

DEPARTMENT OF HEALTH AND SOCIAL SERVICES
DIVISION OF MEDICAID AND MEDICAL ASSISTANCE

Statutory Authority: 31 Delaware Code, Section 512 and 18 Delaware Code, Section 3342A(b)(2) (31
Del.C. §512 & 18 Del.C. §3342A(b)(2))

FINAL

ORDER

Over-the-Counter Drugs Without a Prescription

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 Over-the-Counter Drugs, specifically, to ensure members may request coverage of over-the-counter FDA-approved medications without a prescription. 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 July 2019 Delaware *Register of Regulations*, requiring written materials and suggestions from the public concerning the proposed regulations to be produced by July 31, 2019 at which time the Department would receive information, factual evidence and public comment to the said proposed changes to the regulations.

Background

Delaware Senate Bill 151 became effective on July 11, 2019 and required that FDA-approved emergency contraception be available over-the-counter, whether with a prescription or dispensed consistent with the requirements of Chapter 25 of Title 24.

Statutory Authority

- DE Senate Bill 151 (2018)
- 18 **Del.C.** §3342A(b)(2)
- Social Security Act §1927(k)(4)
- 31 **Del.C.** §512

SUMMARY OF PROPOSAL

Effective for services provided on and after July 11, 2019 Delaware Health and Social Services/Division of Medicaid and Medical Assistance (DHSS/DMMA) proposes to amend Attachment 3.1 Page 5 of Title XIX Medicaid State Plan regarding Over-the-Counter Drugs, specifically, to ensure members may request coverage of over-the-counter FDA approved medications without a prescription when required by law.

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 July 31, 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 to the agency as a result of this proposed change in program policy.

Summary of Comments Received with Agency Response and Explanation of Changes

The following summarized comments were received:

Comment: Two commenters questioned how information related to the benefit and access to it would be communicated to members.

Agency Response: DMMA will require its Managed Care Organizations to inform members as well as sending a message to all participating pharmacies.

Comment: There were two endorsements of the regulation.

Agency Response: DMMA appreciates the support.

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
- Planned Parenthood of Delaware
- State Council for Persons with Disabilities

FINDINGS OF FACT:

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

THEREFORE, IT IS ORDERED, that the proposed regulation to amend Title XIX Medicaid State Plan regarding Over-the-Counter Drugs, specifically, to ensure members may request coverage of over-the-counter FDA-approved medications without a prescription, is adopted and shall be final effective September 11, 2019.

8/8/19

Date of Signature

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

Revision: HCFA-PM-92-1 (MB)
February 1992

Attachment 3.1
Page 5

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) 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; and
 - d. Drugs when used for anorexia, weight loss or weight gain.

- 3) 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.
- 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).

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 #	Approval Date
Supersedes	
TN No. SPA <u>#17-005</u>	Effective Date