

**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**

**Imported 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 3.1-A page 5, specifically, to allow the importation of FDA unapproved medications for drugs that are currently in shortage as determined by FDA/ASHP.

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 July 1, 2024. Please identify in the subject line: Imported 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 Imported Drugs.

**Statutory Authority**

- 42 CFR 440.120
- Section 1905(a)(12) of the Social Security Act

**Background**

This update is required to allow the State of Delaware to apply for the Federal Match for medications that are being imported for an FDA/ASHP declared shortage of an outpatient medication.

**Summary of Proposal**

*Purpose*

The purpose of this proposed regulation is to allow the importation of FDA unapproved medications for drugs that are currently in shortage as determined by FDA/ASHP.

*Summary of Proposed Changes*

Effective August 1, 2024, the DHSS/DMMA proposes to amend Title XIX Medicaid State Plan regarding the medications that are not FDA approved to meet outpatient needs that have been created by a drug supply issue in the United States.

*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 July 1, 2024.

*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 2024	Federal Fiscal Year 2025
General (State) funds	\$10,000	\$50,000
Federal funds	\$10,000	\$50,000

Revision: HCFA-PM-85-3 (BERC)  
May 1985

Attachment 3.1-A  
Page 5  
OMB-No. 0938-0193

### STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT STATE/TERRITORY: **DELAWARE**

#### LIMITATIONS ON AMOUNT, DURATION AND SCOPE OF MEDICAL AND REMEDIAL CARE AND SERVICES PROVIDED TO THE CATEGORICALLY NEEDY

##### 12.a. Prescribed Drugs:

###### **Drug Coverage**

1) Drug products are covered when prescribed or ordered by a physician, or other licensed practitioner within the scope of their practice and when obtained from a licensed pharmacy. When required by state or federal law DMMA members may request coverage of FDA approved medications, distributed by a CMS rebate participating labeler, without a prescription. Covered drugs, as defined in Section 1927(k)(2) of the Act, are those which are prescribed for a medically accepted indication, medically necessary, and produced by any pharmaceutical manufacturer, which has entered into and complies with a drug rebate agreement under Section 1927(a) of the Act.

2) The State will cover agents when used for cosmetic purposes or hair growth only when the state has determined that use to be medically necessary.

The State will cover drugs indicated for the treatment of obesity to address weight loss with co-morbid conditions with prior authorization.

3) Drugs excluded from coverage by Delaware Medicaid as provided by Section 1927(d)(2) of the Act, include:

- a. Drugs designated less than effective by the FDA (DESI drugs) or which are identical, similar, or related to such drugs;
- b. Drugs when used to promote fertility;
- c. Drugs that have an investigational or experimental or unproven efficacy or safety status;
- d. Drugs when used for anorexia, weight gain, or weight loss for the sole purpose of cosmetic reasons.

4) Non-covered services also include: drugs used to correct sexual dysfunction and compound drugs (compound prescriptions must include at least one medication that on its own would be a covered entity).

5) Drug Shortages- Prescribed Drugs that are not covered outpatient drugs (including drugs authorized for import by the Food and Drug Administration are covered when medically necessary during drug shortages identified by at least one of the following:

- a. The United States Food and Drug Administration (US FDA)
- b. The American Society of Health System Pharmacists (ASHP)

###### Quantity and Duration

1. Dosage limits: Medications are limited to a maximum dose recommended by the FDA and appropriate medical compendia described in section 1927(k) of the Social Security Act, that indicate that doses that exceed FDA guidelines are both safe and effective or doses that are specified in regional or national guidelines published by established expert groups such as the American Academy of Pediatrics, or guidelines recommended by the Delaware Medicaid Drug Utilization Review (DUR) Board and accepted by the DHSS Secretary.

TN No. SPA # ~~19-009~~ 24-0010

Approval Date ~~September 14, 2022~~

Supersedes

TN No. # ~~17-005~~ 19-009

Effective Date ~~October 1, 2019~~ August 1, 2024

**27 DE Reg. 950 (06/01/24) (Prop.)**