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State/Territory Name: North Carolina

State Plan Amendment (SPA) #: 21-0008

This file contains the following documents in the order listed:

1) Approval Letter
2) CMS 179 Form/Summary Form
3) Approved SPA Pages
July 16, 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) 21-0008 received in the CMS Medicaid & CHIP Operations Group on April 26, 2021. This SPA proposes to allow North Carolina to include Medicaid MCO drug utilization in the collection of State Supplemental Drug Rebate.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 21-0008 is approved with an effective date of July 1, 2021. We are attaching a copy of the signed, updated CMS-179 form, as well as the pages approved for incorporation into North Carolina’s state plan.

If you have any questions regarding this amendment, please contact Charlotte Aponsah at (410) 786-1092 or charlotte.amponsah@cms.hhs.gov.

Sincerely,

cc: Dave Richard, Deputy Secretary, NC Medicaid
Betty Staton, North Carolina State Plan and Amendments Manager
1. TRANSMITTAL NUMBER: 21-0008
2. STATE: NC
3. PROGRAM IDENTIFICATION:
   TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)
4. PROPOSED EFFECTIVE DATE:
   April 1, 2021
   July 1, 2021
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)

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

10. SUBJECT OF AMENDMENT:
    Supplemental Rebate Collection for the MCO Medicaid Population

11. 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

12. SIGNATURE OF STATE AGENCY OFFICIAL:

13. TYPED NAME:
    Mandy Cohen, MD, MPH
14. TITLE:
    Secretary
15. DATE SUBMITTED:
    4/26/2021

17. DATE RECEIVED: 4/26/2021
18. DATE APPROVED: 7/16/2021

19. EFFECTIVE DATE OF APPROVED MATERIAL: 7/1/2021

20. SIGNATURE OF REGIONAL OFFICIAL:

21. TYPED NAME:
22. TITLE:

23. REMARKS:

The state is authorizing Pen & Ink changes to Box 4 to read:

July 1, 2021
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.