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

Physician Administered Drugs

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 Attachment 4.19-B page 14, specifically, to reimburse physician administered drugs with the Medicare fee schedule rate.

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 by mail 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; or by fax to 302-255-4413 by 4:30 p.m. on June 2, 2025. Please identify in the subject line: Physician Administered Drugs.

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 Physician Administered Drugs.

Statutory Authority

- Executive Order 14087

Background

The Cell and Gene Therapy (CGT) Access Model aims to improve the lives of people with Medicaid living with rare and severe diseases by increasing access to potentially transformative treatments. Cell and gene therapies have high upfront costs but have the potential to reduce health care spending over time by addressing the underlying causes of disease, reducing the severity of illness, and reducing health care utilization. Initially, the model will focus on access to gene therapy treatments for people living with sickle cell disease, a genetic blood disorder that disproportionately affects Black Americans. This is an amended State Plan Amendment to Cellular and Gene Therapy that was published in the *Register* as final January 1, 2025. This amendment is to clarify the reimbursement process that will be used to calculate payment for physician administered drugs (PAD). We are not expecting any change in pricing for PAD medications.

Summary of Proposal

Purpose

The purpose of this proposed regulation is to update the reimbursement methodology of physician administered drugs.

Summary of Proposed Changes

Effective July 1, 2025, the DHSS/DMMA proposes to amend Title XIX Medicaid State Plan to reimburse physician administered drugs with the Medicare fee schedule rate.

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 June 2, 2025.

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

	Federal Fiscal Year 2025	Federal Fiscal Year 2026
General (State) funds	$1,700,000	$1,700,000
Federal funds	$1,700,000	$1,700,000

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE/TERRITORY: **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:
1. All prescribed drugs, including DMAP covered non-legend and legend products that are prescribed by an authorized prescriber, DMAP will reimburse using the following hierarchy methodology.
- National Average Drug Acquisition Cost (NADAC); if no NADAC,

~~National Average Drug Acquisition Cost (NADAC),~~
- Delaware Maximum Allowable Cost, (DMAC) which includes all types of medication, including specialty and hemophilia products). If no NADAC or DMAC.
- Wholesale Acquisition Cost (WAC) plus 0% for legend and WAC minus 2% for non-legend.
  - ~~Wholesale Acquisition Cost (WAC), o WAC for legend~~
  - ~~WAC minus 2% for non-legend~~
- The usual and customary charge submitted by the provider if it is lower.

2. Federal Supply Schedule purchased drugs will be reimbursed at the provider's actual acquisition cost (AAC). AAC is defined as the providers' submitted invoice cost.
3. Drugs acquired at Nominal Price (outside of 340B or Fee for Service) will be reimbursed at the provider's acquisition cost.
4. Long-term care pharmacy providers supplying covered drugs to participants in long-term care facilities shall be reimbursed as outlined in items 1-3 above in this section.
5. Drugs not distributed by a retail community pharmacy and distributed primarily through a Specialty Pharmacy, or the mail (such as specialty drugs) will be reimbursed as outlined in items ~~1-6~~ 1-3 above in this section. DMAC is ~~market based~~ market-based and includes all drug types.
6. Clotting factors from Specialty ~~Pharmacies,~~ Pharmacies and Hemophilia Treatment Centers (HTC) will be reimbursed as outlined in items 1-3 in this section.
7. Physician Administered Drugs (PAD) will be reimbursed using the Medicare Fee Schedule.
8. Investigational Drugs that are prior authorized by DMAP will be reimbursed at provider's AAC.

The High Investment Medication list is available on the state's Medicaid website.

Delaware will pay for High Investment list medications, including cellular and gene therapy medication, as listed on the state's website by ~~susing~~ using the lesser of AAC or the Medicare fee schedule.

DMAP will meet the reimbursement of ~~FUL~~ Federal Upper Limit (FUL) defined drugs in the aggregate by reviewing that the NADAC does not exceed the FUL levels.

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

There is one-time professional dispensing fee per thirty (30)-day period unless the class of drugs is routinely prescribed for a limited number of days.

The professional dispensing fee for ~~covered outpatient~~ prescribed drugs ~~in~~ is $10.00.

The professional dispensing fee for specialty drugs-mailed and clotting factors is $27.00.