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

Medicaid Reimbursement for Prescription Drugs – Multi-State Purchasing Pool Supplemental Drug Rebate Agreement

NATURE OF THE PROCEEDINGS:

Delaware Health and Social Services ("Department") / Division of Medicaid and Medical Assistance (DMMA) initiated proceedings to amend the Delaware Title XIX Medicaid State Plan regarding the *Multi-State Purchasing Pool Supplemental Rebate Agreement (SRA) f*or pharmaceutical products specifically, *to include Medicaid Managed Care Organization (MCO) utilization for accrual of supplemental rebates*. The Department's proceedings to amend its regulations were initiated pursuant to 29 **Delaware Code** Section 10114 and its authority as prescribed by 31 **Delaware Code** Section 512.

The Department published its notice of proposed regulation changes pursuant to 29 **Delaware Code** Section 10115 in the May 2015 Delaware *Register of Regulations*, requiring written materials and suggestions from the public concerning the proposed regulations to be produced by May 31, 2015 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 *Multi-State Purchasing Pool Supplemental Rebate Agreement (SRA)* for pharmaceutical products specifically, *to include Medicaid Managed Care Organization (MCO) utilization for accrual of supplemental rebates*.

Statutory Authority

- Patient Protection and Affordable Care Act (Pub. L. No. 111-148 as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. No. 111-152)), together known as the Affordable Care Act. Specifically, Section 2501, *Prescription Drug Rebates*
- 1927(a)(1) and 1927 (a)(4) of the Social Security Act, *authorizes state to enter directly into separate or supplemental rebate agreements with manufacturers*
- 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 CFR §440.120, *Prescribed drugs*
- 42 CFR §447.201, *State plan requirements*
- 42 CFR §447.205, *Public notice of changes in Statewide methods and standards for setting payment rates*

Background

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. The agreement requires manufacturers to provide state Medicaid programs with rebates for the drugs purchased for recipients on an outpatient basis. Section 2501 of the Patient Protection and Affordable Care Act (ACA) makes two modifications to the prescription

drug rebate program. The first modification, which took effect on January 1, 2010, increases the minimum rebate amount but requires the State to remit 100 percent of the additional rebates collected to the federal government. The second modification, which took effect on March 23, 2010, extends the application of the prescription drug rebates program to prescription drugs that are provided to Medicaid recipients who are enrolled in Medicaid Managed Care Organizations (MCOs).

Summary of Proposal

Among the services provided to recipients of services under the Delaware Medical Assistance Program (DMAP) are prescription drugs and related pharmacy services. Expenditures for pharmacy services are offset in part by rebate agreements with suppliers of prescription drugs. Part of the system by which Delaware receives these rebates is a multi-state purchasing pool supplemental rebate agreement.

The existing multi-state supplemental rebate agreement (SRA) between the State of Delaware and pharmaceutical manufacturers for legend drugs provided fee-for-service to Medicaid individuals was approved by CMS on February 20, 2014 with an effective date of October 1, 2013. Delaware participates in the TOP$ program, the multistate Medicaid pharmaceutical purchasing pool administered by Provider Synergies, LLC, an affiliate of Magellan Medicaid Administration. This agreement was revised by adding definitions and structural changes to the SRA including the option of including Medicaid Managed Care Organization (MCO) utilization for accrual of supplemental rebates. Upon approval of this agreement, CMS advised that a separate state plan amendment (SPA) will be required if the state intends to exercise the option of including MCO utilization for supplemental rebates.

DHSS/DMMA intends to exercise this option and submit to CMS for review and approval a SPA to include MCO utilization for supplemental rebate collection.

Public Notice

Under the provisions of 42 U.S.C., §1902(a)(13)(A) of the Social Security Act, 42 CFR §447.205 and Title 29, Chapter 101 of the **Delaware Code**, DHSS/DMMA gives notice and provides an open comment period for thirty (30) days to allow all stakeholders an opportunity for public input regarding any significant proposed change in its method and standards for setting payment rates for Medicaid services. Comments must have been received by 4:30 p.m. on May 31, 2015.

The provisions of this state plan amendment relating to the methodology and payment rates for prescription drugs and related pharmacy services are subject to approval by 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.

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. A newsletter system is utilized to distribute new or revised manual material and to provide any other pertinent information regarding manual updates.

Fiscal Impact Statement

The following fiscal impact is projected:

	FFY2015	FFY2016	FFY2017
Federal Supplemental	$ (4,860,453)	$ (10,012,534)	$ (10,212,785)
Federal Share	$ (2,606,661)	$ (5,489,872)	$ (5,599,670)
State Share	$ (2,253,792)	$ (4,522,662)	$ (4,613,115)

SUMMARY OF COMMENTS RECEIVED WITH AGENCY RESPONSE

The Governor's Advisory Council for Exceptional Citizens (GACEC) and the State Council for Persons with Disabilities (SCPD) offered the following observations and recommendations summarized below. The Division of Medicaid and Medical Assistance (DMMA) has considered each comment and responds as follows.

GACEC and SCPD

As background, prescription drug manufacturers are required to enter into rebate agreements for drugs purchased through the Medicaid program. Both the federal government and state governments benefit from the rebates. Effective March 23, 2010, the Affordable Care Act extended the application of the prescription drug rebate program to drugs provided to Medicaid beneficiaries enrolled in Medicaid Managed Care Organizations (MCOs). In 2014, CMS approved Delaware's participation in a multi-state drug rebate program known as "TOP$" for fee for service drugs. Qualification for

drug rebates under "TOP$" is available for drugs provided to MCO participants contingent upon Delaware adopting a Medicaid State Plan amendment. Based on the "Fiscal Impact Statement" on p. 840, it appears that Delaware would benefit from the extension of the rebate program to drugs provided to MCO participants. Since qualifying for drug manufacturer rebates for Medicaid beneficiaries participating in the Delaware Medicaid managed care system should result in financial benefit to the State, the GACEC and the SCPD endorse the proposed regulation.

Agency Response: DMMA thanks both Councils for the endorsement.

FINDINGS OF FACT:

The Department finds that the proposed changes as set forth in the May 2015 *Register of Regulations* should be adopted.

THEREFORE, IT IS ORDERED, that the proposed regulation to amend Delaware Title XIX Medicaid State Plan regarding the *Multi-State Purchasing Pool Supplemental Rebate Agreement (SRA)* for pharmaceutical products specifically, *to include Medicaid Managed Care Organization (MCO) utilization for accrual of supplemental rebates*, is adopted and shall be final effective July 10, 2015.

Rita M. Landgraf, Secretary, DHSS

DMMA FINAL ORDER REGULATION #15-12
REVISION:

Attachment 3.1-A
Page 5 Addendum
Continued 2

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