

***CORRECTED VERSION**

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State/Territory Name: West Virginia

State Plan Amendment (SPA)#: WV-25-0002

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

October 7, 2025

Cynthia Beane
Commissioner
WV Bureau for Medical Services
350 Capitol St, Room 251
Charleston, West Virginia 25301

Dear Cynthia Beane,

The CMS Division of Pharmacy team has reviewed West Virginia's State Plan Amendment (SPA) 25-0002 received in the CMS Medicaid Services OneMAC application on March 28, 2025. This SPA proposes to allow West Virginia to enter into Outcome/Value-Based Supplemental Rebate Agreements with drug manufacturers on a voluntary basis. In addition, this SPA proposes to allow 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 25-0002 is approved with an effective date of January 1, 2025. 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 updated CMS-179 form, as well as the page approved for incorporation into West Virginia'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 black rectangular box redacting the signature of Catherine Traugott.

Catherine Traugott
Acting Director
Division of Pharmacy

cc: Kim O'Brien, Assistant to the Commissioner, West Virginia Department of Human Services
Christine Davidson, 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 5 — 0 0 0 2

2. STATE

WV

3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL

SECURITY ACT ☒ XIX ☐ XXI

4. PROPOSED EFFECTIVE DATE

January 1, 2025

TO: CENTER DIRECTOR

CENTERS FOR MEDICAID & CHIP SERVICES

DEPARTMENT OF HEALTH AND HUMAN SERVICES

5. FEDERAL STATUTE/REGULATION CITATION

Title 19 of the Social Security Act

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)

a. FFY 2025 \$ 853,423b. FFY 2026 \$ 1,137,937

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT

Supplement 2 to Attachment 3.1-A and 3.1-B, Pages 3d - 4a

8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION
OR ATTACHMENT (If Applicable)Supplement 2 to Attachment 3.1-A and 3.1-B, Pages 3d -
4a

9. SUBJECT OF AMENDMENT

This SPA will provide coverage for imported prescribed drugs that are not covered outpatient drugs, when medically necessary during drug shortages. This SPA also authorizes WV to enter into Value/Outcomes Based Purchasing agreements.

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:

1

12. TYPED NAME

Cynthia Beane

13. TITLE

Commissioner, WV Bureau for Medical Services

14. DATE SUBMITTED

03/28/2025

15. RETURN TO

Bureau for Medical Services

350 Capitol Street Room 251

Charleston West Virginia 25301

FOR CMS USE ONLY

16. DATE RECEIVED

03/28/2025

17. DATE APPROVED

10/07/2025

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL

01/01/2025

20. TYPED NAME OF APPROVING OFFICIAL

Catherine Traugott

21. TITLE OF APPROVING OFFICIAL

Acting Director, Division of Pharmacy

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.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State: West Virginia

Supplement 2 to Attachments 3.1-A and 3.1-B

Page 3d

12. a. Prescribed Drugs

All covered outpatient drugs, whether legend or non-legend, must be prescribed by a physician, or other practitioner qualified under State law. Applicable State and Federal law governing dispensing of drugs and biological agents must be followed.

The prescribed use of the covered outpatient drug must be for a medically accepted indication as defined in Social Security Act §1927 (k)(6).

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. Coverage of Smoking/Tobacco Cessation products

Drugs used to promote smoking cessation, including over-the-counter (OTC) drugs, are covered under the Medicaid program.

TN No.: 25-0002	Approval Date: October 7, 2025	Effective Date: January 1, 2025
Supersedes: 14-002		

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State: West Virginia

Supplement 2 to Attachments 3.1-A and 3.1-B

Page 3e

3.1. AMOUNT, DURATION AND SCOPE OF ASSISTANCE

Covered outpatient drugs are those produced by any manufacturer, which has entered into and complied with a rebate agreement under Social Security Act § 1927(a), which are prescribed for a medically accepted indication. A covered outpatient drug does not include any drug, biological product or insulin provided as part of or incident to and in the same setting as defined in Social Security Act § 1927(k)(3) for which payment includes drugs, biological products and insulin. Medicaid will not cover Part D drugs for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B.

Limitations in Coverage

A. Exclusions and restrictions on certain drugs or classes of drugs:

The Medicaid agency provides coverage for the following excluded or otherwise restricted drugs or classes of drugs, or their medical uses to all Medicaid recipients, including full benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit -Part D.

The following marked excluded drugs are covered:

- ☐ a. Agents when used for anorexia, weight loss, weight gain.
- ☐ b. Agents when used to promote fertility.
- ☒ c. Selected agents, when used for the symptomatic relief of cough and colds, are covered. These agents can be found on West Virginia Medicaid's approved coverage list, which is updated periodically.
- ☒ d. Selected prescription vitamins and mineral products are covered. These agents can be found on West Virginia Medicaid's approved coverage list which is updated periodically.

TN No.: 25-0002	Approval Date: October 7, 2025	Effective Date: January 1, 2025
Supersedes: 23-0009		

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State: West Virginia

Supplement 2 to Attachments 3.1-A and 3.1-B

Page 4

3.1. AMOUNT, DURATION AND SCOPE OF ASSISTANCE

- ☒ e. Nonprescription drugs: Selective non-prescription (over the counter) medications will be covered as listed on the state's website.
- ☐ f. Drugs described in §107(c)(3) of the drug Amendments of 1962 and identical, similar or related drugs (within the meaning of §310.6(b)(1) of Title 21 of the Code of Federal Regulations ("DESI" drugs).
- ☐ g. Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services will be purchase exclusively from the manufacturer or its designee.

The State will cover agents when used for cosmetic or hair growth only when the State has determined that use to be medically necessary.

B. Drugs covered with limitation (applicable to all covered drug categories)

- a. Certain drugs identified by high cost, high risk or high use are subject to limitations through prior authorization as to units or coverage periods.
- b. Certain drugs are limited by gender or age according to FDA approved indications. Prior authorization is available on a case-by-case basis for exceptions with medical necessity justification.

TN No.: 25-0002	Approval Date: October 7, 2025	Effective Date: January 1, 2025
Supersedes: 23-0009		

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

State: West Virginia

Supplement 2 to Attachments 3.1-A and 3.1-B

Page 4a

3.1. AMOUNT, DURATION AND SCOPE OF ASSISTANCE

C. Quantities and Duration

1. Covered outpatient drugs are reimbursed up to 34-day supply per prescription. The number of refills per prescription will be in accordance with state and federal law and regulations.
2. Certain drugs are limited by quantity, number of allowable refills of duration, or use.

D. Drug Rebate Agreements

The state is in compliance with §1927 of the Social Security Act. The state will cover drugs of federal rebate participating manufacturers. The state is in compliance with reporting requirements for utilization and restrictions to coverage. Pharmaceutical manufacturers can audit utilization data. The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification.

The state will be negotiating supplemental rebates in addition to the federal rebates provided for in Title XIX. Rebate agreements between the state and a pharmaceutical manufacturer will be separate from the federal rebates.

A rebate agreement between the state and a drug manufacturer for drugs provided to the Medicaid program, submitted to CMS on January 1, 2008, and entitled "West Virginia Medicaid Supplemental Drug Rebate Agreement" has been authorized by CMS.

CMS has authorized the state of West Virginia to enter in the Sovereign States Drug Consortium (SSDC) multistate pool. This Supplemental Drug Rebate Agreement was submitted to CMS on September 30, 2008, and has been authorized by CMS effective August 1, 2008. A revised SSDC Supplemental Rebate Agreement was authorized by CMS, effective January 1, 2015, for any renewal and new agreements with pharmaceutical manufacturers for drugs provided to Medicaid recipients.

Supplemental rebates received by the state in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national rebate agreement.

All drugs covered by the program, irrespective of a prior authorization requirement, will comply with the provision of the national drug rebate agreement. An outcome-based model agreement between the state and a drug manufacturer for drugs provided to the West Virginia Medicaid population titled Outcome Based Supplemental Drug Rebate Agreement is authorized effective January 1, 2025.

Certain drugs provided in an inpatient hospital setting will be reimbursed separately from the APR-DRG payment. Drugs separately reimbursed and not part of a bundled inpatient hospital reimbursement methodology will be paid as described in Attachment 4.19B, Pages 8,9,9a and 9b Outpatient Pharmacy Reimbursement.

E. Preferred Drug List with Prior Authorization

1. Pursuant to 42 U.S.C§1396r-8 and WV Code §9-5-15, the state is establishing a preferred drug list with prior authorization for drugs not included on the preferred list. Prior authorization will be provided with a 24-hour turn-around from receipt of request and a 72-hour supply of drugs in an emergency circumstance.
2. Prior authorization will be established for certain drug classes, particular drugs, or medically accepted indication for uses and doses.
3. The state will appoint a Pharmaceutical and Therapeutic Committee or utilize the drug utilization review committee in accordance with federal law.

TN No.: 25-0002	Approval Date: October 7, 2025	Effective Date: January 1, 2025
Supersedes: 23-0009		