

Table of Contents

State/Territory: Pennsylvania

State Plan Amendment (SPA) #: 24-0007

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 Health Programs Group

April 10, 2024

Valerie A. Arkoosh, MD, MPH
Secretary, Department of Human Services
Commonwealth of Pennsylvania
P.O. Box 2675
Harrisburg, PA 17105-2675

Dear Secretary Arkoosh,

The CMS Division of Pharmacy team has reviewed Pennsylvania's State Plan Amendment (SPA) 24-0007 received in the CMS Medicaid & CHIP Operations Group on February 15, 2024. This SPA authorizes revisions to the Pennsylvania Medicaid Outcome-Based Supplemental Rebate Agreement.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 24-0007 is approved with an effective date of March 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 updated, signed CMS-179 form, as well as the page approved for incorporation into Pennsylvania's State Plan. If you have any questions regarding this amendment, please contact Terry Simananda at (410) 786-8144 or terry.simananda@cms.hhs.gov.

Sincerely,

A solid black rectangular box redacting the signature of Cynthia R. Denemark.

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

cc: Sally Kozak, Medicaid Director, Pennsylvania Department of Human Services
Dan Bates, Pennsylvania Department of Human Services
Terri Cathers, Pennsylvania Department of Human Services
Eve Lickers, Pennsylvania Department of Human Services
Lacey Walker, Pennsylvania Department of Human Services
Margaret Kosherzenko, Pennsylvania Medicaid State Lead, CMS

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

1. TRANSMITTAL NUMBER <u>2 4 — 0 0 0 7</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>March 1, 2024</u>
--	--

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>2024</u> \$ <u>0</u> b. FFY <u>2025</u> \$ <u>0</u>
--	---

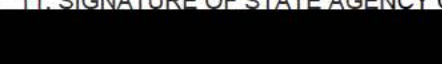
7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT <u>Attachment 3.1A/3.1B, page 5b</u>	8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable) <u>Attachment 3.1A/3.1B, page 5b</u>
--	---

9. SUBJECT OF AMENDMENT
Revised 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>Valerie A. Arkoosh, MD, MPH</u>	
13. TITLE <u>Secretary of Human Services</u>	
14. DATE SUBMITTED <u>February 15, 2024</u>	

FOR CMS USE ONLY

16. DATE RECEIVED <u>February 15, 2024</u>	17. DATE APPROVED <u>April 10, 2024</u>
---	--

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL <u>March 1, 2024</u>	19. 
20. TYPED NAME OF APPROVING OFFICIAL <u>Cynthia R. Denemark, R.Ph.</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, as amended January 1, 2024, 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," as amended March 1, 2024.
- 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.