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State Name: Delaware

State Plan Amendment (SPA) #16-006

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS-179
- 3) Approved SPA Pages

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
150 S. Independence Mall West
Suite 216, The Public Ledger Building
Philadelphia, Pennsylvania 19106-3499



Region III/Division of Medicaid and Children's Health Operations

SWIFT #071420164007

August 15, 2015

Mr. Stephen M. Groff, Director
Division of Medicaid and Medical Assistance
P.O. Box 906
New Castle, DE 19720-0906

Dear Mr. Groff:

We are pleased to inform you of the approval of Delaware State Plan Amendment (SPA) 16-006. This amendment revises Delaware's supplemental drug rebate agreement and place Delaware in the Sovereign State Drug Consortium (SSDC) Medicaid multi-state purchasing pool.

Enclosed is a copy of the approved SPA pages and the signed CMS-179 form. The effective date of this amendment is July 1, 2016.

If you have any questions, you may contact Michael Cleary at (215) 861-4282.

Sincerely,


Francis McCullough
Associate Regional Administrator

Enclosures

**TRANSMITTAL AND NOTICE OF APPROVAL OF
STATE PLAN MATERIAL**

1. TRANSMITTAL NUMBER:
SPA #16-006

2. STATE
DELAWARE

FOR: HEALTH CARE FINANCING ADMINISTRATION

3. PROGRAM IDENTIFICATION: **TITLE XIX OF THE
SOCIAL SECURITY ACT (MEDICAID)**

TO: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE
July 1, 2016

5. TYPE OF PLAN MATERIAL (*Check One*):

NEW STATE PLAN AMENDMENT TO BE CONSIDERED AS NEW PLAN AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (*Separate Transmittal for each amendment*)

6. FEDERAL STATUTE/REGULATION CITATION:
**1927(a)(1); (a)(4); (b)(3)(D); (d)(1)(A) and (d)(5) of the Social Security Act
1902(a)(19) of the Social Security Act
42 U.S.C. §256b**

7. FEDERAL BUDGET IMPACT:
a. FFY **2016** \$ **-0-**
b. FFY **2017** \$ **-0-**

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:

**ATTACHMENT 3.1-A Page 5 Addendum Continued 1
ATTACHMENT 3.1-A Page 5 Addendum Continued 2**

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION
OR ATTACHMENT (*If Applicable*):

**ATTACHMENT 3.1-A Page 5 Addendum Continued 1
ATTACHMENT 3.1-A Page 5 Addendum Continued 2**

10. SUBJECT OF AMENDMENT: **Pharmacy Rebate Agreement**

11. 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:
**Governor's comments under separate
correspondence**

12. SIGNATURE OF STATE AGENCY OFFICIAL:



16. RETURN TO:

**Stephen M. Groff
Director
Division of Medicaid and Medical Assistance
P.O. Box 906
New Castle, Delaware 19720-0906**

13. TYPED NAME:

Stephen M. Groff, Director, Division of Medicaid and Medical Assistance

14. TITLE: **Designee for Rita M. Landgraf, Secretary, Delaware Health and Social Services**

15. DATE SUBMITTED: **6/9/2016**

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:
June 13, 2016

18. DATE APPROVED:
July 14, 2016

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL:
July 1, 2016

20. SIGNATURE OF REGIONAL OFFICIAL:



21. TYPED NAME:
Francis McCullough

22. TITLE:
Associate Regional Administrator

23. REMARKS:

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: DELAWARE

LIMITATIONS ON AMOUNT, DURATION, AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES
PROVIDED TO THE CATEGORICALLY NEEDY

12.a Prescribed Drugs Continued:

Prior Authorization Continued

- k. potential for abuse, misuse and diversion
- l. experimental use opportunity, and
- m. cost effectiveness relative to similar therapies

The recommendations of the Drug Utilization Review (DUR) Board shall constitute interpretive guidelines to be used in the determination whether to grant or deny prior authorization of a prescription drug. The makeup and membership authority for the DUR Board complies with 42 U.S.C. s1396r-8.

3. A request for prior authorization for covered outpatient drugs is processed within 24 hours of receipt of a completed prior authorization request from a prescribing provider by telephone, mail or electronic communication. A 72-hour supply of medically necessary covered drugs is provided in an emergency situation as mandated and pursuant to 42 United States Code s1396r-8.

Preferred Drug Lists with Prior Authorization

A process is established which utilized a preferred drug list (PDL) for selected therapeutic classes. Drugs in those classes that are not included on the PDL shall require prior authorization. A Pharmaceutical & Therapeutics (P&T) Committee, comprised of pharmacists, physicians, and community members, appointed by the Secretary, Delaware Health & Social Services, selects drugs for the PDL.

Delaware will participate in a multi-state pooling program that will negotiate supplemental rebates in addition to the federal rebates provided for in Title XIX of the Social Security Act.

Supplemental Rebate Agreements

Certain covered products in accordance with Section 1927 of the Social Security Act may not be among the baseline preferred drugs identified by the State of Delaware's Drug Utilization Review (DUR) Board and/or the Pharmacy and Therapeutics (P & T) Committee for various therapeutic classes. The state may negotiate supplemental rebate agreements that would reclassify any drug not designated as preferred in the baseline listing for as long as the agreement is in effect.

TN No. SPA #16-006
Supersedes
TN No. SPA #13-019

Approval Date July 14, 2016

Effective Date July 1, 2016

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: 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.

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 #16-006
Supersedes
TN No. SPA #15-001

Approval Date July14, 2016
Effective Date July 1, 2016