

**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**

**Pharmacy Over the Counter (OTC) & Physician Administered Drugs (PAD)**

**NATURE OF THE PROCEEDINGS:**

Delaware Health and Social Services ("Department") / Division of Medicaid and Medical Assistance initiated proceedings to amend Title XIX Medicaid State Plan regarding Pharmacy Over the Counter (OTC) & Physician Administered Drugs (PAD), specifically, to align state plan with current reimbursement and provide for future flexibility. 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 September 2023 *Delaware Register of Regulations*, requiring written materials and suggestions from the public concerning the proposed regulations to be produced by October 1, 2023, 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 proposed regulation is to advise the public that Delaware Health and Social Services (DHSS)/Division of Medicaid and Medical Assistance (DMMA) is proposing to amend Title XIX Medicaid State Plan regarding Pharmacy Over the Counter (OTC) & Physician Administered Drugs (PAD).

**Background**

Historically, CMS' Medicare fee schedule for Part B drugs was calculated as Average Sales Price (ASP)+6%. However, for five years beginning 10/1/2022, CMS changed the rate for some Part B drugs to ASP+8%. Since states get these pre-calculated rates from the quarterly CMS Medicare fee schedule file, they are already paying ASP+8% for these drugs. In addition, CMS will be introducing a future rate type into the Medicare fee schedule that is different than ASP+6% and the ASP+8%. To relieve states from having to submit multiple SPAs for these changes, CMS requested states to update any references to ASP+6% to the "Medicare fee schedule."

Also, CMS anticipates the introduction of new OTC products that Medicaid programs will be required to cover. These include OTC naloxone (in first half 2023) and OTC oral contraceptives (in second half 2023). To reduce the number of SPAs to accommodate these new OTC drug classes, CMS requests that states insert general language into the pharmacy coverage pages of their State Plans that reference covered OTCs listed in the state's provider manual. Delaware's provider manual already has these products listed in a table so will be in compliance with the state plan when this SPA is approved. In addition, there are changes to remove specific drugs/drug classes for coverage of other exceptions, with replacement language that points to the preferred drug list, or when determined to be medically necessary. These were made to achieve the same purpose as the CMS-requested OTC language change.

**Statutory Authority**

42 CFR 447.20

**Purpose**

The purpose of this proposed regulation is to align Delaware's Medicaid State Plan with current reimbursement policy, provide for future flexibility with less administrative burden, and to update the State Plan in anticipation of future OTC drugs/drug classes that Medicaid will be required to cover, thus reducing the need to submit multiple State Plan Amendments.

*Summary of Proposed Changes*

Effective for services provided January 1, 2023, DHSS/DMMA proposes to amend Attachment 3.1-A and Section 4.19-B of the Medicaid State Plan to update over the counter drugs and physician administered drug sections.

*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 440.386 and the state public notice requirements of Title 29, Chapter 101 of the **Delaware Code**, DHSS/DMMA gave public notice and provided an open comment period for 30 days to allow all stakeholders an opportunity to provide input on the proposed regulation. Comments were to have been received by 4:30 p.m. on October 1, 2023.

#### *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 and Communications Update*

Also, there may be additional provider manuals that may require updates as a result of these changes. The applicable Delaware Medical Assistance Program (DMAP) Provider Policy Specific Manuals and/or Delaware Medical Assistance Portal 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 DMAP updates. DMAP updates are available on the Delaware Medical Assistance Portal website: <https://medicaid.dhss.delaware.gov/provider>

#### **Fiscal Impact Statement**

There is no anticipated fiscal impact.

#### **Summary of Comments Received with Agency Response and Explanation of Changes**

**Comment:** There were comments supporting the proposed changes to more easily allow for anticipated changes in drug coverage, reimbursement policies and requirements.

**Agency response:** DMMA appreciates the support.

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

- State Council for Persons with Disabilities (SCPD)
- Governor's Advisory Council for Exceptional Citizens (GACEC)

#### **FINDINGS OF FACT:**

The Department finds that the proposed changes as set forth in the September 2023 *Register of Regulations* should be adopted.

THEREFORE, IT IS ORDERED, that the proposed regulation to amend Title XIX Medicaid State Plan regarding Pharmacy Over the Counter (OTC) & Physician Administered Drugs (PAD), specifically, to align state plan with current reimbursement and provide for future flexibility and shall be final effective November 11, 2023.

10/13/2023 | 3:12 PM EDT

Date of Signature

Josette D. Manning Esq., Secretary, DHSS

#### **Pharmacy Over the Counter (OTC) & Physician Administered Drugs (PAD)**

**\*Please Note: Due to the formatting requirements of the regulation, it is being attached here as PDF documents:**

<http://regulations.delaware.gov/register/november2023/final/4.19-B-p14 Amended.pdf>

[http://regulations.delaware.gov/register/november2023/final/sp\\_attachment\\_3\\_1\\_a\\_2-2b Amended.pdf](http://regulations.delaware.gov/register/november2023/final/sp_attachment_3_1_a_2-2b Amended.pdf)