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State Name: Delaware

State Plan Amendment (SPA) #: 13-0019

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 Form/Summary Form (with 179-like data)
- 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 #121120134013

FEB 20 2014

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) 13-0019. This amendment proposes to modify the Multi-State Pharmaceutical Purchasing Pool Supplemental Rebate Agreement.

Enclosed is a copy of the approved SPA pages and the signed CMS-179 form. The effective date of this amendment is October 1, 2013.

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****FOR: HEALTH CARE FINANCING ADMINISTRATION**TO: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES1. TRANSMITTAL NUMBER:
SPA #13-00192. STATE
DELAWARE3. PROGRAM IDENTIFICATION: TITLE XIX OF THE
SOCIAL SECURITY ACT (MEDICAID)4. PROPOSED EFFECTIVE DATE
OCTOBER 1, 20135. TYPE OF PLAN MATERIAL (*Check One*):☐ NEW STATE PLAN☐ AMENDMENT TO BE CONSIDERED AS NEW PLAN☒ AMENDMENTCOMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (*Separate Transmittal for each amendment*)

6. FEDERAL STATUTE/REGULATION CITATION:

SECTION 1902(a) SOCIAL SECURITY ACT
42 CFR PART 447

7. FEDERAL BUDGET IMPACT:

a. FFY 2014 \$ Minimal (see SPA cover letter)

b. FFY 2015 \$ Minimal (see SPA cover letter)

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:

ATTACHMENT 3.1-A PAGE 5 ADDENDUM (UNNUMBERED)
ATTACHMENT 3.1-A PAGE 5 ADDENDUM (UNNUMBERED)
ATTACHMENT 3.1-A PAGE 5 ADDENDUM CONTINUED 3
ATTACHMENT 3.1-A PAGE 5 ADDENDUM CONTINUED 49. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION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
NEW PAGE
NEW PAGE

10. SUBJECT OF AMENDMENT: MODIFICATIONS TO THE MULTI-STATE PURCHASING POOL SUPPLEMENTAL 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:

13. TYPED NAME:

Stephen M. Groff, Director, Delaware Division of Medicaid and
Medical Assistance14. TITLE: Designee for Rita M. Landgraf, Secretary, Delaware
Health and Social Services

15. DATE SUBMITTED:

December 4, 2013

16. RETURN TO:

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

17. DATE RECEIVED:

12/4/2013

18. DATE APPROVED:

FEB 20 2014

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL:

October 1, 2013

20. SIGNATURE OF REGIONAL OFFICIAL:

21. TYPED NAME:

FRANCIS McCullough

22. TITLE:

Associate Regional Administrator/Director

23. REMARKS:

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: DELAWARE

LIMITATIONS

12.a. Prescribed Drugs 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 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.

Drug Rebate Agreements

The Centers for Medicare and Medicaid Services (CMS) has authorized a rebate agreement between the State and a drug manufacturer that provides supplemental rebates for drugs provided to the Delaware Medicaid program as follows:

- CMS has authorized the state of Delaware to enter into The State of Delaware Department of Health and Social Services supplemental drug rebate agreement. This supplemental drug rebate agreement was submitted to CMS on April 7, 2005 and has been authorized by CMS.
- CMS has authorized the State of Delaware to enter into "The Optimal PDL Solution (TOP\$) State Supplemental Drug Rebate Agreement, a Medicaid multi-state pooling program. The amendment to the Supplemental Drug Rebate Agreement was submitted to CMS on December 20, 2005 and CMS has authorized the State of Delaware to enter into the "TOP\$ Medicaid Program Participation Agreement".

TN No. SPA #13-0019

Supersedes

TN No. SP-412

Approval Date FEB 20 2011

Effective Date October 1, 2013

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: DELAWARE

LIMITATIONS

12.a. Prescribed Drugs Continued:

Drug Rebate Agreements

- A supplemental rebate agreement submitted to CMS on December 10, 2013 amended the December 20, 2005 version of the "State of Delaware TOP\$SM The Optimal PDL \$solution ("TOP\$") State Supplemental Rebate Agreement" authorized under Transmittal Number SP-412, has been authorized by CMS.
 - Pharmaceutical manufacturers are allowed to audit utilization rates;
 - Compliance with the reporting requirements for state utilization information and restrictions to coverage;
 - The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification; and,
 - Rebate agreements between the state and a pharmaceutical manufacturer that are separate from the drug rebate agreements of Section 1927 are authorized by the Centers for Medicare and Medicaid Services. The state reports rebates from separate agreements to the Secretary for Health and Human Services. The state will remit the federal portion of any state supplemental rebates collected.
 - Participation in the TOP\$ multi-state rebate program will not limit the state's ability to submit a SPA to authorize the implementation of a state-specific supplemental rebate agreement.

TN No. SPA #13-0019
Supersedes
TN No. SP-412

Approval Date FEB 20 2014
Effective Date October 1, 2013

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: DELAWARE

LIMITATIONS

12.c. Prosthetic Devices

Prosthetic and orthotic devices, as well as other durable medical equipment and assistive technology services, are covered when documented as medically necessary.

TN No. SPA #13-0019
Supersedes
TN No. SP-412

Approval Date ~~FEB 20 2014~~
Effective Date October 1, 2013

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: DELAWARE

LIMITATIONS

13.a. Diagnostic Services

Medicaid will pay for the rental of an apnea monitor to monitor the breathing of an infant for whom a diagnosis of apneic episodes (near-miss Sudden Infant Death Syndrome) has been made.

TN No. SPA #13-0019
Supersedes
TN No. SP-412

Approval Date FEB 20 14
Effective Date October 1, 2013