

Table of Contents

State/Territory Name: Delaware

State Plan Amendment (SPA)#: 19-0009

This file contains the following documents in the order listed

- 1) Approval Letter
- 2) CMS 179 Form
- 3) Approved SPA Pages

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-14-26
Baltimore, Maryland 21244-1850



Center for Medicaid and CHIP Services
Disabled and Elderly Health Programs Group

September 14, 2022

Stephen M. Groff
State Medicaid Director
Delaware Health and Social Services
P.O Box 906
New Castle, DE 19720-0906

Dear Stephen Groff:

The CMS Division of Pharmacy team has reviewed Delaware's State Plan Amendment (SPA) 19-0009 received in the CMS Division of Program Operations on December 27, 2019. This SPA proposes to allow Medicaid beneficiaries to request coverage from pharmacies of select FDA approved over-the-counter medications through an agreement with the Department of Public Health Medical Director for purpose of generating of prescription, and clarifies the coverage policy related to drugs indicated for the treatment of obesity.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that DE 19-0009 is approved with an effective date of October 1, 2019. Our review was limited to the materials necessary to evaluate the SPA under applicable federal laws and regulations.

If you have any questions regarding this request, please contact Whitney Swears at 410-786-6543 or Whitney.Swears@cms.hhs.gov.

Sincerely,

A solid black rectangular box redacting the signature of John M. Coster.

John M. Coster, Ph.D., R.Ph.
Director, Division of Pharmacy
DEHPG/CMCS/CMS

cc: Lisa Zimmerman, Deputy Director, Delaware Health and Social Services
Nicole Cunningham, State Plan Coordinator, Delaware Health and Social Services
Kimberly Xavier, Policy and Planning, Delaware Health and Social Services
Talbatha Myatt, CMS State Lead, Medicaid and CHIP Operations Group

**TRANSMITTAL AND NOTICE OF APPROVAL OF
STATE PLAN MATERIAL
FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES**

1. TRANSMITTAL NUMBER

19 — 0 0 9

2. STATE

Delaware

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR
CENTERS FOR MEDICARE & MEDICAID SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE

October 1, 2019

5. TYPE OF PLAN MATERIAL (Check One)

NEW STATE PLAN

AMENDMENT TO BE CONSIDERED AS NEW PLAN

AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (Separate transmittal for each amendment)

6. FEDERAL STATUTE/REGULATION CITATION

Title XIX Medicaid State Plan

7. FEDERAL BUDGET IMPACT

a. FFY 0 \$ 0

b. FFY 0 \$ 0

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT

Attachment 3.1 Page 5

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)

Attachment 3.1 Page 5

10. SUBJECT OF AMENDMENT

Drug Coverage - Over-the-Counter Drugs Without a Prescription and Obesity Drugs

11. GOVERNOR'S REVIEW (Check One)

- GOVERNOR'S OFFICE REPORTED NO COMMENT
 COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

OTHER, AS SPECIFIED:

12. SIGNATURE OF STATE AGENCY OFFICIAL

[Redacted Signature]

16. RETURN TO

Stephen M. Groff, Director, DMMA, P.O. Box 906 New Castle, DE19720

13. TYPED NAME
Stephen M. Groff

14. TITLE
Director

15. DATE SUBMITTED
12/27/2019

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED
12/27/2019

18. DATE APPROVED
09/14/2022

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL
10/01/2019

20. SIGNATURE OF REGIONAL OFFICIAL

[Redacted Signature]

21. TYPED NAME
John Coster

22. TITLE
Director, Division of Pharmacy

23. REMARKS

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).

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

Approval Date September 14, 2022

Supersedes

TN No. #17-005

Effective Date October 1, 2019