

Table of Contents

State/Territory Name: Vermont

State Plan Amendment (SPA)#:VT-24-0013

This file contains the following documents in the order listed:

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

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 Health Programs Group

November 27, 2024

Monica Ogelby
Medicaid Director
Agency of Human Services
Department Of Vermont Health Access
280 State Drive
Waterbury, VT 05671-1010

Dear Monica Ogelby,

The CMS Division of Pharmacy team has reviewed Vermont's State Plan Amendment (SPA) 24-0013 received in the CMS Medicaid Services OneMAC application on September 30, 2024. This SPA proposes to allow for coverage of medically necessary prescribed drugs that are not covered outpatient drugs, including drugs authorized for import by the U.S. Food and Drug Administration (FDA), during drug shortages.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 24-0013 is approved with an effective date of July 1, 2024. 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 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 Charlotte Hammond at (410) 786-1092 or charlotte.hammond@cms.hhs.gov.

Sincerely,

A solid black rectangular box redacting the signature of Mickey D. Morgan.

Mickey D. Morgan
Deputy Director
Division of Pharmacy

cc: Dylan Frazer, Department of Vermont Health Access
Gilson Dasilva, CMS, Medicaid and CHIP Operations Group

**TRANSMITTAL AND NOTICE OF APPROVAL OF
STATE PLAN MATERIAL
FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES**

1. TRANSMITTAL NUMBER

2 4 — 0 0 1 3

2. STATE

VT

3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT



XIX



XXI

TO: CENTER DIRECTOR
CENTERS FOR MEDICAID & CHIP SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE

7/1/2024

5. FEDERAL STATUTE/REGULATION CITATION

Section 1902(a)(54) of the SSA

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)

a. FFY 2024 \$ 0

b. FFY 2025 \$ 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 PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)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

Adds coverage of drugs authorized for import by the Food and Drug Administration during drug shortages.

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.

Signed by:

Sean Brown

F643164EBC83432...

11. SIGNATURE OF STATE AGENCY OFFICIAL

Monica Ogelby

13. TITLE
MEDICAID DIRECTOR, AGENCY OF HUMAN SERVICES

14. DATE SUBMITTED
9/30/2024

15. RETURN TO

DYLAN FRAZER
DEPARTMENT OF VERMONT HEALTH ACCESS
280 STATE DRIVE
WATERBURY, VT 05671-1010

DYLAN.FRAZER@VERMONT.GOV

FOR CMS USE ONLY

16. DATE RECEIVED
09/30/2024

17. DATE APPROVED
11/27/2024

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL
07/01/2024

19. SIG

20. TYPED NAME OF APPROVING OFFICIAL
MICKEY MORGAN

21. TITLE OF APPROVING OFFICIAL
DEPUTY DIRECTOR

22. REMARKS

INSTRUCTIONS FOR COMPLETING FORM CMS-179

Use Form CMS-179 to transmit State plan material to the Center for Medicaid & CHIP Services for approval. Submit a separate typed transmittal form with each plan/amendment.

Block 1 - Transmittal Number - Enter the State Plan Amendment transmittal number. Assign consecutive numbers on a **calendar year** basis with the first two digits being the two-digit year (e.g., 21-0001, 21-0002, etc.). Because states have different state fiscal years, a calendar year is required for consistency.

Block 2 - State - Enter the two-letter abbreviation code of the State/District/Territory submitting the plan material.

Block 3 - Program Identification - Enter the applicable Title of the Social Security Act (Title XIX Medicaid or Title XXI CHIP).

Block 4 - Proposed Effective Date - Enter the proposed effective date of material. The effective date of a new plan may not be earlier than the first day of the calendar quarter in which an approvable plan is submitted. With respect to expenditures for assistance under such plan, the effective date may not be earlier than the first day on which the plan is in operation on a statewide basis or earlier than the day following publication of notice of changes.

Block 5 - Federal Statute/Regulation Citation - Enter the appropriate statutory/regulatory citation.

Block 6 - Federal Budget Impact - 6(a) - IN WHOLE DOLLARS, NOT IN THOUSANDS, Enter 1st **Federal Fiscal Year** (FFY) impacted by the SPA & estimated Federal share of the cost of the SPA for 1st FFY. The first FFY should be the FFY inclusive of the earliest effective date of any amended payment language; **6 (b)** - Enter 2nd FFY impacted by the SPA & estimated Federal share of the cost for 2nd FFY. In general, the estimates should include any amount not currently approved in the state's plan for assistance.

Block 7 - Page No.(s) of Plan Section or Attachment - Enter the page number(s) of plan material amended and transmitted. If additional space is needed, use bond paper. **New pages** should be included in Block 7, but not in Block 8.

Block 8 - Page No.(s) of the Superseded Plan Section or Attachment (if Applicable) - Enter the page number(s) (including the transmittal number) that is being superseded. If additional space is needed, use bond paper. **Deleted pages** should be included in Block 8, but not in Block 7.

Block 9 - Subject of Amendment - Briefly describe plan material being transmitted.

Block 10 - Governor's Review - Check the appropriate box. See SMM section 13026 A.

Block 11 - Signature of State Agency Official - Authorized State official signs this block.

Block 12 - Typed Name - Type name of State official who signed block 11.

Block 13 - Title - Type title of State official who signed block 11.

Block 14 - Date Submitted - Enter the date that the state transmits plan material to CMCS. Unless the state officially withdraws this SPA and then resubmits it, this date should not be revised. Documentation of version revisions will be maintained in the CMCS administrative record.

Block 15 - Return To - Type the name and address of State official to whom this form should be returned.

Block 16–22 (FOR CMS USE ONLY).

Block 16 - Date Received - Enter the date plan material is received by CMCS. This is the date that the submission is received by CMCS via the subscribed submission process.

Block 17 - Date Approved - Enter the date CMCS approved the plan material.

Block 18 - Effective Date of Approved Material - Enter the date the plan material becomes effective. If more than one effective date, list each provision and its effective date in Block 22 or attach a sheet.

Block 19 - Signature of Approving Official - Approving official signs this block.

Block 20 - Typed Name of Approving Official - Type approving official's name.

Block 21 - Title of Approving Official - Type approving official's title.

Block 22 - Remarks - Use this block to reference and explain agreed to changes and strike-throughs to the original CMS-179 as submitted, a partial approval, more than one effective date, etc. If additional space is needed, use bond paper.

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.

12. Drug Shortages: Prescribed drugs that are not covered outpatient drugs (including drugs authorized for import by the Food and Drug Administration) are covered when medically necessary during drug shortages identified by the Food and Drug Administration.