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State/Territory Name: Delaware

State Plan Amendment (SPA)#: 23-0003

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



Center for Medicaid and CHIP Services
Medical Benefits and Health Programs Group

December 19, 2023

Theodore Mermigos, Acting Director,
Division of Medicaid and Medical Assistance
Delaware Health and Social Services
P.O. Box 906
New Castle, DE 19720-0906

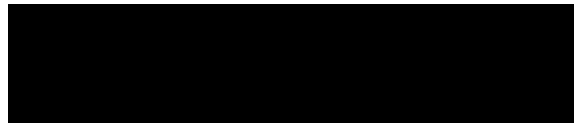
Dear Theodore Mermigos:

We have reviewed Delaware's State Plan Amendment (SPA) 23-0003 received in the Centers for Medicare and Medicaid Services (CMS) OneMAC application on September 23, 2023. This SPA proposes to modify language on the excluded drug coverage pages to reflect coverage of selective medications by referencing the state's webpage and policy handbook resources instead of listing specific covered medications. Additionally, the proposed SPA amends the Title XIX Medicaid State Plan regarding physician administered drug reimbursement rates.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that DE SPA 23-0003 is approved with an effective date of July 1, 2023.



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 Whitney.Swears@cms.hhs.gov.

Sincerely,



Director
Division of Pharmacy

cc: Melissa Dohring, Delaware Division of Medicaid and Medical Assistance
Brian Mabie, Delaware Division of Medicaid and Medical Assistance
Kimberly Xavier, Delaware Division of Medicaid and Medical Assistance
Glyne Williams, Delaware Division of Medicaid and Medical Assistance
Talbatha Myatt, CMS, Medicaid and CHIP Operations Group
Whitney Swears, CMS, Medical Benefits and Health Programs Group

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES		1. TRANSMITTAL NUMBER <u>2 3 — 0 0 0 3</u>	2. STATE <u>DE</u>
TO: CENTER DIRECTOR CENTERS FOR MEDICAID & CHIP SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES		3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT <input checked="" type="radio"/> XIX <input type="radio"/> XXI	
5. FEDERAL STATUTE/REGULATION CITATION • 42 CFR 447.20		4. PROPOSED EFFECTIVE DATE 01/01/2023 07/01/2023	
7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT Attachment 4.19-B Page 14a Attachment 3.I-A.1 page 2 Attachment 3.I-A.1 page 2a Attachment 3.I-A.1 page 2b		6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars) a FFY <u>2023</u> \$ <u>0</u> b FFY <u>2024</u> \$ <u>0</u>	
9. SUBJECT OF AMENDMENT Pharmacy Over the Counter (OTC) & Physician Administered Drugs (PAD)		8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable) Attachment 4.19-B Page 14a Attachment 3.I-A.1 page 2 Attachment 3.I-A.1 page 2a Attachment 3.I-A.1 page 2b	
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. SIGNATURE OF STATE AGENCY OFFICIAL 		15. RETURN TO Theodore Mermigos, Acting Director, DMMA, P.O. Box 906 New Castle, DE19720	
12. TYPED NAME Theodore Mermigos			
13. TITLE Acting Director			
14. DATE SUBMITTED 9/23/2023 1:39 PM EDT			
FOR CMS USE ONLY			
16. DATE RECEIVED 9/23/2023		17. DATE APPROVED 12/19/2023	
PLAN APPROVED - ONE COPY ATTACHED			
18. EFFECTIVE DATE OF APPROVED MATERIAL 07/01/2023		19. 	
20. TYPED NAME OF APPROVING OFFICIAL Cynthia R. Denmark		21. TITLE OF APPROVING OFFICIAL Director, Division of Pharmacy	
22. REMARKS 12/13/2023 – State authorized a Pen & Ink change to Box 4 to update the effective date to 07/01/2023.			

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE/TERRITORY: DELAWARE

MEDICAID PROGRAM: REQUIREMENTS RELATING TO PAYMENT FOR COVERED
OUTPATIENT DRUGS FOR THE CATEGORICALLY NEEDY

Citation (s)	Provision
1927(d)(2) and 1935(d)(2)	<p>1. The Medicaid agency provides coverage for the following excluded or otherwise restricted drugs or classes of drugs, or their medical uses to all Medicaid recipients, including full benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit-Part D.</p> <p><input checked="" type="checkbox"/> The following excluded drugs are covered:</p> <p><input checked="" type="checkbox"/> (a) agents when used for anorexia, weight loss, weight gain: as listed on the Delaware Medicaid Preferred Drug List located on the agency's website.</p> <p><input type="checkbox"/> (b) agents when used to promote fertility (see specific drug categories below)</p> <p><input type="checkbox"/> (c) agents when used for cosmetic purposes or hair growth (see specific drug categories below)</p> <p><input checked="" type="checkbox"/> (d) agents when used for the symptomatic relief cough and colds: as listed on the Delaware Medicaid pharmacy provider manual.</p> <p><input checked="" type="checkbox"/> (e) prescription vitamins and mineral products, except prenatal vitamins and fluoride: as listed on the Delaware pharmacy provider manual.</p> <p><input checked="" type="checkbox"/> (f) nonprescription drugs: as listed on the Delaware Medicaid pharmacy provider manual.</p> <p><input checked="" type="checkbox"/> (g) covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be</p>

TN No. SP# #23-0003

Approval Date December 19, 2023

Supersedes

TN No. 408

Effective Date July 1, 2023

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE/TERRITORY: DELAWARE

MEDICAID PROGRAM: REQUIREMENTS RELATING TO PAYMENT FOR COVERED
OUTPATIENT DRUGS FOR THE CATEGORICALLY NEEDY

Citation (s)	Provision
	purchased exclusively from the manufacturer or its designee (see specific drug categories below)

TN No. SP# #23-0003

Supersedes

TN No. 408

Approval Date December 19, 2023

Effective Date July 1, 2023

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE/TERRITORY: DELAWARE

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES –
OTHER TYPES OF CARE
REIMBURSEMENT FOR PHARMACEUTICALS

Reimbursement Policy:

The lower of Usual and Customary or Actual Acquisition Cost (AAC) for Drug Reimbursement is derived using the methodology in the table below.

Category	Ingredient Cost	Professional Dispensing Fee
Brand Drug	NADAC	\$10
Generic Drug	NADAC	\$10
Drugs Without NADAC	WAC for legend and WAC-2% for non-legend; or a Delaware Maximum Allowable Cost, whichever is lower.	\$10
340B Purchased Drug	AAC for dispensed drugs	\$10
	AAC for physician administered drugs	\$0
Contract 340B Pharmacy	Drugs acquired through the Federal 340B Drug Pricing Program and dispensed by 340B contract pharmacies are not covered.	N/A
Drugs purchased by 340B entities enrolled with DMMA as utilizing public health service products, which based on specific conditions, must purchase drugs outside of the 340B inventory when that drug is not available or eligible for 340B purchase.	NADAC	\$10
Federal Supply Schedule	AAC	\$10
Drugs Acquired at Nominal Price	AAC	\$10
Specialty Drugs-Mailed	AAC (Invoice price)	\$27
Drug Not Dispensed by Retail Pharmacy	NADAC or WAC, whichever is lower.	\$10
Physician Administered Drugs	AAC based on invoice price if maximum unit cost is greater than or equal to \$50. For drugs where the maximum cost is less than \$50, the cost will be based on invoice price or the Medicare fee schedule.	N/A
Clotting Factor	AAC (Invoice Price)	\$27
Investigational Drugs (when prior authorized; as a general rule not covered products)	AAC	\$10

TN No. SPA#23-0003

Supersedes

TN No. SP# 17-002

Approval Date December 19, 2023

Effective Date July 1, 2023