

STATE OF VERMONT
 AGENCY OF HUMAN SERVICES

DCF and OVHA

**Department for Children and Families
 Office of Vermont Health Access**

BULLETIN NO.: 05-24F

FROM: Betsy Forrest, Deputy Commissioner
 Economic Services Division

DATE: December 15, 2005

Joshua N. Slen, Director
 Office of Vermont Health Access

SUBJECT: Changes in Medicaid, VScript, VHAP-Pharmacy, Healthy Vermonters
 and the Vermont Health Access Plan due to the Medicare Modernization Act
 and Implementation of the VPharm Program.

CHANGES ADOPTED EFFECTIVE 1/1/06

INSTRUCTIONS

- Maintain Manual - See instructions below.**
- Proposed Regulation - Retain bulletin and attachments until you receive Manual Maintenance Bulletin: _____**
- Information or Instructions - Retain until _____**

These rule changes implement modifications to Vermont rules necessitated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). This act amended the Social Security Act to include a prescription drug benefit in the Medicare program. State programs will no longer be the primary payer for most prescription drugs. The Vermont Legislature, in Act 71 of the 2005 session, responded to the Governor's commitment to keep Medicare beneficiaries' coverage whole by creating a supplemental program, VPharm, to ensure that Vermonters enrolled in Medicaid or any of the state pharmacy programs would be held harmless by these changes.

MANUAL REFERENCE(S):

M200.4	M800-889	M920.1	3201.5	3304	3401.54
M200.41	M801	M920.2	3202.1	3305	3403.4
M200.43	M813.4	M920.3	3301.2	3401	3500
M200.44	M813.5	3201.42	3301.3	3401.1	4003.11

Specific Changes to Rules Sections:

Section	Description of change
M200.4 M200.41 M200.43	Eliminates spend down of resources prohibition. Resource test eliminated for QMB and SLMB.
M200.44	Allows for QI-1 to get coverage for excluded drugs. Resource test eliminated for QI-1.
M800-M889	Incorporates an interpretive memo clarifying that drugs intended for continuous use may be dispensed in quantities of not more than 90 days. This also complies with the legislative mandate in § 2081 of Act 71 to establish maximum quantities of pharmaceuticals to be dispensed. Clarifies current practices regarding prescribers and generic drugs.
M801	This new section explains drug coverage under Medicaid for Medicare beneficiaries. <u>Since the last filing</u> , the language has been added to clarify that Medicaid will cover Part D copayments for Medicare beneficiaries who are children under age 18 and women who are pregnant or in the 60-day post-pregnancy period. Drugs for smoking cessation have been removed as an excluded drug class because the class will be covered by Part D. Language is clarified to state that the medical necessity decision will be based on a fresh review of the clinical factors. Language is added to provide definition and clarity for good cause and hardship exceptions. Language has been added to exclude those with creditable coverage from the requirement to enroll in a Part D prescription drug plan since they already have coverage that is at least equivalent to Part D.
M813.4 and M813.5	These sections are clarified to refer only to drug classes not covered by Medicare, or to drugs paid for by Medicaid for Medicare beneficiaries. Also, obsolete terms and procedures are updated.
M920.1 M920.2 M920.3	Clarification is made to refer only to drug classes not covered by Medicare. Obsolete terms are updated. References to the Brandon Training School are eliminated.
3201.42 3201.5	Removes references to Medicare. Makes it clear that Medicare beneficiaries are not eligible for VScript.

3202.1	<p>Language is changed to clarify that only maintenance drugs are covered by VScript.</p> <p><u>Since the last filing</u>, language referring to dispensing of the lowest cost brand available is deleted and replaced by a reference to the Generic Drug Bill.</p> <p>A clarification is made that a list of covered drug classes is available upon request.</p>
3301.2	Removes references to Medicare.
3301.3	Makes it clear that Medicare beneficiaries are not eligible for VHAP-Pharmacy.
3304	<p>Clarifies current practices regarding prescribers and generic drugs.</p> <p><u>Since the last filing</u>, the phrase "in stock at the pharmacy" related to the Generic Drug Bill is deleted to correspond to the change in the Bill made by Act 71.</p>
3305	Language is changed to correspond to language in Act 71 that defined VHAP-Pharmacy coverage as the same pharmaceutical coverage as Medicaid.
3401	Removes reference to Medicare.
3401.1	Insures that the HVP discount will extend to excluded Part D drug classes.
3401.54	Removes reference to Medicare.
3403.4	<p>Adds language to describe Healthy Vermonters' coverage for people on Medicare.</p> <p><u>Since the last filing</u>, a correction is made to the first sentence to change the reference from entitlement under Part D to entitlement under Part A.</p> <p>Drugs for smoking cessation have been removed as an excluded drug class because the class will be covered by Part D.</p> <p>Language is clarified to state that the medical necessity decision will be based on a fresh review of the clinical factors.</p> <p>Language is added to provide definition and clarity for good cause and hardship exceptions.</p>

3500	<p>A new section is added with eligibility and coverage rules for VPharm. <u>Since the last filing</u>, in section 3502.5:</p> <p>Language was added to ensure consistency with current pharmacy programs after 1/1/06 so that individuals with private pharmaceutical insurance coverage will not be eligible for VPharm.</p> <p>In section 3504.1 B:</p> <p>A sentence is added to indicate that the state will pay PDP or MA-PD premiums on behalf of VPharm enrollees.</p> <p>The word "termination" replaces "disenrollment" for language consistency in this section.</p> <p>For accuracy and internal consistency, the words "or a MA-PD" were added after "disenrolls from a PDP."</p> <p>In section 3504.3 :</p> <p>The words "under certain conditions" have been deleted for clarity.</p> <p>The words "or reduce" have been added to align continuation rights with appeal rights.</p> <p>In section 3505.7:</p> <p>The phrase "in stock at the pharmacy" related to the Generic Drug Bill is deleted to correspond to the change in the Bill made by Act 71.</p>
	<p>In section 3506:</p> <p>Drugs for smoking cessation have been removed as an excluded drug class because the class will be covered by Part D.</p> <p>The VPharm premium coverage is corrected to be the basic beneficiary premium up to the low-income premium subsidy amount.</p> <p>Language is clarified to state that the medical necessity decision will be based on a fresh review of the clinical factors.</p> <p>Language is added to provide definition and clarity for good cause and hardship exceptions.</p>

4003.11	<p>A section is added to VHAP rules to accommodate the brief time when a beneficiary may overlap VHAP and Medicare coverage, and thus VHAP becomes the secondary payer for drugs covered by Medicare Part C or Part D.</p> <p><u>Since the last filing</u>, drugs for smoking cessation have been removed as an excluded drug class because the class will be covered by Part D.</p> <p>Language is clarified to state that the medical necessity decision will be based on a fresh review of the clinical factors.</p> <p>Language is added to provide definition and clarity for good cause and hardship exceptions.</p>
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Responses to Public Comment:

A public hearing was held on October 31, 2005 at 10:00 a.m., in the Agency of Human Services Skylight Conference Room, State Office Complex, Waterbury, Vermont. No commenters attended.

Written comments were received from the AARP-VT, the Community of Vermont Elders, the Disability Law Project, the Office of Health Care Ombudsman, the Vermont Coalition for Disability Rights and the Vermont Ombudsman Project.

Their comments are summarized below along with AHS's responses.

M200.4

Comment: A commenter noted that the reference to spending down resources is no longer necessary with the elimination of the resource test for the Medicare Cost-Sharing Coverage Groups.

Response: We agree. The reference has been eliminated.

M200.41, M200.43, M200.44

Comment: A commenter asked whether the resource test elimination for the Medicare Cost-Sharing Coverage Groups will be made effective December 1, 2005 by PP&D memo?

Response: Yes. The department will also submit a State Plan Amendment to the Centers for Medicare and Medicaid Services (CMS) to effectuate this change.

M200.44

Comment: A commenter asked whether Qualifying Individuals (QIs) are being treated differently than the other Medicare Cost-Sharing Coverage Groups, in having to reapply each calendar year, due to a federal requirement?

Response: Yes. This is a federal requirement and therefore the Vermont rule currently requires reapplication each calendar year. The Agency has limited its changes to existing rules for purposes of this filing to those precipitated by the MMA and the SFY06 Budget Bill (Act 71).

Comment: A commenter asked whether the language of this regulation means that a QI beneficiary is not eligible for coverage for drugs through VPharm in the same manner that current pharmacy beneficiaries will be?

Response: No. A QI beneficiary is eligible for coverage of drugs through VPharm in the same manner that current pharmacy beneficiaries will be.

Comment: A commenter inquired whether coverage through VPharm fit into the definition of "other federally funded medical assistance?" Another commenter found the exception to other federally funded assistance "for coverage for excluded drug classes under Part D when the individual is enrolled in Part D" in need of clarification.

Response: Pursuant to federal law, unlike QMBs and SLMBs, who may be determined eligible for Medicaid benefits in addition to their QMB or SLMB benefits, QIs cannot be otherwise eligible for medical assistance under the State Plan. Vermont will secure Federal Financial Participation (FFP) for coverage of excluded Part D drugs; to this extent, coverage through VPharm fits into the definition of "other federally funded medical assistance." However, in order to maximize Medicare beneficiaries' access to the federally funded limited income subsidy through the elimination of the resource test for QIs, Vermont will not draw FFP for coverage of excluded Part D drugs for QIs thereby eliminating the "otherwise eligible for medical assistance under the State Plan" eligibility barrier for QIs.

The exception language in the rule is inserted to accomplish this outcome.

M801, 3403.4, 3506, 4003.11

Comment: Commenters requested that OVHA add language giving a broad definition of "good cause" and "hardship" related to obtaining pharmaceutical coverage from a Part C or Part D plan.

Response: We incorporated the suggested language, adding clarification that the beneficiary must make every reasonable effort with the Centers for Medicare and Medicaid Services (CMS) and the prescription drug plan sponsor to obtain coverage, and that OVHA makes the determinations.

Comment: Commenters stated their belief that the legislative intent was to cover prescription drugs not on a Part D plan's formulary.

Response: We disagree. Allowing this coverage would increase the state's financial risk and encourage plans to minimize their covered drugs. Since each plan is mandated to cover at least two drugs in each therapeutic class, and the Centers for Medicare and Medicaid Services (CMS) must approve the plans' formularies, our understanding is that the legislature intended that the state only wrap drug classes not included in the Part D benefit. To do otherwise would undermine the functionality of the formulary management system of Medicare Part D. Furthermore, as Vermont has paid the federal government through the phased-down State contribution, payment for non-formulary drugs on a routine basis would be duplicative and costly. The appeals process was built in to allow beneficiaries to request coverage from the State if appeals for non-formulary drugs through the Part D process did not result in coverage.

Comment: Commenters believed that language regarding appeals should refer only to an individual's exhausting the plan's "internal" appeal process and eliminate the Independent Review Entity (IRE) decision level.

Response: We disagree. Language in Act 71, §2073 says VPharm covers "pharmaceuticals that are not covered after the individual has exhausted the Medicare Part D prescription drug plan's appeal process." At the time this language was developed, it was our understanding that the Part D appeal process outlined in 42 CFR 423.560 through 423.638 was synonymous with the plan's appeal process. Initially, the beneficiary asks for a determination decision on a nonformulary drug. All plans are mandated by federal law to explain to beneficiaries the five appeal levels: redetermination, Independent Review Entity, Administrative Law Judge, Medicare Advisory Council, and judicial review. Decisions can be expedited if the standard timeframe might seriously jeopardize life or health or the ability to regain maximum function. In an expedited situation, the timeframe for determination through the Independent Review Entity decision is seven days. The standard timeframe would be 17 days. There are no timeframes established for further reviews, and they must meet a threshold requirement established by the Health and Human Services Secretary. In writing the regulation, we adapted our approach to mean exhaustion through the levels where a timeframe could be attached (as opposed to requiring the exhaustion of appeals through all possible levels). This interpretation was discussed with the Health Access Oversight Committee on September 6, and there was no disagreement. In addition, an individual may be able to obtain a non-formulary drug by following a PDP's transition process rather than filing an appeal through the PDP. Furthermore, providing for two levels of appeal, including one conducted by a clinically qualified objective third party (the Independent Review Entity), is consistent with the practices of other private insurers in the State of Vermont.

Comment: Commenters pointed out that “review” may not be the appropriate word to describe the process for the OVHA coverage decision when the appeal process has been exhausted. A request was also made to delete wording allowing for a requirement to provide medical or scientific evidence to support the request because it suggests a lengthy and inappropriate process.

Response: The language has been changed to reflect the decision-making nature of the process, and to clarify that it will be based on a fresh study of the clinical factors. Language allowing the option for requiring medical or scientific evidence has been left in to allow the medical director discretion to request whatever evidence he or she believes is needed in order to render a decision.

Comment: Commenters noted that if medical necessity is documented, the drug “shall” be covered as opposed to “may” be covered.

Response: We agree. The language has been changed.

M801

Comment: A commenter pointed out that the rule does not specify how cost-sharing will work for pregnant women who are eligible for both Medicare and Medicaid, or for children under EPSDT. Act 71 requires the state to pay any cost sharing required by Part D, except for copayments for individuals eligible for Medicaid. Children and pregnant women have no copayments under Medicaid, so the commenter believes they should have no copayments under Part D.

Response: We have verified with CMS that pregnant women and children will have copayments under Part D. Copayments for Medicaid beneficiaries under Part D range from \$1 to \$5. We agree that Medicaid should cover the Part D copayments for pregnant women and children and have added language to that effect to the rule.

3201.42

Comment: A commenter asked why the requirement that "individuals in receipt of Railroad disability benefits must have Medicare coverage in order" to be considered disabled was removed?

Response: As of 1/1/06, Medicare beneficiaries will no longer be eligible for VScript; therefore, the subject language is no longer applicable.

3202.1

Comment: A commenter says that OVHA has not been able to provide lists of VScript covered and excluded drugs, and that these drugs should be included in the text of the rule or in a PP&D interpretive memo.

Response: The rule has been unclear in its description. We cannot provide comprehensive lists of individual drugs. There are too many variables that change frequently, such as new drugs coming on the market and old drugs being removed, as well as the rebate status of manufacturers. Prescribers may check with our pharmacy benefits manager about a specific drug, and beneficiaries frequently call Member Services for similar information when a drug is denied. However, that information only explains if a drug is considered maintenance and if we have a rebate agreement in place. It does not tell the beneficiary if a particular pharmacy has the covered drug from that manufacturer in stock. The rule has been changed to clarify that lists of covered drug classes are available.

Comment: Commenters were concerned with the language that specifies providing the lowest cost brand available, stating that it implied substitution without consultation with the prescriber, and requesting statutory authority.

Response: This language was a holdover from the previous statute. We believe the intent is to comply with the Generic Drug Bill, so this language is deleted and a reference to that law has been added.

Comment: A commenter observed that maintaining the requirement for a rebate agreement compromises the legislative intent of keeping individuals harmless. The belief is that the state's bargaining power is significantly lessened because so many people now have Part D as primary insurance, and people may be harmed if fewer manufacturers participate.

Response: Act 71 in §2074 (d) established the rebate requirement so it must be reflected in the rule. A consideration in the negotiations for the state rebate agreement is that in order to have the VPharm benefit for maintenance drugs, the rebate agreement must be in place. Therefore, the state rebate agreement applies to both VScript Expanded and to VPharm maintenance drug coverage for people in the comparable income group.

3301.2

Comment: A commenter asked why the requirement that "individuals in receipt of Railroad disability benefits must have Medicare coverage in order" to be considered disabled was removed?

Response: As of 1/1/06, Medicare beneficiaries will no longer be eligible for VHAP-Pharmacy; therefore, the subject language is no longer applicable.

3301.3

Comment: Commenters found this provision confusing. They asserted that a beneficiary cannot be on both VHAP-Pharmacy and VScript and questioned the exception of VScript.

Response: It is true that beneficiaries cannot be on both VHAP-Pharmacy and VScript. The Agency has limited its changes to existing rules for purposes of this filing to those precipitated by the Medicare Modernization Act (MMA) and the State of Vermont FY06 Budget Bill (Act 71); the only change to this section in the proposed rule was the deletion of the words "or Medicare" after the words "Healthy Vermonters" to ensure that Medicare beneficiaries will no longer be treated as uninsured with regards to VHAP-Pharmacy benefits as of 1/1/06.

3403.4

Comment: A commenter asked if the first reference to Medicare in the first sentence should refer to Part A, not Part D.

Response: Yes. It has been corrected.

3502.4

Comment: A commenter offered the following observation: "[I]t appears that VPharm Rule 3502.4 requires all applicants, even those receiving Long-Term Care Services, to meet the VHAP financial eligibility requirements. Under the proposed rule, individuals with income above 225 percent of poverty would not qualify for VPharm. Many individuals enrolled in Choices for Care (CFC), the State's new long-term care 1115 Medicaid Waiver, have income over this limit however they qualify for Medicaid because they meet the long term care Medicaid income rules.

Prior to the implementation of Medicare Part D, Medicaid covered all prescription costs for these individuals. They did not pay any premiums or copayments. If the purpose of the VPharm rules is to fulfill the Governor's promise that '[N]o Vermonter will be financially disadvantaged as a result of the implementation of the Medicare Modernization Act', then the State should deem these long term care recipients income eligible for VPharm and waive payment of any premiums."

Response: Medicare beneficiaries who spend-down to become eligible for 1115 LTC Waiver Services as part of the special income or medically-needy groups are treated as full-benefit dual eligibles under the MMA and this rule. As such they will be eligible for the full limited income subsidy ("extra help") from the federal government, which will subsidize the premium and other cost-sharing. Under 42 CFR 423.782, full-benefit dual eligible individuals living in institutions have no cost-sharing for Part D drugs. In summary, these Medicare beneficiaries will pay no more out-of-pocket than they do now in accordance with the Governor's promise; please see M801 for coverage details.

3502.5

Comment: A commenter observed that this regulation requires a beneficiary to be enrolled in a PDP or a MA-PD. This requirement should apply unless an individual shows good cause for not being enrolled and resulting hardship.

Response: As of 1/1/06, Medicare beneficiaries will receive a new federal out-patient prescription drug benefit to supplement existing pharmaceutical coverage under Medicare Parts A & B. This new benefit will provide for all Medicare beneficiaries' pharmaceutical coverage as a primary payer; to the extent the state of Vermont or another payer supplements Medicare Parts A & B & D, its ability to resolve operational enrollment issues is de facto constrained. Medicare beneficiaries should first seek to resolve enrollment issues with the Prescription Drug Plan Sponsor and/or CMS. Upon exhaustion of such reasonable efforts, the State of Vermont will adhere to this rule pursuant to sections M801, 3403.4, 3506 and 4003.11.

3502.6

Comment: Commenters asked what the Department means by the requirement that individuals eligible for the limited income subsidy (LIS) "must secure it."

Response: "[M]ust secure it" means become enrolled, if one is eligible pursuant to 42 CFR, Subpart P, § 423.771 through § 423.800 of the MMA.

Comment: Commenters exhorted the State to at least help beneficiaries apply for the limited income subsidy while questioning what specific requirements the department is placing on otherwise eligible Medicare beneficiaries to apply for the LIS.

Response: Department staff is trained and prepared to help Medicare beneficiaries apply for LIS benefits through the Social Security Administration (SSA) in all of its twelve district offices around Vermont and through its central Health Access Eligibility Unit (HAEU). The department will continue to process eligibility applications based on an individual's and/or household's declarations subject only to subsequent verification as the department may deem reasonably necessary (see section 3503). The State has a significant financial interest in assuring that all LIS-eligible individuals secure the federal assistance available to them. No further language in this section is necessitated.

3503

Comment: A commenter indicated an understanding that an application is not required for those seniors and persons with disabilities being converted from existing state pharmacy programs to VPharm. The commenter further opined that the rules should be clarified to remove the application mandate for those presently eligible for our current Rx programs who were intended to see a seamless transition to the new VPharm program and not face unnecessary hurdles to ongoing coverage.

Response: The Agency is pleased that all individuals enrolled in one of the State's pharmacy programs (VHAP-Pharmacy, VScript and VScript Expanded) in December 2005 will experience a seamless transition to the new VPharm program commencing 1/1/06

without the necessity of having to complete and file an application. However, given the VPharm rules have an intended effective date of 1/1/06 and the initial one-time transition to VPharm, without an application requirement, will occur in December of 2005, no rule clarification is warranted.

Comment: Commenters assert that the rules need to explain how current beneficiaries will be enrolled in VPharm as it starts up in January, 2006 and how initial PDP premiums will be paid in 12/05.

Response: The rules are intended to apply as of 1/1/06. Notices prior to 1/1/06 will explain enrollment and payment information concerning PDPs and VPharm to all current beneficiaries. Explanations in the rule with regards to operational issues that will occur prior to 1/1/06 are not applicable. Initial PDP premiums will however be paid prospectively in December (on behalf of those eligible in December) for January coverage.

Comment: A commenter opined that the State should take applications for VPharm benefits for individuals prior to their eligibility in the same way that beneficiaries may enroll in Medicare prior to their 65th birthday or their eligibility for Social Security disability benefits.

Response: We agree. Section 3502.1 of the VPharm rules provide that, in order to qualify on the basis of age, an individual must be at least 65 years of age as of the effective date of coverage under VPharm. This allows an individual to apply one month prior to their 65th birthday or their eligibility for Social Security disability benefits (see section 3502.2). This is consistent with the federal approach to Medicare Part D.

3504.1A

Comment: Commenters asked whether the language in this section of the rule means that individuals enrolling in VPharm in January 2006 will be eligible through June 2007?

Response: Yes; however, a review of eligibility will be completed before the end of each annual certification period.

3504.1B

Comment: A commenter stated that the rules need to explain what happens when a beneficiary fails to pay their VPharm premium in a timely manner.

Response: Section 3505 of the rule indicates that VPharm follows the prospective premium-based system described at rule M150; furthermore, failure to pay the required premium is an indicated basis for termination pursuant to this section provided a notice is mailed to the beneficiary at least 11 days before the termination date. No further rule language is warranted.

Comment: A commenter asserted that the regulation should use the word "termination" of VPharm benefits, rather than "disenrollment," so that the terminology is consistent throughout the regulations?

Response: The wording has been changed to ensure consistency.

Comment: Commenters suggested that the rule elaborate on the relationship between a VPharm beneficiary's premium payment and the State's payment to a PDP or MA-PD on a VPharm beneficiary's behalf; furthermore, commenters inquired about the one-month grace period that VPharm beneficiaries will be afforded as to their PDP or MA-PD enrollment if they fail to pay their VPharm premium and suggested that it should be described in the rule.

Response: A sentence was added to clarify the State's role in this regard. The grace period is implicit in this sentence. The State has sought to minimize the possibility of inadvertent loss of eligibility for Medicare Part D.

Comment: Commenters opined that the rules need to explain how the State will deal with beneficiaries who choose plans that are either over the benchmark or are enhanced, rather than basic. Further, that it must explain how beneficiaries will know about the additional expenses they must pay if they choose such a non-approved plan and what will happen if they don't pay the additional cost sharing.

Response: Medicare beneficiaries currently enrolled in Medicaid and the State's pharmacy programs are being informed via notices mailed directly to them of the financial risk of choosing a plan with a higher premium and how to determine the basic premium amount. Rule 3506 clearly indicates that VPharm covers beneficiary cost-sharing after any federal limited-income subsidy is applied and that this may include basic beneficiary premiums for the PDP up to the low income subsidy amount. No further rule language is warranted.

Comment: Commenters noted that the regulation states that "disenrollment" in VPharm occurs as a result of disenrolling from a PDP. In some cases an individual may disenroll from a PDP and attempt to enroll in another plan but experience difficulties with the transition to a new plan. In these cases, the good cause and hardship provisions should apply.

Response: Medicare beneficiaries should first seek to resolve enrollment issues with the Prescription Drug Plan Sponsor and/or CMS. Upon exhaustion of such reasonable efforts, the State of Vermont will adhere to this rule pursuant to sections M801, 3403.4, 3506 and 4003.11.

3504.3

Comment: Commenters noted that, in the first sentence of third paragraph, the phrase "under certain conditions" should be deleted. The circumstances under which continuing benefits will be granted are listed in the rest of the sentence and the phrase suggests that there may be others not specified.

Response: The words "under certain conditions" have been deleted.

Comment: Commenters expressed concern that the rule states that individuals are entitled to notice and right to appeal when the benefits ...are "reduced or discontinued." However, the rule only gives individuals the right to continuing benefits when the department decides to terminate benefits. Recipients should have the right to continuing benefits when their benefits are either "reduced" or "discontinued."

Response: The rule has been amended to include the words "or reduce" in the first sentence of the third paragraph after the words "to end" to align the appeal and continuation rights as suggested.

3506

Comment: A commenter asked how beneficiaries will know that OVHA might pay or subsidize a higher premium, and suggested that beneficiaries be notified.

Response: During the legislative session, the discussion with OVHA explained that this was a secondary implementation possibility. Therefore, the language uses the word "may." This possibility will be analyzed during the first several months of MMA implementation and, if appropriate, a procedure drafted for later operational implementation. This procedure may need review and approval by the Centers for Medicare and Medicaid Services (CMS) and therefore was not implemented prior to 1/1/06.

Vertical lines in the left margin indicate significant changes. Dotted lines at the left indicate changes to clarify, rearrange, correct references, etc., without changing content.

To get more information about the Administrative Procedures Act and the rules applicable to state rulemaking go to the website of the Office of the Vermont Secretary of State at: <http://vermont-archives.org/apa/rules.html> or call Louise Corliss at 828-2863.

For information on upcoming hearings before the Legislative Committee on Administrative Rules go to the website of the Vermont Legislature at: <http://www.leg.state.vt.us/schedule/schedule2.cfm> or call 828-5760.

Manual Holders: Please maintain manuals assigned to you as follows.

Manual Maintenance

Medicaid Rules

<u>Remove</u>		<u>Insert</u>	
M200.3	(02-11)	M200.3	(05-24)
PP&D facing page			
M200.41	12/1/05	Nothing	
M200.42	(02-11)	M200.42	(05-24)
PP&D facing page			
M200.43	12/1/05	Nothing	
PP&D facing page			
M200.44	12/1/05	Nothing	
M200.44	(02-11)	M200.44	(05-24)
TOC (M800)	(00-31F)	TOC (M800)	(05-24)
M800-M889	(90-35F)	M800-M889	(05-24)
M800-M889 P.2		Nothing	
Nothing		M801	(05-24)
M813.4	(95-17)	M813.4	(05-24)
TOC P.1 (M900)	(93-53F)	TOC P.1 (M900)	(05-24)
Nothing		TOC P.2 (M900)	(05-24)
M920.1	(90-35F)	M920.1	(05-24)

VScript Rules

TOC (3200)	(03-17)	TOC (3200)	(05-24)
3201.4	(97-4F)	3201.4	(05-24)
3202	(05-09)	3202	(05-24)

VHAP-Pharmacy Rules

3300	(03-17)	3300	(05-24)
3304 P. 2	(96-4F)	3304 P. 2	(05-24)
Nothing		3305	(05-24)

Healthy Vermonters Rules

3400	(02-18)	3400	(05-24)
3401	(02-18)	3401	(05-24)
3401.53	(02-18)	3401.53	(05-24)
Nothing		3403.4 P. 2	(05-24)

VPharm Rules

<u>Remove</u>		<u>Insert</u>	
Nothing		TOC (3500)	(05-24)
Nothing		3500	(05-24)
Nothing		3502	(05-24)
Nothing		3503	(05-24)
Nothing		3504	(05-24)
Nothing		3504.2	(05-24)
Nothing		3505	(05-24)
Nothing		3505.4	(05-24)
Nothing		3505.7	(05-24)
Nothing		3506	(05-24)
Nothing		3506 P. 2	(05-24)

VHAP Rules

TOC (4000)	(03-17)	TOC (4000)	(05-24)
Nothing		4003.11	(05-24)
Nothing		4003.11 P. 2	(05-24)

1/1/06

Bulletin No.05-24

M200.3

M200.3 SSI-Related Medically Needy Coverage Group

Individuals who would be members of a categorically needy coverage group may qualify for Medicaid as medically needy even if their income or resources exceed coverage group limits. These individuals may become eligible if they incur enough non-covered medical expenses to reduce their income to the applicable standard. For community Medicaid, individuals must reduce their income to the protected income level (PIL). For long-term care, including waiver and hospice services, individuals also must spend down their income to the PIL. In addition, all individuals must have resources below the categorically needy program resource limit. The rules in M411-M423 specify how individuals may use non-covered medical expenses to “spend down” their income or resources to the applicable limits.

M200.4 SSI-Related Medicare Cost-Sharing Coverage Groups

Limited Medicaid benefits are available to pay for out-of-pocket Medicare cost-sharing expenses for certain Medicare beneficiaries. Such beneficiaries are eligible for Medicaid payment of certain Medicare costs if they meet the additional criteria specified for one of the groups in M200.41-M200.44.

Individuals eligible for one of the following Medicare cost-sharing coverage groups may also be eligible for the full range of Medicaid covered services if they also meet the requirements for one of the categorical (M200.2) or medically needy coverage groups (M200.3).

Applicants may not spend down income to meet the financial eligibility tests for these coverage groups. The department disregards annual cost-of-living (COLA) increases in social security benefits in determining eligibility for these groups until the month after the annual publication of the official poverty line revisions.

M200.41 Qualified Medicare Beneficiaries (QMB)

Individuals are eligible for Medicaid payment of their Medicare Part A and Part B premiums, deductibles, and coinsurance if their Medicaid group has countable income at or below 100 percent of the federal poverty level.

Benefits under this provision become effective on the first day of the calendar month immediately following the month in which the individual is determined to be eligible.

1/1/06

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M200.42

M200.4 SSI-Related Medicare Cost-Sharing Coverage Groups (Continued)M200.42 Qualified Disabled and Working Individuals (QDWI)

Individuals who have lost their Medicare benefits based on disability because they returned to work, are eligible for Medicaid payment of their Medicare Part A premiums if they:

- are disabled;
- belong to a Medicaid group with countable income at or below 200 percent of the federal poverty level applicable to the Medicaid group's size;
- are members of a Medicaid group with resources at or below twice the SSI-related Medicaid limit applicable to the group's size; and
- are not otherwise eligible for Medicaid.

Benefits under this provision become effective on either the date of application or the date on which all eligibility criteria are met, whichever is later. The department may grant benefits for a retroactive period of up to three months prior to that effective date, provided that the individual meets all eligibility criteria.

M200.43 Specified Low-Income Medicare Beneficiaries (SLMB)

Individuals are eligible for Medicaid payment of their Medicare Part B premiums if:

- they receive Medicare Part A; and
- their Medicaid group has countable income greater than 100 percent but no greater than 120 percent of the federal poverty level.

Benefits under this provision become effective on either the date of application or the date on which all eligibility criteria are met, whichever is later. The department may grant benefits for a retroactive period of up to three months prior to that effective date, provided that the individual meets all eligibility criteria.

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M200.44

M200.4 SSI-Related Medicare Cost-Sharing Coverage Groups (Continued)M200.44 Qualified Individuals (QI-1)

Individuals who receive Medicare Part A and do not receive other federally funded medical assistance, except for coverage for excluded drug classes under Part D when the individual is enrolled in Part D, are eligible for Medicaid payment of their Medicare Part B premium.

The QI-1 coverage group includes individuals in a Medicaid group with income that is at least 120 percent but less than 135 percent of the federal poverty level that are eligible for Medicaid payment of their Medicare Part B premium.

Benefits under this provision become effective on the first day of the calendar month immediately following the month in which the individual is determined to be eligible. The department may grant benefits for a retroactive period of up to three months from the date of application, provided that all eligibility criteria are met. The benefit period ends in December of each calendar year. People requesting this coverage must reapply each calendar year.

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M800-M889

M800-M889 Drugs and Pharmaceutical Items, Medical Supplies and Equipment

Pharmaceutical items include drugs, medicine chest supplies, vitamins and related items which are normally obtained through appropriately licensed pharmacies. Medical supplies and equipment include prosthetic devices, durable and non-durable equipment for care of the ill or injured, medical supplies and similar items which may be obtained from a pharmacy, hospital-surgical supply service or home health agency.

Payment for covered items, other than prescribed drugs, is limited to the following providers:

- A Vermont provider approved for participation in Medicare; or
- An out-of-state provider, approved either for Medicare participation or for Medical Assistance (Title XIX) participation by the single state agency administering the Title XIX Program within the state where it is located.

Payment for prescribed drugs is limited to Vermont Medicaid enrolled providers who are:

- Registered Vermont pharmacies, including hospital pharmacies; or
- Pharmacies appropriately licensed in another state; or
- A physician, serving an area without regular pharmacy services, who has been granted special approval to bill these items direct.

Payment is limited to covered items furnished on written prescription of a duly licensed medical professional licensed by the state of Vermont to prescribe within the scope of his or her practice and enrolled in Vermont Medicaid, or on telephoned prescription from a prescriber as previously described and enrolled in Vermont Medicaid processed in compliance with applicable federal and state statutes and regulations. Any drug which is to be used continuously (i.e., daily, twice a day, every other day, etc.) for 30 days or more shall be prescribed and dispensed in an amount sufficient to treat the patient for no less than thirty (30) days and no more than ninety (90) days at a time except medications which the patient takes or uses on an "as needed" basis. Up to five refills are permitted. If there are extenuating circumstances in an individual case which, in the judgment of the physician, dictate a shorter prescribing period, the supply may be for less than 30 days. For recipients in a NF or ICF/MR see M813.5.

The pharmacist shall not fill a prescription in a quantity different from that prescribed by the physician if payment is to be made by Medicaid except in an individual case when the quantity has been changed in consultation with the physician.

When the same drug in the same strength is prescribed for more than one member of a family at one time, the pharmacist shall treat it as one prescription for payment purposes. Specific examples of drugs which might fall into this category are delousing agents (e.g. Kwell) and de-worming preparation (e.g., Vermox).

Claims for vendor payment are submitted to and processed by the fiscal agent only; there is no provision for direct reimbursement to recipients or to nursing homes for payments they may make to a pharmacy or supplier.

M801 Beneficiaries Eligible for Medicaid and Medicare

Beneficiaries who are entitled to Medicare benefits under Part A or enrolled in Medicare Part B, and who live in the service area of a Part D plan, are defined under Medicare rules at 42 CFR §423.30 as eligible for Part D. Vermont is included in the service area for several Part D plans. According to 42 CFR §423.906, Medicare is the primary payer for covered drugs for Part D eligible individuals. Medicaid will cover Part D copayments for beneficiaries under age 18 and women who are pregnant or in the 60-day post pregnancy period. Medicaid does not cover drugs in classes included in the Part D benefit. Medicaid provides secondary pharmacy coverage as described below for those eligible for both Medicare and Medicaid.

Part D is administered either through a prescription drug plan (PDP) or as a component of Part C, Medicare managed care, in a Medicare Advantage – Prescription Drug benefit (MA-PD).

The only drug classes that Medicaid continues to cover for those enrolled in a drug plan, if they are not covered by the PDP/MA-PD, are:

- 1) drugs for anorexia, weight loss, or weight gain (M811.2);
- 2) single vitamins or minerals if the conditions described in M811.3 are met;
- 3) over-the-counter prescriptions if the conditions described in M811.4 are met;
- 4) barbiturates; and
- 5) benzodiazepines.

If a Part D eligible individual elects not to enroll in a PDP/MA-PD plan, or discontinues enrollment in such a plan, coverage for the drug classes listed above will end. Therefore, the individual will no longer have any pharmaceutical coverage from Medicaid. The only exception is an individual who has creditable coverage from a private insurer and has received a letter from that insurer stating that the existing coverage is creditable. These individuals will not be required to enroll in a Part D plan.

When an individual appeals a denial of coverage of a drug under a Part D or Part C plan, and has exhausted the plan's appeal process through the Independent Review Entity (IRE) decision level, or the plan's transition plan as approved by the Centers for Medicare and Medicaid Services (CMS), the individual may apply to the Office of Vermont Health Access (OVHA) for coverage of the drug if it is included in the Medicaid benefit (see M810-M812.1). If the individual's prescriber documents medical necessity in a manner established by the director of the OVHA, and the process for documentation conforms with the pharmacy best practice and cost control program established under subchapter 5 of chapter 19 of Title 33, the drug shall be covered. A denial decision by OVHA is not subject to the provisions of M108.

At the beginning of coverage under Medicare Part D, when an individual has applied for and has attempted to enroll in a Part D or Part C plan and has not yet received pharmaceutical coverage due to an operational problem with Medicare, or has otherwise not received coverage for the needed pharmaceutical, the necessary drugs will be covered, if OVHA finds that good cause and a hardship exist, until such time as the operational problem, good cause and hardship ends. The individual must have made every reasonable effort with CMS and the PDP, given the individual's circumstances, to obtain coverage. The intent of the good cause and hardship exception is remedial in nature and shall be interpreted accordingly. In general "good cause" shall include instances where the lack of coverage can not reasonably be considered the fault of the individual, and "hardship" shall include circumstances where alternative means for the coverage at issue are not reasonably available or will likely result in irreparable loss or serious harm to the individual. OVHA will make determinations of whether or not operational problems, good cause, or hardship exists for purposes of coverage.

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M813.4

M813.4 Beneficiaries in Long-Term Care Facilities

For those entitled to Medicare Part A or enrolled in Medicare Part B and enrolled in a Medicare prescription drug plan, this section applies to drugs not included in a Medicare-covered prescription drug class.

A pharmacy providing drugs to a psychiatric facility, a nursing facility, or an ICF/MR is reimbursed on the basis of cost of ingredients plus the dispensing fee per month for each prescribed drug furnished each recipient. The only exceptions are specific dosage forms including but not limited to aerosols, inhalants, liquids, topicals and injectables. Billing is done monthly with no increase allowed for additional time, services, or costs of containers which may result from use of the unit dose or any other system. The pharmacy may receive payment directly from these facilities for these extra costs and the facility may in turn include in its cost report such expenditure as an element of reasonable cost. The provider of drug items must accept, as payment in full, the amounts received from Medicaid.

M813.5 Return of Unused Drugs From Long-Term Care Facilities

Except for controlled substances, unused unit dose or modified unit dose medication that is in reusable condition, and which may be returned to a pharmacy pursuant to state laws, rules or regulations, shall be returned from long-term care facilities to the provider pharmacy.

When the primary payer is Vermont Medicaid, all returned medications must be credited to the Office of Vermont Health Access through its fiscal agent. The provider pharmacy will reverse the original claim and resubmit the actual amount dispensed.

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M920.1

M920.1 Drugs for Beneficiaries in a Nursing Facility (NF), Intermediate Care Facility (ICF), Psychiatric Facility, Intermediate Care Facility for the Mentally Retarded (ICF/MR)

For those entitled to Medicare Part A or enrolled in Medicare Part B and enrolled in a Medicare prescription drug plan, this section applies to drugs not included in a Medicare-covered prescription drug class.

Drugs prescribed by the attending physician for a beneficiary in a NF, ICF/MR or a psychiatric facility are covered in the same manner as for a beneficiary living in the community. Covered drugs are those available only with a prescription, secured from a participating pharmacy, and billed directly by that pharmacy to the Medicaid fiscal agent; the pharmacy cannot bill the nursing home and the home then re-bill Medicaid. An exception is made for a Medicare participating NF which must collect first from Part A for covered drugs supplied as an ancillary service during the period a beneficiary is receiving NF benefits under Medicare Part A.

All over-the-counter drugs ordered by physicians for their patients are to be furnished by each NF, ICF/MR or psychiatric facility. The facility will secure these drugs from a pharmacy or drug wholesaler and enter the charges incurred in the cost report submitted for purposes of calculating the per diem rate. The facility may not make a charge either to the program or to the beneficiary for over-the-counter drugs.

A pharmacy may, however, receive payment directly from a NF, ICF/MR, or Psychiatric Facility for reasonable costs incurred for unit dose or other systems, consulting services, or other costs incurred by the pharmacy in complying with M813.5 and the facility shall include this cost in its cost report.

M920.2 Drugs for Beneficiaries in the Vermont State Hospital

Prescription and over-the-counter drugs prescribed or ordered by a physician for a beneficiary shall be furnished by the facility and entered in its cost report for purposes of calculating the per diem rate.

M920.3 Personal Comfort Items - All Long-Term Care Facilities

Radio, television, telephone, air conditioners, beauty and barber services, and similar personal comfort items are excluded from coverage under Medicaid. The beneficiary may be charged for any personal comfort item when the beneficiary has requested it and has been advised that he or she will be charged. The facility may also charge the beneficiary for store items secured on the beneficiary's behalf such as magazines, newspapers, candy, tobacco, dry cleaning, denture cream, hairbrush, and deodorant.

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3201.4

3201.4 Member of Covered Group

An individual must be a member of one of the following groups to meet this requirement.

3201.41 Elderly

An individual must be at least 65 years of age on the date the application is filed.

3201.42 Disabled

An individual must be receiving disability benefits from Social Security (OASDI) to be considered disabled.

3201.5 Uninsured

An individual whose prescription drug expenses are paid or reimbursable, either in whole or in part, by any plan of assistance or insurance shall not be eligible for pharmaceutical assistance under VScript. An individual on Medicaid, Medicare or a VHAP program is already receiving assistance with prescription drug expenses and is ineligible for VScript.

3201.6 Financial Need

An individual must be a member of a VScript group with countable income under the applicable income test to meet this requirement.

A VScript group includes all of the following individuals if living in the same home:

- a. the VScript applicant and his or her spouse, and
- b. children under age 21 of the applicant or spouse, and
- c. siblings under age 21, including half siblings and step siblings, of b. and
- d. parents, including a stepparent and adoptive parents of c., and
- e. children of any children in b. and c., and
- f. unborn children of any of the above.

The VScript group shall not include any individual eligible for and receiving SSI/AABD benefits. In addition, the income of all SSI/AABD recipients living in the household shall not be considered in determining whether the VScript group passes the income test for VScript.

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3202

3202 Coverage

Individuals are enrolled in this program and receive assistance in purchasing covered maintenance drugs from participating pharmacies after meeting all eligibility criteria and paying the required premium.

The department's payment for covered pharmaceuticals shall be based upon current Medicaid payment and dispensing policies.

3202.1 Maintenance Drugs

"Maintenance drug" means a drug approved by the FDA for continuous use and prescribed to treat a chronic condition for a prolonged period of time of 30 days or longer, and includes insulin, an insulin syringe and an insulin needle. It may not be dispensed unless prescribed by a licensed physician.

Physicians and pharmacists are required to conform to Act 127 (18 –VSA- Chapter 91), otherwise known as the Generic Drug Bill. In those cases where the Generic Drug Bill permits substitution, only the lowest-priced equivalent shall be considered medically necessary. If, in accordance with Act 127, the patient does not wish to accept substitution, VScript will not pay for the prescription.

Lists of covered drugs classes are maintained and periodically updated by the Office and available upon request.

For beneficiaries whose VScript group income is greater than 175 percent but no greater than 225 percent of the federal poverty level coverage is limited to drugs dispensed by participating pharmacies from manufacturers that as a condition of participation in the program, have signed a rebate agreement with the Office of Vermont Health Access.

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3300

3300 Introduction

Legislative Act 14, authorizing and supporting the Vermont Health Access Plan, was adopted by the Vermont General Assembly and signed into law by the Governor on April 12, 1995. The Vermont Health Access Plan extends a pharmacy benefit and vision care services to low-income disabled and elderly Vermonters to assist them to purchase the prescription medicines that maintain their health and prevent unnecessary health problems. Vision care services do not include eyewear.

The policies which follow describe this coverage group called VHAP-Pharmacy.

3301 Eligibility

An individual must meet all of the following requirements (3301.1 - 3301.74) to be found eligible for this program.

3301.1 Age

An individual qualifying on the basis of age must be at least 65 years of age on the date the application is filed.

3301.2 Disability

An individual qualifying on the basis of disability must be receiving disability benefits from Social Security (OASDI) to be considered disabled.

3301.3 Uninsured

Individuals meet the uninsured requirement if they do not have any plan, including VHAP-Limited and Medicare, which pays or reimburses, either in whole or in part, with the exception of VScript, or Healthy Vermonters, their prescription drug expenses.

3301.4 Citizenship

Individuals are considered citizens if they meet at least one of the following two criteria.

- (1) The individual is a native-born or naturalized U.S. citizen. For purposes of qualifying as a U.S. citizen, the U.S., as defined in the Immigration and Nationality Act, includes the 50 States, the District of Columbia, Puerto Rico, Guam, Virgin Islands, and the Northern Mariana Islands. Nationals from American Samoa or Swain's Island also are regarded as U.S. citizens for purposes of VHAP-Pharmacy.

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3304 Prescribed Drugs (Continued)

Pharmacies appropriately licensed in another state; or

A physician, serving in areas without regular pharmacy services, who has been granted special approval to bill these items direct.

Payment is limited to covered items furnished on written prescription from a duly licensed medical professional licensed by the state of Vermont to prescribe within the scope of his or her practice and enrolled in Vermont Medicaid, or on telephoned prescription from a prescriber as previously described and enrolled in Vermont Medicaid processed in compliance with applicable federal and state statutes and regulations. Any drug which is to be used continuously (i.e., daily, twice a day, every other day, etc.) for 30 days or more shall be prescribed and dispensed in an amount sufficient to treat the patient no fewer than 30 days and no more than 90 days at a time except medications that the patient takes or uses on an "as needed" basis. Up to five refills are permitted. If there are extenuating circumstances in an individual case that, in the judgment of the physician, dictate a shorter prescribing period, the supply may be for fewer than 30 days.

The pharmacist shall not fill a prescription in a quantity different from that prescribed by the physician if payment is to be made by VHAP-Pharmacy, except in an individual case when the quantity has been changed in consultation with the physician.

Payment may be made for any preparation, except those unfavorably evaluated, either included or approved for inclusion in the latest edition of official drug compendia: the U.S. Pharmacopoeia, the National Formulary, the U.S. Homeopathic Pharmacopoeia, AMA Drug Evaluations, or Accepted Dental Therapeutics. These consist of "legend" drugs for which a prescription is required by State or Federal law.

Physicians and pharmacists are required to conform to Act 127 (18-VSA-Chapter 91), otherwise known as the Generic Drug Bill. In those cases where the Generic Drug Bill permits substitution, only the lowest priced equivalent shall be considered medically necessary. If, in accordance with Act 127, the patient does not wish to accept substitution, VHAP-Pharmacy will not pay for the prescription.

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3305

3305 Benefit Coverage

Benefits are provided for:

- the same pharmaceutical coverage as Medicaid,
- one comprehensive visual analysis (including a refraction) and one interim eye exam (including a refraction) within a two-year period, and
- diagnostic visits and tests related to vision.

3400 Introduction

The legislature authorized the creation of the Healthy Vermonters program with the passage of Act 127 (2002). This program provides a pharmacy discount to eligible Vermonters, helping beneficiaries purchase prescription medicines necessary to maintain their health and prevent unnecessary health problems. The rules that follow describe this pharmacy program.

3401 Eligibility

Individuals are eligible for Healthy Vermonters if they have household income no greater than 300 percent of the federal poverty level (FPL), as calculated under the rules for the VHAP program.

Individuals are also eligible for Healthy Vermonters if they have household income no greater than 400 percent of the FPL, as calculated under the rules for the VHAP program (4000), and meet the categorical eligibility requirements.

The following table presents the eligibility requirements.

Income Maximum	Categorical Eligibility Requirement
300 percent of the FPL	none
400 percent of the FPL	age 65 or older
	or disabled
	or disabled and eligible for social security disability benefits

Individuals remain eligible as long as they meet all program requirements.

3400 Eligibility

3401.1 Insurance Coverage

Individuals must be without adequate coverage for prescription drugs to be eligible. Individuals are considered without adequate coverage if they have no insurance policy or program benefit that includes any prescription drug coverage; however, beneficiaries on Part D in an MA-PD or PDP plan will be considered uninsured as to excluded Part D drug classes, except to the extent that such drugs are covered by the MA-PD or PDP plans. They are also considered without adequate coverage if no prescription drugs are covered under their policy because they have reached the annual maximum coverage limit.

The department considers individuals covered by VHAP-Pharmacy insured because that program has prescription drug coverage and no annual maximum. Beneficiaries who are eligible for Part D must be enrolled in a Part D prescription drug plan or a Medicare Advantage-Prescription Drug benefit plan to be eligible for Healthy Vermonters. The department considers individuals covered by VScript, including VScript expanded, to be uninsured for drugs that are excluded from VScript coverage (3202) and for drug classes that are excluded under Part D coverage (3403.4) for Medicare beneficiaries, and automatically extends coverage for these drugs under the Healthy Vermonters program.

3401.2 Citizenship

Individuals are considered citizens if they meet at least one of the following two criteria.

- (1) The individual is a native-born or naturalized U.S. citizen. For purposes of qualifying as a U.S. citizen, the U.S., as defined in the Immigration and Nationality Act, includes the 50 States, the District of Columbia, Puerto Rico, Guam, Virgin Islands, and the Northern Mariana Islands. Nationals from American Samoa or Swain's Island also are regarded as U.S. citizens for purposes of Healthy Vermonters.
- (2) The individual is a resident alien lawfully admitted for permanent residence or permanently residing in the U.S. under color of law, including any alien who is lawfully present in the U.S. under the authority of Sections 203(a)(7) or 212(d)(5) of the Immigration and Nationality Act.

3401.3 State Residence

An individual must be a state resident to be eligible. Individuals are considered state residents if they are living in Vermont at the time of submitting the application for the Healthy Vermonters Program:

- a. with intent to remain permanently or for an indefinite period of time or
- b. while incapable of stating intent.

Temporary absences from Vermont for any of the following purposes do not interrupt or end Vermont residence: visiting, obtaining necessary medical care, or obtaining education or training under a program of vocational rehabilitation or higher education.

An individual must remain in contact with the department by providing an up-to-date address.

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3401.53

3401 Eligibility3401.53 Determining Countable Income

Complete the following steps to determine countable income:

- a. Constitute the Healthy Vermonters group according to the definition included in the Financial Need of a Healthy Vermonters Group (3401.5) section.
- b. Determine the combined countable income for the Healthy Vermonters group, as constituted in (a) above.
- c. Compare the result to the applicable income test for the Healthy Vermonters group size, as constituted in (a) above.

All otherwise eligible individuals in a Healthy Vermonters group who pass the income test are income-eligible for Healthy Vermonters.

Individuals potentially eligible for traditional Medicaid, such as pregnant women and children, have their eligibility determined under those rules but are considered members of the Healthy Vermonters group for purposes of determining the Healthy Vermonters group size and countable income.

3401.54 Income Test

Individuals are eligible for Healthy Vermonters if they have income no greater than 300 percent of the federal poverty level (FPL).

Individuals are also eligible for Healthy Vermonters if they have income no greater than 400 percent of the FPL and are: 65 or older; or disabled and eligible for social security disability benefits.

The income guidelines are updated annually on January 1 using a methodology similar to the one employed by the federal government in setting the FPLs. In years when the actual FPL exceeds ESD's income maximum, ESD will issue a second increase on April 1.

3403.4 Coverage (Continued)

Beneficiaries who are entitled to Medicare benefits under Part A or enrolled in Medicare Part B, and who live in the service area of a Part D plan, are defined under Medicare rules at 42 CFR §423.30 as eligible for Part D. Vermont is included in the service area for several Part D plans. According to 42 CFR §423.906, Medicare is the primary payer for covered drugs for Part D eligible individuals. HVP does not cover these drug classes.

Part D is administered either through a prescription drug plan (PDP) or as a component of Part C, Medicare managed care, in a Medicare Advantage – Prescription Drug benefit (MA-PD).

The only drug classes that Healthy Vermonters covers for those enrolled in a drug plan, if they are not covered by the PDP/MA-PD, are:

- 1) drugs when used for anorexia, weight loss, or weight gain (M811.2);
- 2) single vitamins or minerals if the conditions described in M811.3 are met;
- 3) over-the-counter prescription if the conditions described in M811.4 are met;
- 4) barbiturates
- 5) benzodiazepines

If a Part D eligible individual elects not to enroll in a PDP/MA-PD plan, or discontinues enrollment in such a plan, coverage for these drugs will end.

When an individual appeals a denial of a drug's coverage under a Part D or Part C plan, and has exhausted the plan's appeal process through the IRE (Independent Review Entity) decision level, or the plan's transition plan as approved by the Centers for Medicare and Medicaid Services (CMS), the individual may apply to the Office of Vermont Health Access for the Healthy Vermonters benefit for the drug. If the individual's prescriber can document medical necessity in a manner established by the director of the Office of Vermont Health Access (OVHA), and the process for documentation conforms with the pharmacy best practice and cost control program established under subchapter 5 of chapter 19 of Title 33, the drug shall be allowed under Healthy Vermonters.

At the beginning of coverage under Medicare Part D, when an HVP-eligible individual has applied for and has attempted to enroll in a Part D or Part C plan and has not yet received coverage due to an operational problem with Medicare, or has otherwise not received coverage for the needed pharmaceutical, the necessary drugs will be covered, if OVHA finds that good cause and a hardship exist, until such time as the operational problem, good cause and hardship ends. The individual must have made every reasonable effort with CMS and the PDP, given the individual's circumstances, to obtain coverage. The intent of the good cause and hardship exception is remedial in nature and shall be interpreted accordingly. In general "good cause" shall include instances where the lack of coverage can not reasonably be considered the fault of the individual, and "hardship" shall include circumstances where alternative means for the coverage at issue are not reasonably available or will likely result in irreparable loss or serious harm to the individual. OVHA will make determinations of whether or not operational problems, good cause, or hardship exists for purposes of coverage.

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3500 Introduction

Act 71, an Act making appropriations for the support of Government authorized and established VPharm. It was adopted by the Vermont General Assembly and signed into law by the Governor on June 21, 2005. In order to keep Medicare beneficiaries' coverage whole, VPharm provides supplemental pharmaceutical coverage starting January 1, 2006. An individual may not be enrolled in Medicaid. Medicaid beneficiaries receive their secondary pharmacy coverage through Medicaid (M801).

The rules which follow apply to the coverage group called VPharm.

3501 Definitions

For purposes of this section concerning VPharm:

- (1) "ESD" means the Economic Services Division of the Department for Children and Families.
- (2) "Maintenance drug" means a drug approved by the FDA for continuous use and prescribed to treat a chronic condition for a prolonged period of time of 30 days or longer, and includes insulin, an insulin syringe, and an insulin needle.
- (3) "Medicare Advantage – Prescription Drug Plan" or "MA-PD" means a Medicare Advantage plan that is certified by Centers for Medicare and Medicaid Services (CMS) as meeting contract requirements as specified in 42 C.F.R. § 422.2 that provides qualified prescription drug coverage under Part D of the Social Security Act.
- (4) "Medicare Part D" means the prescription drug program established under the Medicare Prescription Drug, Improvement and Modernization Act of 2003, P.L. 108-173, including the prescription drug plans offered pursuant to the act.
- (5) "OVHA" means the Office of Vermont Health Access.
- (6) "Pharmaceutical" means a drug that may not be dispensed unless prescribed by a health care provider as defined by subdivision 9402(8) of Title 18 of the Vermont Statutes Annotated (V.S.A.) acting within the scope of the provider's license. The term excludes a drug determined less than effective under the federal Food, Drug and Cosmetics Act.
- (7) "Pharmacy" means a retail or institutional drug outlet licensed by the Vermont state board of pharmacy pursuant to chapter 36 of Title 26 of the Vermont Statutes Annotated (V.S.A.), or by an equivalent board in another state, in which pharmaceuticals are sold at retail and which has entered into a written agreement with the state to dispense pharmaceuticals in accordance with the provisions of this chapter.
- (8) "Prescription Drug Plan" or "PDP" means prescription drug coverage that is offered under a policy, contract, or plan that has been approved, as specified in 42 C.F.R. § 423.272, and that is offered by a sponsor that has a contract with the Centers for Medicare and Medicaid Services (CMS).

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3502 Eligibility

An individual must meet the following requirements (3502.1 or 3502.2 and 3502.3 - 3502.6) to be found eligible for the VPharm program.

3502.1 Age

To qualify on the basis of age, an individual must be at least 65 years of age as of the effective date of coverage under VPharm and entitled to Medicare benefits under Part A or enrolled in Medicare Part B and enrolled in Medicare Parts C or D.

3502.2 Disability

To qualify on the basis of disability, an individual must be under 65 years of age as of the effective date of coverage under VPharm and entitled to Medicare benefits under Part A or enrolled in Medicare Part B and enrolled in Medicare Parts C or D.

3502.3 State Residence

An individual must be a resident of Vermont at the time of application.

3502.4 Income

Household income, when calculated in accordance with the rules adopted for the Vermont Health Access Plan (VHAP 4001.81- 4001.83), must be no greater than 225 percent of the federal poverty level.

3502.5 Prescription Drug Plan (PDP) Enrollment

An individual must be enrolled in a PDP or a MA-PD and may not have other private insurance for prescription drugs.

3502.6 Limited Income Subsidy

Individuals eligible for the federal limited income subsidy described in 42 C.F.R. §§ 423.771-423.800 must secure it.

3503 Application

Individuals must file an application for VPharm with the Economic Services Division (ESD) of the Vermont Department for Children and Families and provide information about the individual's situation relevant to the tests for eligibility (Section 3502). Applications are date-stamped to ensure that earlier applications are acted upon first.

Individuals must furnish their social security number or apply for a social security number unless they substantiate that they are a member of a religious organization that objects to the use of a social security number. An applicant who substantiates membership in such an organization shall be given an alternate identification number.

Verification of the information provided is not generally required of individuals unless it is questionable, verification is outstanding for another ESD benefit program, or the individual has refused to provide a social security number because of a religious objection. Social security numbers are used to verify information through tape matches. Individuals are notified on the application form of the verification actions the department may take, including the use of verification obtained for other ESD programs, randomly selected quality control reviews, and the penalties for fraudulent reporting of their situation.

3503.1 Application Decision

ESD shall make an eligibility decision within 30 days of the date the application is received. An applicant not meeting the eligibility requirements shall be denied and may reapply at any time.

ESD will send the applicant a notice regarding the action being taken on the application. An applicant who is denied will be sent a denial notice that includes the reason for the denial and the applicant's appeal rights.

3504 Eligibility Process

3504.1 Period of Eligibility and Enrollment

A. Period of Eligibility

VPharm eligibility continues through June 30 of the year following the year in which the determination of eligibility was made.

A review of eligibility will be completed before the end of each annual certification period to ensure uninterrupted coverage if the individual remains eligible, pays all required premiums, and complies in a timely manner with review requirements. An individual who fails to pay required premiums or fails to comply in a timely manner with review requirements shall receive a termination notice mailed at least 11 days before the termination date.

B. Enrollment

Once eligibility for VPharm is approved and required premiums are received by ESD, beneficiaries will be enrolled on the first day of the month following receipt and processing of the full premium payment. Each month the department shall prospectively pay PDP or MA-PD premiums on behalf of all beneficiaries enrolled in VPharm as described in section 3506.

Termination shall occur whenever a beneficiary:

- is incarcerated;
- fails to pay the required premium;
- moves out-of-state;
- voluntarily withdraws;
- disenrolls from a PDP or a MA-PD;
- does not secure the limited income subsidy for which the beneficiary is eligible;
- is found to have been ineligible on the date coverage began;
- is no longer in contact with ESD and has no known address; or
- dies.

Individuals are required to report any of the above changes, as applicable, and any change of address within 10 days of the change. A beneficiary may be terminated at the end of the month following a notice mailed at least 11 days before the termination date.

If a beneficiary's coverage is terminated solely because of nonpayment of the premium, and the reason is medical incapacity, as specified in section M150.1(A)(1) of the state's Medicaid rules, the beneficiary or the beneficiary's representative may request coverage for the period between the day coverage ended and the last day of the month in which they request coverage. ESD will provide this coverage if it has received verification of medical incapacity and all premiums due for the period of non-coverage. The beneficiary is responsible for all bills incurred during the period of non-coverage until ESD receives the required verification and premium amounts due.

If the health condition related to this medical incapacity is expected to continue or recur, ESD will encourage beneficiaries to sign up for automatic withdrawal of their premium or designate an authorized representative to receive and pay future premiums for as long as the anticipated duration of the condition.

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3504.2 Identification Document

Each individual in the household enrolled in VPharm is provided with an identification card which includes the individual's name and identification number.

3504.3 Notice and Right to Appeal

ESD shall provide individuals with notice whenever they are found ineligible for the VPharm program or when the benefits they may receive under the VPharm program are reduced or discontinued. The notice shall include a statement of the intended action, the reason for the action and an explanation of the individual's right to request a fair hearing before the Human Services Board.

Individuals requesting a fair hearing must make their request within 90 days of the date the notice of decision was mailed.

When beneficiaries appeal a decision to end or reduce VPharm coverage, they have the right to have benefits continue without change until the appeal is decided provided the beneficiary has requested a hearing before the effective date of the change and has paid and continues to pay any required premiums in full. Beneficiaries appealing the amount of their premiums shall pay at the billed amount in order for coverage to continue until the dispute is resolved. Beneficiaries who successfully appeal the amount of their premium will be reimbursed by ESD for any premium amounts overpaid.

Continuation of benefits without change does not apply when the appeal is based solely on a reduction or elimination of a benefit required by federal or state law affecting some or all beneficiaries, or when the decision does not require the minimum advance notice (see Notice of Decision at M141 of the state Medicaid rules).

Beneficiaries who waive their right to continued benefits will be reimbursed by ESD for out-of-pocket expenses for covered services provided during the appeal period in any case in which the Human Services Board reverses the decision.

3504.4 Beneficiary Fraud Investigation

A person who knowingly gives false or misleading information or holds back needed information in order to obtain VPharm benefits, may be prosecuted for fraud under Vermont law or federal law or both; if convicted, the individual may be fined or imprisoned or both.

When ESD learns that fraud may have been committed, it will investigate the case with respect for confidentiality and the legal rights of the beneficiary. If appropriate, the case will be referred to the State's Attorney or Attorney General for a decision on whether or not to prosecute.

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3505 Payment System

VPharm follows the prospective premium-based payment system described at rule M150.

3505.1 Cost-Sharing

An individual shall contribute the following base cost-sharing amounts, which shall be indexed to the increases established under 42 C.F.R. § 423.104(d)(5)(iv) and then rounded to the nearest dollar amount:

- (1) \$13.00 per month or \$156.00 per year in the case of beneficiaries whose household income is no greater than 150 percent of the federal poverty level;
- (2) \$17.00 per month or \$204.00 per year in the case of beneficiaries whose household income is greater than 150 percent of the federal poverty level and no greater than 175 percent of the federal poverty level;
- (3) \$35.00 per month or \$420.00 per year in the case of beneficiaries whose household income is greater than 175 percent of the federal poverty level and no greater than 225 percent of the federal poverty level.

3505.2 Medicare Advocacy Program

In order to ensure the appropriate payment of claims, OVHA may expand the Medicare advocacy program established under chapter 67 of Title 33 of the V.S.A. to individuals receiving benefits from the VPharm program.

3505.3 Lower of Price for Ingredients Plus Dispensing Fee or Charge

Payment for prescribed drugs, whether legend or over-the-counter items, will be made at the lower of the price for ingredients (see 3303.3) plus the dispensing fee on file or the provider's actual amount charged, which shall be the usual and customary charge to the general public.

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3505.4

3505.4 Price for Ingredients

Payment for the ingredients in covered prescriptions is made for two groups of drugs: multiple-source (i.e., therapeutically equivalent or generic drugs) and "other" drugs (i.e., brand name or drugs "other" than multiple-source).

- a. For multiple-source drugs, the price for ingredients will be the lowest of:
 1. an amount established as the upper limit derived from a listing issued by CMS, formerly the Health Care Financing Administration, under the authority of Sec. 902(a)(30)(A) of the Social Security Act, or
 2. an amount established as the upper limit by the Office of Vermont Health Access, or
 3. the Average Wholesale Price (AWP).
- b. For "other" drugs, the price for ingredients will be 88.1 percent of the Average Wholesale Price (AWP less 11.9 percent).

3505.5 Compounded Prescriptions

Payment for compounded prescriptions is made at the lower of the actual amount charged or the price for ingredients plus the dispensing fee plus the compounding fee on file for each minute directly expended in compounding.

3505.6 Participating Pharmacy

"Pharmacy" means a retail or institutional drug outlet licensed by the Vermont State Board of Pharmacy pursuant to chapter 36 of Title 26, or by an equivalent board in another state, in which prescription drugs are sold at retail and which has entered into a written agreement with the state to dispense drugs.

A pharmacy provider must:

- satisfactorily complete and submit to the Office of Vermont Health Access the standard enrollment form;
- conform to the standards of the Vermont State Board of Pharmacy and other federal and state statutes and regulations applicable to the dispensing of prescription drugs to the general public;
- agree to provide reasonable access to records necessary to comply with the provisions for program review set forth in the Provider Agreement;
- never deny services to, or otherwise discriminate, against any individual on the basis of race, color, sex, age, religious preference, national origin, handicap or sexual orientation;
- take appropriate steps to prevent the wrongful utilization of prescription drugs, with special concern for the potentially dangerous interaction of two or more prescription drugs from different prescribers.

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3505.7 Prescribed Drugs

Pharmaceutical items include drugs that are obtained through appropriately licensed pharmacies. Payment for prescribed drugs is limited to the following providers who are enrolled in Vermont Medicaid:

Registered Vermont pharmacies, including hospital pharmacies;

Pharmacies appropriately licensed in another state; or

A physician, serving in areas without regular pharmacy services, who has been granted special approval to bill these items direct.

Payment is limited to covered items furnished on written prescription from a duly licensed medical professional licensed by the state of Vermont to prescribe within the scope of his or her practice and enrolled in Vermont Medicaid, or on telephoned prescription from a prescriber as previously described and enrolled in Vermont Medicaid processed in compliance with applicable federal and state statutes and regulations. Any drug that is to be used continuously (i.e., daily, twice a day, every other day, etc.) for 30 days or more shall be prescribed and dispensed in an amount sufficient to treat the patient no fewer than 30 days and no more than 90 days at a time. Medications that the patient takes or uses on an "as needed" basis are not considered to be used continuously. Up to five refills are permitted. If there are extenuating circumstances in an individual case that, in the judgment of the physician, dictate a shorter prescribing period, the supply may be for fewer than 30 days.

The pharmacist shall not fill a prescription in a quantity different from that prescribed by the physician if payment is to be made by VPharm, except in an individual case when the quantity has been changed in consultation with the physician.

Payment may be made for any covered preparation, except those unfavorably evaluated, either included or approved for inclusion in the latest edition of official drug compendia: the U.S. Pharmacopoeia, the National Formulary, the U.S. Homeopathic Pharmacopoeia, AMA Drug Evaluations, or Accepted Dental Therapeutics. These consist of "legend" drugs for which a prescription is required by State or Federal law.

Physicians and pharmacists are required to conform to Chapter 91 of Title 18 of the Vermont Statutes Annotated (Generic Drugs). In those cases where Chapter 91 permits substitution, only the lowest priced equivalent shall be considered medically necessary. If, in accordance with Chapter 91, the patient does not wish to accept substitution, VPharm will not pay for the prescription.

3506 Coverage

Beneficiaries who are entitled to Medicare benefits under Part A or enrolled in Medicare Part B, and who live in the service area of a Part D plan, are defined under Medicare rules at 42 CFR §423.30 as eligible for Part D. Vermont is included in the service area for several Part D plans. According to 42 CFR §423.906, Medicare is the primary payer for covered drugs for Part D eligible individuals. VPharm does not cover drugs in classes included in the Part D benefit. VPharm provides secondary pharmacy coverage as described below for those eligible for Medicare and VPharm.

Part D is administered either through a prescription drug plan (PDP) or as a component of Part C, Medicare managed care, in a Medicare Advantage – Prescription Drug benefit (MA-PD).

VPharm will provide supplemental coverage for the following categories of drugs if they are not covered by the PDP/MA-PD:

- 1) drugs for anorexia, weight loss, or weight gain (M811.2);
- 2) single vitamins or minerals if the conditions described in M811.3 are met;
- 3) over-the-counter prescriptions if the conditions described in M811.4 are met;
- 4) barbiturates; and
- 5) benzodiazepines.

Payment for the covered pharmaceuticals described above shall be based upon current Medicaid payment and dispensing policies.

For those individuals whose household income is not greater than 150 percent of the federal poverty level (FPL), the drugs in the above categories are covered as they are covered under Medicaid. In addition, benefits are provided for one comprehensive visual analysis (including a refraction) and one interim eye exam (including a refraction) within a two-year period, and diagnostic visits and tests related to vision.

For those individuals whose household income is greater than 150 percent FPL and no greater than 225 percent FPL, VPharm covers the drugs in the above categories only if they are maintenance drugs. "Maintenance drug" means a drug approved by the FDA for continuous use and prescribed to treat a chronic condition for a prolonged period of time of 30 days or longer and includes insulin, an insulin syringe and an insulin needle. It may not be dispensed unless prescribed by a licensed physician.

For those individuals whose household income is greater than 175 percent but no greater than 225 percent of the poverty level, coverage in the classes listed above is limited to drugs dispensed by participating pharmacies from manufacturers that, as a condition of participation in the program, have signed a rebate agreement with the Office of Vermont Health Access.

In addition, VPharm covers beneficiary cost-sharing after any federal limited-income subsidy is applied. This may include basic beneficiary premiums for the PDP up to the low-income premium subsidy amount (as determined by the Centers for Medicare and Medicaid Services), Part D deductible, co-payments, coinsurance, the Part D coverage gap, and catastrophic co-payments according to Medicare Part D rules.

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3506 Coverage (Continued)

For those individuals whose household income is greater than 175 percent but no greater than 225 percent of the poverty level, cost-sharing coverage is limited to maintenance drugs. On a case-by-case basis, OVHA may pay or subsidize a higher premium for a Medicare Part D prescription drug plan offering expanded benefits if it is cost-effective to do so.

When an individual appeals a denial of coverage of a drug under a Part D or Part C plan, and has exhausted the plan's appeal process through the Independent Review Entity (IRE) decision level, or the plan's transition processes as approved by the Centers for Medicare and Medicaid Services (CMS), the individual may apply to the Office of Vermont Health Access (OVHA) for coverage of the drug if it would have been included in the corresponding Vermont pharmacy benefit (Medicaid or maintenance level of coverage) if the individual were not covered by Part D. If the individual's prescriber documents medical necessity in a manner established by the director of the OVHA, and the process for documentation conforms with the pharmacy best practice and cost control program established under subchapter 5 of chapter 19 of Title 33, the drug shall be covered.

At the beginning of coverage under Medicare Part D, when an individual has applied for and has attempted to enroll in a Part D plan and has not yet received coverage due to an operational problem with Medicare, or has otherwise not received coverage for the needed pharmaceutical, the necessary drugs will be covered, if OVHA finds that good cause and a hardship exist, until such time as the operational problem, good cause and hardship ends. The individual must have made every reasonable effort with CMS and the PDP, given the individual's circumstances, to obtain coverage. The intent of the good cause and hardship exception is remedial in nature and shall be interpreted accordingly. In general "good cause" shall include instances where the lack of coverage can not reasonably be considered the fault of the individual, and "hardship" shall include circumstances where alternative means for the coverage at issue are not reasonably available or will likely result in irreparable loss or serious harm to the individual. OVHA will make determinations of whether or not operational problems, good cause, or hardship exists for purposes of coverage.

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4003.11 Beneficiaries Eligible for VHAP and Medicare

When a VHAP beneficiary becomes eligible for Medicare and thus ineligible for VHAP, there may be a brief period of time when the beneficiary is eligible for both programs before the effective date of the VHAP closure. In that case, VHAP becomes the secondary payer. VHAP pharmaceutical coverage for these beneficiaries is subject to the following rules.

Beneficiaries who are entitled to Medicare benefits under Part D or enrolled in Medicare Part B, and who live in the service area of a Part D plan, are defined under Medicare rules at 42 CFR §423.30 as eligible for Part D. Vermont is included in the service area for several Part D plans. According to 42 CFR §423.906, Medicare is the primary payer for covered drugs for Part D eligible individuals. VHAP does not cover drugs in classes included in the Part D benefit.

Part D is administered either through a prescription drug plan (PDP) or as a component of Part C, Medicare managed care, in a Medicare Advantage – Prescription Drug benefit (MA-PD).

The only drug classes that VHAP covers for those enrolled in a drug plan, if they are not covered by the individual's PDP/MA-PD, are:

- 1) drugs for anorexia, weight loss, or weight gain (see M811.2);
- 2) single vitamins or minerals if the conditions described in M811.3 are met;
- 3) over-the-counter prescription if the conditions described in M811.4 are met;
- 4) barbiturates; and
- 5) benzodiazepines.

If a Part D eligible individual elects not to enroll in a PDP/MA-PD plan, or discontinues enrollment in such a plan, eligibility for VPharm will end.

When an individual appeals a denial of coverage of a drug under a Part D or Part C plan, and has exhausted the plan's appeal process through the Independent Review Entity (IRE) decision level, or the plan's transition processes as approved by the Centers for Medicare and Medicaid Services, the individual may apply to the Office of Vermont Health Access (OVHA) for coverage of the drug if it is included in the VHAP benefit (See P-4003 B9 or P-4004 B9). If the individual's prescriber documents medical necessity in a manner established by the director of OVHA, and the process for documentation conforms with the pharmacy best practice and cost control program established under subchapter 5 of chapter 19 of Title 33, the drug shall be covered.

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4003.11 Beneficiaries Eligible for VHAP and Medicare (Continued)

At the beginning of coverage under Medicare Part D, when a VHAP-eligible individual has applied for and has attempted to enroll in a Part D or Part C plan and has not yet received coverage due to an operational problem with Medicare, or has otherwise not received coverage for the needed pharmaceutical, the necessary drugs will be covered, if OVHA finds that good cause and a hardship exist, until such time as the operational problem, good cause and hardship ends. The individual must have made every reasonable effort with CMS and the PDP, given the individual's circumstances, to obtain coverage. The intent of the good cause and hardship exception is remedial in nature and shall be interpreted accordingly. In general "good cause" shall include instances where the lack of coverage can not reasonably be considered the fault of the individual, and "hardship" shall include circumstances where alternative means for the coverage at issue are not reasonably available or will likely result in irreparable loss or serious harm to the individual. OVHA will make determinations of whether or not operational problems, good cause, or hardship exists for purposes of coverage.