

**STATE OF VERMONT
AGENCY OF HUMAN SERVICES
Department of Vermont Health Access (DVHA)**

AHS Bulletin No: 10-11

Secretary of State's ID Number: 10P-031

FROM: Susan Besio, Ph.D., Commissioner
Department of Vermont Health Access

DATE: 10/21/10

SUBJECT: VPharm and VScript Rebate Agreements

CHANGES ADOPTED EFFECTIVE: 11/01/10

TYPE OF RULE CHANGE

Adopted Rule Changes

Final Proposed Rule Change

Proposed Rule Change

RULE REFERENCE(S):

5450 5641

This rule change is being implemented as directed by (H.789) Act 156 of the 2009 -2010 Legislative Session, An Act Making Appropriations for the Support of Government.

Sec. E.309.15 33 V.S.A. § 1901(a)(4) is added to read:

(4) A manufacturer of pharmaceuticals purchased by individuals receiving state pharmaceutical assistance in programs administered under this chapter shall pay to the department of Vermont health access, as the secretary's designee, a rebate on all pharmaceuticals for which state-only funds are expended in an amount at least as favorable as the rebates provided under 42 U.S.C. section 1396r-8 paid to the department in connection with Medicaid and programs funded under the Global Commitment to Health Medicaid Section 1115 waiver.

Sec. E.309.16 33 V.S.A. § 2073(f) is amended to read:

(f) A manufacturer of pharmaceuticals purchased by individuals receiving assistance from VPharm established under this section shall pay to DVHA, as required by section 1901 of this title, a rebate on all pharmaceuticals for which state-only funds are expended in an amount at least as favorable as the rebate paid to DVHA in connection with the Medicaid program.

Sec. E.309.17 33 V.S.A. § 2074(d) is amended to read:

(d) Any manufacturer of pharmaceuticals purchased by individuals receiving assistance from VermontRx established under this section shall pay to DVHA, as required by section 1901 of this title, a rebate on all pharmaceuticals for which state-only funds are expended in an amount at least as favorable as the rebate paid to DVHA in connection with the Medicaid program.

Specific Changes to Rule Sections Since the Last Filing

Section	Description of Change
All Sections	Effective date changed from 11/1/10 to 11/13/10.

Responses to Public Comments

A public hearing was held on September 3, 2010 from 12:00 p.m. - 2:00 p.m. in the Large Conference Room at the Department of Vermont Health Access, 312 Hurricane Lane, Suite 201, Williston, Vermont. There were no attendees.

DVHA received written comments from Stateside Associates. Their comments are summarized below along with DVHA's response.

Comment: Will this rebate affect all pharmaceuticals - specifically diabetic testing supplies, including HCPCS codes A4253, A4259, and E0607?

Response: DVHA does not collect rebates on diabetic supplies through the State (VPharm/VScript) Rebate agreements in either the pharmacy or the medical benefit (the above referenced HCPCS codes), nor do we collect CMS rebates on these products. However, DVHA does have preferred vendor contracts with some manufacturers who pay DVHA State rebates through a separate agreement.

To get more information about the Administrative Procedures Act and the Rules applicable to state rule making go to the website of the Department of the Vermont Secretary of State at: <http://vermont-archives.org/aparules/index.htm> or call Louise Corliss at 828-2863. [General information, not specific rule content information]

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

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.

5450 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:

- A. drugs for anorexia, weight loss, or weight gain (7502.3);
- B. prescription vitamins or minerals if the conditions described in 7502.4 are met;
- C. over-the-counter prescriptions if the conditions described in 7502.5 are met;
- D. barbiturates; and
- E. benzodiazepines.

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

For those beneficiaries 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 beneficiaries 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.

In addition, VPharm covers beneficiary cost-sharing after any federal limited-income subsidy (LIS) 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. Beneficiaries have co-payments as described in 3505.1.

For those beneficiaries 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, DVHA 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.

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5450 Coverage (Continued)

In the case of the statin lipotropic and proton pump inhibitor drug classes, VPharm requires the use of a select OTC and/or a generic drug in order to receive coverage of the Medicare Part D cost-sharing, or of the prescription when the drug would be paid for entirely by VPharm, except that:

- (A) a beneficiary who is taking a brand name drug on June 30, 2009, under a prior authorization through a Medicare Part D plan, may continue to receive coverage under VPharm for that drug; and
- (B) a prescriber may override the substitution of an OTC or generic drug by requesting an exception override from DVHA. The override will be based on the same criteria provided for in section 4606 of Title 18 (generic substitutions). The prescriber must provide a detailed explanation regarding:
 - (1) the OTC or generic drug or drugs that have been previously tried by the beneficiary and:
 - (a) were ineffective; or
 - (b) resulted in the adverse or harmful side effects to the beneficiary; or
 - (2) the reasons why the provider expects that the OTC or generic drug(s) may be ineffective or result in adverse or harmful side effects to the beneficiary if they have not previously tried the drug(s).

The drug utilization review (DUR) board shall determine the list of OTC and generic drugs that shall be available for coverage in each class and shall ensure that the list of generic drugs includes drugs available on the formularies of 90 percent of the Medicare Part D prescription drug plans available in Vermont. In designing the list, the DUR board shall maximize access to a variety of OTC and generic drugs for beneficiaries.

When a beneficiary 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 beneficiary may apply to the Department of Vermont Health Access (DVHA) 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 beneficiary were not covered by Part D. If the beneficiary's prescriber documents medical necessity in a manner established by the director of the DVHA, 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 a beneficiary 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 DVHA finds that good cause and a hardship exist, until such time as the operational problem, good cause and hardship ends. The beneficiary must have made every reasonable effort with CMS and the PDP, given the beneficiary'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 beneficiary, 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 beneficiary. DVHA will make determinations of whether or not operational problems, good cause, or hardship exists for purposes of coverage.

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5450 Coverage (continued)

5450.1 Rebate or Price Discount

VPharm provides secondary pharmacy coverage as described in section 5450 for those eligible for Medicare and VPharm. Manufacturers shall pay to the DVHA a rebate on all pharmaceuticals paid by the State for VPharm beneficiaries in an amount at least as favorable as the rebate or price discount paid in connection with the Medicaid program.

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5641 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 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.

Apart from the select drugs used for maintenance treatment described below, all other maintenance drugs must be prescribed and dispensed for not less than 30 days and not more than 90 days. If there are extenuating circumstances in an individual case which, in the judgment of the prescriber, dictate a shorter prescribing period for these drugs, the supply may be for less than 30 days as long as the prescriber prepares in sufficient written detail a justification for the shorter period. The extenuating circumstance must be related to the health and/or safety of the beneficiary and not for convenience reasons. It is the responsibility of the pharmacy to maintain in the beneficiary's record the prescriber's justification of extenuating circumstances.

Select drugs used for maintenance treatment must be prescribed and dispensed in 90-day supplies. The drug utilization review board shall make recommendations to the director on the drugs to be selected. This limit shall not apply when the beneficiary initially fills the prescription in order to provide an opportunity for the beneficiary to try the medication and for the prescriber to determine that it is appropriate for the beneficiary's medical needs. If there are extenuating circumstances in an individual case which, in the judgment of the prescriber, dictate a shorter prescribing period, an exception form that identifies the individual and the reason for the exception may be filed with the Department of Vermont Health Access (DVHA).

Up to five refills are permitted if allowed by federal or state pharmacy 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 beneficiary 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 Department of Vermont Health Access 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 who pay to the DVHA a rebate on all pharmaceuticals paid by the State for VScript beneficiaries in an amount at least as favorable as the rebate or price discount paid in connection with the Medicaid program.