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

Imported Drugs

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 Imported Drugs, specifically, to allow the importation of FDA unapproved medications for drugs that are currently in shortage as determined by FDA/ASHP. 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 June 2024 *Delaware Register of Regulations,* requiring written materials and suggestions from the public concerning the proposed regulations to be produced by July 1, 2024, 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 Title XIX Medicaid State Plan regarding Imported Drugs.

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.

Statutory Authority

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

Purpose

The purpose of this 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 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 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

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

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

Summary of Comments Received with Agency Response and Explanation of Changes

Comment: There were comments supporting the proposed changes.

Agency response: DMMA appreciates the support.

Comment: We would like additional information on how DMMA plans to act once it has the regulatory authority to do so.

Agency response: The process would only be allowed for medications that FDA identifies as critical to meet public needs.

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

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

IMPACT ON THE STATE'S GREENHOUSE GAS EMISSIONS REDUCTION TARGETS AND RESILIENCY TO CLIMATE CHANGE:

The DMMA Division Director has reviewed the proposed regulation as required by 29 Del. C. §10118(b)(3) and has determined that if promulgated, the regulation would have a de minimis impact on the State's resiliency to climate change because neither implementation nor compliance with the regulation would reasonably involve the increase in greenhouse gas emissions.

FINDINGS OF FACT:

The Department finds that the proposed changes as set forth in the June 2024 *Register of Regulations* should be adopted.

THEREFORE, IT IS ORDERED, that the proposed regulation 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 and shall be final effective August 11, 2024.

7/30/2024 | 1:10 PM EDT
Date of Signature

Josette D. Manning Esq.
Cabinet Secretary, DHSS

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.