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

AHS Bulletin No: 11-13

Secretary of State's ID Number: ##P-###

FROM: Mark Larson, Commissioner
Department of Vermont Health Access

DATE: 10/21/11

SUBJECT:

CHANGES ADOPTED EFFECTIVE: 02/11/2012

TYPE OF RULE CHANGE

Adopted Rule Changes

Final Proposed Rule Change

X Proposed Rule Change

RULE REFERENCE(S):

5450 7502

This rule is being implemented as directed by (H.441) Act 63 of the 2011 -2012 Legislative Session, An Act Making Appropriations for the Support of Government.

> Sec. E.307.3 EMERGENCY RULES
> (b) In order to implement Sec. E. 309.1 (health care coverage; legal immigrant children and pregnant women), Sec. E. 309 (State Children's Health Insurance Program (SCHIP) and Medicaid programs covering children premium grace period), and Sec. E.301.1 (Medicaid pharmacy; radiology tier authorization) of this act no later than July 1, 2011, the agency of human services shall be deemed to have met the standard for adoption of emergency rules as required by 3 V.S.A. § 844(a). Notwithstanding 3 V.S.A. § 844, the agency shall provide a minimum of five business days for public comment in advance of filing the emergency rules as provided for in 3 V.S.A. § 844(c)
>
> Sec. E.301.1 MEDICAID PHARMACY
> (a) The department of Vermont health access shall reduce spending on prescription drugs by managing over-the-counter drugs with the preferred drug list, establishing lower reimbursements for specialty drugs, and requiring justification for prescribing multi-source brand-name drugs.

Specific Changes to Rule Sections upon Filing of Emergency Rules

Section	Description of Change

5450	All references to "payment" changed to "coverage"; paragraph 3: added language "Coverage of these drugs is subject to the requirements of the Preferred Drug List (PDL)"; paragraph 3, subsection B. deleted word "prescription"; paragraph 9, sentence one deleted "a" and deleted "OTC and/or a"; paragraph 9, subsection B.: deleted "OTC and/or a", and subsection (1) deleted "OTC or generic drug or" and added "drug(s)"; paragraph 9, subsection B., number (2): deleted "OTC and/or a" paragraph 10: deleted "OTC and/or a"; added new language under Rule 5450.1 regarding Non-Drug Items; renumbered original language in Rule 5450.1 regarding Rebate or Price Discount to Rule 5450.2.
7502	All references to "payment" changed to "coverage"; paragraph 1: revised references to compendia described in section 1927(g)(1)(B)(i) of the Social Security Act; add paragraph 2 language: "Coverage of these drugs is subject to the requirements of the Preferred Drug List (PDL)"; Rule 7502.1 limitations revised per requirements of the PDL. Rule 7502.2 revised to include reference to diabetic supplies as covered per requirements of the PDL; examples of excluded non-drug items updated per current commonly available products. Rule 7502.2 added language: "Homeopathic Medicines, Alternative Medicine/Natural Products (e.g. Ginseng, Gingko Biloba, etc.)" and "Coverage for liquid nutritional supplements is subject to the requirements of the PDL. Prior authorization is required."; Rule 7502.3 deleted references to amphetamines and other psychomotor stimulants, and added language referencing coverage for usage when in accordance with the PDL; replaced reference to " "Meridia™" with "Alli™". Rule 7502.4 paragraph 1: deleted "generic" and added "select" and deleted "when a physician certifies that condition of the prescription"; add language indicating that generic multivitamins are covered and single vitamins are covered to treat a specific disease; deleted paragraph 3. Rule 7502.5 title and first paragraph: replaced the "Preparations" with "Drugs"; revised specifically excluded items to specify those classes of over-the-counter drugs that are covered in generic form only, where the attending physician has prescribed it as part of the medical treatment of a specific disease and other select products as determined by the DUR Board and are included in the current list of categories of covered vitamins and over-the-counter drugs; deleted paragraph 3; seventh bullet removed "are" and "vitamins and".

Specific Changes to Rule Sections Following Implementation of Emergency Rules

Section	**Description of Change**
5450	Removed: three preceding interpretive memos dated 7/15/09, 5/15/06, and 1/1/06 as they have been incorporated into the rule per Bulletin 10-11 effective 11/13/10.
7502	None

Comment Period

A public hearing is scheduled on Friday, December 2nd, 2011 at 10:00 a.m. in the Department of Vermont Health Access (DVHA) Conference Room, 289 Hurricane Lane, Williston, Vermont.

Written Comments may be submitted no later that 4:30 p.m. on Friday, December 9th, 2011 to Greg Needle, DVHA, 312 Hurricane Lane, Suite 201, Williston, Vermont 05495.

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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]

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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.

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. Coverage of these drugs is subject to the requirements of the Preferred Drug List (PDL):

A. drugs for anorexia, weight loss, or weight gain (7502.3);

B. 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.

Coverage for the 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.

In the case of the statin lipotropic and proton pump inhibitor drug classes, VPharm requires the use of select generic drugs 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 a 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 drug(s) that have been previously tried by the beneficiary and:

- were ineffective; or
- resulted in the adverse or harmful side effects to the beneficiary; or

(2) the reasons why the provider expects that the 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 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 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.

5450.1 Non-Drug Items

VPharm covers beneficiary cost-sharing (after a Medicare Part B or Part D payment) for insulin and other diabetic supplies, including test strips, needles and syringes.

5450.2 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.

7502 Prescribed Drugs

Coverage is provided for any drug which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Social Security Act.

The compendia are:

I. American Hospital Formulary Service Drug Information,

II. DRUGDEX Information System, and

III. United States Pharmacopeia-Drug Information (or its successor publications)

Coverage of all drugs is subject to the requirements of the Preferred Drug List (PDL)

Physicians and pharmacists are required to conform to Act l27 (l8 VSA Chapter 9l), otherwise known as the Generic Drug Bill. In those cases where the Generic Drug Bill permits substitution, only the lowest priced equivalent in stock at the pharmacy shall be considered medically necessary. If, in accordance with Act l27, the patient does not wish to accept substitution, Medicaid will not cover the prescription.

7502.1 Smoking Cessation Products

Coverage of over-the-counter and prescription smoking cessation products is provided to beneficiaries subject to the requirements of the PDL.

7502.2 Non-Drug Items

Most non-drug items are not covered. Coverage is provided for Diabetic Supplies, Spacers, and Peak Flow Meters subject to the requirements of the PDL.

Some examples of excluded non-drug items include:

dentifrices and dental adhesives

baby oil

mouthwash

soap, shampoos

food products and food supplements*

baby formula

sugar substitutes

topical antiseptics

throat lozenges

lotions, rubbing alcohol, and witch hazel

Band-aids, gauze, adhesive tape

ostomy deodorants, oral or external

placebo; all dosage forms

homeopathic Medicines

alternative Medicine/Natural Products (e.g. Ginseng, Gingko Biloba, etc.)

*Coverage for liquid nutritional supplements is subject to the requirements of the PDL. Prior authorization is required.

7502.3 Stimulants and Appetite Depressants

Stimulants are covered only when used in accordance with the requirements of the Preferred Drug List

Non-amphetamine-based weight-loss drugs (for example Alli™, Xenical™) are covered with prior authorization.

7502.4 Vitamins and Minerals

Select pre-natal vitamins are covered for pregnant and lactating women.

Generic multivitamins are covered

Single vitamins B and D, and select minerals (e.g. calcium, iron) are covered when prescribed for the treatment of a specific disease; e.g. Injectable vitamin B-12 in the treatment of certain types of anemia.

7502.5 Over the Counter Drugs

The following classes of over-the-counter drugs are covered in generic form only, where the attending physician has prescribed it as part of the medical treatment of a specific disease; for example, analgesics for the relief of arthritis pain, and laxatives for the bedbound:

- analgesics such as acetaminophen, aspirin and other non-steroidal anti-inflammatory products;
- fecal softeners; such as those containing docusate;
- laxatives and antidiarrheals such as those containing loperamide;
- antacids;
- antihistamines;
- select cough and cold products; and
- other select products as determined by the DUR Board and included in the current list of categories of covered over-the-counter drugs.

7502.6 Family Planning Items

Contraceptive drugs, supplies, and devices are covered when provided on a physicians order. Birth control pills may be dispensed in a quantity not to exceed a 92-day supply. Payments made for these items will be deemed to qualify for the increased federal financial participation contained in section 1903 (a)(5) of the Social Security Act.