

**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**

**Obesity 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 Prescribed Drugs, specifically, to clarify policy related to drugs indicated for the treatment of obesity. The Department's proceedings to amend its regulations were initiated pursuant to 29 Delaware Code Section 10114 and its authority as prescribed by 31 Delaware Code Section 512.

The Department published its notice of proposed regulation changes pursuant to 29 Delaware Code Section 10115 in the September 2019 Delaware *Register of Regulations*, requiring written materials and suggestions from the public concerning the proposed regulations to be produced by October 1, 2019 at which time the Department would receive information, factual evidence and public comment to the said proposed changes to the regulations.

**SUMMARY OF PROPOSAL**

Effective for services provided on and after October 1, 2019 Delaware Health and Social Services/Division of Medicaid and Medical Assistance (DHSS/DMMA) proposes to amend Attachment 3.1-A Page 5 of Title XIX Medicaid State Plan regarding Prescribed Drugs, specifically, to clarify policy related to drugs indicated for the treatment of obesity.

**Background**

Delaware is a founding member of My Healthy Weight, an initiative committed to working with providers and beneficiaries to increase utilization of standardized benefits and to encourage the collection of obesity metrics. The initiative will provide millions of individuals nationally with consistent coverage to support healthy weight change.

As a result of that initiative, DMMA has begun a review of policies related to obesity covered services.

**Statutory Authority**

42 CFR §440.120

**Purpose**

The purpose of this proposed regulation is to clarify policy related to drugs indicated for the treatment of obesity.

*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 447.205 and the *state* public notice requirements of Title 29, Chapter 101 of the Delaware Code, Delaware Health and Social Services (DHSS)/Division of Medicaid and Medical Assistance (DMMA) gives public notice and provides an open comment period for thirty (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, 2019.

*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

The following summarized comments were received:

**Comment:** Two commenters endorsed the proposed changes to the Medicaid State Plan to clarify policy related to drugs indicated for the treatment of obesity.

**Agency Response:** DMMA appreciates the endorsement.

**Comment:** The commenter suggested the amendment overlooks the issue of mental health. Specifically, the commenter asked the agency to consider removing drugs used for anorexia from the list of Medicaid's excluded drugs.

**Agency Response:** The agency appreciates the feedback on the exclusion of anorexia drugs. The state continues to address mental health care and improve treatment option aligned clinical guidelines. The referenced class will be added to future drug utilization board meeting agendas for review.

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;
- State Council for Persons with Disabilities; and
- Nancy G.

### FINDINGS OF FACT:

The Department finds that the proposed changes as set forth in the September 2019 *Register of Regulations* should be adopted.

THEREFORE, IT IS ORDERED, that the proposed regulation to amend Title XIX Medicaid State Plan regarding Prescribed Drugs, specifically, to clarify policy related to drugs indicated for the treatment of obesity, is adopted and shall be final effective December 11, 2019.

10/29/19

Date of Signature

Kara Odom Walker, MD, MPH, MSHS, Secretary,  
DHSS

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

Attachment 3.1-A  
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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. 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.
- 3) The State will cover drugs indicated for the treatment of obesity to address weight loss with co-morbid conditions with prior authorization.
- 4) 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 loss or weight gain, or weight loss for the sole purpose of cosmetic reasons.~~ Drugs indicated for the treatment of obesity to address weight loss with co-morbid conditions are covered by the DMAP with prior authorization.

5) 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).

#### 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# Supersedes TN No. <u>#17-005</u>	Approval Date _____  Effective Date <u>October 1, 2019</u>
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