beneficiaries due to the expectation that the Part D sponsor eventually would reimburse the pharmacy retroactively for such amounts. This
may also be the case in non-LTC pharmacies, though probably not to the same degree, since the LTC pharmacy is more likely to hold a receivable balance on its books, or may have recourse to the LTC facility for uncollected amounts.

Part D sponsors should work with their network pharmacies to provide them with direct reimbursement for any cost-sharing amounts not collected from LIS-eligible enrollees. Before reimbursement is made, Part D sponsors should ensure that the pharmacies in question have not collected cost-sharing amounts, or otherwise have waived the cost-sharing charges, and, in fact, are carrying a debt for the amounts incorrectly charged to the beneficiary. For auditing purposes, sponsors should ensure that pharmacies certify that the amounts reimbursed are appropriate, owed, and payable. Providing direct reimbursement to pharmacies for excess cost-sharing charges that have not been paid by Part D enrollees or that have not been waived by the pharmacy does not conflict with the requirement in 42 CFR 423.800(c) that beneficiaries be made whole. Such amounts were never paid by either the enrollee or others on his or her behalf.

Part D sponsors are also responsible for collecting any underpaid cost-sharing or premiums when a beneficiary is retroactively found not eligible, or qualifies at a less generous cost sharing level. CMS’ rules on uniformity of benefits require recouping such amounts in order to ensure that similarly situated individuals are treated the same, and in order to avoid any waiver of the cost-sharing. Thus, Part D sponsors should make reasonable attempts to collect the outstanding cost-sharing. (Note: This assumes the pharmacy has not waived or reduced this cost-sharing consistent with the safe harbor for pharmacy waiver, or reduction of Part D cost-sharing.) When attempting to collect substantial underpayments, Part D sponsors should consider recovering from the beneficiary over an extended period of time as not to adversely impact the low-income beneficiary’s access to prescriptions and medical services during the period of recovery. Part D sponsors should offer these enrollees the option to pay their premium arrearage by lump sum, by monthly installments spread out over at least the same period for which the premiums were due, or through other arrangements mutually acceptable to the enrollee and the Part D sponsor.

Beginning with contract year 2011, in accordance with the timeframes specified at 42 CFR 423.800(e) and 423.466(a), sponsors will be required to process retroactive claims and premium adjustments for low-income subsidy eligible individuals and make any resulting refunds and recoveries within 45 days of the sponsor’s receipt of complete information. Sponsors are also responsible for accounting for SPAPs and other entities providing prescription drug coverage when reconciling the claims adjustments that create overpayments or underpayments.

70.3.2 - Adjustments to Prescription Drug Event Data
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

The Part D sponsor must adjust the PDE when a reconciliation results in a refund or recoupment situation. Although both the LIS and Patient Pay amounts are TrOOP-eligible amounts, the LIS amount must be corrected because LICS is a cost-based payment mechanism and CMS uses the LIS Amount field to calculate the Part D Payment
Reconciliation for LIS. For refunds, the adjustment PDE shows that LIS increases and Patient Pay decreases by the same amount (provided the beneficiary does not receive assistance from a TrOOP-eligible other payer like an SPAP). For recoupments, the adjustment PDE shows that LIS decreases and Patient Pay increases by the same amount (provided the beneficiary does not receive assistance from a TrOOP-eligible other payer like an SPAP). Plans must use the “Report-As-Adjusted” method to show changes in every affected PDE, and not the “Report-As-Administered” method, anytime a change in LIS amounts is involved.


70.3.3 - Refunds of Overpaid Premiums
(Rev. 13, Issued: 07-29-11, Effective Date: 01-01-11; Implementation Date: 01-01-11)

When a beneficiary is found retroactively eligible for LIS, the Part D sponsor must refund premium amounts in excess of the allowed premium charges for LIS beneficiaries mandated by statute. In accordance with 42 CFR 423.464(a)(3) and (g), Part D sponsors should not automatically reimburse the beneficiary for overpaid premiums if it is known by the Part D sponsor that the beneficiary received drug coverage from either a State Pharmaceutical Assistance Program or other entity providing prescription drug coverage that has paid for the beneficiary’s premiums. Sponsors must process retroactive adjustments and issue refunds or recovery notices within 45 days of the sponsor’s receipt of complete information regarding these adjustments.

70.4 - Low-Income Subsidy and TrOOP Calculation
(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

All low-income, cost-sharing subsidy payments made by the Federal government on behalf of the subsidy eligible individual are counted towards the beneficiary’s annual out-of-pocket threshold. Once the annual out-of-pocket threshold is reached for a full subsidy eligible individual, cost-sharing is reduced to zero for this beneficiary. When the annual out-of-pocket threshold is reached for the partial subsidy eligible individual, cost sharing is reduced to the applicable calendar year copayment amounts provided in Appendix A. Part D plans are responsible for tracking a beneficiary’s TrOOP costs as defined in chapter 5, section 30 of this manual. When the beneficiary reaches his/her TrOOP limit, a Part D plan will adjust the beneficiary’s cost-sharing accordingly.

70.5 - Best Available Evidence (BAE)
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

When situations arise that result in incorrect LIS cost-sharing data at the point-of-sale, Part D sponsors must comply with the “Best Available Evidence” (BAE) policy. This policy requires sponsors to update their systems to reflect the appropriate cost-sharing subsidy for Part D eligible individuals who are full benefit Medicare/ Medicaid dual eligible individuals, MSP, and receiving SSI-only when presented with evidence that information
showing the beneficiary to be ineligible is not correct. This section outlines the requirements Part D sponsors must follow when applying the BAE policy to its members.

**70.5.1 - BAE Policy Communication and Oversight**  
* (Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)  

Part D sponsors must develop appropriate member services and pharmacy help desk scripting to identify cases involving a situation in which the BAE policy applies, and to allow callers either to submit BAE pursuant to the requirements described in section 70.5.2 or to request assistance pursuant to the requirements described in section 70.5.3.

Sponsors must also provide a link on their Web site to the section of CMS’ Web site regarding BAE policy and make information about the BAE policy readily available for those who contact the plan’s call center. The Web site address is: [http://www.cms.hhs.gov/PrescriptionDrugCovContra/17_Best_Available_Evidence_Policy.as](http://www.cms.hhs.gov/PrescriptionDrugCovContra/17_Best_Available_Evidence_Policy.as)

Given the importance of this policy to low-income beneficiaries, CMS has also established a separate complaint tracking category for BAE issues and will be closely monitoring Part D sponsor compliance with this policy.

**70.5.2 - Required Documentation and Verification**  
* (Rev. 13, Issued: 07-29-11, Effective Date: 01-01-11; Implementation Date: 01-01-11)  

Part D sponsors are required to accept any of the following forms of evidence to establish the subsidy status of a full benefit dual eligible or MSP-eligible beneficiary when provided by the beneficiary or the beneficiary’s pharmacist, advocate, representative, family member or other individual acting on behalf of the beneficiary. Sponsors must include a copy of one of the following BAE documents with every update request submitted to CMS’ contractor (see section 70.5.4):

1. A copy of the beneficiary’s Medicaid card that includes the beneficiary’s name and an eligibility date during a month after June of the previous calendar year;

2. A copy of a state document that confirms active Medicaid status during a month after June of the previous calendar year;

3. A print out from the State electronic enrollment file showing Medicaid status during a month after June of the previous calendar year;

4. A screen print from the State’s Medicaid systems showing Medicaid status during a month after June of the previous calendar year;

5. Other documentation provided by the State showing Medicaid status during a month after June of the previous calendar year;
6. A letter from SSA showing that the individual receives SSI; or,

7. An Application Filed by Deemed Eligible confirming that the beneficiary is “…automatically eligible for extra help…” (SSA publication HI 03094.605)

Part D sponsors are required to accept any one of the following forms of evidence from the beneficiary or the beneficiary’s pharmacist, advocate, representative, family member or other individual acting on behalf of the beneficiary to establish that a beneficiary is institutionalized or, beginning on a date specified by the Secretary, but no earlier than January 1, 2012, is an individual receiving home and community based services (HCBS) and qualifies for zero cost-sharing:

1. A remittance from the facility showing Medicaid payment for a full calendar month for that individual during a month after June of the previous calendar year;

2. A copy of a state document that confirms Medicaid payment on behalf of the individual to the facility for a full calendar month after June of the previous calendar year;

3. A screen print from the State’s Medicaid systems showing that individual’s institutional status based on at least a full calendar month stay for Medicaid payment purposes during a month after June of the previous calendar year.

4. Effective as of a date specified by the Secretary, but no earlier than January 1, 2012, a copy of:

   a) A State-issued Notice of Action, Notice of Determination, or Notice of Enrollment that includes the beneficiary’s name and HCBS eligibility date during a month after June of the previous calendar year;

   b) A State-approved HCBS Service Plan that includes the beneficiary’s name and effective date beginning during a month after June of the previous calendar year;

   c) A State-issued prior authorization approval letter for HCBS that includes the beneficiary’s name and effective date beginning during a month after June of the previous calendar year;

   d) Other documentation provided by the State showing HCBS eligibility status during a month after June of the previous calendar year; or,

   e) A state-issued document, such as a remittance advice, confirming payment for HCBS, including the beneficiary’s name and the dates of HCBS.

The sponsor may also prepare a report of contact as evidence of a beneficiary's status as a full benefit dual eligible individual, institutionalized individual, and/or HCBS recipient.
when the sponsor makes a verification call to the State Medicaid Agency. The report of
contact must include the date of the verification call and the name, title and telephone
number of the state staff person who verified the Medicaid status during a month after June
of the previous calendar year.

The documents listed above are valid for the purpose of establishing the correct LIS cost-
sharing level and effective date for individuals who should be deemed eligible for LIS, and
are the only documents permissible for submission to CMS’ contractor for deeming
updates.

- As soon as one of the forms of BAE listed above is presented, provide the
  beneficiary access to covered Part D drugs at a reduced cost-sharing level which
  is no greater than the higher of the LIS cost-sharing levels for full subsidy
  eligible individuals (in 2011, this level is $2.50 per generic or preferred brand
  name drug; $6.30 per brand name drug), or at zero cost-sharing if the BAE also
  verifies the beneficiary’s institutional status.

- Update sponsor systems to reflect the correct LIS status based upon BAE
documentation, override the standard cost-sharing, and maintain an exceptions
process for the beneficiary to obviate the need to require the re-submission of
documentation each month pending the correction of the beneficiary’s LIS
status in CMS systems. Part D sponsors will be required to update their systems
within 48-72 hours of their receipt of BAE documentation. The requirement that
Part D sponsors update their systems within 48-72 hours is in addition to the
requirement that Part D sponsors provide access to covered Part D drugs as soon
as BAE is presented to them.

- Verify that CMS’ systems do not already reflect the beneficiary’s correct LIS
status. If CMS’ systems do not already reflect the updated information for
“deemed” beneficiaries, the sponsor must submit a request for correction in
accordance with the manual LIS status correction process discussed later in this
section. A separate process is under development to permit plans to submit
requests to update CMS’ systems for LIS applicants.

70.5.3 - Part D Sponsors Responsibility When BAE is not Available
(Rev. 13, Issued: 07-29-11, Effective Date: 01-01-11; Implementation Date: 01-01-11)

Part D sponsors must respond to requests for assistance in securing BAE from a beneficiary
or a beneficiary’s pharmacist, advocate, family member or other individual acting directly
or on behalf of the beneficiary in accordance with the following process outlined below.
Note that this process is not intended to serve as a general alternative to the subsidy
eligibility confirmation process. Thus, it does not permit pharmacy organizations or any
other parties to send beneficiary records directly to the Part D sponsor for research in the
absence of a request for assistance from the beneficiary (or other individual on the
beneficiary’s behalf) or in lieu of making reasonable efforts to acquire the documentation
from, or on behalf of, the beneficiary. Part D sponsors are required to take the following actions:

1. Complete columns A through F of the CMS BAE Assistance Worksheet with plan and beneficiary information. The worksheet is found at http://www.cms.hhs.gov/PrescriptionDrugCovContra/17_Best_Available_Evidence_Policy.asp

2. Ask the beneficiary (or the beneficiary’s advocate, pharmacist, authorized representative or other individual acting on the beneficiary’s behalf) what date the beneficiary will run out of medication. If provided, include that information in the worksheet (Column G) and include the appropriate phrase in the subject line of the e-mail to the CMS Regional Office (CMS RO) as shown below:
   a. If the beneficiary has less than 3 days of medication remaining, indicate the phrase “Immediate BAE Assistance Needed” in the subject line.
   b. If the beneficiary has 3 or more days of medication remaining, indicate “Non-Immediate BAE Assistance Needed” in the subject line.
   c. Send the worksheet via an encrypted e-mail to the CMS RO Part D mailbox based on where the individual resides. The list of CMS RO contacts and mailboxes are located at: http://www.cms.hhs.gov/PrescriptionDrugCovContra/17_Best_Available_Evidence_Policy.asp.

3. Absent unusual circumstances, submit the worksheet to the CMS RO within 1 business day of being notified that the beneficiary claims to be subsidy eligible but cannot provide the sponsor with one of the documents listed above. After recording the case in the CMS complaint tracking module (CTM), the CMS RO will attempt to confirm with the State Medicaid agency whether the beneficiary is eligible for LIS, and will return the worksheet to the plan with the CMS portion (Columns H through Q) completed with any information received from the State.

4. Upon receipt of the worksheet from CMS, update the plan sponsor’s internal systems to reflect LIS status, as appropriate, and submit a request for correction to the CMS contractor in accordance with the procedures outlined in section 70.5.4 of this chapter.

5. Notify the beneficiary of the results of CMS’ inquiry as follows:
   a. Sponsors must make an initial attempt to notify the beneficiary of the results of the CMS RO inquiry within 1 business day of receiving those results.
b. If a sponsor is unable to reach the beneficiary as a result of this initial attempt, it must attempt to notify the beneficiary until it succeeds or until it has attempted to do so a total of four times.

c. The fourth attempt, if necessary, shall be in writing, using one of two CMS Model Notices. Both Model notices are located at http://www.cms.hhs.gov/PrescriptionDrugCovContra/17_Best_Available_Evidence_Policy.asp as clarified in the BAE guidance (v08.04.08). If CMS determines that the beneficiary is LIS eligible, use the “Determination of LIS Eligibility” Model Notice. If CMS determines that the beneficiary is not LIS eligible, or is unable to confirm the beneficiary’s LIS status, use the “Determination of LIS Ineligibility”.

d. If a request for a subsidy was made on the beneficiary’s behalf by an advocate or authorized representative, it shall be sufficient for the sponsor to contact that advocate or representative. If, however, the only request made on the beneficiary’s behalf was by a pharmacist, the sponsor must also contact the beneficiary directly. Beneficiaries must be notified that if they do not agree with the results of the inquiry, the sponsor will provide them with appropriate contact information for the appropriate CMS RO. The list of CMS RO contacts is within the BAE guidance (v08.04.08) located at: http://www.cms.hhs.gov/PrescriptionDrugCovContra/17_Best_Available_Evidence_Policy.asp.

6. As soon as the sponsor receives confirmation from the CMS RO that a beneficiary is subsidy eligible, the sponsor must provide the beneficiary access to covered Part D drugs at a reduced cost-sharing level no greater than the higher of the LIS cost-sharing levels for full subsidy eligible individuals, or at zero cost-sharing if the RO also verifies the beneficiary’s institutional status. Effective as of a date specified by the Secretary, but no earlier than January 1, 2012, the sponsor must provide the beneficiary access to covered Part D drugs at zero cost-sharing if the RO confirms that the full benefit dual eligible beneficiary is receiving home and community-based services.

7. Close out the case in the CTM in the new “Beneficiary Needs Assistance with Acquiring Medicaid Eligibility Information” category. The date entered must be the date of the plan sponsor’s final attempt to notify the beneficiary of the results of CMS’ inquiry, in accordance with the procedures described above.

Prior to submitting the request, Part D sponsors should ensure that all beneficiary identifying information, such as name, date of birth, and HICN, is correct.

70.5.4 - Transmitting and Timing of Manual LIS Status Correction
(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

Part D sponsors should provide data to CMS' contractor when BAE is confirmed for an
individual who should be deemed, or deemed at a more advantageous copayment level or earlier effective date. This process is called the manual LIS status correction process. It is not intended to supplant State MMA data files, in which States report their dual eligible beneficiaries to CMS. It is important to note that a manual update will not be necessary in all BAE cases, as updated information on a subsequent State MMA file may automatically correct the data in CMS systems.

Prior to submitting a manual correction request, Part D sponsors should allow a reasonable time for updated information to be automatically entered into the CMS systems and reported to the plan. CMS recommends that the delay be a minimum of 30 and a maximum of 60 days, as it is likely that a significant portion of those who qualify under BAE policy in 1 month will be deemed for LIS via the normal process within the next several weeks.

Part D sponsors should verify that CMS’s systems do not already reflect the beneficiary’s correct status prior to submitting a request for correction. Verification may be accomplished by checking the most recent LIS History Report from CMS or via the Marx Common User Interface.

LIS Status Correction Requests must be submitted to CMS’ contractor via an Excel file, certified per section 70.5.5 and consistent with the transmission security requirements in section 70.5.6. CMS recommends that Part D sponsors establish a schedule for the monthly transmission of these requests. Each Excel file should contain information for all beneficiaries identified since the prior request is necessitating an LIS status correction. In other words, the correction request file should not be a cumulative record of previously submitted beneficiaries. The required Excel file format can be found in Appendix F. Sponsors must include a copy of the supporting BAE documentation with every update request submitted to CMS’ contractor. The documentation may be hard copies or scanned onto the Excel spreadsheet. The “Type of Documentation Supporting Request” field in the drop-down menu on the Excel spreadsheet must match the documentation included with the spreadsheet. Failure to submit documentation or to correctly indicate the “Type of Documentation Supporting Request” by the sponsor will result in rejection of the sponsor’s correction request.

Prior to submitting the request, Part D sponsors should ensure that all beneficiary identifying information, such as name, date of birth, and HICN, is correct.

70.5.5 - Certification
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

A certification of the LIS status correction request signed by an authorized representative of the Part D sponsor must be submitted to CMS’ contractor. The certification form is available in Appendix F. Once the certification is signed, the document should be scanned, saved as a pdf. file and included on the disk that must be used to transmit each Excel correction request file. The disk must include the plan sponsor’s contract number (H#, S#, R#).
70.5.6 - Transmission Security Requirements
(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

Part D sponsors should submit requests for LIS deemed status corrections to the appointed CMS contractor. To ensure the security of the beneficiary information contained in the Excel spreadsheet, the document must be encrypted using a Federal Information Processing Standards approved encryption method. A list of the approved encryption modules is available on the National Institute of Standards and Technology Web site at http://csrc.nist.gov/groups/STMcmvp/validation.html.

Part D sponsors should submit the encrypted document via a disk containing a password-protected Excel spreadsheet, along with attestations, to:

Reed & Associates, CPAs, 14301 FNB Parkway, Omaha, NE 68154

In addition, Part D sponsors should email the password for the spreadsheet to clientservices@reedassociates.org. Once the password has been provided, Reed & Associates will keep it on file. Part D sponsors will not need to either (1) change the password; or, (2) re-email the password.

70.5.7 - CMS Reporting to Part D Sponsors
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

Once CMS' contractor has completed action on the requests in the spreadsheet, the contractor will complete the three fields specified for CMS use and include in the attached Excel file format to report that the new data have been entered. The contractor will return a copy of the updated file to the Part D sponsor’s primary point of contact as reflected on the file.

70.5.8 - Timing of CMS Systems Updates
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

Once a correction request is processed by CMS, the new data will be stored in the MBD. CMS systems will then update the data during the next deeming process and the subsequent weekly TRR will report the updated information verifying the change has been implemented in CMS systems.

The Transaction Reply Code (TRC) 194 Deemed Copay Correction (DEEMD COPAY CORR) is the unique TRC for these manual updates indicating that CMS has added or updated a deemed co-pay period. The effective dates for the added or updated deemed co-pay period are shown in the TRR fields.

70.5.9 - Evidence Retention Requirements
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

To accommodate subsequent periodic Government audits, Part D sponsors must maintain
for 10 years the original documentation used to substantiate the request for manually updating the CMS system.

An alternative to the Part D sponsor maintaining the BAE documentation would be for the Part D sponsor to delegate this activity to trusted business partners, such as a long-term care pharmacy provider. The partners must be contractually obligated to secure BAE, attest to the beneficiary’s LIS status, and retain the documentation until requested by the Part D sponsor to support an audit. Since the risk associated with the delegation would be on the Part D sponsor, the business partner could be required to indemnify the Part D sponsor for the incorrect cost-sharing amount if the partner was unable to produce the required documentation when requested by the Part D sponsor.

70.5.10 - CMS/SSA Documentation Supporting a Beneficiary’s LIS Cost Sharing Level
(Rev. 13, Issued: 07-29-11, Effective Date: 01-01-11; Implementation Date: 01-01-11)

There may be instances in which CMS’ data correctly reflect a beneficiary’s LIS status, but the Part D sponsor’s data do not. The following CMS LIS notices sent to the beneficiary reflecting effective dates during the discrepant period may be used by the LIS beneficiary to show they qualify for LIS:

- Deeming notice – pub. no. 11166 (purple notice);
- Auto-enrollment notice - Prospective only – pub. no. 11154 (yellow notice);
- Auto-enrollment notice – Retroactive and Prospective – pub. no. 11429 (yellow notice);
- Full-facilitated notice – pub. no. 11186 (green notice);
- Partial-facilitated notice – pub. no. 11191 (green notice);
- Copay change notice – pub. no. 11199 (orange notice);
- Reassignment notice – pub. no. 11208 and 11209 (blue notice).
- MA Reassignment – pub. no. 11443 (blue notice);
- LIS Choosers notice – pub. no. 11267 (tan notice);
- Chooser Reminder notice – pub. no. 11465 (tan notice).

Part D sponsors should confirm LIS status using the batch eligibility query (BEQ) or the integrated user interface (IUI), and should correct their systems promptly. See the following Web site for the most recent version of these beneficiary notifications: [http://www.cms.hhs.gov/LimitedIncomeandResources/LISNoticesMailings/](http://www.cms.hhs.gov/LimitedIncomeandResources/LISNoticesMailings/)

70.6 - Interpreting the Social Security Administration’s Low-income Subsidy Letters
(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

Beneficiaries who are not deemed eligible for the LIS, but who apply and qualify for LIS with SSA, are awarded either the full or partial subsidy based on their income and resources. When SSA takes an action on an LIS award, it provides the beneficiary with a
letter that indicates whether the award is for a full subsidy or a partial subsidy, specifies the reduced deductible and reduced co-payments, and identifies the effective date of the action. If the award is for a partial subsidy, the letter will explain the percentage of the premium subsidy award. Examples of these letters can be found at Appendices I through L.

When a beneficiary presents an SSA notice to the Part D sponsor, the notice being presented only applies to the addressee of the letter. If both spouses apply for LIS, each will have his/her own letter. On occasion, there will be reference to a spouse in the body of the letter; however, this reference is solely for the purpose of counting a spouse’s income/resources, not to whether the spouse qualifies for LIS.

70.6.1 - Determining the Subsidy Effective Date

(Rev. 13, Issued: 07-29-11, Effective Date: 01-01-11; Implementation Date: 01-01-11)

Part D sponsors must accept the following five (5) SSA notices as evidence of a member’s low-income subsidy entitlement:

- **Notice of Award** *(SSA publication HI 03094.201)* - This letter is provided to a beneficiary when the LIS subsidy is first awarded.

  To determine the effective date, look at either of the worksheets that will be attached to the letter. These worksheets are similar and both contain the date information. Just below the header, the effective date is in the phrase “For <month, year> and continuing”.

  See *Income Worksheet* *(SSA publication HI 03094.405)* and Resource Worksheet *(SSA publication HI 03094.401)*.

- **Notice of Change** *(SSA publication HI 03094.301)* - This letter is provided to a beneficiary when SSA has made a redetermination on an LIS award AND the award will be increased, such as from a 25% premium subsidy to a 50% premium subsidy.

  The effective date is on the first page, in the first paragraph under “Your Help Will Change”.

- **Notice of Planned Action** *(SSA publication HI 03094.305)* - This letter is provided to a beneficiary when SSA has made a redetermination on an LIS award AND the award will be reduced, such as from a 75% premium subsidy to a 50% premium subsidy.

  The effective date is on the first page, in the first paragraph under “Your Help Will Change”.

The Notice of Change and Notice of Planned Action are provided when SSA has made a redetermination on an LIS award. Beneficiaries are selected for redetermination randomly or when a change in their circumstance has been reported. The name of the letter can be found in the upper left hand corner of the first page of the letter. Note that it is not
uncommon for an individual’s last correspondence from SSA to be a year or more in the past. Part D sponsors must accept SSA notices dated 15 months in the past.

Samples of these letters are also listed under “HI 03094: Medicare Part D Exhibits of Notices” on SSA’s Web site at https://secure.ssa.gov/apps10/poms.nsf/subchapterlist!openview&restricttocategory=06030.

70.6.2 - Determining the Premium Subsidy Level, Deductible, and Co-payment Amounts from SSA Letters
(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

When a beneficiary is awarded 25%, 50%, or 75% premium subsidy, the beneficiary’s plan benefit package’s deductible is reduced, if greater than the maximum allowable deductible (e.g., $63 for $2010). The SSA notices identify key LIS levels as follows:

- Premium subsidy percentage (25%, 50%, 75% or 100%) is on the first page.
- Deductible information is on the first page.
  - “No prescription drug annual deductible” means that the beneficiary has a $0 deductible.
  - “Reduced prescription drug annual deductible” means that the beneficiary will pay no more than the maximum allowable deductible for partial subsidy individuals (See Appendix A for maximum deductible amounts) or less, if the plan benefit package’s deductible is less.

The specific copayment level is not stated explicitly, but can be determined as follows:

- “No prescription drug deductible” means that the beneficiary’s copayment is no more than the maximum copayments for non-full benefit dual eligible individuals (See Appendix A for maximum copayment amounts).
- “Reduced prescription drug annual deductible” means the beneficiary will pay no more than 15% coinsurance after the reduced deductible is satisfied.

80 - Application of Low-Income Subsidy to Employer Group Waiver Plans
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

There are additional low-income subsidy requirements that must be adhered to by Employer Group Waiver Plans. CMS addresses these requirements in chapter 12, Employer/Union Sponsored Group Health Plans of this manual.
The assistance provided to low-income Medicare beneficiaries enrolled in Part D and residing in the U.S. Territories is different than the low-income subsidy program.

Under Section 1860D-14(a)(3)(F) of the Act, Treatment of Territorial Residents, and 42 CFR 423.907, Treatment of Territories, Part D eligible individuals who are not residents of the 50 States or the District of Columbia are not eligible for the low-income subsidy program, but may be eligible for additional financial assistance with their prescription drug expenses under Section 1935(e) of the Act. Territories receive an enhanced allotment to their Medicaid grants that must be used to provide coverage of Part D drugs for their full benefit dual eligible populations. The additional prescription assistance provided under a territory's enhanced allotment plan is implemented through its Medicaid program, by:

1. Supplementing the Part D plan-enrolled beneficiary cost sharing,

2. Paying a Part D sponsor additional premiums to provide the wrap-around coverage,

3. Providing prescription assistance through its Medicaid program.

Additional guidance regarding the application of these amounts will be included in chapter 10, Payment and Bidding of this manual, which is currently being developed.
Appendices

Disclaimer: CMS LIS and Model Notices contained within these appendices are subject to change and may not be updated in this chapter in a timely manner. For the most recent copy of LIS notifications, see - http://www.cms.hhs.gov/LimitedIncomeandResources/
For LIS model notices, see -
http://www.cms.hhs.gov/PrescriptionDrugCovContra/PartDMMM/list.asp
**Appendix A - Part D Benefit Parameters and LIS Cost-Sharing Levels**

*(Rev. 13, Issued: 07-29-11, Effective Date: 01-01-11; Implementation Date: 01-01-11)*

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<thead>
<tr>
<th>Standard Benefit</th>
<th>2011</th>
<th>2012</th>
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<tbody>
<tr>
<td>Deductible</td>
<td>$310</td>
<td>$320</td>
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<tr>
<td>Initial Coverage Limit</td>
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<tr>
<td>Out-of-Pocket Threshold</td>
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<td>$4,700</td>
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<tr>
<td>Total Covered Part D Spending at Out-of-Pocket Threshold for Non-Applicable Beneficiaries (2)</td>
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<td>$6,657.50</td>
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<tr>
<td>Estimated Total Covered Part D Spending at Out-of-Pocket Threshold for Applicable Beneficiaries (3)</td>
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<td>Minimum Cost-Sharing in Catastrophic Coverage Portion of the Benefit</td>
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<td>$2.60</td>
</tr>
<tr>
<td>Generic/Preferred Multi-Source Drug</td>
<td>$6.30</td>
<td>$6.50</td>
</tr>
<tr>
<td>Other</td>
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<td>$6.50</td>
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**Full Subsidy-Full Benefit Dual Eligible (FBDE) Individuals**

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Copayments for Institutionalized Beneficiaries [category code 3]

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Copayments for Beneficiaries Receiving Home and Community-Based Services (4) [category code 3] (if effective date is January 1, 2012 as proposed)

<table>
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Maximum Copayments for Non-Institutionalized Beneficiaries

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Up to or at 100% FPL [category code 2]

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Generic/Preferred Multi-Source Drug

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Above Out-of-Pocket Threshold

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Generic/Preferred Multi-Source Drug

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Full Subsidy-Non-FBDE Individuals

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</thead>
<tbody>
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Eligible for QMB/SLMB/QI, SSI or applied and income at or below 135% FPL and resources ≤ $6,680 (individuals) or ≤ $10,020 (couples) (6) [category code 1]

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<thead>
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Maximum Copayments up to Out-of-Pocket Threshold

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Generic/Preferred Multi-Source Drug

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Other

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Maximum Copayments above Out-of-Pocket Threshold

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Partial Subsidy

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Applied and income below 150% FPL and resources below $11,140 (individual) or $22,260 (couple) [category code 4]

<table>
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<tr>
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Coinsurance up to Out-of-Pocket Threshold

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Generic/Preferred Multi-Source Drug

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Other

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Retiree Drug Subsidy Amounts

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<td>$6,500</td>
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(1) CPI adjustment applies to copayments for non-institutionalized beneficiaries up to or at 100% FPL.

(2) For beneficiaries who are not considered an “applicable beneficiary” as defined at section 1860D-14A(g)(1) of the Act and therefore are not eligible for the coverage gap discount program (i.e., LIS beneficiaries), this is the amount of total drug spending required to attain out-of-pocket threshold in the defined standard benefit if the beneficiary does not have prescription drug coverage through a group health plan, insurance, government-funded health program or similar third party arrangement. Enhanced alternative plans must use this value when mapping enhanced alternative coverage plans to the defined standard benefit, for the purposes of calculating the covered plan paid amounts (CPP) reported on the prescription drug event (PDE) records.

(3) For beneficiaries who are considered an “applicable beneficiary” as defined at section 1860D-14A(g)(1) and therefore are eligible for the coverage gap discount program (i.e., non-LIS beneficiaries), this is the estimated average amount of total drug spending required to attain the out-of-pocket threshold in the defined standard benefit if beneficiary does not have prescription drug coverage through a group health plan, insurance, government-funded health program or similar third party arrangement. Enhanced alternative plans must use this value when mapping enhanced alternative coverage to the defined standard benefit, for purposes of calculating the covered plan paid amounts (CPP) reported on the prescription drug event (PDE) records.

(4) Per section 1860D-14(a)(1)(D)(i), full-benefit dual eligibles who would be institutionalized individuals (or couple) if the individual (or couple) was not receiving home and community-based services qualify for zero cost-sharing as of an effective date (no earlier than January 1, 2012) specified by the Secretary. CMS proposed an effective date of January 1, 2012, and should the proposed rule be finalized with an effective date of January 1, 2012, cost sharing for this population would be zero beginning January 1, 2012.

(5) The increases to the LIS deductible, generic/preferred multi-source drugs and other drugs copayments are applied to the unrounded 2011 values of $63.12, $1.10, and $3.31, respectively.

(6) The actual amount of resources allowable will be updated for contract year 2012.
Appendix B - Model Notice for Beneficiaries Whose Low-Income Subsidy is Terminated (for PDPs, MA-PD Plans, and Cost Plans that offer Part D) (Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

(The marketing material code for this model notice is 7006. If the sponsor uses this model notice without modification, CMS will waive the 5 day waiting period before the sponsor can use the notice in the marketplace.)

[Member #-if member # is SSN, only use last 4 digits]
[RxID]
[RxGroup]
[RxBin]
[RxPCM]

<Date>

Dear <Name of Member>:

Beginning <effective date>, you no longer qualify for extra help with your Medicare prescription drug costs. You will continue to be a member of <Plan name>.

How will your monthly premium change?

The monthly premium you pay to <Plan name> will increase from <insert dollar amount> to <insert dollar amount>. [Add the following if the member currently has premium withhold option. Because your premium is deducted from your monthly Social Security check, the amount withheld from your check will increase.]

How will your other prescription drug costs change?

[Describe plan’s cost sharing structure including the deductible, if applicable, for non-LIS members]

Once you spend <current Out-of-Pocket Threshold> in a year, your co-payment amount(s) will go down. You will pay <current copay for generics> for generic or preferred drugs and <current copay for brand names> for any other drug, or 5% coinsurance, whichever is higher, for the rest of the year.

These changes to your prescription drug costs begin <effective date>. This date may have already passed when you get this letter. If you have filled prescriptions since <effective date>, you may have been charged less than you should have paid. If you do owe us money, we will let you know how much.

[NOTE: If Beneficiary is Deemed, insert the following language:
You may still qualify for extra help, but you must apply to find out. If you haven’t already filled out an application for extra help, you can get an application or apply over the phone by calling Social Security at 1-800-772-1213, or apply online at www.socialsecurity.gov. TTY users should call 1-800-325-0778.

[NOTE: If sponsors offer the optional grace period for the collection of premiums and cost-sharing for deemed beneficiaries who have applied for LIS and are waiting for a decision, insert the following language, if applicable:

If you applied for extra help and haven’t received a response from Social Security, <Plan name> will allow you to continue to pay for your prescriptions at <2022 LIS premium and cost sharing levels> until <date>. Please contact <customer service number> or send a copy of the letter saying Social Security received your application or appeal to <address>.

If you don’t qualify for extra help or are approved at a higher premium and cost sharing level, you may owe money back to January 1, 2009. <Plan name> will send you a notice telling you what you owe for past charges.

If you don’t qualify for extra help from Social Security, you can change plans if you wish to do so. You must join the new plan by March 31, 2009.]

What are your options?

Option 1: You can stay a member of our plan
You can continue to be a member of <plan name>. You will pay the costs described above for your coverage.

Option 2: You can switch to a new plan
Because you no longer qualify for extra help, you can switch to a different Medicare drug plan starting <effective date> until <2 months later>. [If the effective date is January 1, enter March 31. For any other effective date, enter 2 months later.] You may want to choose a different drug plan for next year with costs and coverage that better meet your needs.

Visit www.medicare.gov on the Web or call 1-800-MEDICARE (1-800-633-4227) for more information about Medicare drug plans available in your area. TTY users should call 1-877-486-2048.

Option 3: You can find other ways to get help with your prescription drug costs
Your state may have programs that can help pay your prescription drug costs. Contact your State Medical Assistance (Medicaid) office for more information. Call 1-800-MEDICARE (1-800-633-4227) or visit www.medicare.gov on the Web for their telephone number. TTY users should call 1-877-486-2048.

[NOTE: If Beneficiary is an Applicant, insert the following language:
**What To Do If Your Situation Changes**
You can file a new application for extra help at any time. You can get an application or apply over the phone by calling Social Security at 1-800-772-1213, or apply online at www.socialsecurity.gov. TTY users should call 1-800-325-0778.

**If You Disagree With This Decision**
If you think your extra help was terminated in error, you can call Social Security to appeal at 1-800-772-1213. TTY users should call 1-800-325-0778.

**For More Information**
If you have any questions about this letter, please contact <Customer/Member> Services at <toll-free number><days and hours of operation>. TTY/TDD users should call <toll-free TTY number>.

Thank you.

<Marketing Material ID Number><CMS Approval Date>
Appendix C - Model Notice of Removal of LIS Period(s) for PDPs, MA-PD Plans, and Cost Plans that offer Part D
(Rev. 9, Issued: 02-05-10, Effective/Implementation Date: January 1, 2010)

{NOTE: The marketing material code for this model notice is 7012. If the plan uses the model notice without modification, CMS will waive the 5-day waiting period before the plan can use the notice in the marketplace).

Dear <Name of Member>:

Medicare has informed us that your eligibility for extra help has been terminated from <start date> to <end date>. This means you did not qualify for extra help with your Medicare prescription drug costs during this period. You will continue to be a member of <plan name>.

Since you didn’t qualify for extra help or were approved at a higher premium and cost sharing level for this period, you may owe money back to <Plan name>. <Plan name> will send you a notice telling you what you owe for past charges. If you filled prescriptions during <start date> to <end date>, you may have been charged less than you should have paid. If you do owe us money, we will let you know how much.

[If the beneficiary was deemed, insert the following language:

You may still qualify for extra help, but you must apply to find out. If you haven’t already filled out an application for extra help, you can get an application or apply over the phone by calling Social Security at 1-800-772-1213, or apply online at www.socialsecurity.gov. TTY users should call 1-800-325-0778. If you don’t qualify for extra help from Social Security, you can change plans if you wish to do so.]

What are your options?

Option 1: You can stay a member of our plan
Even if you don’t qualify for extra help, you can continue to be a member of <plan name>. You will pay the following costs for your coverage. [Insert standard cost sharing]

Option 2: You can switch to a new plan
If you no longer qualify for extra help, you can switch to a different Medicare drug plan starting <date>. You may want to choose a different drug plan with costs and coverage that better meet your needs.

- [Insert, if applicable: we offer (an)other plan(s) that may lower your prescription drug plan costs]
- Visit www.medicare.gov on the Web or call 1-800-MEDICARE (1-800-633-4227) for more information about Medicare drug plans available in your area. They can
also refer to you a State Health Insurance Program in your state to obtain additional assistance on choosing another plan. TTY users should call 1-877-486-2048.

**Option 3: You can find other ways to get help with your prescription drug costs**
Your state may have programs that can help pay your prescription drug costs. Contact your State Medical Assistance (Medicaid) office for more information. Call 1-800-MEDICARE (1-800-633-4227) or visit www.medicare.gov on the Web for their telephone number. TTY users should call 1-877-486-2048.

**For More Information**
If you have any questions about this letter, please call <Customer/Member> Services at <toll-free number><days and hours of operation>. TTY users should call <toll-free TTY number>.

Thank you.
Appendix D - Model Notice of Error in Premiums and Cost Sharing  
(Rev. 7, Issued: 11-21-08; Effective/Implementation: 11-21-08)

{This letter is to inform a member that s/he is liable for cost-sharing amounts you have paid on his or her behalf. You will use this model to notify any members who lost deemed status, used the Optional Grace Period, and was subsequently not approved by SSA for an LIS award. The marketing material code for this model notice is 7008. If you use this model notice without modification, CMS will waive the 5-day waiting period associated with file and use pieces.}

[Member#-if member # is SSN, only use last 4 digits]  
[RxID]  
[RxGroup]  
[RxBin]  
[RxPCN]  

<Date>  

Dear <Name of Member>:  

Since <Date>, <Plan name> has been charging you a premium of <insert LIS premium amount that had been charged> and/or a copayment of <insert LIS copayment level that had been charged> for each prescription you filled because you provided us with proof you have applied for extra help with your prescription drug costs.  

Because <Plan name> has <not been able to confirm by <last day of grace period/March 31> that you qualify for extra help> or has <been informed that you do not qualify>, your Medicare prescription drug costs are changing. Effective <date>, you will pay:  

- [insert plan premium] per month for your <Plan name> premium,  
- [insert deductible amount] for your yearly prescription drug plan deductible, and  
- [insert amount] when you fill a prescription covered by <Plan name>.  

The Medicare Program requires <Plan name> to charge you for past prescription drug costs for any premiums, deductible or cost sharing amounts you should have paid since <date>. <Plan name> will send you a notice telling you what you owe for past charges.

If you have any questions, please call our Member Services at <phone number><days and hours of operation>. TTY users should call <TTY number>.}
Appendix E - Establishing Low-Income Subsidy Status

(Rev. 13, Issued: 07-29-11, Effective Date: 01-01-11; Implementation Date: 01-01-11)

In order to establish the correct premium, cost sharing and deductible levels with the correct effective dates for current, prior, and prospective enrollees, Part D sponsors should refer to the Weekly/Monthly Transaction Reply Report (TRR). The Weekly and Monthly TRRs provide full replacement Low Income Subsidy (LIS) profiles to plans in response to Part D enrollments and PBP changes as well as any LIS change that impacts a Part D enrollment period. Therefore, the TRR is the definitive source of LIS eligibility information. Unlike much of the data provided in the TRR, LIS eligibility information is not based on current payment month (CPM) reporting.

Changes in LIS Data Reporting

- CMS no longer returns LIS data in association with the Transaction Reply Codes (TRCs) generated in response to enrollment and Plan Benefit Package (PBP) change transactions. Specifically, LIS data no longer accompanies enrollment and PBP change TRCs 011, 100, 117, 118, 210, and 212. Instead, LIS TRCs will independently accompany enrollment and PBP change transaction responses.

- CMS also no longer identifies specific LIS changes. Instead, plans are provided full replacement LIS profiles in response to low-income subsidy changes that accumulate over the weekly and monthly reporting cycles. Replacement profiles are established using data known to CMS at the end of each reporting cycle. Reported data spans a PBP enrollment.

- CMS eliminated TRCs 167 and 168. Two existing TRCs (121 and 194) are retained but the definition of each has been slightly modified. TRC (223) was added and identifies LIS periods that have been removed from and are no longer affecting an enrollment. For more detailed information and a complete list of changes regarding these TRCs, refer to PCUG Code description H-2: Transaction Reply Codes.

- Full replacement LIS profiles are represented by an ensemble composed of one or more of the TRCs 121, 194, and 223. Each profile returns LIS period start and end dates, premium subsidy percentage, co-payment level, enrollee type flag, and low income subsidy source code. The enrollee type flag identifies a beneficiary as being a prior, current, or prospective enrollee. The source code identifies whether the LIS period is the result of CMS deeming or Social Security Administration (SSA) approval.

Other Sources of LIS Data

Although the TRR has become the primary source of LIS eligibility information, plans will continue to receive a number of reports and/or data sources containing LIS information. While each of these files may contain some LIS information about sponsors’ enrollees, none of these contain the comprehensive LIS profile that is provided on the TRR.
1. **Batch Completion Status Summary (BCSS):** This report is in response to plan submitted transactions. Because it is not provided for CMS generated transactions (i.e., auto/facilitated enrollments), it is not intended to be a source of LIS data.

2. **Low Income Subsidy/Late Enrollment Penalty Data File:** This data file contains beneficiary level low income subsidy and the late enrollment penalty payment and adjustment details. Late enrollment penalty details are provided for direct bill beneficiaries only.

3. **LIS/Part D Premium Data File:** This data file displays beneficiaries from the premium profile table who have a low income designation. It is provided on a bi-weekly basis and is the reference file that is used to determine the LIS Match Rate.

4. **LIS History Data File (LISHIST):** This report provides a comprehensive list of a sponsor’s current LIS membership. The data on each beneficiary spans the most recent 36 consecutive months of contract enrollment. Near year end, this report will also inform plans whether beneficiary is LIS in the next calendar year.

5. **Weekly LIS Activity History (LISAHD):** This report informs plans holding current, prior, and prospective enrollments that some element of LIS changed during the beneficiary’s enrollment in the contract.

In addition to using data in the regularly issued reports above, in December of each year, Part D sponsors should consult the one-time Loss of Subsidy File. This file reports those who have lost their deemed status for the following calendar year. The TRC used for this special file type is TRC-996, and the record layout is E.18 in the PCUG.
### Appendix F - Sponsor Request for LIS Changes

*(Rev. 13, Issued: 07-29-11, Effective Date: 01-01-11; Implementation Date: 01-01-11)*

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#### Request to Update CMS Medicaid Cost-Sharing Information

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<th>Dual Eligible Status (Full/Partial)</th>
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<th>Date Request Entered by CMS</th>
<th>Updated by</th>
<th>Comments</th>
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**Certification:**

“I have read the contents of the LIS Status Correction Request dated *(indicate month, day and year)* for the above-stated Part D plan contract number and attest that the information contained herein, based on best knowledge, information, and belief as of the date indicated below, is true, correct, and complete, and that our organization will retain the original supporting documentation for requested changes for as long as it is required under Federal regulations and for as long as it may be required for subsequent Government audit. I further certify that I am an authorized representative of the business organization that is a Medicare Part D sponsor.”

______________________________       __________
Part D Sponsor Signature         Date

*Effective on a date specified by the Secretary, but no earlier than January 1, 2012, full benefit dual eligible individuals receiving home and community-based services (HCBS) are eligible for zero cost-sharing for covered Part D drugs.*
Instructions:
Complete General Information About Your Organization:
Organization Name
Enter Organization's Legal Name
Contract ID
Enter CMS Assigned Contract ID, e.g. S1234 or H1234 (format as text field)
Organization Mailing Address
Primary and Second Points of Contact

The specifications for each data field are as follows:
Health Insurance Claim Number (HICN)
Format as text field; do not insert dashes, e.g. 123456789A
Bene Last Name
Format as text field
Bene First Name
Format as text field
Bene Date of Birth
Format as M/D/CCYY, e.g. 5/6/1950
Bene Gender
Format as text field; Valid values are "M" or "F" for Male/Female
Bene State of Residence
Format as text field; spell entire state name, e.g. Michigan
Start of Medicaid/Medicaid Institutional/HCBS Status
Format as date field and enter the start date as MM/CCYY, e.g. 05/2007 for May, 2007
Most Recent Month of Medicaid/Medicaid Institutional/HCBS Status
Format as date field and enter the most recent month as MM/CCYY, e.g. 05/2007 for May, 2007
Dual Eligible Status
Format as text field; valid values are "Full" or "Partial" for Full Dual/Partial Dual
Institutional/HCBS Status
Format as text field; valid values are "Yes", "No", "HCBS", or "Unknown"
Type of Documentation Supporting Request
Select from pull-down list.
Description of "Other" State Documentation
Format as text field

Date Request Entered by CMS
FOR CMS COMPLETION ONLY
Updated by
FOR CMS COMPLETION ONLY
Comments
FOR CMS COMPLETION ONLY
We have completed our review of your and your spouse’s eligibility for extra help with Medicare prescription drug plans costs. You and your spouse will continue to receive the same extra help that you have been receiving. The rest of this notice explains how we figured the change, when it will change, what information was used to make this decision, what to do if your situation changes, and your appeal rights.

Your Eligibility

Your and your spouse’s eligibility for extra help, also known as the subsidy, will continue as follows:

- XX% subsidy to help pay your Medicare prescription drug plan premiums;
- <No/Reduced> prescription drug annual deductible; and
- Reduced co-payment amounts when you have a prescription filled.
## Transmittals Issued for this Chapter

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Medicare Prescription Drug Benefit Manual

Chapter 14 - Coordination of Benefits

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(Rev. 17, 08-23-13)

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(Rev.)

ACA-Affordable Care Act
ADAP-AIDS drug assistance program
AI/AN-American Indian/Alaskan Native
ATBT-automated TrOOP balance transfer
BAA-Business Associate Agreement
BIN-Bank Identification Number
BL-Black Lung
CHC-community health center
CMOP-consolidated mail outpatient pharmacy
COB-coordination of benefits
COBA-Coordination of Benefits Agreement
COBC-Coordination of Benefits contractor
CY-calendar year
DOB-date of birth
DSA-data sharing agreement
ECRS-Electronic Correspondence Referral System
EGHP-employer group health plan
EGWP-employer group waiver plan
EOB-Explanation of Benefits
FEHBP-Federal Employee Health Benefits Program
FFP-Federal Financial Participation
FIR-Financial Information Reporting
FPL-federal poverty level
FQHC-Federally Qualified Health Center
FSA-flexible savings accounts
GCDC-gross covered drug cost
HICN-health insurance claim number
HIPAA-Health Insurance Portability and Accountability Act
HPMS-Health Plan Management System
HRA-Health Reimbursement Accounts
HRSA-Health Resources and Services Administration
ICP- initial coverage period
IHS-Indian Health Service
I/T/U-Indian tribes and organizations and urban Indian organizations
LICS-low-income cost-sharing subsidy
LIS - low income subsidy
LTC - long-term care
MA - Medicare Advantage
MAPD - Medicare Advantage-Prescription Drug
MARx - Medicare Advantage-Prescription Drug system
MBD - Medicare Beneficiary Database
MMA - Medicare Modernization Act
MSA - Medicare Savings Accounts
MSP - Medicare Secondary Payer
MSPRC - Medicare as Secondary Payer Recovery Contractor
MTM - medication therapy management
NCPDP - National Council for Prescription Drug Programs
NCY - non-calendar year
NDC - National Drug Code
NDM - Network Data Mover
NET - newly eligible transition
Nx - reporting transaction
OIG - Office of the Inspector General
P2P - plan-to-plan
PACE - Program of All-Inclusive Care for the Elderly
PAP - patient assistance program
PBM - pharmacy benefit manager
PBP - plan benefit package
PCN - Processor Control Number
PCUG - Plan Communications User’s Guide
PDE - prescription drug event
PDP - prescription drug plan
PLRO - Patient Liability Reduction Due to Other Payer Amount
PO - PACE organization
POS - point of sale
PUF - Public Use File
RFQ - request for quote
RHC - rural health clinic
RxGRP - Group ID
RxID - Cardholder ID
SPAP - State Pharmaceutical Assistance Program
TBT - TrOOP balance transfer
TrOOP - true out-of-pocket
TRR-Transaction Reply Report
U&C-usual and customary
VAMC-VA Medical Center
VDSA-Voluntary Data Sharing Agreement
VHA-Veterans Health Administration
WCMSA-Workers’ Compensation Medicare Set-aside Arrangement
10 – Introduction
(Rev. 4; Issued: 09-26-08; Effective/Implementation Date: 09-26-08)

This chapter provides guidance to Part D sponsors regarding our requirements and procedures for coordination of benefits (COB) with other providers of prescription drug coverage. The chapter is divided into five main areas:

- Section 20 – Overview
- Section 30 – CMS Requirements
- Section 40 – Beneficiary Requirements
- Section 50 – Part D Sponsor Requirements
- Section 60 – Coordination of Benefit Activities of Non-Part D Payers

20 – Overview
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

Part D sponsors are required to coordinate with State Pharmaceutical Assistance Programs (SPAPs) and other providers of prescription drug coverage with respect to the payment of premiums and coverage, as well as coverage supplementing the benefits available under Part D. The Medicare Modernization Act (MMA) specified that these coordination requirements must relate to the following elements: (1) enrollment file sharing; (2) claims processing and payment; (3) claims reconciliation reports; (4) application of the protection against high out-of-pocket expenditures by tracking true out-of-pocket (TrOOP) expenditures; and (5) other processes that CMS determines.

When a Medicare Part D enrollee has other prescription drug coverage, COB allows the plans that provide coverage for this same beneficiary to determine each of their payment responsibilities. This process is necessary in order to avoid duplication of payment and to prevent Medicare from paying primary when it is the secondary payer. While this is the principal purpose of COB within the contexts of Medicare Parts A and B, COB also serves an additional function within the Part D context: it provides the mechanism for support of the tracking and calculating of beneficiaries’ “true out-of-pocket” (TrOOP) expenditures, or “incurred costs” as defined in the MMA and CMS’ implementing regulations. Costs for covered Part D drugs are treated as “incurred” only if they were paid by the individual (or by another person, such as a family member, on behalf of the individual), paid by CMS on behalf of a low-income subsidy-eligible individual, or paid under a qualified SPAP as defined in CMS regulations. Costs do not count as “incurred” when: 1) no benefits are provided because of the application of either a formulary or the

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1 Under 42 CFR 423.458(d), Part D requirements may be waived for Programs of All-Inclusive Care for the Elderly (PACE) organizations if the requirements are determined to be duplicative of, or in conflict with, provisions that would otherwise be applicable to these organizations. Appendix F provides additional guidance on the applicability of the COB requirements to PACE organizations.
Medicare Secondary Payer (MSP) laws, or 2) when costs are reimbursed through insurance or otherwise, a group health plan, or similar third party arrangement. Therefore, only certain costs not paid for by the Part D sponsor count toward TrOOP. The Medicare Part D benefit parameters for the defined standard Part D benefit are updated annually and published in the Final Rate Announcement which is issued each April for the following year. The Part D benefit parameters are available in the Rate Announcements on the CMS Web site. See Appendix B for the specific Web address.

The MMA provided CMS with authority to impose user fees to defray the costs of Part D COB activities, as well as to retain a portion of those user fees to offset costs associated with the TrOOP facilitation (or Part D transaction) process. The MMA prohibits CMS from levying user fees on SPAPs, however. In CMS’ regulations, CMS clarifies that only Part D sponsors – not SPAPs or other payers – will be assessed user fees. However, although Part D sponsors may charge user fees to other payers for COB activities, these user fees must be reasonable and related to the Part D sponsors’ actual costs of COB with these entities. In addition, any user fees Part D sponsors charge other entities must specifically exclude those activities that are covered by the user fees CMS is collecting for COB. Thus, for example, Part D sponsors may not charge user fees for activities such as the costs of the claims transaction by supplemental payers (since Part D user fees funded by CMS are used in part for that purpose), but sponsors may charge for activities such as the exchange of claims data.

Section 1860D-23(a)(4) of the Social Security Act requires the Secretary, in establishing the requirements for coordination of benefits under Medicare Part D, to consult with State Pharmaceutical Assistance Programs, MA organizations, States, pharmaceutical benefit managers, employers, representatives of Part D eligible individuals, data processing experts, pharmacists, pharmaceutical manufacturers, and other experts. CMS has undertaken extensive consultation with these stakeholders actively participating with the National Council for Prescription Drug Programs (NCPDP) in developing with the industry Health Insurance Portability and Accountability Act of 1996 (HIPAA) standard processes for coordination of benefits.

Although this chapter provides guidance primarily for Part D sponsors, the various processes associated with COB involve interaction between multiple parties. For that reason, CMS provides detailed guidance regarding the COB requirements applicable to the various parties including beneficiaries, Part D sponsors, and other payers. In addition to the guidance contained in this chapter, NCPDP has created a white paper entitled, “Overview of the Medicare Part D Prescription Drug Coordination of Benefits (COB) Process.” This white paper provides an overview of the processes and entities associated with Part D COB, and includes recommendations for industry standard practices. Section 4 of the paper summarizes the COB requirements in the Social Security Act and Federal regulations and CMS’ implementing guidance. The guidance and recommendations in the subsequent sections of the white paper flow from CMS regulations and guidance. The document is available on the NCPDP Web site. See Appendix B for the specific Web address.
In Appendix A of this guidance, CMS provides an illustration of how the Part D transaction facilitation process works. Appendix B contains a list of Web sites relevant to COB and referenced in this chapter and Appendices C and D respectively include the automated TrOOP balance transfer guidance and the related addendum for PACE organizations. Appendix E provides detail on specific issues that may relate to (or be of particular interest to) other payers and entities with which Part D sponsors, per the requirements of 42 CFR 423.464(f), are required to coordinate, including SPAPs, Medicaid, VA, TRICARE, Indian Health Service and tribal health coverage, safety-net providers, patient assistance programs (PAPs), personal health savings vehicles, AIDS drug assistance programs (ADAPs), PACE plans, and Medicare Part B. Further guidance on systems requirements and technical details involved in the COB process has been issued in other communications and is included here by reference. In Appendix F, CMS addresses the applicability of COB to PACE requirements. Appendix G contains a copy of Section 4 of the NCPDP COB white paper referenced above, and Appendix H contains a glossary of terms.

30 – CMS Requirements
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

CMS leveraged its existing Medicare COB processes to facilitate COB under Part D. In addition, through the use of a Part D transaction facilitation process that uses an existing industry claims transactions set (described in further detail in section 30.4 of this chapter), CMS supports the tracking and calculation of enrollees’ TrOOP balances by Part D sponsors.

30.1 – Enrollment File Sharing
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

Prior to the enactment of the mandatory insurer reporting provision of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Section 111 of P.L. 110-173), except for employers/union plans that are required by MSP-related law to report enrollment information on certain active employees, there was no requirement for other payers of health benefits to report their enrollment to CMS or the plans. The COB enrollment file sharing programs provide inherent incentives for other payers to coordinate drug benefits. Thus, many other payers voluntarily provide information regarding prescription drug coverage they offer that is either primary or supplemental to Part D.

The mandatory insurer reporting of MSP group health coverage requires the reporting of information about group health plan arrangements, and those provisions implemented July 1, 2010 require the reporting of information about liability insurance, no-fault insurance, and workers' compensation. Although these requirements are not specific to Part D, CMS encourages insurers providing prescription drug coverage to include this information in their mandatory reporting.

CMS coordinates benefits with other payers with respect to Part A and B coverage to reduce mistaken payments and administrative expenses that would otherwise be incurred
by the Medicare program. The CMS COB contractor collects information on beneficiaries’ other coverage primarily through the use of data sharing agreements. Voluntary Data Sharing Agreements (VDSAs) and Coordination of Benefits Agreements (COBAs) that already existed were modified to include Part D information. CMS also created new types of agreements, such as those with SPAPs, ADAPs, and PAPs, specifically to facilitate the exchange of Part D information. Collectively, VDSA, SPAP, ADAP, and PAP reporting programs are referred to as “data sharing agreement” – DSA – programs. To maintain consistency throughout all data sources and to expedite transactions, the DSA file submissions should include Rx Bank Identification Numbers (BINs) and Processor Control Numbers (PCNs) for payers whose payments count toward TrOOP (e.g., SPAPs and ADAPs) that are unique from the BINs and PCNs for payers whose payments do not apply to TrOOP (e.g., workers’ compensation and employer group health plans).

After the data sharing agreement is executed, the other payer sends the COB contractor a file of its enrollees. For Part D purposes, the COB contractor: 1) compares the list of the other payer’s enrollees to the current population of Medicare Part D enrollees; 2) captures and maintains the resulting matches and any information updates; and 3) transmits the matches/updates to the CMS Medicare Beneficiary Database (MBD). CMS sends this information as often as daily to the Part D transaction facilitator and the Part D sponsor for the sponsor’s enrollees. The data consist of a detail record for each enrollee whose other payer information is reported in the attachments to the detail record. Attachments to the detail record may include up to 20 primary records containing information on other payers that are primary to Part D, and up to 20 supplemental records containing information on payers that pay after Part D. The data elements that are included, if applicable, in the detail, primary, and supplemental records are reflected in tables below.

**Table 30.1-1 COB File—Data Elements in Detail Record**

<table>
<thead>
<tr>
<th>Record Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>HICN/RRB Number</td>
</tr>
<tr>
<td>SSN</td>
</tr>
<tr>
<td>Date of Birth</td>
</tr>
<tr>
<td>Gender Code</td>
</tr>
<tr>
<td>Contract Number</td>
</tr>
<tr>
<td>Plan Benefit Package</td>
</tr>
<tr>
<td>Action Type</td>
</tr>
</tbody>
</table>

**Table 30.1-2 COB File—Data Elements in Primary Record**

<table>
<thead>
<tr>
<th>Record Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>HICN/RRB Number</td>
</tr>
<tr>
<td>SSN</td>
</tr>
<tr>
<td>Date of Birth</td>
</tr>
<tr>
<td>Gender Code</td>
</tr>
<tr>
<td>RxID Number</td>
</tr>
<tr>
<td>RxGroup Number</td>
</tr>
<tr>
<td>Field</td>
</tr>
<tr>
<td>-------------------------------</td>
</tr>
<tr>
<td>RxBIN Number</td>
</tr>
<tr>
<td>RxPCN Number</td>
</tr>
<tr>
<td>Rx Plan Toll Free Number</td>
</tr>
<tr>
<td>Sequence Number</td>
</tr>
<tr>
<td>COB Source Code</td>
</tr>
<tr>
<td>MSP Reason (Entitlement Reason from COB)</td>
</tr>
<tr>
<td>Coverage Code</td>
</tr>
<tr>
<td>Insurer's Name</td>
</tr>
<tr>
<td>Insurer's Address-1</td>
</tr>
<tr>
<td>Insurer's Address-2</td>
</tr>
<tr>
<td>Insurer's City</td>
</tr>
<tr>
<td>Insurer's State</td>
</tr>
<tr>
<td>Insurer's ZIP Code</td>
</tr>
<tr>
<td>Insurer TIN</td>
</tr>
<tr>
<td>Individual Policy Number</td>
</tr>
<tr>
<td>Group Policy Number</td>
</tr>
<tr>
<td>Effective Date</td>
</tr>
<tr>
<td>Termination Date</td>
</tr>
<tr>
<td>Relationship Code</td>
</tr>
<tr>
<td>Payor ID</td>
</tr>
<tr>
<td>Person Code</td>
</tr>
<tr>
<td>Payer Order</td>
</tr>
<tr>
<td>Policy Holder's First Name</td>
</tr>
<tr>
<td>Policy Holder's Last Name</td>
</tr>
<tr>
<td>Policy Holder's SSN</td>
</tr>
<tr>
<td>Employee Information Code</td>
</tr>
<tr>
<td>Employer's Name</td>
</tr>
<tr>
<td>Employer's Address 1</td>
</tr>
<tr>
<td>Employer's Address 2</td>
</tr>
<tr>
<td>Employer's City</td>
</tr>
<tr>
<td>Employer's State</td>
</tr>
<tr>
<td>Employer's ZIP Code</td>
</tr>
<tr>
<td>Filler</td>
</tr>
<tr>
<td>Employer TIN</td>
</tr>
<tr>
<td>Filler</td>
</tr>
<tr>
<td>Claim Diagnosis Code 1</td>
</tr>
<tr>
<td>Claim Diagnosis Code 2</td>
</tr>
<tr>
<td>Claim Diagnosis Code 3</td>
</tr>
<tr>
<td>Claim Diagnosis Code 4</td>
</tr>
<tr>
<td>Claim Diagnosis Code 5</td>
</tr>
<tr>
<td>Attorney's Name</td>
</tr>
<tr>
<td>Attorney's Address 1</td>
</tr>
<tr>
<td>Attorney's Address 2</td>
</tr>
<tr>
<td>Attorney's City</td>
</tr>
<tr>
<td>Attorney's State</td>
</tr>
<tr>
<td>Attorney's ZIP</td>
</tr>
</tbody>
</table>
Table 30.1-3 COB File—Data Elements in Supplemental Record

<table>
<thead>
<tr>
<th>Record Type</th>
<th>HICN/RRB Number</th>
<th>SSN</th>
<th>Date of Birth</th>
<th>Gender Code</th>
<th>RxID Number</th>
<th>RxGroup Number</th>
<th>RxBIN Number</th>
<th>RxPCN Number</th>
<th>Rx Plan Toll Free Number</th>
<th>Sequence Number</th>
<th>COB Source Code</th>
<th>Supplemental Type Code</th>
<th>Coverage Code</th>
<th>Insurer's Name</th>
<th>Insurer's Address-1</th>
<th>Insurer's Address-2</th>
<th>Insurer's City</th>
<th>Insurer's State</th>
<th>Insurer's ZIP Code</th>
<th>Individual Policy Number</th>
<th>Group Policy Number</th>
<th>Effective Date</th>
<th>Termination Date</th>
<th>Relationship Code</th>
<th>Payor ID</th>
<th>Person Code</th>
<th>Payer Order</th>
</tr>
</thead>
</table>
Further information about the format and business rules of the COB file to sponsors is contained in Section 11 of the Plan Communications User’s Guide (PCUG); the guide is available on the CMS Web site. For further information about current Medicare COB processes, see the Medicare Part D COB Web site. (See Appendix B for the specific Web addresses for these sites.)

The COB contractor will send as much information as is available. In some cases, CMS through the COB contractor may determine there is other prescription drug coverage, but may be unable to recognize the Rx identifiers. In such cases, CMS will supply the information so that the sponsors are at least aware of the other coverage.

30.2 – Validation of Information about Other Payers
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

When a Part D sponsor or a beneficiary provides information to the COB contractor about other coverage, the COB contractor validates the completeness of this information, then applies and maintains it in MBD. MBD transmits this information to both the TrOOP facilitator and Part D sponsors from the Medicare Advantage-Prescription Drug (MARx) system via the COB file.

The COB contractor’s role in Part D COB is to assist sponsors in identifying other coverage and in determining whether other payments count toward the beneficiary’s TrOOP by specifying the supplemental payer type.

The table below crosswalks the TrOOP eligibility of payments by other payers with the MSP reason codes and insurance or coverage type codes on the COB file.

<table>
<thead>
<tr>
<th>Other Payer</th>
<th>MSP Reason Code</th>
<th>Insurance or Coverage Type Code</th>
<th>Relationship of Coverage to Medicare</th>
<th>TrOOP Eligibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employer Group Health Plan</td>
<td>A (Working Aged)</td>
<td></td>
<td>Primary</td>
<td>N</td>
</tr>
<tr>
<td></td>
<td>B (ESRD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>G (Disabled)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-Employer Group Health Plan</td>
<td>D (Auto insurance; no fault)</td>
<td></td>
<td>Primary</td>
<td>N</td>
</tr>
<tr>
<td></td>
<td>E (Workers’ Compensation (WC))</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>L (Liability)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>H (Black Lung (BL))</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secondary Insurance</td>
<td>L (Supplemental insurance)</td>
<td></td>
<td>Secondary</td>
<td>N</td>
</tr>
<tr>
<td></td>
<td>M (Medigap)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Payer</td>
<td>MSP Reason Code</td>
<td>Insurance or Coverage Type Code</td>
<td>Relationship of Coverage to Medicare</td>
<td>TrOOP Eligibility</td>
</tr>
<tr>
<td>------------------------------------------------</td>
<td>-----------------</td>
<td>---------------------------------</td>
<td>--------------------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>O (Other)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Federal Government Programs</td>
<td>T (Federal Employees Health Benefit Program [FEHBP]), Veterans Administration (VA) coverage, 2 (TRICARE)</td>
<td>Secondary</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Qualified State Pharmaceutical Assistance Program (SPAP)</td>
<td>Q</td>
<td>Secondary</td>
<td>Y (Effective 01/01/2011)</td>
<td></td>
</tr>
<tr>
<td>Non-qualified SPAP</td>
<td>N</td>
<td>Secondary</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Medicaid</td>
<td>I</td>
<td>Secondary</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Manufacturer Patient Assistance Program (PAP)</td>
<td>P</td>
<td>Secondary</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>AIDS Drug Assistance Programs (ADAPs)</td>
<td>S</td>
<td>Secondary</td>
<td>Y (Effective 01/01/2011)</td>
<td></td>
</tr>
<tr>
<td>Charities</td>
<td>R</td>
<td>Secondary</td>
<td>Y</td>
<td></td>
</tr>
<tr>
<td>Health Reimbursement Accounts (HRAS)</td>
<td>Z</td>
<td>Secondary</td>
<td>N</td>
<td></td>
</tr>
</tbody>
</table>

1 Coverage is separate and distinct from Part D; see Appendix E for further discussion.
2 State-only funded SPAPs
3 For non-working, aged beneficiaries, payments are secondary to Medicare and non-TrOOP-eligible
30.3 – Establishing the Order of Payment for Part D Coordination of Benefits (COB)
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

In order to provide a consistent set of rules for the order of payment on Part D claims and establish a basis for the accurate calculation of the TrOOP balance, CMS establishes that Part D sponsors and all secondary payers on Part D claims should adhere to the following standards for order of payment: 1) All payers are legally required to adhere to MSP laws and any other federal and state laws establishing payers of last resort (e.g., TRICARE). 2) In all other situations, the Rules for Coordination of Benefits adopted in the most current National Association of Insurance Commissioners Coordination of Benefits Model Regulation should be followed.

The COB contractor includes payment order indicators on other payer records it sends to MBD. Sponsors use this data element to sort COB records for display in reply transactions to the pharmacy. The COB contractor calculates payer order based on MSP rules, relationship to policyholder, and type of supplemental insurance. Rules for using the payment order indicator are contained in the PCUG.

30.4 – Contracting with a Part D Transaction Facilitator
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

All Part D sponsors must correctly calculate the TrOOP amount in order to properly adjudicate beneficiary claims, as well as to communicate this information to plan enrollees. This process is logistically complex because there may be multiple payers (for example, SPAPs or employer or union plans). True COB, in which the order of payment among multiple payers with responsibility for paying prescription drug claims on behalf of an individual is established and programmed into the systems of the secondary payers, did not generally take place in pharmacy benefit management prior to Part D implementation.

To reduce the need for Part D sponsors to separately create procedures to coordinate benefits with every other payer with responsibility for drug coverage for one of their Part D enrollees, CMS published a request for comment on the feasibility of an online real-time process. In response to this CMS request, representatives from pharmacies, pharmacy benefit manager (PBM) companies, pharmacy data processing and standard-setting organizations provided extensive input and comments to design an automated solution for COB and the facilitation of the TrOOP accounting process. The industry, working in collaboration with the NCPDP, developed a TrOOP facilitation process that allows the majority of pharmacy claims processing to take place “real time” at the pharmacy at point of sale (POS). To this end, supplemental payers are required to utilize the Health Insurance Portability and Accountability Act (HIPAA) coordination of benefits transaction standard, which requires the use of the NCPDP Telecommunication Standard to communicate secondary payer transactions back to the primary Part D sponsor for purposes of tracking TrOOP in real time. Version C.1 of the NCPDP Implementation Guide first detailed the processing requirements involved in the TrOOP
facilitation process: the process continues to be defined in the NCPDP Telecommunication Standard Implementation Guide (Version D and above).

In 2005, CMS awarded a contract to NDC Health (d.b.a RelayHealth) to act as the TrOOP facilitator for Part D claims processing. In 2011, CMS re-competed a contract awarded to NDC Health to better describe the nature and scope of the contractor’s responsibilities and changed the name of the contractor’s role to the Part D transaction facilitator. The facilitator is responsible, in conjunction with CMS, for establishing procedures for facilitating eligibility queries (E1 transactions) at POS, identifying costs that are being reimbursed by other payers and alerting Part D sponsors about such transactions, and facilitating the transfer of TrOOP-related data when a beneficiary changes plan enrollment during the coverage year.

30.4.1 – Part D Transaction Facilitation Process (Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

With the implementation of Medicare Part D, new electronic transaction capabilities became available to pharmacies. These capabilities allow pharmacies to submit eligibility inquiries without the need to fill a prescription and to bill payers supplemental to Medicare.

A pharmacy uses the eligibility inquiry process, known as an E1 transaction, to submit real-time transactions to the Part D transaction facilitator. Eligibility transactions are used to determine a Medicare beneficiary’s Part D coverage information. Pharmacies use this service when the beneficiary does not have their Medicare Part D Plan Card information to retrieve information needed to bill a claim to a patient’s insurance plan, or to determine billing order if the beneficiary has other drug coverage. Note that long term care (LTC) facilities should batch their end-of-year E1 requests for transmission to the facilitator.

Part D sponsors, supplemental payers, switches (claims routers), and the Part D transaction facilitator must interact to accurately track a patient’s true out-of-pocket expenses. Claims to supplemental payers, known as B transactions, are submitted by the pharmacy to their switch. The switch will forward to the transaction facilitator the B transactions that are not rejected by the supplemental payer and that contain an RxBIN/Processor Control Number (PCN) combination for a plan that covers Medicare Part D beneficiaries. This RxBIN/PCN combination is the flag that switches use to route the data to the facilitator.

The transaction facilitator uses the B transaction to trigger the creation of a reporting transaction (Nx) and delivers the N transaction to the Part D sponsor in real-time. All supplemental billing claims must be processed through a switch, which delivers the transactions to the transaction facilitator to enable accurate TrOOP reporting at the Part D sponsor.
30.4.2 – Enhancements to E1 Transactions
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

Enhanced E1 capability, first introduced before the implementation of Medicare Part D, enables pharmacies to separately request verification of a beneficiary’s Medicare Part A/B eligibility—an essential step in the enrollment process for low-income newly eligible beneficiaries (described in section 50.10 of this chapter).

Further enhancements to the E1 inquiry added data elements and explicit messaging to the E1 response. Expanding the E1 response to include, for example, the Part D sponsor’s contract number, benefit ID, benefit effective date and benefit termination date, better informs pharmacies of beneficiaries’ enrollment in a Part D plan and assists pharmacists with processing beneficiary prescriptions. Because of the significant advantages associated with the enhanced E1, effective April 1, 2009, CMS discontinued support for the original E1 eligibility query and now supports only the enhanced E1.

Beginning December 14, 2010, the transaction facilitator, in accordance with the version D.0 implementation timeline outlined in the January 16, 2009 Final Rule (CMS-0009-F) regarding the adoption of updated HIPAA electronic transaction standards, began accepting NCPDP version D.0 transactions. As of that date, pharmacies were able to submit E1 requests for Medicare Part A/B as well as Part D eligibility information in either NCPDP version D.0 or version 5.1. However, effective July 1, 2012, all E1 requests must be in version D.0.

As experience with the Medicare Part D program has grown, CMS has continued to explore areas that offer opportunities for improvement. As part of this effort, effective January 1, 2011, the transaction facilitator implemented new matching logic for E1 queries. Under the new matching logic, pharmacies provide the following patient information on all E1 requests:

1. Cardholder ID;
2. Patient’s last name;
3. At least the first character of the patient’s first name; and
4. Patient’s date of birth.

Use of the enhanced matching logic enables the transaction facilitator to provide pharmacists and pharmacies with more accurate eligibility and enrollment information by decreasing the probability of false positive matches as well as the need for pharmacy reprocessing of the claims associated with the mismatches.

When a match is found, the industry has requested further enhancements to the E1 transaction response to include:

1. Specific low-income cost-sharing subsidy (LICS) level, rather than the general “Yes” or “No” that is currently included in the transaction;
2. Indicators to identify PACE plans and demonstration plans; and

3. A longer period of time (currently, the date of service must be 90 days before or after the submission date of the E1).

Two of these requested enhancements will be implemented on May 23, 2013. As of this date, when a match is found the E1 response will include the following:

- The beneficiary’s LICS level;
- The LICS effective date;
- The LICS termination date; and
- The Medicare plan type (for example, MAPD, PDP, employer group waiver plan (EGWP), PACE).

For more information about the E1 transactions, see the RelayHealth Web site. See Appendix B for the specific Web address.

30.4.3 – Real-time Versus Batch Processing
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

For instances in which Part D plan enrollees’ secondary coverage is identified in advance by CMS systems (as described in section 30.1 of this chapter), multiple-payer claims are automatically adjudicated at the POS. The transaction facilitator captures secondary payer claims transactions based on unique routing information collected previously at enrollment or through the COB contractor’s system. The transaction facilitator also has a batch process available for claims that it receives in a manner other than real time (for example, claims from programs such as the Indian Health Service (IHS) or those presented by the beneficiary to a secondary payer in hard copy). Other payers can then send their paid claims data directly to the transaction facilitator in batch form. Once the facilitator receives the batched paid claims data, it will follow the same online process, creating an NCPDP Nx transaction and sending it to the beneficiary’s Part D sponsor for accurate TrOOP recalculation.

30.4.4 – Enhancements to Nx Transactions
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

CMS, through the Part D transaction facilitator, continues to seek to enhance Nx transactions. One such enhancement involved the creation by the transaction facilitator of a unique Transaction Reference ID for each N1 transaction created and the inclusion of this ID in subsequent N transactions routed to the Part D sponsor. In handling adjustments and reversals, the transaction facilitator uses the following six fields to match the B transactions to prior N1 transactions: Service Provider ID, Date of Service, Rx/Service Reference Number, Product/Service ID, Cardholder ID, and Fill Number. When a B2 transaction is received without a Cardholder ID, the facilitator uses these fields to match the B2 transaction to the prior N1 transaction in order to retrieve the Cardholder ID for inclusion in the N2 transaction to the Part D sponsor. If an
adjustment/reversal matches a prior B1 transaction on all six fields, the facilitator includes the Transaction Reference ID from the N1 transaction for the matched claim on the N2 and N3 transactions routed to the Part D sponsor. So, when the facilitator sends an N2, N3 and/or a final N1 transaction to a Part D sponsor, the transaction reference number is consistent among all transactions for the same prescription/service claim.

On December 14, 2010, the transaction facilitator, in accordance with the version D.0 implementation timeline outlined in the January 16, 2009 Final Rule (CMS-0009-F) regarding the adoption of updated HIPAA electronic transaction standards, began accepting NCPDP version D.0 transactions. As of that date, to ensure supplemental claims were appropriately captured and Nx transactions generated, the transaction facilitator accepted supplemental payer billing transactions (B1 and B2) in real time or batch mode in either NCPDP version D.0 or version 5.1 and created N1 and N2 transactions in real time or batch mode based on the version of the billing transaction received until July 1, 2012. The facilitator continued to accept supplemental payer B transactions in either Version 5.1 or D.0; however, beginning January 1, 2012, the facilitator converted supplemental payer claims received in either 5.1 or D.0 format to D.0 Nx transactions. As of July 1, 2012, the facilitator rejects supplemental payer B transactions that are not in Version D.0. As a result, as of July 1, 2012, TrOOP-eligible supplemental payers must use Version D.0; otherwise, their payments will not be credited toward TrOOP.

30.4.5 – TrOOP Accounting
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

Part D sponsors are responsible for tracking, accumulating and reporting TrOOP. The role of the transaction facilitator and other parties is to collect and report information in real-time, but others do not do TrOOP accounting. See Appendix A for detail about the Part D transaction facilitation process. This process matters because Nx transactions can affect TrOOP. Part D sponsors should note the TrOOP eligibility status of other payers based on the information in the COB file to determine whether or not a payment should count toward TrOOP.

30.5 – Assessment of COB User Fees
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

The MMA provided CMS with the authority to impose user fees to facilitate the transfer of information necessary for benefit coordination. In conjunction with this authority, CMS uses the fees for activities such as covering the cost of Nx transactions, funding the COB contractor, and supporting CMS systems upgrades for transferring COB data to sponsors. Since this user fee reflects the costs associated with such COB-related activities, user fees may vary (increasing or decreasing) yearly to reflect those needs.

The annual COB user fee is announced in the Medicare Part C and D Call Letter which is an attachment to the Final Rate Announcement issued in April for the following year.
Each year’s Part C and D Call Letters are available in the Rate Announcements on the CMS Web site. See Appendix B for the specific Web address.

40 – Beneficiary Requirements
(Rev. 4; Issued: 09-26-08; Effective/Implementation Date: 09-26-08)

40.1 – Providing Information to Sponsors on Other Coverage
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

Beneficiaries must supply Part D sponsors with information about other prescription drug coverage they have. As provided in the MMA, beneficiaries are legally obligated to report this information, and any material misrepresentation of such information by a beneficiary may constitute grounds for termination of coverage from Part D. CMS guidance on material misrepresentation regarding third party reimbursement and disenrollments for this reason is provided in section 50.2.5 of Chapter 3 covering Part D Enrollment and Disenrollment Guidance available on the CMS Web site. See Appendix B for the specific Web address. Part D sponsors annually notify their enrollees of the other prescription drug coverage information on the COB file from CMS (as described in section 50.2 of this chapter) and report new and/or updated information reported by the beneficiary to the COB contractor for validation. Further information on coordination of benefits when a beneficiary has other prescription drug coverage is available in Medicare & You and Your Guide to Medicare Prescription Drug Coverage; both of these guides are released annually. These are available on the Medicare Web site; see Appendix B for the specific Web address to access Medicare beneficiary publications.

40.2 – Using On-line Processing
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

CMS expects beneficiaries to take advantage of automated real-time prescription drug claim processing whenever it is available so that the supplemental payer information can be utilized to coordinate benefits seamlessly at the point of sale. Paper claim (receipt) submission should be limited to those situations in which on-line claims processing is not available at the pharmacy in order to promote accurate TrOOP accounting (such as out-of-network pharmacies), and to minimize both administrative costs to the Part D sponsors and the Medicare program as well as opportunities for fraudulent, duplicative claim reimbursements. Further information on CMS rules for sponsor processing of paper claims is in section 50.4.3 of this chapter entitled, Direct Member Reimbursement.

40.3 – Submitting Documentation for Off-line Processing on a Timely Basis
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

Beneficiaries are responsible for submitting documentation for purchases that are made off-line (i.e., when on-line claims processing is not available at the pharmacy). These would include out-of-network claims and other occasions when the beneficiary had to pay and submit a paper claim to the plan. It is the beneficiary’s responsibility to submit
documentation to the Part D sponsor so that their TrOOP balance and other accumulators can be updated timely. However, not all of these claims may be reimbursable; further details are available in section 50.4.3 of this chapter.

50 – Part D Sponsor Requirements
(Rev. 4; Issued: 09-26-08; Effective/Implementation Date: 09-26-08)

50.1 – Providing 4Rx Data on Primary Coverage
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

Beginning August 2007, all plan-submitted enrollment transactions to the MARx system must include 4Rx data. The 4Rx data, including the RxBIN, Processor Control Number (PCN), Group ID (RxGRP) and Cardholder ID (RxID), are identifying data required for claims routing. If CMS accepts the enrollment transaction, the enrollment information with the 4Rx data are sent by the MBD to the Part D transaction facilitation contractor to support eligibility (E1) transactions from pharmacies, which are needed anytime a beneficiary presents for the first time at a pharmacy and does not have a plan-issued card for drug benefits. For CMS-generated enrollment transactions, including auto-enrollments, facilitated enrollments, plan rollovers, reassignments, and user interface transactions, Part D sponsors are required to submit the 4Rx data via a Plan change (72) transaction to CMS within 72 hours of the sponsor’s receipt of the Transaction Reply Report (TRR), which reports these enrollments to the sponsor.

Two important developments result from this change in the enrollment process. CMS and the transaction facilitation contractor have a set of 4Rx data for all enrollees whose transactions have been processed successfully in CMS systems. In addition, most of the time lag between CMS accepting an enrollment and the transaction facilitator having 4Rx data has been eliminated.

Prior to April 2011, Part D enrollment and 4Rx data in the CMS MBD were linked. As a result, if a member’s 4Rx data changed (due, for example, to his or her sponsor’s change of claims processor necessitating an RxBIN change), the new 4Rx data for the member replaced the former data. Thus, any transactions that required processing by the former processor were inappropriately routed to the new processor. With the implementation of the changes in the April 2011 CMS systems release, multiple occurrences of 4Rx data within an enrollment period are permitted and transactions can be correctly routed based on the 4Rx effective dates.

In addition, in accordance with 42 CFR §423.120(c)(4), beginning January 1, 2012, sponsors must assign and exclusively use unique Part D 4Rx identifiers. These requirements will ensure beneficiary access to Part D negotiated prices and also ensure that proper concurrent drug utilization review (including safety checks) is performed. Further information on these requirements is provided in chapter 5 section 90.1, of this manual. This chapter is available on the CMS Web site. See Appendix B for the specific Web address.
50.2 – Notifying Beneficiaries Regarding Other Prescription Drug Coverage on File and Transmitting Updated Information to CMS
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

As provided in the MMA, and also mentioned in section 40.1 in this chapter, beneficiaries are legally obligated to report information about other prescription drug coverage or reimbursement for prescription drug costs that they have or expect to receive; any material misrepresentation of such information by a beneficiary may constitute grounds for termination of coverage from a Part D plan. Consequently, prior to 2009, Part D sponsors were required to regularly survey their enrollees regarding any other prescription drug coverage they may have had, and report the results of those surveys – including, if known, any Rx data (RxBIN, PCN, RxGRP, and RxID) – to the COB contractor so that it could be validated, captured, and maintained in MBD for COB purposes.

Since the implementation of Part D, the number of other payers participating in voluntary data sharing agreements with CMS has grown, improving the volume and quality of the other payer information available to Part D sponsors on the COB file. Additionally, the implementation of the new MSP reporting in 2009 for group health plan and non-group health plan insurers, including liability (including self-insurance), no-fault insurance, and workers’ compensation, will continue to expand the other payer information available for COB. Given these developments, CMS revised the Part D beneficiary COB survey requirements. Beginning in 2010, in lieu of a survey, Part D sponsors are required to notify each beneficiary of his/her other prescription drug coverage information as reflected in the COB file from CMS, and request that the beneficiary review the information and report back only updates (that is, corrections to existing information and new coverage information) to the sponsor.

This process is required annually for current enrollees and for new enrollees within 30 days of the date the sponsor processes a beneficiary’s enrollment. The annual and 30-day COB notifications will be sent only to enrollees with existing other coverage information on the COB file. If there is no coverage information on the COB file for the beneficiary, no annual or 30-day COB notification is required. However, if a new enrollee has no other drug coverage information on the COB file, but provided an affirmative response on the application regarding other drug coverage, the sponsor must follow up with the beneficiary to obtain sufficient credible information concerning their other coverage to report to the COB contractor via Electronic Correspondence Referral System (ECRS).

Absent a report of corrected or new information from the beneficiary, sponsors can assume the existing information is correct, and there will be no need for follow-up with non-responding beneficiaries. Likewise, if a sponsor receives no response to their initial follow-up with a new enrollee who responded affirmatively on the application regarding other prescription drug coverage, but has no other coverage on the COB file, sponsors can assume the application response was in error and no further sponsor action is required. CMS believes this new process, which provides for periodic review and
correction of the CMS COB data, will further enhance the quality of the data available to Part D sponsors for COB.

Sponsors have the flexibility to design their COB notification process according to their own needs. Likewise, sponsors have the flexibility to design their COB notices and are not required to submit them to CMS for marketing material review. Sponsors may provide the COB notification by telephone, mail, email if available, or in-person. The notification process should not require that the beneficiary provide his or her SSN; instead, sponsors should use other identifiers, such as the Member ID. Also, if the COB notices are mailed, in addition to providing a self-addressed return envelope for beneficiaries to report updated or new coverage information, sponsors should include a mailing address and telephone number on the notice to be used in case the envelope is lost or damaged and the beneficiary has new or updated coverage information to report.

Anytime a Part D sponsor receives information concerning an addition or revision to an enrollee’s existing other coverage information, the new or revised information should be sent electronically via ECRS to the COB contractor within 30 days of receipt. Sponsors should not transmit information about other coverage that the COB contractor has already applied to MBD and that the sponsor has already received in the COB file, but rather only change transactions. In addition, updates to liability coverage, including liability insurance, no-fault insurance and workers’ compensation, cannot be processed through ECRS, but must be handled by the liability carrier. Therefore, sponsors should direct their members to contact the liability carrier directly if the liability coverage information requires correction.

Note that effective January 6, 2012, Part D sponsors are not permitted to update SPAP or ADAP records in ECRS. If an enrollee’s other coverage information includes an SPAP or an ADAP, Part D sponsors should not report either of these types of payers to ECRS as an “Other” payer. Doing so results in the SPAP’s or ADAP’s payment being counted as Patient Liability Reduction Due to Other Payer Amount (PLRO), which is a non-TrOOP-eligible amount, rather than being counted as other TrOOP. Instead, plan sponsors should contact the SPAP or ADAP to request that the program update the enrollee’s information in its next report of enrollment information to the COB contractor.

When an ECRS transaction is received from a Part D sponsor, that transaction’s information is automatically stored in the COB contractor system. The contractor edits the transaction to ensure the information furnished is valid, complete and consistent. Transactions failing these front-end edits are rejected back to the sponsor. Transactions that pass the front-end edits are moved through the COB contractor system for further processing. If the information on the transaction from the sponsor is determined insufficient to process the transaction to completion, the COB contractor will undertake development action to obtain additional information. Development action can take up to 100 days -- 45 days each for an initial development letter and a second development letter, and 5 days for mailing time per letter. If the COB contractor sent development letters but received no response, the contractor will attempt to take the requested action; however, if the contractor is unable to take action, the contractor will close the
transaction and indicate on the response file to the sponsor that no development response was received.

50.3 – Connecting to Systems Supporting COB
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

Data from CMS to sponsors

The COB contractor performs a daily update of information on other coverage to MBD. Part D sponsors must establish connectivity with CMS systems, which, among other things, allows them to have direct access to other payer status information as often as their business requirements indicate. Every Federal business day, the COB contractor pushes out updated information to MBD and then CMS sends the COB file to the Part D sponsors. For more information on receiving COB files, see the Plan Communications User’s Guide (PCUG) available on the CMS Web site. (Refer to Appendix B for the Web address.) It is incumbent upon Part D sponsors to identify any changes to existing other payer information available in CMS systems, and to send those changes to the COB contractor.

In March 2010, CMS initiated the process of annually creating and issuing to each Part D sponsor a full replacement COB file for all the sponsor’s enrollees. A full replacement file is created for each prescription drug plan based on the sponsor’s Part D enrollees as of the date the file is processed. Each plan’s file includes both the record updates that would normally be included in the daily COB notification files and the full replacement COB data for all enrollees with other coverage. As a result, during the days the combined daily update records and full replacement files are being issued, no separate daily COB notification files are sent. Due to file size constraints, sponsors with a large number of Part D enrollees with other coverage may receive multiple COB files over the period during which the replacement files are sent.

The combined daily update/full replacement COB files contain no special identifiers to distinguish them from the normal daily COB notification files, but they may be identifiable based on the date of receipt and the large size of the files. Each plan’s file(s) include only detail records for any beneficiaries whose other coverage information has been deleted; these records normally would be in the plan’s daily COB notification file. The plan’s file also includes the records for all its current Part D enrollees who have at least one occurrence of either primary or supplemental coverage. Not included in the file are records for any Part D enrollee without other coverage information. As a result, for the enrollees included in the file, the information is a full-record replacement that should be processed by the plan replacing its entire existing other coverage information for these enrollees with the daily update/full replacement file data. For its remaining Part D enrollees (that is, those members without other primary or supplemental coverage), the plan must retain the members’ existing detail records.

As with other COB notification files, the full replacement COB files include the last 27 months of other coverage information as of the date the file is processed. Thus, each year’s
full replacement files are sent not only to the current plans of record, but also to any prior plans with enrollment periods for that beneficiary within the last 27 months.

Data from sponsors to the COB system

There is an electronic interface between Part D sponsors and the COB contractor known as the Electronic Correspondence Referral System (ECRS). ECRS allows Part D sponsors to submit post-enrollment transactions that change or add to currently known COB information. Part D sponsors may send ECRS transactions in any of three possible ways: 1) by using Network Data Mover (NDM) (a secure file transfer process) to connect to the ECRS Online Application; 2) by using NDM to send an ECRS flat file; or 3) by using a current SFTP connection to send an ECRS flat file. Part D sponsors are updated on the status of these transactions as they move through the COB systems and are informed of the determination made by the COB contractor on the transactions via a COB data report/file. Further information on ECRS is contained in the ECRS User Guide available on the CMS Web site; see Appendix B for the specific Web address.

The data provided by the COB contractor on supplemental payers and order of payment is generally the best available information for Part D sponsors and pharmacies to act upon. However, it is important to note that Part D sponsors must coordinate benefits with all other payers providing coverage for covered Part D drugs, even if the COB contractor is unaware of some payers who have submitted batched claims after the point-of-sale transaction at a network pharmacy. Although the COB contractor may be unaware of them, these other payers may submit claims directly to the Part D sponsor, thereby enabling benefit coordination by the Part D sponsor. Once a sponsor becomes aware of these other payers, it must submit this information via ECRS to the COB contractor.

In accordance with the regulatory requirements at 42 CFR 423.464(h), Part D sponsors must report credible new or changed supplemental prescription drug coverage information to the COB contractor according to CMS-specified processes and timeframes. By “credible,” we mean information that is consistent with conventions for how group health insurance coverage is identified, for instance, information that includes the name and address of the insurance company and the policy identification number. As noted in section 50.2 of this chapter, sponsors must report new or changes coverage information to the COB contractor within 30 days of receipt.

Sponsors should utilize the electronic interface established with CMS (via the MARx system) to handle plan enrollments, to transmit certain other payer data elements upon enrollment, and to receive daily transmissions of validated COB information. As new information about other prescription drug coverage is discovered, sponsors should use ECRS to send the information to CMS. Sponsors should not use the enrollment update transaction to communicate this subsequent information.

Beyond the electronic data transfers requirements described above, Part D sponsors must establish procedures for at least weekly COB file processing. Sponsors are required to not only receive information, but also to apply it to their systems.
50.4 – Processing Claims and Tracking TrOOP
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

Part D sponsors must correctly calculate the TrOOP amount in order to properly adjudicate beneficiary claims, as well as to communicate this information to plan enrollees. In order to calculate TrOOP, Part D sponsors will have to determine if other entities have made payments on covered drugs, and whether such payments fall under the legal definition of incurred costs as described in 42 CFR §423.100. CMS assists in this process by providing a transaction facilitator (described in section 30.4 of this chapter). The transaction facilitation process requires that supplemental payers utilize the HIPAA coordination of benefits transaction standard, which necessitates the use of the NCPDP Telecommunication Standard to communicate other payer transactions back to the primary Part D sponsor for purposes of tracking TrOOP in real time. Part D sponsors are required to process claims and track TrOOP in real time, including providing known supplemental payer information to the pharmacy, and accepting and processing Nx transactions.

In accordance with the requirement at 42 CFR 423.120(c)(3), Part D sponsors must require their network pharmacies to submit claims to the Part D sponsor or its intermediary whenever the Part D member ID card is presented or is on file at the pharmacy unless the enrollee expressly requests that a particular claim not be submitted to the sponsor or its intermediary. Not only is requiring on-line adjudication of prescription drug claims the only way to ensure that enrollees have access to the plan’s negotiated price at the point of sale, it also ensures that proper concurrent drug utilization review (including safety checks) is performed.

 Appropriately restricting the use of paper claims to those situations in which on-line claims processing is not available to the beneficiary at the point of sale will promote accurate TrOOP accounting, as well as minimize administrative costs to the Part D sponsors and the Medicare program, and limit opportunities for fraudulent duplicative claim reimbursements. When secondary payer information is not captured up front in CMS systems, however, Part D sponsors are required to retroactively adjust claims and TrOOP balances.

CMS establishes the payer order (see section 30.3) for the validated other payer data that is transmitted to both the transaction facilitator and the Part D sponsors from MARx via the COB file. This payer order assists sponsors in processing claims when there are multiple other payers on a beneficiary’s record. This is important, particularly for payers considered payers of last resort (e.g., SPAPs). Because Part D sponsors are ultimately responsible for accurately tracking TrOOP, they are required to retroactively adjust claims and TrOOP balances when errors in order of payment are made.

Special procedures for SPAPs and ADAPs

To ensure any payments made by SPAPs and ADAPs on behalf of their Part D eligible enrollees count toward TrOOP, these programs must have unique RxBINs and RxPCNs
for their Part D-eligible beneficiaries. When a Part D sponsor receives an initial claim transaction and identifies the member as an SPAP or ADAP enrollee, the sponsor sends the member’s SPAP/ADAP 4Rx data back to the pharmacy in the claim response so that the pharmacy may appropriately bill the SPAP or ADAP for their portion of the enrollee’s cost sharing. The transaction facilitator uses the SPAP/ADAP claim request and response to create an Information Reporting (Nx) transaction report to the Part D sponsor. The sponsor uses the N transaction information to adjust the beneficiary’s TrOOP, calculating the amount of the SPAP/ADAP payment as the difference between the Part D cost-sharing and the beneficiary cost-sharing after the supplemental payment, and reporting the SPAP/ADAP payment as an “other TrOOP” amount.

SPAPs and ADAPs can only submit updates (i.e., changes, deletions and additions) to their eligibility files to the COB contractor once per month. Monthly file submission creates an inherent delay in the subsequent reporting of updated information to the MBD, the transaction facilitator and plan sponsors. To address this delay, CMS worked with the transaction facilitator and NCPDP to create a special list of SPAP/ADAP BIN/PCNs to which sponsors may refer if the information is not yet available on the COB file. The SPAP/ADAP BIN/PCN list is available on the NCPDP public Web site under the “Resources” tab. See Appendix B for the specific Web address.

As a result of recent systems changes, Part D sponsors can no longer make corrections to SPAPs’ and ADAPs’ eligibility file information using ECRS. Only SPAPs and ADAPs are now able to edit their data. However, as noted above, these programs can only submit eligibility files to the COB contractor once per month, which creates an inherent delay in reporting updated information to plan sponsors. Part D sponsors should not attempt to work around the delay by using ECRS to report SPAP or ADAP enrollment as “other” coverage. Doing so will result in incorrect coverage information on the COB file and the possible incorrect reporting of SPAP or ADAP payments as PLRO instead of other TrOOP on the PDE. The transaction facilitator has implemented a process to accommodate the eligibility reporting delay. This process involves continued attempts to create an N transaction reporting the SPAP/ADAP payments for up to 90 days to permit the eligibility information to be reported to the Part D sponsor.

Other sources of information on the facilitation process

While this document is not meant to capture the transaction facilitation process in exhaustive detail, other sources are available in:

- Appendix A of this chapter, which contains more information in the form of a flow chart, about what the transaction facilitation process entails.

- The transaction facilitation contractor Web site; see Appendix B for the specific Web address.
• The NCPDP Telecommunication Standard Implementation Guide D.0, which provides the official guidelines for electronic prescription drug claim transaction processing.

• The Prescription Drug Event (PDE) Data Guidance on the CMS Web site, which explains TrOOP and PDE data reporting; see Appendix B for the Web address.

• Chapter 5 of this manual, which addresses benefits, beneficiary protections, and benefit design and contains information on incurred costs counting toward TrOOP.

50.4.1 – Receiving an Nx Transaction, Without Supplemental Payer on File
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

Part D sponsors should accept Nx transactions even in those instances where they have no supplemental payer information on file to identify the payer. CMS encourages sponsors to subsequently follow up by contacting the beneficiary to identify the supplemental payer. Once the sponsor receives this information, except for SPAP/ADAP coverage, it should be transmitted to the COB contractor for verification of the secondary coverage.

Note that in the event that a Part D sponsor is a secondary payer in accordance with the application of MSP rules, the Part D sponsor is required to process claims in real time to support the TrOOP facilitation process.

Explanations of benefits (EOBs) provide enrollees with their year-to-date TrOOP balances and gross covered drug costs and information on the enrollees’ position in the Part D benefit. To ensure enrollees are appropriately informed, CMS requires that sponsors develop EOBs that provide information in a form understandable to all enrollees. Acceptable EOB formats are included in the Medicare Marketing Guidelines available on the Web site; see Appendix B for the specific Web address.

50.4.2 – Beneficiary Cash Purchases
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

Previously, CMS permitted enrollees to purchase a covered Part D drug without using his or her Part D benefit or a supplemental card and have the cash price count toward the enrollees’ total drug spending and TrOOP. The policy applied if the enrollee could obtain a lower price at a network pharmacy than the plan’s negotiated price in any applicable deductible or coverage gap when the enrollee incurs 100 percent of the drug cost. The enrollee was required to submit the appropriate documentation to his or her plan for the incurred drug cost to be included in gross covered drug cost and TrOOP.

Since the beneficiary cash purchase policy was issued, the Part D benefit has undergone significant change. Beginning January 1, 2011, the changes created by the Affordable
Care Act (the ACA) started closing the **coverage gap** for beneficiaries not receiving LIS. By establishing the Coverage Gap Discount Program, which makes manufacturer discounts available at point-of-sale to non-LIS beneficiaries in the coverage gap, and gradually increasing coverage in the coverage gap for both generic and brand name drugs and biologics, the ACA for the most part has eliminated the need for this policy.

Although beneficiaries can still purchase a covered Part D drug at a network pharmacy without using their Part D benefit or a supplemental card, CMS encourages beneficiaries to use their Part D benefit. Use of the benefit affords beneficiaries access not only to the plan’s negotiated prices, which in most cases are the lowest price available, but also to the plan’s drug utilization review and other safety edits that only can be provided when the plan adjudicates the claim. Beneficiaries who choose to make a cash purchase will continue to be responsible for submitting documentation to the plan for determination of whether they are eligible for reimbursement and for costs to be included in gross covered drug costs and TrOOP. Guidance included in section 50.4.3 below replaces CMS’ former cash purchase policy and clarifies plan processing of beneficiary-submitted claims for cash purchases as well as enrollee costs and amounts to be included in the enrollee’s gross covered drug costs and TrOOP.

50.4.3 – Direct Member Reimbursement  
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10; Implementation Date: 02-01-14)

Since publication of the Part D Final Rule (70 FR 4194) in 2005, CMS guidance for out-of-network access to covered Part D drugs, as stated in the preamble, notes that enrollees will likely be required to pay more for a covered Part D drug purchased out-of-network than one purchased at a network pharmacy, but explains that any out-of-network differential (that is, the difference between the out-of-network pharmacy’s usual and customary (U&C) price and the plan allowance) that an enrollee is required to pay for purchases made consistent with the Part D sponsor’s out-of-network access policy will count toward his or her TrOOP balance. For LIS-eligible individuals, the guidance states that CMS will pay the out-of-network differential, as applicable, for appropriate out-of-network purchases. The guidance was silent regarding the handling of the out-of-network differential for non-LIS-eligible individuals. As a result, the policy was ambiguous and sponsors have chosen to handle the differential in different ways. For example, some sponsors include only the negotiated price for the drug in the enrollee’s total gross covered drug cost accumulator (Prescription Drug Event (PDE) record field 45,) but include the differential in TrOOP.

Additionally, aside from the beneficiary cash purchase policy explained in section 50.4.2 of this chapter, no clear guidance has been available to sponsors concerning the reimbursement of beneficiary paper claims for covered Part D drugs from network pharmacies. To ensure consistent handling of out-of-network claims for both LIS and non-LIS eligible beneficiaries as well as paper claims for drugs accessed from network pharmacies, effective beginning in 2013 CMS is providing consistent guidance on direct member reimbursement in this section.
Section 1860D-4(b)(1)(C)(iii) of the Social Security Act required CMS to establish pharmacy access standards that include rules for adequate emergency access to covered Part D drugs by Part D enrollees. The special rules for out-of-network access to covered Part D drugs at pharmacies are specified in regulation (42 CFR 423.124) and discussed in chapter 5, section 60.1 of this manual. For out-of-network claims to meet the conditions for emergency access requires that the enrollee cannot be reasonably expected to obtain the covered Part D drugs at an in-network pharmacy and such access cannot be routine.

CMS regulations and guidance specifically address the requirement for Part D sponsors to issue standardized cards that may be used by an enrollee to ensure access to negotiated prices under section 1860D-2(d) of the Act. The only way that an enrollee can be assured access to the negotiated price at the point of sale is through online adjudication of the prescription drug claim. Therefore, to ensure access to these negotiated prices, the billing information on the standardized cards issued by the Part D sponsor must be used by the pharmacies at which beneficiaries fill their prescriptions to submit claims to an enrollee’s plan sponsor (or its intermediary). Thus, another price available to the beneficiary at the point of sale, for instance, the pharmacy’s “cash price,” would not be the negotiated price because it is not accessed by the use of the standardized card.

CMS encourages beneficiaries to use the Part D benefit, because generally it believes it is in the best interest of Part D enrollees to have their claims consistently processed through the Part D sponsor (or its intermediary). Not only does processing claims through the Part D sponsor ensure access to Part D negotiated prices, but it also ensures that proper concurrent drug utilization review (including safety checks) is performed (as required under 1860D-4(c) of the Act). Only the plan can prevent payment to excluded providers or conduct accurate concurrent drug utilization review when a beneficiary uses multiple pharmacies. Online, real-time processing also facilitates accurate accounting for enrollees’ true out-of-pocket (TrOOP) and total drug costs by the Part D sponsor so that each claim is processed in the appropriate phase of the benefit and accurate cost sharing assessed.

Guidance in section 50.4 of this chapter instructs plan sponsors to process all claims online and in real time. The requirements of accurate TrOOP accumulations, Part D benefit administration of multiple coverage intervals, and coordination of benefits with other payers all necessitate online, real-time adjudication of individual pharmacy claims. This guidance states further that CMS expects Part D sponsors will establish policies and procedures appropriately restricting the use of beneficiary-submitted paper claims to those situations in which online claims processing is not available to the beneficiary at point-of-sale (such as out-of-network pharmacies) in order to promote accurate TrOOP accounting as well as to minimize administrative costs to the Part D sponsors and the Medicare program and reduce opportunities for fraudulent duplicative claim reimbursements.
Having been made aware of an increasing number of instances in which network pharmacies were not submitting on-line pharmacy claims to Part D on behalf of Part D enrollees, CMS codified this guidance in regulation at §423.120(c)(3.) The pharmacies were discouraging beneficiaries from using their Part D benefit when going outside the benefit would have resulted in the same cost to the beneficiary because the pharmacies wanted to avoid incurring the claims transaction costs. As a result, the enrollee paid cash for the drug and submitted a paper claim to Part D for reimbursement. The regulation requires Part D sponsors to contractually mandate that their network pharmacies submit claims electronically to the Part D sponsor or its intermediary on behalf of the beneficiary whenever feasible unless the enrollee expressly requests that a particular claim not be submitted to the Part D sponsor or its intermediary.

Requirements for Direct Member Reimbursement: To ensure uniformity, the following table clarifies what these regulations require in terms of direct member reimbursement. The table specifies the requirements for direct member reimbursement involving out-of-network and in-network pharmacies and applies to all LIS beneficiaries and all others.
### Table 50.4.3-1-Direct Member Reimbursement Requirements

<table>
<thead>
<tr>
<th>Direct Member Reimbursement Situation</th>
<th>Part D Processing and Plan Paid Amount</th>
<th>Enrollee Costs</th>
<th>PDE Reporting of Total Gross Covered Drug Cost and TrOOP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Out-of-network pharmacy claim and requirements of 423.124 are met</td>
<td>Reimburse the plan allowance based on the U&amp;C price</td>
<td>Enrollee pays the cost-sharing under the plan based on the plan allowance plus the difference between the cash price and the plan allowance if the cash price is higher (i.e., the out-of-network differential)</td>
<td>Total Gross Covered Drug Cost = Cash price of drug</td>
</tr>
<tr>
<td></td>
<td></td>
<td>For LIS beneficiaries, the out-of-network differential is paid by CMS</td>
<td>TrOOP = Cost-sharing under the plan plus the difference between the cash price and the plan allowance if the cash price is higher</td>
</tr>
<tr>
<td>Out-of-network pharmacy claim and requirements of 423.124 are not met Enrollee voluntarily pays out-of-pocket at an in-network pharmacy and doesn’t submit a claim for reimbursement</td>
<td>Drug does not meet requirements for coverage</td>
<td>Enrollee is responsible for the total cash price</td>
<td>No Total Gross Covered Drug Cost or TrOOP are reportable</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No action required</td>
<td>No claim; therefore, no PDE and TrOOP is not reported</td>
</tr>
<tr>
<td>Enrollee voluntarily pays out-of-pocket at an in-network pharmacy and submits a claim for reimbursement</td>
<td>Reimburse the plan allowance based on the negotiated price for the drug</td>
<td>Enrollee pays the cost-sharing under the plan plus the difference between the cash price and the plan’s negotiated price if the cash price is higher</td>
<td>Total Gross Covered Drug Cost = negotiated price for the drug</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>TrOOP = Only the cost-sharing under the plan (calculated based on the plan allowance)</td>
</tr>
</tbody>
</table>
For out-of-network situations, CMS policy reflects the statutory protection for provision of adequate emergency access for Part D enrollees to covered Part D drugs. In out-of-network situations when the requirements of §423.124 are not met, the drug is not covered. Part D sponsors should employ their out-of-network policy to evaluate out-of-network claims and make payment determinations.

For cash purchases made at in-network pharmacies, CMS expects the enrollee to be responsible for the difference between the cash price and the plan’s negotiated price. As noted previously, under section1860D-2(d), Part D sponsors must provide enrollees with access to negotiated prices used for payment of covered Part D drugs. This requirement limits sponsor reimbursement to the negotiated price for the drug. Under §423.100, incurred costs are defined to include only costs incurred by the beneficiary for the annual deductible, or other cost-sharing prior to satisfying the out-of-pocket threshold, including the out-of-network price differential for which the individual is responsible when the requirements of §423.124 are met. Because in this instance the requirements of §423.124 are not met, the price differential incurred for cash purchases at an in-network pharmacy are not included in either the member’s gross covered drug costs or TrOOP.

Although CMS recognizes there may be circumstances when a cash purchase is reasonable—such as when the pharmacy’s or payer’s system is down—these would be extremely rare and, in the case of a systems outage, of brief duration. There may also be instances when a family member or other person who is filling a prescription on the enrollee’s behalf doesn’t have the enrollee’s card and the enrollee is not in the pharmacy’s system. However, at this point, CMS expects enrollees to use their Part D plan’s card or the family member or other person to identify the patient to the pharmacy as a Medicare beneficiary for the pharmacy to submit an E1 eligibility query to the Part D transaction facilitator. As noted above, because in these instances the differential between the cash price and the negotiated price would exceed the negotiated price, but would not meet the regulatory definition of incurred costs, the differential would not be reimbursed and would not count toward the enrollee’s gross drug costs or TrOOP.

CMS expects sponsors to implement this policy as soon as possible, but no later than February 1, 2014.

50.5 – Use of Standardized Technology
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

In the CMS-4085 Final Rule (75 FR 19678) published on April 15, 2010, CMS added a new paragraph (c)(2) to §423.120 which codified existing guidance that Part D sponsors use standard electronic transactions for processing Part D claims in compliance with CMS guidance on the use of optional or conditional fields in the HIPAA standard transactions when so instructed through Call Letter and Prescription Drug Benefit Manual instructions. The prior guidance in this section of the manual, previously entitled, “Standardized Claims Messaging,” was superseded by the new regulatory provision requiring Part D sponsors to utilize standardized electronic transactions
established by 45 CFR 162.1102 for processing Part D claims. The preamble of the above-referenced regulation notes that CMS routinely works with NCPDP and industry representatives to arrive at recommendations for standardized use of optional or conditional fields when necessary to improve the administration of the Part D benefit and will issue guidance on the use of these fields within such standards. An example of such guidance would include section 50.4 of this chapter on “Processing Claims and Tracking TrOOP.” Such instructions are consistent with the rules governing use of HIPAA transactions whereby use of optional and conditional fields is governed by contractual terms between trading partners.

50.5.1 – Primary Payer Use of Optional Fields to Support COB
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

CMS recognizes version D.0 (and any future version) of the NCPDP Telecommunication Standard Implementation Guide as the official vehicle for establishing the special electronic processing rules to be used in coordinating benefits and generating the N1 transaction. Unlike earlier versions, D.0 requires that primary payers provide certain fields in the response pricing segment of the telecommunication standard that support COB. These fields include “Amount Applied to Periodic Deductible” [517-FH] and “Amount of Copay,” [518-FI] if the amount reported in “Patient Pay Amount” [505-F5] includes a deductible and/or copay amount, and “Benefit Stage Amount” [394-MW] and “Benefit Stage Qualifier” [393-MV]. These fields assist secondary payers in administering their benefit and when provided by the primary payer, can be transmitted by the pharmacy to the secondary payer.

50.6 – Accepting Payment of Premiums from Other Payers
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

As provided by the MMA, supplemental payers may wish to pay premiums on behalf of Part D enrollees instead of (or in addition to) providing wrap-around coverage. Part D sponsors are required to facilitate the billing and collection of such premiums. While Part D sponsors must accept premium payments by supplemental payers on behalf of their Part D enrollees, the details of such arrangements are strictly between Part D sponsors and those payers. Part D sponsors should ensure that in accordance with the uniform premium requirement, the total premium payment for a beneficiary does not vary among plan enrollees, except in the case of employer group plans for which this requirement has been waived in part.

A beneficiary must not be disenrolled from a Part D sponsor if it has been notified that the premiums are being paid by an SPAP or other payer and the sponsor has not yet coordinated receipt of the premium payments with the SPAP or other payer. In these cases, Part D sponsors are required to work directly with the SPAPs or other payers to systematically coordinate and accept premium payments in accordance with the Federal regulations at 42 CFR 423.464(a)(1). That is, sponsors must bill the SPAP or other payers directly for the beneficiary’s premium and not bill the beneficiary. Until the sponsor can bill the SPAP or other payers directly, sponsors will not be in compliance.
with the coordination of benefit requirements. Sponsors must not take any action, including sending disenrollment notices directly to the beneficiary, to disenroll the beneficiary for failure to pay premiums when the sponsor has failed to coordinate the collection of premiums from other payers.

Sponsors currently receive data from CMS in the COB file indicating which beneficiaries are covered under SPAPs. The Supplemental Type Code data field of the COB file (see the PCUG, Appendix F.5.4) indicates the type of supplemental coverage a beneficiary has. An indicator of 'Q' identifies a beneficiary with qualified SPAP coverage. (Refer to Appendix B for the PCUG Web site.) Sponsors could use this data to withhold systematic release of disenrollment notices to these enrollees when an SPAP is paying on behalf of the enrollee.

In addition to accepting payment of premiums from other payers, Part D sponsors may wish to consider providing advance notice to such payers when an enrollee is at risk of losing coverage due to failure to pay their portion of a premium.

50.7 – Coordinating Payment of a Lump Sum for Supplemental Coverage
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

The MMA specifies that CMS’ COB requirements must include a method for the application by a Part D sponsor of specified funding amounts (i.e., a lump sum per capita method) from an SPAP for supplemental prescription drug benefits. These COB requirements also apply to other entities providing supplemental drug coverage. Consequently, Part D sponsors are required to coordinate the receipt and management of lump sum arrangements with other payers. It is important to note, however, that the cost sharing funded by lump sum amounts will generally only apply toward TrOOP if made by a qualified SPAP, an ADAP, the IHS/Tribal coverage, or a bona fide charity, and if made for expenditures on covered Part D drugs before the beneficiary reaches the annual out-of-pocket threshold.

SPAPs (and other prescription drug plans) may choose to provide their wrap-around benefits to Part D beneficiaries using four basic approaches:

1. Pay premiums for basic and/or supplemental benefits offered by Part D sponsors.

2. Wrap-around benefits at the point-of-sale; i.e., the pharmacy files a secondary claim to the SPAP (or its processor) for payment.

3. Contract with Part D sponsors on a risk or non-risk-based lump sum per capita method; i.e., solicit lump sum per capita bids from Part D sponsors in exchange for the provision of wrap-around benefits.

4. Provide some combination of these approaches.
Regardless of the approach adopted, SPAPs and other prescription drug plans:

- In accordance with §1860D-23(b)(2) of the Social Security Act, must not discriminate in determining either eligibility or the amount of assistance to Part D enrollees based on the Part D plan in which the SPAP beneficiary enrolls. The non-discriminatory standards also apply to education and enrollment of beneficiaries by the SPAP and to co-branding with Part D sponsors. Therefore, the State must ensure that its beneficiaries receive equal access to enrollment in, and comparable information on, all the Part D sponsors participating in the chosen approach, without any steering to particular plans.

- Cannot request Part D sponsors violate Part D rules.

- May offer a benefit package to eligible beneficiaries that is more than Part D, but cannot be less.

Guidance concerning the requirements on SPAPs with respect to non-discriminatory beneficiary education, enrollment and co-branding activities exists on CMS’ Web site; for example, guidance on co-branding with SPAPs is included in the Medicare Marketing Guidelines available on the CMS Web site; see Appendix B for the specific Web address.

50.7.1 – **Lump Sum Per Capita Approach**  
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

States that elect to adopt a lump sum per capita approach must issue a request for quote (RFQ) inviting all Part D sponsors in the region to submit a quote (note – the quote is for the increment above basic benefits) and must work with all sponsors that respond. As part of the State’s RFQ and contract, any Part D sponsor that submits a quote would be required to accept the lump sum per capita payments made by the State under its chosen approach.

Part D sponsors that do not opt to participate in this market are not required to submit quotes. However, if a sponsor is not participating in the State’s lump sum approach, the State should still explain that beneficiaries may enroll in that sponsor’s plan, but the beneficiaries will get only basic coverage – without the SPAP additional defined benefit – if they do so. Also, States are not obligated to provide wrap-around benefits to any beneficiaries choosing to enroll in non-participating Part D plans, or to promote these Part D plans, but a State electing to do so may provide wrap-around coverage on behalf of SPAP beneficiaries choosing to enroll non-participating Part D plans. In fact, if the SPAP also elects to pay the premium for all basic benefits, this approach does not permit the SPAP to exclude payment of premium for any Part D sponsors not participating in the lump sum approach.

The regulation at 42 CFR 423.464(a) requires that Part D sponsors must coordinate with SPAPs and other entities providing other prescription drug coverage. This includes scenarios when the SPAP or other payer is adopting a lump sum per capita approach.
when supplementing Part D benefits in accordance with section 42 CFR 423.464(a)(2). Therefore, CMS requires all Part D sponsors to have the capacity to participate in non-risk based arrangements, if offered by the State, SPAPs or other payers so that their enrollees can receive coordinated, wrap-around coverage at the point-of-sale. If a sponsor is out of compliance with this regulatory requirement, CMS will not disqualify a state program from its qualified SPAP status. CMS will not view SPAPs as discriminating, in violation of section 1860D-23(b)(2) of the Act, due to a Part D sponsor’s failure to adhere to this COB requirement.

50.8 – Transferring TrOOP Balance When a Beneficiary Changes Part D Sponsors
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

Part D rules require sponsors to track the beneficiary’s TrOOP and correctly apply these costs to the TrOOP limit in order to provide enrollees the catastrophic level of coverage at the appropriate time. The TrOOP threshold is calculated on an annual basis and must be transferred between Part D sponsors if a beneficiary disenrolls and re-enrolls at any time before the end of a coverage year or whenever a PartD plan other than the plan of record has paid. Sponsor collection, and transfer if appropriate, of the TrOOP and gross covered drug spending balances are essential for sponsors to correctly manage the Part D benefit.

50.8.1 – Automated TrOOP Balance Transfer Process
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

In 2009, Part D sponsors began using the NCPDP Financial Information Reporting (FIR) standard to transfer TrOOP balances and gross covered drug costs whenever a beneficiary makes an enrollment change at the contract-level during the coverage year. The transfer process begins with the transaction facilitator's identification of a change in enrollment at the contract level. Upon identification of the change, the facilitator generates a FIR transaction to each prior sponsor with which the beneficiary was enrolled or that paid covered part D drug claims for the beneficiary during the coverage year. Transactions begin with a FIR Inquiry to the earliest sponsor on record in the coverage year; that sponsor's Inquiry response is returned to the facilitator. Each sponsor responds with their monthly gross covered drug costs and TrOOP amounts. If there are multiple plans prior to the current plan of record, the accumulator values from the response just received are placed in a FIR Exchange transaction and forwarded to the next sponsor. The facilitator receives that next sponsor’s transaction response and continues the process of receiving and forwarding the prior accumulators until each subsequent sponsor in consecutive order has received and responded to a FIR Exchange transaction. The final Exchange transaction response contains the year-to-date monthly TrOOP-related data for all plans prior to the current plan of record; these accumulated monthly amounts are then forwarded by the facilitator via a FIR Update transaction to the current plan of record.
An updated version of the CMS automated TrOOP balance transfer implementation guidance issued by CMS on October 20, 2008, is included in Appendix C. Detail on the FIR transaction standard is provided in the NCPDP Financial Information Reporting Standard Implementation Guide v1.0 and is available to NCPDP members on their Web site; see Appendix B for the specific Web address.

Plan sponsors are notified of unsuccessful transactions via daily beneficiary-level exception reports from the transaction facilitator to both the sponsor’s processor’s and the sponsor’s automated Troop Balance Transfer (TBT) contacts (as entered in the Health Plan Management System (HPMS)). CMS expects that when issues arise, they are resolved expeditiously to achieve successful transfer of the beneficiary data in a timely manner 100 percent of the time. Sponsors should not delegate problem-solving to their claims processor alone; certain issues leading to transaction failure are beyond the scope of the processor’s responsibility. For example, a significant number of problems that have occurred to-date appear to stem from inconsistencies between the 4Rx data reported to CMS and used by the transaction facilitator for the TBT transactions, and the 4Rx data in the sponsor’s processor system. It is the responsibility of the Part D sponsor to ensure that consistent beneficiary-identifying data are reported to CMS and its Part D claims processor, and that any inconsistencies are corrected. Part D sponsors must ensure not only that they or their delegated enrollment-processing vendors submit accurate 4Rx data on behalf of all enrollees upon enrollment in accordance with section 50.1 of this chapter, but also that previously submitted 4Rx data are updated within CMS whenever processing arrangements cause this data to change for existing enrollees.

NOTE: If a sponsor changes its FIR processor, the sponsor must ensure that FIR transactions are routed to the appropriate processor and that transactions related to the prior year can continue to be processed for the 36-month period required by CMS (42 CFR 423.466(b)). This may require making arrangements either with the former processor to continue processing prior year FIRs or with the new processor to assume that responsibility. However, since the automated FIR process for a year continues only until the end of the subsequent June, any TrOOP balance transfers after that point would require manual processing. See section 50.14 of this chapter for more information on the 36-month time period and Appendix C for more information on the FIR process.

50.8.2 – TrOOP Balance Transfer When CMS Terminates a Part D Sponsor Contract
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

In 2011, CMS added §423.509 (e) to Part D regulations, to articulate the requirement to provide the timely transfer of beneficiary data and files, including TrOOP-related accumulators, from those Part D sponsor contracts terminated by CMS to a beneficiary’s new Part D sponsor. When CMS terminates a contract it must have assurances that the sponsor will maintain sufficient staff and operations to make a smooth transition of the sponsor’s enrollees to their new Part D plan, while facilitating continuity of care and fiscal responsibility.
This new regulation informs Part D sponsors that they are required by Federal regulation to maintain and provide access to all requested data and files to CMS or its designee for the required time as specified under §423.505 (d) and (e). Plans that fail to comply with this requirement may be subject to a Civil Monetary Penalty as defined in §422.752 (c) and §423.753 (c).

50.9 – **Special Transition Period for Retroactive Enrollment Situations**  
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

In 2007, CMS implemented a special transition period, which is available to all Medicare beneficiaries, with important COB implications that require Part D sponsors to provide limited reimbursement for covered Part D drugs for a time immediately preceding the minimum 30- or 90-day transition period. This requirement applies to those situations involving:

a) Enrollees whose enrollment request was not processed to completion until after the effective date of coverage; and

b) Enrollees who have been retroactively enrolled in a Part D sponsor by CMS. These latter situations almost exclusively involve enrollees who are full-benefit dual eligible beneficiaries.

Although CMS works with the States to identify beneficiaries in advance of the date they will become dually eligible in order to minimize issues involving retroactivity, there are some situations when CMS will not be able to identify a dual eligible beneficiary in advance. Because eligibility for Medicaid may be retroactive for up to 3 months prior to the month in which the Medicaid application was filed, and Medicaid applications frequently require significant time for the State to process, periods of retroactivity can continue to be several months in duration. CMS expects that this problem will usually be mitigated by the fact that, as a Medicare beneficiary, the individual will have had an opportunity to enroll in a Part D sponsor’s plan and apply for the low-income subsidy. For those who do enroll in a Part D plan, and then are determined retroactively eligible for Medicaid, the effective date of their Part D plan enrollment will be adjusted to the later of the first of the month the beneficiary is dually eligible, or January 2006.

In 2006, with respect to claims incurred during a period covered under actual Part D enrollment, Part D sponsors were responsible for paying or reimbursing the costs of an enrollee’s Part D covered drugs to the extent that the sponsor would have paid as a primary payer. If the enrollee’s existing drug regimen required prior authorization or included non-formulary drugs, and the retroactive period preceded the sponsor’s transition period, this may have resulted in gaps in coverage. Coverage gaps may also have resulted from out-of-network pharmacy status or pricing in excess of the sponsor’s negotiated rates that were paid by the enrollee or another payer on the enrollee’s behalf.

In the years 2007 through 2009, CMS required sponsors to provide a special transition period to accommodate claims incurred during a 7 month (or less) period of retroactive
eligibility. As mentioned at the beginning of this section, this special transition period is available to all Medicare beneficiaries. During the special transition period, standard transition rules apply, but sponsors are responsible for the allowable charges paid by other third party payers for all Part D drugs, including non-formulary drugs provided outside the transition period and formulary drugs with prior authorization requirements. The enrollee, or CMS in the case of low-income subsidy individuals, is responsible for any out-of-network or pricing differentials.

In January 2010, CMS implemented a new demonstration project, known as the limited income newly eligible transition (NET) program, to handle situations involving retroactive Part D enrollment. Under the demonstration, a single, competitively procured Part D sponsor will cover all Part D prescription drug claims for all periods of retroactive Part D coverage for full benefit dual eligible and SSI-eligible enrollees as well as POS coverage at the pharmacy for certain LIS individuals who are not yet enrolled in a Part D plan. Beneficiaries who are retroactively auto/facilitated enrolled by CMS and LIS beneficiaries confirmed eligible for the demonstration will be temporarily enrolled in the demonstration contractor’s plan. These enrollees will subsequently be randomly prospectively auto/facilitated enrolled in a qualified PDP. The low-income NET demonstration eliminates the routine need for sponsors to reimburse claims incurred by individuals eligible for the program during periods of retroactive Part D enrollment.

Sponsors, however, retain responsibility for making retroactive claims adjustments for beneficiaries enrolled in a sponsor’s Part D plan who become retroactively eligible for Medicaid during the period of Part D enrollment. For example, a beneficiary has been enrolled in a Part D plan since January 1, 2009 and in December 2009 receives a notice of Medicaid eligibility effective March 1, 2009. The sponsor is responsible for retroactively adjusting the enrollee’s cost-sharing for claims incurred beginning March 1, 2009 forward, in accordance with the guidance in section 50.14.3.

50.9.1 – Automated TrOOP Balance Transfer Process
(Rev. 12, Issued: 03-19-10, Effective Date: 01-01-10; Implementation Date: 01-01-10)

Effective January 1, 2009, Part D sponsors must use the new NCPDP Financial Information Reporting (FIR) standard to transfer TrOOP balances and gross covered drug costs whenever a beneficiary makes an enrollment change at the contract-level during the coverage year. The transfer process begins with TrOOP facilitator's identification of a change in enrollment at the contract-level. Upon identification of the change, the facilitator generates a FIR transaction to each prior sponsor with which the beneficiary was enrolled or which paid covered part D drug claims for the beneficiary during the coverage year. Transactions begin with a FIR Inquiry to the earliest sponsor on record in the coverage year; that sponsor's inquiry response is then returned to the facilitator. Each sponsor responds with their monthly gross covered drug costs and TrOOP amounts. If there are multiple plans prior to the current plan of record, the accumulator values from the response just received are placed in a FIR Exchange transaction and forwarded to the
next sponsor. The facilitator receives that next sponsor’s transaction response and continues the process of receiving and forwarding the prior accumulators until each subsequent sponsor in consecutive order has received and responded to a FIR Exchange transaction. The final Exchange transaction response contains the year-to-date monthly TrOOP-related data for all plans prior to the current plan of record; these accumulated monthly amounts are then forwarded by the facilitator via a FIR Update transaction to the current plan of record.

An updated version of the CMS automated TrOOP balance transfer implementation guidance issued by CMS on October 20, 2008, is included in Appendix C. Detail on the FIR transaction standard is provided in the NCPDP Financial Information Reporting Standard Implementation Guide v1.0 is available to NCPDP members on their Web site; see Appendix B for the specific Web address.

Plan sponsors are notified of unsuccessful transactions via daily beneficiary-level exception reports from the TrOOP facilitator to both the sponsor’s processor’s and the sponsor’s automated Troop Balance Transfer (TBT) contacts (as entered in the Health Plan Management System). CMS expects that when problems arise, problems are resolved expeditiously to achieve successful transfer of the beneficiary data in a timely manner 100 percent of the time. Sponsors should not delegate problem-solving to the sponsor’s claims processor alone; certain issues leading to transaction failure are beyond the scope of the processor’s responsibility. For example, a significant number of the problems that have occurred to-date appear to stem from inconsistencies between the 4Rx data reported to CMS and used by the TrOOP facilitator for the TBT transactions and the 4Rx data in the sponsor’s processor system. It is the responsibility of the Part D sponsor to ensure consistent beneficiary-identifying data are reported to CMS and its Part D claims processor and any inconsistencies are corrected. Part D sponsors must ensure not only that they or their delegated enrollment-processing vendors submit accurate 4Rx data on behalf of all enrollees upon enrollment in accordance with section 50.1 of this chapter, but also that previously-submitted 4Rx data are updated with CMS whenever processing arrangements cause the 4Rx data to change for existing enrollees.

50.10 – Sharing Formulary Information with Other Payers
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

Although Part D sponsors may share detailed information about their formularies (in electronic format) with other payers upon request, there is no specific requirement that they do so. CMS has made the Medicare Prescription Drug plan information available for purchase in Public Use Files (PUFs). These files contain all plan and formulary data for all of the plans with the exception of the pricing data, which is considered proprietary. This is the only data set that is publicly available. Further information is available on the CMS Web site; see Appendix B for the specific Web address.

In addition, as required by 42 CFR 423.120(b)(5)(i), sponsors will be required to inform other payers of formulary changes (i.e., formulary deletions or changes in the tiering status of a drug) at least 60 days in advance of the change. This may
be accomplished by posting the new or changed information on Part D sponsor Web sites.

50.11 – **Sharing Claims Data**
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

CMS does not have the authority to require data exchanges between Part D sponsors and States except as required for COB purposes. While the MMA requires Part D sponsors to allow SPAPs and other entities providing prescription drug coverage to “coordinate” with them, this language does not support requirements on the coordination of anything but payment. However, CMS strongly encourages Part D sponsors to independently share historical and ongoing data on any shared enrollees with other payers – particularly with States – provided such disclosure is consistent with the requirements of the HIPAA Privacy Rule. CMS encourages Part D sponsors to discuss reciprocal arrangements with State Medicaid Plans under which Part D sponsors would provide Part D drug claims data in exchange for both historical prescription drug claims data and ongoing medical claims (particularly diagnoses) on the dual eligible population to assist with medication therapy management (MTM) and other quality assurance programs. CMS also encourages sponsors to provide this reciprocal data exchange without charging any user fees.

Part D sponsors and States may negotiate details regarding the development of a Standard File Format for Patient Drug History and Standard Data Sharing Agreement. NCPDP, which is the national standards organization for pharmacy claims, has adopted the Post Adjudication Standard. Section 10 of the “Post Adjudication Standard Implementation Guide, Version 4.2” contains the “Post Adjudication Utilization Record,” which is the recommended standard record States and Medicare Part D sponsors could use to exchange drug history information. In order to access the NCPDP documentation and use the Post Adjudication Utilization Record, States and/or their contractors must be members of NCPDP.

If the States and Medicare Part D sponsors agree to exchange enrollees’ drug history information, then States and sponsors are new business associates. Thus, it is necessary that the exchange of data complies with HIPAA requirements. To adhere to HIPAA requirements, a Patient Drug History Data Sharing Agreement signed by the Medicare Part D sponsor and the State must be in place prior to executing file transfers between these entities.

CMS believes States have the authority under 42 USC §1396a(a)(25) to request information to coordinate benefits they may have paid under the State Medicaid program. CMS encourages Part D sponsors to review 42 USC §1396a(a)(25) as well as the related CMS guidance.

50.12 – **Applying Medicare Secondary Payer (MSP) Requirements**
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)
The MMA (§1860D-2(a)(4)) extended MSP requirements that are applicable to MA organizations to include Part D sponsors. Accordingly, Part D sponsors will have the same responsibilities under MSP requirements as MA plans, including the collection of mistaken primary payment from insurers, group health plans, employer sponsors, enrollees, and other entities; and the relationship between MSP rules and State laws. Part D sponsors must properly apply MSP requirements and regulations to their payments (e.g., working aged, worker’s compensation (WC)).

Part D sponsors are responsible for adjudicating enrollees’ claims in accordance with the following MSP requirements. Also, sponsors are responsible for identifying and recovering any MSP-related mistaken payments and submitting associated adjustments to CMS.

According to statute, Medicare is the secondary payer in the following situations:

1. **Employer group health plans (EGHP) MSP**
   
a. **Working Aged GHP** – The beneficiary is actively working and is covered under the employer's GHP or the beneficiary's spouse is actively working and the beneficiary is covered under the spouse's employer GHP (≥20 employees; or another employer in GHP≥20 employees.) (42 U.S.C. §1395(y)(b)).

b. **Disability with GHP** – The beneficiary is actively working for a large employer and is covered under the employer's GHP, or a beneficiary’s family member is actively working for a large employer and the beneficiary is covered under the family member’s employer GHP (LGHP, ≥100 employees).

c. **End Stage Renal Disease (ESRD) GHP** – GHP (any size) is primary for the first 30 months when an individual also becomes eligible for Medicare Part A due to ESRD status. After 30 months of Part A eligibility, Medicare becomes primary.

2. **Non-GHP MSP**
   
a. **WC** – Beneficiary covered under WC due to job-related illness or injury.

b. **Black Lung (BL)** – The beneficiary has black lung disease and is covered under the Federal Black Lung Program.

c. **No-Fault/Liability** – The beneficiary is covered by no-fault or liability insurance due to an accident.

However, Part D sponsors should not immediately pay only as a secondary payer. The action required of the Part D sponsor is dependent on the type of other primary payer as follows:
1. For the types of Employer Group Health Plans (EGHP) listed above, the Part D sponsor will always deny primary claims that fall within the EGHP’s applicable coverage dates and default to MSP. The types, as listed above, include: working aged GHP, disability GHP, and ESRD GHP for first 30 months of Medicare Part A eligibility.

2. For WC, BL, and No-Fault or Liability coverage, the sponsor will always make conditional primary payment unless the sponsor is aware that the enrollee has WC/BL/No-Fault/Liability coverage and has previously established that a certain drug is being used exclusively to treat a related injury. For example, when a beneficiary refills a prescription previously paid for by WC, the Part D sponsor may deny primary payment and default to MSP.

In all other instances, the Part D sponsor is required to make conditional primary payment then recover any mistaken payments where it should have only paid secondary to WC/BL/No-Fault/Liability coverage. For example, if a sponsor does not know whether a given drug for which it is billed is related to the covered injury, the sponsor must pay for the drug (if it is a covered Part D drug) and later recoup any amounts that the other insurance should have covered.

If the sponsor has established it should pay only secondary for a Part D enrollee and receives a primary claim, the sponsor should not pay the primary claim. Rather, receipt of the primary claim should prompt the sponsor to question whether MSP requirements continue to apply. If MSP is no longer applicable, this information should be reported to the COB contractor via ECRS to update CMS.

Similarly, absent information on the COB file that Part D is secondary for a Part D enrollee, should the sponsor receive a secondary claim, the claim cannot be paid. Instead, the sponsor should determine if the enrollee has coverage that is primary to Medicare and, if so, report this information to the COB contractor via ECRS to update CMS.

The following sections provide clarification regarding a limited number of MSP situations; however, Part D sponsors are required to apply all MSP requirements, whether or not they are specifically mentioned here.

50.12.1 – Workers’ Compensation
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

Medicare may not pay for any item or service when payment has been made, or can reasonably be expected to be made, for such item or service under a WC law or plan of the United States or any State. CMS recognizes that diagnostic information is not collected at the point of sale, however, Part D sponsors are expected to make good faith efforts to identify claims associated with WC.
It is imperative that Medicare’s interests be protected when parties enter into WC settlements. One method of protecting Medicare’s interest in a WC situation is a Workers’ Compensation Medicare Set-aside Arrangement (WCMSA), which allocates a portion of the WC settlement for future medicals and future prescription drug expenses. “Future medicals and future prescription drugs” are those services and items provided after the final WC settlement. CMS recommends Medicare beneficiaries (and individuals who expect to become entitled to Medicare within 30 months of receiving a WC settlement) who are parties to WC settlements, judgments or awards submit WCMSA proposals to CMS for review prior to settlement to ensure Medicare’s interests are considered. CMS reviews WCMSA proposals for Medicare beneficiaries with WC settlements greater than $25,000 and for individuals who are within 30 months of Medicare entitlement and possess a WC settlement greater than $250,000. Based on this review, CMS will either concur with the proposal or determine a different amount deemed adequate in order to protect Medicare’s interest. Additional information regarding CMS’ WCMSA policies, procedures and guidelines is available on the CMS Web site; refer to Appendix B for the specific Web address.

WCMSA funds are administered by the claimant or a professional administrator employed by the workers’ compensation employer, carrier or the claimant. CMS keeps a record of the WCMSA amount determined by CMS to be adequate to protect Medicare’s interests with regard to the claimant’s future medical treatment and/or prescription drug expenses. The claimant/professional administrator is responsible for submitting an annual attestation form or professional accounting to the Medicare contractor. This document attests that the claimant has appropriately expended the WCMSA funds for that year.

In order to assist the Part D sponsors in making proper payments to WCMSAs, at the end of 2009, CMS began including costs related to prescription drugs in its settlements and reporting WCMSAs under a distinct non-GHP MSP cost on the COB file. The WCMSA amount reported on the COB file is the combined amount for future medicals and future prescription drug costs related to the WC injury. In addition, the file will include the administrator’s name, address and telephone number, the WCMSA settlement date, the total prescription drug settlement amount, and an indicator specifying whether prescription drug costs are included in the WCMSA amount.

Beginning in 2010, if the COB file record received from CMS indicated prescription drugs are included in the WCMSA, Part D sponsors continued to make conditional primary payment under Part D and promptly contact the administrator to determine which claims should not be paid for under Part D. Once the Part D sponsor established that a certain drug was included in the set-aside, the sponsor set appropriate point-of-sale edits, denied payment and rejected the claim for billing to the primary payer.

Exhaustion of the combined WCMSA amount includes both services (i.e., future prescription drug treatment and future medicals). For example, if the total WCMSA amount provided to the Part D sponsors is $10,000, this amount can include $7,000 for future prescription drug treatment and $3,000 for future medical expenses. However,
Part D sponsors must understand that although the total WCMSA amount is $10,000, the final actual expenditures could be $6,000 for future prescription drug treatment and $4,000 for the future medical expenses, which will still appropriately exhaust the WCMSA.

The Part D sponsors do not have the ability, via ECRS, to report the exhaustion of a WCMSA fund. The beneficiary is provided paperwork, in the WCMSA approval package, to complete and mail to the MSPRC when WCMSA funds have been exhausted. Once the documents are received, the MSPRC will then take the steps necessary to notify the COBC of this development. The CMS Regional Offices also have the ability, via ECRS, to report the exhaustion of WCMSA funds. Once the entire CMS-approved WCMSA has been properly exhausted, the Medicare Part D plan sponsor resumes responsibility for paying claims for covered Part D drugs.

50.12.2 – Flexible Savings Accounts (FSAs), Health Savings Accounts (HSAs), Archer Medicare Savings Accounts (MSAs), and Health Reimbursement Accounts (HRAs)
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

HSAs, FSAs, and MSAs

Part D sponsors should not require enrollees to use the funds in their FSAs, HSAs, or MSAs before making payments when the group health plans attached to those accounts are primary under the MSP laws. However, note that an enrollee would only have an FSA or HSA when these accounts are carried over from an employee health plan. An enrollee may have an MSA at any time; it is similar to the plan attached to an HSA, but is offered exclusively to Medicare beneficiaries.

HRAs

However, under the MSP group health plan laws (e.g., when an enrollee with current employment status has an HRA through his employer), sponsors should make secondary payments after HRA funds are used.

When an enrollee is non-working, an HRA is secondary to Medicare, but drug costs paid or reimbursed from the HRA are not TrOOP-eligible.

50.13 – Executing Business Associate Agreement (BAA) with Part D Transaction Facilitator
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

Consistent with the HIPAA Privacy Rule (45 CFR Parts 160 and 164), the transaction facilitator will be a business associate of Part D sponsors for the purpose of performing TrOOP facilitation and COB functions when it receives data directly from the sponsor. Currently, the facilitator receives data from a sponsor whenever a beneficiary makes a contract-level enrollment change during the coverage year, and the automated TrOOP
balance transfer process is triggered. In that process, the transaction facilitator receives data from the disenrolling Part D plan as well as from any prior Part D plan in which the beneficiary was enrolled during that coverage year. Note that the BAA requirement is applicable not only to sponsors directly reporting the TrOOP accumulators to the transaction facilitator, but also to sponsors using a processor for the automated TrOOP balance transfer process. Therefore, it is critical that each Part D sponsor has a signed agreement with the Transaction Facilitator. However, the requirement for a BAA can be met by either the sponsor having a signed agreement with the transaction facilitator or the sponsor’s processor entering into a BAA with the facilitator on behalf of the plan sponsor. A BAA executed between the sponsor and their processor is not sufficient to meet this requirement because, in the automated TrOOP balance transfer process, the facilitator is doing work on behalf of the plan sponsor. Therefore, there must be an executed BAA between either the sponsor or the sponsor’s subcontractor (that is, the processor) and the transaction facilitator. If the sponsor has a BAA with the facilitator, the sponsor’s PBM/processor is not required to enter into separate BAA with the transaction facilitator, since data at the PBM/processor will be protected through the BAA between the Part D sponsor and the PBM. To facilitate the execution of these agreements between the transaction facilitator and the Part D sponsors, CMS has developed a standard language business associate agreement and sponsors are strongly encouraged to sign this agreement without modification.

50.14 – Payment Reconciliation
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

Because of program start-up issues in 2006, lags in the information available to pharmacies at the point-of-sale regarding which Part D sponsor to bill for a prescription may have resulted in the pharmacies’ having access to outdated or incomplete information. Because pharmacies generally relied in good faith on this information, in some cases the wrong payer paid for a prescription. Given the volume of drug claims that pharmacies would need to re-adjudicate as a result of incorrect Part D enrollment information available at the point-of-sale, re-adjudication would have imposed a significant administrative and financial burden on pharmacies. Therefore, payer-to-payer reconciliation procedures were developed to mitigate the administrative and financial burden involved with re-adjudication of claims.

Although this payer-to-payer process was designed initially to be a temporary measure during Part D’s start-up phase, CMS requires that sponsors continue to use the payer-to-payer process. In addition, unforeseeable future events may necessitate processes to reconcile payments when a payer other than the correct Part D sponsor of record pays as primary for a covered Part D drug for an enrollee. These other reconciliation processes may be developed by CMS to accomplish payment reconciliation without involving pharmacy reversal and re-adjudication of claims or the public release of a payer’s proprietary information, such as negotiated rates.

50.14.1 – Plan-to-Plan Reconciliation During Transition Periods
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)
Beneficiaries have the opportunity to change their Part D plan enrollment during the coverage year, which consequently creates situations in which, due to lags associated with the enrollment process and information systems updates, the sponsor from which a beneficiary has transferred makes payment for covered prescription drug costs incurred after the effective date of the beneficiary's enrollment in the new sponsor of record. In 2006, CMS developed a plan-to-plan (P2P) reconciliation process with sponsor participation. This process, implemented in three phases, enables CMS to process prescription drug event (PDE) data in these P2P transition situations and allow for financial reconciliation between the affected Part D sponsors. The process's design reflects the consensus of sponsor participants to prevent disclosure of proprietary pricing information by masking the NDC coding. Furthermore, to protect sponsors from exposure to costs outside the initial formulary transition period, CMS established a 30-day P2P transition period. Therefore, the P2P transition period includes claims with dates of service less than or equal to the later of:

1. 30 days after the effective date of the new plan enrollment, or
2. 30 days after the date CMS processes the new contract of record enrollment.

To address the payment reconciliations needed to resolve these enrollment transition issues, CMS requires the ongoing use of the P2P reconciliation and reimbursement process. Therefore, throughout each coverage year, Part D sponsors will continue to receive monthly P2P reports showing the payables and receivables for which financial settlement is required. PDE guidance describing the process is available on the CMS Web site; see Appendix B for the specific Web address.

50.14.2 – Other CMS-Defined Reconciliation Processes
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

Unforeseeable future events may create the need for processes requiring Part D sponsors to coordinate benefits on a timely basis with other third parties and use CMS-developed reconciliation processes, when established, in situations in which a payer other than the correct Part D sponsor of record pays for covered Part D drug costs as a primary payer. This includes, for example, the scenario in 2006, with the State-to-Plan Reconciliation Project in which some States made drug payments for dual eligible beneficiaries and low-income subsidy entitled beneficiaries enrolled in Part D and were subsequently reimbursed by CMS through a special demonstration authority. Processes similar to the State-to-Plan Reconciliation process employed in 2006 may need to be developed by CMS in lieu of requesting pharmacy claims reversals and re-adjudications or the public release of a payer’s proprietary information (e.g., negotiated prices).

50.14.3 – Retroactive Claims Adjustments
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)
Part D sponsors must coordinate benefits with SPAPs and other providers of prescription drug coverage and appropriately adjudicate claims. Compliance with this requirement entails that the sponsor not only coordinate benefits with other payers at POS, but also work with beneficiaries and other payers to resolve post-adjudicative payment issues arising from retroactive claims changes.

Retroactive claims adjustments can be necessitated by beneficiary changes (such as those resulting from retroactive LIS eligibility determinations, LIS status changes, or midyear Part D enrollment changes), sponsor receipt of other payer information, or errors in payer order. Some of these changes, i.e., those occurring within the payers’ timely filing window (which must be a minimum of 90 days for Part D, but may be as short as 30 days, for other (non-Part D) payers) may be addressed through pharmacy-initiated reverse and rebill transactions. However, as specified in section 50.15.5 of this chapter, sponsors generally should limit requests for pharmacy reprocessing to those situations involving a payment error. All retroactive claims adjustments that cannot be addressed through pharmacy reverse and rebilling must be handled by the Part D sponsor through other means.

Post-adjudicative changes, such as those that are due to enrollment changes, are changes that affect beneficiary cost-sharing, premiums and/or plan benefit phase. Part D sponsors must make the retroactive adjustments timely and promptly issue refunds or initiate recovery once complete information regarding the claims adjustment is received. Federal regulations at §423.466(a) require sponsors to process the adjustment and issue refunds or recovery notices within 45 days of receipt of information necessitating the claims adjustment. Federal regulations at §423.800(e) apply this same timeframe to retroactive adjustments to cost-sharing for low-income subsidy eligible individuals.

Federal regulations at §423.800(c) require plan sponsors to reimburse beneficiaries amounts owed due to changes in LIS status. However, as specified in chapter 13, section 70.3.1 of this manual, sponsors must make reasonable efforts to determine which party should be reimbursed; i.e., the beneficiary or other party who paid on the beneficiary’s behalf, for the excess cost sharing paid during a period of LIS retroactive coverage. Sponsors should develop procedures for making these reimbursement determinations and not adopt a “one size fits all” approach. Specifically, sponsors should not automatically reimburse beneficiaries residing in LTC facilities, since it is unlikely that the LTC pharmacy has collected the applicable cost-sharing due to the expectation that the sponsor would eventually reimburse the pharmacy retroactively for these amounts. Rather, sponsors should work with their network pharmacies to provide direct reimbursement for any cost-sharing amounts not collected from LIS-eligible enrollees. Chapter 13 is available on the CMS Web site; see Appendix B for the specific Web address.

The instability of LIS data and Part D enrollments creates a significant volume of retroactive adjustments, and it has become evident that sponsors are facing more claims adjustments than current pharmacy claim reversal and rebilling approaches can adequately address. In the case of a claims adjustment, if the beneficiary is no longer at
the counter and a supplemental payer's claim filing window is closed, the pharmacy can no longer effectively coordinate benefits between payers. In addition, payers cannot effectively coordinate among themselves, both because of the absence of electronic standards for post-adjudication claim adjustments among payers (as opposed to between pharmacies and payers), and the presence of contractual prohibitions between payers and pharmacies on the disclosure of proprietary pricing information. Therefore, CMS continues to work with the industry to determine how best to handle retroactive claims adjustments whenever the adjustment cannot be resolved simply between the sponsor and the pharmacy.

Regardless of the cause of the retroactive claims adjustment, sponsors have two choices for determining the change to beneficiary TrOOP. The sponsor may adjust each claim that was affected by the retroactive change, or they may process the adjustment as they administer the benefit, provided that:

- TrOOP accumulators are updated immediately;
- Monies owed beneficiaries are refunded promptly;
- Claims are restacked and adjustments are processed at least quarterly; and
- An exceptions process exists for more frequent processing to meet beneficiary needs, such as at disenrollment during the coverage year.

The methodologies for handling retroactive changes in TrOOP are described in Section 9 of the Prescription Drug Event (PDE) guidance available on the CMS Web site. See Appendix B for the specific Web address. For further detail on reconciling payments, see section 50.14 of this chapter.

Part D sponsors also must determine whether or not any amount paid by any other payers was TrOOP-eligible and must adjust, as necessary, the affected beneficiaries’ TrOOP balances.

50.14.4 – Resolution Directly with Other Payers
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

The plan-to-plan reconciliation process resolves those situations in which a Part D sponsor other than the sponsor of record paid claims for a beneficiary during the initial transition period. However, situations will continue to arise outside the plan-to-plan process in which other payers that are not Part D sponsors either pay when they should not have paid at all, or pay more than they should have, because they paid out of the correct payer order. In these situations, Part D sponsors are required to work with these providers of other prescription drug coverage to resolve these types of payment issues. Other payers, as well as beneficiaries, are entitled to seek compensation from the Part D sponsor once the Part D enrollment is confirmed.
Therefore, sponsors should implement processes to handle payment resolution directly with other payers, beneficiaries, and others who are holding receivables on the beneficiaries’ behalf. Sponsors may not restrict the payment resolution process by imposing timely filing requirements on these other parties that are more restrictive than the timeframe required in Federal regulations at 42 CFR 423.466(b). This provision requires Part D sponsors to coordinate benefits with SPAPs and other entities providing prescription drug coverage, beneficiaries and others paying on the beneficiaries’ behalf for a period not to exceed 3 years from the date on which the prescription for a covered Part D drug was filled.

In instances when Medicaid has paid for a covered Part D drug and then seeks reimbursement from Part D, the sponsor should handle the Medicaid subrogation as follows:

1. Refund Medicaid the lesser of the sponsor’s out-of-network pharmacy allowed amount or the amount sought by Medicaid.

2. Apply no beneficiary cost-sharing or low-income subsidy to the claim.

The pharmacy-initiated reverse and rebill approach supports only a portion of the retroactive claims adjustments a Part D sponsor must handle. Therefore, sponsors must work directly with other payers to resolve reimbursements and recoveries for the majority of retroactive claims adjustments. Resolution of these latter adjustment actions becomes more complex by the absence of the other payers’ amount paid on the N transaction to the Part D plan. In order to ensure the confidentiality of pharmacy pricing information, coordination of benefits on initial claims is accomplished by reporting to the Part D sponsor only the amount of the beneficiary’s payment after the supplemental payment. As a result, a Part D sponsor attempting to determine refund or recovery amounts without having the pharmacy reverse and rebill the original claim must calculate the amount of any supplemental payment made by another payer by determining the difference between the Part D cost-sharing and the beneficiary amount paid after the supplemental payment. While CMS acknowledges that electronic transaction standards are not yet available to support timely, reliable, and precise coordination on adjusted claims when multiple payers are involved, it continues to hold sponsors accountable for making best efforts to coordinate benefits generated by claim adjustments.

50.14.5 – Re-adjudication Versus Pharmacy Reprocessing
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

If the total payment to the pharmacy for a claim was correct, but the sponsor subsequently determines that an adjustment is required that does not affect the total payment and does alter the sponsor-beneficiary liability split, the sponsor must re-adjudicate the claim within its own system without involving the pharmacy. This is most likely to occur when the sponsor corrects low-income beneficiary cost-sharing subsidy levels.
Part D sponsors are encouraged to avoid pharmacy reprocessing, but CMS recognizes that reversals may be appropriate under certain circumstances. Sponsor requests for pharmacy reprocessing should generally be limited to those situations where the total payment to the pharmacy changes (e.g., when there is a pricing error). Sponsors are responsible for reimbursing or collecting amounts from beneficiaries that result from the reprocessing of these claims and should not transfer this responsibility to pharmacies.

50.14.6 – Timeframes for Claims Filing
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

A number of issues associated with Part D, such as incidents involving multiple payers, payer order, and retroactive eligibility, create challenges for coordinating benefits among Part D sponsors and other providers of prescription drug coverage. When all payer information is available at the point-of-sale, pharmacies typically serve as the intermediary, facilitating coordination between Part D sponsors and other payers. However, when the information necessary to identify the correct primary payer for Part D drugs provided to Medicare beneficiaries enrolled in Part D sponsors is incomplete or lacking, pharmacies may, through no fault of their own, bill the State and other payers instead of a beneficiary’s Part D sponsor.

CMS may address many of these situations through a special, one-time reconciliation process. However, some of these situations may require resolution through claims reversal and rebilling. In their role of facilitating coordination between Part D sponsors and payers, some pharmacies agree to reverse incorrect claims and bill the proper Part D sponsor. CMS believes that in those circumstances in which the pharmacy is not at fault, it would be inappropriate for Part D sponsors to impose the conventional 30-90 day timely filing limits rather than a less restrictive timeframe, since this industry standard generally applies only when the pharmacy is in a position to correctly bill but fails to do so. CMS believes that this process is also appropriate for use in the Point of Sale Facilitated Enrollment process when incorrect health insurance claim numbers (HICNs) were used.

Beginning in 2007, in lieu of a requirement for a 180-day timeframe, which was implemented to accommodate the identification and resolution of coordination of benefits issues requiring claims reversal and rebilling to appropriate payers when Medicare Part D was introduced in 2006, CMS requires sponsors to establish at least a 90-day claims filing timeframe and to make appropriate allowances for COB claims on a case-by-case basis. It is important to note also that plans may be liable for claims from the prior year that are received after March 31st. While in these instances contractual provisions regarding timely claims filing may limit claims from network pharmacies, non-network pharmacies and beneficiaries must still have the opportunity to submit claims for reimbursement.

With the inclusion in the claim segment of the transaction standard for retail pharmacy drug claims of field number 357-NV, Part D sponsors may use certain delay reason
codes in the external code list, to specify the reason for the delay in claims submission, in order to differentiate COB-related delays from other types of delays.

60 – Coordination of Benefit Activities of Non-Part D Payers
(Rev. 4; Issued: 09-26-08; Effective/Implementation Date: 09-26-08)

60.1 – Reporting the Existence of Prescription Drug Coverage Provided to Enrollees
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

As discussed in section 30.1 of this chapter, CMS expects that other payers will provide information regarding any other prescription drug coverage that their Medicare enrollees may have. As noted in section 40.1 of this chapter, Medicare beneficiaries are required to disclose this information to Part D sponsors; consequently, other payers responsible for payment or reimbursement of Part D claim cost sharing should assist their enrollees in releasing this obligation. Certain legal requirements exist to inform CMS when another payer provides coverage that is primary to Medicare under the MSP laws (e.g., employers sent the Data Match questionnaire described later in this chapter, the 42 CFR 411.25 notice requirement). MSP reporting entails that affected entities use the MSP-specific reporting methods CMS requires (e.g., Data Match forms) or provides (e.g., VDSA in lieu of Data Match forms). However, for seamless benefit coordination and accurate TrOOP accounting, CMS strongly encourages payers to report their coverage information even when it is not legally required.

To do this, CMS makes available a direct and easy data exchange process through a vendor, the COB contractor. A data exchange with CMS allows other payers:

1. To assist beneficiaries in fulfilling their statutory obligation to disclose third party reimbursement for Part D drug costs.

2. To avoid the cost of paying as primary when the payment should be secondary to Part D.

3. As a sponsor of record, to be notified if a paid claim is reversed or adjusted outside an on-line adjudication process.

4. If TrOOP-eligible, to cease payments for beneficiaries receiving the full low-income subsidy who reach the catastrophic phase of the benefit, since at that point, Medicare fully subsidizes the beneficiary's incurred costs for covered Part D drugs.

The data exchange agreements require payers to periodically submit an input file containing certain enrollee populations. In return, the payer will receive a response file from the COB contractor indicating which of its enrollees are Medicare Part D beneficiaries. More information about the COB process offered by CMS is available on the Medicare COB Web site. See Appendix B for the specific Web address.
60.2 – Obtaining and Reporting Rx Identifiers
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

Payers supplemental to Medicare should obtain a unique RxBIN and/or PCN combination for Medicare eligible beneficiaries that will identify their paid claim requests and responses for TrOOP tracking purposes when Part D is the primary payer. CMS recommends that payers obtain an RxBIN and/or PCN combination unique to each separate plan they offer in order to distinguish each of their plans from one another. This allows each benefit plan to fulfill its obligation as a supplemental payer if it is identified on the COB file as secondary coverage.

In order for Rx identifier information to be available at point-of-sale through the transaction facilitator and Part D sponsors, payers must report these unique identifiers to CMS through the COB reporting process described in section 30 of this chapter. Payers primary to Medicare will continue to use their existing BIN and/or PCN.

NOTE: Not all other prescription drug coverage will have Rx identifiers. For instance, incident-driven coverage, such as Worker’s Compensation, does not usually provide electronic, point-of-sale benefits and thus does not need such identifiers; also, SPAPs that only offer premium assistance will not have Rx identifiers.

60.3 – Supplying Claims Information When a Supplemental Payment Is Made
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

In order for the COB and TrOOP tracking processes to function effectively, other payers should supply paid claims information to the Part D sponsor after making a payment that is supplemental to a Medicare payment. This will happen automatically if the other payer reports their coverage information to CMS in accordance with the processes described in section 60.1 of this chapter with the appropriate Rx BIN and/or PCN combination to enable the transaction facilitator to identify the supplemental payer’s status.

However, if the other payer is aware that the transaction facilitation process was not used, or if the other payer does not have electronic claims capability, the payer may alternatively submit a batch file of supplemental claims information or make arrangements to submit information in another format to the transaction facilitator. The supplemental claims data submitted to the facilitator will then be supplied to Part D sponsors for TrOOP calculation. If a payer uses the batch process, it must still establish a unique RxBIN and/or PCN combination and participate in the data sharing exchange with CMS' COB contractor. Further information on the batched claims process is available on the transaction facilitator’s Web site; see Appendix B for the facilitator's Web address. If a payer does not either support the on-line or batch process, no Nx transaction will be created and Part D sponsors will not be required to coordinate benefits if post-adjudicative claims adjustments are made.
60.4 – Coordinating with Part D Sponsors for Payment of Premiums
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

If one of the “other payers” listed in 42 CFR 423.464 chooses to pay Part D premiums on behalf of its members who are enrolled in Part D sponsors’ plans, that payer should coordinate directly with the appropriate Part D sponsor. Part D sponsors are required to allow and facilitate premium payment coordination with other payers. If the sponsor fails to comply with this requirement, it cannot disenroll a beneficiary for failure to pay premiums. Further discussion on coordination of premiums is contained in section 50.6 of this chapter.

60.5 – Following MSP Laws and Order of Payment Standards
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

MSP laws apply to all payers, including those providing prescription drug coverage, and all payers are legally required to make themselves aware of and follow these laws. This chapter provides clarification regarding the limited number of MSP situations described below; however, payers are required to know and apply all MSP laws whether or not they are mentioned in this chapter.

60.5.1 – Internal Revenue Service (IRS)/Social Security Administration (SSA)/CMS Data Match
(Rev. 4; Issued: 09-26-08; Effective/Implementation Date: 09-26-08)

IRS/SSA/CMS Data Match requirements pursuant to the Consolidated Omnibus Budget Resolution Act of 1989 apply to prescription drug coverage. Employers required to complete Data Match forms must include prescription drug information – including their ordinary RxBINs, PCNs, RxGRPs, and RxIDs – on their Data Match forms. Data Match requirements may be fulfilled by obtaining a VDSA, (see section 30.1 of this chapter for a brief description), and providing coverage information through that process. Note that for Data Match and other MSP purposes, payers primary to Medicare do not need to report the unique RxBIN and PCN combination they acquired for TrOOP purposes because MSP claims do not go through the TrOOP facilitation process. (However, beneficiary cost sharing on Part D sponsor claim payments as a secondary payer will count toward TrOOP.)

60.5.2 – FSAs, HSAs, MSAs, and HRAs
(Rev. 12, Issued: 03-19-10, Effective Date: 01-01-10; Implementation Date: 01-01-10)

HSAs, FSAs, and MSAs

Payers that are required to report group health plan coverage to CMS under the MSP laws do not have to report the FSAs, HSAs, or MSAs that may be attached to such coverage.

HRAs
However, HRAs are group health plans, and payers should report HRAs to CMS in the same manner as group health plan information is reported. Note that all of these accounts must be structured to comply with Federal laws, including laws that may restrict their use by Medicare beneficiaries.
Appendix A – Transaction Facilitation Process
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)
NCPDP v.D.0  B1 Transaction Flow

First Transaction

START ➔ Pharmacy Primary Submission ➔ NCPDP D.0 Claim (Real Time) ➔ Router ➔ Primary PDP

Note: Router represents connectivity to Payers. Pharmacy method of establishing connectivity to Payers is accomplished via direct connect or through the use of "Switch" Companies.

Subsequent Transaction(s)

Pharmacy Secondary Submission ➔ Primary PDP Payment into NCPDP D.0 with BIN/PCN and COB segment (Real Time) ➔ Router ➔ Secondary/Tertiary Payer

Note: For secondary transaction, router represents connectivity to Payers via Switch Companies ONLY.

Primary will obtain the BIN, PCN, Group and Cardholder ID from CMS on the eligibility file

Secondary rejects if PCN is not submitted as required by payer sheet. If secondary chooses not to reject, they take responsibility to send secondary to Transaction Facilitator

Note: For the purposes of discussions: Router= process of directing secondary/tertiary prescription claim to the designated Payer and directing the secondary/tertiary prescription claim information to a process for capture of prescription claim data and subsequent generation of NI Prescription Claim transactions to be sent to the Primary PDP for TrOOP calculation
N Transactions

Transaction Facilitator builds and routes the "N" transaction to the appropriate Part D Plan.

Part D Plan

NCPDP N Transaction

transaction contains the TrOOP costs for Part D Plans. Also accommodates adjustments & reversals

Solid = Request transaction
Dashed = Response transaction

File has Part D enrollment and other insurer information

Claims Router/switch
Eligibility (E1) Transactions

Pharmacy submits an E1 Request

Pharmacy's switch routes E1 to Transaction Facilitator

Transaction Facilitator
CMS Contractor that stores beneficiary eligibility from CMS and validates enrollment

Transaction Facilitator responds with eligibility information if match is found, otherwise transaction is rejected

CMS Provides Enrollment File to Transaction Facilitator
Appendix B – COB-related Web Sites

(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

CMS Medicare Prescription Drug Coverage Contracting
http://www.cms.hhs.gov/PrescriptionDrugCovContra/

CMS WCMSA Policy
http://www.cms.hhs.gov/WorkersCompAgencyServices

Dual Eligible PACE Plan Beneficiary Accumulated True Out-of-Pocket Cost Calculator
http://www.cms.hhs.gov/apps/troopcalculator/

ECRS User Guide

Medicare Beneficiary Publications

Medicare COB
http://www.cms.hhs.gov/COBGeneralInformation/

Medicare Marketing Guidelines

Medicare Part C and D Call Letters and Part D Benefit Parameters
http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html

National Council for Prescription Drug Programs
www.ncepdp.org

National Institute of Standards and Technology
http://csrc.nist.gov/groups/STM/cmvp/documents/140-1/1401vend.htm

OIG Guidance on Part D and PAP
http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2006/AdvOpn06-03F.pdf

PAP Data Sharing Agreements
http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/PAPDSA.pdf

PDE Guidance
PDE Participant Guide

Part D Eligibility, Enrollment and Disenrollment Guidance

Plan Communications User’s Guide (PCUG)

Public Use Files (PUFs)

Part D Transaction Facilitator (NDCHealth d/b/a RelayHealth)
http://medifacd.relayhealth.com/
Appendix C – Part D Sponsor Guidance—Automated TrOOP Balance Transfer
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

Part D Plan Sponsor Guidance on the Financial Information Reporting (FIR) Transactions for Transferring True Out-of-Pocket Balances

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Background on TrOOP Balance Transfers

Part D rules require sponsors to track the beneficiary’s true out-of-pocket (TrOOP) costs and gross covered drug spending and properly apply these costs to the TrOOP and benefit limits in order to correctly place the beneficiary in the benefit and provide the catastrophic level of coverage at the appropriate time. The TrOOP threshold and gross covered drug spending are calculated on an annual basis and must be transferred between Part D plans if a beneficiary disenrolls and re-enrolls at any time before the end of the coverage year.

The TrOOP-related data must also be transferred between Part D plans in those circumstances in which a Part D plan other than the plan of record paid for covered Part D drug costs as a primary payer and subsequently becomes aware, for example, through a CMS enrollment reconciliation process, that the beneficiary is enrolled in another Part D plan.

*Prior to the implementation of the FIR transaction standard that supports the automated plan-to-plan transfer of TrOOP-related data, CMS required the use of a manual process to transfer these data between plans. Once the NCPDP approved the FIR transaction standard, the “transaction facilitation process,” established by CMS to capture TrOOP-relevant data from Part D sponsors on-line and send these data to the appropriate Part D Plan for TrOOP calculation, uses the FIR to electronically transfer any TrOOP-related data between plans.*

With the January 1, 2009, implementation of the new FIR transactions to electronically transfer TrOOP and gross covered drug costs, further routine need for the manual data transfer process was eliminated.

Testing and Certification Requirements

The *Part D transaction* facilitator in collaboration with CMS, NCPDP and industry representatives developed a set of testing scenarios and a FIR testing certification process. Guidance describing this process is available on the transaction facilitator’s Web site; see Appendix B for the specific Web address. Each coverage year, new Part D sponsors (with the exception of PACE organizations that opt not to use the automated process) must ensure that their PBM or other processors are certified. Therefore, new Part D sponsors should require their PBM/processor to cooperate fully with and respond timely to all contacts from the transaction facilitator, to participate in the testing process and achieve certification. During certification testing, the facilitator will monitor the process and notify CMS of any new contract sponsors that have not met the requirements. CMS will initiate appropriate compliance action.

*Additionally, as new versions of the FIR transaction standard are approved by NCPDP and scheduled for implementation, sponsors must ensure their PBMs/processors undergo certification testing for the new version of the transaction. Thus, prior to the September 1, 2012, implementation of the Contract/Plan Benefit Package fields in new Version 1.2 of the FIR transaction, certification testing was conducted by the transaction facilitator.*
The certification test cases for the FIR version 1.2 are available on the facilitator’s website under the heading “Certification Test Cases Description- Version 1.2”

**Compliance**

CMS reminds sponsors that under the regulations at 42 CFR 423.464, Part D sponsors are required to coordinate benefits with other Part D plans, which includes the transfer of TrOOP and gross covered drug costs when a beneficiary changes enrollment during the coverage year to enable the new plan of record to properly position the beneficiary in the benefit. According to this regulation, sponsors must also comply with CMS established processes to ensure coordination between plans. If the procedures and timelines outlined in the FIR testing and certification guidance are not adhered to by Part D sponsors and any applicable plan contractors, CMS has the authority to consider the sponsor out of compliance with the Part D requirements and to take appropriate action.

In 2010, CMS indicated that it expected Part D sponsors to successfully transfer TrOOP accumulator data for beneficiaries making contract-level enrollment changes during the coverage year in a timely manner 100% of the time. To measure compliance, CMS established a 30-day timeframe for successful transfer of the data beginning with the effective date of the enrollment change or, if later, the first automated TrOOP balance transfer (ATBT) transaction. Sponsors failing to meet this timeframe were considered to be out of compliance and subject to compliance actions. Beginning in January 2013, sponsors are required to successfully transfer TrOOP accumulator data within 15 days of the effective date of the new enrollment or, if later, the date of the initial ATBT transaction. For example, if the effective date of the enrollment change is March 1, 2013, the beneficiary’s TrOOP accumulators must be successfully transferred on or before March 15. However, if the Part D transaction facilitator did not receive notice of the enrollment change until March 6, the initial ATBT transaction would be sent on March 6 and the TrOOP data would need to be successfully transferred on or before March 20.

**Plan Enrollment Types**

For purposes of the automated TrOOP balance transfer process:

1. A “plan of record” is a Part D sponsor with a valid, effective enrollment in the CMS system for a Medicare beneficiary for whom the sponsor receives final monthly payment. A sponsor may be the beneficiary’s initial plan of record for the coverage year, a subsequent plan of record with a closed period of enrollment, and/or the current plan of record.

2. A “non-plan of record” is a Part D sponsor that paid covered Part D drug claims for a Medicare beneficiary for whom the sponsor did not have a valid and effective enrollment in the CMS system and for whom the sponsor did not receive final monthly payment. This may occur in situations where the sponsor submitted an enrollment transaction that was processed, but then audited it off due to CMS’ receipt of a subsequent valid enrollment transaction for the same effective date, or if
the sponsor’s enrollment transaction was not accepted by CMS and, therefore, is not in the CMS system. There might be multiple non-plans of record for a beneficiary during a coverage year, even for the same month.

Procedures for TrOOP Balance Transfer Using FIR Transactions

Role of the Transaction Facilitator

Using the information the CMS transaction facilitator receives nightly from the CMS MBD, the facilitator identifies when a change in enrollment at the contract-level has occurred and generates a FIR transaction to each prior sponsor with which the beneficiary was enrolled or that paid covered part D drug claims for the beneficiary during the coverage year. Transactions begin with a FIR Inquiry to the earliest sponsor on record in the coverage year; that sponsor's Inquiry response is returned to the facilitator. Each sponsor responds with their monthly gross covered drug costs and TrOOP amounts. If there are multiple plans prior to the current plan of record, the accumulator values from the last response received are placed in a FIR Exchange transaction and forwarded to the next sponsor. The facilitator receives that next sponsor’s transaction response and continues the process of receiving and forwarding the prior accumulators until each subsequent sponsor in consecutive order has received and responded to a FIR Exchange transaction. The final Exchange transaction response contains the year-to-date monthly TrOOP-related data for all plans prior to the current plan of record; these accumulated monthly amounts are forwarded by the facilitator via a FIR Update transaction to the current plan of record. The FIR transaction process flows, involving a single prior plan and multiple prior plans, are detailed in section 4 of the NCPDP Financial Information Reporting Standard Implementation Guide v1.2.

Inclusion of non-plans of record

As noted previously, TrOOP-related data must also be transferred between Part D plans when a Part D plan other than the plan of record (i.e., a non-plan of record) paid for covered Part D drug costs as a primary payer and subsequently becomes aware that the beneficiary is enrolled in another Part D plan. This may occur if the other plan’s enrollment was processed and then audited off due to CMS’ receipt of a subsequent valid enrollment transaction for the same effective date, or if the enrollment in the other plan was not accepted by CMS and, therefore is not in the CMS system. Most audited enrollments will be identifiable by the facilitator, unless more than one record was audited off on the same day; in this case, only the latest audited record will be reflected on the TrOOP file.

In situations when the facilitator is unable to identify the existence of a non-plan of record (e.g., when the enrollment was never accepted by CMS, but the plan paid claims), in order for the TrOOP data to be transferred, the non-plan of record sponsor must contact the facilitator and request inclusion in the FIR reporting. To include these non-plan-of-record sponsors in the FIR process, the facilitator must create a “proxy” enrollment record identifying the sponsor, rather than CMS, as the source of the information, including the contact person providing the information and the date of
Evaluation of transaction responses

The transaction facilitator uses a set of business rules to evaluate the acceptability of the sponsor’s FIR response; these rules are limited to edits to verify that there are no missing/invalid data elements in the response that are required by the facilitator to generate the next FIR transaction in the sequence. If any of these business rules are violated, the facilitator will suspend the transaction sequence and notify the sponsor of the rejected transaction on the daily report. The transaction facilitator will re-initiate the transactions with the next regularly scheduled FIR sequence.

Part D Sponsors’ Requirements

Part D sponsors must track TrOOP-related data for their months of coverage for beneficiaries who disenroll during the coverage year and report these data, even if the accumulator values are zeros (see NCPDP FIR Standard Implementation Guide for reporting no claim activity), to the facilitator in response to FIR transaction requests. FIR accumulators should be based on the month of service, not the month the claim was processed.

Sponsors must also receive FIR transactions reporting TrOOP-related data reported by prior plan sponsors through the facilitator, update their systems to incorporate these data, examine their claims history and any previously reported amounts from prior plan sponsors to determine the impact of any changes in reported data on the beneficiary’s position in the benefit and re-calculate, as necessary, any prior claims affected by changes in the TrOOP accumulators.

It is CMS’ expectation that FIR transactions are processed in real-time. This includes not only reporting data, but also receiving the data reported by prior plans and using this information in benefit administration.

NOTE: A change at the contract level will trigger the FIR transaction process. If the beneficiary changes plan benefit packages (PBPs) within a contract and the BIN/PCN is unchanged, the sponsor is responsible for ensuring that the TrOOP balance and gross covered drug costs for all months of the first PBP’s coverage are available to the subsequent if the PBPs within the contract use the same processor.

Further, some sponsors use different contractors for eligibility/enrollment functions and claims processing. It is the sponsor’s responsibility to ensure that the contractor responsible for TrOOP balance transfer has all eligibility and enrollment information to properly administer the TrOOP balance transfer process, consistent with this guidance and the NCPDP Financial Information Reporting Standard Implementation Guide. This includes having information to identify the beneficiary (e.g., the CMS date of birth), and his or her eligibility and enrollment periods consistent with CMS requirements.
Multiple enrollments within a contract

When a beneficiary has multiple enrollments within a contract prior to a contract-level enrollment change, whether the BIN/PCN for the multiple enrollments within the contract are the same or different, the facilitator will send the transactions in the usual manner. When the BIN/PCN for multiple enrollments within the contract are the same, the processor, however, has two options for reporting for their months of coverage:

1. Report all periods of coverage on all transactions received for the member; or
2. Report each period sequentially as the transactions are received.

The following scenarios describe the FIR reporting requirements under both options for situations when a beneficiary has multiple plan enrollments within a contract during the coverage year, involving the same BIN/PCN combinations.

Scenario 1- Option 1 Reporting

Beneficiary Enrollment History

<table>
<thead>
<tr>
<th>Months of Coverage</th>
<th>Contract/PBP Number</th>
<th>Plan</th>
<th>BIN/PCN</th>
<th>FIR Transaction</th>
<th>Processor Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan. – Mar.</td>
<td>S0001-001</td>
<td>A</td>
<td>611220/1234567890</td>
<td>FIR Inquiry</td>
<td>Reports Jan. – May data</td>
</tr>
<tr>
<td>Apr. – May</td>
<td>S0001-002</td>
<td>B</td>
<td>611220/1234567890</td>
<td>FIR Exchange</td>
<td>Reports Jan. – May data</td>
</tr>
<tr>
<td>Effective June</td>
<td>S0002-001</td>
<td>C</td>
<td>121212/23232323bb</td>
<td>FIR Update</td>
<td></td>
</tr>
</tbody>
</table>

When the facilitator identifies the contract-level enrollment change to Plan C, a FIR Inquiry transaction will be sent to the BIN/PCN for Contract S0001. Since the BIN/PCN combination is the same for both contract S0001 PBPs, the processor responds with the January through May accumulators, reporting all months of enrollment in Plans A and B. The Plan B sponsor processor will then receive a FIR Exchange transaction and responds by reporting the January through May accumulators. The processor must exercise care to avoid duplicating their accumulators when using this reporting option. The monthly accumulators for January through May will be forwarded by the facilitator to the Plan C sponsor in a FIR Update transaction.

Scenario 1- Option 2 Reporting

Beneficiary Enrollment History

<table>
<thead>
<tr>
<th>Months of Coverage</th>
<th>Contract/PBP Number</th>
<th>Plan</th>
<th>BIN/PCN</th>
<th>FIR Transaction</th>
<th>Processor Response</th>
</tr>
</thead>
</table>
When the facilitator identifies the contract-level enrollment change to Plan C, a FIR Inquiry transaction will be sent to the BIN/PCN for Contract S0001. Although the BIN/PCN combination is the same for both contract S0001 PBPs, the processor responds with the January through March accumulators, reporting the months of enrollment in Plan A only. The Plan B sponsor processor will then receive a FIR Exchange transaction and responds by reporting the April through May accumulators. The monthly accumulators for January through May will be forwarded by the facilitator to the Plan C sponsor in a FIR Update transaction.

Scenario 2- Option 1 Reporting

<table>
<thead>
<tr>
<th>Months of Coverage</th>
<th>Contract/PBP Number</th>
<th>Plan</th>
<th>BIN/PCN</th>
<th>FIR Transaction</th>
<th>Processor Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apr.- May</td>
<td>S0002-001</td>
<td>B</td>
<td>121212/23232323bb</td>
<td>FIR Exchange</td>
<td>Reports Apr. – May data</td>
</tr>
<tr>
<td>June – Aug.</td>
<td>S0001-001</td>
<td>C</td>
<td>611220/1234567890</td>
<td>FIR Exchange</td>
<td>Initially reports Jan.- Mar data &amp; June - Aug data (Subsequently reports any changes to June – Aug. data resulting from Apr.- Aug. data)</td>
</tr>
<tr>
<td>Effective Sept.</td>
<td>S0003-001</td>
<td>D</td>
<td>999991/1552bbbbbb</td>
<td>FIR Update</td>
<td></td>
</tr>
</tbody>
</table>

When the facilitator identifies the contract-level enrollment change to Plan D, a FIR Inquiry transaction will be sent to the BIN/PCN for Contract S0001. Since the BIN/PCN is the same for both Plans A and C, the processor responds with the January through March and June through August accumulators, reporting all months of enrollment in Plans A and C. The Plan B sponsor will then receive a FIR Exchange transaction and must respond by adding the April through May accumulators. Next, although Plan C has
already reported the June through August accumulators, the processor will receive a FIR Exchange transaction from the facilitator to provide Plan B data from April to May. Plan C will respond with their January through March and June through August accumulators pending any necessary adjustments resulting from reprocessing based on their receipt and review of the April through May data from Plan B. Plan C will report adjusted amounts in the next/later response to the facilitator; these adjustments must be made within 45 days of the plan’s receipt of the data from Plan B. The accumulators for all months January through August will be forwarded by the facilitator to the Plan D sponsor in a FIR Update transaction.

Scenario 2- Option 2 Reporting

Beneficiary Enrollment History

<table>
<thead>
<tr>
<th>Months of Coverage</th>
<th>Contract/PBP Number</th>
<th>Plan</th>
<th>BIN/PCN</th>
<th>FIR Transaction</th>
<th>Processor Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apr. – May</td>
<td>S0002-001</td>
<td>B</td>
<td>121212/232323223bb</td>
<td>FIR Exchange</td>
<td>Reports Apr. – May data</td>
</tr>
<tr>
<td>June – Aug.</td>
<td>S0001-001</td>
<td>C</td>
<td>611220/1234567890</td>
<td>FIR Exchange</td>
<td>Initially reports June - Aug. data (Subsequently reports any changes to June – Aug. data resulting from Apr.-May data)</td>
</tr>
<tr>
<td>Effective Sept.</td>
<td>S0003-001</td>
<td>D</td>
<td>999991/1552bbbbbb</td>
<td>FIR Update</td>
<td></td>
</tr>
</tbody>
</table>

When the facilitator identifies the contract-level enrollment change to Plan D, a FIR Inquiry transaction will be sent to the BIN/PCN for Contract S0001. Although the BIN/PCN is the same for both Plans A and C, the processor responds with the January through March accumulators, reporting only months of enrollment in Plan A. The Plan B sponsor will then receive a FIR Exchange transaction and must respond by adding the April through May accumulators. Next, the Plan C processor will receive a FIR Exchange transaction from the facilitator to provide Plan B data from April to May. Plan C will be required to make any necessary adjustments resulting from reprocessing based on their receipt and review of the April through May data from Plan B and will report adjusted amounts in the next/later response to the facilitator. The accumulators for all months January through August will be forwarded by the facilitator to the Plan D sponsor in a FIR Update transaction.
The following scenario describes the FIR reporting requirements for situations when a beneficiary has multiple plan enrollments within a contract during the coverage year involving different BIN/PCN combinations:

Scenario 3

Beneficiary Enrollment History

<table>
<thead>
<tr>
<th>Months of Coverage</th>
<th>Contract/PBP Number</th>
<th>Plan</th>
<th>BIN/PCN</th>
<th>FIR Transaction</th>
<th>Processor Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apr. - May</td>
<td>S0002-001</td>
<td>B</td>
<td>121212/23232323bb</td>
<td>FIR Exchange</td>
<td>Reports Apr. – May data</td>
</tr>
<tr>
<td>June – Aug.</td>
<td>S0002-002</td>
<td>C</td>
<td>166666/88Abbbbbbb</td>
<td>FIR Exchange</td>
<td>Reports June – Aug. data</td>
</tr>
<tr>
<td>Effective Sept.</td>
<td>S0003-001</td>
<td>D</td>
<td>999991/1552bbbbbb</td>
<td>FIR Update</td>
<td></td>
</tr>
</tbody>
</table>

When the facilitator identifies the contract-level enrollment change to Plan D, a FIR Inquiry transaction will be sent to the BIN/PCN for Contract S0001. The processor will respond with the January through March accumulators. Although Plan B and C are within the same contract, the PBPs have different BIN/PCNs. Therefore, the facilitator will send a FIR Exchange transaction to the Plan B BIN/PCN and the processor will respond by providing the April through May accumulators. A subsequent FIR Exchange transaction will be sent to the Plan C BIN/PCN for that processor to report the data for the months of Plan C enrollment; this is the June through August accumulator data. The accumulators for all months January through August will be forwarded to the Plan D sponsor in a FIR Update transaction.

While these scenarios do not depict every possible situation involving multiple plan enrollments within a contract, they are illustrative of the application of the NCPDP FIR transaction flow to these situations and the potential need for sponsors to respond to sequential FIR transaction requests.

Any time a plan sponsor has paid Part D drug claims for a beneficiary who is later determined to be enrolled in another plan but has not received a FIR transaction to report the beneficiary’s TrOOP-related data, the sponsor must contact the transaction facilitator to initiate the FIR process and include the additional sponsor in the transaction flow.

Contract-level enrollment changes involving a single processor

When a beneficiary has had prior contract-level enrollment changes involving a single processor with the same BIN/PCN, the processor may report accumulator data for all months of enrollment in both contracts or may report only data related to the first
contract enrollment when responding to a FIR Inquiry transaction. In either case, the processor will also subsequently receive a FIR Exchange transaction. Because the processor will not know whether there was an intervening enrollment in another contract, the Exchange transaction will have to be examined to determine if the accumulators have changed and adjustments are necessary.

<table>
<thead>
<tr>
<th>Months of Coverage</th>
<th>Contract/PBP Number</th>
<th>Plan</th>
<th>BIN/PCN</th>
<th>FIR Transaction</th>
<th>Processor Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apr.- May</td>
<td>S0002-002</td>
<td>B</td>
<td>611220/1234567890</td>
<td>FIR Exchange</td>
<td>Reports Jan. - May</td>
</tr>
<tr>
<td>Effective June</td>
<td>S0003-001</td>
<td>C</td>
<td>121212/23232323bb</td>
<td>FIR Update</td>
<td></td>
</tr>
</tbody>
</table>

When the facilitator identifies the contract-level enrollment change to Plan C, a FIR Inquiry transaction will be sent to the BIN/PCN for Contract S0001. Since the BIN/PCN is the same for both Plans A and B, the processor may respond with the January through May accumulators, reporting all months of enrollment in Plans A and B, or may report only the Contract S0001 accumulators for January through March. Then the same processor will receive a FIR Exchange transaction, determine that the accumulators are as previously reported and respond with the previously reported information. If the processor reported all months on the FIR Inquiry, the response to the FIR Exchange will include the previously reported information. If the processor previously reported only the Contract S0001 accumulators, the processor must include the Contract S0002 accumulators in their response to the FIR Exchange. The accumulators for all months January through May will be forwarded by the facilitator to the Plan C sponsor in a FIR Update transaction.

Multiple enrollment types

Regardless of whether a sponsor is a plan of record or a non-plan of record, the sponsor must receive FIR transactions with TrOOP-related data reported by prior plans (both prior plans of record and non-plans of record), update their systems to incorporate these data, examine their claims history and previously reported amounts from the prior plans to determine the impact of these data on the beneficiary’s position in the benefit, and recalculate as necessary any prior claims affected by the new TrOOP accumulator data. The recalculation of prior claims by both non-plans of record and plans of record based on the receipt of new TrOOP-related data reported to them is necessary to ensure that beneficiary adjustments resulting from the recalculation are appropriately handled by the sponsor that adjudicated the affected claim(s).

In addition, for any month in which a plan other than the actual plan of record for the month (whether a prior plan of record or non-plan of record) has paid claims, the other
plan will precede the actual plan of record for the month in the FIR transaction sequence. The other plan’s accumulator data also will precede the actual plan of record’s claims data for that month.

The following scenario describes FIR reporting in situations involving multiple enrollment types.

### Beneficiary Enrollment History

<table>
<thead>
<tr>
<th>Months of Coverage</th>
<th>Contract/PBP Number</th>
<th>Plan</th>
<th>BIN/PCN</th>
<th>FIR Transaction</th>
<th>Processor Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jan. – Feb., but paid claims for Mar.</td>
<td>S0001-001</td>
<td>A (plan of record)</td>
<td>611220/1234567890</td>
<td>FIR Inquiry</td>
<td>Reports Jan. – Mar. data</td>
</tr>
<tr>
<td>Mar. - June</td>
<td>S0002-001</td>
<td>B (plan of record)</td>
<td>121212/23232323bb</td>
<td>FIR Exchange</td>
<td>Initially, reports Mar–June data (Subsequently, reports any changes to Mar.-June date resulting from Plan A’s Jan. – Mar. data)</td>
</tr>
<tr>
<td>July – Aug.</td>
<td>S0003-001</td>
<td>C (non-plan of record)</td>
<td>999991/1552bbbbbb</td>
<td>FIR Exchange</td>
<td>Reports July – Aug. data</td>
</tr>
<tr>
<td>Effective July</td>
<td>S0004-001</td>
<td>D (plan of record)</td>
<td>166666/88Abbbbbbb</td>
<td>FIR Update</td>
<td></td>
</tr>
</tbody>
</table>

In August, the facilitator identifies a contract-level enrollment change involving the auditing off of the Plan C enrollment and the new enrollment in Plan D effective July. A FIR Inquiry will be sent to the BIN/PCN for Contract S0001. The processor will respond with the accumulator data for their months of enrollment, January and February. In addition, because the Plan A paid claims in early March prior to receiving the TRR from CMS reporting the beneficiary’s change in enrollment, the processor will include their accumulator data for March as well.

The facilitator will send a FIR Exchange transaction to the BIN/PNC for Contract S0002. Initially, the processor responds with the accumulator data for their months of enrollment March through June. However, Plan B must incorporate the Plan A data into their system, including applying the March data from Plan A prior to the Plan B claims for March. After examining the amounts previously reported and their own claims history and recalculating any prior claims as necessary, the sponsor will respond to future transactions from the facilitator with their revised March through June accumulators.
A subsequent FIR Exchange transaction will be sent to the BIN/PCN for the non-plan of record Plan C. Initially, this sponsor will respond with July through August accumulators. However, the sponsor must incorporate the Plan A and B data into their system. After examining the amounts previously reported and their own claims history and recalculating any prior claims, as necessary, the sponsor will respond to future transactions from the facilitator with their revised July through August accumulators.

The monthly accumulators for January through August will be forwarded to the Plan D sponsor in a FIR Update transaction. With the retroactive enrollment of the beneficiary in Plan D back to July, the Plan D sponsor must apply the July and August accumulators reported by Plan C to each of those months prior to any claims Plan D adjudicated in July and August.

**Receipt of Inquiry when a prior plan is known**

If a plan receives an Inquiry transaction from the facilitator, but is aware there was a prior plan, the plan should process the FIR Inquiry transaction. The identity of the prior sponsor must be known and may be determined by the sponsor’s previous receipt of a P2P Plan Payable Report (Report 43) from CMS requiring payment to another Part D sponsor, or the beneficiary’s presentation to the current plan of a paper Explanation of Benefits (EOB) from a prior Part D payer.

In the Inquiry response, the sponsor will report the financial accumulators for their months of enrollment only. The sponsor should contact the TBT contact listed in HPMS for the prior plan to alert that sponsor of the need to request that the facilitator initiate a new transaction series.

**Sponsor requested FIR transactions**

Sponsors receiving a P2P Plan Receivable Report (Report 41) from CMS indicating the amount due from the beneficiary’s plan or record should request that the facilitator create a proxy enrollment record and add the sponsor to the FIR process flow. This request will cause a new FIR sequence to be initiated and permit the plan to report their accumulators to the subsequent plan(s) into which the beneficiary was enrolled during the coverage year.

Also, if a change in a beneficiary’s TrOOP-related data occurs outside the scheduled timing and is of such a magnitude that the sponsor believes it is important to transfer the updated data without waiting for the next scheduled transaction, the sponsor should complete the form to request a sequence be initiated and email the completed form to the transaction facilitator. Details regarding these procedures are available on the RelayHealth Web site. See Appendix B for the specific Web address.
Other automatically generated FIR transactions

In addition to the FIR transaction series initiated as a result of an enrollment change (i.e., a contract ID change or PBP ID change with a BIN and/or PCN change) or in response to a sponsor request, if a series is already underway and the facilitator receives either a change to the beneficiary’s 4Rx data (without PBP/Contract ID change) or a change to the beneficiary’s date of birth (DOB), a one-time FIR sequence will be initiated if one is not already scheduled on the day of receipt of the change. A transaction sequence will also be initiated if a FIR series has completed as long the 4Rx or DOB change is received prior to March 31st following the plan year.

Correction of unacceptable responses

When the facilitator rejects a FIR response transaction as unacceptable, (e.g., if the accumulated TrOOP reported for a month is a negative number) the sponsor must make the necessary changes to ensure the transaction is successful when the facilitator triggers the next regularly scheduled FIR sequence. Each sponsor must identify in the HPMS a TBT contact at the entity responsible for processing the sponsor’s FIR transactions. The facilitator will contact this person as necessary to explore any significant problems/issues identified with the transaction flow and notify CMS.

Previously, if a transaction was suspended, the facilitator continued the transaction sequence with the next payer. This permitted the new/current plan of record to receive the accumulators from all the other prior plans to position the beneficiary in the benefit. However, unintended consequences associated with this procedure were identified in 2012. As a result, effective July 1, 2012, the facilitator terminated the procedure. Whenever a transaction is rejected, the FIR sequence is ended and is re-initiated with the next regularly scheduled sequence.

Sponsors should not routinely question balances reported on the FIR transactions, including accumulated TrOOP reported in excess of the maximum. A sponsor may initially report accumulated TrOOP amounts that exceed the maximum for the coverage year, but must reduce reported TrOOP to the maximum in a subsequent transaction sequence. The resolution of an amount reported in excess of the TrOOP limit will require that the sponsor examine claims-level data to determine which claims will require reprocessing.

FIR transaction rejects

Part D sponsors may reject FIR transactions for missing or invalid data (e.g., a missing/invalid BIN number). However, under current CMS rules, X2 (Accumulated Gross Covered Drug Cost exceeds maximum) will not be used.

The FIR transaction standard requires a patient date of birth, if known, in the patient segment. If the date of birth is reported, the date reported in this field must match the CMS date of birth to avoid a reject for a missing/invalid date of birth.
Other FIR-related sponsor activity

Special requests for an automated FIR sequence

Once the regularly scheduled FIR sequences in the series have concluded, sponsors needing to report updated TrOOP accumulator data may do so by submitting a special request to the transaction facilitator to initiate a FIR sequence. A form for requesting a special sequence is available on the RelayHealth Web site. See Appendix B for the specific Web address.

Adjustment actions

When there is a change in a FIR accumulator due to a claims reversal or other change, such as a retroactive LIS adjustment, that affects the beneficiary’s TrOOP and/or gross covered drug costs, the change is accumulated in the month of service for FIR reporting purposes. When a change alters the benefit phase of a subsequent claim(s), CMS expects the plan to take this change into account, either by processing future claim(s) in a different benefit phase or by adjusting existing claims. If the change was identified after the year has ended, the plan has only one option; it must adjust the affected claim(s) because no future claims are expected. This is consistent with CMS’ 2008 PDE Regional Training Participant Guide (sections 4.5 and 5.8), which explains that plans “pay back the benefit” by adjusting claims when a reversal occurs after the end of the benefit year or following disenrollment. The PDE Participant Guide is available online; see Appendix B for the specific Web address.

Whenever the data reported on a FIR transaction causes a sponsor to recalculate a claim and recoup payments from the beneficiary in order to “pay back the benefit,” the sponsor need not actually recover the payment before updating the beneficiary’s accumulators. Recovery should be sought, accumulators updated, and PDE data adjusted promptly. The maximum time for a “true up;” i.e., adjustments to accumulators due to claims reversals, etc. that occur during the coverage year, is 45 days.

Record retention

FIR transactions are subject to the 10-year record retention requirements specified in the Federal regulations at 42 CFR 423.505(d). For imaged or electronically stored records, follow the Federal guidelines outlined by CMS in Pub. 100-01, chapter 7, section 30.30.1.4.

Negative accumulator values

If a sponsor currently has negative value for the beneficiary’s TrOOP, the sponsor may respond to a FIR transaction with a forced zero amount. However, the current frequency of the FIR sequence must be considered in these cases. If the next sequence will be soon (i.e., the sequences are in the first month) and correct accumulator data can be reported at that time, the forced zero is permissible. However, if the next scheduled sequence will
not occur within a week, as soon as correct data are available, a request for the initiation of a sequence should be made to the facilitator.

**FIR processor changes**

If a Part D sponsor changes its FIR processor, the sponsor must ensure that FIR transactions are routed to the appropriate processor and that transactions related to the prior year can continue to be processed for the period required by CMS. This may require making arrangements either with the former processor to continue processing prior year FIRs or with the new processor to assume that responsibility. The transaction facilitator and CMS in conjunction with the NCPDP Work Group 1 Financial Information Reporting Task Group developed a white paper outlining the scenarios relevant to Medicare Part D Plans changing processors and the tasks to ensure that coordination of benefits occurs for the plan years originally contracted with the prior processor. The white paper, entitled “Medicare Part D Plans Moving Processors,” is available on the NCPDP Web site; see Appendix B for the specific Web address.

**Non-Calendar Year Plans**

The TrOOP facilitator will be unable to distinguish non-calendar year (NCY) from calendar year (CY) EGWPs. Therefore, all EGWPs must be treated the same for automated TBT purposes.

For EGWPs, the following principles apply:

1. NCY plans, like CY plans, will report the FIR transactions on a CY basis.

2. CMS will assume there is no need to transfer TrOOP accumulators for any end-of-CY enrollment changes.

3. CMS has taken the position that if a beneficiary changes enrollment during the CY to a NCY plan, the Part D benefit will start anew if the effective date of the NCY enrollment is the same as the beginning of the NCY plan’s coverage year. Data reported on the FIR transactions will be ignored by the NCY plan. However, the FIR transaction itself should be accepted, despite the fact that the dollar values and data reported in the FIR will not be applied.

4. If a beneficiary changes enrollment during the CY to a NCY plan and the effective date of the NCY enrollment does not correspond to the beginning of the NCY plan’s coverage year, the plan will receive and add the accumulators reported from the prior plan(s) for the months from the beginning of the plan year to the month of the enrollment change to position the beneficiary in the NCY plan’s benefit.

The scenarios below demonstrate the application of these principles.
<table>
<thead>
<tr>
<th>Scenario</th>
<th>Effective Date of Transfer</th>
<th>Automated FIR Triggered?</th>
<th>Plan Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>9/1/2011 based on a special enrollment period (SEP)</td>
<td>Yes</td>
<td>Plan A reports Jan-Aug 2011 data. Plan B uses accumulators from July-Aug. to position the beneficiary in the Plan B benefit.</td>
</tr>
<tr>
<td>2</td>
<td>1/1/2012</td>
<td>No, end of year changes do not trigger FIR transactions</td>
<td>Plan B begins beneficiary in the benefit with $0 accumulators.</td>
</tr>
<tr>
<td>3</td>
<td>3/1/2012</td>
<td>Yes</td>
<td>Plan A reports Jan-Feb 2012 data. Plan B ignores the reported data as the Plan benefit year begins with the effective date of enrollment. The receiving plan determines which months apply to its benefit.</td>
</tr>
<tr>
<td>5</td>
<td>1/1/2012</td>
<td>No, end of year changes do not trigger FIR transactions</td>
<td>Plan B begins beneficiary in the benefit with $0 accumulators at the beginning of the new plan year.</td>
</tr>
<tr>
<td>6</td>
<td>3/1/2012 based on a SEP</td>
<td>Yes</td>
<td>Plan A reports Jan-Feb 2012 data. Plan B uses the Jan-Feb data to position the beneficiary</td>
</tr>
<tr>
<td>Scenario</td>
<td>Effective Date of Transfer</td>
<td>Automated FIR Triggered?</td>
<td>Plan Action</td>
</tr>
<tr>
<td>----------</td>
<td>---------------------------</td>
<td>--------------------------</td>
<td>-------------</td>
</tr>
<tr>
<td>7</td>
<td>12/1/2011</td>
<td>Yes, but, although the FIR will be triggered 1/15/2012, the transaction will be for 2011 data.</td>
<td>Plan A reports Jan-Dec 2011 data. Plan B uses the July-Dec accumulators. The TrOOP facilitator should identify a change in the Jan 2012 plan of record, add Plan A as a proxy plan and initiate a FIR inquiry to Plan A for Jan 2012 accumulators. If this does not occur, Plan A will need to request the facilitator initiate a FIR inquiry.</td>
</tr>
<tr>
<td>7b</td>
<td>1/1/2012</td>
<td>No, end of year changes, even when processed in January, will not trigger FIR transactions.</td>
<td>If Plan A paid claims in January prior to receiving the TRR with the disenrollment, the plan should request the facilitator initiate a FIR inquiry. If this does not occur, once Plan A submits the PDEs for the January claims, Plan B will be aware via plan-to-plan recon of the need for a FIR transaction stream and can request it.</td>
</tr>
</tbody>
</table>

If, for example in scenario 3, the beneficiary remains enrolled in Plan B into the subsequent calendar year (i.e., 2013), the TrOOP accumulators will be rolled over and used to determine the beneficiary’s position in the benefit until the end of the benefit year or disenrollment from the plan, whichever is earlier.

In scenario 7b, because the beneficiary changed enrollment in a subsequent CY, accumulators from the prior CY cannot be transferred and used by the new plan, even if the transfer is done outside the FIR process. Transfer-out balances are accumulated and forwarded only on a CY basis.
Timing of the FIR Transaction Sequences

Given the new 15-day compliance period specified in the Compliance section of this guidance, CMS worked with the NCPDP Work Group 1 Financial Information Reporting Task Group to revise the timing of the FIR transactions to increase the number of the transactions sent during the 15-day compliance period. Thus, beginning April 1, 2013, for enrollment changes occurring in 2013 or later FIR transactions are sent as follows:

- **The first FIR transaction sequence is sent one day prior to the effective date of the change or on the day the facilitator receives notice of the enrollment change, if later.**

- **The second sequence is sent on the day following the initial sequence.**

- **During the first month, subsequent transaction sequences are sent on days 8, 10, 12, 14, 21 and 28 following the second sequence.**

- **The next transaction sequence is sent on day 73; i.e., 45 days (or a month and half) after the sequence sent on day 28.**

- **The next sequence is sent on day 118; i.e., 45 days (or a month and half) later.**

Additionally, to enable sponsors to report data changes that occur late in the current year or in the early months of the subsequent year, a change was made to the timing of the last FIR transaction sequences in the series. As a result, the last 3 FIR sequences are sent on December 1, of the current year and January 15 and February 28 of the subsequent year.

Under this schedule, the last regularly scheduled FIR transaction sequences are sent on the last day of February instead of March 31st, which was the previous ending data. Sponsors needing to update beneficiaries’ TrOOP accumulator data may submit a special request to the transaction facilitator during the period March 1 through May 31st for a FIR transaction series to be initiated for those beneficiaries.

The revised timing provides substantial additional opportunity to transfer updated beneficiaries’ TrOOP accumulator data and for subsequent plans to consider these changes in administering the Part D benefit. As a result, CMS expects that changes that would have previously required manual transfer will be transferred under the revised automated process and, absent extraordinary circumstances, it will no longer be necessary for sponsors to transfer updated accumulator data manually after June 15 of the subsequent year. However, sponsors must continue to receive and act on information that necessitates a claim adjustment for the 36-month COB timeframe and to submit PDEs reflecting the changes.
**FIR Transaction Response Time**

The facilitator will timeout transactions without a response in 15 seconds. If a transaction is timed-out, the facilitator will retry the transaction every 15 minutes for 48 hours. If after the 48-hour period the plan never responds, the facilitator will suspend the sequence and initiate another at the next regularly scheduled time. The suspended sequence will be reported on the next daily report after the 48 hour period has expired.

**Exceptions from Automated Processing**

Part D sponsors should accept FIR data as reported unless a problem is identified. Problems may be identified through conflicting information, such as paper EOBs presented by, or on behalf of, the beneficiary, that suggests reported data are wrong. Also, there will be rare situations in which a discrepancy exists between the CMS and sponsor’s enrollment information for a beneficiary, which affects the FIR-reported data. These situations, or those in which the beneficiary complains that his/her TrOOP accumulators are materially incorrect, must be removed from automated processing. In these instances, the sponsor should contact the facilitator’s help desk to request the facilitator suspend the FIR transactions until the discrepancy is resolved or, if necessary, for the remainder of the coverage year. Once the error is resolved, the facilitator will remove the suspension and re-initiate the FIR process.

**Reports to Sponsors**

_The Transaction Facilitator produces a number of reports to permit sponsors and their FIR processors to identify and resolve problems. These include the new Daily Cumulative FIR Aging Report which identifies for each sponsor all beneficiaries for whom balances have not successfully transferred and provides additional information to assist sponsors in complying with CMS’ ATBT requirements. This report replaced the prior daily reports of rejected TBT transactions as well as the bi-monthly report of unresolved TBT exceptions. The Daily Cumulative FIR Aging Report layout and a report guide, including a sample report, are available on the Transaction Facilitator Web site; see Appendix B for the specific Web address. In addition to the daily report, sponsors receive a weekly statistical report of the numbers of transactions successfully processed and rejected by type of reject._
FIR Scenarios

Scenario One: The beneficiary was enrolled in Plan A in January, 2008, in Plan B in February, 2008 and in Plan C for the remainder of the year. Both Plan A and B had claim activity as reflected below.

<table>
<thead>
<tr>
<th>Month</th>
<th>Plan A</th>
<th>Plan B</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Accumulated TrOOP</td>
<td>Accumulated Gross Covered Drug Cost</td>
</tr>
<tr>
<td>January</td>
<td>200.00</td>
<td>275.00</td>
</tr>
<tr>
<td>February</td>
<td></td>
<td>50.00</td>
</tr>
<tr>
<td>March</td>
<td>New plan C begins coverage</td>
<td></td>
</tr>
</tbody>
</table>

Plan C began adjudicating claims with the $475 drug spend and $250 TrOOP amounts received from Plan B. In April, Plan A received a reversal on a $100 claim and in response to the next FIR Inquiry reported the following updated information to Plan B.

<table>
<thead>
<tr>
<th>Month</th>
<th>Plan A</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Accumulated TrOOP</td>
</tr>
<tr>
<td>January</td>
<td>150.00</td>
</tr>
</tbody>
</table>

Plan B compared the previous transaction from Plan A and determined that the drug spend accumulator decreased by $100. Plan B administers the defined standard benefit. The plan reviewed its claims history and determined that the $100 decrease moved Plan B’s first $100 claim from the Initial Coverage Period (ICP) back to the Deductible. Because Plan B needed to recalculate this claim to change it from $75 plan pay, $25 patient pay to $100 patient pay, the plan passed on the new Plan A accumulators and its existing February amounts to Plan C. In order to “pay back the benefit” Plan B was responsible for recouping the $75 differential from the beneficiary. In response to the next FIR Exchange transaction received, Plan B reported its updated amounts to Plan C as shown below.

<table>
<thead>
<tr>
<th>Month</th>
<th>Plan A</th>
<th>Plan B</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Accumulated TrOOP</td>
<td>Accumulated Gross Covered Drug Cost</td>
</tr>
<tr>
<td>January</td>
<td>150.00</td>
<td>175.00</td>
</tr>
<tr>
<td>February</td>
<td></td>
<td>125.00</td>
</tr>
<tr>
<td>March</td>
<td>New plan C begins coverage</td>
<td></td>
</tr>
</tbody>
</table>
Scenario Two: The circumstances are the same as those described in Scenario One, except Plan B administers a Basic Alternative benefit with no deductible; for the first $2500 the plan pays 75% and the beneficiary pays 25%. Plan B reviewed its claims history and determined that the $100 decrease in Plan A gross covered drug cost had no claims impact, because no claims were repositioned in different benefit phases. Plan B forwarded to Plan C the updated Plan A amounts for January and the existing Plan B accumulators for February.

Scenario Three: The beneficiary was enrolled in Plan A in January, 2008, in Plan B in February, 2008 and in Plan C for the remainder of the year. Both Plan A and B had claim activity as reflected below.

<table>
<thead>
<tr>
<th>Month</th>
<th>Plan A</th>
<th>Plan B</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Accumulated TrOOP</td>
<td>Accumulated Gross Covered Drug Cost</td>
</tr>
<tr>
<td>January</td>
<td>175.00</td>
<td>175.00</td>
</tr>
<tr>
<td>February</td>
<td></td>
<td>125.00</td>
</tr>
<tr>
<td>March</td>
<td>New plan C begins coverage</td>
<td></td>
</tr>
</tbody>
</table>

Plan C began adjudicating claims with the $375 drug spend and $300 TrOOP amounts received from Plan B. In April, Plan A received documentation from the beneficiary showing a $100 out-of-network prescription drug purchase. Plan A adjudicated the paper claim and in response to the next FIR Inquiry reported the following updated information to Plan B.

<table>
<thead>
<tr>
<th>Month</th>
<th>Plan A</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Accumulated TrOOP</td>
</tr>
<tr>
<td>January</td>
<td>275.00</td>
</tr>
</tbody>
</table>

Plan B compared the previous transaction from Plan A and determined that the drug spend accumulator increased by $100. The plan reviewed its claims history and determined that the $100 increase moved Plan B’s first $100 claim from the Deductible into the ICP. Because Plan B needed to recalculate this claim to change it from $100 patient pay to $75 plan pay, $25 patient pay, the plan responded to the next FIR Exchange transaction by passing on to Plan C the updated Plan A amounts for January and Plan B’s existing February amounts. Plan B was responsible for reimbursing $75 to the beneficiary.

In response to the next FIR Exchange transaction received, Plan B forwarded its updated TrOOP accumulator to Plan C.
**Scenario Four:** The beneficiary was enrolled in Plan A in January, 2008, in Plan B in February, 2008 and in Plan C for the remainder of the year. Both Plan A and B had claim activity as reflected below.

<table>
<thead>
<tr>
<th>Month</th>
<th>Plan A</th>
<th>Plan B</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Accumulated TrOOP</td>
<td>Accumulated Gross Covered Drug Cost</td>
</tr>
<tr>
<td>January</td>
<td>275.00</td>
<td>275.00</td>
</tr>
<tr>
<td>February</td>
<td></td>
<td>50.00</td>
</tr>
<tr>
<td>March</td>
<td>New plan C begins coverage</td>
<td></td>
</tr>
</tbody>
</table>

Plan C began adjudicating claims with the $475 drug spend accumulator it received from Plan B. In April, Plan A received documentation from the beneficiary showing a $100 out-of-network prescription drug purchase. Plan A adjudicated the paper claim and in response to the next FIR Inquiry reported the following updated information to Plan B.

<table>
<thead>
<tr>
<th>Month</th>
<th>Plan A</th>
<th>Plan B</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Accumulated TrOOP</td>
<td>Accumulated Gross Covered Drug Cost</td>
</tr>
<tr>
<td>January</td>
<td>300.00</td>
<td>375.00</td>
</tr>
</tbody>
</table>

Plan B compared the previously reported amounts from Plan A and determined that the gross covered drug cost had increased. Plan B administers the defined standard benefit. Based on a review of its claims history, Plan B determined that the $100 increase had no claims impact, because no claims were repositioned in different benefit phases.

Therefore, Plan B responded to the FIR Exchange transaction by reporting the following amounts to Plan C.

<table>
<thead>
<tr>
<th>Month</th>
<th>Plan A</th>
<th>Plan B</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Accumulated TrOOP</td>
<td>Accumulated Gross Covered Drug Cost</td>
</tr>
<tr>
<td>January</td>
<td>300.00</td>
<td>375.00</td>
</tr>
</tbody>
</table>
Scenario Five: The beneficiary was enrolled in Plan A in January and February, 2008 and in Plan B for March, 2008 and forward. Plan B administers the defined standard benefit. Because Plan A had no claim activity, it reported zero accumulators to Plan B on the initial Inquiry transaction and Plan B adjudicated a $100 claim in the Deductible on March 1.

Later on March 1, Plan B received a FIR Update transaction reporting the following amounts from Plan A.

<table>
<thead>
<tr>
<th>Month</th>
<th>Plan A</th>
<th>Plan B</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Accumulated TrOOP</td>
<td>Accumulated Gross Covered Drug Cost</td>
</tr>
<tr>
<td>January</td>
<td>200.00</td>
<td>225.00</td>
</tr>
<tr>
<td>February</td>
<td>100.00</td>
<td>250.00</td>
</tr>
</tbody>
</table>

Upon receipt of this transaction, Plan B reviewed its claims history and determined that the $475 increase moved Plan B’s first $100 claim from the Deductible into the ICP. Plan B recalculated this claim to change it from $100 patient pay to $75 plan pay, $25 patient pay. Plan B was also responsible for reimbursing $75 to the beneficiary.

Scenario Six: The beneficiary initially enrolled in Plan A during the AEP in December 2007. On December 31, 2007, the beneficiary sends an application to Plan B for enrollment effective January 2008. Both plans administer the defined standard benefit, and both issue a member ID card to the beneficiary. In February, the beneficiary changed enrollment to Plan C.

During the month of January, the beneficiary used the ID cards from both Plan A and B. Prior to receiving the transaction reply report (TRR) reflecting the enrollment change, Plan A paid claims in January totaling $100 all patient pay in the Deductible. Plan B then paid a $50 claim in January, also all patient pay in the Deductible. Because the Plan A enrollment was processed for January, the transaction facilitator was able to identify the change of enrollment to Plan B and sent a FIR Inquiry to Plan A. Upon the subsequent enrollment change to Plan C, the Plan A and B amounts are reported as follows:

<table>
<thead>
<tr>
<th>Month</th>
<th>Plan A</th>
<th>Plan B</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Accumulated TrOOP</td>
<td>Accumulated Gross Covered Drug Cost</td>
</tr>
<tr>
<td>January</td>
<td>100.00</td>
<td>100.00</td>
</tr>
</tbody>
</table>
February New plan C begins coverage

In March, one of Plan A’s paid claims from January was reversed by the pharmacy decreasing the beneficiary’s gross covered drug cost and TrOOP amounts to $50. Plan A reported the new accumulators to Plan B on the next FIR Inquiry transaction and submitted a deletion PDE for the reversed claim.

Plan B reviewed its claims history and determined that the $50 decrease had no claims impact, because no claims were repositioned in different benefit phases. Plan B sent the updated amounts to Plan C as follows:

<table>
<thead>
<tr>
<th>Month</th>
<th>Plan A</th>
<th>Plan B</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Accumulated TrOOP</td>
<td>Accumulated Gross Covered Drug Cost</td>
</tr>
<tr>
<td>January</td>
<td>50.00</td>
<td>50.00</td>
</tr>
<tr>
<td></td>
<td>50.00 (Plan A) + 50.00 (Plan B) = 100.00(to new plan)</td>
<td>50.00 (Plan A) + 50.00 (Plan B) = 100.00(to new plan)</td>
</tr>
<tr>
<td>February</td>
<td>Plan C begins coverage</td>
<td></td>
</tr>
</tbody>
</table>

**Scenario Seven**: The beneficiary was in Plan A January-March 2008, in Plan B in April and May 2008, and in Plan C for the remainder of the year. Both Plan A and B had claim activity as reflected below.

<table>
<thead>
<tr>
<th>Month</th>
<th>Plan A</th>
<th>Plan B</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Accumulated TrOOP</td>
<td>Accumulated Gross Covered Drug Cost</td>
</tr>
<tr>
<td>January</td>
<td>150.00</td>
<td>150.00</td>
</tr>
<tr>
<td>February</td>
<td>125.00</td>
<td>125.00</td>
</tr>
<tr>
<td>March</td>
<td>31.25</td>
<td>125.00</td>
</tr>
<tr>
<td>April</td>
<td></td>
<td>187.50</td>
</tr>
<tr>
<td>May</td>
<td></td>
<td>62.50</td>
</tr>
<tr>
<td>June</td>
<td>New plan C begins coverage</td>
<td></td>
</tr>
</tbody>
</table>
Plan C began adjudicating claims with the $1400 in gross covered drug cost it received from Plan B.

Plan A responded to the next FIR Inquiry transaction by reporting its existing accumulators of $400 in gross covered drug costs and $306.25 in TrOOP to Plan B, but Plan B was unable to respond before the Exchange transaction was timed out. The transaction facilitator retried Plan B as specified in their FIR protocol. Once Plan B responded, a FIR Inquiry was again sent to Plan A, and on their Exchange transaction, Plan B responded with their current balances. The transaction facilitator then sent a FIR Update transaction to Plan C reporting Plan A and B balances.

**Scenario Eight**: The beneficiary was in Plan A January-March 2008. During these months, Plan A had claims activity. On March 12, the beneficiary elected enrollment in Plan B for April, but subsequently, on March 29, elected enrollment for April in Plan C. Because the Plan B enrollment was processed prior to the April cut-off, Plan B received a TRR reporting the enrollment and issued a member ID card to the beneficiary. During April, the Plan C enrollment was processed and Plan B enrollment was audited. The beneficiary remained in Plan C through May and enrolled in Plan D effective June 2008. With the transaction facilitator’s identification of the Plan B enrollment, Plan A received a FIR Inquiry transaction on March 31st and reported accumulators to Plan B.

<table>
<thead>
<tr>
<th>Month</th>
<th>Plan A</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Accumulated TrOOP</td>
<td>Accumulated Gross Covered Drug Cost</td>
</tr>
<tr>
<td>January</td>
<td>100.00</td>
<td>100.00</td>
</tr>
<tr>
<td>February</td>
<td>175.00</td>
<td>175.00</td>
</tr>
<tr>
<td>March</td>
<td>31.25</td>
<td>125.00</td>
</tr>
</tbody>
</table>

Plan B began adjudicating claims in April with the $400 drug spend accumulator. The Plan C enrollment was processed in April with a retroactive enrollment data of April 1. Both Plan B and Plan C received TRRs reporting the Plan C enrollment, however prior to receipt of this TRR, Plan B paid $100 in claims.

With the transaction facilitator’s notification of the Plan C enrollment, Plan A again received a FIR Inquiry transaction and reported their accumulators to Plan B. Plan B compared this with the previous FIR transaction from Plan A, determined there had been no change, and forwarded the following accumulators to Plan C.

<table>
<thead>
<tr>
<th>Month</th>
<th>Plan A</th>
<th></th>
<th>Plan B</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Accumulated TrOOP</td>
<td>Accumulated Gross Covered Drug Cost</td>
<td>Accumulated TrOOP</td>
<td>Accumulated Gross Covered Drug Cost</td>
</tr>
<tr>
<td>January</td>
<td>100.00</td>
<td>100.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>February</td>
<td>175.00</td>
<td>175.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>March</td>
<td>31.25</td>
<td>125.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>April</td>
<td></td>
<td></td>
<td>25.00</td>
<td>100.00</td>
</tr>
</tbody>
</table>
Plan C began adjudicating claims with the $500 drug spend accumulator it received from Plan B, and had claims activity. With the transaction facilitator’s identification of the Plan D enrollment, Plan A again received a FIR Inquiry transaction and reported their accumulators to Plan B. Plan B again compared this with the previously reported amounts from Plan A, determined there had been no change, and forwarded the balances to Plan C. Plan C compared this with the previous FIR Exchange transaction from Plan B, determined there had been no change, and forwarded the balances to Plan D.

<table>
<thead>
<tr>
<th>Month</th>
<th>Plan A</th>
<th>Plan B</th>
<th>Plan C</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Accumulated TrOOP</td>
<td>Accumulated Gross Covered Drug Cost</td>
<td>Accumulated TrOOP</td>
</tr>
<tr>
<td>January</td>
<td>100.00</td>
<td>100.00</td>
<td></td>
</tr>
<tr>
<td>February</td>
<td>175.00</td>
<td>175.00</td>
<td></td>
</tr>
<tr>
<td>March</td>
<td>31.25</td>
<td>125.00</td>
<td></td>
</tr>
<tr>
<td>April</td>
<td></td>
<td>25.00</td>
<td>100.00</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>May</td>
<td></td>
<td></td>
<td>125.00</td>
</tr>
<tr>
<td>June</td>
<td>New Plan D</td>
<td></td>
<td>500.00</td>
</tr>
</tbody>
</table>

Plan D began adjudicating claims with the $1150 drug spend accumulator it received from Plan C.

**Scenario Nine:** The beneficiary was enrolled in Plan A effective January 1, 2008 and the plan had claims activity. On January 30, the beneficiary elected enrollment in Plan B effective February 1. Because the Plan B enrollment was processed after the February cut-off, Plan A continued processing claims until mid-February when the Plan B enrollment was processed and Plan A received a TRR reporting the audited enrollment. On March 10, the beneficiary’s enrollment request for Plan C was processed with an effective date of April 1. In February, when the transaction facilitator identified the Plan B enrollment, Plan A received a FIR Inquiry transaction and reported the beneficiary’s accumulators to Plan B.

<table>
<thead>
<tr>
<th>Month</th>
<th>Plan A</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Accumulated TrOOP</td>
</tr>
<tr>
<td>January</td>
<td>175.00</td>
</tr>
<tr>
<td>February</td>
<td>112.50</td>
</tr>
</tbody>
</table>
Plan B began adjudicating claims with the $325 drug spend accumulator. In March, the pharmacy reversed a $75 February claim to Plan A changing the plan’s accumulators for February. When the Plan C enrollment was processed in March, the transaction facilitator identified the enrollment change and sent a FIR Inquiry transaction to Plan A which reported the following updated accumulators to Plan B.

<table>
<thead>
<tr>
<th>Month</th>
<th>Plan A</th>
<th>Plan B</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Accumulated TrOOP</td>
<td>Accumulated Gross Covered Drug Cost</td>
</tr>
<tr>
<td>January</td>
<td>175.00</td>
<td>175.00</td>
</tr>
<tr>
<td></td>
<td>75.00</td>
<td>75.00</td>
</tr>
<tr>
<td>February</td>
<td>75.00</td>
<td>75.00</td>
</tr>
<tr>
<td></td>
<td>75.00</td>
<td>75.00</td>
</tr>
</tbody>
</table>

Plan B reviewed its claims history and determined that the $75 decrease moved Plan B’s first February claim from wholly in the ICP to straddling the Deductible and ICP. Because Plan B needed to recalculate this claim, the plan reported to Plan C the updated Plan A January accumulators, the combined Plan A and B February drug costs, and the total of the updated Plan A February TrOOP amount with the previous Plan B February TrOOP balance.

With the next FIR Inquiry transaction, Plan A reported unchanged accumulators for January and February to Plan B. Plan B reported the accumulators as previously sent to Plan C, except the plan was also able to send an updated TrOOP balance for February reflecting the re-adjudication of the straddle claim.
After re-adjudicating the first February claim that had previously been processed in the ICP as $75 plan pay and $25 patient pay, Plan B was responsible for recovering the additional amount owed by the beneficiary.

**Scenario Ten:** The beneficiary was in Plan A January-February 2008, then Plan B during March through June. Both plans had claims activity during the months of the beneficiary’s enrollment in their plan. Effective July, the beneficiary chooses to re-enroll in Plan A.

With the *transaction* facilitator’s identification of the Plan B enrollment, Plan A received a FIR Inquiry transaction and reported accumulators to Plan B as follows:

<table>
<thead>
<tr>
<th>Month</th>
<th>Plan A</th>
<th>Plan B</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Accumulated TrOOP</td>
<td>Accumulated Gross Covered Drug Cost</td>
</tr>
<tr>
<td>January</td>
<td>75.00</td>
<td>75.00</td>
</tr>
<tr>
<td>February</td>
<td>75.00</td>
<td>75.00</td>
</tr>
</tbody>
</table>

Subsequent FIR Inquiry transactions were sent to Plan A according to the established schedule and the accumulators reported to Plan B. Then, with the *transaction* facilitator’s identification in late June of prospective Plan A re-enrollment effective July 1st, Plan A received a FIR Inquiry transaction and reported the accumulators to Plan B. Plan B received and responded to a FIR Exchange transaction with the combined accumulators. The following data were sent to Plan A in a FIR Update transaction and Plan A began to adjudicate claims in July using $450 in gross covered drug costs.

<table>
<thead>
<tr>
<th>Month</th>
<th>Plan A</th>
<th>Plan B</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Accumulated TrOOP</td>
<td>Accumulated Gross Covered Drug Cost</td>
</tr>
<tr>
<td>January</td>
<td>75.00</td>
<td>75.00</td>
</tr>
<tr>
<td>February</td>
<td>75.00</td>
<td>75.00</td>
</tr>
<tr>
<td>March</td>
<td>75.00</td>
<td>75.00</td>
</tr>
<tr>
<td>April</td>
<td>100.00</td>
<td>100.00</td>
</tr>
<tr>
<td>May</td>
<td>14.25</td>
<td>75.00</td>
</tr>
<tr>
<td>June</td>
<td>25.00</td>
<td>100.00</td>
</tr>
<tr>
<td>July</td>
<td>Re-enrollment Plan A</td>
<td></td>
</tr>
</tbody>
</table>

Subsequently in early July, Plans A and B received TRRs indicating that the Plan A re-enrollment was audited due to the beneficiary’s election to remain enrolled in Plan B. However, because the Plan A re-enrollment was processed, Plan A paid claims in July prior to receipt of the TRR. With the *transaction* facilitator’s identification of the audited
Plan A re-enrollment and the continuation of Plan B enrollment, Plan A received a FIR Inquiry transaction and reported their January, February and July accumulators to Plan B.

<table>
<thead>
<tr>
<th>Month</th>
<th>Plan A</th>
<th>Plan B</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Accumulated TrOOP</td>
<td>Accumulated Gross Covered Drug Cost</td>
</tr>
<tr>
<td>January</td>
<td>75.00</td>
<td>75.00</td>
</tr>
<tr>
<td>February</td>
<td>75.00</td>
<td>75.00</td>
</tr>
<tr>
<td>March</td>
<td>25.00</td>
<td>25.00</td>
</tr>
<tr>
<td>April</td>
<td>100.00</td>
<td>100.00</td>
</tr>
<tr>
<td>May</td>
<td>14.25</td>
<td>75.00</td>
</tr>
<tr>
<td>June</td>
<td>25.00</td>
<td>100.00</td>
</tr>
<tr>
<td>July</td>
<td>23.75</td>
<td>95.00</td>
</tr>
</tbody>
</table>

Plan B compared these data with the January and February accumulators previously reported by Plan A to determine if there had been a change that would affect Plan B’s adjudication of the claims processed during the period March through June. Plan B then began processing claims in July with $545 in gross covered drug costs.
POLICY:

Part D sponsors must report TrOOP-related data for their months of coverage for beneficiaries who disenroll during the coverage year to the beneficiary’s subsequent Part D plan sponsor. Plan sponsors, with the exception of PACE organizations, will report these data to the transaction facilitator in response to FIR transaction requests. Because PACE organizations have been exempted from this automated TrOOP transfer process, TrOOP related data will be transferred as follows:

- For beneficiaries enrolling into a PACE plan after disenrolling from another Part D plan, the PACE plan will request from the beneficiary the most recent explanation of benefits (EOB) provided by the prior Part D sponsor.
- For beneficiaries disenrolling from a PACE plan to enroll in another Part D plan, the PACE plan will report the data to the beneficiary to communicate to his or her subsequent plan sponsor.

PACE plans may elect to participate in the automated TrOOP balance transfer process. Plans electing to participate should contact the transaction facilitator and request inclusion.

AUTHORITY:

42 CFR §423.104 – Requirements related to qualified prescription drug coverage.

42 CFR §423.464 – Coordination of benefits with other providers of prescription drug coverage.

APPLICABLE GUIDANCE:

Pub. 100-18, Medicare Prescription Drug Manual- Chapter 14 Coordination of Benefits, Section 50.9.2- Automated TrOOP Balance Transfer Process.

HPMS Memo, Medicare Drug Benefit Group, Change in Implementation Schedule for Automated TrOOP Balance Transfer (March 18, 2008).

HPMS Memo, Updated Part D Sponsor Automated TrOOP Balance Transfer Operational Guidance (October 21, 2008)

BACKGROUND:
Part D rules require sponsors to track the beneficiary’s TrOOP costs and gross covered drug costs and properly apply these costs to the TrOOP and benefit limits in order to correctly place the beneficiary in the benefit and provide the catastrophic level of coverage at the appropriate time. The TrOOP threshold and gross covered drug costs are calculated on an annual basis and must be transferred between Part D plans if a beneficiary disenrolls and re-enrolls at any time before the end of the coverage year.

FACILITATOR PROCEDURE:

The facilitator will access the monthly list of active Part D contracts available on the CMS Web site at: http://www.cms.hhs.gov/MCRAdvPartDEnrolData/01_Overview.asp#TopOfPage to identify the contract numbers for all PACE organizations with a Part D contract. The list is in a zip file under the “Monthly Enrollment by Contract” link, and provides all active contracts and their organization type.

When the facilitator identifies a beneficiary plan enrollment change at the contract level, the facilitator must determine if a PACE contract is the disenrolling sponsor. If so, the facilitator should follow the TrOOP balance transfer sequence outlined below.

**TrOOP balance transfer sequence involving PACE plan enrollment**

Once the facilitator determines the disenrolling plan is a PACE contract, it must determine if there was Part D plan enrollment during the coverage year.

- If there was prior Part D enrollment, the facilitator will exempt the beneficiary from all automated TrOOP balance transfers and refer the case to CMS for coordination of the transfer of the TrOOP-related data.

- If there was no prior Part D enrollment, the new plan will receive the accumulator data from the beneficiary and use these data to correctly position the beneficiary in the benefit.

- If the beneficiary makes subsequent plan enrollment changes during the coverage year, the facilitator will initiate the FIR sequence without regard to the PACE plan enrollment with an Inquiry transaction to the first non-PACE plan, Exchange transactions to any subsequent plans, and an Update transaction to the newly enrolling plan.

  - The first non-PACE plan will respond to the Inquiry transaction, reporting the PACE accumulators in the month prior to the first month of enrollment in the non-PACE plan and the plan’s own accumulator data.

PACE ORGANIZATION PROCEDURES:

**Enrollment into a PACE plan from another Part D plan**
For these beneficiaries, the PACE plan will request the beneficiary’s most recent prior Part D plan EOB to determine the member’s gross covered drug costs and TrOOP.

**Disenrollment from a PACE plan into another Part D plan**

For these beneficiaries, the PACE plan will report the TrOOP-related data to the beneficiary and direct the beneficiary to communicate the information to his or her subsequent plan sponsor. The data reported will depend upon whether the PACE is a Medicare-only or dual eligible plan.

**Medicare-only PACE Plans**

If a member disenrolls from a Medicare-only PACE plan and re-enrolls with a new Part D plan sponsor, the PACE organization must take the following steps:

1. Compute the member’s PACE-only gross covered drug costs. TrOOP amounts for these beneficiaries will always be zero.

2. Provide these data as well as the months during the coverage year the member had incurred costs for prescription drugs and the coverage year being reported to the member in writing with instructions to communicate the information to his or her new plan. This report must be provided to the beneficiary within 7 days of the date of the TRR notifying the PACE organization of the member’s disenrollment.

3. If the PACE plan’s GCDC for the beneficiary change for any reason during the current calendar year through March of the subsequent year, the PACE plan must notify the beneficiary of the changed data in writing with instructions to communicate the updated information to his or her new plan. This notification to the beneficiary must be sent by the 15th of the month following the month in which the GCDC change occurred.

**Dual Eligible PACE Plans**

If a member disenrolls from a dual-eligible PACE plan and re-enrolls with a new Part D plan sponsor, the PACE organization must take the following steps:

1. Compute the member’s PACE-only GCDC.

2. Enter the PACE-only GCDC (i.e., total gross covered drug costs) into the Dual Eligible PACE TrOOP Calculator to determine the PACE TrOOP amount.

3. Provide these data as well as the months during the coverage year the member had incurred costs for prescription drugs and the coverage year being reported to the member in writing with instructions to communicate the information to his or her new plan. This report must be provided to the beneficiary within 7 days of the date of the TRR notifying the PACE organization of the member’s disenrollment.
4. If the PACE organization’s accumulators for the beneficiary change for any reason during the current calendar year through March of the subsequent year, the PACE must notify the beneficiary of the changed data in writing with instructions to *communicate* the updated information to his or her new plan. This notification to the beneficiary must be sent by the 15th of the month following the month in which the change in the accumulators occurred.
Sample format for the beneficiary notice:

Notice of Benefit Information for Your New Medicare Prescription Drug (Part D) Plan

THIS IS NOT A BILL. Report this information to your new prescription drug plan and keep this notice for your records.

<Member Name>   <Date>
<Street Address>    Member ID Number: <Member ID>
<City, State ZIP Code>  <Rx PCN or Rx Group Number>:

This notice includes:
1. TrOOP and Gross Drug Costs balances from the PACE plan during <coverage year>.

2. Any adjustments to your out-of-pocket costs or total drug costs due to new claims, reversed claims, or any other adjustments.

Totals
- (Insert total of all covered drug costs paid, including by the plan, the enrollee, the LIS subsidy, and all others who paid on the enrollee’s behalf, i.e., Gross Covered Drug Costs) Total PACE Drug Costs from <date> to <date>:

- (Insert total of all covered drug costs paid by the enrollee, the LIS subsidy, and all others whose payments count toward the enrollee’s TrOOP costs, i.e., TrOOP amount) Out-of-Pocket costs during PACE plan enrollment:

Out-of-Pocket Costs - Includes payments that you and/or certain others on your behalf paid for covered drugs during the coverage year. This includes payments made in the [deductible,] [and/or] initial coverage period [and/or coverage gap] this coverage year. Payments made by certain others that count toward your out-of-pocket costs include those made by family members, [(applicable to LIS only) Medicare’s extra help,] State Pharmaceutical Assistance Programs (SPAPs), and most charities. This amount does not include amounts paid by <plan name> or certain others making payments on your behalf. Payments made by certain others that don’t count toward your out-of-pocket costs include those made by group health plans (like from a current or former employer or union), other insurance, or Government-funded health programs. Once your out-of-pocket costs reach <$xx>, you move into the catastrophic coverage period.

Total Drug Costs - This is the total amount spent on your covered drugs this coverage year by <Plan Name>, you, and/or all others making payments on your behalf during all coverage periods. [(Applicable to LIS only.) This amount also includes any extra help you got from Medicare this year.]
Example:
A beneficiary disenrolled from a dual eligible PACE plan effective August 2009. The beneficiary had prescription drug claims in all months January - July totaling $2660.74. Using the dual eligible PACE plan beneficiary accumulated TrOOP calculator, the plan determines the member’s accumulated TrOOP equaled $931.28.

This notice includes:
1. TrOOP and Gross Covered Drug Cost balances from the PACE plan during 2009.

2. Any adjustments to your out-of-pocket costs or total covered drug costs due to new claims, reversed claims, or any other adjustments.

Totals
- Total PACE Covered Drug Costs from January 1, 2009 to July 31, 2009: $2660.74
- Out-of-Pocket costs during PACE plan enrollment: $931.28
Appendix E – Issues for Other Entities Providing Prescription Drug Coverage
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

As provided in 42 CFR 423.464(f), Part D plans must permit SPAPs and entities providing other prescription drug coverage to coordinate benefits with them. Examples of entities providing other prescription drug coverage include SPAPs, Medicaid programs, group health plans, Federal Employees Health Benefits Program (FEHBP) plans, military coverage, IHS coverage, charities, manufacturer PAPs, Federally qualified health centers (FQHCs), and rural health centers (RHCs). In this appendix, CMS discusses COB issues applicable to some of these entities.

State Pharmaceutical Assistance Programs

Qualified SPAPs are unique among other payers because any payments they make that supplement the benefits available under Part D coverage before reaching the plan’s annual out-of-pocket limit count toward TrOOP. CMS expects that qualified SPAPs will share enrollment files with CMS through the data sharing arrangements outlined in section 30.1. Although SPAP wrap-around coverage automatically counts toward TrOOP – and some programs have questioned the need for SPAPs to participate in CMS’ COB and TrOOP facilitation processes – there are benefits to participation in the COB process as other payers. For example, as part of the enrollment file sharing with SPAPs, CMS provides SPAPs with certain information fields (for example, low-income subsidy status and details) that they will need to effectively wrap-around Part D coverage on behalf of their Part D enrollees. In addition, as noted above, by making their claim payments a matter of record with the Part D plans, SPAPs provide the means for Part D sponsors to execute reimbursement of erroneous payments, such as those that may occur in reimbursing cost sharing incurred by low-income subsidy eligible enrollees between the date of their eligibility and the time the subsidy has been programmed by the Part D sponsor. Most importantly, participation in the TrOOP facilitation process allows the beneficiary’s multiple benefits to process seamlessly at the point of sale, even if they do not present all of their ID cards.

Exchanging Historical and Ongoing Claims Data

As mentioned in section 50.11 of this chapter regarding the sharing of claims data, CMS cannot require data exchanges between Part D sponsors and the States, except as required for COB purposes. However, CMS strongly encourages sponsors to independently share historical and ongoing data on these shared enrollees with SPAPs, provided such disclosure is consistent with the requirements of the HIPAA Privacy Rule. Drug history exchanges between States and sponsors are discussed further in section 50.11 of this chapter.

Coordinating Payment

As provided in these guidelines, SPAPs may choose to coordinate their benefits with Part D sponsors using a variety of approaches. With the exception of the risk-based approach,
all Part D sponsors are required to coordinate with the SPAP. As indicated in the prior section discussing the non-risk approach, CMS will take compliance action against all sponsors that do not comply with the non-risk requirement. If a sponsor is out of compliance with this requirement, CMS will not disqualify a state program from its qualified SPAP status. SPAPs will not be viewed as discriminating based on a Part D sponsor’s non-compliance because CMS believes the sponsor, by failing to adhere to this COB requirement, has effectuated the discrimination. CMS will require states to collect an attestation from the sponsor that it does not want to participate in the non-risk approach. States will submit this attestation to CMS so that CMS may work with the sponsors to comply with this COB requirement. A sponsor will also be required to communicate to its beneficiaries that it is not participating in the State’s program.

In addition to the lump sum scenarios mentioned in section 50.7 of this chapter, SPAPs may provide their own wrap-around benefit at the point-of-sale, or solicit a sponsor or processor who agrees to administer their wrap-around benefit for them. The sponsor or processor (who may or may not be a Part D sponsor) will administer their SPAP wrap-around benefit. This organization will agree to administer the SPAP benefit to all Part D beneficiaries that qualify for the SPAP benefit regardless of the Part D sponsor in which the beneficiary is enrolled. As the administrator of the benefit, SPAPs will most likely require these organizations to:

- Process secondary claims using the NCPDP V. 5.1 electronic claims format.
- Require COB segment on the secondary claim.
- Provide coverage of drugs on the State’s formulary.
- Provide coverage of drugs at SPAP network pharmacies.
- Administer rebates applicable to the SPAP wrap benefit.

Enrollment

Certain SPAPs may have the authority to enroll their members directly into Part D sponsors if using an enrollment methodology expressly approved by CMS, and have expressed a desire to be allowed to use a standard electronic file format to complete the enrollment process. While Part D sponsors will not be required to accept a standard electronic file directly from an SPAP, CMS encourages Part D sponsors to negotiate with SPAPs on this point so as to facilitate a streamlined enrollment process.

Medicaid

Medicaid cannot receive Federal Financial Participation (FFP) for drugs covered under Part D that are provided to full benefit dual eligibles. State Medicaid programs may provide Medicaid coverage of drugs listed under section 1927(d)(2) of the Social Security Act, which the MMA excludes from the definition of coverage under Part D drugs. To the extent that Medicaid covers those excluded drugs, the state can receive FFP for that
coverage. However, coverage of non-Part D drugs by State Medicaid programs will not count toward a beneficiary’s TrOOP balance.

**Drug coverage** - CMS understands that many Medicaid programs may wish to provide coverage for non-Part D drugs to provide continuity of coverage to dual eligible Part D enrollees. To that end, Part D sponsors may wish to develop a process whereby the pharmacy is informed that Medicaid is a payer only if a claim is denied as a non-Part D drug and there are no other secondary/tertiary payers that may pay the claim. Part D sponsors are required to implement reject messaging that will allow pharmacies to identify claims for excluded Part D drugs that can be billed to the State.

**Data exchange** - As discussed previously in section 50.11 of this chapter, CMS does not have the authority to require data exchanges between Part D sponsors and the States, except as required for COB purposes. However, CMS strongly encourages Part D sponsors to independently share historical and ongoing data on these shared enrollees with State Medicaid agencies, provided such disclosure is consistent with the requirements of the HIPAA Privacy Rule. CMS believes claims data exchanges will be mutually beneficial to States and Part D sponsors as they structure their benefits.

**Veterans Administration Coverage**

VA benefits – including prescription drug coverage – are separate and distinct from benefits provided under Part D. By law, VA cannot bill Medicare. In other words, coordination of benefits between Part D and VA benefits is not possible. While a beneficiary may be eligible to receive VA prescription drug benefits and enroll in a Part D sponsor, he or she cannot use both benefits for a single prescription. VA prescriptions generally must be written by a VA physician and can only be filled in a VA facility or through VA’s Consolidated Mail Outpatient Pharmacy (CMOP) operations. VA does not fill prescriptions for Part D sponsors. Since VA and Part D benefits are separate and distinct, a veteran’s payment of a VA medication copayment does not count toward his or her gross covered drug costs or TrOOP expenditures under his or her Part D benefit.

*Because* VA prescription drug coverage is creditable coverage, beneficiaries will not face a penalty if they delay enrollment in a Part D plan. However, some beneficiaries who receive less than full VA prescription drug benefits may benefit from enrollment in a Part D plan, particularly if they are eligible for the low-income subsidy.

**TRICARE**

TRICARE for Life pays secondary to Medicare to the extent that a benefit is payable by both Medicare and TRICARE. TRICARE for Life’s pharmacy benefit wraps around Medicare Part D and will pay any beneficiary cost-sharing remaining, up through the cost-sharing that beneficiary would have had otherwise paid under TRICARE. *However, this applies* only if a beneficiary is enrolled in a Part D plan, the drug is a covered Part D drug, the covered Part D drug is also covered by TRICARE, and the drug is obtained at a pharmacy participating in both the Part D plan’s and TRICARE’s network.
Because TRICARE for Life is creditable coverage, beneficiaries will not face a penalty if they delay enrollment in a Part D plan. However, some beneficiaries who receive TRICARE for Life benefits may benefit from enrollment in a Part D plan—particularly if they are eligible for the low-income subsidy. To the extent that a beneficiary is enrolled in both TRICARE for Life and a Part D plan, information about that beneficiary’s TRICARE coverage should be captured and maintained by the COB contractor, and available to Part D sponsors as part of the COB process, through the MARx system. Any wrap-around payments made by TRICARE for covered Part D drugs will count toward a Part D enrollee’s gross covered drug costs but not toward TrOOP since TRICARE is a government-funded health program and, as such, a TrOOP-excluded payer.

**Indian Health Service (IHS)/Tribal Health Coverage**

The Indian health care system, consisting of tribal, urban, and federally operated IHS programs, delivers a spectrum of clinical and preventive health services to its beneficiaries, via a network of hospitals, clinics, and other entities. Section 42 CFR 423.464(f) implementing the Part D COB requirements requires sponsors to coordinate benefits with the IHS and providers of other prescription drug coverage. Tribal health coverage is recognized by CMS as a provider of other prescription drug coverage.

Initially, supplemental coverage by IHS, Indian tribes and organizations, and urban Indian organizations (collectively I/T/U) facilities were not TrOOP eligible because these entities fall under CMS’ definition of “government-funded health program,” in 42 CFR 423.100. However, in certain cases tribes, when providing other prescription drug coverage were independent entities that used only non-government funding to pay secondary coverage for all medical services, including Part D drugs. In those cases, the secondary coverage could have been TrOOP-eligible.

Effective January 1, 2011, section 1860D-2(b)(4)(C) of the Social Security Act was amended to permit assistance with Part D cost-sharing by I/T/U pharmacies to count as incurred costs toward meeting the out-of-pocket threshold at which catastrophic coverage under the Part D benefit begins. CMS regulations continue to require all Part D sponsors to offer network contracts to all I/T/U pharmacies operating in their service area and, in addition, will have to demonstrate to CMS that they provide convenient access to I/T/U pharmacies for American Indians/Alaskan Natives (AI/AN). Thus, COB with the IHS and tribes is inextricably tied to pharmacy network contracting with I/T/U pharmacies. I/T/U pharmacies may submit claims to Part D sponsors electronically (or via paper claims, since some of the more remote I/T/U sites lack electronic capability).

If a tribal member new to the Part D benefit is initially unable to receive Part D benefits through his/her Part D plan, the tribe may have stepped in to pay for the AI/AN Medicare eligible’s Part D prescription drugs in lieu of a Part D plan’s primary coverage. In such cases, tribes are entitled to seek compensation from the Part D plan once enrollment is confirmed. Consistent with CMS COB requirements, plans will be required to reimburse tribes when the tribe has paid primary, just like any other provider of prescription drug coverage.
Safety-Net Providers

A majority of Medicare beneficiaries served by safety-net provider organizations have limited incomes. These safety-net providers typically include Federal, State, and locally supported community health centers (CHCs) or clinics, many of which are deemed FQHCs, public hospital systems, and local health departments. In some communities, they also include mission-driven teaching hospitals, community hospitals and ambulatory care clinics (which are often located in central city areas or serve as the sole provider of health care in the community). RHCs, small rural hospitals, critical access hospitals, clinics that receive Ryan White HIV/AIDS grant funding, and nurse-managed clinics also constitute key components of the safety net.

An estimated 12,000 safety-net providers participate in the Health Resources and Services Administration’s (HRSA) 340B Drug Pricing Program, which allows them to buy their prescription drugs at significantly discounted prices. Participation in the 340B Program can enable pharmacies to provide prescriptions to their patients at lower-than-market price. Because many safety-net providers acquire their prescription drugs through Federal purchasing programs such as the 340B Drug Pricing Program, access to prescription drugs and pharmacy services may be limited to their own patients and not to the public at large. Such “closed pharmacies” may therefore not be open to the general public. For this reason, safety-net pharmacies are typically smaller and less visible to the public than retail pharmacies.

Part D sponsors are not required to contract with safety-net providers. However, CMS created an incentive for Part D sponsors to contract with certain safety-net providers – FQHCs and RHCs – by allowing them to count these pharmacies toward their retail pharmacy networks.

COB between Part D sponsors and safety-net providers is inextricably tied to pharmacy network contracting with safety net pharmacies because the assistance with cost-sharing provided by safety-net pharmacies consists of waived or reduced Part D cost-sharing amounts for beneficiaries enrolled in plans with which the pharmacies contract. The MMA added a new exception to the anti-kickback statute under which pharmacies are permitted to waive or reduce Part D cost-sharing amounts under certain circumstances. For more information about this exception to the anti-kickback statute and the potential impact on TrOOP of Part D cost-sharing waived or reduced by safety-net pharmacies, refer to Pub. 100-18, Medicare Prescription Drug Benefit Manual, chapter 5, section 30.4.

Charities

Regardless of whether a charity is a bona fide charity – and unless the charity is a group health plan, insurance or otherwise, or other third party payment arrangement – any assistance with Part D cost-sharing a charity provides on behalf of a Part D enrollee will count toward a beneficiary’s TrOOP balance. However, any charity is TrOOP eligible only if it’s a legitimate charity. Additionally, to the extent that a charity provides assistance in the form of in-kind donations, CMS generally considers that entity to be a manufacturer patient assistance program (PAP) operating outside Part D, and the value of
that assistance does not count toward a beneficiary’s TrOOP balance (refer to the section below on manufacturer PAPs for more detail).

**Manufacturer Patient Assistance Programs**

Pharmaceutical manufacturers sponsor a number of PAPs that provide free product (through in-kind product donations) to low income patients – particularly those with incomes below 200 percent of the federal poverty level (FPL) – with insufficient or no prescription drug coverage. Part D sponsors are required to coordinate with manufacturer PAPs (hereinafter referred to simply as “PAPs”), as detailed below.

Although sponsors are required to coordinate with PAPs, because PAPs operate entirely outside the Part D benefit (unlike charities offering cost-sharing assistance), this coordination is different in nature than coordination of benefits with supplemental payers operating within the benefit. This is because any assistance a PAP provides to a Part D enrollee for drugs that would have been covered under his/her Part D plan cannot count as an incurred cost that would be applied toward the enrollee’s TrOOP balance or total drug spend. In other words, beginning when a beneficiary’s assistance under a PAP is effective (and for as long as the beneficiary remains eligible for PAP assistance), a claim for a drug for which a PAP has provided assistance will never be submitted to a beneficiary’s Part D plan.

The most effective – and, ultimately, for the beneficiary, the safest – way for PAPs to operate outside the Part D benefit involves front-end data exchanges with CMS through the use of PAP data sharing agreements (DSAs). General information about eligibility file exchange with supplemental payers and other entities is provided in section 30.1 of this chapter. Specific information about PAP DSAs is available on the CMS Web site; see Appendix B for the Web address.

To address safety concerns associated with prescription drugs provided outside the Part D benefits, the front-end data exchange process will enable sponsors to follow-up with PAPs to identify those Part D drugs an enrollee is receiving outside the Part D benefit. This will facilitate sponsors' provision of required drug utilization review and, if applicable, medication therapy management program activities. Alternatively, a PAP that does not participate in CMS's DSA process may provide its enrollees with a notice indicating that they are receiving one or more drug products from that PAP. Sponsors should follow up with PAPs regardless of how they receive information about the possibility of PAP-provided assistance for any of their enrollees.

When a PAP exchanges an eligibility file with CMS, it is identified on the COB data file as Coverage Type “P,” which is not TrOOP-eligible. When a sponsor receives a COB data file for an individual indicating a Coverage Type of “P,” it must follow up with the PAP to obtain the drug-specific information it needs in order to: (1) set its systems to recognize that drug as part of a patient’s profile for purposes of drug utilization review; and (2) set its systems edits to prevent any payment for that prescription. This will be a manual follow-up process because the COB file does not provide sponsors with information about the specific drugs being provided to enrollees by the PAP. Although CMS provides PAP sponsors with a list of COB contacts for each sponsor on the CMS
Web site to facilitate this communication, it remains a sponsor requirement to coordinate the exchange of information with PAPs operating outside the Part D benefit.

Contact information for PAPs will be available in the COB data file, and sponsors should use this number to initiate this manual follow-up and data exchange process. The PAP’s phone number will appear in the PDP COB data file, Appendix E.6.4 Supplemental Record: Subordinate to DTL (Unlimited Occurrences), which can be found in the PCUG. The phone number will be located in the data field labeled “Rx Plan Toll Free Number” when the “Supplemental Code Type” is “P=Patient Assistance Program.”

CMS has encouraged PAPs operating outside the Part D benefit to enter into DSAs with CMS similar to those entered into by supplemental payers coordinating benefit administration with Medicare. Manufacturers sponsoring PAPs continue to express interest in entering into DSAs with CMS, and CMS expects that sponsors will see an increase in “P” (PAP) coverage type indicators on their COB data files as more PAPs enter into DSAs and enroll Part D enrollees.

Sponsors may provide information on or even facilitate enrollment in PAPs for financially needy enrollees, particularly as they reach the coverage gap. To the extent that they do so, however, their bids will need to account for the potential decrease in utilization resulting from enrollees’ receipt of free assistance.

Operating outside the Part D benefit does not preclude a PAP from requiring its enrollees – including those enrolled in a Part D plan – from paying a nominal copayment when they fill a prescription for a covered Part D drug for which they provide assistance. CMS believes that any copayments assessed by PAPs operating outside the Part D benefit should be nominal, since only nominal beneficiary cost-sharing is consistent with the concept of operating outside Part D. Moreover, given that copayments are typically assessed for purposes of minimizing drug overutilization, the assessment of anything but nominal cost-sharing by PAPs is seemingly inconsistent with the mission of a charitable organization structured to provide assistance with prescription drug costs to low-income patients.

Although PAP payments made for those covered Part D drugs outside the benefit may never count toward enrollees’ TrOOP or total drug spend balances, CMS clarifies that any nominal PAP copayment amounts paid by Part D enrollees will be aggregated to their TrOOP and total drug spend balances, provided the enrollees take responsibility for submitting the appropriate documentation to their plan. It will not be permissible, however, for beneficiary payments structured as administrative fees or premiums to be aggregated to Part D TrOOP and total drug spend balances, as these types of beneficiary out-of-pocket expenditures do not meet the definition of “incurred costs” at 42 CFR 423.100 and in Pub. 100-18, Medicare Prescription Drug Benefit Manual, chapter 5, section 30.

Enrollee submission of this documentation is necessary because a PAP operating outside the Part D benefit should never submit a claim for assistance provided for a covered Part D drug to an enrollee’s Part D plan. Consistent with CMS guidance on claims
processing, plans should process these enrollee-submitted claims in the order in which they are received, not based on date of service.

Organizations or entities offering PAPs must comply with all relevant fraud and abuse laws, including, when applicable, the Federal anti-kickback statute and the civil monetary penalty prohibiting inducements to beneficiaries. Liability under the anti-kickback statute requires a case-by-case analysis of the particular facts and circumstances, including the intent of the parties. The HHS Office of the Inspector General (OIG) enforces Federal fraud and abuse statutes, and all questions regarding the compliance of specific arrangements with these statutes should be referred to the OIG. General OIG guidance regarding Part D and PAPs is available on the OIG Web site; see Appendix B for the specific Web address.

**Personal Health Savings Vehicles**

**HSAs, FSAs, and MSAs**

In the final Part D regulations, CMS indicated that HSAs, FSAs, and MSAs are not group health plans for TrOOP purposes, and that distributions from these personal health savings vehicles will count as incurred costs for the purposes of TrOOP accounting. Thus, information about these accounts need not be reported to CMS. However, if any of these accounts is set up to pay benefits at the point-of-sale, and wishes to be included in the automated payer data exchange provided by the *transaction facilitator*, the administrators of such accounts would need to exchange eligibility files with CMS and be included in the COB files provided by CMS. Alternatively, account administrators may require beneficiaries to submit paper claims after the POS transaction so they can then submit those claims to the TrOOP facilitation contractor in batch form. *The transaction facilitator* will create an NCPDP Nx transaction based on that batched claims data and will send it back to the beneficiary’s Part D sponsor for accurate TrOOP recalculation.

**HRAs**

HRAs, however, generally are considered group health plans for purposes of Part D, and distributions from these accounts will not count toward TrOOP. HRAs are therefore group health plans subject to all the requirements that apply to other payers providing prescription drug coverage. HRA administrators will have the option of entering into data sharing agreements offered by CMS, or they can submit batched claims data to the *transaction facilitator* after the POS transaction. This will help supplement the information about other payers that beneficiaries must relay to their Part D sponsors and aid in the accurate calculation of TrOOP.

**AIDS Drug Assistance Programs (ADAP)**

AIDS Drug Assistance Programs (ADAPs), which are funded under the Ryan White CARE Act, are an integral component of the safety-net for HIV/AIDS patients because they fill coverage gaps in public and private insurance for critical HIV/AIDS drug treatments. Although *initially* assistance with Part D cost-sharing by ADAPs *did* not count as incurred costs toward meeting the out-of-pocket threshold at which catastrophic
coverage under the Part D benefit begins, effective January 1, 2011, section 1860D-2(b)(4)(C) of the Social Security Act was amended to permit costs borne or paid for by an ADAP to count toward a beneficiary's TrOOP.

To the extent that ADAPs want to be set up to pay benefits at the point-of-sale and wish to be included in the automated payer data exchange provided by the COB contractor, they will need to exchange eligibility files with CMS and be included in the COB files provided by CMS. The advantage to this approach is that claims will be automatically adjudicated at point-of-sale (POS) and routed to the Transaction Facilitator.

Alternatively, ADAPs may require beneficiaries to submit paper claims after the POS transaction so they can then submit those claims to the transaction facilitator in batch electronic format per the NCPDP standard. The transaction facilitator will create an NCPDP Nx transaction based on that batched claims data and will send it back to the beneficiary’s Part D sponsor for accurate TrOOP recalculation.

CMS and the transaction facilitator have developed a process to increase the likelihood that these SPAP and ADAP claims are appropriately applied to the member’s TrOOP and that the appropriate entity is refunded in the event of a copay/coinsurance adjustment. Guidance describing this process is available on the NCPDP Web site under the “Resources” tab. See Appendix B for the specific Web address.
Appendix F – Part D Requirements Waived for PACE Organizations

(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

PACE is a comprehensive, coordinated model of care designed to meet the needs of frail elders. There are several key differences between the way in which PACE organizations (POs) provide the Part D benefit and how it is provided by other Part D sponsors.

Tracking of TrOOP

- Dual Eligible Beneficiaries:

  CMS fully subsidizes dual eligible individuals’ Part D coverage in PACE organizations. Therefore, consistent with PACE rules, there is no beneficiary out-of-pocket expense, which eliminates the applicability of TrOOP for these beneficiaries.

- Beneficiaries Eligible for Only Medicare:

  PACE beneficiaries who are only Medicare eligible pay a supplemental premium based on the anticipated cost-sharing covered by the PACE plan. As a result, for these beneficiaries TrOOP does not apply.

Accessing Covered Part D Drugs

For the most part, POs fully coordinate their participants’ access to covered Part D drugs, providing prescriptions directly to the participant. As a result, most POs are not set up for real-time, on-line prescription drug claims processing and neither have nor report 4Rx data to CMS.

Transferring Data When a Beneficiary Changes Sponsors

When a beneficiary disenrolls from a PO and re-enrolls in another Part D sponsor at any time during the coverage year, the PO is required to transfer the TrOOP balance (if any) and the gross covered drug costs to the new sponsor of record to permit the correct placement of the beneficiary in the benefit.

Prior to the January 1, 2009, implementation of the automated TBT process, POs must send the beneficiary’s year-to-date TrOOP and gross covered drug costs, including amounts accumulated during the beneficiary’s period of enrollment in the PO plus amounts previously reported to the PO by a prior plan sponsor for months of enrollment during the same coverage year. For beneficiaries who are dually eligible, POs should use the Dual Eligible PACE Plan Beneficiary Accumulated True Out-of-Pocket Cost Calculator to calculate the amount of TrOOP to be reported to the new plan sponsor. The calculator is available on the CMS Web site; see Appendix B for the specific Web address.
POs are exempt from the automated TBT process implemented January 2009; however, POs are not precluded from using the automated process and may elect to do so. Guidance outlining the requirements for the transfer of TrOOP balances involving PO enrollees was issued as an addendum to the automated TrOOP balance transfer guidance and is in Appendix D.

Waiver for Veterans Administration (VA)-eligible PACE Enrollees

In 2010, the Veterans Health Administration (VHA) awarded funds to VA Medical Centers (VAMC) to pursue and implement service agreements with PACE organizations to coordinate prescription drug coverage between the VA and VA-eligible PACE enrollees. Seven VAMCS contracted with 11 PACE organizations to provide prescription drug coverage for veterans enrolled in PACE.

Existing PACE regulations at 42 CFR 460.92 require that the PACE provide all Medicare-covered services, including Part D prescription drug coverage. In addition, Part D regulations at 42 CFR 423.30(c) require PACE enrollees to obtain their prescription drug benefits from their PACE organization. As a result, PACE enrollees who are also eligible for the VA benefit must receive prescription drug coverage through their PACE organization and Medicare-only PACE veterans must pay a significant Medicare Part D premium to the PACE organization to obtain the drug coverage.

The arrangements between the VA and PACE organizations, by facilitating coordination of prescription drug benefits between the VA and Medicare, permitted CMS to waive the requirements in §423.30(c) thus permitting PACE veterans to receive prescription drug coverage through the VA and avoid paying the Part D premium. PACE organizations with a service agreement with a VAMC received notification from CMS of the waiver of §423.30(c), which was issued under the authority of §423.458(d) which permits waivers of requirements as necessary to improve coordination between Part D and PACE. The notice also stated that CMS was granting the PACE organizations a conditional, organization-wide waiver of §460.92 of the PACE regulation under the authority of section 903 of the Benefits Improvement and Protection Act of 2000, permitting PACE enrollees eligible for VA drug coverage to choose to receive drug coverage through the VA.

It is expected that these waivers will continue as long as the service agreements are in place and the VHA continues to provide funding.

CMS will continue to develop guidance to further clarify the applicability of the COB requirements to the POs.
Appendix G – NCPDP White Paper- Overview of the Medicare Part D Prescription Drug Coordination of Benefits (COB) Process
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

4. OVERVIEW OF MEDICARE COB REQUIREMENTS FOR PART D ENROLLEES

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (P.L.108-173) was enacted in December 2003 and amended Title XVIII of the Social Security Act by establishing a new Part D: the Voluntary Prescription Drug Program effective January 1, 2006. Under the prescription drug benefit program, eligible Medicare beneficiaries are provided access to coverage options, including options with enhanced benefits, and additional beneficiary protections and assistance, such as access to negotiated prices, catastrophic coverage limits, and premium and cost-sharing subsidies for certain low-income beneficiaries. The requirements and recommendations in the following sections of this white paper flow from CMS regulations and policy guidance that are updated periodically and reflect the cooperation between CMS and the industry working in collaboration with NCPDP as required under 1860D-23(a)(4) of the Social Security Act.

Part D sponsors are required to coordinate with State Pharmaceutical Assistance Programs (SPAPs) and other providers of prescription drug coverage with respect to the payment of premiums and coverage, as well as coverage supplementing the benefits available under Part D. Entities that provide other prescription drug coverage with which Part D sponsors must coordinate include: Medicaid programs; group health plans; the Federal Employee Health Benefit Program; military coverage; the Indian Health Service (IHS); Federally qualified health centers, rural health clinics; other Part D plans; and other prescription drug coverage as CMS may specify. The MMA specified that these coordination requirements must relate to the following elements:

- Enrollment file sharing;
- Claims processing and payment;
- Claims reconciliation reports;
- Application of the protection against high out-of-pocket expenditures by tracking true out-of-pocket (TrOOP) expenditures; and
- Other processes that CMS determines.

When a Medicare Part D enrollee has other prescription drug coverage, coordination of benefits allows the plans that provide coverage for this same beneficiary to determine each of their payment responsibilities. This process is necessary in order to avoid duplication of payment and to prevent Medicare from paying primary when it is the secondary payer. As required by the MMA, Medicare secondary payer procedures apply to Part D sponsors in the same way as they apply to Medicare Advantage organizations under Part C. Regulations require Part D sponsors to report credible new or changed primary payer and supplemental prescription drug coverage information to the CMS COB Contractor; CMS guidance specifies that this reporting should be accomplished electronically via the Electronic Correspondence Referral System (ECRS) within 30 days of the sponsor’s receipt of the information. Updated primary and supplemental coverage
information reported to the COB Contractor is entered into CMS systems and CMS forwards the information as often as daily to the Part D Transaction Facilitator and Part D sponsors for their enrollees.

Under Part D, COB also provides the mechanism for support of the tracking and calculating of beneficiaries’ “true out-of-pocket” (TrOOP) expenditures, or “incurred costs” as defined in the MMA and CMS’ implementing regulations. Incurred costs under Part D include only costs incurred by the beneficiary for the annual deductible, or other cost-sharing prior to satisfying the out-of-pocket threshold, including the out-of-network price differential for which the individual is responsible when the emergency access requirements are met. Incurred costs are costs paid by the beneficiary, by another person on the beneficiary’s behalf, by CMS on behalf of a low-income subsidy (LIS) eligible individual, or by a qualified SPAP, the IHS or an AIDS Drug Assistance Program (ADAP) that are not reimbursed through or paid under insurance or otherwise, a group health plan, or other third party arrangement. Incurred costs must be incurred for a covered Part D drug which is a Part D drug included in the individual’s Part D plan’s formulary, or treated as being included as a result of a coverage determination or appeal, and obtained at a network pharmacy, unless emergency access provisions have been met. Part D sponsors must exclude costs that do not meet these requirements from a beneficiary’s TrOOP.

Section 1860D-2(b)(4)(D) of the Act authorizes CMS to establish procedures for the exchange of information for determining whether costs reimbursed by third parties for Part D enrollees may be included in their TrOOP and for alerting Part D sponsors about such reimbursements. The TrOOP facilitation process developed by CMS and the industry in collaboration with NCPDP allows the majority of pharmacy claims processing and benefit coordination to take place in real-time at the pharmacy point of sale. CMS’ Transaction Facilitator contractor, in conjunction with CMS, is responsible for establishing procedures for facilitating eligibility queries, identifying costs being reimbursed by other payers and reporting such transactions to Part D sponsors, and facilitating the transfer of TrOOP-related data when a beneficiary changes plans during the coverage year.

The CMS COB Contractor consolidates the activities that support the collection, management, and reporting of other coverage for Medicare beneficiaries. Through the data exchange processes, many payers voluntarily report information regarding prescription drug coverage they offer which is either primary or supplemental to Part D. In addition, many other insurers providing group health coverage, liability insurance, no-fault insurance, and workers’ compensation, include prescription drug coverage in conjunction with their mandatory reporting under section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (P.L. 110-173). A data exchange with CMS allows other payers:

1. To assist beneficiaries in fulfilling their statutory obligation to disclose third party reimbursement for Part D drug costs.

2. To avoid the cost of paying as primary when the payment should be secondary to Part D.
3. As a sponsor of record, to be notified if a paid claim is reversed or adjusted outside an on-line adjudication process.

4. If TrOOP-eligible, to cease payments for beneficiaries receiving the full low-income subsidy who reach the catastrophic phase of the benefit, since at that point, Medicare fully subsidizes the beneficiary's incurred costs for covered Part D drugs.

For this process to work, payers supplemental to Part D should obtain a unique RxBIN and/or RxPCN combination that will identify their paid claim responses for TrOOP tracking purposes when Part D is the primary payer. CMS also recommends that supplemental payers obtain an RxBIN and/or RxPCN combination unique to each separate plan they offer in order to distinguish each of their plans from one another. This allows each benefit plan to fulfill its obligation as a supplemental payer if it is identified on the COB file as secondary coverage. CMS guidance notes that for the COB and TrOOP tracking processes to function effectively, other payers should supply paid claims information to the Part D sponsor after making a payment that is supplemental to a Medicare payment. This will happen automatically only if the other payer reports their coverage information with the appropriate RxBIN and/or RxPCN combination to CMS thereby enabling the Transaction Facilitator to identify the supplemental payer’s status. Therefore, it is critical that the RxBIN/RxPCN and Rx Cardholder ID (RxID) reported by the supplemental payer to the CMS COB contractor, entered into CMS systems and reported to the Transaction Facilitator matches the RxBIN/RxPCN and RxID on the supplemental claim request transaction. A match is required for the Transaction Facilitator to create the Information Reporting (N) transaction.

CMS requires that Part D sponsors coordinate benefits with supplemental payers that adhere to the CMS Data Sharing Agreement and transmit their eligibility data to CMS. Those supplemental payers that use the established on-line or batch COB process will derive the benefits associated with the creation of N transactions and their transmission to the beneficiary’s Part D sponsor. Other supplemental payers that do not comply with the on-line or batch COB process forfeit COB and the benefits associated with it.

CMS regulations specify the requirements for plans sponsors to coordinate benefits with both other Part D plans when a Part D sponsor other than the sponsor of record paid claims for a beneficiary during the initial transition period and with other entities providing prescription drug coverage when that entity incorrectly paid as primary. Sponsors must follow CMS-established processes for plan-to-plan reconciliation in the former instances, and in the latter instances work directly with the other entities to achieve timely reconciliation.

Responsibility for Part D sponsors to account for other providers of prescription drug coverage when a retroactive claims adjustment creates an overpayment or underpayment is addressed in the Part D regulations. Part D sponsors must coordinate benefits with SPAPs and other providers of prescription drug coverage and appropriately adjudicate claims. Compliance with this requirement entails the sponsor not only coordinate benefits with other payers at POS, but also work with beneficiaries and other payers to resolve post-adjudicative payment issues arising from retroactive claims changes.
Retroactive claims adjustments can be necessitated by beneficiary changes (such as those resulting from retroactive LIS eligibility determinations, LIS status changes, or midyear Part D enrollment changes), sponsor receipt of other payer information, or errors in payer order. Some of these changes, those occurring within the payers’ timely filing window, may be addressed through pharmacy-initiated reverse and rebill transactions. However, CMS guidance states that sponsors generally should limit requests for pharmacy reprocessing to those situations involving a payment error. All retroactive claims adjustments that cannot be addressed through pharmacy reverse and rebilling must be handled by the Part D sponsor through other means. Part D sponsors must determine whether or not any amount paid by any other payers was TrOOP-eligible and must adjust, as necessary, the affected beneficiaries’ TrOOP balances.

CMS has established timeframes for Part D COB. Plan sponsors must coordinate benefits with SPAPs, other entities providing prescription drug coverage, beneficiaries, and others paying on the beneficiaries’ behalf for a period not to exceed 3 years from the date the prescription for a covered Part D drug was filled. CMS also requires that whenever a sponsor receives information that necessitates a retroactive claims adjustment, the sponsor must process the adjustment and issue refunds or recovery notices within 45 days of the sponsor’s receipt of complete information regarding the adjustment.

Requirements for Part D COB are specified in statute and codified in Federal regulations. CMS Part D COB guidance is provided in Chapter 14 of the Medicare Prescription Drug Benefit Manual available on the CMS Web site at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter14.pdf. This section does not supersede official CMS guidance, but is intended to convey a very general understanding of Part D COB requirements.
Appendix H – Glossary
(Rev. 17, Issued: 08-23-13, Effective Date: 06-07-10, Implementation Date: 01-01-11)

(NOTE: These definitions are for purposes of this manual chapter only.)

- **4RX Information**: Identifying data used for the electronic routing of pharmacy claims. The information includes:
  - Rx Bank Identification Number (BIN)
  - Rx Processor Control Number (PCN)
  - Rx Group
  - Rx Member ID

- **AIDS Drug Assistance Program (ADAP)**: A State-administered program authorized under Title II of the CARE Act that provides FDA-approved medications to low-income individuals with HIV disease who have limited or no coverage from private insurance or Medicaid.

- **Coordination of Benefits (COB)**: Effective exchange of information and coordination between a Part D plan and other entities providing other prescription drug coverage for—
  1. (i) Payment of premiums and coverage;
  2. (ii) Payment for supplemental prescription drug benefits as described in §423.104(f)(1)(ii) (including payment to a Part D plan on a lump sum per capita basis) for Part D eligible individuals enrolled in the Part D plan and the SPAP or entity providing other prescription drug coverage; and
  3. (iii) Retroactive claims adjustments, underpayment reimbursements, and overpayment recoveries as described in paragraph (g) of this section and § 423.466(a) of this subpart.

- **Financial Information Reporting (FIR)**: When a Part D enrollee has changed from one benefit plan to another during the plan year, Financial Information Reporting is the NCPDP standard process whereby point-in-time financial information (accumulated TrOOP and Gross Covered Drug Cost) is moved from the previous plan processor to the new processor. This information is necessary for the new plan to accurately process claims and position the enrollee in the correct stage of the Part D benefit.

- **Gross Covered Drug Cost**: On a claim level, this is the amount (Ingredient Cost Paid + Dispensing Fee Paid + Total Amount Attributed to Sales Tax) paid to the pharmacy for a covered drug. Accumulated gross covered drug costs represent the year-to-date sum of the beneficiary’s covered drug costs and determine what phase of the benefit the beneficiary is in.
Other Health Insurance (OHI): Other insurance that can be primary or supplemental to Part D.

Other TrOOP: Qualified third party payments that contribute to a beneficiary's TrOOP, except for LICS and Patient Pay Amount. Examples include payments made on behalf of a beneficiary by qualified SPAPs, ADAPs and charities.

Part D Transaction Facilitator: The CMS contractor responsible for receiving and responding to eligibility queries (E1 transactions) from the pharmacy at point-of-sale, identifying costs that are reimbursed by other payers and reporting supplemental claims information to Part D sponsors (N transactions), identifying beneficiary enrollment changes requiring TrOOP balance transfers and sending and receiving the FIR transactions. (Formerly the TrOOP facilitator.)

Patient Liability Reduction Due to Other Payer (PLRO): Amounts by which patient liability is reduced due to payments by other payers that do not participate in Part D and are not TrOOP-eligible. Examples include payments made on behalf of a beneficiary by Workers' Compensation, group health plans and liability insurance.

Qualified status: The status assigned to supplemental third parties whose payments made on a beneficiary’s behalf count towards TrOOP.

State Pharmacy Assistance Programs (SPAP): A State program is considered to be a State Pharmaceutical Assistance Program if it-

- Provides financial assistance for the purchase or provision of supplemental prescription drug coverage or benefits on behalf of Part D eligible individuals;
- Provides assistance to Part D eligible individuals in all Part D plans without discriminating based upon the Part D plan in which an individual enrolls;
- Meets the benefit coordination requirements specified in Federal regulations at 42 CFR 423.464; and
- Does not follow or adopt rules that change or affect the primary payer status of a Part D plan.

Switch: A pharmacy claims router. Pharmacies use switches to route claims to the appropriate processor and, if applicable, to the Part D transaction facilitator.

Transactions:

- B Transaction: A pharmacy claim or service billing.
- N Transaction: Information reporting transaction containing information on a paid supplemental claim and sent by the transaction facilitator to the enrollee’s Part D plan.
• **E1 Transaction**: Eligibility query, used by a pharmacy to verify an individual’s Medicare A/B eligibility or Part D enrollment information.

**True Out-of-Pocket (TrOOP)**: Incurred allowable costs that are paid by the beneficiary or by specified third parties on their behalf within the limits of the standard benefit, up to a legislatively specified out-of-pocket threshold.
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10 - Part D Enrollee Grievances, Coverage Determinations, and Appeals
(Rev. 9, 2/22/13)

This chapter addresses coverage determinations and appeals for Part D plan enrollees, and other complaints enrollees may have with a Part D plan sponsor or any of its contractors.

Additional information related to Part D grievances, coverage determinations, and appeals may be found on the Part D Appeals and Grievances guidance page:

Please note that this chapter does not address or provide guidance for Medicare Advantage (MA) issues that do not relate to the Medicare Part D prescription drug benefit. MA organizations or Medicare cost plans and health care prepayment plans should consult Chapter 13 of the Managed Care Manual for issues related to grievances, organization determinations, or appeals concerning benefits under Part C or Section 1876, as appropriate.

10.1 - Definition of Terms
(Rev. 9, 2/22/13)

Unless otherwise stated in this chapter, the following definitions apply:

**Appeal:** Any of the procedures that deal with the review of adverse coverage determinations made by the Part D plan sponsor on the benefits under a Part D plan the enrollee believes he or she is entitled to receive, including a delay in providing or approving the drug coverage (when a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for the drug coverage, as defined in §423.566(b). These procedures include redeterminations by the Part D plan sponsor, reconsiderations by the independent review entity (IRE), Administrative Law Judge (ALJ) hearings, reviews by the Medicare Appeals Council (MAC), and judicial reviews.

**Complaint:** A complaint may involve a grievance, coverage determination, or both. A complaint also may involve a late enrollment penalty (LEP) determination. Every complaint must be handled under the appropriate process.

**Coverage Determination:** Any decision made by or on behalf of a Part D plan sponsor regarding payment or benefits to which an enrollee believes he or she is entitled.

**Effectuation:** Payment of a claim, authorization or provision of a benefit the plan sponsor has approved, or compliance with a complete or partial reversal of a Part D plan sponsor’s original adverse coverage determination.

**Enrollee:** A Part D eligible individual who has elected a Part D plan offered by a Part D plan sponsor.
**Grievance:** Any complaint or dispute, other than a coverage determination or an LEP determination, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Part D plan sponsor, regardless of whether remedial action is requested. A grievance may also include a complaint that a Part D plan sponsor refused to expedite a coverage determination or redetermination. Grievances may include complaints regarding the timeliness, appropriateness, access to, and/or setting of a provided item.

**Independent Review Entity (IRE):** An independent entity contracted by CMS to review Part D plan sponsor denials of coverage determinations.

**Inquiry:** Any oral or written request to a Part D plan sponsor or one of its contractors that does not involve a request for a coverage determination/exception request.

**Other Prescriber:** A health care professional other than a physician who is authorized under State law or other applicable law to write prescriptions.

**Quality Improvement Organization (QIO):** Organizations comprised of practicing doctors and other health care experts under contract to the Federal government to monitor and improve the care given to Medicare enrollees. They review complaints raised by enrollees about the quality of care provided by physicians, inpatient hospitals, hospital outpatient departments, hospital emergency rooms, skilled nursing facilities, home health agencies, Medicare managed care plans, Medicare Part D prescription drug plans, and ambulatory surgical centers. The QIOs also review continued stay denials in acute inpatient hospital facilities as well as coverage terminations in skilled nursing facilities (SNFs), home health agencies (HHAs) and comprehensive outpatient rehabilitation facilities (CORFs).

**Quality of Care Issue:** A quality of care issue may be filed through the Part D plan sponsor’s grievance process and/or a QIO. A QIO must determine whether the quality of services (including both inpatient and outpatient services) provided by a Part D plan sponsor meets professionally recognized standards of health care, including whether appropriate health care services have not been provided or have been provided in inappropriate settings.

**Redetermination:** The first level of the appeal process, which involves a Part D plan sponsor reevaluating an adverse coverage determination, the findings upon which it was based, and any other evidence submitted or obtained.

**Representative:** An individual either appointed by an enrollee or authorized under State or other applicable law to act on behalf of the enrollee in filing a grievance, requesting a coverage determination, or in dealing with any of the levels of the appeals process. Unless otherwise stated in part 423, subpart M of the Medicare Part D regulations, the representative has all of the rights and responsibilities of an enrollee in obtaining a coverage determination or in dealing with any of the levels of the appeals process, subject to the rules described in part 422, subpart M of the Medicare Part C regulations.
10.2 - Responsibilities of the Part D Plan Sponsor

(Rev. 9, 2/22/13)

Each Part D plan sponsor and each Part D plan that it offers must establish and maintain procedures for:

1. Standard and expedited coverage determinations;

2. Standard and expedited appeals; and


Part D plan sponsors also must provide written information to enrollees about the grievance and appeal procedures that are available to them through the Part D plan sponsor, at the following times:

1. Grievance procedure - at initial enrollment, upon involuntary disenrollment initiated by the Part D plan sponsor, upon denial of an enrollee's request for expedited review, upon an enrollee's request, and annually thereafter;

2. Appeal procedure, including the right to expedited review - at initial enrollment, upon notification of an adverse coverage determination or denial, and annually thereafter. If a plan changes its formulary or the cost-sharing status of a drug that has been prescribed for an enrollee, the plan must provide written information about the grievance and appeal procedures to enrollees who are affected by the change; and

3. Quality of care complaint process available under the Quality Improvement Organization (QIO) process as described in §1154(a)(14) of the Social Security Act (the Act) - at initial enrollment, and annually thereafter.

Each plan sponsor must conduct meaningful and thorough coverage determinations and redeterminations by:

1. Attempting to contact prescribing physicians or other prescribers to obtain supporting statements and additional medical documentation necessary to evaluate a request, as appropriate;

2. Attempting to obtain representation documentation from a non-enrollee appellant who presents as a representative;

3. Ascertaining state law and validating the representative status of a non-enrollee appellant who presents as a representative on behalf of an incompetent or incapacitated enrollee; and

4. Issuing determinations in a timely manner and in accordance with exceptions policies and criteria.
Plan sponsors must promote timely, efficient, and meaningful reconsideration appeals at the IRE level by:

1. Promptly identifying all requests for case files from the IRE, including requests that are made by fax;

2. Pursuant to an expedited case file request, delivering (by overnight delivery or fax) the complete case file to the IRE no later than 24 hours after receiving the request from the IRE;

3. Pursuant to a standard case file request, delivering (by overnight delivery or fax) the complete case file to the IRE as promptly as possible, but no later than 48 hours after receiving the request from the IRE;

4. Effectuating any IRE reversals within the required timeframe, including providing the IRE with affirmative notice of effectuation; and


As with all contractual responsibilities in the Part D program, the plan may delegate any of its grievance, coverage determination, and/or appeals responsibilities (with the exception below) to another entity or individual that provides or arranges Part D benefits. In cases of delegation, the Part D plan sponsor remains responsible and must therefore ensure that requirements are met completely by its delegated entity and/or individual.

Exception: In accordance with 42 CFR 423.562(a)(5), Part D plan sponsors must employ a medical director who is responsible for ensuring the clinical accuracy of all coverage determinations and redeterminations involving medical necessity. The medical director must be a physician with a current license to practice medicine in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

10.3 – Rights of Part D Enrollees
(Rev. 1, 11/30/05)

Relative to grievances, coverage determinations, and appeals, the rights of Part D enrollees include, but are not limited to, the following:

10.3.1 - Grievances
(Rev. 1, 11/30/05)

1. The right to have grievances heard and resolved in accordance with the guidelines that are described in this chapter of the manual;

2. The right to request quality of care grievance data from Part D plan sponsors; and
3. The right to make a quality of care complaint under the QIO process.

**10.3.2 - Coverage Determinations**  
(*Rev. 9, 2/22/13*)

1. The right to a timely coverage determination;

2. The right to request an expedited coverage determination as described in this chapter;

3. The right to receive *written* information from a network pharmacist regarding the enrollee’s ability to obtain a detailed written notice from the Part D plan sponsor regarding the enrollee’s Part D benefits;

4. The right to a detailed written notice of a Part D plan sponsor’s decision to deny a benefit in whole or in part, which includes the enrollee’s appeal rights; and

5. The right to receive notice when a coverage determination is forwarded to the IRE.

**10.3.3 - Appeals**  
(*Rev. 1, 11/30/05*)

1. The right to a timely redetermination;

2. The right to request an expedited redetermination as provided in this chapter;

3. The right to request and receive appeal data from Part D plan sponsors;

4. The right to receive notice when an appeal is forwarded to the IRE;

5. The right to a reconsideration by the IRE, upon request, if the plan sponsor upholds the original adverse determination in whole or in part;

6. The right to request an expedited reconsideration as provided in this chapter.

7. The right to an ALJ hearing if the IRE upholds the original adverse determination in whole or in part and the remaining amount in controversy meets the appropriate threshold requirement;

8. The right to request MAC review if the ALJ hearing decision is unfavorable to the enrollee in whole or in part;

9. The right to judicial review of the hearing decision if the ALJ hearing and/or MAC review is unfavorable to the enrollee, in whole or in part, and the amount remaining in controversy meets the appropriate threshold requirement;
The right to request and be given timely access to the enrollee’s case file and a copy of that case file subject to federal and state law regarding confidentiality of patient information. The Part D plan sponsor shall have the right to charge the enrollee a reasonable amount for providing a copy of the case file (e.g., the costs of mailing and/or an amount comparable to the charges established by a QIO for duplicating the case file material). At the time the request for case file material is made, the Part D plan sponsor should inform the enrollee of the per page duplicating cost. Based on the extent of the case file material requested, the Part D plan sponsor should provide an estimate of the total duplicating cost for which the enrollee will be responsible. The Part D plan sponsor may also charge the enrollee the cost of mailing the material to the address specified. If enrollee case files are stored offsite, then the Part D plan sponsor may not charge the enrollee an additional cost for courier delivery to a plan location that would be over and above the cost of mailing the material to the enrollee.

10.4 - Representatives

10.4.1 - Representative Filing on Behalf of the Enrollee
(Rev. 9, 2/22/13)

An enrollee may have a representative who is either appointed by the enrollee or authorized under State or other applicable law to act on behalf of the enrollee in filing a grievance, requesting a coverage determination, or in dealing with any of the levels of the appeals process. An enrollee may appoint any individual (such as a relative, friend, advocate, attorney, physician or other prescriber, or an employee of a pharmacy, charity, state pharmaceutical assistance program, or other secondary payer) to act as his or her representative. Alternatively, an enrollee’s representative (surrogate) may be appointed by a court or authorized under State or other applicable law to act on the enrollee’s behalf. A surrogate could include, but is not limited to, a court appointed guardian, an individual who has Durable Power of Attorney or a health care proxy, or a person designated under a health care consent statute.

Note: Part D plan sponsors with benefit areas comprising more than one state must develop internal policies to ensure that they are aware of the different State representation requirements in their benefit areas. With the exception of incapacitated or legally incompetent enrollees where appropriate legal papers, or other legal authority, support this representation, or where a state's authorized representative rules require otherwise, both the enrollee making the appointment and the representative accepting the appointment must sign, date, and complete an appointment of representative form or similar written statement.

If an enrollee wishes to appoint a representative to act on his or her behalf, the enrollee must submit a written representative statement to the Part D plan sponsor. An enrollee may use Form CMS-1696 (see Appendix 2) or an equivalent written notice to make the appointment. A notice is an "equivalent written notice" if it:

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1. Includes the name, address, and telephone number of enrollee;

2. Includes the enrollee’s HICN [or Medicare Identifier (ID) Number];

3. Includes the name, address, and telephone number of the individual being appointed;

4. Contains a statement that the enrollee is authorizing the representative to act on his or her behalf for the claim(s) at issue, and a statement authorizing disclosure of individually identifying information to the representative;

5. Is signed and dated by the enrollee making the appointment; and

6. Is signed and dated by the individual being appointed as representative, and is accompanied by a statement that the individual accepts the appointment.

If an appointment is made using Form CMS-1696 or an equivalent written notice, the plan sponsor must accept it. Plan sponsors are prohibited from requiring the use of a specific form (other than Form CMS-1696 or an equivalent written notice) for appointments.

A surrogate asserting that he or she is acting in accordance with a state's authorized representative requirements must include a statement verifying his or her status under State law in the same manner that an appointed representative must submit a valid Form CMS-1696 or other equivalent notice. The Part D plan sponsor is responsible for determining whether a person or entity who asserts surrogate status is an appropriate surrogate under state law. If a surrogate submits the statement described above and the plan sponsor determines that the surrogate is acting in accordance with a state's authorized representative requirements, the plan sponsor or other appeal entity cannot also require the authorized representative to submit an additional Form CMS-1696 or other equivalent notice. The plan sponsor must submit an attestation to the IRE certifying the validity of the representation under state law if the IRE requests an enrollee's case file.

A signed Form CMS-1696 or other equivalent notice must be included with each oral or written request for a grievance, coverage determination, or appeal. However, once a signed form or statement has been submitted, the enrollee is not required to obtain a new signed form or statement for the life of an appeal, so long as a copy of the original signed form or statement is included in the enrollee's case file or is submitted with each appeal request. In addition, an enrollee is not required to obtain a new signed form or statement for any new appeal filed by the representative within one calendar year from the date that a valid representative form is executed. However, the representative must file a copy of the original form or other conforming written instrument with each new request for a grievance or coverage determination.

Except in the case of incapacitated or incompetent enrollees, a grievance or a request for a coverage determination or redetermination from a representative is not valid until
supported with an executed appointment of representative form or statement. It is the Part D plan sponsor’s obligation to inform the enrollee and purported representative, in writing, that the grievance or request will not be considered until the appropriate documentation is provided.

When a grievance or a request for a coverage determination or redetermination is filed by a person claiming to be a representative, but the party does not provide appropriate documentation upon the Part D plan sponsor’s request, the Part D plan sponsor must make and document its reasonable efforts to secure the necessary appointment forms. What is reasonable depends on the circumstances. For example, if a request is expedited, contacting the enrollee and/or representative by mail to obtain the necessary appointment forms or notice may not be reasonable. However, if the enrollee and/or the party who submitted the request does not have a telephone, the plan sponsor may determine that contacting the enrollee and/or the party by overnight delivery is reasonable. The Part D plan sponsor is not required to undertake a review until or unless such forms are obtained, but it may choose to begin the review while continuing efforts to obtain a valid appointment of representation form. However, the time frame for acting on a grievance or a request for a coverage determination or redetermination does not commence until the properly executed appointment form is received. If the Part D plan sponsor does not receive the form or statement within a reasonable time, the Part D plan sponsor should dismiss the request on the grounds that a valid request was not received. What is reasonable depends on the circumstances. If the plan sponsor determines that a dismissal is appropriate, it must send a written dismissal letter to the enrollee and the person asserting representative status. The plan sponsor must explain in the dismissal letter that it will process the request if the enrollee or representative resubmits the request with a properly executed Form CMS-1696 or other equivalent notice. If the person asserting representative status is requesting a redetermination, the plan sponsor should also explain that any submission of a properly executed form or equivalent notice after the 60-day filing deadline for requesting the appeal has expired must be accompanied by a good cause statement explaining why the form/notice was not filed timely (see §70.3 for more information about good cause extensions).

If an appeal is initiated by a representative and submitted to the IRE, the IRE will examine the form or equivalent written notice for compliance with the appointment of representative requirements or other legal authority, such as a Power of Attorney or Durable Power of Attorney executed pursuant to state law. In addition, the IRE may review a plan sponsor's attestation certifying the validity of a surrogate acting on behalf of an enrollee under state law. If the IRE discovers a defect in the form or other notice submitted with the request (e.g., the form or notice is not valid and/or was not properly executed), the IRE may require the representative to submit a valid Form CMS-1696 or other equivalent written notice. In addition, the IRE may dismiss cases in which a required appointment of representative form is absent. The IRE must make its determination regarding the validity of the form or notice and notify the representative of its decision within a timely manner. If a copy of a valid Form CMS-1696 or other equivalent notice (i.e., a photocopy of the original form or notice) has been submitted with the request for IRE review, or the IRE is satisfied with a plan sponsor's attestation certifying the validity of a surrogate acting on behalf of an enrollee under state law, the IRE cannot require the
representative to submit a new form (either Form CMS-1696 or any other form, including a form developed by the IRE) or notice to obtain a review by the IRE.

**Note:** If an enrollee's prescribing physician or other prescriber requests a standard or expedited coverage determination, a standard or expedited redetermination on an enrollee's behalf, and the plan sponsor misses the decision-making time frame and automatically forwards the request to the IRE for review for failure to meet the adjudication time frame under §§40.4, 50.6, and 70.8.2, the prescribing physician or other prescriber is not required to submit a signed Form CMS-1696 or other equivalent notice to the IRE because a prescribing physician or other prescriber may request a standard or expedited coverage determination, a standard or expedited redetermination or a standard or expedited IRE reconsideration on an enrollee's behalf without being a representative.

### 10.4.2 - Authority of a Representative

_(Rev. 9, 2/22/13)_

Unless otherwise stated in the rules described in subpart M of part 423, the representative has all of the rights and responsibilities of an enrollee in filing a grievance, requesting a coverage determination, or in dealing with any of the levels of the Part D appeals process. For instance, a representative may, on behalf of an enrollee:

1. Obtain information about the enrollee’s claim to the extent consistent with current Federal and state law;

2. Submit evidence;

3. Make statements about facts and law; and

4. Make any request or give any notice about the proceedings.

If an enrollee has identified a representative, any notice or other correspondence that must be sent to the enrollee under subpart M of part 423 must be sent to the enrollee's representative instead of to the enrollee.

**Note:** The CMS-1696 form, as written, applies to all Title XVIII Medicare benefits. However, a valid appointment of representative form (or other conforming written instrument) submitted with a request that specifically limits the appointment to MA benefits is not valid for requests that involve Part D prescription drug benefits. In this situation, the enrollee must properly execute a separate Form CMS-1696 or equivalent if he or she wishes the MA representative to also serve as his or her Part D representative (or vice versa). If a representative (who is representing an enrollee in regards to an MA claim) files a Part D grievance or requests a coverage determination or appeal that involves a Part D benefit without a newly executed appointment of representation form or other conforming written instrument, the plan should explain to the representative that a new representative form must be executed, and provide the representative with a reasonable opportunity to submit the new form or other conforming written instrument before dismissing the request.
10.5 - Authority of an Enrollee’s Prescribing Physician or Other Prescriber
(Rev. 9, 2/22/13)

A prescribing physician or other prescriber may act on behalf of an enrollee in requesting a standard or expedited coverage determination, a standard or expedited redetermination or a standard or expedited IRE reconsideration without being the enrollee’s representative. In these situations, the physician does not have all of the rights and responsibilities of an enrollee as described in §10.4.2. However, an enrollee’s prescribing physician or other prescriber is entitled to receive the notifications described in §§40.2, 40.3.2, 40.3.4, 40.3.5, 50.3, 50.4, 50.5, 70.8.1, and 70.9.

Note: The regulations do not prohibit an enrollee’s prescribing physician or other prescriber from becoming an enrollee’s representative.

20 - Complaints

20.1 - Complaints That Apply to Both Grievances and Coverage Determinations
(Rev. 1, 11/30/05)

Complaints may include both grievances and coverage determinations (i.e., a single complaint may contain a grievable issue and an appealable issue). If an enrollee addresses two or more issues in one complaint, each issue should be processed separately and simultaneously (to the extent possible) under the proper procedure.

20.2 - Distinguishing Between Grievances and Coverage Determinations
(Rev. 9, 2/22/13)

Grievance procedures are separate and distinct from the procedures that apply to coverage determinations. Plan sponsors must determine whether the issues in an enrollee’s complaint meet the definition of a grievance, coverage determination, or both, and resolve an enrollee’s complaints or disputes through the appropriate procedure.

Complaints that may fall into the grievance category include, but are not limited to, complaints about:

- Difficulty getting through to the plan sponsor on the telephone;
- The quality of care or benefits provided;
- Interpersonal aspects of care, such as rudeness by a pharmacist or staff member;
- A plan's benefit design;
• A plan sponsor's failure to issue a decision in a timely manner (this type of
grievance is not a substitute for automatically forwarding an enrollee's request to
the IRE if the plan fails to act timely, but is an additional right that may be
exercised by an enrollee);

• A plan sponsor's denial of an enrollee's request for an expedited coverage
determination or expedited redetermination;

• The appeals process; or

• A plan's written communications, including its written notices.

The facts surrounding a complaint will determine whether the grievance or coverage
determination process should be initiated. If the facts don’t clearly indicate that a
complaint is a grievance, the plan sponsor should process the complaint as a request for a
coverage determination. The following are offered as examples of when each process
should begin:

Example 1
An enrollee who currently takes a particular brand-name drug is dismayed to find out
that the plan has made a formulary change and will no longer cover the drug used by
the enrollee. The enrollee calls the plan and complains. The enrollee states that he/she
has tried the generic equivalent before and it was not effective, and therefore wants the
plan to continue coverage of the brand-name drug. This complaint should be treated
as a request for a coverage determination, subject to the appeals process, for
continuation of coverage for the brand-name drug.

Example 2
An enrollee who currently does not take any prescription medications reads in his
annual notice of change that the plan will no longer be covering a particular brand-
name drug. The enrollee calls the plan to complain about this reduction in benefits,
even though it does not directly affect the enrollee at the current time. Because the
enrollee does not take the prescription drug affected by the change, the complaint
should not be interpreted as a request for a coverage determination. The complaint
should therefore be handled as a grievance.

Example 3
A Part D enrollee's plan benefits cover six 500 mg tablets of Zithromax over a 30 day
period. The enrollee presents the prescription to the pharmacist, and the prescription is
covered by the plan. The enrollee returns to the pharmacist, asserting that the
pharmacist gave the enrollee six 250 mg tablets of Zithromax, and asks the pharmacist
to correct the mistake by providing six 500 mg tablets of Zithromax (i.e., the enrollee
does not have a new prescription for Zithromax). Where an enrollee complains that
contractually covered and previously rendered benefits were not properly delivered,
this type of complaint (i.e., the request for the pharmacist to correct the mistake)
should be classified as a grievance (quality of care complaint) as opposed to an appeal.
Note that not all complaints about dosages should be treated as grievances. As discussed in §30.2.2, some complaints involving dosing issues must be processed as coverage determinations/formulary exceptions.

In some cases, Part D plan sponsors will need to process complaints using the Part D plan sponsor’s grievance procedures and its coverage determination procedures. For example, an enrollee might complain that because he/she had to wait so long to fill a prescription, he/she obtained the medication out of network and wants to be reimbursed for out-of-pocket expenses. The enrollee’s complaint contains both a request for payment (i.e., a request for a coverage determination) and a grievance about the timeliness of benefits. Therefore, complaints must be reviewed on a case-by-case basis.

20.2.1 - Quality of Care Complaints
(Rev. 2, 6/22/06)

Complaints concerning the quality of care received under Medicare may be acted upon by the Part D plan sponsor, but also may be addressed through the QIO complaint process under §1154(a)(14) of the Act. (See also the QIO Manual chapter regarding the Beneficiary Complaint Process.) This process is separate and distinct from the Part D plan sponsor’s grievance process. All grievances regarding quality of care that are submitted to the Part D plan sponsor, regardless of whether they are filed orally or in writing, must be responded to in writing by the Part D plan sponsor. When the Part D plan responds to an enrollee’s grievance in writing, it must include a description of the enrollee’s right to file the grievance with the QIO. For any complaint filed with the QIO, the Part D plan must cooperate with the QIO in resolving the complaint.

In situations where an enrollee files a grievance with the QIO and the Part D plan sponsor, the plan sponsor must comply with the requirements at 42 CFR Part 476 regarding timely submission of requested information/documentation to the QIO.

20.2.2 - Co-Payment Complaints
(Rev. 8, 1/1/10)

Part D plan sponsors must determine how to categorize complaints about co-payments on a case-by-case basis. The plan sponsor is responsible for determining if an enrollee has a general inquiry or complaint about the co-payment amount, or if there are facts and circumstances specific to that enrollee that warrant treating the complaint as a request for a coverage determination.

Example 1
Part D plan sponsors must subject complaints about co-payments to the coverage determination process when an enrollee believes that a Part D plan sponsor has asked him or her to pay a different cost-sharing amount than the enrollee believes he or she is
required to pay for a prescription drug. [See the related note below pertaining to co-payment disagreements that involve the calculation of true out-of-pocket costs.]

**Example 2**
When a Part D enrollee receives a retroactive determination of Low-Income Subsidy (LIS) eligibility, the Part D plan sponsor is required to automatically reimburse the enrollee for any excess cost-sharing that occurred due to the retroactive LIS determination. Under this process, an enrollee may be eligible to receive reimbursement for excess premiums and co-payments for Part D drugs paid during the retroactive period of LIS eligibility. This type of reimbursement activity does not fall under the Part D coverage determination or appeals processes, and is not subject to the rules contained in part 423, subpart M of the Medicare Part D regulations or the guidance contained in this chapter. Instead, Part D plan sponsors must make LIS reimbursement adjustments in accordance with the guidance contained in Chapter 13, §70.3.1 of the Prescription Drug Benefit Manual.

**Example 3**
When an enrollee requests a plan sponsor to cover a particular non-preferred drug at the preferred cost-sharing level for reasons of medical necessity and indicates that he or she has a prescription for the drug, the plan must process the request as a tiering exception.

**Example 4**
If an enrollee expresses general dissatisfaction about a co-payment amount, the Part D plan sponsor should process the enrollee’s complaint as a grievance.

**Disagreements about the calculation of True Out-of-Pocket (TrOOP) Costs**
In general, complaints about the calculation of TrOOP costs should be processed as grievances. However, the regulations at 42 CFR 423.566(b)(5) state that a dispute about a plan sponsor's decision on the amount of cost-sharing for a drug is considered a coverage determination and is subject to appeal. Therefore, when an enrollee disputes the amount he or she is asked to pay for a drug and the basis for the dispute is the plan sponsor's TrOOP calculation, the complaint must be resolved as a coverage determination (whether or not the co-payment complaint involving the TrOOP calculation was previously raised by the enrollee and processed as a grievance). In such circumstances, the enrollee must:

- Allege that a plan sponsor made an error in calculating his or her TrOOP costs, and the error caused the plan sponsor to charge him or her full-price for a drug because the enrollee was placed between the initial coverage limit and annual out-of-pocket threshold as a result of the calculation, and
- Produce some evidence (e.g., receipts, records, an Explanation of Benefits) in support of the allegation.
**Note:** A disagreement about TrOOP calculation that results from a dispute over low-income subsidy eligibility cannot be resolved under the Medicare Part D coverage determination and appeals processes. Instead, such a dispute must be resolved with the agency responsible for making the determination. The decision letter from the agency making the eligibility determination will provide specific instructions about appealing the decision. See §70 in the Guidance to States on the Low-Income Subsidy for more information: [http://www.cms.gov/Medicare/Eligibility-and-Enrollment/LowIncSubMedicarePresCov/Downloads/StateLISGuidance021009.pdf](http://www.cms.gov/Medicare/Eligibility-and-Enrollment/LowIncSubMedicarePresCov/Downloads/StateLISGuidance021009.pdf). Also see the Social Security Agency (SSA) website for more information about appealing Part D subsidy determinations made by SSA: [https://secure.ssa.gov/apps10/poms.nsf/lnx/0603040000/opendocument](https://secure.ssa.gov/apps10/poms.nsf/lnx/0603040000/opendocument)

### 20.2.3 - Benefit Design Complaints
(Rev. 2, 6/22/06)

Although complaints about a plan sponsor's benefit design should generally be processed as grievances, plan sponsors must take great care in processing such complaints because some complaints that involve a plan's benefit design should be processed as requests for coverage determinations.

**Example 1**
An enrollee receives a prescription for Drug X and is told at the pharmacy counter that she must pay a $25 co-pay for the drug (the co-pay amount that applies to drugs in the plan's high-cost or unique drug tier). The enrollee requests a tiering exception for Drug X. Under the plan's formulary, Drug X is contained in the high-cost or unique drug tier, and the plan has exempted drugs in that tier from the exceptions process (which is permissible under 42 CFR 423.578(a)(7)). The enrollee is aware, and is not disputing, that Drug X is contained in the plan's high-cost or unique drug tier, but she would like the drug to be covered at the cost-sharing amount applicable to drugs in the preferred tier. This is a benefit design issue that must be handled through the **grievance** process.

**Example 2**
An enrollee receives a prescription for Drug X and is told at the pharmacy counter that she must pay a $25 co-pay for the drug (the co-pay amount that applies to drugs in the plan's high-cost or unique drug tier). The enrollee requests a coverage determination for Drug X and argues that she should only be required to pay a $10 co-pay because Drug X is in the plan's preferred brand tier (the co-pay amount that applies to drugs in the plan’s preferred brand tier is $10) and the plan incorrectly charged the co-pay amount that applies to drugs in the plan’s high-cost or unique drug tier. This type of complaint involves a dispute about the amount an enrollee believes he/she is required to pay for a drug and must be handled through the **coverage determination** process, even if Drug X is in the plan’s high-cost or unique drug tier. See 42 CFR 423.566(b)(5).
A transaction with an enrollee or a physician or other prescriber that involves a request for coverage of a drug that is either not a covered Part D drug (as defined in section 1860D-2(e)(1) of the Act) or is statutorily excluded from coverage under Part D may be handled as an inquiry, grievance, or coverage determination, depending on the nature of the transaction.

Under 42 CFR 423.566(b)(1), a coverage determination is a decision by a plan sponsor not to provide or pay for a Part D drug that the enrollee believes may be covered by the plan. Drugs that do not meet the definition of a "covered Part D drug" under section 1860D-2(e)(1) of the Act and drugs excluded from coverage under section 1860D-2(e)(2) or 1860D-43 of the Act are not Part D drugs. Thus, strictly interpreted, a decision by a plan sponsor not to cover a drug that does not meet the definition of a covered Part D drug under section 1860D-2(e)(1) of the Act or is excluded from coverage under section 1860D-2(e)(2) or 1860D-43 of the Act is not a coverage determination (note that drugs that could be excluded if section 1862(a) of the Act were applied to Medicare Part D are subject to the coverage determination process). However, in some cases, an enrollee may use the coverage determination process to argue that:

- A drug is a covered Part D drug under section 1860D-2(e)(1) of the Act or is covered under section 1860D-2(e)(1) for a specific indication;
- A drug is not excluded under section 1860D-2(e)(2) of the Act or is not excluded under section 1860D-2(e)(2) for a specific indication;
- A drug is not excluded under section 1860D-43 of the Act; or
- A drug is covered by the plan as a supplemental benefit.

These cases must be treated as requests for coverage determinations to ensure that the issue is properly resolved. Conversely, if an enrollee is not disputing that a drug is not a covered Part D drug or is excluded from coverage, but has a question or general complaint about the drug not being covered, the transaction should be processed as an inquiry or a grievance.

If a drug is not a covered Part D drug or is excluded from coverage, it is never covered by Medicare, regardless of medical necessity. However, an appeal entity may overturn a plan’s decision not to cover a drug if the appeal entity determines that the drug is:

- A covered Part D drug under section 1860D-2(e)(1) of the Act or covered under section 1860D-2(e)(1) for the indication it is being prescribed for;
- Not excluded from coverage under section 1860D-2(e)(2) of the Act or being used for an indication that isn't excluded under section 1860D-2(e)(2);
• *Not Excluded from coverage under section 1860D-43 of the Act*; or

• Included on the plan sponsor's formulary as a supplemental benefit.

The following examples illustrate when a transaction should be processed as an inquiry, grievance, or coverage determination.

### 20.2.4.1 – Inquiry
(*Rev. 9, 2/22/13*)

Not all transactions that involve non-covered Part D or excluded drugs should be classified as grievances or coverage determinations. In general, an initial transaction involving a non-covered Part D or excluded drug should be treated as an inquiry unless the enrollee or the enrollee's physician or other prescriber files a grievance or requests a coverage determination by:

- Complaining about the policy that causes the drug not to be a covered Part D drug (i.e., files a grievance);

- Complaining about the policy that causes the drug to be an excluded drug (i.e., files a grievance);

- Arguing that the drug is a covered Part D drug under 1860D-2(e)(1) of the Act or is covered under 1860D-2(e)(1) for the indication it was prescribed for (i.e., makes a request for a coverage determination);

- Arguing that the drug is not excluded under 1860D-2(e)(2) of the Act or is not excluded under 1860D-2(e)(1) for the indication it was prescribed for (i.e., makes a request for a coverage determination);

- *Arguing that the drug is not excluded under 1860D-43 of the Act*; or

- Arguing that the drug is covered by the plan as a supplemental benefit (i.e., makes a request for a coverage determination).

Inquiries are routine questions about a benefit (i.e., inquiries are not complaints), and do not automatically invoke a plan sponsor's grievance or coverage determination process.

When a plan sponsor receives an inquiry about drug that is not a covered Part D drug or is an excluded drug, it must provide the person making the request with the following information:
1. The plan sponsor must explain that certain drugs are not covered Part D drugs under 1860D-2(e)(1) of the Act, or are excluded from coverage under section 1860D-2(e)(2) or 1860D-43 of the Act;

2. The plan sponsor must explain that the requested drug is not a covered Part D drug under 1860D-2(e)(1) of the Act or is statutorily excluded under section 1860D-2(e)(2) or 1860D-43 of the Act and the plan does not offer the drug as a supplemental benefit;

3. The plan sponsor must emphasize that, because the drug is not a covered Part D drug under 1860D-2(e)(1) of the Act or is excluded from coverage under 1860D-2(e)(2) or 1860D-43 and is not offered as a supplemental benefit, the enrollee may not obtain it through the coverage determination, exceptions, or appeals processes.

4. The plan sponsor must explain that the enrollee should work with his or her physician or other prescriber to determine if a drug on the plan sponsor's formulary is medically appropriate for treating the enrollee's condition; and

5. The plan sponsor must explain that the enrollee, physician, or other prescriber has the right to contact the plan sponsor and request a coverage determination if he or she believes that the drug is:

   - A covered Part D drug under section 1860D-2(e)(1) of the Act or covered under 1860D-2(e)(1) for the indication it is being prescribed for;

   - Not excluded under section 1860D-2(e)(2) of the Act or not excluded under 1860D-2(e)(2) for the purpose for which it was prescribed;

   - Not excluded under section 1860D-43 of the Act; or

   - Covered by the plan as a supplemental benefit.

The plan sponsor must also explain how the enrollee, physician, or other prescriber can make the request for a coverage determination.

A plan sponsor must provide this information either orally or in writing. If a plan sponsor chooses to provide this information in writing, it may use the model notice contained in Appendix 12. If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures. If a plan sponsor chooses to provide this information orally, the information provided must include all information that is required to be included in a written notice, and must be documented by the plan sponsor.

Example of an inquiry involving an excluded drug:
1. An enrollee calls his or her plan sponsor to determine if Vitamin D is covered for him or her (it doesn't matter if the enrollee has a prescription for the drug or not).
2. The plan sponsor tells the enrollee that certain drugs are excluded from coverage under Part D, and *Vitamin D* is one of those drugs.

3. The enrollee does not complain about the exclusion of the requested drug from coverage. Nor does the enrollee argue that the plan sponsor incorrectly classified/identified the requested drug as excluded from coverage, the drug is not excluded for the purpose for which it was prescribed, or the drug is covered by the plan as a supplemental benefit.

4. The transaction should be treated as an inquiry.

**Example of an inquiry involving a drug that is not a covered Part D drug:**

1. An enrollee attempts to fill a prescription for Actiq. The pharmacist receives an electronic notice indicating that the drug is subject to a prior authorization (PA) requirement. The PA requires the enrollee's physician or other prescriber to contact the plan sponsor and indicate the condition that the drug is being prescribed for.

2. The enrollee's physician or other prescriber calls the plan sponsor and explains that Actiq was prescribed to treat the enrollee's back pain. The plan sponsor explains to the physician or other prescriber that certain drugs are not covered Part D drugs under 1860D-2(e)(1) of the Act when not prescribed for a medically accepted indication (as defined in section 1927(k)(6) of the Act). Because the only medically accepted indication for Actiq is breakthrough cancer pain, Actiq is not a covered Part D drug when prescribed for the management of other types of pain.

3. The transaction should be treated as an inquiry, unless the physician or other prescriber:
   - Complains about the policy that causes the drug not to be a covered Part D drug (process the complaint as a grievance); or
   - Argues that Actiq is being used to treat a medically accepted indication (as defined in section 1927(k)(6) of the Act) (process the complaint as a coverage determination).

**20.2.4.2 – Grievance**

*(Rev. 9, 2/22/13)*

If an enrollee is not disputing that a drug is not a covered Part D drug (as defined in 1860D-2(e)(1) of the Act) or is excluded under 1860D-2(e)(2) or 1860D-43 of the Act, but he/she is complaining about the policy that causes the drug to be excluded or not a covered Part D drug, the complaint should be processed as a grievance because it's a complaint about the plan sponsor's benefit design structure. This complaint may occur after an inquiry is made, or it may be the initial transaction with the enrollee, physician, or other prescriber. Decisions made under a plan sponsor's grievance process are not subject to appeal.

**Example of a grievance involving an excluded drug:**
1. An enrollee attempts to fill a *Vitamin D* prescription. The pharmacist receives an electronic notice indicating that the drug is not covered and provides the enrollee with the Pharmacy Notice.

2. The enrollee calls the plan sponsor to ask why the prescription was not covered. The plan sponsor explains to the enrollee that certain drugs are excluded from coverage under Part D, and *Vitamin D* is one of those drugs.

3. The enrollee has a general complaint about the drug being excluded, but does not argue that the plan sponsor incorrectly classified/identified the requested drug as excluded from coverage, the drug is not excluded for the purpose for which it was prescribed, or the drug is covered by the plan as a supplemental benefit after the plan explains that it is an excluded drug.

4. This request should be treated as a **grievance**.

**20.2.4.3 - Coverage Determination**  
*(Rev. 9, 2/22/13)*

A plan sponsor must process a complaint as a coverage determination (which is subject to appeal) if an enrollee, physician, or other prescriber argues that a drug is a covered Part D drug under section 1860D-2(e)(1) of the Act, a covered Part D drug under 1860D-2(e)(1) of the Act for the purpose it is being prescribed, not an excluded drug under 1860D-2(e)(2) of the Act, not excluded under 1860D-2(e)(2) of the Act for the purpose for which it was prescribed, **not excluded under 1860D-43 of the Act**, or covered by the plan as a supplemental benefit. This complaint may occur after an inquiry is made, or it may be the initial transaction with the enrollee, physician, or other prescriber. If such a complaint is not processed as a coverage determination (and, for example, a plan sponsor mistakenly classified a covered Part D drug as an excluded drug), the enrollee would not have appeal rights and the issue could not be properly resolved.

If, after receiving the complaint, the plan sponsor verifies that the drug is not a covered Part D drug under 1860D-2(e)(1) of the Act or is excluded from coverage under 1860D-2(e)(2) **or 1860D-43 of the Act**, it must issue an adverse coverage determination explaining that certain drugs are not covered Part D drugs or are excluded from coverage under Part D and the requested drug is one of those drugs. As with any adverse coverage determination, the enrollee can appeal the decision (it would not be handled as a grievance). On appeal, the plan sponsor or any subsequent appeal entity will determine if the drug is a covered Part D drug under section 1860D-2(e)(1) of the Act or is excluded from coverage under section 1860D-2(e)(2) **or 1860D-43 of the Act**. If it is not a covered Part D drug or is excluded, the appeal entity will uphold the plan sponsor's coverage determination (i.e., the scope of review on appeal is limited to whether the requested drug is a covered Part D or excluded drug, is a covered Part D or excluded drug for the purpose for which it was prescribed, or is covered by the plan as a supplemental benefit).

**Example of a coverage determination involving an excluded drug:**
1. An enrollee attempts to fill a prescription for Orlistat. The pharmacist receives an electronic notice indicating that the drug is not covered and provides the enrollee with the Pharmacy Notice.

2. The enrollee calls the plan sponsor to ask why the prescription is not covered. The plan sponsor explains to the enrollee that certain drugs are excluded from Part D coverage under section 1927(d)(2) of the Act, and Orlistat is one of those drugs because its FDA labeled indications relate to the treatment for and maintenance of weight loss.

3. The enrollee argues that Orlistat is being used to treat her diabetes, which is a medically accepted off-label use that is not excluded under section 1927(d)(2) of the Act, and requests the plan sponsor to cover the drug.

4. This request must be treated as a coverage determination.

5. If the plan sponsor determines that the drug is excluded from Part D coverage because it is being prescribed for a use that is excluded under section 1927(d)(2) of the Act, it must issue an adverse coverage determination explaining that the requested drug is excluded from Part D coverage. See the Orlistat example in §40.3.4 of this chapter for sample language that should be included in this type of decision.

6. The enrollee has the right to appeal this decision and argue that the drug isn't excluded from coverage because it is being used to treat a medically accepted off-label use that is not excluded under section 1927(d)(2) of the Act. If the IRE determines that the requested drug is being prescribed for a use that is excluded under section 1927(d)(2) of the Act, it will issue an adverse decision explaining that the drug is excluded from coverage under Part D.

20.2.5 - Enrollment or Disenrollment Complaints
(Rev. 8, 1/1/10)

Complaints that involve CMS determinations related to enrollment in, or disenrollment from a Part D plan must be processed according to the procedures set forth in Chapter 3 of this manual:

20.3 - Procedures for Handling a Grievance
(Rev. 9, 2/22/13)

An enrollee may file a grievance with the Part D plan sponsor either orally or in writing no later than 60 days after the event or incident that precipitates the grievance.

Although the regulations at 42 CFR 423.564(d)(2) do not require a Part D plan sponsor to consider a grievance that is filed after the 60-day deadline, nothing in the regulations
prevents a plan sponsor from doing so on a case-by-case basis. If a plan intends to accept grievances that are not filed timely, it is responsible for developing the criteria it will use to evaluate such requests. However, an enrollee who files a quality of care grievance with a QIO is not required to file the grievance within a specific time period. Therefore, quality of care grievances filed with a QIO may be filed and investigated beyond the 60-day time frame stated in 42 CFR 423.564(d)(2).

Each Part D plan sponsor must provide meaningful procedures for timely hearing and resolving standard and expedited grievances between enrollees and the Part D plan sponsor or any other entity or individual through which the Part D plan sponsor provides benefits.

The Part D plan sponsor must include the following requirements in its grievance procedures:

1. Ability to accept any information or evidence concerning the grievance;

2. Ability to respond within 24 hours to an enrollee’s expedited grievance that a Part D plan sponsor refused to grant a request for an expedited coverage determination under 42 CFR 423.570 or an expedited redetermination under 42 CFR 423.584, and the enrollee has not received the drug in dispute;

3. Timely transmission of grievances to appropriate decision-making levels when appropriate;

4. Prompt, appropriate action, including a full investigation of the complaint if necessary;

5. Notification of investigation results to all concerned parties, as expeditiously as the enrollee’s case requires, based on the enrollee's health status, but not later than 30 days after the plan receives the oral or written grievance, consistent with applicable Federal law. The Part D plan sponsor may extend the 30-day time frame by up to 14 days if the enrollee requests the extension or if the Part D plan sponsor justifies a need for additional information and documents how the delay is in the interest of the enrollee. When the Part D plan sponsor extends the deadline, it must immediately notify the enrollee in writing of the reason(s) for the delay. CMS has developed a model notice that Part D plan sponsors can use to notify enrollees whenever a Part D plan sponsor extends the deadline, (see Appendix 7). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures;

6. The Part D plan sponsor must inform the enrollee of the disposition of the grievance in accordance with the following procedures:

   a. All grievances submitted in writing must be responded to in writing.

   b. Grievances submitted orally may be responded to either orally or in writing, unless the enrollee requests a written response.
c. All grievances related to quality of care, regardless of how the grievance is filed, must be responded to in writing. The response must include a description of the enrollee's right to file a written complaint with the QIO. For any complaint submitted to a QIO, the Part D plan sponsor must cooperate with the QIO in resolving the complaint; and

7. Procedures for tracking and maintaining records about the receipt and disposition of grievances. Consistent with §140 of this chapter, Part D plan sponsors must disclose grievance data to Medicare enrollees upon request. Part D plan sponsors must be able to log or capture enrollees’ grievances in a centralized location that may be readily accessed. The record should include documentation of all telephone calls, correspondence and case notes related to the grievance.

CMS has developed a model notice that a Part D plan sponsor can use to notify an enrollee of its decision regarding a grievance (see Appendix 8). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.

20.3.1 - Procedures for Handling Grievances Misclassified as Appeals (Rev. 1, 11/30/05)

If a Part D plan sponsor misclassifies a grievance as an appeal and issues a denial notice, and the IRE determines that the complaint was misclassified as an appeal, the IRE must dismiss the appeal and return the complaint to the Part D plan sponsor for proper processing. The Part D plan sponsor must notify the enrollee in writing that the complaint was misclassified and will be handled through the Part D plan sponsor’s grievance process. Part D plan sponsors are expected to audit their own appeals and grievance systems for the presence of errors, and institute appropriate quality improvement projects as needed.

20.4 - Written Explanation of Grievance Procedures (Rev. 1, 11/30/05)

The Part D plan sponsor must provide all enrollees with written grievance procedures upon initial enrollment, involuntary disenrollment (i.e., initiated by the Part D plan sponsor under 42 CFR 423.44), annually, and upon request. Additionally, the Part D plan sponsor must notify enrollees about any changes to its grievance procedures 30 days in advance of the effective date of the change. A plan sponsor must provide an enrollee with written notice about his or her right to file an expedited grievance when a plan sponsor denies the enrollee’s request for an expedited coverage determination or expedited redetermination. CMS has developed a model notice that plan sponsors may use to notify enrollees whenever these actions occur (see Appendix 3). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.
Any time a written grievance notification is required, Part D plan sponsors must include at least the following information:

1. How and where to file a grievance; and

2. The differences between appeals and grievances.

30 - Coverage Determinations

(Rev. 9, 2/22/13)

A coverage determination is any determination (i.e., an approval or denial) made by the Part D plan sponsor, or its delegated entity, with respect to the following:

1. A decision about whether to provide or pay for a Part D drug (including a decision not to pay because the drug is not on the plan’s formulary, because the drug is determined not to be medically necessary, because the drug is furnished by an out-of-network pharmacy, or because the Part D plan sponsor determines that the drug is otherwise excluded under section 1862(a) of the Act if applied to Medicare Part D) that the enrollee believes may be covered by the plan;

2. Failure to provide a coverage determination in a timely manner, when a delay would adversely affect the health of the enrollee;

3. A decision concerning a tiering exceptions request under 42 CFR 423.578(a);

4. A decision concerning a formulary exceptions request under 42 CFR 423.578(b);

5. A decision on the amount of cost sharing for a drug; or

6. A decision whether an enrollee has, or has not, satisfied a prior authorization or other utilization management requirement. See §30.1.

Each Part D plan sponsor must establish procedures for making timely coverage determinations regarding the benefits an enrollee is entitled to receive under a Part D plan.

Once a coverage determination has been made, the appeals process may be triggered if the Part D plan sponsor’s decision is unfavorable. If a Part D enrollee disputes a coverage determination, the case must be handled using the federally mandated appeals process. If an enrollee complains about any other aspect of the Part D plan sponsor's operations (e.g. the manner in which a benefit was provided), the Part D plan sponsor must address the issue through the grievance process.

When the Part D plan sponsor decides not to provide or pay for a requested benefit, in whole or in part, the decision is an adverse coverage determination. If a Part D plan sponsor makes an adverse coverage determination, it must provide the enrollee with a written denial notice that includes his or her appeal rights. See §40.3.2 and §40.3.3.
A plan sponsor is not required to treat the presentation of a prescription at the pharmacy counter as a request for a coverage determination. Accordingly, the plan sponsor is not required to provide the enrollee with a written denial notice at the pharmacy as a result of the transaction. However, as required under 42 CFR 423.562(a)(3), plans must arrange with their network pharmacies to distribute the standardized notice developed by CMS to notify enrollees of their right to request and receive a coverage determination from their plan. See §40.3.1.

30.1 - Prior Authorization or Other Utilization Management Requirements
(Rev. 9, 2/22/13)

When a plan sponsor processes a coverage determination request that involves a prior authorization (PA) or other utilization management (UM) requirement, the plan sponsor's determination on whether to grant approval of a drug for an individual enrollee constitutes a coverage determination and is subject to appeal. In addition, if a plan sponsor denies a drug because the enrollee failed to seek PA, the denial also constitutes a coverage determination and is subject to appeal (Note: this denial would occur after an enrollee has formally requested a coverage determination with a plan sponsor because, as indicated in §30 above, the presentation of a prescription at the pharmacy counter is not considered a request for a coverage determination unless a plan sponsor chooses to treat it as such). Thus, the adjudication time frame, notice, and other requirements applicable to coverage determinations under part 423, subpart M of the Medicare Part D regulations apply to requests that involve a PA or other UM requirement in the same manner that they apply to all coverage determination requests. However, the decision to place a medication on a PA list or subject it to a UM requirement is not a coverage determination and is not subject to appeal.

Part D plan sponsors must determine how to categorize requests that involve PAs or other UM requirements on a case-by-case basis because some of these requests are subject to the exceptions process while others are not. If the request does not contain adequate information for the plan sponsor to ascertain whether an enrollee is attempting to satisfy a PA requirement or asking the plan to waive a PA requirement, the plan sponsor must make reasonable and diligent efforts to obtain the necessary information.

Attempting to Satisfy a PA or other UM requirement
A case where an enrollee/physician/other prescriber is attempting to satisfy a PA requirement (i.e., the enrollee/physician/other prescriber is aware that a PA requirement exists and, for example, submits a PA form to the plan sponsor in an attempt to satisfy the PA requirement) should be processed as a coverage determination. The plan must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision no later than 24 hours after receiving the request for expedited cases, or no later than 72 hours after receiving the request for standard cases. Where an enrollee/physician/other prescriber is attempting to satisfy a PA requirement and the plan has a PA form available for seeking prior authorization for the requested drug, the plan
should promptly provide the physician or other prescriber with the PA form. An enrollee, physician or other prescriber may use the model Medicare Part D Coverage Determination Request Form to request an override to a PA or other UM requirement: http://cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Forms.html.

**Asking a Plan Sponsor to Waive a PA or other UM Requirement**

Where an enrollee or an enrollee's prescribing physician or other prescriber is asking a plan sponsor to waive a PA or other UM requirement (e.g., a physician or other prescriber indicates that an enrollee would suffer adverse effects if he or she were required to satisfy the PA requirement), he or she is asking for an exception and the prescribing physician or other prescriber must submit a statement to support the request consistent with the requirements set forth in 42 CFR 423.578(b)(5). A physician or other prescriber may use the model Medicare Part D Coverage Determination Request Form to request an exception and/or submit a supporting statement. If the request or supporting statement is made in writing, plan sponsors are prohibited from requiring a physician or other prescriber to submit the request or supporting statement on a specific form. If the exception request involves benefits not yet received, the plan must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision no later than 24 hours after receiving the physician's or other prescriber's supporting statement for expedited cases, or no later than 72 hours after receiving the physician’s or other prescriber's supporting statement for standard cases. If the exception request involves reimbursement for benefits already received, the plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision (and make payment when appropriate) no later than 14 calendar days after receiving the request.

**Examples**

The following examples illustrate when a transaction involving a PA or other UM requirement is, or is not, a coverage determination:

**Example 1**

1. An enrollee provides his or her pharmacist with a prescription.

2. The pharmacist enters the prescription into the system and receives an electronic notice indicating that the claim has been rejected due to a requirement for PA review and approval. Without the approval, the enrollee must pay the full price for the prescription.

3. A transaction that occurs at a pharmacy, including a rejection from a plan sponsor or pharmacy benefit manager (PBM), is not a coverage determination, unless the plan sponsor chooses to treat the presentation of the prescription at the pharmacy as a claim for benefits.
4. If the enrollee, physician, or other prescriber subsequently submits a request for the prescription with supporting information to the plan sponsor (i.e., the information is submitted in an attempt to satisfy the PA or UM requirement and/or support the medical necessity of the prescription), the plan sponsor's decision to approve or deny coverage of the prescription is a coverage determination.

**Note:** If a plan determines that the PA or UM requirement has been satisfied and approves coverage, it must take whatever steps are necessary to ensure that the edit will be overridden at the pharmacy and the prescription can be filled immediately.

**Example 2**

1. An enrollee calls his or her plan sponsor to determine if Prilosec is covered for him or her (it doesn't matter if the enrollee has a prescription for the drug).

2. Under the plan's formulary, Prilosec is subject to a PA requirement.

3. The plan sponsor tells the enrollee that there is a PA requirement and explains how the PA requirement can be satisfied.

4. The transaction is not a coverage determination because the plan sponsor is explaining the plan's benefit design structure, and the enrollee/physician/other prescriber is not attempting to satisfy the UM requirement or argue that the UM requirement should not apply for reasons of medical necessity.

**Example 3**

1. An enrollee presents a prescription to his or her pharmacist.

2. The pharmacist receives an electronic notice indicating that the drug is subject to a PA requirement and *provides the enrollee with a copy of the standardized pharmacy notice “Medicare Prescription Drug Coverage and Your Rights.”*

3. The enrollee/physician/other prescriber calls the plan sponsor to ask about the UM requirement and the plan sponsor explains the procedures that the enrollee/physician/other prescriber must follow for the PA requirement to be satisfied.

4. The transaction is not a coverage determination because the plan sponsor is explaining the plan's benefit design structure (and the enrollee/physician/other prescriber has not attempted to satisfy the UM requirement).

**Example 4**

1. An enrollee presents a prescription to his or her pharmacist.
2. The pharmacist receives an electronic notice indicating that the drug is subject to a PA or other UM requirement and provides the enrollee with a copy of the standardized pharmacy notice “Medicare Prescription Drug Coverage and Your Rights.”

3. The enrollee/physician/other prescriber calls the plan sponsor and the plan sponsor explains the procedures that the enrollee/physician/other prescriber must follow for the PA requirement to be satisfied.

4. The enrollee/physician/other prescriber attempts to satisfy the PA requirement.

5. The plan sponsor’s decision to approve or deny coverage is a coverage determination because the enrollee/physician/other prescriber has attempted to satisfy the UM requirement.

30.2 - Exceptions
(Rev. 9, 2/22/13)

Coverage determinations include a plan sponsor’s decision on an enrollee’s exception request. Enrollees may request an exception to a plan's tiered cost-sharing structure, or formulary.

Once an exception is granted, the plan sponsor is prohibited from requiring the enrollee to request approval for a refill or new prescription to continue using the Part D prescription drug approved under the exceptions process for the remainder of the plan year, so long as the enrollee remains enrolled in the plan, the physician or other prescriber continues to prescribe the drug and it continues to be safe for treating the enrollee’s condition. A plan sponsor may choose not to require an enrollee to resubmit an exception request at the beginning of a new plan year. For example, if a plan sponsor grants an exception request near the end of a plan year, it may choose not to require the enrollee to request a new exception when the new plan year begins.

If a plan sponsor decides not to continue coverage under an approved exception into the subsequent plan year for a renewing enrollee, the plan must send a written notice to the enrollee at least 60 days prior to the end of the plan year, unless:

The plan sponsor sent an approval letter to the enrollee when it granted the exception at the coverage determination or redetermination level which clearly identified the date that coverage will end in the approval letter; or

The plan sponsor sent an approval letter to the enrollee when it effectuated a reversal of its adverse coverage determination or redetermination decision by the IRE or other appeal entity, and clearly identified the date that coverage will end in the approval letter. The approval letter is not the decision letter, but is a letter explaining the terms of the approval as ordered by the IRE or other appeal adjudicator.
Alternatively, if a plan sponsor decides to allow coverage under an approved exception to continue into the subsequent plan year for a renewing enrollee, the plan sponsor must send a written notice to the enrollee at least 60 days prior to the date coverage ends, unless:

- The plan sponsor sent an approval letter to the enrollee when it granted the exception at the coverage determination or redetermination level which clearly identified the date that coverage will end in the approval letter; or

- The plan sponsor sent an approval letter to the enrollee when it effectuated a reversal of its adverse coverage determination or redetermination decision by the IRE or other appeal entity, and clearly identified the date that coverage will end in the approval letter.

If a plan sponsor is required to send a written notice to the enrollee at least 60 days prior to the end of the plan year or the date coverage ends, the notice must:

- Explain that the exception will not be extended,
- Provide the date that coverage will end (e.g., on December 31, 2013),
- Explain the right to request a new exception once the current exception expires, and
- Provide instructions for making a new exceptions request.

Plans are prohibited from assigning drugs approved under the exceptions process to a special tier, co-payment, or other cost-sharing requirement.

If a plan sponsor changes its formulary or the cost-sharing status of a drug during the plan year, it must: (1) give direct written notice to affected enrollees at least 60 days in advance of such change becoming effective, or (2) if the 60-day notice is not given, provide enrollees with a 60-day supply of the drug affected by the change and the notice when the enrollee requests a refill. The written notice must contain the following information:

1. The name of the affected covered Part D drug;

2. Whether the plan is removing the covered Part D drug from the formulary, or changing its preferred or tiered cost-sharing status;

3. The reason why the plan is removing such covered Part D drug from the formulary, or changing its preferred (lower cost-sharing than cost-sharing associated with non-preferred drugs) or tiered cost-sharing status;

4. Alternative drugs in the same therapeutic category, class, or cost-sharing tier, and expected cost-sharing for those drugs; and
5. The means by which enrollees may obtain a coverage determination under 42 CFR 423.566 or an exception under 42 CFR 423.578.

CMS has developed a model notice that a Part D plan sponsor can use to notify enrollees whenever it changes its formulary or the cost-sharing status of a drug during the plan year (see Appendix 10). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures. A plan may also use the EOB to notify enrollees of mid-year formulary or cost-sharing status changes.

**Note**: Except as provided under 42 CFR 423.120 (b)(5)(iii), a Part D sponsor may not remove a covered Part D drug from its formulary, or make any change in the preferred or tiered cost-sharing status of a covered Part D drug on its formulary, between the beginning of the annual coordinated election period described in 42 CFR 423.38(b) and 60 days after the beginning of the contract year associated with that annual coordinated election period. See 42 CFR 423.120(b)(6).

### 30.2.1 - Tiering Exception
*(Rev. 9, 2/22/13)*

If a plan utilizes a tiered cost-sharing structure to manage its Part D drug benefits, it must establish and maintain reasonable and complete exceptions procedures that permit enrollees to obtain a non-preferred drug in a higher cost-sharing tier at the more favorable cost-sharing terms applicable to drugs in a lower cost-sharing tier.

*If an enrollee wishes to obtain a tiering exception, his or her prescribing physician or other prescriber must provide the plan sponsor with a statement indicating factor(s) (1) and/or (2) discussed in section 30.2.1.1. The physician or other prescriber may provide either a written or an oral supporting statement. If the physician or other prescriber provides an oral supporting statement, the plan may require the physician or other prescriber to subsequently provide a written supporting statement to demonstrate medical necessity of the drug. A supporting statement provided by a physician or other prescriber is entitled to great weight when reviewing the exception or other coverage determination request.*

*A physician or other prescriber may use the model Medicare Part D Coverage Determination Request Form to request an exception and/or submit a supporting statement: [http://cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Forms.html](http://cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Forms.html).*

*Plan sponsors are prohibited from requiring a physician or other prescriber to submit a supporting statement on a specific form.*

*Note*: Under 42 CFR §423.578(c)(4)(iii), an enrollee is prohibited from requesting a tiering exception for a non-formulary drug approved under the formulary exception process. However, a drug that is subject to a UM requirement is a formulary drug (i.e., a
UM requirement placed on a formulary drug does not make that drug a non-formulary drug. Therefore, an enrollee who requests a UM exception and receives an approval, may also request a tiering exception for the same formulary drug.

30.2.1.1 – Supporting Statement Criteria
(Rev. 9, 2/22/13)

The physician's or other prescriber's supporting statement must indicate that the drug in the lower cost-sharing tier for the treatment of the enrollee's condition--

(1) Would not be as effective as the requested drug in the higher cost-sharing tier; and/or

(2) Would have adverse effects.

30.2.1.2 - Processing Timeframes
(Rev. 9, 2/22/13)

Requests for Benefits
If an enrollee or an enrollee’s prescriber is requesting an exception for a benefit not yet received, the 24 hour (expedited request) or 72-hour (standard request) timeframe for resolving the request does not begin until the enrollee’s prescribing physician or other prescriber provides a supporting statement indicating factor(s) (1) and/or (2) discussed in §30.2.1.1. See §§40.2 and 50.4. Also see §30.2.1.3.

Requests for Reimbursement
If an enrollee or an enrollee’s prescriber is requesting reimbursement for a prescription drug that must be resolved under the exceptions process, the 14-day timeframe for resolving the request begins when the request is received (i.e., the 14 calendar-day timeframe for processing a reimbursement request is not tolled pending receipt of a prescriber’s supporting statement when a reimbursement request involves an exception). See §§30.3 and 40.2. Also see §30.2.1.3.

30.2.1.3 - Requests for Additional Information
(Rev. 9, 2/22/13)

Written Supporting Statements
If the physician or other prescriber provides a written statement indicating factors (1) and/or (2) discussed in §30.2.1.1, but the plan sponsor believes it needs additional information to support one of those factors, the plan sponsor must obtain the additional information, make its decision, and notify the enrollee and/or physician or other prescriber, as appropriate, within 24 hours (expedited requests for benefits), 72 hours (standard requests for benefits), or 14 calendar days (reimbursement requests) after receiving the initial written statement (i.e., the time frame is not tolled if the plan asks for additional
information after it has received a written supporting statement indicating factors (1) and/or (2)).

CMS has developed a model notice that Part D plan sponsors can use to request a supporting statement and/or additional information (see Appendix 11). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.

Oral Supporting Statements
If the physician or other prescriber provides an oral statement and the plan sponsor determines that the oral statement does not sufficiently demonstrate the medical necessity of the requested drug, the Part D plan sponsor may require the physician or other prescriber to subsequently provide a written supporting statement indicating factors (1) and (2) discussed in §30.2.1.1. If the plan sponsor requires a written statement, it must immediately contact the enrollee's prescribing physician or other prescriber (or the enrollee and the enrollee's prescribing physician or other prescriber) and request the supporting statement. The plan sponsor's request must explicitly state that the physician or other prescriber is required to indicate factors (1) and/or (2) in the written supporting statement. The plan sponsor may also request the prescribing physician or other prescriber to provide additional supporting medical documentation as part of the written statement. If the plan sponsor requires the prescribing physician or other prescriber to provide additional supporting medical documentation as part of the written statement, the plan sponsor must clearly identify the type of information that should be submitted.

- **Requests for Reimbursement**
  When a reimbursement request must be resolved under the exceptions process and the plan sponsor requires the prescribing physician or other prescriber to submit a written supporting statement following an oral statement, the written statement must be obtained within the 14 calendar-day timeframe discussed in §§30.2.1.2, 30.3, and 40.2 if the enrollee or prescriber wants the information to be considered (i.e., the 14 calendar-day timeframe for processing a reimbursement request is not tolled pending receipt of a prescriber’s supporting statement when a reimbursement request involves an exception).

- **Requests for Benefits**
  If the exception request involves benefits not yet received and the plan sponsor requires the prescribing physician or other prescriber to submit a written supporting statement following the oral statement, the adjudication time frame begins when the plan sponsor receives the physician's or other prescriber's written supporting statement indicating factors (1) and/or (2) discussed in §30.2.1.1.

Although the adjudication time frame does not begin until the plan receives the written supporting statement, a plan sponsor must not keep the request open indefinitely. If the plan does not receive the physician's or other prescriber's supporting statement indicating factors (1) and/or (2) within a reasonable period of time, the plan should make its determination based on whatever evidence exists, if any. Therefore, in cases involving an exceptions request where the plan sponsor is waiting for submission of the supporting
statement, the plan sponsor must wait at least 24 hours after the expiration of the time frame that would otherwise apply to a coverage determination request. In other words, a plan must wait a minimum of 96 hours after receiving a standard request or a minimum of 48 hours after receiving an expedited request before issuing its determination.

Example:

1/1/13: Plan sponsor receives a standard request for a coverage determination at 12 PM. The enrollee is requesting approval for a Part D drug that is not on the plan's formulary (i.e., a formulary exceptions request). Neither the enrollee nor the enrollee's prescribing physician or other prescriber submitted the prescribing physician's or other prescriber's supporting statement with the request. The adjudication time frame does not begin until the prescribing physician's or other prescriber's supporting statement indicating factors (1) and/or (2) is received.

1/2/13: The plan sponsor contacts the enrollee and the enrollee's prescribing physician or other prescriber in an attempt to obtain the prescribing physician's or other prescriber's supporting statement.

1/3/13: The plan sponsor again contacts the enrollee and the enrollee's prescribing physician or other prescriber in an attempt to obtain the prescribing physician's or other prescriber's supporting statement.

1/4/13: If the standard coverage determination request in this example did not involve an exception request, the plan sponsor would have been required to notify the enrollee of its decision by 12 PM (i.e., 72 hours after receipt of the request). However, because the request in this example involves an exception, the plan sponsor must wait at least 24 more hours for the prescribing physician's or other prescriber's supporting statement before making a decision.

1/5/13: If the plan sponsor has not received the physician's or other prescriber's supporting statement by 12 PM, the plan sponsor may make a decision based on any evidence it has received, if any.

In the absence of the prescribing physician’s or other prescriber's supporting statement, the plan may choose to wait longer than these minimum time frames to issue a coverage determination, but the plan should not leave the request open indefinitely (as noted above, a plan sponsor has an obligation to contact the enrollee and/or physician or other prescriber and clearly identify the information needed to process the request). If no evidence exists to support the exception request, the plan sponsor should deny the request for lack of medical necessity. The denial notice to the enrollee must clearly explain that the request was denied due to a lack of medical necessity and the prescribing physician or other prescriber did not produce the necessary supporting statement. The enrollee then has the right to appeal the denial.

30.2.1.4 – Approval of a Request
(Rev. 9, 2/22/13)
A plan must grant a tiering exception when it determines that factor(s) (1) and/or (2) discussed in §30.2.1.1 have been met. The regulations at 42 CFR 423.578(f) affirmatively state that nothing in the regulations should be construed to mean that the physician’s or other prescriber's supporting statement will result in an automatic favorable determination.

When a tiering exception is approved, the plan sponsor must provide coverage for the drug in the higher cost-sharing tier at the cost-sharing level that applies to the drug in the applicable lower cost-sharing tier. However, tiering exceptions granted by the Part D plan sponsor may be limited. A Part D sponsor is not required to approve a tiering exception for a drug in a higher cost-sharing tier at the generic tier cost-sharing level if the plan maintains a separate tier that only includes generic drugs as defined in 42 CFR §423.4.

§423.4. In addition, a Part D sponsor that maintains a formulary tier in which it places very high cost and unique items (i.e., specialty tier), it may design its exception process so that drugs placed in that tier are not eligible for a tiering exception. The following examples illustrate possible cost-sharing tier structures and permissible tiering exceptions between the tiers:

**Example 1**
Tier 1 (least expensive tier): Generic Drugs
Tier 2: Brand Drugs
Tier 3 (most expensive tier): Specialty Tier Drugs
The Part D sponsor would likely not have a tiering exception process for this type of cost-sharing tier structure, unless the plan allows tiering exceptions for drugs on the specialty tier.

**Example 2**
Tier 1 (least expensive tier): Generic Drugs
Tier 2: Preferred Brand Drugs
Tier 3: Non-preferred Brand Drugs
Tier 4 (most expensive tier): Specialty Tier Drugs
An enrollee may request a tiering exception to cover a Tier 3 drug at the Tier 2 cost-sharing level so long as there is a drug on Tier 2 approved for treating the same condition that the requested Tier 3 drug is being used to treat.

**Example 3**
- Tier 1 (least expensive tier): Preferred Generic Drugs
- Tier 2: Non-preferred Generic Drugs
- Tier 3: Preferred Brand Drugs
- Tier 4: Non-preferred Brand Drugs
- Tier 5 (most expensive tier): Specialty Tier Drugs
An enrollee may request a tiering exception to cover a Tier 4 drug at the Tier 3 cost-sharing level (so long as there is a drug on Tier 3 approved for treating the same condition that the requested Tier 4 drug is being used to treat), or a tiering exception to cover a Tier 2 drug at
the Tier 1 cost-sharing level (so long as there is a drug in Tier 1 for treating the same condition that the requested Tier 2 drug is being used to treat).

Please refer to the 2012 Call Letter for additional information on tier structure and labeling.

Note: Under 42 CFR §423.578(c)(4)(iii), an enrollee is prohibited from requesting a tiering exception for a non-formulary drug approved under the formulary exception process. However, a drug that is subject to a UM requirement is a formulary drug (i.e., a UM requirement placed on a formulary drug does not make that drug a non-formulary drug). Therefore, an enrollee who requests a UM exception and receives an approval, may also request a tiering exception for the same formulary drug.

30.2.2 - Formulary Exception
(Rev. 9, 2/22/13)

If a plan utilizes a formulary to manage its Part D drug benefits, it must have procedures in place that ensure enrollees have access to Part D drugs that are not included on its formulary.

Formulary use includes the application of cost utilization tools, such as:

(1) A dose restriction, including the number and/or dosage form, that causes a particular Part D drug not to be covered for the number of doses and/or dosage form prescribed,

(2) A step therapy requirement that causes a particular Part D drug not to be covered until the requirements of the plan’s coverage policy are met, or

(3) A therapeutic substitution requirement.

Note: Not all complaints about a plan sponsor's application of costs utilization tools should be handled through the formulary exceptions process. If an enrollee is merely complaining about the existence of a utilization management requirement, the complaint must be handled through the grievance process. If an enrollee is attempting to satisfy a utilization management requirement, the plan must handle the complaint through the coverage determination process. However, if an enrollee argues that a utilization management requirement should not apply in his or her situation because one of the three factors discussed below exist, the plan sponsor must process the complaint as a request for a formulary exception.

If an enrollee wishes to obtain a formulary exception, his or her prescribing physician or other prescriber must provide the plan sponsor with a statement indicating factor(s) (1), (2), and/or (3) discussed in §30.2.2.1 below. Plan sponsors have the option of accepting an oral statement indicating factor(s) (1), (2), and/or (3) from an enrollee’s prescribing physician or other prescriber. If the physician or other prescriber provides an oral
supporting statement, the plan may require the physician or other prescriber to subsequently provide a written supporting statement to demonstrate medical necessity of the drug. A supporting statement provided by a physician or other prescriber is entitled to great weight when reviewing the exception or other coverage determination request.

A physician or other prescriber may use the model Medicare Part D Coverage Determination Request Form to request an exception and/or submit a supporting statement: [http://cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Forms.html](http://cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Forms.html).

Plan sponsors are prohibited from requiring a physician or other prescriber to submit a supporting statement on a specific form.

### 30.2.2.1 – Supporting Statement Criteria  
(Rev. 9, 2/22/13)

The physician's or other prescriber's supporting statement must indicate that the requested prescription drug should be approved because:

1. All covered Part D drugs on any tier of a plan's formulary would not be as effective for the enrollee as the non-formulary drug, and/or would have adverse effects;

2. The number of doses available under a dose restriction for the prescription drug:
   - (a) Has been ineffective in the treatment of the enrollee's disease or medical condition or,
   - (b) Based on both sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug’s effectiveness or patient compliance; or

3. The prescription drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements:
   - (a) Has been ineffective in the treatment of the enrollee’s disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug’s effectiveness or patient compliance; or
   - (b) Has caused or, based on sound clinical evidence and medical and scientific evidence, is likely to cause an adverse reaction or other harm to the enrollee.

### 30.2.2.2 - Processing Timeframes
Requests for Benefits
If an enrollee or an enrollee’s prescriber is requesting an exception for a benefit not yet received, the 24 hour (expedited request) or 72-hour (standard request) timeframe for resolving the request does not begin until the enrollee’s prescribing physician or other prescriber provides a supporting statement indicating factor(s) (1), (2), and/or (3) discussed in §30.2.2.1. See §§40.2 and 50.4. Also see §30.2.2.3.

Requests for Reimbursement
If an enrollee or an enrollee’s prescriber is requesting reimbursement for a prescription drug that must be resolved under the exceptions process, the 14-day timeframe for resolving the request begins when the request is received (i.e., the 14 calendar-day timeframe for processing a reimbursement request is not tolled pending receipt of a prescriber’s supporting statement when a reimbursement request involves an exception) See §§30.3 and 40.2. Also see §30.2.2.3.

30.2.2.3 - Requests for Additional Information
(Rev. 9, 2/22/13)

Written Supporting Statements
If the physician or other prescriber provides a written statement indicating factor(s) (1), (2), and/or (3) discussed in §30.2.2.1, but the plan sponsor believes it needs additional information to support one of those factors, the plan sponsor must obtain the additional information, make its decision, and notify the enrollee and/or physician or other prescriber, as appropriate, within 24 hours (expedited requests for benefits), 72 hours (standard requests for benefits), or 14 calendar days (reimbursement requests) after receiving the initial written statement (i.e., the time frame is not tolled if the plan asks for additional information after it has received a written supporting statement indicating one of the three factors).

CMS has developed a model notice that Part D plan sponsors can use to request a supporting statement and/or additional information (see Appendix 11). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.

Plan sponsors are prohibited from requiring a physician or other prescriber to submit a supporting statement on a specific form.

Oral Supporting Statements
If the physician or other prescriber provides an oral supporting statement, and the plan sponsor determines that the oral statement does not sufficiently demonstrate the medical necessity of the requested drug, the Part D plan sponsor may require the physician or other prescriber to subsequently provide a written supporting statement indicating factor(s) (1), (2), and/or (3) discussed in section 30.2.2.1. If the plan sponsor requires a written statement, it must immediately contact the enrollee's prescribing physician or other prescriber (or the enrollee and the enrollee's prescribing physician or other prescriber)
and request the supporting statement. The plan sponsor's request must explicitly state that the physician or other prescriber is required to indicate factor(s) (1), (2), and/or (3) in the written supporting statement. The plan sponsor may also request the prescribing physician or other prescriber to provide additional supporting medical documentation as part of the written statement. If the plan sponsor requires the prescribing physician or other prescriber to provide additional supporting medical documentation as part of the written statement, it must clearly identify the type of information that must be submitted.

- **Requests for Reimbursement**

  When a reimbursement request must be resolved under the exceptions process and the plan sponsor requires the prescribing physician or other prescriber to submit a written supporting statement following an oral statement, the written statement indicating factor(s) (1), (2), and/or (3) discussed in §30.2.2.1 must be obtained within the 14 calendar-day timeframe discussed in §§30.3 and 40.2 if the enrollee or prescriber wants the information to be considered (i.e., the 14 calendar-day timeframe for processing a reimbursement request is not tolled pending receipt of a prescriber’s supporting statement when a reimbursement request must be resolved under the exceptions process).

- **Requests for Benefits**

  If the exception request involves benefits not yet received and the plan sponsor requires the prescribing physician or other prescriber to submit a written supporting statement after the prescribing physician or other prescriber submits an oral supporting statement, the adjudication time frame begins when the plan receives the physician's or other prescriber's written supporting statement indicating factor(s) (1), (2), and/or (3) discussed in §30.2.2.1.

Although the adjudication time frame does not begin until the plan receives the written supporting statement, a plan sponsor must not keep the request open indefinitely. A plan must provide the prescribing physician or other prescriber with a reasonable opportunity to provide the supporting statement before making its determination. If the plan does not receive the physician's or other prescriber's supporting statement indicating one of the three factors within a reasonable period of time, the plan should make its determination based on whatever evidence exists, if any. Therefore, in cases involving an exceptions request for benefits where the plan sponsor is waiting for submission of the supporting statement, the plan sponsor must wait at least 24 hours after the expiration of the time frame that would otherwise apply to a coverage determination request. In other words, a plan sponsor must wait a minimum of 96 hours after receiving a standard request or a minimum of 48 hours after receiving an expedited request before issuing its determination.

Example:

1/1/13: Plan sponsor receives a standard request for a coverage determination at 12 PM. The enrollee is requesting approval for a Part D drug that is not on the plan's formulary (i.e., a formulary exceptions request) and the enrollee has not purchased the drug in dispute. Neither the enrollee nor the enrollee's prescribing physician or
other prescriber submitted the prescribing physician's or other prescriber's supporting statement with the request. The adjudication time frame does not begin until the prescribing physician's or other prescriber's supporting statement indicating one of the three factors discussed above is received.

1/2/13: The plan sponsor contacts the enrollee and the enrollee's prescribing physician or other prescriber in an attempt to obtain the prescribing physician's or other prescriber's supporting statement.

1/3/13: The plan sponsor contacts the enrollee and the enrollee's prescribing physician or other prescriber in an attempt to obtain the prescribing physician's or other prescriber's supporting statement.

1/4/13: If the standard coverage determination request in this example involved an exceptions request, the plan sponsor would have been required to notify the enrollee of its decision by 12 PM (i.e., 72 hours after receipt of the request). However, because the request in this example involves an exception, the plan sponsor must wait at least 24 more hours for the prescribing physician's or other prescriber's supporting statement before making a decision.

1/5/13: If the plan sponsor has not received the physician's or other prescriber's supporting statement by 12 PM, the plan sponsor may make a decision based on any evidence it has received, if any.

In the absence of the prescribing physician’s or other prescriber's supporting statement, the plan may choose to wait longer than these minimum time frames to issue a coverage determination, but the plan should not leave the request open indefinitely (as noted above, a plan sponsor has an obligation to contact the enrollee and/or physician or other prescriber and clearly identify the information needed to process the request). If no evidence exists to support the exception request, the plan should deny the request for lack of medical necessity. The denial notice to the enrollee must clearly explain that the request was denied due to a lack of medical necessity because the prescribing physician or other prescriber did not produce the necessary supporting statement. The enrollee then has the right to appeal the denial.

30.2.2.4 – Approval of a Request
(Rev. 9, 2/22/13)

A plan must grant a formulary exception when it determines that factor(s) (1), (2), and/or (3) discussed in §30.2.2.1 have been met. This language ensures that drugs that otherwise would not be covered (for example, because they are obtained out of network or excluded under §1862(a) of the Act), are not covered through the exceptions process. The regulations at 42 CFR 423.578(f) affirmatively state that nothing in the regulations should be construed to mean that the physician’s or other prescriber's supporting statement will result in an automatic favorable determination.
Unlike under the tiering exceptions process, the regulations do not specify what level of cost sharing applies when an exception is approved under the formulary exceptions process. Instead, a plan sponsor has the flexibility to determine what level of cost sharing will apply for non-formulary drugs approved under the exceptions process. However, a plan sponsor is limited to choosing a single cost-sharing level that applies to one of its existing formulary tiers. For example, a plan sponsor may apply the non-preferred level of cost sharing for all non-formulary drugs approved under the exception process. Part D sponsors may also elect to apply a second less expensive level of cost sharing for approved formulary exceptions for generic drugs, so long as the second level of cost sharing is associated with an existing formulary tier and is uniformly applied to all approved formulary exceptions for generic drugs.

Note: Under 42 CFR §423.578(c)(4)(iii), an enrollee is prohibited from requesting a tiering exception for a non-formulary drug approved under the formulary exception process. However, a drug that is subject to a UM requirement is a formulary drug (i.e., a UM requirement placed on a formulary drug does not make that drug a non-formulary drug). Therefore, an enrollee who requests a UM exception and receives an approval, may also request a tiering exception for the same formulary drug.

30.3 - Requests for Reimbursement
(Rev. 9, 2/22/13)

The regulations at 42 CFR 423.566(b)(1) state that any decision by a plan sponsor to reimburse an enrollee for a Part D drug, including a decision about reimbursing an enrollee for a drug obtained at an out-of-network pharmacy and a decision to reimburse an enrollee for all or part of a cost share amount that the enrollee believes he or she was incorrectly charged, is a coverage determination. Therefore, plan sponsors must process all requests for reimbursement submitted by enrollees as coverage determinations pursuant to the rules provided in §423.568 of the regulations and §§40 and 130.1 of this chapter.

30.3.1 - Form and Content of Reimbursement Requests
(Rev. 9, 2/22/13)

Consistent with §40.1 of this chapter, plan sponsors are required to accept all reimbursement requests that are made in writing (when submitted by an enrollee, an enrollee's prescribing physician or other prescriber, or an enrollee's representative) and are prohibited from requiring use of a specific form. A plan sponsor may develop a form for requesting reimbursement and encourage its members to use the form, but the plan sponsor cannot require its members to use the form. Similarly, a plan sponsor may encourage its members to include copies of their prescriptions with their reimbursement requests, but the plan sponsor cannot require it.

Note: When a reimbursement request must be resolved under the exceptions process described in §30.2, the 14 calendar-day timeframe for processing a reimbursement request is not tolled pending receipt of a prescriber’s supporting statement. The enrollee or prescriber must submit the prescriber’s supporting statement with the reimbursement request.
request (or within the 14 calendar-day adjudication time frame) if she or he wants the plan sponsor to consider the information. If an enrollee or prescriber does not submit the prescriber’s supporting statement with the reimbursement request, the plan sponsor must make reasonable and diligent efforts to obtain the missing information within the 14 calendar-day timeframe. See §§30.2.1.3, 30.2.2.3, and 30.3.2 for more information.

30.3.2 - Processing Reimbursement Requests
(Rev. 9, 2/22/13)

As noted in §30.3, plan sponsors must process all requests for reimbursement submitted by enrollees (or their representatives, prescribing physicians, or other prescribers) as standard coverage determinations (see §40 of this chapter for more information about standard coverage determinations). However, the timeframe for processing standard requests for reimbursement is different from the timeframe for processing standard requests for benefits:

- If a plan sponsor is issuing an unfavorable reimbursement decision, it must make the decision and provide notice of the decision no later than 14 calendar days after receiving the reimbursement request.

- If a plan sponsor is issuing a favorable reimbursement decision, it must make the decision, provide notice of the decision and make payment no later than 14 calendar days after receiving the reimbursement request.

If a plan sponsor is not able to obtain all of the information it needs to reach a favorable decision on the merits of the case within the 14 calendar-day timeframe, it should issue an unfavorable decision.

- If a plan sponsor does not have all of the information it needs to make a decision, the plan sponsor must make reasonable and diligent efforts to obtain the missing information within the 14 calendar-day timeframe. When a plan sponsor could acquire missing information, such as a National Drug Code (NDC) number, by contacting the enrollee's pharmacist, physician, or other prescriber, it should do so instead of relying on the enrollee to provide the information.

- If a plan is issuing an unfavorable decision because it was not able to obtain all of the information it needed to make a favorable decision, the plan sponsor must, pursuant to §423.568(c) of the regulations and §40.3.3 of this chapter, clearly explain in the decision letter the reason for the denial using language the enrollee can understand. Merely providing the technical reason for the denial without additional information generally will not satisfy the notice requirements. For example, if a plan sponsor denies a request because the enrollee did not provide the NDC number (and the plan sponsor could not obtain it from the enrollee's pharmacist, physician, or other prescriber within the allowable timeframe), the plan sponsor should not simply state that the claim was denied because the member did
not provide the NDC number. The plan should also briefly explain what an NDC number is (e.g., a ten-digit, three-segment number used to identify a drug), where he or she can get it (e.g., from the pharmacist who filled the prescription or the physician or other prescriber who wrote the prescription), and how the enrollee can submit the information with his or her appeal request.

30.4 - Procedures for Handling Misclassified Coverage Determinations
(Rev. 8, 1/1/10)

All adverse coverage determinations are subject to the appeals procedures. Sometimes complaints do not appear to involve coverage determinations and are misclassified as grievances exclusively. This may occur because the plan did not issue the written notice of an adverse coverage determination (i.e., a denial notice). Upon discovery of such an error, the Part D plan sponsor must notify the enrollee in writing that the complaint was misclassified and will be handled through the appeals process. The time frame for processing the complaint begins on the date the complaint is received by the Part D plan sponsor, as opposed to the date the Part D plan sponsor discovers its error. Part D plan sponsors are expected to audit their own appeals and grievance systems for the presence of errors and institute appropriate quality improvement projects as needed.

30.4.1 - Quality of Care
(Rev. 9, 2/22/13)

A complaint received by a Part D plan sponsor concerning the quality of a benefit received by an enrollee is generally treated as a grievance. However, quality of care complaints occasionally involve complaints about the denial of benefits. For example, if an enrollee complains of poor care because his/her pharmacist would not provide a prescribed medication, the complaint may involve a request for benefits that should be simultaneously processed through the grievance and coverage determination processes (i.e., the complaint about the pharmacist is a grievance, and the complaint about not receiving the prescribed medication is a request for benefits).

30.4.2 - Service Accessibility
(Rev. 9, 2/22/13)

A complaint concerning the timely receipt of a Part D drug that has already been provided may be treated as a grievance. However, when enrollees complain that they have been unable to obtain Part D drugs that they believe they are entitled to receive (and a delay would adversely affect the health of the enrollees), the complaints must be processed as coverage determinations, which may be appealed.

When an enrollee complains that he/she had to wait so long for a Part D drug that he/she obtained the drug out-of-network, the complaint should be treated as a coverage determination (i.e., a request to be reimbursed for the out-of-network benefits) as well as a grievance (i.e., a complaint about the timeliness of the benefit).
30.4.3 - Employer-Sponsored Benefits
(Rev. 8, 1/1/10)

Part D appeal procedures apply to all Part D benefits offered under an Employer/Union-Only Group Waiver Plan (EGWP). These plans are offered by Medicare Advantage Organizations, PDP Sponsors, or Cost Plan Sponsors. For employers and unions that directly contract with CMS to offer these plans ("Direct EGWPs"), Part D appeal procedures apply to all Part D benefits unless the applicable contract governing this arrangement provides otherwise. Non-Medicare supplemental benefits offered by an EGWP or Direct EGWP are not considered Part D benefits and are not subject to the Part D guidelines contained in this chapter. Please see Chapter 12 of this Manual for additional information on prescription drug benefits for EGWPs and Direct EGWPs.

40 - Standard Coverage Determinations

40.1 - How to Request a Standard Coverage Determination
(Rev. 9, 2/22/13)

An enrollee, an enrollee's representative, or an enrollee's prescribing physician or other prescriber may request a standard coverage determination.

If a request involves Part D drug benefits that an enrollee has not received yet, the request may be filed with the plan sponsor by phone or in writing. Plan sponsors must provide immediate access to the coverage determination process via their internet web site. We strongly encourage plans to establish interactive, web-based systems to meet this requirement. At a minimum, however, plans must have a process in place for allowing an enrollee, an enrollee’s representative, or an enrollee’s prescribing physician or other prescriber to initiate a coverage determination by making a secure request from a location that is prominently displayed on the plan’s web site. The mechanism used by a plan sponsor to accept coverage determination requests via their website is subject to the same privacy and security safeguards as the rest of the plan sponsor’s operations in accordance with 42 C.F.R. § 423.136.

If a request involves reimbursement for a Part D drug that an enrollee has already received, the request must be filed with the plan sponsor in writing (unless the plan sponsor allows enrollees to submit oral requests for reimbursement).

Written requests may be made on CMS's Model Coverage Determination Request Form (http://www.cms.gov/MedPrescriptDrugApplGriev/13_Forms.asp#TopOfPage), a request form developed by a plan sponsor or any other entity, or any other written document. Plan sponsors are required to accept any written request (when made by an enrollee, an enrollee's prescribing physician or other prescriber, or an enrollee's representative) and are prohibited from requiring an enrollee or physician or other prescriber to make a written request on a specific form.
Plan sponsors must establish and maintain a process for documenting oral requests and retaining the documentation in the case file.

If an enrollee attempts to request reimbursement by phone but the plan sponsor does not accept oral requests for reimbursement, the plan sponsor must explain the procedures the enrollee must follow to file a written request for reimbursement. For example, the plan may explain the procedures orally and direct the enrollee to the appropriate section of the Evidence of Coverage for additional information.

40.2 - Standard Time Frames for Coverage Determinations
(Rev. 9, 2/22/13)

Requests for Benefits
When a party has made a request for coverage of a Part D drug benefit that has not been received yet, the Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee’s health condition requires, but no later than 72 hours after the date and time the plan receives the request for a standard coverage determination, or no later than 72 hours after receiving the physician's or other prescriber's supporting statement if the request involves an exception (see §30.2 of this chapter for more information about exception requests). If the Part D plan sponsor's decision is favorable, it must effectuate the decision in accordance with §130.1.

Requests for Reimbursement
When a party requests reimbursement for a Part D drug that an enrollee has already received, the plan sponsor must make the decision and provide notice of the decision as expeditiously as the enrollee’s health condition requires, but no later than 14 calendar days after receiving the reimbursement request.

If a plan sponsor is issuing a favorable reimbursement decision, it must make the decision, provide notice of the decision, and make payment as expeditiously as the enrollee’s health condition requires, but no later than 14 calendar days after receiving the reimbursement request (see §130.1 for more information about effectuating favorable decisions).

When a reimbursement request must be resolved under the exceptions process described in §30.2, the 14 calendar-day timeframe for processing a reimbursement request is not tolled pending receipt of a prescriber’s supporting statement. See §§30.2.1.3, 30.2.2.3, and 30.3.2 for more information.

All Standard Requests (Benefits or Reimbursement)
Plan sponsors must have processes in place to accept coverage determination requests and physicians' or other prescribers' supporting statements 24 hours a day, 7 days a week (including holidays). Although it is not necessary to begin processing requests as soon as they are received, plan sponsors must make determinations within the appropriate time
frame. Because some requests will be received after normal business hours, it will be necessary for plan sponsors to have a process for handling such requests appropriately. For example, if an enrollee submits an oral expedited coverage determination request at midnight on a Saturday, the plan sponsor must have procedures in place to make a decision and notify the enrollee of its decision by midnight on Sunday. Each plan sponsor generally has the flexibility to develop the procedures it uses to ensure that timely coverage determinations and redeterminations are made. For example, a plan sponsor may employ an answering service for after-hours requests. An enrollee can make his or her request with the answering service and the call-center representative can page a pharmacist or other on-call reviewer to handle the request within the applicable time frame.

Requests or supporting statements are deemed "received" on:

- The date and time the plan sponsor initially stamps a document sent by regular mail (e.g., via US Postal Service);
- The date and time a delivery service that has the ability to track when a shipment is delivered (e.g., US Postal Service, UPS, Federal Express, or DHL) delivers the document;
- The date and time a faxed document is successfully transmitted to the plan sponsor, as indicated on the fax confirmation sheet;
- The date and time an oral request is made by telephone with a customer service representative; or
- The date and time a message is left on the plan sponsor's voicemail system if the plan sponsor utilizes a voicemail system to accept requests or supporting statements after normal business hours.

- The date and time a request is received through the plan's web site.

A plan sponsor may not extend the applicable adjudication time frame by dispensing a temporary supply of the requested medication. For example, if a plan sponsor receives a request outside of its normal business hours, it cannot approve a 72-hour supply of the requested medication and defer issuing a decision for 72 hours; the plan sponsor must make its determination within the appropriate time frame.

Occasionally, the Part D plan sponsor may not have all of the information it needs to make a determination. The plan must make reasonable and diligent efforts to obtain all necessary medical records and other pertinent information within the required time limits and document its attempts. If the Part D plan sponsor cannot obtain all relevant documentation, it must make the decision based on the evidence available. If a plan does not make a decision in the applicable time frame, the plan must forward the request and
case file containing any oral and/or written evidence obtained to the IRE for review as described in §40.4.

The decision-making and notification time frames that are measured in hours must be met within the number of hours indicated (plans must indicate the date and time that each request is received).

Example:

3/1/13, 1:00 PM: The plan receives a request for a standard coverage determination. The 72-hour decision-making and notification time frame begins.

3/4/13: The plan must make its coverage determination and notify the enrollee of its decision by 1:00 PM. If it does not, it must forward the enrollee's request and case file containing any oral and/or written evidence obtained to the IRE for review within 24 hours of the expiration of the time frame. See §40.4.

40.2.1 – Who Must Review a Coverage Determination
(Rev. 9, 2/22/13)

If the Part D plan sponsor expects to issue a partially or fully adverse medical necessity decision based on the initial review of the request, the coverage determination must be reviewed by a physician or other appropriate health care professional with sufficient medical and other expertise, including knowledge of Medicare coverage criteria, before the Part D plan sponsor issues the coverage determination decision. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia. A pharmacist would generally be considered an appropriate health care professional for purposes of meeting this requirement.

Part D plan sponsors should implement 42 C.F.R. § 423.566(d) in a manner similar to how they have implemented the regulatory requirement that a plan level appeal be made by a physician with appropriate medical expertise if the initial denial of coverage was based on a lack of medical necessity. See: 42 C.F.R. § 423.590(f)(2). In general, the application of a clear statutory or contract exclusion does not constitute a decision based on the lack of medical necessity. Conversely, an adverse decision based on a determination that the clinical documentation supporting the coverage request is unavailable or insufficient (i.e., there is unmet criteria) is generally considered a denial based on the lack of medical necessity.

40.3 - Notice Requirements for Standard Coverage Determinations

40.3.1 - Notification by Network Pharmacists
(Rev. 9, 2/22/13)
The Part D plan sponsor must educate network pharmacies about their responsibilities to Part D enrollees. When a pharmacist explains to an enrollee that a drug is not on a plan's formulary, or is subject to prior authorization, step therapy, or other limitation, the transaction does not constitute a coverage determination, unless the plan treats the presentation of the prescription as a request for a coverage determination.

Plans must arrange with network or preferred pharmacies to provide enrollees with a written copy of the standardized pharmacy notice when the enrollees’ prescription cannot be filled under the Part D benefit and the issue cannot be resolved at the point of sale. Permissible exceptions to this requirement are detailed below. The Part D plan sponsor must use the approved notice in Appendix 5. The notice instructs the enrollee on how to contact their plan and explains an enrollee’s right to receive, upon request, a coverage determination (including a detailed written decision) from the Part D plan sponsor regarding his or her Part D prescription drug benefits, including information about the exceptions process. Plan sponsors must arrange with their network pharmacies (including mail-order and specialty pharmacies) to distribute the notice to enrollees.

The pharmacy notice must be provided to the enrollee if the pharmacy receives a transaction response indicating the claim is not covered by Part D and the designated NCPDP response code is returned.

The designated NCPDP response code is NOT returned in the following scenarios:

- the claim rejects only because it does not contain all necessary data elements for adjudication;
- the drug in question is an over the counter (OTC) drug that is not covered by the enrollee’s Part D plan sponsor;
- the prescription is written by a sanctioned provider who has been excluded from participation in the Medicare program;
- the drug is not listed on the participating CMS Manufacturer Labeler Code List;
- the drug is not listed on the FDA Electronic List—NDC Structured Product Labeling Data Elements File (NSDE);
- the Part D plan rejects the claim for the drug in question only because of a “refill too soon/early refill” edit;
- the drug in question is not covered by the Part D plan benefit, but is covered by a co-administered insured benefit managed by a single processor. In this scenario, the pharmacy submits a single claim transaction for the drug and the drug is covered by the co-administered insured benefit after being rejected by Part D and processed in accordance with the benefits offered by the supplemental payer. [NOTE: If the drug is not covered by the Part D plan, but the enrollee pays for the cost of the drug pursuant to plan-sponsored negotiated pricing or a discount card
program (which may provide a lower price but leaves the enrollee responsible for 100% of the drug cost), a designated NCPDP response code will be returned notifying the pharmacy to provide the enrollee with a copy of the pharmacy notice.

Printing the pharmacy notice on prescription label stock or an integrated prescription receipt is permitted, so long as the notice is provided in at least 12-point font. Electronic distribution of the notice is permitted if the enrollee or the enrollee’s appointed representative has provided an e-mail address and has indicated a preference for that method of communication. The only permissible customization of the pharmacy notice is the addition of the plan sponsor’s logo and population of optional fields for the enrollee’s name and the drug/Rx# to be added to the notice.

Failure to distribute the standardized pharmacy notice does not in any way limit an enrollee’s right to request a coverage determination from their plan sponsor.

**Mail Order Pharmacies**

As stated above, plan sponsors must make arrangements with network mail order pharmacies to meet the requirements of this section: if a prescription cannot be covered (“filled”) under the Medicare Part D benefit as described above, the mail order pharmacy must distribute the standardized pharmacy notice to the enrollee. The mail order pharmacy has the option of working with the plan and the prescriber to resolve the matter and provide the needed medication or an appropriate substitute. If the matter cannot be resolved and the pharmacy cannot fill the prescription, the notice must be provided to the enrollee via the enrollee’s preferred method of communication (fax, electronic or first class mail) as expeditiously as the enrollee’s health condition requires, but no later than 72 hours from the pharmacy’s receipt of the original transaction response indicating the claim is not covered by Part D.

**Home Infusion Pharmacies**

Plan sponsors must make arrangements with network home infusion pharmacies to meet the requirements of this section. If a prescription cannot be covered (“filled”) under the Medicare Part D benefit as described above, the home infusion pharmacy must distribute the standardized pharmacy notice to the enrollee either electronically, by fax, in person or by first class mail. The home infusion pharmacy has the option of working with the plan and the prescriber to resolve the matter and provide the needed medication or an appropriate substitute. If the matter cannot be resolved and the pharmacy cannot fill the prescription, the notice must be provided to the enrollee as expeditiously as the enrollee’s health condition requires, but no later than 72 hours from the pharmacy’s receipt of the original transaction response indicating the claim is not covered by Part D. For enrollees brought on service by the home infusion pharmacy, the pharmacy can also choose to deliver the notice in person with delivery of home infusion drugs or through an infusion nurse, as long as the next scheduled visit is within 72 hours of the receipt of the transaction code indicating the claim cannot be covered by Part D.
Pharmacies Serving Long-Term-Care Facilities

Given the uniqueness of the long-term-care (LTC) setting, there is typically no point-of-sale encounter between the pharmacy and the enrollee (LTC resident) and, therefore, no practical means for the pharmacy to provide the notice directly to the enrollee. In most instances where there is an issue with the prescription, CMS expects that the pharmacist will contact the prescriber or an appropriate staff person at the LTC facility to resolve the matter and ensure the resident receives the needed medication or an appropriate substitute, obviating the need to deliver the notice. If the matter cannot be resolved, the pharmacy must fax or otherwise deliver the notice to the enrollee, the enrollee’s representative, prescriber or an appropriate staff person at the LTC facility as expeditiously as the enrollee’s health condition requires, but no later than 72 hours from the pharmacy’s receipt of the original transaction response indicating the claim is not covered by Part D.

NOTE: If the enrollee is a self-pay resident and the pharmacy cannot fill the prescription under the Part D benefit, the pharmacy must, upon receipt of the transaction response, fax or otherwise deliver the notice to the enrollee, the enrollee’s representative, prescriber or an appropriate staff person at the LTC facility. After distribution of the notice, the LTC pharmacy should continue to work with the prescriber or facility to resolve the matter and ensure the resident receives the needed medication or an appropriate substitute.

Indian Health Service, Tribe and Tribal Organization and Urban Indian Organization (I/T/U) Pharmacies

Because IHS members’ prescription drugs, when dispensed through I/T/U pharmacies, are filled and dispensed at no cost to the enrollee regardless of whether the drug is rejected at POS by the Part D plan, I/T/U pharmacies are exempt from the requirement to distribute the pharmacy notice.

NOTE: This exemption applies only to I/T/U pharmacies that dispense prescriptions at no cost to the enrollee. Any network commercial pharmacy providing services to IHS-eligible Part D enrollees must distribute the notice in accordance with the requirements in this section.

Compliance with this Requirement

CMS expects plan sponsors to have internal controls in place to reasonably ensure that network pharmacies are complying with the requirement to distribute the standardized pharmacy notice to enrollees when a prescription cannot be covered (“filled”) under the Medicare Part D benefit at point-of-sale. For example, plan sponsors should be able to demonstrate:

- Periodic communication with network pharmacies (including non-retail pharmacies) regarding the requirement to distribute the pharmacy notice (e.g.,
reminders on related policies and procedures, training materials for pharmacy staff). An appropriate internal control may also include periodic “secret shopper” or beneficiary survey/outreach calls.

- A means of identifying enrollee complaints about a failure to receive the pharmacy notice that would lead to ad hoc investigations and compliance actions on the part of the plan sponsor.

40.3.2 - Oral Notification by Part D Plan Sponsors (Rev. 9, 2/22/13)

A plan sponsor must provide written notice of any favorable or adverse decision it issues. However, a plan sponsor may make its initial notification orally so long as it also mails a written follow-up decision within 3 calendar days of the oral notification. If a plan sponsor's decision is adverse, the oral (if provided) and written notices must satisfy the requirements in §40.3.4. If a plan sponsor's decision is favorable, the oral (if provided) and written notices must satisfy the requirements in §40.3.5.

- If an enrollee files the request, notice must be provided to the enrollee.

- As noted in §10.4.2, if an enrollee has identified a representative, the plan sponsor must send the written notice to the enrollee's representative instead of the enrollee.

- If an enrollee's prescribing physician or other prescriber files a request on behalf of an enrollee, the plan sponsor must notify both the prescriber and the enrollee. However, a plan sponsor is not required to provide an enrollee's prescribing physician or other prescriber with a written follow-up decision after providing oral notice to the physician or other prescriber.

40.3.3 – Good Faith Effort to Provide Oral Notice (Rev. 8, 1/1/10)

In certain situations, the regulations permit a plan sponsor to satisfy a notification requirement by first providing oral notice of a coverage determination or expedited redetermination decision to an enrollee. If a plan sponsor intends to provide oral notice, it is responsible for obtaining a telephone number from the enrollee (if a plan sponsor doesn’t have an enrollee’s telephone number on file when a request is made, it should obtain the telephone number when the request is being made). If the plan sponsor does not have an enrollee’s telephone number on file when a request is made, it cannot expect to notify the enrollee of a decision orally and must ensure that the notification requirement is satisfied in writing. When a plan sponsor has an enrollee’s telephone number on file, relies on it to provide oral notice, but is unable to reach the enrollee at the number provided because, for example, it is either incorrect, out-of-service, or no person (or voice-mail system) answers, the plan sponsor's good-faith effort to provide oral notice satisfies the notification requirement if:
1. The good-faith effort is documented in writing and included in the case file,

2. Written notice of the decision is immediately sent to the enrollee, and

3. The plan sponsor is not at fault for its inability to reach the enrollee by phone (e.g., the plan sponsor did not make a transcribing error when writing the telephone number).

40.3.4 - Written Notification of Adverse Decisions
(Rev. 9, 2/22/13)

If the Part D plan sponsor denies, in whole or in part, a request for a Part D benefit or payment for a prescription drug purchased by an enrollee, it must provide written notice of its determination (Part D plan sponsors that do not provide notice of a decision within the required timeframe should not use the notice described in this section to notify the enrollee that his or her decision was not made timely and is being forwarded to the IRE, but should provide notice as described in §40.4 instead).

- If an enrollee files the request, notice must be provided to the enrollee.

- As noted in §10.4.2, if an enrollee has identified a representative, the plan sponsor must send the written notice to the enrollee's representative instead of the enrollee.

- If an enrollee's prescribing physician or other prescriber files a request on behalf of an enrollee, the plan sponsor must notify both the prescriber and the enrollee. The enrollee must receive written notice of the decision. However, as described in §40.3.2, a plan sponsor is not required to provide an enrollee's prescribing physician or other prescriber with a written follow-up decision after providing oral notice to the physician or other prescriber.

The Part D plan sponsor must use the approved notice in Appendix 1. The standardized denial notice form has been written in a manner that is understandable to the enrollee and provides:

1. The specific reason for the denial that takes into account the enrollee’s presenting medical condition, disabilities, and special language requirements, if any;

2. A description of any applicable Medicare coverage rule or any other applicable Part D plan policy upon which the denial decision was based, including any specific formulary criteria that must be satisfied for approval. If the drug could be approved under the exception rules, the denial notice must explicitly state the need for a prescriber’s supporting statement and clearly identify the type of information that
should be submitted when seeking a formulary or tiering exception. For example, if the drug is subject to step therapy, the denial notice must clearly explain the step criteria and indicate that if the enrollee can’t take the step drug(s), the enrollee’s prescriber must submit a supporting statement explaining why the enrollee can’t tolerate the step drug(s).

3. Information regarding the right to appoint a representative to file an appeal on the enrollee’s behalf;

4. For coverage denials, a description of both the standard and expedited redetermination processes and time frames, including conditions for obtaining an expedited reconsideration, and the rest of the appeals process; and

5. For payment denials, a description of the standard redetermination process and time frames, and the rest of the appeals process.

The denial rationale must be specific to each individual case and written in a manner calculated for an enrollee to understand. Examples of language that satisfies point 1 above (because it is specific to the individual’s case):

Example 1 (fully unfavorable)
The drug that you have requested, Protium, is not on our formulary. We are denying your request to receive Protium because the drug Nexium is on our formulary and is indicated for treating your condition. If you obtain a prescription for Nexium, we will cover it. We may be able to make an exception and cover Protium, if your prescriber sends us a statement that explains why you can’t take the formulary drug, Nexium. Neither you nor your prescriber has submitted any documentation or medical records supporting the medical necessity for receiving Protium instead of Nexium. We will need this information before Protium can be approved.

Example 2 (fully unfavorable)
This decision is in response to your request for the drug Vitamin D. Section 1927(d)(2) of the Social Security Act (the Act) permits the exclusion of certain drugs or classes of drugs from coverage under Part D. Vitamin D is a prescription vitamin product, which is one of the excluded classes of drugs under section 1927(d)(2) of the Act. Because Vitamin D is excluded from coverage and we do not offer it as a supplemental benefit, we are denying your request. [Note: This language is an example of the language that should be included in a plan sponsor's adverse coverage determination decision when an enrollee argues that a requested drug is not an excluded drug. See §20.2.4]

Example 3 (fully unfavorable)
This decision is in response to your request for the drug Orlistat. Sections 1860D-2(e)(2) and 1927(d)(2) of the Social Security Act (the Act) permit the exclusion of certain drugs or classes of drugs from coverage under Medicare Part D when the drugs are being prescribed to treat uses excluded under the Act. Drugs used for the
treatment and maintenance of weight loss are excluded from Medicare Part D coverage under section 1927(d)(2) of the Act. Your physician or other prescriber prescribed Orlistat for the treatment and maintenance of weight loss. Because Orlistat is excluded from coverage under Medicare Part D for the treatment and maintenance of weight loss and we do not offer it as a supplemental benefit, we are denying your request. [Note: This language is an example of the language that should be included in a plan sponsor's adverse coverage determination decision when an enrollee argues that a requested drug is not an excluded drug because it is being used for an indication that isn't excluded under sections 1860D-2(e)(2) and 1927(d)(2) of the Act. See §20.2.4]

Example 4 (partially favorable)
The drug that you have requested, Nexium, is subject to step therapy. You have satisfied the step therapy criteria. However, we cannot approve your request for 90 tablets for 30 days because Nexium has a quantity limit of 30 tablets for 30 days. Therefore, we've approved 30 tablets of Nexium for 30 days. We may be able to make an exception to the quantity limit. Your prescriber will need to send us a statement explaining why you need 90 tablets for a 30 day period.

Note: In Example 4, only part of the decision is favorable, so the plan sponsor must use the notice in Appendix 1 and explain the enrollee’s right to appeal the unfavorable portion of the decision. Also, the plan sponsor should explain what other information is necessary to make a decision regarding the denied portion of the request.

Plan sponsors must complete the applicable sections of the model Request for Redetermination form (see Appendix 16) and send it to the enrollee (and physician or other prescriber when appropriate) with each adverse coverage determination notice. If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.

40.3.5 - Written Notification of Favorable Decisions
(Rev. 9, 2/22/13)

If a Part D plan sponsor completely approves a request for a Part D benefit or payment for a prescription drug purchased by an enrollee, it must provide written notice of its determination. A plan sponsor may make its initial notification orally, so long as it also mails a written follow-up decision within 3 calendar days of the oral notification.

• If an enrollee files the request, notice must be provided to the enrollee.

• If an enrollee has identified a representative, the plan sponsor must send the written notice to the enrollee's representative instead of the enrollee (see §10.4.2).

• If an enrollee's prescribing physician or other prescriber files a request on behalf of an enrollee, the plan sponsor must notify both the prescriber and the enrollee. The
enrollee must receive written notice of the decision. However, consistent with §40.3.2, a plan sponsor is not required to provide an enrollee's prescribing physician or other prescriber with a written follow-up decision after providing oral notice to the physician or other prescriber.

The note in §40.3.2 regarding a good-faith effort to provide oral notice also applies to this section.

Any written notice must be written in a manner that is understandable to the enrollee. In addition, the oral (if provided) and written approval notice must explain the conditions of the approval. The conditions of approval may include (but are not limited to):

- The duration of an approval;
- Limitations associated with an approval; and/or
- Any coverage rules applicable to subsequent refills.

The plan sponsor may develop its own notice that meets the regulatory requirements in 42 CFR 423.568(e) and any applicable CMS marketing requirements.

Part D plan sponsors that do not provide notice of a decision within the required timeframe should not use the notice described in this section to notify the enrollee that his or her decision was not made timely and is being forwarded to the IRE, but should provide notice as described in §40.4 instead.

40.4 - Effect of Failure to Provide Timely Notice
(Rev. 98, 2/22/13)

If a Part D plan sponsor does not provide notice of its standard coverage determination within the required time frame, it must forward the complete case file to the IRE contracted by CMS within 24 hours of the expiration of the adjudication time frame.

Note: Because the adjudication time frame for an exceptions request involving a request for benefits does not begin until the plan sponsor receives the physician's or other prescriber's supporting statement as indicated in §§30.2.1.2 and 30.2.2.2, plan sponsors must not automatically forward case files to the IRE if a physician or other prescriber has not submitted an oral or written supporting statement. Instead, plan sponsors should issue decisions in accordance with the guidance provided in §§30.2.1 and 30.2.2.

Note: If a plan sponsor makes a completely favorable decision soon after the adjudication timeframes expires (i.e., within 24 hours) and notifies the enrollee of the decision, the plan sponsor should not forward the case file to the IRE and provide the notice described in this section. Plan sponsors should use this exception sparingly. If a plan sponsor does not regularly meet the adjudication timeframe and CMS finds that
the plan sponsor uses this exception frequently, CMS may consider the plan sponsor in breach of its Medicare contract and/or subject to intermediate sanctions in accordance with subpart O of 42 CFR Part 423.

The case file must contain the enrollee's request and any oral and/or written evidence obtained by the plan sponsor. **Part D plan sponsors should also refer to §§70.30 and 70.40 to determine how to prepare the case file for the IRE and what documents/items to send with the case file.** The Part D plan sponsor must deliver a hard copy of the case file to the IRE by overnight delivery at its designated address, or by fax at its designated fax number. The Part D plan sponsor should refer to the IRE’s Reconsideration Process Manual for additional instructions.

Although the Part D plan sponsor's failure to provide notice of a decision within the required timeframe constitutes an adverse decision, the plan sponsor must not send a standard denial notice to the enrollee. Instead, the Part D plan sponsor must notify the enrollee that it has forwarded his or her request to the IRE for review. The plan sponsor must send the notification within 24 hours of the expiration of the adjudication time frame. The notice must advise the enrollee of his/her right to submit additional evidence that may be pertinent to the enrollee’s case, if the enrollee chooses, and direct the enrollee to submit such evidence to the IRE, and include information on how to contact the IRE. CMS has developed a model notice that Part D plan sponsors can use to notify enrollees whenever cases are forwarded to the IRE (see Appendix 6). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.

If CMS determines that the Part D plan sponsor has a pattern of not concluding standard coverage determinations within the required time frame or not forwarding the enrollee's request to the IRE for review within the required time frame, the Part D plan sponsor may be considered to be in breach of its Medicare contract and/or subject to intermediate sanctions in accordance with subpart O of 42 CFR Part 423.

**Transition Period Note:**
Plan sponsors must ensure new enrollees receive a meaningful transition process when they have been, prior to enrollment, stabilized on a medication that is either not on the plan formulary or is subject to utilization management requirements. Two of the steps involve plan sponsors providing a temporary supply of the requested medication and sending the enrollee a written notice explaining when the supply will end and the procedures for requesting an exception. A transition process is not meaningful if an enrollee who is in the transition period files an exception request and the plan sponsor does not make a decision timely or does not forward the enrollee's request/case file to the IRE within the appropriate time frame. Therefore, when an enrollee who is in the transition period files an exception request and the plan does not make its decision timely and/or fails to forward a request/case file to the IRE as required, the plan sponsor must provide the enrollee with a temporary supply of the requested prescription drug (when not medically contraindicated) until the case is resolved by the plan sponsor or the IRE issues a reconsideration decision.
For more information about the transition policy, see Chapter 6 (Part D Drugs and Formulary Requirements), §30.4 of the Prescription Drug Benefit Manual: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html

50 - Expedited Coverage Determinations  
(Rev. 8, 1/1/10)

An enrollee, his or her representative, or the enrollee's prescribing physician or other prescriber, may request that a Part D plan sponsor expedite a coverage determination when the enrollee or his/her physician or other prescriber believes that waiting for a decision under the standard time frame may place the enrollee’s life, health, or ability to regain maximum function in serious jeopardy.

A claim for payment for prescription drugs that the enrollee has already received will not be expedited. However, if a case includes both a payment denial and a pre-benefit denial, the enrollee has a right to request an expedited coverage determination for the pre-benefit denial.

50.1 - Making a Request for an Expedited Coverage Determination  
(Rev. 9, 2/22/13)

An enrollee, an enrollee's representative, or an enrollee's prescribing physician or other prescriber may request an expedited coverage determination.

The request may be filed with the plan sponsor by phone or in writing. Plan sponsors must establish and maintain a process for documenting oral requests and retaining the documentation in the case file. A written request may be made on CMS's Model Coverage Determination Request Form (http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Forms.html), a request form developed by a plan sponsor or any other entity, or any other written document. Plan sponsors are required to accept any request that is made in writing (when made by an enrollee, an enrollee's prescribing physician or other prescriber, or an enrollee's representative) and are prohibited from requiring an enrollee or physician or other prescriber to make a written request on a specific form.

A prescribing physician or other prescriber may provide oral or written support for an enrollee’s request for an expedited determination. The Part D plan sponsor must automatically expedite the coverage determination when a request is made or supported by a prescribing physician or other prescriber, and the physician or other prescriber indicates, either orally or in writing, that applying the standard time for making a determination may seriously jeopardize the life or health of the enrollee or the enrollee’s ability to regain maximum function. The prescribing physician or other prescriber need not be the enrollee’s representative to make the request.
For a request made by an enrollee, the Part D plan sponsor must expedite the determination if the plan sponsor finds that the enrollee’s health, life, or ability to regain maximum function may be seriously jeopardized by waiting for a standard coverage determination.

If the Part D plan sponsor decides to expedite the coverage determination, it must render a decision in accordance with the provisions specified in §50.4.

If the Part D plan sponsor denies the request to expedite, the plan follows the requirements specified in §50.3.

50.2 - How the Part D Plan Sponsor Processes Requests for Expedited Coverage Determinations
(Rev. 8, 1/1/10)

The Part D plan sponsor must establish and maintain procedures that:

1. Establish efficient and convenient means for enrollees and/or their prescribing physicians or other prescribers to submit oral/written requests;

2. Document all oral requests in writing and maintain the documentation in the case file;

3. Promptly decide whether to expedite a determination based on whether applying the standard time frame for making a determination could seriously jeopardize the life or health of the enrollee or the enrollee’s ability to regain maximum function; and

4. Develop a meaningful process for receiving requests for expedited reviews. These procedures must include Designating an office and/or department to receive both oral and written requests, including a telephone number for oral requests, and may include a facsimile number to facilitate receipt of requests for expedited coverage determinations. The procedures must be clearly explained in member materials. In addition, Part D plan sponsors will be accountable for educating staff to ensure that requests for expedited review are referred immediately to the Part D plan sponsor’s designated office or department for processing such requests. The 24-hour period begins when the enrollee’s request is received by the Part D plan sponsor. If the enrollee’s request involves an exception, the 24-hour period begins when the plan receives the prescribing physician’s or other prescriber’s supporting statement. See the note in §40.2 regarding when a request or supporting statement is deemed received by a plan sponsor.
50.2.1 - Defining the Medical Exigency Standard
(Rev. 1, 11/30/05)

The medical exigency standard requires a Part D plan sponsor and the IRE to make
decisions as “expeditiously as an enrollee’s health condition requires.” This standard is set
forth in regulations at 42 CFR 423.568(a) (standard coverage determinations), 423.572(a)
(expedited coverage determinations), 423.590(a) (standard redeterminations),
423.590(d)(1) (expedited redeterminations), 423.600(d) (reconsiderations by the IRE),
423.636(a)(1) (plan sponsor effectuating standard redeterminations), 423.638(a) (plan
sponsor effectuating expedited redeterminations), and 423.638(b) (plan sponsor
effectuating expedited reversals by the IRE or higher level of appeal). This standard
requires the plan sponsor or IRE to apply, at a minimum, established, accepted standards of
medical practice in assessing an individual’s medical condition. Evidence of an
individual’s condition can be demonstrated by indications from the treating provider or
from the individual’s medical record (e.g., an individual’s diagnosis, symptoms, or test
results).

The medical exigency standard was established by regulation to ensure that plan sponsors
develop a system for determining the urgency of both standard and expedited requests for
Part D prescription drug benefits, evaluate incoming requests against pre-established
criteria, and give each request priority according to that system (i.e., plan sponsors must
treat every case in a manner that is appropriate to its medical particulars or urgency). Plan
sponsors should not systematically take the maximum time permitted for making decisions.

50.3 - Action Following Denial for Expediting Review
(Rev. 9, 2/22/13)

If a Part D plan sponsor denies a request to expedite a coverage determination, it must
automatically transfer the request to the standard coverage determination process (as
described in §40.2 above), provide prompt oral notice of the denial, and subsequently
deliver (i.e., mail) written notice within 3 calendar days after proving oral notice.

- As noted in §10.4.2, if an enrollee has identified a representative, the plan
  sponsor must provide notice to the enrollee’s representative instead of the
  enrollee.

- If an enrollee’s prescribing physician or other prescriber files a request on
  behalf of an enrollee, the plan sponsor must notify both the prescriber and the
  enrollee. The enrollee must receive written notice of the decision. However,
  consistent with §40.3.2, a plan sponsor is not required to provide an enrollee’s
  prescribing physician or other prescriber with a written follow-up decision after
  providing oral notice to the physician or other prescriber.

The oral notice and written follow-up notice must:
1. Explain that the plan will automatically transfer and process the request using the 72 hour time frame for standard determinations;

2. Inform the enrollee of the right to file an expedited grievance if he or she disagrees with the plan’s decision not to expedite the determination;

3. Inform the enrollee of the right to resubmit a request for an expedited determination and that, if the enrollee gets his or her prescribing physician’s or other prescriber's support indicating that applying the standard time frame for making determinations could seriously jeopardize the life or health of the enrollee or the enrollee’s ability to regain maximum function, the request will be expedited automatically; and

4. Provide instructions about the expedited grievance process and its time frames.

CMS has developed a model notice that Part D plan sponsors can use whenever a request to expedite is denied, (see Appendix 3). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.

50.4 - Action on Accepted Requests for Expedited Determinations
(Rev. 9, 2/22/13)

If a plan sponsor grants a request to expedite a coverage determination, a determination must be made in accordance with the following requirements:

1. A Part D plan sponsor that approves a request to expedite a coverage determination must make the determination, whether favorable or adverse, and provide notice of its decision as expeditiously as the enrollee’s health condition requires, but no later than 24 hours after receiving the request. See the note in §40.2 regarding when a request or supporting statement is deemed received by a plan sponsor. If the Part D plan sponsor's decision is favorable, it must effectuate the decision in accordance with §130.1.

2. If the request involves an exception, the Part D plan sponsor must provide notice of its determination as expeditiously as the enrollee’s health condition requires, but no later than 24 hours after the date the plan receives the physician's or other prescriber's supporting statement. See the note in §40.2 regarding when a request or supporting statement is deemed received by a plan sponsor. If the Part D plan sponsor's decision is favorable, it must effectuate the decision in accordance with §130.1.

Note: A plan sponsor may not extend the applicable adjudication time frame by dispensing a temporary supply of the requested medication. For example, if a plan sponsor receives a request outside of its normal business hours, it cannot approve a 72-
hour supply of the requested medication and defer issuing a decision for 72 hours; the plan sponsor must make its determination within the appropriate time frame.

**Note:** A Part D plan sponsor that does not provide notice of a decision within the required timeframe should not use the written notice described in this section to notify the enrollee that his or her decision was not made timely and was forwarded to the IRE, but should provide the enrollee with the notice described in §50.6 instead.

### 50.5 - Notification of the Result of an Expedited Coverage Determination (Rev. 9, 2/22/13)

#### 50.5.1 - Written Notification of Adverse Expedited Decisions (Rev. 9, 2/22/13)

If the Part D plan sponsor denies, in whole or in part, a Part D benefit, it must provide written notice of its determination.

A plan sponsor may make its initial notification orally, so long as it also mails a written follow-up decision within 3 calendar days of the oral notification.

- **If an enrollee files the request, notice must be provided to the enrollee.**

- **If an enrollee has identified a representative, the plan sponsor must send the written notice to the enrollee's representative instead of the enrollee (see §10.4.2).**

- **If an enrollee's prescribing physician or other prescriber files a request on behalf of an enrollee, the plan sponsor must notify both the prescriber and the enrollee. The enrollee must receive written notice of the decision. However, consistent with §40.3.2, a plan sponsor is not required to provide an enrollee's prescribing physician or other prescriber with a written follow-up decision after providing oral notice to the physician or other prescriber.**

The note in §40.3.3 regarding a good-faith effort to provide oral notice also applies to this section.

*If a plan sponsor's decision is adverse, the oral (if provided) and written notices must satisfy the requirements stated below.* The Part D plan sponsor must use approved notice language in Appendix 1. The standardized denial notice form has been written in a manner that is understandable to the enrollee and provides:

1. The specific reason for the denial that takes into account the enrollee’s presenting medical condition, disabilities, and special language requirements, if any;

2. A description of any applicable Medicare coverage rule or any other applicable Part D plan policy upon which the denial decision was based, including any specific formulary criteria that must be satisfied for approval. If the drug could be approved under the
exception rules, the denial notice must explicitly state the need for a prescriber’s supporting statement and clearly identify the type of information that should be submitted when seeking a formulary or tiering exception. For example, if the drug is subject to step therapy, the denial notice must clearly explain the step criteria and indicate that if the enrollee can’t take the step drug(s), the enrollee’s prescriber must submit a supporting statement explaining why the enrollee can’t tolerate the step drug(s).

2. Information regarding the right to appoint a representative to file an appeal on the enrollee’s behalf; and

3. A description of both the standard and expedited redetermination processes and time frames, including conditions for obtaining an expedited redetermination, and the rest of the appeals process.

The denial rationale must be specific to each individual case and written in a manner calculated for an enrollee to understand.

See §40.3.3 for examples of language that satisfies point 1 above (because it is specific to the individual’s case).

Plan sponsors must complete the applicable sections of the model Request for Redetermination form (see Appendix 16) and send it to the enrollee (and physician or other prescriber when appropriate) with each adverse coverage determination notice. If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.

50.5.2 - Written Notification of Favorable Decisions (Rev. 9, 2/22/13)

If a Part D plan sponsor completely approves a request for a Part D benefit, it must provide written notice of its determination. A plan sponsor may make its initial notification orally, so long as it also mails a written follow-up decision within 3 calendar days of the oral notification.

- If an enrollee files the request, notice must be provided to the enrollee.

- If an enrollee has identified a representative, the plan sponsor must send the written notice to the enrollee's representative instead of the enrollee (see §10.4.2).

- If an enrollee's prescribing physician or other prescriber files a request on behalf of an enrollee, the plan sponsor must notify both the prescriber and the enrollee. The enrollee must receive written notice of the decision. However, consistent with §40.3.2, a plan sponsor is not required to provide an enrollee's prescribing
physician or other prescriber with a written follow-up decision after providing oral notice to the physician or other prescriber.

The note in §40.3.2 regarding a good-faith effort to provide oral notice also applies to this section.

Any written notice must be written in a manner that is understandable to the enrollee. In addition, the oral (if provided) and written approval notice must explain the conditions of the approval. The conditions of approval may include (but are not limited to):

- The duration of an approval;
- Limitations associated with an approval; and/or
- Any coverage rules applicable to subsequent refills.

The plan sponsor may develop its own notice that meets the regulatory requirements in 42 CFR 423.568(e) and any applicable CMS marketing requirements.

Part D plan sponsors that do not provide notice of a decision within the required timeframe should not use the notice described in this section to notify the enrollee that his or her decision was not made timely and is being forwarded to the IRE, but should provide notice as described in §50.6 instead.

50.6 - Effect of Failure to Provide Timely Notice
(Rev. 9, 2/22/13)

If a Part D plan sponsor does not provide notice of its expedited coverage determination within the required time frame, it must forward the complete case file to the IRE contracted by CMS within 24 hours of the expiration of the adjudication time frame.

**Note:** Because the adjudication time frame for an exceptions request involving a request for benefits does not begin until the plan sponsor receives the physician's or other prescriber's supporting statement as indicated in §§30.2.1.2 and 30.2.2.2, plan sponsors must not automatically forward case files to the IRE if a physician or other prescriber has not submitted an oral or written supporting statement. Instead, plan sponsors should issue decisions in accordance with the guidance provided in §§30.2.1 and 30.2.2.

**Note:** If a plan sponsor makes a completely favorable decision soon after the adjudication timeframes expires (i.e., within 24 hours) and notifies the enrollee of the decision, the plan sponsor should not forward the case file to the IRE and provide the notice described in this section. Plan sponsors should use this exception sparingly. If a plan sponsor does not regularly meet the adjudication timeframe and CMS finds that the plan sponsor uses this exception frequently, CMS may consider the plan sponsor in
The case file must contain the enrollee's request and any oral and/or written evidence obtained by the plan sponsor. **Part D plan sponsors should also refer to §§70.30 and 70.40 to determine how to prepare the case file for the IRE and what documents/items to send with the case file.** The Part D plan sponsor must deliver a hard copy of the case file to the IRE by overnight delivery at its designated address, or by fax at its designated fax number. The Part D plan sponsor should refer to the IRE’s Reconsideration Process Manual for additional instructions.

Although the Part D plan sponsor's failure to provide notice of a decision within the required timeframe constitutes an adverse decision, the plan sponsor must not send the decision notice described in §50.5.1 to the enrollee. Instead, the Part D plan sponsor must notify the enrollee that it has forwarded his or her request to the independent entity for review. The plan sponsor must send the notification within 24 hours of the expiration of the adjudication time frame. The notice must advise the enrollee of his/her right to submit additional evidence that may be pertinent to the enrollee’s case, if the enrollee chooses. The notice must direct the enrollee to submit such evidence to the IRE, and must include information on how to contact the IRE. CMS has developed a model notice that Part D plan sponsors can use to notify enrollees whenever cases are forwarded to the IRE, (see Appendix 6). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.

If CMS determines that the Part D plan sponsor has a pattern of not concluding expedited coverage determinations within the required time frame or not forwarding the enrollee's request to the IRE for review within the required time frame, the Part D plan sponsor may be considered to be in breach of its Medicare contract and/or subject to intermediate sanctions in accordance with subpart O of 42 CFR Part 423.

**Transition Period Note:**
The "Transition Period Note" in §40.4 also applies to this section.

### 60 - Appeals

**60.1 - Parties to the Coverage Determination for Purposes of an Appeal** *(Rev. 9, 2/22/13)*

The parties to a coverage determination include the enrollee and the enrollee's representative, if applicable. In some cases, as described in §10.5, the enrollee's prescribing physician or other prescriber is also a party. However, an enrollee's prescribing physician or other prescriber does not have all of the rights and responsibilities of the enrollee with respect to party status, unless the physician or other prescriber is the enrollee's representative.
Only the enrollee or the enrollee's representative may request an appeal, with the exception that the enrollee's prescribing physician or other prescriber may request a standard or expedited redetermination.

**70 - Redetermination**  
*(Rev. 1, 11/30/05)*

The Part D plan sponsor’s adverse coverage determination must inform the enrollee of his/her right to a redetermination and the right to be represented by an attorney or other representative in the appeals process. Instructions on how and where to file a request for redetermination must also be included. In addition, the member handbook or other materials must include information about free legal services available for qualified individuals. The redetermination consists of a review of an adverse coverage determination, the evidence and findings upon which it was based, and any other evidence that the parties submit or that is obtained by the Part D plan sponsor.

**70.1 - Who May Request a Redetermination**  
*(Rev. 9, 2/22/13)*

The parties who may request a standard or expedited redetermination include an enrollee, an enrollee’s representative, or an enrollee's prescribing physician or other prescriber.

**Note:** Under 42 CFR 423.580, a non-representative physician or other prescriber may request a standard redetermination on an enrollee’s behalf only after he or she has provided notice to the enrollee that he or she is making the appeal request (physicians or other prescribers are not required to provide such notice to enrollees when requesting expedited redeterminations).

- (MA-PD plans only) If the redetermination request comes from an enrollee’s primary care physician in the MA-PD plan’s network, enrollee notice verification (i.e., proof that the physician notified the enrollee of the redetermination request) is not required.

- (PDP and MA-PD plans) If the enrollee’s records indicate that he or she previously visited the requesting physician or other prescriber, the plan sponsor may assume the physician or other prescriber has informed the enrollee about the request and further verification is not needed.

- (PDP and MA-PD plans) If the enrollee’s records indicate that he or she has not previously visited the requesting physician or other prescriber, the plan sponsor should undertake reasonable efforts to confirm that the physician or other prescriber has given the enrollee appropriate notice of the appeal. For example:
  - If the physician/prescriber makes the request by phone, the plan sponsor may verbally confirm with the physician/prescriber that the enrollee knows...
the physician/prescriber is making the request on the enrollee’s behalf.

- If the plan sponsor has developed its own redetermination request form, it may amend the form to include boilerplate language and a checkbox indicating the physician/prescriber is making the request on the enrollee’s behalf with the enrollee’s knowledge and approval.

- If the physician/prescriber makes the request by fax, letter, or email, the enrollee is copied on the correspondence, and/or the request includes a statement affirming the enrollee knows the physician/prescriber is making the request on the enrollee’s behalf with the enrollee’s knowledge and approval.

- A customer service representative may call the enrollee and ask if the physician/prescriber is making the request on his or her behalf with his or her knowledge and approval.

70.2 - How to Request a Standard Redetermination  
(Rev. 9, 2/22/13)

An enrollee, enrollee’s representative or enrollee’s prescribing physician or other prescriber (see §70.1) may request a standard redetermination by filing a written request with the Part D plan sponsor. Except when the filing time frame is extended, the request must be filed within 60 calendar days from the date printed or written on the written coverage determination denial notice (i.e., the 60-day timeframe does not begin on the date oral notice is received).

A Part D plan sponsor may accept oral requests for standard redeterminations. If a Part D plan sponsor chooses to accept an oral appeal request, the Part D plan sponsor must document the oral request in writing in the enrollee's own words, repeat the request back to the enrollee to confirm the accuracy, and place the request into a tracking system. If a department other than one that responds to redeterminations receives the request, it should transfer the call to the appropriate department.

In the event that a plan does not accept oral requests for standard redeterminations, and it determines that an enrollee's, prescribing physician’s or other prescriber's oral complaint should be classified as a standard request for a redetermination, the plan must explain the procedures the enrollee must follow to file a written request for a standard redetermination. If an enrollee files an oral request for an expedited redetermination (which must be accepted orally and in writing) and the plan sponsor does not grant the request to expedite, the plan sponsor cannot require the enrollee to re-file the request in writing. Instead, the plan sponsor must transfer the request to the standard process as described in §70.7.
Plan sponsors must provide immediate access to the redetermination process via their internet web site. We strongly encourage plans to establish interactive, web-based systems to meet this requirement. At a minimum, however, plans must have a process in place for allowing an enrollee, an enrollee’s representative, or an enrollee’s prescribing physician or other prescriber to initiate a redetermination by making a secure request from a location that is prominently displayed on the plan’s web site. The mechanism used by a plan sponsor to accept redetermination requests via their website is subject to the same privacy and security safeguards as the rest of the plan sponsor’s operations in accordance with 42 C.F.R. §423.136.

70.3 - Good Cause Extension
(Rev. 9, 2/22/13)

If a party shows good cause, the Part D plan sponsor may extend the time frame for filing a request for redetermination. The Part D plan sponsor must consider the circumstance that kept the party from making the request on time and whether any actions by the plan may have misled the party. Examples of circumstances where good cause may exist include (but are not limited to) the following situations:

1. The party was prevented by serious illness from contacting the plan in person, in writing, or through a friend, relative, or other person;

2. The party had a death or serious illness in his or her immediate family;

3. Important records were destroyed or damaged by fire or other accidental cause;

4. The plan or its designated entity gave the enrollee, the enrollee’s representative, or the enrollee’s prescribing physician or other prescriber incorrect or incomplete information about when and how to request a redetermination;

5. The enrollee, representative, or prescribing physician or other prescriber did not receive notice of the determination or decision; or

6. The enrollee, representative, or prescribing physician or other prescriber sent the request to another Government agency in good faith within the time limit and the request did not reach the correct plan until after the time period had expired.

The party requesting the good-cause extension must file a written request with the Part D plan sponsor, and include the reason why the request was not filed timely. If the Part D plan sponsor denies a party’s request for a good cause extension, the party may file a grievance with the Part D plan sponsor, but the party does not have the right to appeal the plan sponsor’s denial of the good-cause extension.
70.4 - Withdrawal of Request for Redetermination  
(Rev. 9, 2/22/13)

The party (see §70.1) who files a request for redetermination may submit a written request to the Part D plan asking to withdraw the request at any time before a decision is mailed. A plan sponsor may also accept such requests orally, provided that the Part D plan sponsor sends (i.e., mails) a written confirmation of the withdrawal to the party within 3 calendar days from the date of the oral request.

If a withdrawal request is received by a Part D plan sponsor before the plan has made its redetermination decision, the plan may dismiss the appeal. However, if the withdrawal request is received after the Part D plan sponsor has forwarded a case file to the IRE because the plan sponsor did not provide notice of its decision within the appropriate time frame, the plan must forward the withdrawal request to the IRE for processing.

70.5 - Opportunity to Submit Evidence  
(Rev. 8, 1/1/10)

The Part D plan sponsor must provide the enrollee or the prescribing physician or other prescriber, as appropriate, with a reasonable opportunity to present evidence and allegations of fact or law related to the issues in dispute, in person as well as in writing. A plan sponsor satisfies the in-person requirement if it accepts evidence by telephone or fax, or accepts evidence that is hand-delivered by enrollees to a plan's physical location.

Note: The in-person requirement is not intended to require plan sponsors to provide in-person hearings for enrollees.

In the case of an expedited redetermination, the opportunity to present evidence is limited by the short time frame for making a decision. Therefore the Part D plan sponsor may develop reasonable conditions for submitting evidence and must inform the parties of such conditions. For example, a plan may set a deadline for submitting evidence or require oral evidence to be submitted by telephone.

The Part D plan sponsor must take all of the evidence submitted orally and/or in writing into account when making a decision. In addition, the Part D plan sponsor must, upon an enrollee’s request, provide the enrollee with a copy of the contents of the case file, including, but not limited to, a copy of supporting medical records and other pertinent information used to support the decision. The Part D plan sponsor must abide by all Federal and state laws regarding confidentiality and disclosure for mental health records, medical records, or other health information. See 45 CFR 164.500 et seq. (regarding the privacy of individually identifiable health information).

The Part D plan sponsor must make every reasonable effort to accommodate an enrollee’s request for case file material including, but not limited to, allowing the enrollee or representative to obtain the material at a plan location or mailing the material to any
address specified by the enrollee or representative. The Part D plan sponsor shall have the right to charge the enrollee a reasonable amount (e.g., comparable to charges established by a QIO) for duplicating the case file material. At the time that the request for case file material is made, the Part D plan sponsor must inform the enrollee of the per page duplicating cost, and based on the extent of the case file material requested, provide an estimate of the total duplicating cost for which the enrollee will be responsible. The Part D plan sponsor may also charge the enrollee the cost of mailing the material to the address specified. The Part D plan sponsor may not charge the enrollee an additional cost for courier delivery of the material to a plan location that would be over and above the cost of mailing the material to the enrollee.

70.6 - Who Must Conduct a Redetermination
(Rev. 9, 2/22/13)

The Part D plan sponsor must designate someone other than the person involved in making the initial coverage determination to make a redetermination. If the original denial was based on a lack of medical necessity (i.e., the non-preferred or non-formulary drug was not medically necessary for treating the enrollee’s condition when compared with the preferred or formulary drug, or a determination was made that insufficient information was received to make such a determination, or the drug was denied because it was not reasonable and necessary under section 1862(a)(1) of the Act), the redetermination must be performed by a physician with expertise in the field of medicine that is appropriate for the drug benefits at issue.

70.6.1 - Meaning of Physician with Expertise in the Field of Medicine
(Rev. 8, 1/1/10)

The physician need not, in all cases, be of the same specialty or subspecialty as the enrollee's prescribing physician or other prescriber. The physician must, however, possess the appropriate level of training and expertise to evaluate the necessity of the requested drug. This does not require the physician to always possess identical specialty training. For example, where there are few practitioners in a highly specialized field of medicine, a plan sponsor may not be able to hire a physician of the same specialty or sub-specialty to review the adverse coverage determination.

70.7 - Time Frames and Responsibilities for Conducting Standard Redeterminations
(Rev. 9, 2/22/13)

The Part D plan sponsor must provide written notice of its redetermination, whether favorable or adverse, as expeditiously as the enrollee’s health condition requires, but no later than 7 calendar days from the date the Part D plan sponsor receives the request for a standard redetermination (See the note in §40.2 regarding when a request is deemed received by a plan sponsor).
Part D plan sponsors that do not provide notice of a decision within the required timeframe should not use the notice described in this section to notify an enrollee that his or her decision was not made timely and was forwarded to the IRE, but should provide notice as described in §70.7.1 instead.

If the decision is adverse, the plan sponsor must process the decision in accordance with §70.9.1. If the decision is completely favorable, the plan sponsor must process the decision in accordance with §70.9.2. In addition, if the Part D plan sponsor overturns its adverse coverage determination, it must effectuate it in accordance with §130.2.

A plan sponsor may not extend the applicable adjudication time frame by dispensing a temporary supply of the requested medication. For example, if a plan sponsor receives a request outside of its normal business hours, it cannot approve a 72-hour supply of the requested medication and defer issuing a decision for 72 hours; the plan sponsor must make its determination within the appropriate time frame.

Occasionally, the Part D plan sponsor may not have all of the information it needs to make a redetermination. The plan must make reasonable and diligent efforts to obtain all necessary medical records and other pertinent information within the required time limits and document its attempts. If the Part D plan sponsor cannot obtain all relevant documentation, it must make the decision based on the evidence available. If a plan does not make a decision in the applicable time frame, the plan must forward the request and case file containing any oral and/or written evidence obtained to the IRE for review as described in §70.7.1.

70.7.1 - Effect of Failure to Meet the Time Frame for Standard Redetermination
(Rev. 3, 2/1/07)

Although the Part D plan sponsor's failure to provide notice of a decision within the required timeframe constitutes an adverse decision, the plan sponsor must not send the adverse decision notice described in §70.7 to the enrollee. Instead, if the Part D plan sponsor fails to provide the enrollee with a redetermination within the time frames specified in §70.7, it must forward the complete file to the IRE and provide notice, according to the procedures set forth in §70.10. If CMS determines that the Part D plan sponsor has a pattern of not concluding its standard redeterminations within the required time frames or not making reasonable and diligent effort to gather and forward information to the IRE, then the Part D plan sponsor may be considered to be in breach of its Medicare contract and/or subject to intermediate sanctions in accordance with subpart O of 42 CFR Part 423.

Transition Period Note:
The "Transition Period Note" in §40.4 also applies to this section.
70.7.2 - Processing a Standard Pre-Benefit Redetermination as a Request for Payment (Rev. 8, 1/1/10)

If an enrollee has requested a standard pre-benefit redetermination and the Part D plan sponsor becomes aware that the enrollee has obtained the prescription drug before it completes its redetermination, the Part D plan sponsor must stop processing the claim as a pre-benefit redetermination, and process the claim as a request for payment instead (i.e., process the claim as a redetermination request for payment).

If, after the enrollee submitted the pre-benefit appeal, the Part D plan sponsor is not aware that the enrollee has already received the requested drug and the plan continues to deny the pre-benefit redetermination and sends the case to the IRE on appeal, the IRE must stop processing the claim as a pre-benefit reconsideration, and process the claim as a request for payment if it receives information indicating that the drug has been obtained.

70.8 - Expediting Certain Redeterminations (Rev. 9, 2/22/13)

A party (see §70.1) may request an expedited redetermination in situations where applying the standard time frame could seriously jeopardize the enrollee's life, health, or ability to regain maximum function. A request for payment of a benefit already provided to an enrollee is not eligible to be reviewed as an expedited redetermination.

To ask for an expedited redetermination, the party must submit an oral or written request directly to the plan or entity responsible for making the redetermination within 60 calendar days from the date of the notice of the coverage determination. Part D plan sponsors must accept both oral and written requests. The Part D plan sponsor may extend the time frame for filing an expedited request as noted in §70.3. A request may be withdrawn as described in §70.4.

The enrollee’s prescribing physician or other prescriber may provide oral or written support for a request made by an enrollee. The Part D plan sponsor must expedite a redetermination if it determines, or an enrollee’s prescribing physician or other prescriber indicates, that applying the standard time frame could seriously jeopardize the life or health of the enrollee or the enrollee’s ability to regain maximum function.

If an enrollee requests an appeal of a plan sponsor’s adverse expedited coverage determination, the plan may choose to expedite the redetermination without requiring the enrollee's prescribing physician or other prescriber to submit a new statement indicating that applying the standard time frame could seriously jeopardize the life or health of the enrollee or the enrollee’s ability to regain maximum function. However, if a plan sponsor chooses to do so, it should, at a minimum, ensure that the enrollee has not obtained the drug in dispute (i.e., paid for the drug out-of-pocket).
70.8.1 - How the Part D Plan Sponsor Processes Requests for Expedited Redetermination

(Rev. 9, 2/22/13)

The plan must establish and maintain procedures for expediting redeterminations, including procedures that establish an efficient and convenient method for individuals to submit oral or written requests for expedited appeals, documenting oral requests (e.g., entering oral requests into an internal tracking system), and maintaining the documentation in the case file. The Part D plan sponsor must designate an office and/or department to receive both oral or written requests and a telephone number for oral requests, and may include a facsimile number to facilitate receipt of requests for expedited appeals.

A Part D plan sponsor must promptly determine if a request must be expedited. If the oral or written request is made by a physician or other prescriber, or supported by a physician's or other prescriber's oral or written statement, the Part D plan sponsor must grant the request to expedite if the physician or other prescriber indicates that the enrollee's life, health, or ability to regain maximum function could be jeopardized by applying the standard time frame for processing the redetermination request. If a Part D plan sponsor denies a request for an expedited redetermination, it must automatically transfer the request to the standard redetermination process and provide the enrollee with prompt oral notice of the denial and the enrollee’s rights. The oral notice must meet requirements 1-4 described below. The plan sponsor must subsequently deliver a written notice to the enrollee within 3 calendar days of the oral notification. The written notice must:

1. Explain that the Part D plan sponsor will automatically transfer and process the request using the 7-day time frame for standard redeterminations;

2. Inform the enrollee of the right to file an expedited grievance if he or she disagrees with the plan’s decision not to expedite the redetermination;

3. Inform the enrollee of the right to resubmit a request for an expedited redetermination with the prescribing physician's or other prescriber's support, and explain that if the physician or other prescriber indicates that applying the standard time frame for making a determination could seriously jeopardize the enrollee’s life, health or ability to regain maximum function, the request will be expedited automatically; and

4. Provide instructions about the grievance process and the applicable time frames.

CMS has developed a model notice that Part D plan sponsors can use to notify enrollees whenever a request to expedite is denied, (see Appendix 3). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.
If the Part D plan sponsor approves a request to expedite a redetermination, it must complete the expedited redetermination and give notice of its decision as expeditiously as the enrollee’s health condition requires, but no later than 72 hours after receiving the request. See the note in §40.2 regarding when a request is deemed received by a plan sponsor.

Notice of completely favorable expedited redeterminations must be provided in writing in accordance with §70.9.4. Notice of adverse expedited redeterminations must be provided in writing in accordance with §70.9.3.

A Part D plan sponsor that does not provide notice of a decision within the required timeframe should not use the notice described in this section to notify an enrollee that his or her decision was not made timely and was forwarded to the IRE, but should provide notice as described in §70.8.2 instead.

A plan sponsor may not extend the applicable adjudication time frame by dispensing a temporary supply of the requested medication. For example, if a plan sponsor receives a request outside of its normal business hours, it cannot approve a 72-hour supply of the requested medication in dispute and defer issuing a decision for 72 hours; the plan sponsor must make its determination within the appropriate time frame.

If the Part D plan sponsor requires additional medical information, it must request the necessary information within 24 hours of receiving the initial request for an expedited redetermination. See the note in §40.2 regarding when a request is deemed received by a plan sponsor. A prescribing physician, other prescriber, or other staff responsible for responding to a plan sponsor's request should make reasonable and diligent efforts to expeditiously gather and forward all necessary information to assist the Part D plan sponsor in meeting the required time frame. Regardless of whether the Part D plan sponsor requests additional information, the Part D plan sponsor is responsible for meeting the time frame and notice requirements. CMS has developed a model notice that Part D plan sponsors can use to request additional information (see Appendix 11). If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.

70.8.2 - Effect of Failure to Meet the Time Frame for Expedited Redetermination
(Rev. 3, 2/1/07)

Although the Part D plan sponsor's failure to provide notice of a decision within the required timeframe constitutes an adverse decision, the plan sponsor must not send the adverse decision notice described in §70.8.1 to the enrollee. Instead, if a Part D plan sponsor does not notify the enrollee within the required time frame set forth in §70.8.1, the failure constitutes an adverse decision and the Part D plan sponsor must forward the complete file to the IRE and provide notice according to the procedures set forth in §70.10. If CMS determines that the Part D plan sponsor has a pattern of not concluding its expedited redeterminations within the required time frames or not making reasonable and
diligent efforts to gather and forward information to the independent review entity, then the Part D plan sponsor may be considered to be in breach of its Medicare contract and/or subject to intermediate sanctions in accordance with subpart O of 42 CFR Part 423.

Transition Period Note:
The "Transition Period Note" in §40.4 also applies to this section.

70.9 - Notification of the Result of a Redetermination

70.9.1 - Adverse Standard Redeterminations
(Rev. 9, 2/22/13)

If a Part D plan sponsor's standard redetermination decision is adverse, in whole or in part, it must provide written notice of its decision as expeditiously as the enrollee’s health condition requires, but no later than 7 calendar days from the date the Part D plan sponsor receives the request (see the note in §40.2 regarding when a request is deemed received by a plan sponsor).

- If an enrollee files the request, notice must be provided to the enrollee.
- If an enrollee has identified a representative, the plan sponsor must send the written notice to the enrollee's representative instead of the enrollee (see §10.4.2).
- If an enrollee's prescribing physician or other prescriber files a request on behalf of an enrollee, the plan sponsor must provide notice to the prescriber and written notice to the enrollee.

The plan sponsor may use the model notice language contained in Appendix 4, or it may develop its own notice that meets the regulatory requirements in 42 CFR 423.590(g). If a plan sponsor makes any substantive change to a model notice or develops its own notice that meets the regulatory requirements in 42 CFR 423.590(g), the proposed change or notice must be approved through the appropriate CMS marketing procedures. The denial notice must be written in a manner that is understandable to the enrollee, and must:

1. State the specific reason for the denial that takes into account the enrollee’s presenting medical condition, disabilities, and special language requirements, if any;

2. A description of any applicable Medicare coverage rule or any other applicable Part D plan policy upon which the denial decision was based, including any specific formulary criteria that must be satisfied for approval. If the drug could be approved under the exception rules, the denial notice must explicitly state the need for a prescriber’s supporting statement and clearly identify the type of information that should be submitted when seeking a formulary or tiering exception. For example, if the drug is
subject to step therapy, the denial notice must clearly explain the step criteria and indicate that if the enrollee can’t take the step drug(s), the enrollee’s prescriber must submit a supporting statement explaining why the enrollee can’t tolerate the step drug(s).

3. Inform the enrollee of his or her right to a reconsideration;
   a. For adverse drug coverage redeterminations, describe both the standard and expedited reconsideration processes, including the enrollee’s right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeals process;
   b. For adverse payment redeterminations, describe the standard reconsideration process and the rest of the appeals process; and

4. Contain the enrollee's HIC number, the plan name, the plan identification number, the contract identification number, and the formulary identification number.

Plan sponsors must complete the applicable sections of the model Request for Reconsideration form (see Appendix 13 and send it to the enrollee (and physician or other prescriber when appropriate) with each adverse redetermination notice. If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.

A Part D plan sponsor that does not provide notice of a decision within the required timeframe should not use the notice described in this section to notify an enrollee that his or her decision was not made timely and was forwarded to the IRE, but should provide notice as described in §70.7.1 instead.

70.9.2 - Favorable Standard Redeterminations
(Rev. 9, 2/22/13)

If a Part D plan sponsor's standard redetermination decision is completely favorable, it must provide written notice of its decision as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date the Part D plan sponsor receives the request (see the note in §40.2 regarding when a request is deemed received by a plan sponsor).

- If an enrollee files the request, notice must be provided to the enrollee.
- If an enrollee has identified a representative, the plan sponsor must send the written notice to the enrollee's representative instead of the enrollee (see §10.4.2).
If an enrollee's prescribing physician or other prescriber files a request on behalf of an enrollee, the plan sponsor must provide notice to the prescriber and written notice to the enrollee.

The approval notice must be written in a manner that is understandable to the enrollee, and must explain the conditions of the approval. The conditions of approval may include (but are not limited to):

- The duration of an approval;
- Limitations associated with an approval; and/or
- Any coverage rules applicable to subsequent refills.

The plan sponsor may develop its own notice that meets the regulatory requirements in 42 CFR 423.590(h).

A Part D plan sponsor that does not provide notice of a decision within the required timeframe should not use the notice described in this section to notify an enrollee that his or her decision was not made timely and was forwarded to the IRE, but should provide notice as described in §70.7.1 instead.

70.9.3 - Adverse Expedited Redeterminations (Rev. 9, 2/22/13)

If a Part D plan sponsor's expedited redetermination decision is adverse, in whole or in part, it must provide notice of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours from the date and time the Part D plan sponsor receives the request (see the note in §40.2 regarding when a request is deemed received by a plan sponsor). A plan sponsor may make its initial notification orally. However, if a plan sponsor issues an adverse expedited redetermination, in whole or part, it must provide written notice of the decision. Therefore, if a plan sponsor first makes its adverse notification orally, a follow-up written decision must be mailed within 3 calendar days of the oral notification.

- If an enrollee files the request, notice must be provided to the enrollee.
- If an enrollee has identified a representative, the plan sponsor must send the written notice to the enrollee's representative instead of the enrollee (see §10.4.2).
- If an enrollee's prescribing physician or other prescriber files a request on behalf of an enrollee, the plan sponsor must notify both the prescriber and the enrollee. The enrollee must receive written notice of the decision. However, consistent with §40.3.2, a plan sponsor is not required to provide an enrollee's prescribing physician or other prescriber with a written follow-up decision after providing oral notice to the physician or other prescriber.
The note in §40.3.3 regarding a good-faith effort to provide oral notice also applies to this section.

Any written notice must be written in a manner that is understandable to the enrollee. In addition, the oral (if provided) and written denial notice must:

1. State the specific reason for the denial that takes into account the enrollee’s medical condition, disabilities, and special language requirements, if any;

2. Include a description of any applicable Medicare coverage rule or any other applicable Part D plan policy upon which the denial decision was based, including any specific formulary criteria that must be satisfied for approval. If the drug could be approved under the exception rules, the denial notice must explicitly state the need for a prescriber’s supporting statement and clearly identify the type of information that should be submitted when seeking a formulary or tiering exception. For example, if the drug is subject to step therapy, the denial notice must clearly explain the step criteria and indicate that if the enrollee can’t take the step drug(s), the enrollee’s prescriber must submit a supporting statement explaining why the enrollee can’t tolerate the step drug(s).

3. Inform the enrollee of his or her right to a reconsideration;
   a. For adverse drug coverage redeterminations, describe both the standard and expedited reconsideration processes, including the enrollee’s right to, and conditions for, obtaining an expedited reconsideration and the rest of the appeals process;
   b. For adverse payment redeterminations, describe the standard reconsideration process and the rest of the appeals process; and

4. Contain the enrollee's HIC number, the plan name, the plan identification number, the contract identification number, and the formulary identification number.

The plan sponsor may use the model notice language contained in Appendix 4, or it may develop its own notice that meets the regulatory requirements in 42 CFR 423.590(g). If a plan sponsor makes any substantive change to a model notice, or it develops its own notice that meets the regulatory requirements in 42 CFR 423.590(g), the proposed change or notice must be approved through the appropriate CMS marketing procedures.

Plan sponsors must complete the applicable sections of the model Request for Reconsideration form (see Appendix 13) and send it to the enrollee (and physician or other prescriber when appropriate) with each adverse redetermination notice. If a plan sponsor makes any substantive change to a model notice, the proposed change must be approved through the appropriate CMS marketing procedures.
A Part D plan sponsor that does not provide notice of a decision within the required timeframe should not use the notice described in this section to notify an enrollee that his or her decision was not made timely and was forwarded to the IRE, but should provide notice as described in §70.8.2 instead.

70.9.4 - Favorable Expedited Redeterminations
(Rev. 9, 2/22/13)

If a Part D plan sponsor's expedited redetermination decision is completely favorable, it must provide written notice of its decision as expeditiously as the enrollee's health condition requires, but no later than 72 hours from the date and time the Part D plan sponsor receives the request (see the note in §40.2 regarding when a request is deemed received by a plan sponsor. A plan sponsor may make its initial notification orally. However, if a plan sponsor issues a completely favorable expedited redetermination, it must provide written notice of the decision. Therefore, if a plan sponsor first makes its favorable notification orally, a follow-up written decision must be mailed within 3 calendar days of the oral notification.

- If an enrollee files the request, notice must be provided to the enrollee.
- If an enrollee has identified a representative, the plan sponsor must send the written notice to the enrollee's representative instead of the enrollee (see §10.4.2).
- If an enrollee's prescribing physician or other prescriber files a request on behalf of an enrollee, the plan sponsor must notify both the prescriber and the enrollee. The enrollee must receive written notice of the decision. However, consistent with §40.3.2, a plan sponsor is not required to provide an enrollee's prescribing physician or other prescriber with a written follow-up decision after providing oral notice to the physician or other prescriber.

The note in §40.3.2 regarding a good-faith effort to provide oral notice also applies to this section.

Any written notice must be written in a manner that is understandable to the enrollee. In addition, the oral (if provided) and written approval notice must explain the conditions of the approval. The conditions of approval may include (but are not limited to):

- The duration of an approval;
- Limitations associated with an approval; and/or
- Any coverage rules applicable to subsequent refills.
The plan sponsor may develop its own notice that meets the regulatory requirements in 42 CFR 423.590(h) and any applicable CMS marketing requirements.

A Part D plan sponsor that does not provide notice of a decision within the required timeframe should not use the notice described in this section to notify an enrollee that his or her decision was not made timely and was forwarded to the IRE, but should provide notice as described in §70.7.1 instead.

70.10 - Forwarding Untimely Redeterminations to the Independent Review Entity
(Rev. 9, 2/22/13)

If a Part D plan sponsor does not provide notice of its standard or expedited redetermination within the required time frame, it must forward the complete case file to the IRE within 24 hours of the expiration of the adjudication time frame. The case file must satisfy the requirements in §70.30. The Part D plan sponsor must deliver a hard copy of the case file to the IRE by overnight delivery at its designated address, or by fax at its designated fax number. The Part D plan sponsor should refer to the IRE’s Reconsideration Process Manual for additional instructions.

Note: If a plan sponsor makes a completely favorable decision soon after the adjudication timeframes expires (i.e., within 24 hours) and notifies the enrollee of the decision, the plan sponsor should not forward the case file to the IRE and provide the notice described in this section. Plan sponsors should use this exception sparingly. If a plan sponsor does not regularly meet the adjudication timeframe and CMS finds that the plan sponsor uses this exception frequently, CMS may consider the plan sponsor in breach of its Medicare contract and/or subject to intermediate sanctions in accordance with subpart O of 42 CFR Part 423.

Note: As indicated in §10.5, an enrollee's prescribing physician or other prescriber may request a coverage determination, redetermination or IRE reconsideration on an enrollee's behalf, but is prohibited from requesting a higher appeal without being the enrollee's representative. If the IRE issues an adverse decision, the enrollee's physician or other prescriber must become the enrollee's representative, as indicated in §10.4, to file any further appeal on the enrollee's behalf.

Although the Part D plan sponsor's failure to provide notice of a decision within the required timeframe constitutes an adverse decision, the plan sponsor must not send the adverse decision notice described in §70.7 or §70.8.1 to the enrollee. Instead, the Part D plan sponsor must notify the enrollee that it has forwarded his or her request to the IRE for review. The plan sponsor must send the notification within 24 hours of the expiration of the adjudication time frame. The notice must advise the enrollee of his/her right to submit additional evidence to the IRE and must include information on how to contact the IRE. CMS has developed a model notice that Part D plan sponsors can use to notify enrollees whenever cases are forwarded to the IRE, (see Appendix 6). If a plan sponsor makes any
If CMS determines that the Part D plan sponsor has a pattern of not concluding its redeterminations within the required time frames or not making reasonable and diligent effort to gather and forward information to the IRE, then the Part D plan sponsor may be considered to be in breach of its Medicare contract and/or subject to intermediate sanctions in accordance with subpart O of 42 CFR Part 423.

**Transition Period Note:**
The "Transition Period Note" in §40.4 also applies to this section.

### 70.20 - Time Frame for Forwarding Case Files to the Independent Review Entity

(*Rev. 9, 2/22/13*)

In cases where an enrollee has filed a reconsideration request and the IRE has requested the enrollee's file from the Part D plan sponsor, the plan sponsor must ensure that the IRE receives a hard copy of the case file and all of its contents within 24 hours (expedited requests) or 48 hours (standard requests) from the time it receives the IRE's request for the case file. The case file must contain the information described in §70.30. The Part D plan sponsor may determine what method of delivery will ensure that the IRE will receive the case file within the applicable time frame (e.g., overnight delivery at the IRE’s designated address or by fax at its designated fax number). The Part D plan sponsor should refer to the IRE’s Reconsideration Process Manual for additional instructions.

**Transition Period Note:**
The "Transition Period Note" in §40.4 also applies to this section.

### 70.30 - Preparing the Case File for the Independent Review Entity

(*Rev. 8, 1/1/10*)

**Note:** Part D plan sponsors should also refer to §70.40 to determine what documents/items to send with the case file.

All case files involving a completed coverage determination and redetermination must include the following documents:

- Reconsideration Case File Transmittal Form and Case Narrative Form.
- Request for a Coverage Determination and the Coverage Determination Notice.
- Request for a Redetermination and the Redetermination Notice.
- Redetermination evidence presented by the enrollee and/or the prescribing physician or other prescriber.
- Representation documentation for representative appeals.
- Expedited information regarding the Coverage Determination and Redetermination.
- A complete copy of the relevant Evidence of Coverage or other subscriber materials on a CD.
In addition to the documents that must be included with all case files sent to the IRE, case files involving an exceptions request should include:

- A statement from the prescribing physician or other prescriber addressing the medical necessity for an exceptions request in accordance with the standards set forth in 42 CFR 423.578(a)(4) and 423.578(b)(5). Any initial oral or written statement, and any subsequently submitted written statements, should be provided. Additionally, the name and specialty of the prescribing physician or other prescriber should be clearly identified, and contact numbers for office address, telephone, fax and email should be provided.
- A complete copy of the relevant plan formulary on a CD, including descriptions of any utilization management requirements relative to the drug in dispute.
- Exceptions process/criteria for determining medical necessity for the drug in dispute.
- Medical Records relevant to the drug in dispute.
- A detailed statement explaining the basis for the plan sponsor’s denial. The plan sponsor’s statement should mirror the steps of the plan sponsor’s exceptions process/criteria, and indicate precisely which criteria were not met.
- Any internal plan sponsor medical reviews that were obtained during redetermination review with regard to the disputed drug benefit.
- A precise description of medical documentation that is missing from the case file if the plan sponsor’s adverse decision is based on the failure of the prescribing physician or other prescriber to submit additional medical documentation as requested by the plan sponsor.

In addition to the documents that must be included with all case files sent to the IRE, case files involving a medical necessity issue (that is not an exceptions request) should include:

- A complete copy of the relevant plan formulary on a CD, including descriptions of any utilization management requirements relative to the drug in dispute.
- Written or oral statements provided by the prescribing physician or other prescriber. The name and specialty of the prescribing physician or other prescriber should be clearly identified, and contact numbers for street address, telephone, fax and email should be provided.
- Medical Records relevant to the drug in dispute.
- A detailed statement explaining the basis for the plan sponsor’s denial.
- Any internal plan sponsor medical reviews that were obtained during redetermination review with regard to the disputed drug benefit.
- A precise description of medical documentation that is missing from the case file if the plan sponsor’s adverse decision is based on the failure of the prescribing physician or other prescriber to submit additional medical documentation as requested by the plan sponsor.

Part D plan sponsors should refer to the most current version of the IRE’s Reconsideration Process Manual for information concerning the Reconsideration Case File Transmittal Form and Case Narrative Form. These forms can be downloaded at http://www.medicarepartdappeals.com. Plan sponsors are expected to fully complete all
appropriate sections of the Reconsideration Case File Transmittal Form in support of CMS’ appeals data collection activities.

An enrollee is entitled to request a copy of his or her complete case file upon request. Although not required, a plan sponsor may charge a fee for providing the copy.

70.40 - Including the Evidence of Coverage and Formulary in Case Files (Rev. 8, 1/1/10)

CMS strongly recommends that Part D plan sponsors include complete copies of the relevant Evidence of Coverage (EOC) and formulary with any case files sent to the IRE for review (the EOC and formulary should be copied onto a CD which is sent to the IRE; do not send paper copies of the EOC and formulary to the IRE). The previous practice, with respect to EOCs and formularies, was to include relevant excerpts of these plan documents, rather than entire copies, in case files requested by an Administrative Law Judge (ALJ). However, the Office of Medicare Hearings & Appeals (OMHA) ALJs have indicated that these documents are needed in their entirety in order to properly adjudicate appeals. Additionally, the Medicare Appeals Council (MAC) has declined to review certain Part D cases referred for own motion review because the ALJ did not have access to a complete copy of the relevant Part D plan formulary and/or EOC at the time of the ALJ hearing. Therefore, it is in a plan's best interest to ensure that each case file sent to the Part D IRE includes a CD with complete versions of the EOC and formulary relevant to an enrollee's specific case. Failure to include this information could result in an unfavorable appeals decision and/or CMS declining to refer an ALJ decision to the MAC for review.

If a plan sponsor chooses to implement this recommendation, the complete EOC and formulary (if applicable) that is relevant to the enrollee’s appeal must be put on a CD and included with the case file that is sent to the Part D IRE. Plans may not mail or fax paper copies of the complete EOC and/or formulary to the IRE.

Plan sponsors choosing to include the CD with the case file must do so in the following manner:

- The CD must be properly labeled with the plan name and contract number, formulary ID, enrollee name/HICN, and appeal number;
- The CD must be securely affixed to the paper case file;
- All documents on the CD must be in PDF or Word format and should not be encrypted (none of the documents on the CD contain PHI); and
- The CD should only include the EOC and formulary applicable to the specific case being adjudicated (a plan must not place copies of all of its EOCs and formularies on the CD).

80 - Reconsiderations by the Independent Review Entity (Rev. 2, 6/22/06)

The IRE, which is commonly referred to as the Part D Qualified Independent Contractor (QIC), must conduct the reconsideration as expeditiously as the enrollee’s health condition
requires, but not exceed the time frames applicable for Part D plan sponsors when making redeterminations under §§70.7 and 70.8.1.

When the IRE completes its reconsideration, it is responsible for mailing or otherwise transmitting notification of the decision to all the parties.

The reconsideration notice must be written in a manner that is understandable to the enrollee and that takes into account the enrollee's presenting medical condition(s), disabilities, or special language requirements, if any, and:

1. Include specific reasons for the entity’s decision;

2. If the decision is adverse (i.e., does not completely reverse the plan’s adverse determination), inform the enrollee of his or her right to an ALJ hearing if the amount in controversy meets the appropriate threshold requirement; and

3. Describe procedures that the enrollee must follow to obtain an ALJ hearing, including the filing location.

80.1 - Storage of Appeal Case Files by the Independent Review Entity (Rev. 2, 6/22/06)

The Part D QIC is responsible for maintaining reconsideration case files in accordance with CMS’ Records Management Program. The inventory of case files includes the redetermination case files forwarded from the Part D plan sponsor and processed by the IRE which are not appealed further, and ALJ hearing case files returned to the IRE. Generally, reconsideration case files are retained for a period of seven (7) years from the end of the calendar year in which final action occurs. Final action means a decision on an appeal by the highest level of appeal, not the decision made by the Part D QIC.

Until further instructions are released by CMS, no reconsideration case files can be destroyed. However, in an effort to reduce associated costs for storing Medicare documents, electronic imaging is an acceptable method of storage. Therefore, if the IRE stores reconsideration case files electronically, it may destroy paper documents, as long as the following conditions are met:

- The IRE must certify the scanned image is an identical replication of the paper document in every way;

- The scanned image becomes the recordkeeping copy and is verified and documented as an identical replication of the paper document; and

- The IRE must maintain accessibility and the ability to read the document in accordance with changes in technology.
Reconsideration files will be made accessible to CMS and to any authorized party consistent with the Privacy Act regulations.

80.2 - Who May Request a Reconsideration  
(Rev. 9, 2/22/13)

An enrollee, an enrollee’s representative, or an enrollee’s prescribing physician or other prescriber may request a reconsideration.

Note: As indicated in §10.5, an enrollee's prescribing physician or other prescriber may request a coverage determination, redetermination or IRE reconsideration on an enrollee's behalf, but is prohibited from requesting a higher appeal without being the enrollee's representative. If the IRE issues an adverse decision, the enrollee's physician or other prescriber must become the enrollee's representative, as indicated in §10.4, to file any further appeal on the enrollee's behalf (i.e., the physician or other prescriber would be responsible for becoming the enrollee’s representative and submitting the proper representation documentation with the appeal request).

80.3 - How to Request a Reconsideration  
(Rev. 9, 2/22/13)

A party (see §80.2) may request a standard or expedited reconsideration by filing a written request with the IRE. The request for reconsideration must be filed within 60 calendar days from the date of the notice of the redetermination, unless the time frame is extended by the IRE as described in §80.4 below.

A written request may be made on the model Request for Reconsideration contained in Appendix 13, or on any other written document. As indicated in §§70.9.1 and 70.9.3, plan sponsors must complete the applicable sections of the model Request for Reconsideration form and send it to the enrollee with each adverse redetermination notice.

In order for a party to request an IRE reconsideration of a determination by a Part D plan sponsor not to provide a Part D drug that is not on the plan sponsor's formulary, the prescribing physician or other prescriber must determine that all covered Part D drugs, on any tier of the formulary, for treatment of the same condition would not be as effective for the individual as the non-formulary drug, would have adverse effects for the individual, or both.

80.4 - Good Cause Extension  
(Rev. 9, 2/22/13)

If a party misses the 60-day timeframe for requesting a reconsideration, he or she may request a good-cause extension. The extension request must be filed with the IRE, in writing, and include the reason why he or she did not request a reconsideration timely. If the party shows good cause, the IRE may extend the time frame for filing a request for reconsideration. The IRE should consider the circumstance that kept the party from
making the request on time and whether any actions by the plan may have misled the party. Examples of circumstances where good cause may exist include (but are not limited to) the situations described in §70.3. The decision by the IRE on whether to grant an extension for good cause is final and not subject to appeal.

80.5 - Withdrawal of Request for Reconsideration  
(Rev. 9, 2/22/13)

The party (see §80.2) who files a request for reconsideration may withdraw the request at any time by writing to the IRE and requesting the withdrawal before the IRE mails its decision.

80.6 - Effect of a Reconsideration Determination  
(Rev. 1, 11/30/05)

A reconsideration determination is final and binding on the enrollee and the Part D plan sponsor, unless the enrollee files a request for a hearing before an ALJ.

80.7 - Other Determinations Subject to Independent Review  

80.7.1 - Reconsideration of Late Enrollment Penalty Determinations  
(Rev. 8, 1/1/10)

Under §1860D-13(b) of the Social Security Act and 42 C.F.R. §§423.46 and 423.56(g), the Secretary or his or her designee imposes a late enrollment penalty (LEP) if there is a continuous period of 63 days or more at any time after the end of the individual’s Part D initial enrollment period during which the individual was eligible to enroll in a Part D plan, but was not enrolled in a Part D plan and was not covered under any creditable prescription drug coverage. “Creditable prescription drug coverage” is coverage that meets Medicare’s minimum standards since it is expected to pay, on average, at least as much as Medicare’s standard prescription drug coverage.

Creditable drug coverage may include but is not limited to:

- Employer-based prescription drug coverage, including the Federal employees health benefits program (FEHBP);
- State Pharmaceutical Assistance Programs (SPAPs);
- Military-related coverage (for example, VA, TRICARE coverage); and
- Certain Medicare supplemental (Medigap) policies.

See 42 C.F.R. §423.56(b) for a complete list of types of prescription drug coverage that may be determined to be creditable.

As outlined at 42 CFR 423.56(c) and (d), with the exception of Prescription Drug Plan Sponsors, Medicare Advantage Organizations, Section 1876 Cost-Based Contractors, and PACE organizations offering prescription drug plans, entities that offer prescription drug coverage must make an annual determination of creditable coverage status and provide a
disclosure notice to Medicare eligible individuals (see the appropriate plan enrollment guidance for information related to Part D enrollment eligibility). See Chapter 4 of this manual for additional guidance regarding creditable coverage period determinations and the calculation and assessment of the LEP.)

**Note:** Prescription drug discount cards, free clinics, or drug discount websites do not constitute creditable prescription drug coverage. Also, the “certificate of creditable coverage” an enrollee may receive when his or her health coverage ends does not mean the prescription drug coverage met Medicare’s minimum standards – unless the notice specifically mentioned the enrollee had “creditable” prescription drug coverage that expected to pay as much as Medicare’s standard prescription drug plan pays. For additional guidance concerning creditable coverage-related requirements, see the material posted on the CMS website: [http://www.cms.hhs.gov/creditablecoverage/](http://www.cms.hhs.gov/creditablecoverage/)

An enrollee, or his or her representative (as defined in §10.4 of this chapter), may request a review, or reconsideration, of a decision to impose an LEP. An enrollee may only obtain review under the circumstances listed on the LEP Reconsideration Request Form (Appendix 15) and described under §80.7.1.4 of this chapter. Unless otherwise stated in §10.4 of this chapter, the enrollee’s representative has all of the rights and responsibilities of an enrollee under Part D LEP reconsideration procedures.

The LEP reconsideration is conducted by an Independent Review Entity (IRE) under contract with Medicare. At this time, the IRE is MAXIMUS.

**80.7.1.1 - Summary of the LEP Reconsideration Process**  
(Rev. 8, 1/1/10)

The LEP Reconsideration Process is described below:

- When a Part D plan sponsor sends a letter notifying an enrollee of the imposition of or increase in the LEP (“LEP letter”), and the increase is due to reporting additional uncovered months, except in a case where the number of uncovered months increases as a result of an IRE decision, the sponsor shall include the Part D LEP Reconsideration Notice: “Your Right to Ask Medicare to Review Your Medicare Part D Late Enrollment Penalty” and the LEP Reconsideration Request Form (Appendix 14 and Appendix 15, respectively).

- The LEP letter, Part D LEP Reconsideration Notice, and the LEP Reconsideration Request Form advise the enrollee that he or she has 60 calendar days from the date on the LEP letter to request reconsideration of the LEP, or the request may not be considered. If the 60-day timeframe for filing an LEP reconsideration has expired, the enrollee may request a good-cause extension, subject to the requirements described in §80.4 of this chapter. The enrollee must explain his or her reason for filing late on a separate sheet and send this explanation along with the LEP Reconsideration Request Form.
• The enrollee sends his or her signed, completed LEP Reconsideration Request Form to the IRE under contract with Medicare, in accordance with the filing instructions provided on the form (Appendix 15). Enrollees also may write a letter requesting an LEP reconsideration, provided the letter contains the elements on the LEP Reconsideration Request Form.

• The IRE shall request a copy of the case file from the Part D plan sponsor and make a reconsideration decision based on the case file, the information supplied by the enrollee, and any other information the IRE deems relevant.

• The IRE will inform the enrollee and the Part D plan sponsor of the final decision.

• The Part D plan sponsor, if applicable, shall report a revised creditable coverage determination to CMS and notify the enrollee in writing of the new LEP amount and any refund due. (Refer to Chapter 4 of this manual for more information.)

• The final LEP reconsideration decision is not subject to appeal (that is, is not subject to further review by an Administrative Law Judge (ALJ), Medicare Appeals Council (MAC), or in a district court of the U.S.).

80.7.1.2 - Part D Plan Sponsor Responsibilities Under the LEP Reconsideration Process
(Rev. 8, 1/1/10)

The Part D plan sponsor shall become familiar with LEP procedures so it is able to assist enrollees throughout the LEP reconsideration process. For example, the Part D plan sponsor shall:

• Attempt to obtain a completed Declaration of Prior Prescription Drug Coverage from the enrollee at the beginning of the creditable coverage determination process, where the enrollee appears to have a qualifying break in creditable prescription drug coverage, as set forth in Chapter 4 of this manual. Obtaining the Declaration may avoid the assessment of a LEP and the need for reconsideration if the enrollee had prior creditable drug coverage for the uncovered months in question.

• Send the enrollee the Part D LEP Reconsideration Notice, “Your Right to Ask Medicare to Review Your Part D Late Enrollment Penalty” (Appendix 14), and the LEP Reconsideration Request Form (Appendix 15) at the same time the plan sends an enrollee his or her LEP letter.

Note: Part D plan sponsors shall only send the LEP reconsideration notice and form when notifying an enrollee of an imposition of or increase in the LEP where the increase is due to reporting additional uncovered months, except in a case where an increase in the number of uncovered months is a result of an IRE decision. While an increase in the number of uncovered
months following an LEP reconsideration does not happen frequently, it can occur if the plan under-reported the number of uncovered months.

- Retain a copy of the LEP letter sent to an enrollee. The information included in the LEP letter about the end of the individual’s IEP and the dates of the potential gap in creditable coverage is important in the event the enrollee requests a reconsideration. If the Part D plan sponsor retains a copy of the LEP letter in the enrollee’s file, that information will be readily and easily available if the enrollee requests review of the LEP and the IRE requests this information.

- Assist the enrollee in completing the LEP Reconsideration Request Form upon request. For example, the Part D plan sponsor shall help an enrollee determine which checkbox to mark as his or her reason for seeking reconsideration.

- Send the IRE a copy of the enrollee’s case file, which includes copies of any information the plan used in making its creditable coverage determination for the enrollee, including, but not limited to: the enrollee’s Part D IEP or subsequent IEP end date (and how it was derived), the enrollee’s creditable coverage attestation materials (“Declaration of Prior Prescription Drug Coverage” form), and any documentation from CMS of the enrollee’s enrollment in a Part D plan or in a plan whose sponsor received the retiree drug subsidy. (See Chapter 4 of this manual for specific guidance on information retention requirements related to creditable coverage and the LEP.)

80.7.1.3 - Elements of an LEP Reconsideration Request
(Rev. 8, 1/1/10)

The Part D plan sponsor shall inform the enrollee that his or her LEP reconsideration request must include the following elements:

- A completed, signed LEP Reconsideration Request Form (Appendix 15) or a signed, written request for reconsideration containing the elements on the LEP reconsideration request form; and

- If the enrollee has named a representative, proof that the individual has authority to represent the enrollee.

In addition to the items above, the Part D plan sponsor shall inform the enrollee that his or her LEP reconsideration request should include:

- Any additional information that may help the enrollee’s case, including evidence that the IRE should consider (e.g., notice from an employer sponsored health plan indicating that prior drug coverage was creditable). See §80.7.1.4.
80.7.1.4 - Reasons for Requesting LEP Reconsideration and Presentation of Evidence
(Rev. 8, 1/1/10)

As listed on the LEP Reconsideration Request Form, enrollees may request review of their LEP decision for one of the following specific reasons:

- The individual had prior creditable prescription drug coverage that the enrollee believes may have not been considered.

- The individual had prior prescription drug coverage but didn’t get a notice that clearly explained if the drug coverage was creditable. In this case, the enrollee should submit any evidence, such as a copy of an organization’s letter or other material, for example, a Summary of Benefits that the enrollee found unclear or misleading.

- The individual believes the LEP is wrong because he or she was not eligible to enroll in a Medicare drug plan during the period stated by the Medicare drug plan.

- The individual believes the LEP is wrong because he or she was unable to enroll in a Medicare drug plan due to a serious medical emergency during the period the individual was eligible to enroll in a drug plan.

- The individual has/had extra help from Medicare to pay for prescription drug coverage; that is, the low-income subsidy for Medicare prescription drug coverage.

- The individual lived in an area affected by Hurricane Katrina at the time of the Hurricane (August 2005), and he or she joined a Part D plan before December 31, 2009. NOTE: Certain Medicare beneficiaries who were affected by Hurricane Katrina were allowed to enroll in a Medicare prescription drug plan with no penalty before December 31, 2006 if, at the time of the hurricane (August 2005), they resided in any of the parishes or counties declared as meeting the level of “individual assistance” by the Federal Emergency Management Agency (FEMA).

Refer to Chapter 4 for additional guidance on the opportunity for certain individuals to enroll in Medicare Part D without an LEP: http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp

If additional information or evidence can help explain why an enrollee’s LEP is incorrect, he or she should submit such proof with the LEP Reconsideration Request Form. Enrollees are asked to send to the IRE any proof that helps support the request. Part D plan sponsors shall instruct enrollees to send this material to the IRE at the address or fax number shown on page 2 of the LEP Reconsideration Request Form, to include their Medicare Health Insurance Claim number on any separate materials, and to only send photocopies of their original documents.
80.7.1.5 - LEP Reconsideration Process Timeline
(Rev. 8, 1/1/10)

Below is a summary of the timelines the IRE generally will follow during the LEP reconsideration process:

- Unless the IRE finds good cause to extend its decision-making timeframe, the IRE generally will notify the enrollee of the final LEP reconsideration decision (including a decision to dismiss the reconsideration request), within 90 calendar days of receiving an enrollee’s request for reconsideration.

- The IRE may take an additional 14 days if the enrollee requests an extension or if the IRE finds good cause to extend the timeframe. Good cause would include, for example, when the IRE finds a need for additional information and considers the delay to be in the interest of the enrollee, such as receipt of additional information that may reduce the number of uncovered months upon which the LEP was based.

- In cases where an individual other than the enrollee files for reconsideration, the reconsideration timeframe will not commence until the IRE receives documentation verifying that the individual is the enrollee’s representative or is authorized under state law to act on behalf of an enrollee, as described in §10.4 of this chapter. The IRE will attempt to cure any defect in an Appointment of Representative form (CMS-1696) or other equivalent written notice – e.g., the form or notice was not properly executed – by requesting information from the individual who filed the reconsideration. If the IRE cannot verify an individual’s status as the representative within a reasonable time period, not to exceed 30 calendar days after the date of the reconsideration request, the IRE will determine that the reconsideration request be dismissed.

Note: In all cases, the IRE strives to notify an enrollee of its final decision as quickly as possible. However, the IRE may take longer than the 90-day timeframe to process an LEP reconsideration decision in certain cases depending, among other issues, on the amount of research the IRE has to perform to verify whether an individual’s prior prescription drug coverage was creditable.

80.7.1.6 - Withdrawal of an LEP Reconsideration Request
(Rev. 4, 6/8/07)

An enrollee may withdraw his or her LEP reconsideration request in writing at any time before the IRE mails the final decision. For purposes of a withdrawal, “enrollee” also includes a former enrollee or his or her representative.
80.7.1.7 - Dismissal of an LEP Reconsideration Request
(Rev. 8, 1/1/10)

Instances in which the IRE may determine that a reconsideration request be dismissed include, but are not limited to, the following:

- An enrollee failed to request a timely LEP reconsideration and did not have good cause for missing the filing deadline;

- An enrollee dies while the reconsideration is pending and the enrollee’s surviving spouse or estate has no remaining financial interest in the reconsideration;

- An individual requesting the reconsideration is not the enrollee, and the authority of the individual seeking a reconsideration cannot be verified within a reasonable time period, not to exceed 30 calendar days after the date of the reconsideration request; or

- An enrollee requests a reconsideration of an issue that is ineligible for LEP reconsideration or is otherwise ineligible for review. For example, the IRE will not make actuarial determinations concerning whether an enrollee’s prescription drug coverage was creditable; that is, an enrollee may not use the LEP reconsideration process to seek review of the decision that his or her coverage under an employer-sponsored prescription drug plan was not creditable coverage.

80.7.1.8 - Requests for Information
(Rev. 8, 1/1/10)

Upon request, the Part D plan sponsor shall forward to the IRE any information necessary to make a reconsideration decision, including all creditable coverage and LEP-related information received in accordance with Chapter 4 of this manual, such as information from a current or previous enrollee.

Upon request, the Part D plan sponsor delivers (by mail or fax) a hard copy of the requested information within 14 calendar days after receiving the request for information. Requested information may include, for example, an enrollee’s attestation materials (“Declaration of Prior Prescription Drug Coverage” form), including forms received late.

In the event a Part D plan sponsor has no information to forward, the Part D plan sponsor shall deliver (by mail or fax) a brief letter to the IRE within 14 calendar days after receiving the request for information. The letter acknowledges that the requested information is unavailable and explains the reason; for example, the enrollee never submitted an attestation form (a “Declaration of Prior Prescription Drug Coverage” form).
80.7.1.9 - [Reserved]
(Rev. 4, 6/8/07)

80.7.1.10 - Dismissals
(Rev. 4, 6/8/07)

Dismissals are not appealable.

80.7.1.10.1 - Vacating a Dismissal
(Rev. 4, 6/8/07)

The dismissal is binding, unless the dismissal is vacated. If a Part D enrollee requests the dismissal be vacated and he or she shows good cause that the reconsideration request should not be dismissed, the dismissal of the reconsideration request may be vacated. The enrollee must request that the dismissal be vacated within 60 days after the date of the dismissal notice. The IRE will notify the enrollee and the Part D plan sponsor in writing if the dismissal is vacated.

80.7.1.11 - Requirements Following LEP Reconsideration

80.7.1.11.1 - IRE Responsibilities
(Rev. 8, 1/1/10)

The IRE will notify the enrollee and the Part D plan sponsor of the final reconsideration decision generally within 90 calendar days after receiving the enrollee’s request for reconsideration. If an enrollee has identified a representative, the IRE will send any notice or other correspondence required under §80.7.1 to the individual’s representative instead of to the enrollee.

80.7.1.11.2 - Part D Plan Sponsor Responsibilities
(Rev. 8, 1/1/10)

If the IRE partially or fully reverses a Part D plan sponsor’s creditable coverage determination, the Part D plan sponsor shall comply with the requirements described under Chapter 4 of this manual concerning adjustment or removal of an LEP.

90 - Administrative Law Judge (ALJ) Hearings
(Rev. 1, 11/30/05)

If the amount remaining in controversy meets the appropriate threshold requirement established annually by the Secretary, an enrollee who is dissatisfied with the IRE’s reconsideration decision has a right to a hearing before an ALJ.
90.1 - Request for an ALJ Hearing
(Rev. 9, 2/22/13)

A request for an ALJ hearing must be filed with the entity specified in the IRE's reconsideration notice. *A request for a standard ALJ hearing must be submitted in writing. A request for an expedited ALJ hearing may be submitted orally or in writing (an enrollee cannot request an expedited hearing if the only issue involves a request for payment of Part D drugs already furnished).*

The oral or written request must include all of the following information:

1. The name, address, telephone number, and Medicare health insurance claim number of the enrollee;
2. The name, address, and telephone number of the appointed representative, if any;
3. The appeals case number assigned to the appeal by the IRE, if any;
4. The name of the prescription drug in dispute;
5. The plan name;
6. The reasons the enrollee disagrees with the IRE's reconsideration;
7. A statement of any additional evidence to be submitted and the date it will be submitted; and
8. A statement that the enrollee is requesting an expedited hearing, if applicable. The request should also explain why applying the standard timeframe may seriously jeopardize the life or health of the enrollee.

If a Part D plan sponsor receives a request for an ALJ hearing from an enrollee, the Part D plan sponsor must immediately forward the enrollee’s request to the appropriate ALJ hearing office.

Except when an ALJ extends the time frame as provided in 42 CFR 423.2014(d), an enrollee must file a request for an ALJ hearing within 60 calendar days of the date of the written notice of a reconsideration. Any request for a “good cause” extension must be in writing and state the reasons why the request was late. If the enrollee shows good cause for missing the deadline, the ALJ may grant an extension. (See 42 CFR 405.942(b)(2) and (b)(3) for the ALJ standards for good cause.)

90.2 - Determination of Amount in Controversy
(Rev. 9, 2/22/13)

Beginning in January 2005, the amount in controversy (AIC) threshold for an ALJ hearing will increase by the percentage increase in the medical care component of the consumer price index for all urban consumers (U.S. city average) for July 2003 to the July preceding the year involved. Any amount that is not a multiple of $10 will be rounded to the nearest multiple of $10. If there is a change in the amount in controversy requirement, the new requirement will be published by the Office of Medicare Hearings and Appeals.

For 2013, the AIC threshold for an ALJ hearing is $140.
The ALJ determines whether the amount remaining in controversy meets the appropriate threshold.

If the basis for the appeal is the Part D plan’s refusal to provide prescription drug benefits, the amount remaining in controversy will be calculated by subtracting any allowed amount under Part D, and any deductible, co-payments, and coinsurance amounts applicable to the Part D drug at issue, from the projected value of the drug benefits in dispute. Projected value includes any costs the enrollee could incur based on the number of refills prescribed for the drug(s) in dispute during the plan year. Projected value includes enrollee co-pays, all expenditures incurred after an enrollee's expenditures exceed the initial coverage limit, and expenditures paid by other entities.

If the enrollee is seeking reimbursement for out-of-pocket costs incurred in obtaining a disputed Part D drug, the amount remaining in controversy will be calculated by subtracting any allowed amount under Part D, and any deductible, co-payments, and coinsurance amounts applicable to the Part D drug at issue, from the actual amount charged the enrollee or a third party for the Part D drug.

When necessary, the Part D plan sponsor is expected to cooperate with the ALJ in computing the amount remaining in controversy (e.g., the ALJ may need the Part D plan sponsor to provide information regarding the amount an enrollee was required to pay for a drug at the time the coverage determination request was made).

The hearing may be conducted on more than one claim. The enrollee may combine claims he or she is appealing to meet the threshold requirement if the following elements are met:

1. The claims involve the delivery of prescription drugs to a single enrollee;
2. The claims must each have received a determination through the IRE reconsideration process;
3. The 60-day filing time limit must be met for all claims involved; and
4. The hearing request identifies all claims.

In addition, more than one enrollee may combine claims they are appealing to meet the threshold requirement, if the following elements are met:

1. The claims involve the delivery of the same prescription drug to each enrollee;
2. The claims must each have received a determination through the IRE reconsideration process;
3. The 60-day filing time limit must be met for all claims involved; and
4. The hearing request identifies all claims.
When claims are combined to meet the AIC threshold, the projected value of those benefits may be used to determine whether the requirement has been satisfied.

The ALJ dismisses cases if the AIC threshold is not met. If, after a hearing is initiated, the ALJ finds that the AIC threshold has not been satisfied, he/she will discontinue the hearing and will not rule on the substantive issues raised in the appeal. An enrollee may request review of the dismissal of a hearing through the Medicare Appeals Council (MAC) review. The MAC's decision is final and not subject to review.

90.3 - Submitting Evidence Before an ALJ  
(Rev. 9, 2/22/13)

An enrollee may submit written evidence that he or she wishes to have considered at an ALJ hearing in accordance with the following:

Standard Hearings
A represented enrollee must submit all written evidence he or she wishes to have considered at the hearing with the request for hearing, or within 10 calendar days of receiving the notice of hearing. If a represented enrollee submits written evidence later than 10 calendar days after receiving the notice of hearing, the period between the time the evidence was required to have been submitted and the time it is received does not count toward the adjudication deadline specified in §90.4. These requirements do not apply to unrepresented enrollees, or to oral testimony given at a hearing.

Expedited Hearings
An enrollee must submit all written evidence he or she wishes to have considered at the expedited hearing with the request for expedited hearing, or within 2 calendar days of receiving the notice of hearing. If an enrollee submits written evidence later than 2 calendar days after receiving the notice of hearing, the period between the time the evidence was required to have been submitted and the time it is received does not count toward the adjudication deadline specified in §90.4. These requirements do not apply to oral testimony given at a hearing.

Evidence of a Change in Medical Condition
If an enrollee’s medical condition changes after the coverage determination is made, the ALJ will not consider that evidence at the hearing. If an enrollee wishes such evidence to be considered, the ALJ will remand the case to the Part D IRE.

90.4 – Time Frame for Deciding an Appeal Before an ALJ  
(Rev. 9, 2/22/13)

Standard Hearing
The ALJ must generally issue a decision, dismissal order, or remand, as appropriate, no later than the end of the 90 calendar day period beginning on the date the ALJ receives the request for a standard ALJ hearing, unless the 90 calendar day period is extended.
**Expedited Hearing**

If an ALJ grants a request for an expedited review, the ALJ must generally issue a decision, dismissal order, or remand, as appropriate, as expeditiously as the enrollee’s health condition requires, but no later than the end of the 10 calendar day period beginning on the date the ALJ receives the request for an expedited ALJ hearing, unless the 10 calendar day period has been extended.

**100 - Medicare Appeals Council (MAC) Review**

(Rev. 8, 1/1/10)

An enrollee who is dissatisfied with an ALJ’s hearing decision may request that the MAC review the ALJ’s decision or dismissal. Where applicable, the regulations located at 42 CFR Part 423, subpart U apply to MAC review for matters addressed in this chapter.

The MAC may grant or deny the request for review. If it grants the request, it may either issue a final decision or dismissal, or remand the case to the ALJ with instructions on how to proceed with the case.

**100.1 - Filing a Request for MAC Review**

(Rev. 9, 2/22/13)

A request for a MAC review must be submitted to the entity specified in the notice of the ALJ’s action. A request for a standard MAC review must be submitted in writing. A request for an expedited MAC review may be submitted orally or in writing (an enrollee cannot request an expedited MAC review if the only issue involves a request for payment of Part D drugs already furnished).


A written request not made on Form DAB-101, or an oral request for an expedited review, must include all of the following information:

1. The name, address, telephone number, and Medicare health insurance claim number of the enrollee;
2. The name of the appointed representative, if any;
3. The appeals case number assigned to the appeal by the ALJ, if any;
4. The prescription drug in dispute;
5. The plan name;
6. The reasons the enrollee disagrees with the ALJ’s decision, dismissal or other determination being appealed;
7. A statement that the enrollee is requesting an expedited hearing, if applicable; and
8. The signature of the enrollee or the representative of the enrollee, if any.
The appeal request must identify the parts of the ALJ’s decision with which the enrollee disagrees, and explain why the enrollee disagrees. For example, if an enrollee believes that the ALJ’s decision is inconsistent with a statute, regulation, Medicare agency ruling, or other authority, the enrollee should explain why the ALJ’s decision is inconsistent with that authority.

Written requests must be submitted directly to the MAC at the following address:
Department of Health and Human Services
Departmental Appeals Board
Medicare Appeals Council, MS 6127
Cohen Building Room G-644
330 Independence Ave., S.W.
Washington, D.C. 20201

Alternatively, a written appeal request may be faxed to the MAC at (202) 565-0238. If the request is faxed, the enrollee should not also mail a copy of the request to the MAC.

Oral requests for expedited MAC review can be made by calling 202-565-0200.

An enrollee who files an appeal request with the MAC should send a copy of the ALJ’s decision with the appeal request.

100.2 - Time Limit for Filing a Request for MAC Review
(Rev. 9, 2/22/13)

The request for a MAC review must be filed within 60 calendar days of the date of receipt of the written ALJ hearing decision or dismissal. The MAC assumes the ALJ decision was received within 5 days of the date of the decision, unless evidence indicates otherwise. The MAC may grant an extension of the request for a review if the enrollee can show “good cause” for missing the deadline. (See 42 CFR 405.942(b)(2) and (b)(3) for the standards applicable for determining good cause.)

100.3 - MAC Initiation of Review
(Rev. 9, 2/22/13)

The MAC may initiate a review on its own motion or at the request of CMS or the IRE within 60 calendar days after an ALJ’s written hearing decision or dismissal is issued. If the MAC initiates a review, it mails notice of this action to the enrollee at his or her last address of record, and to CMS or the IRE, as appropriate.

100.4 - MAC Review Procedures
(Rev. 9, 2/22/13)

As noted in §100.1, the appeal request must identify the parts of the ALJ’s decision with which the enrollee disagrees, and explain why the enrollee disagrees. The MAC will limit
its review to those exceptions raised by the enrollee in the request for review, unless the enrollee is not represented.

The MAC limits its review of the evidence to the evidence contained in the record of the proceedings before the ALJ, and any new evidence that relates to the period before the coverage determination. However, under 42 CFR 423.2122, the MAC may also consider new evidence submitted for the first time to the MAC if the ALJ's decision decides a new issue that the parties were not afforded an opportunity to address at the ALJ level.

If the MAC determines that additional evidence is needed to resolve the issues in the case and the hearing record indicates that the previous decision-makers have not attempted to obtain the evidence, the MAC may remand the case to an ALJ to obtain the evidence and issue a new decision.

The MAC will not consider any new evidence submitted regarding a change in condition of an enrollee after a coverage determination is made. If an enrollee wishes to have such information considered, the MAC will remand the case to the Part D IRE for review.

Upon request, the MAC will give the enrollee requesting review a reasonable opportunity to file a brief or other written statement about the facts and law relevant to the case. Unless the enrollee requesting review files the brief or other statement with the request for review, the time that elapses between the date the MAC receives the request to submit the brief and the date the brief is received by the MAC will not count toward the adjudication timeframe set forth in §100.5.

100.5 – Time Frame for Deciding an Appeal Before the MAC
(Rev. 9, 2/22/13)

The MAC will issue a decision, dismissal order, or remand in accordance with the following:

**Standard Hearing**
The MAC must generally issue a decision, dismissal order, or remand, as appropriate, no later than 90 calendar days from the date the MAC receives the request for a standard MAC review.

**Expedit ed Hearing**
If the MAC grants a request for an expedited review (a decision which the MAC must make within 5 calendar days of the receipt of the request for expedited review), the MAC must generally issue a decision, dismissal order, or remand, as appropriate, as expeditiously as the enrollee’s health condition requires, but no later than 10 calendar days from the date the MAC receives the request for an expedited MAC review.

A copy of the MAC’s decision will be mailed to the enrollee at his or her last known address, CMS, the IRE, and the Part D plan sponsor.
110 - Judicial Review  
(Rev. 9, 2/22/13)  

An enrollee may request judicial review of an ALJ’s decision if:

1. The MAC denied the enrollee's request for review; and  

2. The amount remaining in controversy meets the appropriate threshold established annually by the Secretary.

In addition, an enrollee may request judicial review of a MAC decision if:

1. It is the final decision of the Secretary; and  

2. The amount remaining in controversy meets the appropriate threshold established annually by the Secretary.

For 2013, the AIC threshold for judicial review is $1,400.

110.1 - Requesting Judicial Review  
(Rev. 8, 1/1/10)  

An enrollee must file a civil action in a district court of the United States in accordance with §205(g) of the Act (see the procedures outlined in 42 CFR Part 423, subpart U, for a description of the procedures to follow in requesting judicial review). The action should be initiated in the judicial district in which the enrollee lives or where the Part D plan sponsor has its principal place of business. If neither the plan nor the member is in such a judicial district, the action should be filed in the United States district court for the District of Columbia.

110.2 – Expedited Access to Judicial Review  
(Rev. 9, 2/22/13)  

In certain situations, an enrollee may request expedited access to judicial review (EAJR) in place of an ALJ hearing or MAC review. An enrollee may make a request for EAJR only once with respect to a question of law or regulation for a specific matter in dispute in an appeal.

110.2.1 - Conditions for Making the Request  
(Rev. 9, 2/22/13)  

An enrollee may request EAJR if all of the following conditions are met:

1. A review entity (i.e., an entity of up to three reviewers who are ALJs or members of the Departmental Appeals Board, as determined by the Secretary) must certify that the MAC does not have the authority to decide the question of law or regulation
relevant to the matters in dispute and that there is no material issue of fact in dispute (see §110.2.4);

2. An IRE has made a reconsideration determination and the enrollee has filed a request for an ALJ hearing in accordance with §90 and a final decision, dismissal order, or remand order of the ALJ has not been issued, or an ALJ has made a decision and the enrollee has filed a request for MAC review in accordance with §100 and a final decision, dismissal order, or remand order of the MAC has not been issued;

3. The amount remaining in controversy meets the threshold requirements established annually by the Secretary (see §110.1); and

4. If there is more than one enrollee to the hearing or MAC review, each enrollee concurs, in writing, with the request for the EAJR.

110.2.2 - Content of the Request
(Rev. 9, 2/22/13)

The request for EAJR must:

1. Allege that there are no material issues of fact in dispute and identify the facts that the enrollee considers material and that are not disputed; and

2. Assert that the only factor precluding a decision favorable to the enrollee is:
   a. A statutory provision that is unconstitutional, or a provision of a regulation that is invalid and specify the statutory provision that the enrollee considers unconstitutional or the provision of a regulation that the enrollee considers invalid; or
   b. A CMS Ruling that the enrollee considers invalid;

3. Include a copy of the IRE reconsideration and of any ALJ hearing decision that the enrollee has received;

4. If the IRE reconsideration or ALJ hearing decision was based on facts that the enrollee is disputing, state why the enrollee considers those facts to be immaterial; and

5. If the IRE reconsideration or ALJ hearing decision was based on a provision of a law, regulation, or CMS Ruling in addition to the one the enrollee considers unconstitutional or invalid, state why further administrative review of how that provision applies to the facts is not necessary.
110.2.3 - How to File a Request  
(Rev. 9, 2/22/13)

The enrollee may include an EAJR request in his or her request for an ALJ hearing or MAC review. If an appeal is already pending with an ALJ, the enrollee may file the EAJR request with the ALJ at any time before receipt of the notice of the ALJ's decision. If an appeal is already pending with the MAC, the enrollee may file the EAJR request with the MAC at any time before receipt of notice of the MAC's decision.

The ALJ hearing office or MAC forwards the request to the review entity within 5 calendar days of receipt.

110.2.4 – Review Entity Determination  
(Rev. 9, 2/22/13)

Within 60 calendar days after the date the review entity described in §110.2.1 receives an EAJR request (and accompanying documents and materials) meeting the conditions stated in §§110.2.1, 110.2.2, and 110.2.3, the review entity will issue either a certification or a denial of the EAJR request.

Note: If the review entity fails to make a determination within the 60 day timeframe, the enrollee may bring a civil action in Federal District Court within 60 calendar days of the end of the timeframe.

If the review entity issues a certification, the enrollee has 60 calendar days (beginning on the date of the review entity's certification) to bring the civil action in Federal District Court.

Note: The enrollee must satisfy the requirements under section 205(g) of the Act, as well as the requirements for filing a civil action in a Federal District Court under 42 CFR 423.2136.

Note: The enrollee that requested the EAJR is considered to have waived any right to completion of the remaining steps of the administrative appeals process regarding the matter certified.

If the review entity denies a request for EAJR, it advises the enrollee in writing that the request has been denied, and returns the request to the ALJ hearing office or the MAC, which will treat it as a request for an ALJ hearing or for MAC review, as appropriate.

Note: Whenever a review entity forwards a rejected EAJR request to an ALJ hearing office or the MAC, the appeal is considered timely filed and the 90 calendar day decision making timeframe begins on the day the request is received by the hearing office or the MAC.
A determination by the review entity either certifying that the requirements for EAJR are met or denying the request is not subject to review by an ALJ or the MAC.

120 - Reopening and Revising Determinations and Decisions
(Rev. 9, 2/22/13)

A reopening is a remedial action taken to change a binding determination or decision even though the binding determination or decision may have been correct at the time it was made based on the evidence of record. That action may be taken by:

1. A Part D plan sponsor to revise a coverage determination or redetermination;
2. An IRE to revise a reconsideration;
3. An ALJ to revise a hearing decision; or
4. The MAC to revise an ALJ hearing or review decision.

A Part D plan sponsor must process clerical errors (which include minor errors and omissions) as reopenings, instead of redeterminations. A clerical error may occur, for example, when a plan sponsor miscalculates the amount paid by the enrollee towards satisfying the catastrophic coverage threshold. The plan sponsor has discretion in determining what meets the definition of clerical error, and therefore, what could be corrected through a reopening. It should be noted that there are few clerical errors that should be handled through reopening. If the plan sponsor receives a request for reopening and does not agree that the issue is a clerical error, the plan sponsor must dismiss the reopening request and advise the enrollee of any appeal rights, provided the time frame to request an appeal on the original denial has not expired. For purposes of this section, clerical error includes human and mechanical errors on the part of the plan sponsor such as:

1. Mathematical or computational mistakes;
2. Inaccurate data entry; or
3. Denials of claims as duplicates.

When an enrollee has filed a valid request for an appeal of a coverage determination, redetermination, reconsideration, ALJ hearing, or MAC review, the previous adjudicator no longer has jurisdiction to reopen and modify its decision until all appeal rights are exhausted, or a subsequent request by the appellant to withdraw has been granted. Once the appeal rights have been exhausted or a subsequent request by the appellant to withdraw has been granted, the Part D plan sponsor, IRE, ALJ, or MAC may conduct a reopening as set forth in this section.

A plan sponsor cannot reopen and modify its decision if additional information is received after an enrollee files a request for an IRE reconsideration or the adjudication time frame at the coverage determination or redetermination levels have expired and the plan is required
to forward the enrollee's request to the IRE, unless a subsequent request by the appellant to withdraw has been granted. If an enrollee has not requested a review by the IRE (or the applicable adjudication time frame has not expired) and the plan sponsor receives additional information that would change the plan's decision, the plan may reopen its decision and modify it as described under 42 CFR 423.1978.

The decision by the Part D plan sponsor, IRE, ALJ, or MAC on whether to reopen is final and not subject to appeal.

The filing of a request for a reopening with the IRE, ALJ, or MAC, does not relieve the Part D plan sponsor of its obligation to make payment for, authorize, or provide benefits as specified in this chapter.

120.1 - Guidelines for Reopening
(Rev. 1, 11-30-05)

A request for reopening must:

1. Be made in writing;
2. Be clearly stated;
3. Include the specific reason for requesting the reopening (a statement of dissatisfaction is not grounds for a reopening); and
4. Be made within the time frames permitted for reopening (as set forth in §120.2).

120.2 - Time Frames and Requirements for Reopening
(Rev. 9, 2/22/13)

A Part D plan sponsor may reopen a coverage determination or redetermination on its own initiative:

1. Within 1 year from the date of the coverage determination or redetermination for any reason.
2. Within 4 years from the date of the coverage determination or redetermination for good cause as defined in §120.3.
3. At any time if there exists reliable evidence (i.e., relevant, credible, and material) that the coverage determination or redetermination was procured by fraud or similar fault.

Note: Plan sponsors must afford enrollees appropriate access to the appeals process by not repeatedly reopening coverage determinations and redeterminations after denial notices have been sent. As noted above, per 42 C.F.R. 423.1980(b) a Part D plan sponsor
may reopen its coverage determination or redetermination for any reason within 1 year from the date of the decision. However, per 423.1980(a)(2), if an enrollee has filed a valid request for an appeal, no adjudicator has jurisdiction to reopen an issue that is under appeal. So, if the enrollee or prescriber has submitted evidence after the coverage determination or redetermination request has been denied, the plan must ascertain whether the enrollee or prescriber is seeking an appeal. A reopening is a remedial action and, as such, routine use of the reopening process may indicate that the plan is routinely not processing coverage determinations properly, for example, when a plan sponsor is not diligent in soliciting necessary clinical information from prescribers to support coverage determination requests. If the plan sponsor has issued a denial letter with appeal rights and the enrollee or prescriber then submits additional information or a request disputing the denial then that should generally be treated as an appeal.

A Part D plan sponsor may reopen a coverage determination or redetermination at the request of an enrollee under the following conditions:

1. An enrollee may request that a Part D plan sponsor reopen its coverage determination or redetermination within 1 year from the date of the coverage determination or redetermination for any reason.

2. An enrollee may request that a Part D plan sponsor reopen its coverage determination or redetermination within 4 years from the date of the coverage determination or redetermination for good cause in accordance with §120.3.

Reopening IRE reconsiderations, ALJ hearing decisions, and MAC reviews:

1. An IRE may reopen a reconsideration on its own motion, or at an enrollee's or plan sponsor’s request, within 180 calendar days from the date of the reconsideration for good cause in accordance with §120.3. If the IRE's reconsideration was procured by fraud or similar fault, the IRE may reopen at any time on its own motion.

2. An ALJ or the MAC may reopen a hearing decision on his or her own motion, or at an enrollee's or plan sponsor’s request, within 180 calendar days from the date of the hearing decision for good cause in accordance with §120.3. If the ALJ's hearing decision was procured by fraud or similar fault, the ALJ or the MAC may reopen at any time on its own motion.

3. The MAC may reopen its review decision on its own motion or at an enrollee's or plan sponsor’s request, within 180 calendar days from the date of the review decision for good cause in accordance with §120.3. If the MAC's decision was procured by fraud or similar fault, the MAC may reopen at any time on its own motion.
120.3 - Good Cause for Reopening
(Rev. 9, 2/22/13)

Good cause for reopening may be established when:

1. There is new and material evidence that was not available or known at the time of the determination or decision, and may result in a different conclusion; or

2. The evidence that was considered in making the determination or decision clearly shows on its face that an obvious error was made at the time of the determination or decision.

Change in Substantive Law or Interpretative Policy
A change of legal interpretation or policy by CMS in a regulation, CMS ruling, or CMS general instruction, whether made in response to judicial precedent or otherwise, is not a basis for reopening a determination or hearing decision under this section. This provision does not preclude Part D plan sponsors from conducting reopenings to effectuate coverage determinations.

An adjudicator may reopen a determination or decision to apply the current law or CMS or the Part D plan sponsor policy rather than the law or CMS or the Part D plan sponsor policy at the time the coverage determination is made in situations where the enrollee has not yet received the drug and the current law or CMS or the Part D plan sponsor policy may affect whether the drug should be received.

Third Party Payer Error
A request to reopen a claim based upon a third party payer's error in making a primary payment determination when Medicare processed the claim in accordance with the information in its system of records or on the claim form does not constitute good cause for reopening.

120.4 - Definition of Terms in the Reopening Process

120.4.1 - Meaning of New and Material Evidence
(Rev. 1, 11/30/05)

The mere submission of additional evidence is not a basis for reopening in and of itself. “New and material evidence” is evidence not considered when making the previous decision. This evidence must show facts not previously available, which could possibly result in a different decision. New information also includes a new interpretation of existing information (e.g., a different interpretation of a benefit). New and material evidence may include medical evidence not available at the time of decision, but does not include medical, clinical, or other scientific evidence that was, or reasonably could have been, available to the decision-maker at the time the decision was made.
120.4.2 - Meaning of Clerical Error  
(Rev. 1, 11/30/05)

A clerical error includes human and mechanical errors such as mathematical or computational mistakes, inaccurate coding, and computer errors.

120.4.3 - Meaning of Obvious Error on the Face of the Evidence  
(Rev. 1, 11/30/05)

An obvious error on the face of the evidence exists if the determination or decision is clearly incorrect based on all the evidence present in the case file. For example, a piece of evidence could have been contained in the file, but misinterpreted or overlooked by the person making the determination.

120.5 - Notice of a Revised Determination or Decision

120.5.1 - Reopenings Initiated by Adjudicators  
(Rev. 9, 2/22/13)

When any determination or decision is reopened and revised as provided in §120 by adjudicators, the Part D plan sponsor, IRE, ALJ, or MAC must mail its revised determination or decision to the enrollee at his or her last known address, and to the Part D plan sponsor. An adverse revised determination or decision must state the rationale and basis for the reopening and revision and any right to appeal.

120.5.2 - Reopenings Initiated at the Request of a Party  
(Rev. 9, 2/22/13)

The Part D plan sponsor, IRE, ALJ, or MAC must mail a revised determination or decision to the enrollee at his or her last known address, and to the Part D plan sponsor. An adverse revised determination or decision must state the rationale and basis for the reopening and revision and any right to appeal.

120.6 - Effect of a Revised Determination or Decision  
(Rev. 9, 2/22/13)

A revised determination or decision is binding unless it is appealed or otherwise reopened.

If an enrollee wishes to appeal a revised determination or decision, only the portion of the determination or decision revised by the reopening may be appealed.
In general, a favorable coverage determination or appeal decision is retroactive to the date of the earliest request or prescription purchase approved in a coverage determination or appeal decision.

Since exceptions are valid for the remainder of the plan year, all prescriptions purchased between the date of the earliest prescription approved under a coverage determination or appeal decision (that involves an exception) and the end of the plan year are reimbursable.

**Example:** UM requirement allows a 30-day supply for Drug X if a certain requirement is satisfied. The enrollee purchases a 30-day supply of Drug X on 6/1/12. On 9/1/12, the enrollee submits a request for reimbursement for the 6/1/12 purchase and asks the plan not to apply the UM requirement for reasons of medical necessity (i.e., files a formulary exception request). On 9/15/12, the plan approves the request on appeal. The approval is retroactive to the 6/1/12 purchase, and all subsequent purchases for Drug X in 2012 are approved (i.e., the plan cannot require the enrollee to go through the coverage determination process for approval of Drug X from 6/1/12 until the end of the plan year).

If a request involves a UM requirement (and the member is not requesting an exception), the favorable decision is retroactive to the date of the earliest prescription purchase approved under a coverage determination or appeal decision, but does not extend beyond the terms of the UM requirement for any purchase not approved in the decision except for any purchase for which the plan chooses to do so.

**Example 1:** A UM requirement allows a 30-day supply for Drug X if a certain requirement is satisfied. The enrollee purchases a 30-day supply of Drug X on 6/1/12. On 9/1/12, the enrollee submits a request for reimbursement for the 6/1/12 purchase and attempts to show that the UM requirement has been met. On 9/15/12, the plan approves the request on appeal. The 9/15/12 decision is retroactive to the 6/1/12 purchase. The member is required to complete the coverage determination/UM process for Drug X purchases made after 6/1/12. **Note:** A plan may choose not to require enrollees to submit subsequent requests once a coverage determination involving a UM is approved.

**Example 2:** A UM requirement allows a 30-day supply for Drug X if a certain requirement is satisfied. The enrollee purchases a 30-day supply of Drug X on 6/1/12, and a 30-day supply of Drug X on 7/1/12. On 9/1/12, the enrollee submits a request for reimbursement for the 6/1/12 and 7/1/12 purchases and attempts to show that the UM requirement has been met for both dates. On 9/15/12, the plan approves the request on appeal. The 9/15/12 decision is retroactive to the 6/1/12 purchase and also covers the 7/1/12 purchase. The member is required to complete the coverage determination/UM process for Drug X purchases made after 7/1/12. **Note:** A plan may choose not to require enrollees to submit subsequent requests once a coverage determine involving a UM is approved.
130.1 - Effectuating Coverage Determinations
(Rev. 9, 2/22/13)

If a plan sponsor approves a standard request for benefits, it must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receiving the request for coverage determination or physician's or other prescriber's supporting statement (for an exception request). See the note in §40.2 regarding when a request or supporting statement is deemed received by a plan sponsor.

If a plan sponsor approves a standard request for payment, it must make payment within 14 calendar days after receiving the request. See the note in §40.2 regarding when a request is deemed received by a plan sponsor.

If a plan sponsor approves an expedited request for benefits, it must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the coverage determination request or physician's or other prescriber's supporting statement (for an exception request). See the note in §40.2 regarding when a request or supporting statement is deemed received by a plan sponsor.

130.2 - Effectuating Determinations Reversed by the Part D Plan Sponsor

130.2.1 - Standard Requests for Benefits
(Rev. 2, 6/22/06)

If the Part D plan sponsor reverses its initial adverse coverage determination (i.e., initial benefit denial), the plan must authorize or provide the benefit under dispute as expeditiously as the enrollee’s health condition requires, but no later than 7 calendar days from the date it receives the request for redetermination. See the note in §40.2 regarding when a request is deemed received by a plan sponsor.

130.2.2 - Expedited Requests for Benefits
(Rev. 2, 6/22/06)

If, on appeal of an expedited request for benefit, the Part D plan sponsor reverses its initial coverage determination, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee’s health condition requires, but no later than 72 hours after the date the Part D plan sponsor receives the request for redetermination. See the note in §40.2 regarding when a request is deemed received by a plan sponsor.

130.2.3 - Payment Requests
(Rev. 2, 6/22/06)

If the Part D plan sponsor reverses its initial adverse coverage determination (i.e., initial payment denial), the plan must authorize payment for the benefit within 7 calendar days from the date it receives the request for redetermination, and make payment (i.e., mail the
payment) no later than 30 calendar days after the date the plan sponsor receives the request for redetermination. See the note in §40.2 regarding when a request is deemed received by a plan sponsor.

130.3 - Effectuating Decisions by All Other Review Entities

130.3.1 - Standard Requests for Benefits
(Rev. 6, 1/1/09)

If the Part D plan sponsor’s decision is reversed in whole or in part by any other appeal entity, the Part D plan sponsor must authorize or provide the benefit under dispute within 72 hours from the date it receives notice from the appeal entity reversing the determination. The Part D plan sponsor must inform the IRE that the Part D plan sponsor has effectuated the decision.

CMS has developed a model notice that Part D plan sponsors can use to notify the IRE when it has effectuated a decision (see Appendix 9).

130.3.2 - Expedited Requests for Benefits
(Rev. 6, 1/1/09)

If the Part D plan sponsor’s decision is reversed in whole or in part by any other appeal entity, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee’s health condition requires, but no later than 24 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the IRE that the Part D plan sponsor has effectuated the decision.

CMS has developed a model notice that Part D plan sponsors can use to notify the IRE when it has effectuated a decision (see Appendix 9).

130.3.3 - Payment Requests
(Rev. 6, 1/1/09)

If the Part D plan sponsor’s decision is reversed in whole or in part by any other appeal entity, the Part D plan sponsor must authorize payment for the benefit within 72 hours, and make payment (i.e., mail the payment) no later than 30 calendar days from the date it receives notice reversing the coverage determination. The Part D plan sponsor must inform the IRE that the Part D plan sponsor has effectuated the decision.

CMS has developed a model notice that Part D plan sponsors can use to notify the IRE when it has effectuated a decision (see Appendix 9).
130.4 - Independent Review Entity Monitoring of Effectuation Requirements  
(Rev. 1, 11/30/05)

CMS requires its IRE to monitor Part D plan sponsor's compliance with determinations or decisions that fully or partially reverse a Part D plan sponsor's adverse coverage determination. The process is as follows:

1. The IRE forwards a copy of the fully or partially favorable decision and other information necessary to effectuate the decision to the Part D plan along with a Notice of Requirement to Comply.

2. Pursuant to the compliance notice, the Part D plan sponsor is required to mail the IRE a statement attesting to compliance with the decision by the IRE, ALJ, MAC, or Federal court. This documentation must state when and how compliance occurred (e.g., benefit authorization, payment made, etc.). Notification to the IRE that the Part D plan sponsor intends to pay for or provide the benefit will not be considered appropriate compliance with the effectuation requirements. The Part D plan sponsor must provide the IRE with affirmative notice of effectuation (see Appendix 9). The Part D plan sponsor’s notice of compliance should be forwarded to the IRE concurrent with the Part D plan sponsor’s effectuation.

3. If the IRE does not obtain the compliance notice, it must mail the Part D plan sponsor a reminder notice.

4. If the IRE does not receive the Part D plan sponsor’s compliance notice within 30 days of the reminder notice, the IRE must report the Part D plan sponsor’s failure to comply to CMS. The Part D plan sponsor is not copied on the notice to CMS.

130.5 - Effectuation Requirements for Former Part D Plan Sponsor Members  
(Rev. 1, 11/30/05)

If a Part D plan sponsor terminates its contract with CMS, appeals that are pending with the Part D plan sponsor, IRE, or any higher appeal level after such termination must be effectuated if the plan sponsor, IRE, or other higher appeal entity overturns the Part D plan sponsor’s initial adverse coverage determination. Since the Part D contract and the regulations at 42 CFR 423.505(b)(4) require Part D plan sponsors to provide basic prescription drug coverage (and to the extent applicable, supplemental coverage) for the duration of their contracts, Part D plan sponsors are obligated to process and effectuate any appeals from coverage determinations (in connection with both prescription drug benefits and/or payment of benefits) that are determined to be covered, and which should have been provided or paid for while Medicare enrollees were enrolled in the plan. Thus, if appeals are pending at the time a plan sponsor terminates its contract with CMS, the plan must
effectuate any favorable determinations that are issued following the date of termination in accordance with §130.

140 - Data
(Rev. 3, 2/1/07)

Part D plan sponsors are responsible for reporting certain data related to grievances, coverage determinations, and appeals. Information about the reporting requirements can be obtained on CMS' Plan Reporting and Oversight webpage:
http://www.cms.hhs.gov/PrescriptionDrugCovContra/08_RxContracting_ReportngOversight.asp.
Appendix 1 - Notice of Denial of Medicare Prescription Drug Coverage

(Rev. 9, 2/22/13)

Appendix 2 - Appointment of Representative - Form CMS-1696

(Rev. 9, 2/22/13)

The form, Appointment of Representative - Form CMS-1696 can be found on the CMS forms page: http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-Items/CMS012207.html. If an appointment is made using Form CMS-1696 or an equivalent written notice, the plan sponsor must accept it. Plan sponsors are prohibited from requiring the use of a specific form (other than Form CMS-1696 or an equivalent written notice) for appointments.
Appendix 3 - (Model) Notice of Right to an Expedited Grievance  
(Rev. 9, 2/22/13)

[INSERT NAME OF MEDICARE PART D PLAN]

Date: Patient Name: Patient ID Number:

<Street Address>  <City, State Zip Code>

Notice of Right to an Expedited Grievance

You are receiving this notice because we are denying your request to expedite (put on a fast track) your initial request for a Part D drug.

You are receiving this notice because we are denying your request to expedite (put on a fast track) your appeal for a Part D drug.

Your request has been transferred to our regular processing time frame.

Initial requests will be processed no later than 72 hours and appeal requests will be will be processed no later than 7 calendar days from the day we received your request.

You may resubmit your request.

You may resubmit your request to expedite (put on a fast track) your initial request or appeal. If your prescribing physician or other prescriber tells us that applying the standard time frame could put your life or health at risk, we will automatically expedite your request.

You may file an expedited grievance.

If you disagree with our decision not to give you a fast decision, you may file an expedited grievance with us. We must decide within 24 hours if our decision to deny making a fast decision puts your life or health at risk.

If we determine that we should have expedited your request, we will do so immediately and notify you of our decision.

Please call us at {insert phone number of health plan contact} if you want to file an expedited grievance, or want more information.

You can also call 1-800-MEDICARE for more information about the expedited grievance process.
Appendix 4 - (Model) Notice of Redetermination

(Rev. 9, 2/22/13)

[LOGO]

Redetermination Notice
Denial of Medicare Prescription Drug Coverage

Date:

Enrollee’s name:  <Insert Name>   Enrollee’s Medicare (HIC) number:  <Insert HICN>
<Street Address>
<City, State Zip Code>

Plan Name:  <Insert Plan Name>   Contract ID: <Insert Contract ID>
Formulary ID: <Insert Formulary ID>    Plan ID: <Insert Plan ID>

We agree with our initial coverage determination and are denying the following prescription drug(s) that you or your physician or other prescriber requested:

We denied this request because: 


What If I Don’t Agree With This Decision?

You have the right to ask for an independent review (appeal) of our decision. If your case involves an exception request and your physician or other prescriber did not already provide your plan with a statement supporting your request, your physician or other prescriber must provide a statement to support your exception request and you should attach a copy of this statement to your appeal request. If you want to appeal our decision, you must request your appeal in writing within 60 calendar days after the date of this notice. You must mail or fax your written request to the independent reviewer at:

Requests from PDP and MA-PD Plans:  Customer Service:
MAXIMUS Federal Services   Toll-free: (877) 456-5302
3750 Monroe Ave., Suite #703
Pittsford, NY  14534-1302

Fax Numbers:
Toll-free: (866) 825-9507
(585) 425-5301

Who May Request an Appeal?

You, your prescriber, or someone you name to act for you (your representative) may request an appeal. You can name a relative, friend, advocate, attorney, doctor, or someone else to act for you. An Appointment of Representation is not needed if the person appealing is your prescriber or is authorized under State law to act for you (for example, through a health care power of attorney or health care proxy).

You can call us at: (      ) _________________ to learn how to name your representative. If you have a hearing or speech impairment, please call us at TTY (      ) _________________.

IMPORTANT INFORMATION ABOUT YOUR APPEAL RIGHTS
For more information about your appeal rights, call us or see your Evidence of Coverage.

There Are Two Kinds of Appeals You Can Request

Expedited (72 hours) - You can request an expedited (fast) appeal for cases that involve coverage, if you or your doctor believes that your health could be seriously harmed by waiting up to 7 days for a decision. If your request to expedite is granted, the independent reviewer must give you a decision no later than 72 hours after receiving your appeal (the timeframe may be extended in limited circumstances).

- If the doctor who prescribed the drug(s) asks for an expedited appeal for you, or supports you in asking for one, and the doctor indicates that waiting for 7 days could seriously harm your health, the independent reviewer will automatically expedite the appeal.
- If you ask for an expedited appeal without support from a doctor, the independent reviewer will decide if your health requires an expedited appeal. If you do not get an expedited appeal, your appeal will be decided within 7 days.
- Your appeal will not be expedited if you've already received the drug you are appealing.

Standard (7 days) - You can request a standard appeal for a case involving coverage or payment. The independent reviewer must give you a decision no later than 7 days after receiving your appeal (the timeframe may be extended in limited circumstances).

What Do I Include with My Appeal?
You should include your name, address, HIC number, the reasons for appealing, and any evidence you wish to attach. If the appeal is made by someone other than you or your doctor or other prescriber, the person must submit a document appointing him or her to act for you. If your appeal relates to a decision by us to deny a drug that is not on our list of covered drugs (formulary) or if you are asking for an exception to a prior authorization (PA) or other utilization management (UM) requirement, your prescribing doctor or other prescriber must submit a statement with your appeal request indicating that all the drugs on any tier of our formulary (or the PA/UM requirement) would not be as effective to treat your condition as the requested drug, or would harm your health.

How Do I Request an Appeal?
You, your prescriber or your representative should mail or fax your written appeal request to:

[Insert Part D QIC address and fax number]

What Happens Next? If you appeal, the independent reviewer will review your case and give you a decision. If any of the prescription drugs you requested are still denied, you can appeal to an administrative law judge (ALJ) if the value of your appeal is at least $130. If you disagree with the ALJ decision, you will have the right to further appeal. You will be notified of your appeal rights if this happens.

Contact Information:
If you need information or help, call us at:
Toll Free: [Insert toll free number]
TTY: [Insert TTY number]

Other Resources To Help You:
Medicare Rights Center
Toll Free: 1-888-HMO-9050
TTY: [Insert TTY number]

Elder Care Locator
Toll Free: 1-800-677-1116

1-800-MEDICARE (1-800-633-4227)
Appendix 5 - Medicare Prescription Drug Coverage and Your Rights

(Rev. 9, 2/22/13)

NOTICE OF CASE STATUS

<Date>
Member Name  
Street Address  
City, State Zip Code  
Member ID Number: <111-11-1111A>  
Case Number: <insert number>

Dear <insert name>:

This letter is to inform you that your request for a [“standard initial decision for benefits”] [“standard initial decision for reimbursement”] [“fast initial decision”] [“standard” appeal] [“fast” appeal] was forwarded to an independent organization for review on <insert date>.

[For a “standard initial decision” request [for benefits] [for reimbursement]: Your case file was forwarded to an independent review organization because we did not provide you with an answer within [72 hours] [14 days] after receiving your request.]

[For a “fast initial decision” request: Your case file was forwarded to an independent review organization because we did not provide you with an answer within 24 hours after receiving your request.]

[For a “standard” appeal: Your case file was forwarded to an independent review organization because we did not provide you with an answer within 7 calendar days after receiving your appeal.]

[For a “fast” appeal: Your case file was forwarded to an independent review organization because we did not provide you with an answer within 72 hours after receiving your appeal.]

The law requires us to forward your case file to an independent review organization within 24 hours if we do not provide you with an answer within the required time frame.

The independent review organization has a contract with the Centers for Medicare & Medicaid Services (CMS), the government agency that runs the Medicare program. The independent review organization has no connection to us. You have the right to ask us for a copy of your case file that we sent to this organization. [Plans must indicate if there is a charge for the copy.]

You have the right to submit additional evidence about your case. If you choose to submit additional evidence, you should send it promptly to the independent review organization at <address><fax>.

If you have any questions, or if you would like to request a copy of your case file, please contact Customer Services at <toll-free number> <days and hours of operation>. TTY users should call <toll-free TTY number>.

Thank You.

<Plan name>
Appendix 7 - (Model) Notice of Plan's Decision to Extend the Deadline for Making a Decision Regarding a Grievance
(Rev. 1, 11/30/05)

<Date>

Member Name
Street Address
City, State Zip Code

Member ID Number: <111-11-1111A>

Dear <Insert name>:

This letter is in response to your grievance (complaint) that you filed with us on <insert date>.

Based upon our review, we are extending the time frame for making a decision until <insert date> because <Plan should list reason for extension, i.e., if the enrollee requested the extension or if the Plan needs more information. If the Plan needs more information, the Plan must also detail how the delay is in the best interest of the enrollee>.

If you have any questions, please contact Customer Services at <toll-free number> <days and hours of operation>. TTY/TDD users should call <toll-free TTY number>.

Thank you for your concern.

<Plan name>
Appendix 8 - (Model) Notice of Plan’s Decision Regarding a Grievance  
(Rev. 1, 11/30/05)

<Date>

Member Name  
Street Address  
City, State Zip Code

Member ID Number: <111-11-1111A>

Dear <Insert name>:

This letter is in response to your grievance (complaint) that you filed with us on <insert date>.

Based upon our review, <Plan should insert decision>.

<For grievances related to quality of care, the notice to the enrollee must include a description of the enrollee’s right to file a written complaint with the quality improvement organization (QIO)>. 

If you have any questions, please contact Customer Services at <toll-free number> <days and hours of operation>. TTY/TDD users should call <toll-free TTY number>.

Thank you for your concern.

<Plan name>
Appendix 9 - (Model) Notice of Effectuation to Part D Independent Review Organization
(Rev. 1, 11/30/05)

<Date>

[Part D QIC]
Street Address
City, State Zip Code

Member ID Number: <111-11-1111A>
Case Number: <insert number>

Dear <insert name>:

[For requests for benefits:

We received notice of the decision made on <insert date> for Case Number <insert number>.
In accordance with this decision, the benefit(s) under dispute was/were provided to the enrollee on <insert date>.]

[For requests for payment:

We received notice of the decision made on <insert date> for Case Number <insert number>.
In accordance with this decision, payment for the benefit was made on <insert date>.]

Thank you.

<Plan name>
Appendix 10 - (Model) Notice of Formulary or Cost-sharing Change
(Rev. 8, 2/24/10)

<Date>

Member Name
Street Address
City, State Zip Code

Member ID Number: <111-11-1111A>

Dear <insert name>:

This letter is to inform you of a change to our formulary.

Effective on <insert date>, <insert name of drug> <Plan must state if the drug is being removed from the formulary or if there has been a change to the drug’s preferred or tiered cost-sharing status. >

We are <removing or changing the tiering structure of> <insert name of drug> because <Plan must explain the reason for removal of the drug from the formulary or why there is a change to the drug’s preferred or tiered cost-sharing status. >

You may be able to use another drug to treat your medical condition that <is on our formulary or is in the same drug tier as > <insert drug name. > These drugs include <Plan must indicate alternative drugs that are in the same therapeutic category/class or in the same cost-sharing tier. > You should ask your prescriber if one of these drugs is right for you. If your prescriber prescribes one of these drugs for you, your expected cost will be <Plans must indicate the expected cost of the alternative drug(s). >

If your prescriber believes that none of the drugs listed above is right for you due to your medical condition, you may request <an exception to our formulary or a tiering exception. > To file a request, <Plan must describe the process for filing an exception, including the need for the prescribing physician’s or other prescriber's supporting statement, and refer the enrollee to the appropriate section(s) in the EOC for more information. >

Or, you can call us at <insert toll-free number> for help in asking for this type of decision.

If you disagree with our decision to <remove or change the tiering structure of> <insert name of drug>, you may also file a grievance with us. Please call us at <toll-free number> if you want to file a grievance. You may also send your grievance to us in writing by <Describe the process for filing a written grievance, and refer the enrollee to the appropriate section(s) in the EOC for more information>.  

Thank you.

<Plan name>
Appendix 11 - (Model) Request for Additional Information
(Rev. 8, 1/1/10)

<Date>

Member Name
Street Address
City, State Zip Code

Member ID Number: <111-11-1111A>
Case Number: <insert number>

Dear <insert name>:

This letter is in response to your request for a <indicate type of request, e.g., formulary or tiering exception, expedited redetermination> that <you OR your physician or other prescriber> filed with us on <insert date>. <A “formulary exception” request is when you ask for a drug that is not on <Plan name>’s list of covered drugs (called a "formulary"), or ask us not to apply a prior authorization or other requirement to a drug on our formulary >. OR <A “tiering exception” request is when you ask for a non-preferred drug at the preferred cost level>.

In order to process your request, we need additional information from your physician or other prescriber.

<Plans must specifically describe the type of written documentation they require from the physician. or other prescriber >

For formulary exceptions: Plans may require a statement that the drug is medically necessary to treat the enrollee’s condition because: (1) all of the covered drugs on the Plan’s formulary for the same condition would not be as effective for the enrollee as the non-formulary drug, would have adverse effects for the enrollee, or both; (2) step therapy has been or is likely to be ineffective or adversely affect the drug’s effectiveness or patient compliance, or has caused or is likely to cause an adverse reaction to the enrollee; or (3) the number of doses that is available under a dose restriction for the drug has been or is likely to be ineffective or adversely affect the drug’s effectiveness or patient compliance.

For tiering exceptions: Plans may require a statement that the preferred drug for the treatment of the enrollee’s condition would not be as effective as the requested drug and/or that the preferred drug would have adverse effects for the enrollee.

If applicable, for either type of exception request, Plans must also indicate if this letter is a request for additional supporting medical documentation>.

If you have any questions, please contact Customer Services at <toll-free number> <days and hours of operation>. TTY/TDD users should call <toll-free TTY number>.

Thank you.

<Plan name>
Appendix 12 - (Model) Notice of Inquiry  
(Rev. 9, 2/22/13)

>Date>

Member Name  
Street Address  
City, State Zip Code

Member ID Number: <111-11-1111A>

Dear <insert name>:

This letter is in response to your inquiry on <insert date>.

You asked if <insert name of drug> is covered for you.

<Under section 1860D-2(e)(1) of the Social Security Act (the Act), certain drugs are not covered Part D drugs or are not covered Part D drugs when used to treat certain medical conditions.> or <Under section 1860D-2(e)(2) of the Social Security Act (the Act), certain drugs are excluded from Medicare coverage or are excluded from coverage when used to treat certain medical conditions.> or <Under section 1860D-43 of the Social Security Act (the Act), certain drugs are excluded from Medicare coverage if the manufacturer did not sign an agreement to participate in the Medicare Coverage Gap Discount Program.>

<Insert name of drug> is one of the drugs that is <not a covered Part D drug> or <excluded from Medicare coverage> by law, and we do not offer the drug as a supplemental benefit.

[If a drug is not a covered Part D drug or is excluded from coverage because of the indication, insert language explaining why the drug isn't covered and the indication(s) that the drug would be covered for. For example: 
Under Medicare law, Actiq is a covered Part D drug only when it is prescribed for breakthrough cancer pain. Because your physician or other prescriber prescribed Actiq to relieve your back pain, it is not a covered Part D drug.]

You should work with your physician or other prescriber to determine if a drug on our list of covered drugs (our formulary) is medically appropriate for treating your condition.

[If the drug is excluded from coverage, insert the following language:] <If you receive Medicaid, you may be able to obtain coverage for this drug under the Medicaid program. Check with your state Medicaid office.>
If, after reading this letter, you have reason to believe that we made a mistake and <insert name of drug> is <a covered Part D drug under section 1860D-2(e)(1) of the Act> or <not excluded under section 1860D-2(e)(2) of the Act> or <not excluded under section 1860D-43 of the Act> or is covered by the plan as a supplemental benefit, you or your physician or other prescriber have the right to contact us and request a coverage determination. Contact us at the number below or refer to your evidence of coverage to find out how to ask us for a coverage determination.

If you have any questions, please contact Customer Services at <toll-free number> <days and hours of operation>. TTY/TDD users should call <toll-free TTY number>.

Thank you.

<Plan name>
Appendix 13 - (Model) Request for Reconsideration  
(Rev. 9, 2/22/13)
Part D plans must include this Request for Reconsideration form with each adverse Redetermination Notice and must complete the following plan identifying information:

Plan Name: <Insert Plan Name>  
Contract ID: <Insert Contract ID>

Formulary ID: <Insert Formulary ID>  
Plan ID: <Insert Plan ID>

Request for Reconsideration of Medicare Prescription Drug Denial

Because your Medicare drug plan has upheld its initial decision to deny coverage of, or payment for, a prescription drug you requested, you have the right to ask for an independent review of the plan’s decision. **You may use this form to request an independent review of your drug plan’s decision.** You have 60 days from the date of the plan’s Redetermination Notice to ask for an independent review. Please complete this form and mail or fax it to:

Requests from PDP and MA-PD Plans:  
MAXIMUS, Federal Services  
3750 Monroe Ave., Suite #703  
Pittsford, NY  14534-1302

Customer Service:  
Toll-free: (877) 456-5302

Fax Numbers:  
Toll-free: (866) 825-9507  
(585) 425-5301

Note about Representatives:  **Your prescriber may file a reconsideration request on your behalf without being an appointed representative.** If you want another individual, such as a family member or friend, to request an independent review for you, that individual must be your representative. Contact your Medicare drug plan to learn how to name a representative.

<table>
<thead>
<tr>
<th>Enrollee’s Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrollee’s Name ___________________________ Date of Birth ____________</td>
</tr>
<tr>
<td>Enrollee’s Address ________________________________________________</td>
</tr>
<tr>
<td>City ___________________________ State ____________ Zip Code ____________</td>
</tr>
<tr>
<td>Phone ___________________________</td>
</tr>
<tr>
<td>Enrollee’s Medicare (HIC) Number (as shown on your Medicare card) ____________________________</td>
</tr>
</tbody>
</table>

Complete the following section ONLY if the person making this request is not the enrollee or the enrollee’s prescriber (make sure to attach documentation showing the person’s authority to represent enrollee for purposes of this request):

<table>
<thead>
<tr>
<th>Requestor’s Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requestor’s Name ____________________________</td>
</tr>
<tr>
<td>Requestor’s Relationship to Enrollee ____________________________</td>
</tr>
<tr>
<td>Address ________________________________________________</td>
</tr>
<tr>
<td>City_________________________ State ____________ Zip Code ____________</td>
</tr>
<tr>
<td>Phone ( ) ____________________________</td>
</tr>
</tbody>
</table>
Representation documentation for appeal requests made by someone other than enrollee or prescriber:

Attach documentation showing the authority to represent the enrollee (a completed Form CMS-1696 or a written equivalent) if it was not submitted at the coverage determination or redetermination level. A physician or other prescriber may request an appeal on behalf of an enrollee without being an appointed representative.

Prescription drug you asked your plan to cover: ________________________________

Prescribing Physician's Information

Name ____________________________________________

Address ____________________________________________

City ___________________ State ____________ Zip Code ____________

Office Phone: ____________________ Fax: ____________________

Office Contact Person ____________________________________________

Expedited Decisions

If you or your prescribing physician or other prescriber believe that waiting for a standard decision (which will be provided within 7 days) could seriously harm your life, health, or ability to regain maximum function, you can ask for an expedited (fast) decision. If your prescribing physician or other prescriber indicates that waiting 7 days could seriously harm your life or health or ability to regain maximum function, the independent review organization will automatically give you a decision within 72 hours. This timeframe may be extended for up to 14 calendar days if your case involves an exception request and we have not received the supporting statement from your doctor or other prescriber supporting the request, OR the person acting for you files an appeal request but does not submit proper documentation of representation. If you do not obtain your physician’s or other prescriber's support for an expedited appeal, the independent review organization will decide if your health condition requires a fast decision.

☐ Check this box if you believe you need a decision within 72 hours (if you have a supporting statement from your prescribing physician, attach it to this request)

Please attach any additional information you have related to your appeal such as a statement from your prescribing physician or other prescriber and relevant medical records.

Additional information we should consider: ____________________________________________

__________________________________________

__________________________________________

Important: Please include a copy of the Redetermination (denial) Notice you received from your drug plan with this request.
Signature of person requesting the appeal (the enrollee or the representative):

______________________________  Date: ________________
YOUR RIGHT TO ASK MEDICARE TO REVIEW
YOUR MEDICARE PART D LATE ENROLLMENT PENALTY

What if I Don’t Agree with Medicare’s Late Enrollment Penalty Decision?
“Creditable prescription drug coverage” is coverage (for example from an employer or union) that meets Medicare’s minimum standards since it is expected to pay, on average, at least as much as Medicare’s standard prescription drug coverage. If you don’t join a Medicare drug plan when you are first eligible, and you don’t have other “creditable prescription drug coverage,” you may have to pay a late enrollment penalty (LEP). In some cases you have the right to ask Medicare to review your late enrollment penalty decision. This is called a “reconsideration.” For example, you could request a reconsideration if you think Medicare did not count all of your creditable coverage or if you didn’t get a notice that clearly explained whether your previous prescription drug coverage was creditable. Other reasons for requesting a reconsideration are listed on the request form sent with this notice.

Who Can Ask for a Reconsideration?
You or someone you name to act for you (your representative) can ask for a reconsideration. If someone requests a reconsideration for you, he or she must send proof of his or her right to represent you with the request form. Proof could be a power of attorney form, a court order, or an “Appointment of Representative” form. This last form can be found at http://www.medicare.gov/Basics/forms on the web. You also can call the Medicare helpline (see below) and ask for Form CMS-1696.

How Do I Ask for a Reconsideration?
The reconsideration request form is sent with this notice. Complete the form. Mail it to the address or fax it to the number listed on the form within 60 days from the date on the letter you got stating you had to pay a late enrollment penalty. You should also send any proof that supports your case, like information about previous creditable prescription drug coverage. If you wait more than 60 days, you must explain why your request is late. Medicare will decide if you had good cause to send a late request.

What Do I Need to Include with My LEP Reconsideration Request?
1. A completed, signed LEP reconsideration request (keep a copy).
2. Copies of information you believe may help your case.
3. If you’ve named someone to act for you, a copy of the proof the individual can represent you.

NOTE: Do not send original documents.

Where Can I Get More Information?
Call <Plan Name> at <plan toll-free number> <days and hours of operation>. TTY users should call the plan at <plan TTY number>. <A plan also may include a URL to its website here to provide additional information.> Or, visit www.medicare.gov on the web or call 1-800-MEDICARE (1-800-633-4227) for help. TTY users should call Medicare at 1-877-486-2048
Appendix 15 - (Model) Part D Late Enrollment Penalty (LEP) Reconsideration Request Form
(Rev. 9, 2/22/13)
Please use one (1) Reconsideration Request Form for each Enrollee.

Date: _______________ Medicare Appeal # ________________________________
(For MAXIMUS Federal Services use only)

Enrollee Name: ______________________________________________________
Address: ____________________________________________________________________________________________
City, State, Zip Code: ______________________________________________________________________________________
Phone: (________) ______________________

Medicare Health Insurance Claim # ____________________________________________
(From red, white, and blue Medicare card)

Date of Birth (MM/DD/YYYY): ______________________________

Name of current Part D Drug Plan: ________________________________

IMPORTANT: A signature by the enrollee is required on this form in order to process an appeal.
Complete, sign and mail this request to the address at the end of this form, or fax it to the number listed on the form within 60 days from the date on the letter you received stating you have to pay a late enrollment penalty. If it has been more than 60 days, explain your reason for delay on a separate sheet and send it with this form.

Check all boxes that apply to you (your case will only be reviewed for one or more of the following reasons):

☐ I had other prescription drug coverage as good as Medicare’s (creditable coverage). Please provide evidence of prior creditable prescription drug coverage. For example:

• If you had drug coverage from an employer or union plan, provide a copy of the Notice of Creditable Prescription Drug Coverage or Certificate of Prior Creditable Prescription Drug Coverage from the employer or union plan.
• If you had drug coverage with the Department of Veterans Affairs (VA), please provide any of the following: Notice of Creditable Prescription Drug Coverage; a copy of your VA Health Benefit Card; a letter from the VA certifying eligibility; or an Explanation of Benefits (EOB).
• If you have drug coverage through the Indian Health Service, a Tribe or Tribal organization, or an Urban Indian Organization (I/T/U), please provide a copy of any of the following: IHS registration card; letter verifying eligibility and/or enrollment.

Name of former employer/union/other insurer: ________________________________
Dates of coverage (mm/dd/yyyy) from ________/_______/_______ to ________/_______/_______
Plan Address & Phone: ______________________________________________________________________________________
Contact Name: __________________________________________ Phone: ______________________

☐ I had prescription drug coverage but I didn’t get a notice that clearly explained if my drug coverage was creditable coverage.

Reminder: Most non-Medicare plans that offer prescription drug coverage, like employer or union coverage, must send enrollees a notice explaining how their prescription drug coverage compares to Medicare prescription drug coverage. Plans may provide this information in their benefits handbook or as a separate written notice.
If you don’t know if your prescription drug coverage was creditable:
To help your case, you may want to send a letter to your previous plan and ask if your coverage was creditable. Attach your letter and any response to this form. You shouldn’t wait to receive a response before you send this request form, and there is no need to send a letter if your prior coverage was with a Medicare Part D plan.

☐ I believe the LEP is wrong because I was not eligible to enroll in a Medicare Part D plan during the period stated by my current Medicare Part D plan. Example: You lived outside of the United States during the initial enrollment period stated by your Medicare Part D plan. You must submit proof why you believe the LEP is wrong, such as proof of overseas residency.

☐ I believe the LEP is wrong because I was unable to enroll in a Medicare Part D plan due to a serious medical emergency. You must submit proof that you experienced a serious medical emergency (e.g. unexpected hospitalization) that affected your ability to timely enroll in a Medicare Part D plan.

☐ I have/had extra help from Medicare to pay for my prescription drug coverage.

  • Dates of extra help: from _________________ to _________________.
  • Use a separate sheet if necessary.

☐ I lived in an area affected by Hurricane Katrina at the time of the hurricane (August 2005) and I joined a Medicare drug plan before December 2006.

  • I am attaching evidence of my residency in 2005.
  • Name of Parish: ______________________

By signing this form, I give permission to any entity to release information needed by Medicare or its independent contractor (MAXIMUS Federal Services) to review my Medicare Part D late enrollment penalty appeal.

I certify that the information on this form is true, accurate and complete. I understand that if I have submitted any false documents, made any false claims or statements, or concealed any material facts, I may be subject to civil or criminal liability.

_________________________________   ________________________
Signature of Enrollee           Date

• Be sure to include your Medicare Health Insurance Claim number on any materials you send.
• Do not send original documents.
• Please make sure the enrollee and representative, if applicable, have signed this form.

Send this form and any extra pages to:
MAXIMUS Federal Services
3750 Monroe Avenue, Suite 704
Pittsford, NY 14534-1302
Fax number: (585) 869-3320
Toll Free fax number: (866) 589-5241

Note about Representatives:
If you want another individual, such as a family member, friend, or your doctor to request a reconsideration for you, that individual must be your representative.
Appendix 16 - (Model) Request for Redetermination of Medicare Prescription Drug Denial  
(Rev. 9, 2/22/13)

Request for Redetermination of Medicare Prescription Drug Denial

Because we [Part D plan sponsor] denied your request for coverage of (or payment for) a prescription drug, you have the right to ask us for a redetermination (appeal) of our decision. You have 60 days from the date of our Notice of Denial of Medicare Prescription Drug Coverage to ask us for a redetermination. This form may be sent to us by mail or fax:

Address:       Fax Number:
[Insert plan address(es)]       [Insert plan fax number(s)]

You may also ask us for an appeal through our website at [insert plan web address]. Expedited appeal requests can be made by phone at [insert plan telephone number].

Who May Make a Request: Your prescriber may ask us for an appeal on your behalf. If you want another individual (such as a family member or friend) to request an appeal for you, that individual must be your representative. Contact us to learn how to name a representative.

Enrollee’s Information

Enrollee’s Name _______________________________ Date of Birth ________________

Enrollee’s Address _______________________________________________________________________________

City ___________________ State _______ Zip Code ______________
Phone _______________________

Enrollee’s Plan ID Number _______________________

Complete the following section ONLY if the person making this request is not the enrollee:

Requestor’s Name ____________________________________________

Requestor’s Relationship to Enrollee ____________________________________________

Address _______________________________________________________________________________

City ___________________ State _______ Zip Code ______________
Phone _______________________

Representation documentation for appeal requests made by someone other than enrollee or the enrollee’s prescriber:

Attach documentation showing the authority to represent the enrollee (a completed
Authorization of Representation Form CMS-1696 or a written equivalent) if it was not submitted at the coverage determination level. For more information on appointing a representative, contact your plan or 1-800-Medicare.

**Prescription drug you are requesting:**

Name of drug: ________________________ Strength/quantity/dose: ________________________

Have you purchased the drug pending appeal?  ☐ Yes  ☐ No

If “Yes”:

Date purchased: ________________________ Amount paid: $ ________ (attach copy of receipt)

Name and telephone number of pharmacy: __________________________________________

**Prescriber’s Information**

Name ________________________________

Address ________________________________

City __________________________ State _______ Zip Code _____________________

Office Phone __________________________ Fax __________________________

Office Contact Person __________________________

**Important Note: Expedited Decisions**

If you or your prescriber believe that waiting 7 days for a standard decision could seriously harm your life, health, or ability to regain maximum function, you can ask for an expedited (fast) decision. If your prescriber indicates that waiting 7 days could seriously harm your health, we will automatically give you a decision within 72 hours. If you do not obtain your prescriber’s support for an expedited appeal, we will decide if your case requires a fast decision. You cannot request an expedited appeal if you are asking us to pay you back for a drug you already received.

☐ CHECK THIS BOX IF YOU BELIEVE YOU NEED A DECISION WITHIN 72 HOURS

If you have a supporting statement from your prescriber, attach it to this request.

**Please explain your reasons for appealing.** Attach additional pages, if necessary. Attach any additional information you believe may help your case, such as a statement from your prescriber and relevant medical records. You may want to refer to the explanation we provided in the Notice of Denial of Medicare Prescription Drug Coverage.

____________________________________

____________________________________

____________________________________

Signature of person requesting the appeal (the enrollee, or the enrollee’s prescriber or representative): __________________________ Date: __________________________