Office of the Registrar of Regulations,
Legislative Council,
State of Delaware

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF MEDICAID AND MEDICAL ASSISTANCE

Statutory Authority: 31 Delaware Code, Section 512 (31 **Del.C.** §512)

FINAL

ORDER

Prescription Drug Supplemental Rebate Agreement

NATURE OF THE PROCEEDINGS:

Delaware Health and Social Services ("Department") / Division of Medicaid and Medical Assistance initiated proceedings to amend the Title XIX Medicaid State Plan regarding the State's Prescription Drug Supplemental Rebate Agreement, *specifically, to amend Delaware's supplemental drug rebate agreement and place Delaware in "The Sovereign State Drug Consortium (SSDC)" Medicaid multi-state purchasing pool*. The Department's proceedings to amend its regulations were initiated pursuant to 29 **Del.C.** §10114 and its authority as prescribed by 31 **Del.C.** §512.

The Department published its notice of proposed regulation changes pursuant to 29 **Del.C.** §10115 in the April 2016 Delaware *Register of Regulations*, requiring written materials and suggestions from the public concerning the proposed regulations to be produced by May 2, 2016 at which time the Department would receive information, factual evidence and public comment to the said proposed changes to the regulations.

SUMMARY OF PROPOSAL

The purpose of this notice is to advise the public that Delaware Health and Social Services (DHSS)/Division of Medicaid and Medical Assistance (DMMA) is proposing to amend the Title XIX Medicaid State Plan regarding the State's Prescription Drug Supplemental Rebate Agreement, specifically, *to amend Delaware's supplemental drug rebate agreement and place Delaware in "The Sovereign State Drug Consortium (SSDC)" Medicaid multi-state purchasing pool.*

Statutory Authority

- 1927(a)(1), 1927 (a)(4) of the Social Security Act and 42 U.S.C. §13966-8, *authorizes state to enter directly into separate or supplemental rebate agreements with manufacturers*
- 1927(b)(3)(D) of the Social Security Act, *confidentiality of information disclosed by manufacturers or wholesalers*
- 1927(d)(1)(A) of the Social Security Act, *prior authorization on covered outpatient drug*
- 1927(d)(5) of the Social Security Act, *requirements of prior authorization programs*
- 1902(a)(19) of the Social Security Act, *care and services under a Medicaid state plan be provided in a manner consistent with simplicity of administration and the best interests of beneficiaries*
- 42 U.S.C. §256b, *imposes ceilings on prices drug manufacturers may charge for medications sold to specified health care facilities*

Background

Under the Medicaid program, states may provide coverage of outpatient drugs as an optional service under section 1905(a)(12) of the Social Security Act (the Act). Section 1903(a) of the Act provides for Federal Financial Participation (FFP) in state expenditures for these drugs. In general, in order for payment to be made available under section 1903 for covered outpatient drugs, manufacturers must enter into a Medicaid drug rebate agreement as set forth in section 1927(a) of the Act. Section 1927 of the Act provides specific requirements for rebate agreements, drug pricing submission and confidentiality requirements, the formulas for calculating rebate payments, and requirements for states for covered outpatient drugs.

Medicaid Supplemental Drug Rebate Agreements

The federal Omnibus Budget Reconciliation Act of 1990, section 4401 added §1927 to the Social Security Act. Section 1927 provides that states may enter separate or supplemental drug rebate agreements as long as such agreements achieve drug rebates equal to or greater than the drug rebates set forth in the Secretary's national rebate agreement with drug manufacturers, which is published at 56 F.R. 7049 (1991). Specifically, the drug rebate statute, at section 1927(a)(1) of the Social Security Act (Act), provides that "the Secretary may authorize a State to enter directly into agreements with a manufacturer." Also, section 1927(a)(4) of the Act provides that any drug rebate agreement between a state and drug manufacturers and in effect on November 5, 1990, may constitute a rebate agreement in compliance with the statute if the Centers for Medicare and Medicaid Services (CMS) determines that any such agreement "provides for rebates that are at least as large as the rebates otherwise required under this section." CMS accordingly believes that Congress intended that

states that seek CMS approval under section 1927(a)(1) to enter directly into agreements with manufacturers must ensure that any such agreement will achieve drug rebates that are at least equal to the rebates set forth in the Secretary's rebate agreements with manufacturers. Currently, prescription drug manufacturers are required to enter into a rebate agreement.

Section 1927(d)(1)(A) of the Act permits states to subject any covered outpatient drug to a requirement of prior authorization as long as the state complies with the requirements set forth in section 1927(d)(5). A prior authorization program used to negotiate drug discounts for the Medicaid program is consistent with those provisions as well as the paramount purpose of the drug rebate provisions which is to reduce the costs to the Medicaid program for prescription drugs.

Summary of Proposal

Rationale and Justifications

Supplemental rebate agreements are unique to each state. The Centers for Medicare and Medicaid Services (CMS) authorized the Delaware Division of Medicaid and Medical Assistance (DMMA)'s April 7, 2005, December 20, 2005, and December 10, 2013 versions of the "Delaware State Supplemental Rebate Agreement." These versions of the rebate agreement placed Delaware in Therapeutic Optimum Programs (TOP$) Medicaid multi-state purchasing pool. These agreements were effective for drugs dispensed prior to July 1, 2016.

The administration of the TOP$ Medicaid multi-state purchasing pool has since changed. This change has caused costs to increase, and made DMMA's ability to administer the drug rebate program more difficult. The Sovereign State Drug Consortium (SSDC) Medicaid multi-state purchasing pool provides states with more options and control when negotiating supplemental rebate rates, and allows for easier administration of the drug rebate program.

Purpose

To add language to the Medicaid State Plan regarding CMS's authorization for DMMA to enter into "The Sovereign States Drug Consortium (SSDC)" Medicaid multi-state purchasing pool and to provide clarification on the state's policies for the supplemental rebate program.

Summary of Proposed Changes

This SPA action addresses the need to ensure that DMMA is able to efficiently and cost effectively administer the supplemental drug rebate program.

If implemented as proposed, plan amendment will accomplish the following, effective July 1, 2016:

CMS will authorize DMMA 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 will amend the December 10, 2013 version of the "Delaware State Supplemental Drug Rebate Agreement" authorized under Transmittal Number SPA #15-001. CMS will authorize this amended version of the "Delaware State Supplemental Drug Rebate Agreement." This agreement and will apply to drugs paid for beginning July 1, 2016.

The agency's proposal involves no change in the definition of those eligible to receive pharmaceutical services, and the Medicaid prescribed drugs benefit available to eligible recipients remains the same. In addition, the agency's proposal involves no change to providers' current practices.

Public Notice

In accordance with the *federal* public notice requirements established at Section 1902(a)(13)(A) of the Social Security Act and 42 CFR 447.205 and the *state* public notice requirements of Title 29, Chapter 101 of the Delaware Code, Delaware Health and Social Services (DHSS)/Division of Medicaid and Medical Assistance (DMMA) gives public notice and provides an open comment period for thirty (30) days to allow all stakeholders an opportunity to provide input to Delaware's decision amend the state's supplemental drug rebate agreement and place Delaware in "The Sovereign State Drug Consortium (SSDC)" Medicaid multi-state purchasing pool. Comments were to be received by 4:30 p.m. on Monday May 2, 2016.

Centers for Medicare and Medicaid Services Review and Approval

The provisions of this state plan amendment (SPA) are subject to approval by the Centers for Medicare and Medicaid Services (CMS). The draft SPA page(s) may undergo further revisions before and after submittal to CMS based upon public comment and/or CMS feedback. The final version may be subject to significant change.

Provider Manuals Update

Also, upon CMS approval, the applicable Delaware Medical Assistance Program (DMAP) Provider Policy Specific Manuals will be updated. Manual updates, revised pages or additions to the provider manual are issued, as required, for new policy, policy clarification, and/or revisions to the DMAP program. Provider billing guidelines or instructions to incorporate any new requirement may also be issued. A newsletter system is utilized to distribute new or revised manual material and to provide any other pertinent information regarding manual updates. DMAP provider manuals and official notices are available on the DMAP website: http://www.dmap.state.de.us/home/index.html

Fiscal Impact

The proposed amendment is an administrative change being implemented to more efficiently and effectively administer the State's Supplemental Drug Rebate Program. Therefore, there is no impact on the General Fund.

Summary of Comments Received with Agency Response and Explanation of Changes

The Governor's Advisory Council for Exceptional Citizens (GACEC) and the State Council for Persons with Disabilities (SCPD) offered the following summarized observations:

Council (GACEC) endorses the proposed amendments since the switch to the Sovereign State Drug Consortium (SSDC) Medicaid multi-state purchasing pool will provide Delaware with more options and control when negotiating supplemental rebate rates. Switching to SSDC will also apparently allow for easier administration of the drug rebate program.

Agency Response: DMMA thanks the Council for its endorsement. No change was made to the regulation as a result of these comments.

As background, drug manufacturers are required to offer rebates on drugs used in the Medicaid program. States may enter into separate or supplemental drug rebate agreements as long as they achieve drug rebates equal to or greater than the drug rebates contained in a national HHS rebate agreement. Delaware currently participates in a multi-state purchasing pool ("TOP$") which generates rebates. However, DMMA proposes to discontinue participation in "TOP$" and enroll in the "SSDC" pool based on the following rationale:

The administration of the TOP$ Medicaid multi-state purchasing pool has (since) changed. This change has caused costs to increase, and made DMMA's ability to administer the drug rebate program more difficult. The Sovereign State Drug Consortium (SSDC) Medicaid multi-state purchasing pool provides states with more options and control when negotiating supplemental rebate rates, and allows for easier administration of the drug rebate program.

Enrollment in the new pool would be effective July 1, 2016. There would be no direct impact on Medicaid beneficiaries:

The agency's proposal involves no change in the definition of those eligible to receive pharmaceutical services, and the Medicaid prescribed drugs benefit available to eligible recipients remains the same. In addition, the agency's proposal involves no change to providers' current practices.

SCPD endorses the proposed regulation since the switch to a new pool is expected to provide increased flexibility and easier administration of the drug rebate program.

Agency Response: DMMA thanks the Council for its endorsement. No change was made to the regulation as a result of these comments.

FINDINGS OF FACT:

The Department finds that the proposed changes as set forth in the April 2016 *Register of Regulations* should be adopted.

THEREFORE, IT IS ORDERED, that the proposed regulation to amend the Title XIX Medicaid State Plan regarding the State's Prescription Drug Supplemental Rebate Agreement, *specifically, to amend Delaware's supplemental drug rebate agreement and place Delaware in "The Sovereign State Drug Consortium (SSDC)" Medicaid multi-state purchasing pool* is adopted and shall be final effective June 11, 2016.

Rita M. Landgraf, Secretary, DHSS

DMMA FINAL ORDER #16-011a
REVISION

Attachment 3.1-A
Page 5 Addendum
Continued 1

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.c 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.

~~Drug~~ Supplemental 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".~~

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.

DMMA FINAL ORDER #16-011b
REVISION

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.c Prescribed Drugs Continued:

~~Drug~~ Supplemental Rebate Agreements Continued

- ~~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.~~
- ~~Supplemental rebate agreements would apply to the drug benefit, both fee-for-service and those paid by contracted managed care organizations (MCOs).~~

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.

19 DE Reg. 1088 (06/01/16) (Final)