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State/Territory Name: Pennsylvania

State Plan Amendment (SPA) #: 22-0005

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

Disabled and Elderly Health Programs Group

August 19, 2022

Meg Snead
Acting Secretary of Human Services
Department of Human Services
Office of Medical Assistance Programs
Bureau of Policy, Analysis and Planning
P.O. Box 2675
Harrisburg, Pennsylvania 17105-2675

Dear Meg Snead:

The CMS Division of Pharmacy team has reviewed Pennsylvania's State Plan Amendment (SPA) 22-0005 received in the CMS Division of Program Operations on May 27, 2022. This SPA approves a template that will authorize the state to enter into Outcome-Based Supplemental Rebate Agreements with drug manufacturers for drugs provided under the Medicaid program.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 22-0005 is approved with an effective date of July 1, 2022. 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 pages approved for incorporation into Pennsylvania's state plan. If you have any questions regarding this amendment, please contact Charlotte Amponsah at (410) 786-1092 or charlotte.amponsah@cms.hhs.gov.

Sincerely,

John M. Coster, Ph.D., R.Ph.
Director
Division of Pharmacy

cc: Lacey Gates, Human Services Analyst, Commonwealth of Pennsylvania
Terri Cathers, Pharm.D., Pharmacy Director, Commonwealth of Pennsylvania

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

1. TRANSMITTAL NUMBER <u>2 2</u> — <u>0 0 0 5</u>	2. STATE <u>PA</u>
3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT <input checked="" type="radio"/> XIX <input type="radio"/> XXI	

TO: CENTER DIRECTOR CENTERS FOR MEDICAID & CHIP SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE <u>July 1, 2022</u>
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5. FEDERAL STATUTE/REGULATION CITATION <u>42 CFR 440.120(a); 42 CFR Subpart I</u>	6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars) a. FFY <u>2022</u> \$ <u>0</u> b. FFY <u>2023</u> \$ <u>0</u>
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7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT <u>Attachment 3.1A/3.1B, page 5b</u>	8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable) <u>Attachment 3.1A/3.1B, page 5b</u>
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9. SUBJECT OF AMENDMENT
Outcomes-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:

11. SIGNATURE OF STATE AGENCY OFFICIAL	15. RETURN TO Commonwealth of Pennsylvania Department of Human Services Office of Medical Assistance Programs Bureau of Policy, Analysis and Planning P.O. Box 2675 Harrisburg, Pennsylvania 17105-2675
12. TYPED NAME <u>M. Snead</u>	
13. TITLE <u>Acting Secretary of Human Services</u>	
14. DATE SUBMITTED <u>May 27, 2022</u>	

FOR CMS USE ONLY	
16. DATE RECEIVED <u>May 27, 2022</u>	17. DATE APPROVED <u>August 19, 2022</u>

PLAN APPROVED - ONE COPY ATTACHED	
18. EFFECTIVE DATE OF APPROVED MATERIAL <u>July 1, 2022</u>	19. SIGNATURE OF APP
20. TYPED NAME OF APPROVING OFFICIAL <u>JOHN M. COSTER</u>	21. TITLE OF APPROVING OFFICIAL <u>Director, Division of Pharmacy</u>

22. REMARKS

SERVICES

12. Prescribed Drugs, Dentures, Prosthetic Devices and Eyeglasses

12a. Prescribed Drugs (42 CFR 440.120(a)) (continued)

1. Drug Rebate Agreements

- a. The Commonwealth is in compliance with section 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.
- b. The Commonwealth will be negotiating supplemental rebates in addition to federal rebates provided for in Title XIX. Rebate agreements between the Commonwealth and a pharmaceutical manufacturer will be separate from the federal rebates.
- c. CMS authorized a rebate agreement between the Commonwealth and a drug manufacturer for drugs provided to Medicaid beneficiaries, the Pennsylvania Medicaid Supplemental Rebate Agreement.
- d. The Commonwealth will continue single state-specific supplemental rebates in addition to federal rebates provided for in Title XIX. The single state rebate agreements will be separate from the federal rebates. Supplemental rebates received by the Commonwealth in excess of those required under the federal drug rebate agreement will be shared with the federal government on the same percentage basis as applied under the federal rebate agreement.
- e. CMS has authorized the Commonwealth of Pennsylvania to enter into the Pennsylvania Medicaid Supplemental Rebate Agreement effective January 1, 2020, for the Commonwealth of Pennsylvania.
- f. CMS has authorized the Commonwealth of Pennsylvania to enter into outcomes-based agreements with pharmaceutical manufacturers, for drugs provided to Medicaid beneficiaries using the "Pennsylvania Medicaid Outcomes-Based Supplemental Rebate Agreement," beginning July 1, 2022.
- g. Supplemental rebates received by the Commonwealth 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.
- h. All drugs covered by the program, irrespective of a prior authorization requirement, will comply with provisions of the national drug rebate agreement.