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State/Territory Name: Delaware

State Plan Amendment (SPA)#: 24-0010

This file contains the following documents in the order listed below:

- 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



Medicaid Benefits and Health Programs Group

August 1, 2024

Andrew Wilson, Director
Division of Medicaid and Medical Assistance
P.O. Box 906
New Castle, DE 19720

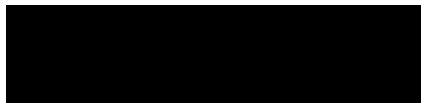
Dear Director Wilson,

We have reviewed Delaware's State Plan Amendment (SPA) 24-0010 received in the Centers for Medicare and Medicaid Services (CMS) OneMAC application on June 10, 2024. This SPA proposes to amend the State Plan to add coverage of prescribed drugs when medically necessary during drug shortages.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that DE-24-0010 is approved with an effective date of August 1, 2024.

We are attaching a copy of the signed CMS-179 form, as well as the page approved for incorporation into Delaware's state plan. If you have any questions regarding this amendment, please contact Whitney Swears at (410) 786-6543 or Whitney.Swears@cms.hhs.gov.

Sincerely,



Cynthia R. Denemark, R.Ph.
Director
Division of Pharmacy

cc: Melissa Dohring, Delaware Division of Medicaid and Medical Assistance
Brian Mabie, Delaware Division of Medicaid and Medical Assistance
Talbatha Myatt, CMS, Medicaid and CHIP Operations Group

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES	1. TRANSMITTAL NUMBER <u>2</u> <u>4</u> — <u>0</u> <u>0</u> <u>1</u> <u>0</u>	2. STATE <u>DE</u>
	3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT <input checked="" type="radio"/> XIX <input type="radio"/> XXI	
TO: CENTER DIRECTOR CENTERS FOR MEDICAID & CHIP SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE <u>08/01/2024</u>	
5. FEDERAL STATUTE/REGULATION CITATION <u>Section 1905(a)(12) of the Social Security Act, 42 CFR 440.120</u>	6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars) a. FFY <u>2024</u> \$ <u>10,000</u> b. FFY <u>2025</u> \$ <u>50,000</u>	
7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT <u>Attachment 3.1-A page 5</u>	8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable) <u>Attachment 3.1-A page 5</u>	
9. SUBJECT OF AMENDMENT <u>Imported Drugs</u>		
10. GOVERNOR'S REVIEW (Check One) <input checked="" type="radio"/> GOVERNOR'S OFFICE REPORTED NO COMMENT <input type="radio"/> COMMENTS OF GOVERNOR'S OFFICE ENCLOSED <input type="radio"/> NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL <input type="radio"/> OTHER, AS SPECIFIED:		
11. [REDACTED] AL	15. RETURN TO Andrew Wilson, Director, DMMA, P.O. Box 906 New Castle, DE19720	
12. Andrew Wilson		
13. TITLE Director		
14. DATE SUBMITTED 6/7/2024 2:43 PM EDT		
FOR CMS USE ONLY		
16. DATE RECEIVED 6/10/2024	17. DATE APPROVED 08/01/2024	
PLAN APPROVED - ONE COPY ATTACHED		
18. EFFECTIVE DATE OF APPROVED MATERIAL 08/01/2024	[REDACTED]	
20. TYPED NAME OF APPROVING OFFICIAL Cynthia R. Denemark	21. TITLE OF APPROVING OFFICIAL Director, Division of Pharmacy	
22. 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.
 - e. Non-covered services also include: drugs used to correct sexualdysfunction and compound drugs(compound prescriptions must include at least one medication that on its own would be a covered entity).
- 4) 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 the Food and Drug Administration.

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# # 24-0010
Supersedes
TN No. 19-009

Approval Date August 1, 2024

Effective Date August 1, 2024