

# **Table of Contents**

**State/Territory Name: North Carolina**

**State Plan Amendment (SPA)#: NC-24-0025**

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 Form/Summary 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 Health Programs Group**

August 29, 2024

Jay Ludlam  
Office of the Deputy Secretary  
Department of Health and Human Services  
2001 Mail Service Center  
Raleigh, NC 27699-20014

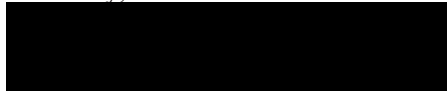
Dear Jay Ludlam,

The CMS Division of Pharmacy team has reviewed North Carolina's State Plan Amendment (SPA) 24-0025 received in the CMS Medicaid Services OneMAC application on June 10, 2024. This SPA proposes to allow coverage of medically necessary prescribed drugs that are not covered outpatient drugs, including drugs authorized for import by the U.S. Food and Drug Administration (FDA) 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 SPA 24-0025 is approved with an effective date of April 1, 2024. Our review was limited to the materials necessary to evaluate the SPA under applicable federal laws and regulations.

We are attaching a copy of the updated, signed CMS-179 form, as well as the page approved for incorporation into North Carolina's state plan. If you have any questions regarding this amendment, please contact Charlotte Hammond at (410) 786-1092 or [charlotte.hammond@cms.hhs.gov](mailto:charlotte.hammond@cms.hhs.gov).

Sincerely,



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

cc: Ashley Blango, North Carolina State Plan and Amendments Manager  
Morlan Lannaman, CMS, Medicaid and CHIP Operations Group

<b>TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL</b> <b>FOR: CENTERS FOR MEDICARE &amp; MEDICAID SERVICES</b>	1. TRANSMITTAL NUMBER <u>2 4 — 0 0 2 5</u>	2. STATE <u>NC</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 <b>April 01, 2024</b>	
5. FEDERAL STATUTE/REGULATION CITATION <b>42 C.F.R. §440.20</b>	6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars) a. FFY <u>24</u> \$ <u>178,885</u> b. FFY <u>25</u> \$ <u>176,578</u>	
7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT <b>Attachment 3.1-A.1, Page 14d</b> <b>Attachment 4.19-B Page, Section 12, Page 1</b>	8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable) <b>Attachment 3.1-A.1, Page 14d</b> <b>Attachment 4.19-B Page, Section 12, Page 1</b>	

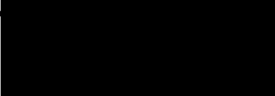
9. SUBJECT OF AMENDMENT

**Coverage of Imported Prescribed Drugs**

10. 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: **Secretary**

11. SIGNATURE OF STATE AGENCY OFFICIAL



12. TYPED NAME

Jay Ludlam

13. RETURN TO  
Office of the Deputy Secretary  
Department of Health and Human Services  
2001 Mail Service Center  
Raleigh, NC 27699-20014

14. DATE SUBMITTED 05/28/24 | 2:22 PM EDT

15. TITLE  
Deputy Secretary

**FOR CMS USE ONLY**

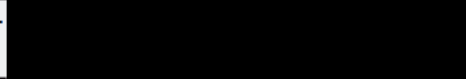
16. DATE RECEIVED  
06/10/2024

17. DATE APPROVED  
08/29/2024

**PLAN APPROVED - ONE COPY ATTACHED**

18. EFFECTIVE DATE OF APPROVED MATERIAL  
04/01/2024

19.



20. TYPED NAME OF APPROVING OFFICIAL  
Cynthia R. Denmark

21. TITLE OF APPROVING OFFICIAL  
Director, Division of Pharmacy

22. REMARKS North Carolina authorized the following pen and ink change of box 8 on the 179 form to reflect the following:

Add 4.19 B Section 12, Page 1 to box 8 to the 179 Form

12.a. Prescribed Drugs (continued)

- (7) Drugs of manufacturers who do not participate in the supplemental rebate program will be made available to Medicaid recipients through prior authorization (PA). Payment of supplemental rebates results in a drug being included on the PDL and/or the recommended drug list.

Certain products may be limited by on-line clinical or fiscal edits to monitor appropriate utilization and secure cost savings.

North Carolina is establishing a Preferred Drug List (PDL) with PA for drugs not included on the PDL pursuant to 42 USC § 1396r-8. PA is established for certain drug classes, particular drugs or medically accepted indication for uses and doses.

The State will appoint a Pharmacy and Therapeutics Committee or utilize the drug utilization review committee in accordance with Federal law.

The State ensures that the PDL is consistent with Medicaid goals and objectives. The State will seek continuity of care of patients who were stabilized on previously prescribed, non-preferred medications. The PDL will address needs of recipients with special and complex medical conditions.

The Program complies with PA requirements set forth in Section 1927(d)(5) of the Social Security Act pertaining to PA programs.

The State ensures that during the contracting process all payments, the methodology for determining payments, and any other information regarding costs and incentives and the PDL development are disclosed by the vendor. Information includes any and all payment from manufacturers, distributors and other entities involved in the sale of pharmaceuticals.

- (8) In accordance with 42 CFR 431.54 and the Medicaid State Plan section 4.10, the State has the authority to lock-in recipients who over-utilize Medicaid services. The State will lock Medicaid enrollees into a single pharmacy and prescriber when the Medicaid enrollee's utilization of selected medications meets the lock-in criteria approved by the North Carolina Physicians Advisory Group.
- (9) Prescribed drugs that are not covered outpatient drugs, including drugs authorized for import by the Food and Drug Administration (FDA), are covered when medically necessary during drug shortages identified by the FDA.

MEDICAL ASSISTANCE  
State: NORTH CAROLINA

PAYMENTS FOR MEDICAL AND REMEDIAL CARE AND SERVICE

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12. Covered Outpatient Drugs (COD)

a. COD include the following:

- Legend and Non-legend drugs
- Drugs dispensed by a Retail Community Pharmacy, Long Term Care Pharmacy
- Specialty Drugs not Dispensed by a Retail Community Pharmacy and Dispensed Primarily through the Mail
- Payment for Drug Purchased Outside of the 340B Program by Covered Entities

Reimbursement for the above drugs dispensed to covered beneficiaries shall not exceed the federal upper limit defined as the lowest of:

1. The Actual Acquisition Cost (AAC) plus a professional dispensing fee.
2. The provider's usual and customary charge (U&C) to the general public.
3. The provider's gross amount due (GAD (430-DU) = Total price claimed from all sources: sum of 'Ingredient Cost Submitted' (409-D9), 'Dispensing Fee Submitted' (412-DC), 'Flat Sales Tax Amount Submitted' (481-HA), 'Percentage Sales Tax Amount Submitted' (482-GE), 'Incentive Amount Submitted' (438-E3), 'Other Amount Claimed' (480-H9), or
4. The amount established by the State of North Carolina to determine the upper payment limit plus a professional dispensing fee.

Payment for prescribed drugs that are not considered covered outpatient drugs will follow the same reimbursement methodologies as covered outpatient drugs.

In compliance with 42 Code of Federal Regulations 447.512 and 447.514, reimbursement for drugs subject to Federal Upper Limits (FULs) may not exceed FULs in the aggregate.

Multiple Source Drugs – North Carolina has implemented a State determined list of multiple source drugs. All drugs on this list are reimbursed at limits set by the State unless the provider writes in their own handwriting, brand name drug is “medically necessary”.