

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

Over-the-Counter Drugs Without a Prescription

In compliance with the State's Administrative Procedures Act (APA - Title 29, Chapter 101 of the Delaware Code), 42 CFR §447.205, and under the authority of Title 31 of the Delaware Code, Chapter 5, Section 512, Delaware Health and Social Services (DHSS) / Division of Medicaid and Medical Assistance (DMMA) is proposing 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.

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, Policy and Quality Unit, Division of Medicaid and Medical Assistance, 1901 North DuPont Highway, P.O. Box 906, New Castle, Delaware 19720-0906, by email to Nicole.M.Cunningham@delaware.gov, or by fax to 302-255-4413 by 4:30 p.m. on July 31, 2019. Please identify in the subject line: Over-the-Counter Drugs Without a Prescription.

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 Over-the-Counter Drugs, specifically, to ensure members may request coverage of FDA approved medications without a prescription.

Statutory Authority

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

Background

Delaware Senate Bill 151 became effective on July 11, 2018 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.

Summary of Proposal

Summary of Proposed Changes

Effective for services provided on and after July 1, 2018 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 must be 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

There is no anticipated fiscal impact to the agency as a result of this proposed change in program policy.

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

Attachment 3.1
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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.

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

23 DE Reg. 10 (07/01/19) (Prop.)