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State/Territory Name: Vermont

State Plan Amendment (SPA) #: VT-23-0009

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 Form/Summary Form
- 3) Approved SPA Page

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

Medical Benefits and Health Programs Group

September 1, 2023

Monica Ogelby Medicaid Director Vermont Agency of Human Services 280 State Drive - Center Building Waterbury, VT 05671

Dear Monica Ogelby,

The CMS Division of Pharmacy team has reviewed Vermont's State Plan Amendment (SPA) 23-0009 received in the CMS Medicaid & CHIP Operations Group on June 9, 2023. This SPA proposes to allow the state to enter into value/outcomes-based contracts with manufacturers.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 23-0009 is approved with an effective date of April 1, 2023. Our review was limited to the materials necessary to evaluate the SPA under applicable federal laws and regulations.

We are attaching a copy of the signed, revised CMS-179 form, as well as the page approved for incorporation into Vermont's state plan. If you have any questions regarding this amendment, please contact Omar Alemi at (720) 853-2724 or omar.alemi@cms.hhs.gov.

Sincerely,

Cynthia R. Denemark, R.Ph. Director
Division of Pharmacy

cc: Dylan Frazier, Deputy Director of Medicaid Policy, Vermont Agency of Human Services Gilson DaSilva, CMS, Vermont State Lead

CENTERS FOR MEDICARE & MEDICAID SERVICES	OMD NO. 0330-0133
TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES	3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT
	SECONTITACT () XIX () XXI
TO: CENTER DIRECTOR CENTERS FOR MEDICAID & CHIP SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE 4/1/2023
5. FEDERAL STATUTE/REGULATION CITATION	6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)
42 CFR Part 447 Subpart I	a FFY 2023 \$ 0 b. FFY 2024 \$ 0
7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT Att. 3.1-A page 5b	8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable) Att. 3.1-A page 5b
9. SUBJECT OF AMENDMENT Establishment of Value-Based Supplemental Rebate Agreement	
10. 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: Approval from Agency of Admin.
11. SIGNATURE OF STATE AGENCY OFFICIAL	15. RETURN TO
12. TYPED NAME	DYLAN FRAZER DEPARTMENT OF VERMONT HEALTH ACCESS
40 TITLE	280 STATE DRIVE
SECRETARY, AGENCY OF HUMAN SERVICES	WATERBURY , VT 05671-1010
	DYLAN.FRAZER@VERMONT.GOV
FOR CMS USE ONLY	
16. DATE RECEIVED June 9, 2023	17. DATE APPROVED September 1, 2023
PLAN APPROVED - ON	IE COPY ATTACHED
18. EFFECTIVE DATE OF APPROVED MATERIAL April 1, 2023	19. SIGNATURE OF APPROVING OFFICIAL
20. TYPED NAME OF APPROVING OFFICIAL	21. TITLE OF APPROVING OFFICIAL
Cynthia R. Denemark, R.Ph.	Director, Division of Pharmacy
22. REMARKS	

TITLE XIX
State: VERMONT
Page 5b

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 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 in November 2019 amends the "VT 2016 Supplemental Drug Rebate Agreement" authorized by CMS effective July 30, 2015. The November 2019 supplemental rebate agreement applies to drugs dispensed beginning November 15, 2019.
- 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. Such data will be retained for 10 years.
- 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.
- The State may enter into value/outcomes-based contracts with manufacturers. The contracts will be executed on the model agreement or contract titled "Value-Based Supplemental Rebate Agreement" approved by the Centers for Medicaid and Medicare Services (CMS).
- 11. 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 on the DVHA website.

TN No. 23-0009 Effective Date: 4/1/2023

Supersedes

TN No. <u>19-0005</u> Approval Date: <u>9/1/2023</u>