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

Pharmaceutical Services Reimbursement – 340B Drug Products

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 Pharmaceutical Services, specifically, *to clarify reimbursement methodology for entities that purchase 340B drug products*. 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 November 2015 Delaware *Register of Regulations*, requiring written materials and suggestions from the public concerning the proposed regulations to be produced by November 30, 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 Pharmaceutical Services, specifically, *to clarify reimbursement methodology for entities that purchase 340B drug products*.

Statutory Authority

- Veterans Health Care Act of 1992, Public Law 102-585, Section 602, *limitations on prices of drugs purchased by certain clinics and hospitals*, as amended by the Patient Protection and Affordable Care Act (Pub. L. No. 111-148), Health Care and Education Reconciliation Act of 2010 (Pub. L. No. 111-152) and Medicare and Medicaid Extenders Act of 2010 (Public Law 111-309)
- 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*
- Section 340 of the Public Health Service Act, 42 U.S.C. §256b, *imposes ceilings on prices drug manufacturers may charge for medications sold to specified health care facilities*
- 42 CFR Part 10, 340B *Drug Pricing Program*
- 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

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 340B Drug Discount Program

The drug rebate program was amended in November 1992 by Public Law 102-585, the Veterans' Health Care Act (VHCA) of 1992. Under VHCA, Congress created the 340B program which is administered by the Health Resources and Services Administration (HRSA), Office of Pharmacy Affairs (OPA). The 340B program requires manufacturers of drugs that are paid for by state Medicaid programs to enter into an agreement with HRSA to provide statutory discounts on drugs to "covered entities". This legislation was designed to establish price controls to limit the cost of drugs to Federal purchasers and to certain Federal grantees. It was a follow-up to the Medicaid Drug Rebate Program, enacted as part of the Omnibus Budget Reconciliation Act of 1990 (OBRA90). Title IV of the VHCA contains three sections-all of which deal with drug pricing issues:

- Section 601 is an introduction to general issues about drugs purchased by the Department of Veterans Affairs and other specific types of clinics and hospitals.
- Section 602 provides drug discounts to certain grantees and other eligible covered entities.
- Section 603 establishes limitations on prices that a manufacturer may charge for drugs purchased by the Department of Veterans Affairs and certain other Federal agencies.

Section 602 of the VHCA enacted Section 340B of the Public Health Service (PHS) Act.

Section 340B of the Public Health Service Act, 42 U.S.C. §256b, "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health care facilities." The 340B program requires manufacturers to enter into a Pharmaceutical Pricing Agreement (PPA) with the Secretary of Health and Human Services. Under the 340B program and in accordance with the PPA, pharmaceutical manufacturers agree to charge at or below statutorily defined prices, known as the 340B ceiling prices, for sales to qualified 340B entities.

When reimbursing for 340B-purchased drugs, State Medicaid agencies have a responsibility to accurately reimburse covered entities and appropriately claim Medicaid rebates from drug manufacturers. State Medicaid agencies can use pre-pay edits and post-pay reviews to ensure accurate reimbursements. With respect to rebates, State Medicaid agencies should exclude claims for 340B-purchased drugs (340B claims) from Medicaid rebate requests to prevent subjecting drug manufacturers to duplicate discounts (i.e., selling 340B-purchased drugs to covered entities at the discounted ceiling prices and providing Medicaid rebates on the same drugs).

Participation in the 340B program is voluntary; eligible entities must notify HRSA of their intention to participate by completing appropriate registration forms. Upon receipt and approval of the forms, HRSA adds the entity to its covered entity database, which is available on HRSA's web site. The 340B entity is responsible for alerting wholesalers and manufacturers of its participation and referring them to the database for confirmation so it can purchase covered outpatient drugs at or below the ceiling prices. The Section 340B Drug Discount Program is a complex program. Utilization of this program requires an understanding of detailed concepts of drug pricing and procurement.

Summary of Proposal

Rationale and Justification

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.

Drug manufacturers use the potential for a 340B discounted price to dispute rebate payment. Pharmacy providers enrolled with the Delaware Medical Assistance Program (DMAP) have declared that they do not use public health service products. This policy change will formalize this process and prevent incurring additional operational costs/resources to collect rebates due the state.

Purpose

To add language to the Medicaid State plan to clarify that providers of pharmaceutical services who have access to 340B medications are not dispensing nor administering them to treat Medicaid patients. This will allow claims from these entities to be included in the Federal and supplemental rebate programs.

Summary of Proposed Changes

This SPA action addresses the need to ensure the state is able to meet the full scope of responsibilities to manage the Delaware Medical Assistance Program's interactions with the 340B program.

If implemented as proposed, this reimbursement methodology plan amendment will accomplish the following, effective January 1, 2016:

The amendment is to specifically prohibit the use of 340B-purchased medications for Medicaid patients. This will simplify the rebate program and eliminate one area for provider audits. Public health service providers have the ability to purchase medications at severely discounted prices. These products are excluded from all rebate programs associated with Medicaid patients. Based on HRSA guidelines, these contracted entities have the ability to include or exclude Medicaid patients from using these medications. If contracted entities chose to use drugs purchased via the 340B discount, they must only charge the actual acquisition cost and a professional dispensing fee, when the medication is dispensed, and not administered.

To date, with few exceptions, every contracted entity listed on the 340B participating providers' file has responded in writing that they do not use these products for Delaware Medicaid patients. The Affordable Care Act has added another level of complexity to this process by excluding some drugs based on specific diagnoses. The 340B program has become increasingly difficult to manage based on retrospective changes to the HRSA website as there are no tools to gather 340B prices nor is there any accountability mechanism to monitor if the drug was purchased through a wholesaler or through the public health service process.

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.

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 the methods and standards governing payment methodology for pharmaceutical services. All comments were to be received by 4:30 p.m. on November 30, 2015.

CMS Review and Approval

The provisions of this draft state plan amendment (SPA) are subject to the Centers for Medicare and Medicaid Services (CMS) review and approval. 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 Manual 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.

Cost/Budgetary Impact

The proposed amendment is being implemented to clarify current practices attested to by DMAP pharmacy providers. Therefore, there is no impact on the General Fund.

Summary of Comments Received with Agency Response And Explanation of Change(s)

The Biotechnology Industry Organization (BIO) 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.

BIO

BIO represents an industry devoted to discovering new treatments and ensuring patient access to them. Accordingly, we support both the Medicaid and 340B programs as important mechanisms to improve access to therapies for indigent patients. We believe that compliance with applicable program requirements by all parties-including manufacturers-is an important part of ensuring the sustainability of both programs. We therefore applaud the state of Delaware for taking action to address the duplicate discount prohibition (i.e., the prohibition on obtaining both a Medicaid drug rebate and a 340B discount on the same unit of product), which is an issue that cuts across both programs. We submit these comments to recommend that the Division outline how the state will ensure compliance with the Proposed Amendment, if adopted, as well as issue accompanying guidance to assist stakeholders in operationalizing the proposed new requirement.

BIO Supports State Medicaid Policies that Build Upon Federal Efforts to Prevent Duplicate Discounts.

The 340B and Medicaid programs overlap in a number of areas, which complicates efforts by federal regulators and others to ensure compliance with the respective program requirements. BIO is extremely concerned that, particularly over the last five years, manufacturers have been subject to a significant volume of duplicate discounts, in violation of the requirements of the 340B and Medicaid statutes. While we are supportive of recent steps taken by both HRSA and the

Centers for Medicare & Medicaid Services (CMS) to prevent and identify duplicate discounts, we do not believe that these steps are sufficient. For this reason, we are extremely supportive of state policies that build upon federal efforts to minimize the potential for duplicate discounts. To the extent that the Proposed Amendment is adopted, we strongly urge the Division both to establish mechanisms to ensure compliance with the proposed policy and to issue further guidance to assist stakeholders in operationalizing it. We also urge the Division to adopt additional policies that reflect best practices in this area. Finally, we also recommend that the Division consider establishing an exceptions process whereby covered entities could seek permission to "carve in," provided that protections are in place to prevent duplicate discounts. We describe our specific recommendations in each of these areas in the balance of this letter.

The Division Should Articulate How It Intends to Oversee and Enforce Compliance with the proposed Amendment.

In the Proposed Amendment, the Division has proposed to "clarify the reimbursement methodology for entities that purchase 340B drug products." We strongly support the state's efforts to require covered entities to adopt a uniform billing methodology for both Medicaid FFS and MCO utilization. However, BIO urges the Division to specify the mechanisms it will use to ensure that any 340B products these providers inadvertently furnish to Medicaid patients would be excluded from Medicaid rebate invoices submitted to manufacturers, resulting in duplicate discounts.

In addition, while we applaud the state for its efforts to ensure compliance with all 340B and MDRP requirements, we urge the Division to continue to play an active role in resolving those disputes that do arise regarding rebate invoices, including disputes pertaining to potential duplicate discounts. While we appreciate the state's efforts to minimize the potential for such disputes through the Proposed Amendment, these efforts do not eliminate the state's role and obligations related to the operation of the MDRP.

The Division Should Issue Further Guidance to Assist Stakeholders in Operationalizing Its Proposed Policy, If Finalized, as Well as Adopt Policies that Reflect Best Practices in this Area.

In addition to establishing oversight and enforcement mechanisms to ensure compliance with the Proposed Amendment, if adopted, BIO also urges the Division to provide further guidance to stakeholders regarding how the proposed policy of mandatory carve-out should be operationalized, particularly in the contexts of managed care utilization, replenishment models, and contract pharmacy arrangements. We also urge the Division to adopt certain best practices to assist the state to both prevent and identify duplicate discounts moving forward.

The Division Should Provide Additional Guidance Regarding How the Proposed Policy of Mandatory "Carve Out" Should be Operationalized in the Managed Medicaid Context.

As noted previously, covered entities that "carve out" (i.e., use only non-340B- priced drugs for Medicaid patients) must be able to identify who is a Medicaid patient so that the covered entity can ensure that it is not dispensing 340B-priced drugs to that patient. Otherwise, these entities will unquestionably be providing 340B-priced products to their Medicaid patients, which, as described above, would likely result in duplicate discounts. However, there are systemic limitations with respect to covered entities' ability to identify Medicaid patients, particularly for those beneficiaries enrolled in Medicaid MCOs. We therefore urge the Division to ensure that the state's two Medicaid MCOs have Medicaid-specific BIN/PCN combinations, so that each BIN/PCN combination denotes either Medicaid or commercial utilization. In addition, we urge the Division to establish mechanisms to assist entities in identifying Medicaid patients more effectively, such as, cross-checking Medicaid MCO utilization data against lists of 340B covered entities- a policy recommended by OIG.

The Division Should Provide Additional Guidance Regarding How the Proposed Policy of Mandatory "Carve Out" Should be Operationalized in the Contexts of Replenishment Models and Contract Pharmacy Arrangements.

The Division also should issue guidance as to how the proposed policy should be operationalized by those 340B-participating Medicaid providers that utilize a "replenishment model" to virtually manage their prescription drug inventories. We urge the Division to work with covered entities in the state to ensure that there is a mechanism for tracking Medicaid patients in the context of replenishment models. If this proves to be impractical or impossible, we would urge the Division to direct 340B-participating Medicaid providers to identify prescriptions as 340B at the point-of-sale.

A similar concern exists with respect to contract pharmacy arrangements. By way of background, HRSA has allowed covered entities to contract with outside pharmacies (aka "contract pharmacies") to dispense 340B-purchased drugs since 1996. Under these arrangements, the covered entity purchases the drug, but the product is shipped to and dispensed by the contract pharmacy-an arrangement referred to as "bill to, ship to"-and it is generally the pharmacy that then seeks reimbursement for the product. We urge the Division to specify requirements for contract pharmacies to identify patients as Medicaid (including managed Medicaid) at the point-of-sale, and to ensure that this information is consistently reported both directly to covered entities, as well as through the inventory management software utilized to manage the contract pharmacy arrangement to ensure 340B stock is not sued or reported for these prescriptions.

The Division Should Adopt Certain Best Practices to Assist the State in Both Preventing and Identifying Duplicate Discounts Moving Forward.

Because we understand that Delaware currently does not have comprehensive Medicaid billing policies related to the

340B Program, we believe that the Division also should take this opportunity to outline comprehensive policies on this topic to assist the state in both preventing and identifying duplicate discounts.

The Division Should Consider Creating an Exceptions Process for Covered Entities to Elect to Carve-In, Provided that Protections are In Place to Prevent Duplicate Discounts.

BIO supports Delaware's efforts to address the duplicate discount prohibition. We are particularly supportive of the state's proposal to require covered entities to adopt a uniform determination across both Medicaid FFS and managed care. However, we are concerned that requiring all covered entities to uniformly carve out (i.e., use non-340B products for Medicaid patients) could impose an undue administrative burden on some of the most vulnerable safety-net providers in the state. Accordingly, we urge the Division to consider creating an exceptions process for covered entities to elect to carve-in, provided that protections are in place to prevent duplicate discounts.

Conclusion.

BIO appreciates the opportunity to comment on the Division's Proposed Amendment. We very much support the state's efforts to prevent duplicate discounts and promote program integrity and hope that our comments will be a useful tool as the Division refines its proposed regulations.

Agency Response: DMMA thanks BIO for its support of the proposed changes to our outpatient drug reimbursement regulations. We are grateful for the insight and suggestions that you have shared with us. We will take your comments into consideration as we move forward with implementation of this regulation. No change was made to the regulation as a result of these comments.

SCPD

As background, federal law authorizes states to negotiate rebate agreements with drug manufacturers. Federal law (340B program) also requires drug manufacturers to enter into agreements with HRSA to provide discounts on drugs to covered entities. The interplay of these laws is complicated. However, State Medicaid agencies must exclude from State rebate requests drugs that have already been discounted under the 340B program.

In practice, drug manufacturers are contesting State rebate requests based on their perception that the drugs have already been discounted under the 340B program. DMMA has determined that its providers do not generally use 340B discounted drugs for Medicaid patients. To obviate drug manufacturer argument, DMMA is amending the State Plan to categorically bar providers from using 340B discounted drugs for Medicaid patients. SCPD endorses the proposed regulation since the proposed regulation should remove an impediment to drug manufacturer rebate payments to the State.

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 November 2015 *Register of Regulations* should be adopted.

THEREFORE, IT IS ORDERED, that the proposed regulation to amend Delaware Title XIX Medicaid State Plan regarding Pharmaceutical Services, specifically, *to clarify reimbursement methodology for entities that purchase 340B drug products*, is adopted and shall be final effective February 11, 2016.

January 19, 2016
Rita M. Landgraf, Secretary, DHSS

DMMA FINAL ORDER REGULATION #16-001
REVISION:

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT

STATE: DELAWARE

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES – OTHER TYPES OF CARE

REIMBURSEMENT FOR PHARMACEUTICALS

Overview

The Delaware Medical Assistance Program (DMAP) will reimburse pharmaceuticals using the lower of:

- The usual and customary (U & C) charge to the general public for the product,
- National Average Drug Acquisition Cost (NADAC) or if a NADAC is not available the Average Wholesale Price (AWP) minus 19%,
- A State-specific maximum allowable cost (DMAC) when the purchase price is not appropriately represented by either the NADAC or the Average Wholesale Price (AWP) minus 19%,
- The Federal Upper Limit (FUL) will not be used since the NADAC reflects the actual acquisition cost.

[Contracted] [~~E~~e]ntities that qualify for special purchasing under Section 602 of the Veterans Health Care Act of 1992~~, Section 340-B of the Public Health Service Act covered entities, selected disproportionate share hospitals~~ and entities exempt from the Robinson-Patman Price Discrimination Act of 1936 must charge the DMAP no more than their actual acquisition cost (AAC) plus a professional dispensing fee. The AAC must be supported by invoice and payment documentation.

[Contracted] [~~E~~e]ntities that purchase Section 340B of the Public Health Service Act products are prohibited from using their stock for DMAP patients either directly or through coverage of the Managed Care Organization.

Professional Dispensing Fee
The professional dispensing fee rate is ten dollars ($10.00). There is one-time professional fee per thirty (30)-day period unless the class of drugs is routinely prescribed for a limited number of days.

Definitions
Delaware Maximum Allowable Cost (DMAC) - a maximum price set for reimbursement:

- when a single source product has Average Selling Prices provided by the manufacturer that indicates the AWP is exaggerated, or
- when the NADAC does not reflect the most current cost of a multiple source drug, or
- if a single provider agrees to a special price.

Any willing provider can dispense the product.

19 DE Reg. 748 (02/01/16) (Final)