# 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 of Covered Outpatient Drugs

### 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 Pharmaceutical Services, specifically, *to clarify reimbursement methodology for covered outpatient drugs*. 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 November 2016 Delaware *Register of Regulations*, requiring written materials and suggestions from the public concerning the proposed regulations to be produced by December 1, 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 Pharmaceutical Services, specifically, *to clarify reimbursement methodology for covered outpatient drugs*.

**Statutory Authority**

- 1927 of the Social Security Act, *Payment for Covered Outpatient Drugs*
- 42 CFR §447.512, Drugs: *Aggregate upper limits of payment*
- 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. States generally reimburse pharmacies for prescribed covered outpatient drugs dispensed to Medicaid beneficiaries based on a two-part formula consisting of the ingredient cost of a drug and a professional dispensing fee. States have flexibility to determine reimbursement amounts, consistent with applicable statutory and regulatory requirements. These reimbursement amounts are subject to review and approval by the Centers for Medicare & Medicaid Services (CMS) through the State Plan Approval (SPA) process.

On February 1, 2016 CMS published the Covered Outpatient Drug Rule. This rule became final on April 1, 2016 and implements provisions of the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively referred to as the Affordable Care Act) pertaining to Medicaid reimbursement for covered outpatient drugs (CODs). The regulations direct the Medicaid programs to reimburse all outpatient covered drugs based on the actual acquisition cost of the medication and the professional dispensing fee if applicable.

The Division of Medicaid & Medical Assistance (DMMA) has been applying an Actual Acquisition Cost (AAC) plus a professional dispensing fee since April 1, 2016 for all dispensed products, as well as for medications that are administered in a clinical setting. Medications can be purchased through different avenues depending on the type of entity purchasing the drugs. Prices can be published using multiple methods. DMMA will no longer be using the drug file that list Average Wholesale Prices. The new drug file will contain the Wholesale Acquisition Cost. Additionally, CMS has requested that all possible sources of drugs have a corresponding definition for reimbursement. Drugs reimbursed when administered either in a clinic or physician's office are submitted using a procedure code. These codes have been manually reviewed to establish an acquisition cost for any provider. The SPA is documenting the steps that are taken to develop those reimbursement levels.

**Summary of Proposal**

*Purpose*

To add language to the Medicaid State plan to clarify the reimbursement methodology for covered outpatient drugs.

*Summary of Proposed Changes*

Effective for services provided on and after January 1, 2017 Delaware Health and Social Services/Division of Medicaid and Medical Assistance (DHSS/DMMA) proposes to amend Attachment 4.19-B Page 14 and Page 14a to clarify the reimbursement methodology for all outpatient medications for the DMMA beneficiaries, by defining the Actual Acquisition Cost Methodology used

*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 were to be received by 4:30 p.m. on December 1, 2016.

*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**

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 Changes**

The State Council for Persons with Disabilities (SCPD), Governor's Advisory Council for Exceptional Citizens (GACEC), Planned Parenthood, Nanticoke Health Services, Henrietta Johnson Medical Center, La Red Health Center, Christiana Care Health Systems, Saint Francis Healthcare, and Bay Health Medical Center offered the following summarized observations:

First, the dispensing fee standard is less "blunt" under the initiative. Instead of a blanket $10 fee, a table is inserted which has higher dispensing rates in a few contexts ("specialty drugs-mailed"; "clotting factor"). There is also an apt "catch-all" provision "carried over" from the current version of the State Plan: "Exceptions will be made if documentation provided demonstrates that the product can only be obtained at a higher rate."

***Agency Response:*** The table was inserted to clarify the specific requirements that CMS requires DMMA to address. The table format was adopted to keep each required response addressed. Providers have separate contracts with the managed care plans. State Plan reimbursement policies are for providers that submit fee-for-service claims directly to DMMA for reimbursement.

Second, the Plan amendment (p. 346) includes the following deletion:

> ~~Exceptions of the reimbursement of FUL and DMAC can be made if a physician certifies in their own handwriting that a specific brand is medically necessary. The medical necessity must be documented on a FDA Med Watch form based on the client experiencing an adverse reaction.~~

DMMA has traditionally implemented a system in which physicians could request approval of a non-generic drug based on medical necessity for an individual client considering factors such as efficacy and adverse reactions.

***Agency Response:*** The ability to obtain a brand product, for multi-sourced products, when clinical necessary is still available to the practitioners who provide service to the DMMA clients.

Third, Delaware should refrain from applying an actual acquisition cost for reimbursement limitation to physician-administered drugs and to drugs that are reimbursed as part of a patient's medical benefit.

***Agency Response:*** DMMA is reimbursing for all outpatient drugs based on actual acquisition cost regardless of the source of obtaining these medications. The professional dispensing fee or clinical component of the service should address the additional cost for providing the medication.

Fourth, the state's professional dispensing fee methodology should recognize the higher cost incurred by 340-B providers.

***Agency Response:*** The professional dispensing fee is based on the delivery of the medication to the DMMA client for self-administration. Your comments note four areas where counseling and administration are provided. The costs associated with the provision of these services are covered under the office visit or the clinical coverage.

Fifth, the state should not apply actual acquisition cost restrictions to drugs purchased through the 340-B program.

***Agency Response:*** DMMA's approach to the reimbursement of all outpatient drugs is to cover the cost of the product specifically. The service to deliver the product can be reimbursed based on the clinician's scope of effort to provide the medication. With this approach DMMA can treat all providers equally, regardless of the special circumstances regarding the acquisition of the medications.

Sixth, DMMA should clarify that this proposal's reimbursement does not apply to Medicaid Managed Care plans. Specifically, DMMA should confirmation that DMMA's proposed rule, including the AAC billing and contract pharmacy carve-out requirements, does not apply to Medicaid managed care drugs.

***Agency Response:*** The proposed regulation, 20 DE Reg. 342, referred to as 16-023 in your letter, sets forth the method by which DMMA will reimburse a covered entity for any claim submitted by that covered entity for reimbursement of a covered outpatient drug (COD). To the extent the cost for most managed care CODs is bundled into the capitated rate paid by DMMA to each of the managed care organizations, such costs are generally not submitted by covered entities directly to DMMA for payment and, therefore, are not contemplated by this proposed regulation. Providers have separate contracts with the managed care plans. State Plan reimbursement policies are for providers that submit fee-for-service claims directly to DMMA for reimbursement. The state plan amendment should not be interpreted as applying to claims paid by other processors.

Seventh, you request clarity on the use of 340B for Medicaid populations, specifically that a covered entity's carve-in request to use 340B drugs for its Medicaid population "will be granted automatically if DMAP and the covered entities have a system for avoiding duplicate discounts."

***Agency Response:*** This question does not relate to the proposed regulation, 20 DE Reg. 342, but rather appears to seek clarification of Delaware's previously approved State Plan Amendment (SPA 16-001), the purpose of which was to clarify reimbursement methodology for entities that purchase 340B drug products. The deadline for any public comments to SPA 16-001, which was noticed for public comment in the November 2015 Delaware *Register of Regulations*, was November 30, 2015. Furthermore, SPA 16-001 in its final form was approved by the Centers for Medicare and Medicaid Services ("CMS") on October 13, 2016. Because this inquiry falls outside of the deadline for public comments and, more importantly, concerns a regulation that has already been approved by CMS, DMMA declines to address that question.

No changes were made to the regulation as a result of these comments.

DMMA is pleased to provide the opportunity to receive public comments and greatly appreciates the thoughtful input given.

**FINDINGS OF FACT:**

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

THEREFORE, IT IS ORDERED, that the proposed regulation to amend the Title XIX Medicaid State Plan regarding Pharmaceutical Services, specifically, *to clarify reimbursement methodology for covered outpatient drugs,* is adopted and shall be final effective March 11, 2017.

Date of Signature: 2/20/17
Kara Odom Walker, MD, MPH, MSHS
Secretary, DHSS

**DMMA FINAL REGULATION #17-009a**
**REVISED**

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.~~
- Wholesale Acquisition Cost (WAC),
  - WAC for legend
  - WAC minus 2% for non-legend
- Delaware Maximum Allowable Cost (DMAC), or
- Actual Acquisition Cost (AAC).

Methodology for establishing AAC is provided in the table on page Attachment 4.19-B Page 14a.
~~Entities that qualify for special purchasing under Section 602 of the Veterans Health Care Act of 1992, 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 must request to use these drugs for all DMAP patients, including Medicaid fee-for-service patients and for patients whose care is covered by Medicaid Managed Care Organizations.

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~~ WAC is exaggerated,
- 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.

**DMMA FINAL REGULATION #17-009b**
**REVISED**



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

~~**Federal Upper Limit (FUL)** - The FUL is a federally defined price and constitutes the upper limit of reimbursement where a DMAC limit does not exist.~~

~~**Non-Traditional Pharmacy** - long term care and specialty pharmacies.~~

~~**Traditional Pharmacy** - retail independent and retail chain pharmacies.~~

*Reimbursement Policy:*

- Medicaid reimbursement is limited to only those drugs supplied from manufacturers that have a signed national agreement or approved existing agreement under Section 1927(a) of the Social Security Act. Restrictions in drug coverage are listed on Page 5 Addendum of Attachment 3.1-A of this Plan.
- The Actual Acquisition Cost (AAC) for Drug Reimbursement is derived using the methodology in the table below.

| Category | Ingredient Cost | Professional Dispensing Fee |
|---|---|---|
| Brand Drug | NADAC | $10 |
| Generic Drug | NADAC | $10 |
| Drugs Without NADAC | WAC for legend and WAC-2% for non-legend; or a Delaware Maximum Allowable Cost, whichever is lower. | $10 |
| 340B Purchased Drug | AAC for dispensed and physician administered drugs. | $10 |
| Contract 340B Pharmacy | Drugs acquired through the Federal 340B Drug Pricing Program and dispensed by 340B contract pharmacies are not covered. | N/A |
| Drugs purchased by 340B entities enrolled with DMMA as utilizing public health service products, which based on specific conditions, must purchase drugs outside of the 340B inventory when that drug is not available or eligible for 340B purchase. | NADAC | $10 |
| Indian Health Service | N/A | N/A |
| Federal Supply Schedule | AAC | $10 |
| Drugs Acquired at Nominal Price | AAC | $10 |
| Specialty Drugs-Mailed | AAC (Invoice price) | $27 |
| Drug Not Dispensed by Retail Pharmacy | NADAC or WAC, whichever is lower. | $10 |
| Physician Administered Drugs | AAC | N/A |
| Clotting Factor | AAC | $27 |
| Investigational Drugs (when prior authorized; as a general rule not covered products) | AAC | $10 |

*Exceptions:*

- ~~Exceptions of the reimbursement of FUL and DMAC can be made if a physician certifies in their own handwriting that a specific brand is medically necessary. The medical necessity must be documented on a FDA Med-Watch form based on the client experiencing an adverse reaction.~~
- ~~Other~~ Exceptions will be made if documentation provided demonstrates that the product can only be obtained at a higher rate.

**20 DE Reg. 720 (03/01/17) (Final)**