

Table of Contents

State/Territory Name: Maryland

State Plan Amendment (SPA) #: 24-0013

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 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

Medicaid Benefits and Health Programs Group

September 05, 2024

Ryan Moran
Medicaid Director
Maryland Department of Health
201 W. Preston St. 5th Floor
Baltimore, MD 21201

re: Maryland State Plan Amendment (SPA) 24-0013

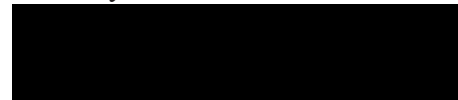
Dear Director Moran:

The CMS Division of Pharmacy team has reviewed Maryland's SPA 24-0013, received in the CMS Medicaid Services OneMAC application on June 26, 2024. This amendment proposes to allow Maryland to cover select imported drugs due to shortages identified by the Food and Drug Administration, as well as to provide the reimbursement methodology for select prescribed drugs.

Based on the information provided and consistent with the regulations at 42 CFR 447.20, we are pleased to inform you MD-24-0013 is approved with an effective date of May 14, 2024. We are attaching a copy of the updated, signed CMS-179 form, as well as the pages approved for incorporation into Maryland's state plan.

If you have any questions regarding this state plan amendment, please contact Desiree Elekwa Izuakor at 667-290-9590 or desiree.elekwaizuakor@cms.hhs.gov.

Sincerely,



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

cc: Alison Donley, Maryland Department of Health
Tyler Colomb, Maryland Department of Health
Talbatha Myatt, CMS, Maryland State Lead

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

1. TRANSMITTAL NUMBER <u>2 4 — 0 0 1 3</u>	2. STATE <u>MD</u>
-----------------------------------------------	-----------------------

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
May 14, 2024

5. FEDERAL STATUTE/REGULATION CITATION
42 CFR 447.201

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
Attachment 3.1A Page 25-25-1 (24-0013)
Attachment 4.19B Page 35A (24-0013)

8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)
Attachment 3.1A Page 25 (11-16)
Attachment 3.1A Page 25-1 (13-29)
Attachment 4.19B Page 35A (17-0004)

9. SUBJECT OF AMENDMENT
This SPA updates Maryland's State Plan to reflect current pharmacy practices for prescription drugs that are not covered outpatient drugs but eligible for Federal Financial Participation (FFP) when medically necessary during drug shortages identified by the Food and Drug Administration. The proposed effective date for this SPA is May 14, 2024.

10. GOVERNOR'S REVIEW (Check One)

GOVERNOR'S OFFICE REPORTED NO COMMENT OTHER, AS SPECIFIED:
 COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

[Redacted]
Tricia Roddy
13. TITLE
Deputy Medicaid Director
14. DATE SUBMITTED
6/26/24

15. RETURN TO
Ryan Moran
Medicaid Director
Maryland Department of Health
201 W. Preston St., 5th Floor
Baltimore, MD 21201

FOR CMS USE ONLY

16. DATE RECEIVED
06/26/24

17. DATE APPROVED
09/05/24

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL
05/14/24

19. [Redacted]

20. TYPED NAME OF APPROVING OFFICIAL
Cynthia R. Denmark, R.Ph.

21. [Redacted]
Director, Division of Pharmacy

22. REMARKS
09/03/24- State authorized a Pen & Ink Change to Box 7.
09/03/24- State authorized a Pen & Ink Change to Box 8.

STATE PLAN FOR MEDICAL ASSISTANCE

UNDER TITLE XIX OF TI-IE SOCIAL SECURITY ACT

STATE OF MARYLAND

12. A. Prescribed Drugs

A. The following are not covered:

1. Non-legend drugs other than; insulin, Schedule V cough preparations, family planning products, enteric coated aspirin used in the treatment of arthritic conditions and any other cost effective medications as specified by the Program.
2. Any original prescription:
 - a) For a controlled substance dispensed more than 30 days after the prescribing date; and
 - b) For a non-controlled substance dispensed more than 120 days after the prescribing date.
3. Drugs supplied to hospital inpatients.
4. Experimental or investigational drugs.
5. Oral drugs or injections for central nervous system stimulants and anorectic agents when used for weight control.
6. Drug products for which Federal Financial Participation is prohibited pursuant to 42 CFR 441.25.
7. Ovulation stimulants for oral or parenteral administration.
8. Any Part D drug for individuals who are eligible for Medicare Part D benefits.
9. Drug products marketed by a manufacturer or distributor who has not entered into a rebate agreement with the Secretary of the Department of Health and Human Services as described in Section 1903 of the Social Security Act or a manufacturer who has not signed a rebate agreement with the State of Maryland prior to April 1, 1991, except Coverage will be allowed for single source drugs and innovator multiple source drugs if:
 - a) The State has made a determination that the drug is essential to the health of the beneficiaries;
 - b) The drug has been rated as 1-A by the Food Drug Administration (FDA); and
 - c) The authorized prescriber has obtained approval for use of the drug in accordance with the States' prior authorization program as described in D of this Section (Preauthorization Requirements) of the Secretary has reviewed and approved the State's determinations.
10. No covered drug shall be reimbursed if:
 - a) Federal financial participation from the Centers for Medicare and Medicaid Services is not available for the drug; or
 - b) Prior authorization was required for the drug, but was not obtained.

A. Following are covered:

1. 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.

- b. Wholesale Acquisition Cost (WAC) + 0% plus a Professional Dispensing Fee (PDF) of \$10.49, or
 - c. The Actual Acquisition cost (AAC) + 8% plus a PDF of \$10.49. AAC is defined as the invoice submitted by the provider to the Program for a clotting factor.
2. 3408 covered entities and Federally Qualified Health Centers (FQHCs) that fill Medicaid member prescriptions with drugs purchased at the prices authorized under Section 3408 of the Public Health Services Act will be reimbursed no more than the actual acquisition cost for the drug plus a \$12.12 Professional Dispensing Fee. 3408 covered entities that fill Medicaid member prescriptions with drugs not purchased under the Section 3408 of the Public Health Services Act will be reimbursed in accordance to section (A) (1)-(4).
3. Drugs purchased through the Federal Supply Schedule (FSS) will be reimbursed no more than the actual acquisition cost for the drug plus a \$10.49 Professional Dispensing Fee.
4. Drugs purchased at Nominal Price (outside of 3408 or FSS) will be reimbursed no more than the actual acquisition cost for the drug plus a \$10.49 Professional Dispensing Fee.
5. Physician administered drugs (PADs) submitted under the medical benefit will be reimbursed at the provider's acquisition cost. PADs purchased at the prices authorized under Section 340B of the Public Health Services Act and submitted by FQHCs under the medical benefit will be part of all-inclusive payment rate.
6. Investigational drugs are not a covered service under the Maryland Medicaid.
7. Select prescribed drugs that do not meet the definition of covered outpatient drugs will be reimbursed at the same rate as covered outpatient drugs.