

**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**

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

In compliance with the State's Administrative Procedures Act (APA - Title 29, Chapter 101 of the **Delaware Code**) and under the authority of 31 **Del.C.** §512, Delaware Health and Social Services ("Department") / Division of Medicaid and Medical Assistance (DHSS/DMMA) is proposing 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.

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, Planning and Policy Unit, Division of Medicaid and Medical Assistance, 1901 North DuPont Highway, P.O. Box 906, New Castle, Delaware 19720-0906, by email to [DHSS\\_DMMA\\_Publiccomment@Delaware.gov](mailto:DHSS_DMMA_Publiccomment@Delaware.gov), or by fax to 302-255-4413 by 4:30 p.m. on October 1, 2023. Please identify in the subject line: Pharmacy Over the Counter (OTC) & Physician Administered Drugs (PAD).

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 Title XIX Medicaid State Plan regarding Pharmacy Over the Counter (OTC) & Physician Administered Drugs (PAD).

**Statutory Authority**

- 42 CFR 447.20

**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.

**Summary of Proposal**

*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 in 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 gives public notice and provides an open comment period for 30 days to allow all stakeholders an opportunity to provide input on the proposed regulation. Comments must be 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 provide 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**

There is no anticipated fiscal impact.

### **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/september2023/proposed/Attachment 4.19-B-p14 Amended.pdf>**

**<http://regulations.delaware.gov/register/september2023/proposed/Attachment 3.1-A.1-p2-2b Amended.pdf>**

**27 DE Reg. 147 (09/01/23) (Prop.)**