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)

PROPOSED

PUBLIC NOTICE

Pharmaceutical Services Reimbursement – 340B Drug Products

In compliance with the State's Administrative Procedures Act (APA - Title 29, Chapter 101 of the Delaware Code), 42 U.S.C., §1902(a)(13)(A) of the Social Security Act, 42 CFR §447.205, and under the authority of Title 31 of the Delaware Code, Chapter 5, Section 512, Delaware Health and Social Services (DHSS) / Division of Medicaid and Medical Assistance (DMMA) is proposing to amend the Delaware Title XIX Medicaid State Plan regarding Pharmaceutical Services, specifically, *to clarify reimbursement methodology for entities that purchase 340B drug products*.

Any person who wishes to make written suggestions, compilations of data, testimony, briefs or other written materials concerning the proposed new regulations must submit same to Glyne Williams, Planning, Policy and Quality Unit, Division of Medicaid and Medical Assistance, 1901 North DuPont Highway, P.O. Box 906, New Castle, Delaware 19720-0906 or by fax to 302-255-4425 by December 1, 2015.

The action concerning the determination of whether to adopt the proposed regulation will be based upon the results of Department and Division staff analysis and the consideration of the comments and written materials filed by other interested persons.

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. Comments must be received by 4:30 p.m. on December 1, 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.

Fiscal Impact Statement

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.

DMMA PROPOSED REGULATION #15-20
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.

Entities 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.

Entities 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. 369 (11/01/15) (Prop.)