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State/Territory Name: Delaware

State Plan Amendment (SPA)#: 23-0007

This file contains the following documents in the order listed below:

- 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
Medical Benefits and Health Programs Group

January 4, 2024

Andrew Wilson, Director,
Division of Medicaid and Medical Assistance
Delaware Health and Social Services
P.O. Box 906
New Castle, DE 19720-0906

Dear Andrew Wilson:

We have reviewed Delaware's State Plan Amendment (SPA) 23-0007 received in the Centers for Medicare and Medicaid Services (CMS) OneMAC application on October 16, 2023. This SPA proposes to amend the State Plan to allow the State to enter into value-based contract arrangements with drug manufacturers through supplemental rebate agreements.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that DE SPA 23-0007 is approved with an effective date of January 1, 2024.

We are attaching a copy of the signed CMS-179 form, as well as the page approved for incorporation into Delaware's state plan. If you have any questions regarding this amendment, please contact Whitney Swears at Whitney.Swears@cms.hhs.gov.

Sincerely,



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

cc: Melissa Dohring, Delaware Division of Medicaid and Medical Assistance
Brian Mabie, Delaware Division of Medicaid and Medical Assistance
Kimberly Xavier, Delaware Division of Medicaid and Medical Assistance
Glyne Williams, Delaware Division of Medicaid and Medical Assistance
Talbatha Myatt, CMS, Medicaid and CHIP Operations Group
Whitney Swears, CMS, Medical Benefits and Health Programs Group

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

1. TRANSMITTAL NUMBER

2 3 — 0 0 0 7

2. STATE

DE

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

01/01/2024

5. FEDERAL STATUTE/REGULATION CITATION

• 42 CFR 447.502

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)

a. FFY 2023 \$ 0
b. FFY 2024 \$ 0

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT

Attachment 3.1-A. page 5 Addendum 2

8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)

Attachment 3.1-A. page 5 Addendum 2

9. SUBJECT OF AMENDMENT

Pharmacy Value Based Purchasing (VBP)

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

[Redacted Signature]

15. RETURN TO

Theodore Mermigos, Acting Director, DMMA, P.O. Box 906
New Castle, DE19720

12. TYPED NAME

Theodore Mermigos

13. TITLE

Acting Director

14. DATE SUBMITTED

12/4/2023 | 3:17 PM EST 10/16/2023 | 10:02 AM EDT

FOR CMS USE ONLY

16. DATE RECEIVED

October 16, 2023

17. DATE APPROVED

January 4, 2024

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL

January 1, 2024

19.

[Redacted]

20. TYPED NAME OF APPROVING OFFICIAL

Cynthia R. Denemark

21. TITLE OF APPROVING OFFICIAL

Director, Division of Pharmacy

22. REMARKS

12/28/23- State authorized a pen and ink change to box 14 to reflect the original submission date of this SPA.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE/TERRITORY: DELAWARE LIMITATIONS ON AMOUNT, DURATION AND SCOPE OF MEDICAL AND
REMEDIAL CARE AND SERVICES PROVIDED TO THE CATEGORICALLY NEEDY

12.a Prescribed Drugs Continued:

Supplemental Rebate Agreements Continued

Supplemental rebate agreements are unique to each state. The Centers for Medicare and Medicaid Services (CMS) has authorized the April 7, 2005, December 20, 2005, and December 10, 2013 versions of the "Delaware State Supplemental Rebate Agreement." These agreements were effective for drugs dispensed prior to July 1, 2016.

CMS has authorized Delaware to enter into "The Sovereign States Drug Consortium (SSDC)" Medicaid multi-State purchasing pool. The supplemental rebate agreement submitted to CMS on July 1, 2016 amends the December 10, 2013 version of the "Delaware State Supplemental Drug Rebate Agreement" authorized under Transmittal Number SPA #15-001. CMS has authorized this amended version of the "Delaware State Supplemental Drug Rebate Agreement" and the January 1, 2015 addendum to this agreement, entitled "Sovereign States Drug Consortium, Addendum to Member States Agreements". This agreement and the Addendum apply to drugs dispensed beginning July 1, 2016.

The State may enter into value-based contracts with manufacturers on a voluntary basis. These contracts will be executed on the model agreement entitled "Value-Based Supplemental Rebate Agreement" submitted to CMS and authorized for use beginning 1/1/24.

In addition the State has the following policies for the supplemental rebate program for the Medicaid population:

1. Funds received from supplemental rebate agreements will be reported to CMS. The state will remit the federal portion of any supplemental rebates collected.
2. Manufacturers with supplemental rebate agreements are allowed to audit utilization data.
3. The unit rebate amount is confidential and cannot be disclosed in accordance with Section 1927(b)(3)(D) of the Social Security Act.
4. The State of Delaware's Division of Medicaid and Medical Assistance (DMMA) may require prior authorization for covered outpatient drugs. Non-preferred drugs are available with prior authorization.
5. The prior authorization process for covered outpatient drugs will conform to the provisions of section 1927(d)(5) of the Social Security Act.

TN No. SPA # 23-0007

Approval Date January 4, 2024

Supersedes

TN No. SPA #16-006

Effective Date January 1, 2024