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State/Territory Name: North Carolina

State Plan Amendment (SPA) #: 21-0012

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

Disabled and Elderly Health Programs Group

September 30, 2021

Dr. Mandy Cohen, MD, MPH
Secretary, North Carolina Medicaid
Office of the Secretary
NC Department of Health and Human Services
2001 Mail Service Center
Raleigh, North Carolina 27699-20014

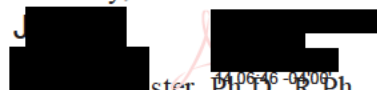
Dear Dr. Cohen:

The CMS Division of Pharmacy team has reviewed North Carolina's State Plan Amendment (SPA) 21-0012 received in the CMS Division of Program Operations on July 12th, 2021. This SPA approves a template that will authorize the state to enter Value-Based Purchasing (VBP) rebate agreements with drug manufacturers for drugs provided under the Medicaid program.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 21-0012 is approved with an effective date of July 1, 2021. Our review was limited to the materials necessary to evaluate the SPA under applicable federal laws and regulations.

A copy of the signed CMS-179 form, as well as the pages approved for incorporation into North Carolina's state plan will be forwarded by the CMS Division of Program Operations. If you have any questions regarding this amendment, please contact Charlotte Amponsah at (410) 786-1092 or charlotte.amponsah@cms.hhs.gov

Sincerely,


ster, Ph.D., R.Ph.

Director
Division of Pharmacy

cc: Betty Staton, North Carolina State Plan and Amendments Manager

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL	1. TRANSMITTAL NUMBER: 21-0012	2. STATE NC
	3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)	
FOR: HEALTH CARE FINANCING ADMINISTRATION	4. PROPOSED EFFECTIVE DATE July 1, 2021	
TO: REGIONAL ADMINISTRATOR HEALTH CARE FINANCING ADMINISTRATION DEPARTMENT OF HEALTH AND HUMAN SERVICES		

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)

42 U.S.C. § 1396r-8-42	7. FEDERAL BUDGET IMPACT: a. FFY 2021 \$0.00 b. FFY 2022 \$0.00
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment 3.1-A.1, page 14c	 Attachment 3.1-A.1, page 14c


Supplemental Rebate using the Value-Based Purchasing Agreement

11. GOVERNOR'S REVIEW (Check One):

- GOVERNOR'S OFFICE REPORTED NO COMMENT OTHER, AS SPECIFIED: Secretary
 COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

12. SIGNATURE OF STATE AGENCY OFFICIAL: 	16. RETURN TO: Office of the Secretary Department of Health and Human Services 2001 Mail Service Center Raleigh, NC 27699-20014
13. TYPED NAME: Mandy Cohen, MD, MPH	
14. TITLE: Secretary	
15. DATE SUBMITTED: July 12, 2021	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: 07/12/2021	18. DATE APPROVED: 09/30/2021
PLAN APPROVED – ONE COPY ATTACHED	
19. EFFECTIVE DATE OF APPROVED MATERIAL: 07/01/2021	20. SIGNATURE OF REGIONAL OFFICIAL: 
21. TYPED NAME:	22. TITLE:

23. REMARKS:

State Plan Under Title XIX of the Social Security Act
Medical Assistance Program
State: NORTH CAROLINA

12.a. Prescribed Drugs (continued)

- (4) DESI drugs and any identical, similar or related products or combinations of these products are not covered.
- (5) Supplemental Medicaid Drug Rebate Agreements

A rebate agreement between the State and a drug manufacturer for drugs provided to the Medicaid population, submitted to CMS on December 30, 2009 and entitled, "State of North Carolina Magellan Medicaid Administration National Medicaid Pooling Initiative (NMPI)," has been authorized by CMS.

The State assures compliance with Section 1927 of the Social Security Act. Drugs of federal rebate participating manufacturers are covered. Policies for the supplemental rebate program for Medicaid beneficiaries are as follows:

- a) Supplemental rebates received by the State in excess of those required under the national drug rebate agreement will be shared with the Federal government on the same percentage basis as applied under the national rebate agreement.
- b) Supplemental rebates are for the Medicaid population only and will be collected from manufacturers based on drug utilization for both fee-for-service and managed care plan participants effective July 1, 2021.
- c) The State will be negotiating supplemental rebates in addition to the federal rebates provided for in Title XIX. Rebate agreements between the State and a pharmaceutical manufacturer will be separate from the federal rebates.
- d) All drugs covered by the program, irrespective of placement on the recommended drug list, will comply with the provisions of the national drug rebate agreement.
- e) The State is in compliance with reporting requirements for utilization and restrictions to coverage. Pharmaceutical manufacturers may audit utilization data. The unit rebate amount is confidential and cannot be disclosed for purposes other than rebate invoicing and verification.
- f) Participation in the Magellan Medicaid Administration National Medicaid Pooling Initiative (NMPI) will not limit the State's ability to negotiate state-specific supplemental rebate agreements for specific drug classes that are not part of the NMPI. These agreements must be authorized by CMS
- g) The State may enter into value/outcomes-based contracts with manufacturers. The contracts will be executed on the model agreement or contract titled "Value-Based Supplemental Rebate Agreement" approved by the Centers for Medicaid and Medicare Services (CMS). The Value-Based Supplemental Rebate Agreement will apply to the Medicaid drug benefit for both the fee-for-service drugs in accordance with the state plan and drugs paid for by Medicaid contracted managed care organizations (MCOs).

TN No.: 21-0012
Supersedes
TN. No.: 21-0008

Approval Date: 09-30-2021

Effective Date: 07-01-2021