Table of Contents

State/Territory Name: Vermont

State Plan Amendment (SPA) #: 11-023B

This file contains the following documents in the order listed:

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
JFK Federal Building, Government Center
Room 2275
Boston, Massachusetts 02203

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Division of Medicaid and Children's Health Operations / Boston Regional Office

April 30, 2012

Douglas A. Racine, Secretary
Department of Vermont Health Access
208 Hurricane Lane, Suite 103
Williston, VT 05495

Dear Secretary Racine:

On April 26, 2012, our Central Office sent you a letter approving your proposed State Plan Amendment (SPA) No. 11-023B effective July 1, 2011. This letter transmits the Transmittal and Notice of Approval of State Plan Material (CMS-179) and the approved State Plan pages.

SPA 11-023B amends the State's approved Title XIX State Plan to reduce the current Medicaid reimbursement methodology for limited distribution specialty pharmacies from average wholesale price (AWP) minus 14.2 percent to 16.5 percent, cover generic over-the-counter drugs when medically necessary without the option of prior authorization for brand name drugs and cover active pharmaceutical ingredient (API) drugs.

Changes are reflected in the following sections of your approved State Plan:

- Attachment 3.1-A, page 5a and 5b
- Attachment 4.19-B, page 4a and 4b

If you have any questions regarding this matter you may contact Robert Cruz (617) 565-1257 or by e-mail at Robert.Cruz @cms.hhs.gov.

Sincerely,

[redacted]

Richard R. McGreal
Associate Regional Administrator

cc: Mark Larson, Commissioner
Suzanne Santarcangelo, Ph.D., Director, AHS Healthcare Operations, Compliance & Improvement
Lindsey Wells, Health Programs Administrator, Department of Vermont Health Access

Enclosure/s

Department of Health & Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-14-26
Baltimore, Maryland 21244-1850

Center for Medicaid and CHIP Services

Disabled and Elderly Health Programs Group

April 26, 2012

Douglas A. Racine, Secretary
Department of Vermont Health Access
Agency of Human Services
208 Hurricane Lane, Suite 103
Williston, Vermont 05495

Attention: Lindsey Wells

Dear Mr. Racine:

We have reviewed Vermont State Plan Amendment (SPA) 11-023B received in the Boston Regional Office on September 30, 2011. Under this SPA, the State proposes to reduce the current Medicaid reimbursement methodology for limited distribution specialty pharmacies from average wholesale price (AWP) minus 14.2 percent to 16.5 percent, cover generic over-the-counter drugs when medically necessary without the option of prior authorization for brand name drugs and cover active pharmaceutical ingredient (API) drugs. The effective date for this SPA is July 1, 2011.

We are pleased to inform you that Vermont SPA 11-023B is approved, effective July 1, 2011. The Boston Regional Office will forward to you a copy of the CMS-179 form, as well as the pages approved for incorporation into the Vermont Medicaid State Plan. If you have any questions regarding this amendment, please contact Bernadette Leeds at (410) 786-9463.

Sincerely,

/s/

Larry Reed
Director
Division of Pharmacy

cc: Richard McGreal, ARA, Boston Regional Office
Mark Larson, Department of Vermont Health Access
Robert Cruz, Boston Regional Office

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE AND MEDICAID SERVICES	1. TRANSMITTAL NUMBER: 11 -- 023-B	2. STATE: VERMONT
	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
TO: REGIONAL ADMINISTRATOR CENTERS FOR MEDICARE & MEDICAID SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE(S) JULY 1, 2011	

5. TYPE OF PLAN MATERIAL *(CHECK ONE)*:

☐ NEW STATE PLAN ☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN ☒ AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT *(Separate Transmittal for each amendment)*

6. FEDERAL STATUTE/REGULATION CITATION: 42 CFR §430.12(c)(ii)	7. FEDERAL BUDGET IMPACT: a. FFY 2011 $ (62,960) savings b. FFY 2012 $ (249,225) savings
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: ATT 3.1-A PG 5A & 5B ATT 4.19-B PG -------- 4A & 4B	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)* ATT 3.1-A PG 5A & 5B ATT 4.19-B PG -------- 4A

10. SUBJECT OF AMENDMENT: Pharmacy

11. GOVERNOR'S REVIEW *(Check One)*: ☑ GOVERNOR'S OFFICE REPORTED NO COMMENT ☐ COMMENTS OF GOVERNOR'S OFFICE ENCLOSED ☐ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL	☒ OTHER, AS SPECIFIED SIGNATURE OF SECRETARY OF ADMINISTRATION [redacted]
12. SIGNATURE OF STATE AGENCY OFFICIAL: [redacted]	16. RETURN TO:
13. TYPED NAME: DOUGLAS A. RACINE	LINDSEY WELLS
14. TITLE: SECRETARY, AGENCY FOR HUMAN SERVICES	DEPARTMENT OF VERMONT HEALTH ACCESS 312 HURRICANE LANE, SUITE 201 WILLISTON, VT 05495
15. DATE SUBMITTED: 09/30/2011	

[redacted] 9/30/11	[redacted] 4/26/12
[redacted] 7/1/11	[redacted]
[redacted] Richard R. McGreal	[redacted] Associate Regional Administrator, Division of Medicaid and Children's Health Operations, Boston Regional Office

State and Federal officials agree via e-mail 11/23/2011 to pen&ink changes to Boxes 1, 7, 8, 9 and 10 to facilitate splitting the original SPA submission 11-023 into three smaller SPAs (A-C) at CMS request.

ITEM 12. PRESCRIBED DRUGS, DENTURES, AND PROSTHETIC DEVICES; EYEGLASSES PRESCRIBED BY A PHYSICIAN SKILLED IN DISEASES OF THE EYE OR BY AN OPTOMETRIST

A. Prescribed Drugs

1. Drugs listed by the FDA as less than effective are not covered by Medicaid, nor are the generic equivalents of the listed drugs covered.
2. Physicians and Pharmacists are required to conform to Act 127 (18 VSA Chapter 91), otherwise known as the Vermont Generic Drug Law. In those cases where the Generic Drug Law permits substitution, only the lowest priced equivalent in stock at the pharmacy shall be considered medically necessary. Medicaid will not pay if the recipient refuses the substitution required by law.
3. A pharmacist must fill prescriptions in quantities of between 30 and 90 days supply for all drugs prescribed for continued regular use. The physician may prescribe for particular patients or conditions in lesser amounts and in these instances the pharmacist is required to fill as directed. Effective July 15, 2009, when the DVHA is the primary payer, pharmacies will be required to dispense designated classes of maintenance drugs in 90-day supplies after the first fill. The first fill allows prescribers to test for therapeutic effectiveness and patient tolerance.
4. Coverage for certain other drugs is limited to specific conditions, e.g. amphetamines for the treatment of narcolepsy cataplexy syndrome only.
5. Generic over-the-counter (OTC) drugs are covered when medically necessary; without the option of prior authorization for brand products; prescribed by a qualified Medicaid provider; and a federal rebate agreement with the manufacturer is in force. Some OTC medications already managed on the Preferred Drug list (PDL) may have additional restrictions. The PDL can be found at http://dvha.vermont.gov/for-providers/preferred-drug-list-clinical-criteria.
6. Contraceptive drugs are covered and claimed at the increased Federal match under Family Planning.
7. No coverage is provided for items such as:

   - topical antiseptics
   - rubbing alcohol

8. [Reserved]

ITEM 12. PRESCRIBED DRUGS, DENTURES, AND PROSTHETIC DEVICES; EYEGLASSES PRESCRIBED BY A PHYSICIAN SKILLED IN DISEASES OF THE EYE OR BY AN OPTOMETRIST (Continued)

A. Prescribed Drugs (Continued)

10. Supplemental Rebate Agreements: Certain covered products in accordance with Section 1927 of the Social Security Act may not be among the baseline preferred drugs identified by the State of Vermont's Drug Utilization Review (DUR) Board and/or the Pharmacy and Therapeutics (P & T) Committee for various therapeutic classes. The state may negotiate supplemental rebate agreements that would reclassify any drug not designated as preferred in the baseline listing for as long as the agreement is in effect.

    In addition the State has the following policies for the supplemental rebate program for the Medicaid population:

    - Supplemental rebate agreements are unique to each state. The supplemental rebate agreement submitted to CMS on June 6, 2009 amends the March 31, 2006 version of the "Vermont State Supplemental Drug Rebate Agreement" authorized under Transmittal 06-05. CMS has authorized this amended version of the "Vermont State Supplemental Drug Rebate Agreement." The addendum to this agreement, approved by CMS, entitled "Sovereign States Drug Consortium, Addendum to Member States Agreements" is not changed by this amendment. The June 6, 2009 supplemental rebate agreement and the approved SSDC Addendum apply to drugs dispensed beginning January 1, 2009.
    - Funds received from supplemental rebate agreements will be reported to CMS. The state will remit the federal portion of any supplemental rebates collected.
    - Manufacturers with supplemental rebate agreements are allowed to audit utilization data.
    - The unit rebate amount is confidential and cannot be disclosed in accordance with Section 1927(b)(3)(D) of the Social Security Act.
    - The Department of Vermont Health Access (DVHA) may require prior authorization for covered outpatient drugs. Non-preferred drugs are available with prior authorization.
    - The prior authorization process for covered outpatient drugs will conform to the provisions of section 1927(d)(5) of the Social Security Act.

11. The DVHA covers select active pharmaceutical ingredients (API) and excipients used in extemporaneously compounded prescriptions when dispensed by a participating pharmacy provider and issued by a licensed prescriber following state and federal laws. Select APIs are published at http://dvha.vermont.gov/for-providers.

METHODS AND STANDARDS OF ESTABLISHING PAYMENT RATES - OTHER MEDICAL CARE
(Continued)

12 a. Prescribed Drugs

(1) "Multiple Source" drugs are paid, as of 7/15/09, at the lowest of:
  (a) AWP-14.2% + dispensing fee;
  (b) CMS Federal Upper Limit (FUL) + dispensing fee;
  (c) State Maximum Allowable Cost (MAC) + dispensing fee; or
  (d) the Usual and Customary (U&C) (includes dispensing fee).

(2) "Single-source" drugs are paid, as of 07/15/09, at the lower of:
  (a) AWP-14.2% + dispensing fee; or
  (b) Usual and Customary (U&C) (includes dispensing fee).

(3) "Physician Certified as Brand Necessary" are paid, as of 07/15/09, at the lower of:
  (a) AWP-14.2% + dispensing fee; or
  (b) the Usual and Customary (U&C) (includes dispensing fee).

(4) All compounded prescriptions must contain more than one ingredient, and:
  (a) As of 07/15/09, ingredients will be priced at the lesser of AWP – 14.2%, the MAC, or the FUL (plus a dispensing fee).
  (b) The ingredients' costs will be totaled and priced at the lesser of the calculated cost in (a) or the claim's U&C cost.

(5) Drugs dispensed by limited distribution pharmacies are paid, at the lower of
  (a) "Multiple Source" drugs are paid, at the lowest of:
    - AWP-16.5% + dispensing fee;
    - CMS Federal Upper Limit (FUL) + dispensing fee;
    - State Maximum Allowable Cost (MAC) + dispensing fee; or
    - the Usual and Customary (U&C) (includes dispensing fee).
  (b) "Single-source" drugs are paid, at the lower of:
    - AWP-16.5% + dispensing fee; or
    - Usual and Customary (U&C) (includes dispensing fee)

Effective July 1, 2009, the dispensing fee for all fills and refills will be:
a. $ 4.75 for Vermont pharmacies,
b. $19.75 for compounded prescriptions at Vermont pharmacies,
c. $2.50 for out-of-state pharmacies, and
d. $17.50 for compounded prescriptions at out-of-state pharmacies.

METHODS AND STANDARDS OF ESTABLISHING PAYMENT RATES - OTHER MEDICAL CARE
(Continued)

'MAC' is a commonly utilized acronym in prescription drug management, translating to 'maximum allowable cost'. MAC represents the highest price a pharmacy will be reimbursed for the dispensing of a specific dose and formulation of a generic medication when that medication is available from multiple manufacturers. The goal of MAC pricing is to establish a fair and equitable level of reimbursement for all pharmacies, while simultaneously assuring that our clients are paying the lowest possible cost for such drug products. For a MAC price to be established on any given product, there needs to be a minimum of three suppliers. This generally consists of the originator brand and at least two generic sources. MAC pricing is established through an in-depth review of the prices paid by a typical pharmacy for the generic sources of the product. From there, a MAC price is established using a formula that ensures an adequate balance of low cost to our clients, yet a reasonable profit for the dispensing pharmacy.

Our MAC list is fully updated on a quarterly basis, with mid-quarter changes routinely taking place when significant pricing changes arise or when new generics enter the market from multiple generic manufacturers. We also commit to a more expeditious and aggressive updating of our MAC list when the generic exclusivity period expires on key products. This helps to avoid any substantial lost savings opportunity that may result from delays in MAC list updating.

Limited Distribution Pharmacies dispense medications that may have special requirements for dosing or close lab monitoring. Because of these special requirements, drug manufacturers sometimes choose to limit the distribution of their drugs to only one or a few select pharmacies or, as part of the drug approval process, the Food and Drug Administration (FDA) may recommend this type of distribution. This type of restricted distribution allows the manufacturer to properly control the inventory of the drug; educating dispensing pharmacists about appropriate patient education and monitoring required; and ensure that any risks associated with the medication are minimized.