Department of Health & Human Services
Centers for Medicare & Medicaid Services
61 Forsyth St., Suite 4T20
Atlanta, Georgia 30303-8909

April 23, 2010

Craigan Gray, MD, MBA, JD
Director
Division of Medical Assistance
North Carolina Department of Health and Human Services
2501 Mail Service Center
Raleigh, North Carolina 27699-2501

Attention: Teresa Smith

RE: North Carolina Title XIX State Plan Amendment, Transmittal #10-003

Dear Dr. Gray:

This is a follow up to the approval letter that you should have received from Mr. Larry Reed, Director, Division of Pharmacy, and Centers for Medicare & Medicaid Services, dated April 20, 2010. Enclosed is a copy of the approval letter, the signed form HCFA-179 and the approved plan pages.

The effective date of this amendment is March 15, 2010.

Sincerely,

//S//

Jackie Glaze
Acting Associate Regional Administrator
Division of Medicaid & Children's Health Operations

Enclosures

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-14-26
Baltimore, Maryland 21244-1850

CMS
CENTER for MEDICARE & MEDICAID SERVICES

Centers for Medicaid & State Operations

Disabled and Elderly Health Programs Group

APR 2 0 2010

Lanier M. Cansler
Office of the Secretary
North Carolina Department of Health and Human Services
2001 Mail Service Center
Raleigh, North Carolina 27699-2001

Dear Mr. Cansler:

We have reviewed North Carolina State Plan Amendment (SPA) 10-003, Prescribed Drugs, including the additional information provided by the state at the request of CMS. This amendment proposes for the implementation of a Preferred Drug List (PDL) with prior authorization for drugs not included on the list in conjunction with the State's participation in the First Health National Medicaid Pooling Initiative (NMPI) Multi-State Pooling Supplemental Rebate Agreement (SRA). We are pleased to inform you that the amendment is approved, effective March 15, 2010. We believe that the prior authorization program and PDL are designed to increase the efficiency and economy of the Medicaid program and benefit the Medicaid population.

A copy of the CMS-179 form, as well as the pages approved for incorporation into the North Carolina's state plan will be forwarded by the Atlanta Regional Office. If you have any further questions or require additional information, please contact Kim Howell at (410) 786-6762.

Sincerely,

//s//

Larry Reed
Director
Division of Pharmacy

cc: Mary Kaye Justis, Acting ARA Atlanta Regional Office
Cheryl Brimage, Atlanta Regional Office
Elaine Elmore, Atlanta Regional Office

DEPARTMENT OF HEALTH AND HUMAN SERVICES
HEALTH CARE FINANCING ADMINISTRATION

FORM APPROVED
OMB NO. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: HEALTH CARE FINANCING ADMINISTRATION

1. TRANSMITTAL NUMBER: **10-003**

2. STATE: **NC**

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE: **March 15, 2010**

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)*

6. FEDERAL STATUTE/REGULATION CITATION:

SSA – Sect. 1927(a)(1), Sect. 1927(a)(4), Sect. 1927(d)(5)

7. FEDERAL BUDGET IMPACT:
a. **FFY 2010** **($ 49,875,497)**
b. **FFY 2011** **($ 92,488,202)**

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:

Attachment 3.1-A.1, pages 14d

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:

n/a

10. SUBJECT OF AMENDMENT:

Outpatient Drugs – Supplemental Rebates With Mandatory PDL

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:
//s//

13. TYPED NAME:
Lanier M. Cansler

14. TITLE: Secretary

15. DATE SUBMITTED:

16. RETURN TO:
Office of the Secretary
Department of Health and Human Services
2001 Mail Service Center
Raleigh, North Carolina 27699-2001

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:
02-03-10

18. DATE APPROVED: 04-20-10

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL:
02-03-10

20. SIGNATURE OF REGIONAL OFFICIAL:
//s//

21. TYPED NAME:
Jackie Glaze

22. TITLE: Associate Regional Administrator
Division of Medicaid & Children Health Opns

23. REMARKS:
Approved with the following changes to item 8 and 9 as authorized by State Agency e-mail dated 04/26/10:

Block # 8 Attachment 3.1-A.1, page 14 changed to read; Attachment 3.1-A.1 pages 14c and 14d.

Block # 9 Attachment 3.1-A.1, page 14 changed to read; Attachment 3.1-A.1 pages 14c and 14d.

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 First Health Services 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.

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 First Health Services 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.

12.a. Prescribed Drugs *(continued)*

(6) 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.

The State will conduct an annual evaluation with a public report of any multi-state or state-specific PDL, PA or supplemental rebate agreement regarding the cost savings associated with the State participation and impact on related services such as hospitalizations.