NC DEPARTMENT OF HEALTH AND HUMAN SERVICES
Division of Health Benefits

ROY COOPER • Governor
KODY H. KINSLEY • Secretary
JAY LUDLAM • Deputy Secretary, NC Medicaid

SIGNATURE REQUEST MEMORANDUM

TO: Jay Ludlam DS

FROM: Ashley Blango, SPA Coordinator

RE: State Plan Amendment

Title XIX, Social Security Act
Transmittal #2024-0025

Purpose
Attached for your review and signature is a Medicaid State Plan Amendment (Coverage of Imported Prescribed Drugs) summarized below, and submitted on May 24, 2024, with a due date of May 31, 2024.

Clearance
This amendment has been reviewed for both accuracy and completeness by:

Ashley Blango, Betty J. Staton, Emma Sandoe, Melanie Bush, Adam Levinson

Background and Summary of Request
It is recommended that you sign this State Plan Amendment submission per Centers for Medicare and Medicaid Services (CMS) protocol as head of the Single State Agency administering the Medicaid program.

This SPA will 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. The shortage must be identified by the FDA or American Society of Health-System Pharmacists. Following an approved SPA, NC Medicaid may cover imported drugs, which are ineligible for rebates, and receive federal match (Federal Financial Participation). Reimbursement will follow the State's existing approved ingredient cost and professional dispensing fee, as applicable.

The proposed effective date of the SPA is April 1, 2024.

Your approval of this State Plan Amendment is requested. If you have any questions or concerns, please contact me or Ashley Blango at 919-812-6145.

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) are covered when medically necessary during drug shortages identified by either the United States Food and Drug Administration (US FDA) or the American Society of Health-System Pharmacists (ASHP). Reimbursement should follow the State's existing approved ingredient cost and professional dispensing fee, as applicable.