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

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

March 23, 2011

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 #10-024

Dear Dr. Gray:

This is to affirm approval of the above referenced State Plan Amendment which was submitted to the Regional Office on March 21, 2011. The request date of September 1, 2010 has been accepted.

Enclosed for your records is a copy of the letter submitted to the State by Larry Reed, Director, Division of Pharmacy informing North Carolina of the approval, the original signed 179 with the "pen and Ink" changes to block 7a and copy of the approved plan pages.

If you have any additional question regarding this amendment, please contact Elaine Elmore at 404-562-7408.

Sincerely,

//s//

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

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

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid, CHIP and Survey & Certification

Disabled and Elderly Health Programs Group

March 21, 2011

Craigan Gray, M.D., M.B.A., J.D.
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

Dear Dr. Gray:

We have reviewed North Carolina State Plan Amendment (SPA) 10-024 received in the Atlanta Regional Office on September 1, 2010. This amendment proposes to prevent the substitution of a generic equivalent drug when the net cost to the State for the brand name drug, after rebates, is less than the cost of the generic equivalent. The State also proposes to impose prior authorization requirements on brand-name drugs when "medically necessary" is written on the prescription. We are pleased to inform you that the amendment is approved, effective September 1, 2010.

A copy of the pages approved for incorporation into the North Carolina's State Plan will be forwarded by the Atlanta Regional Office. If you have any questions regarding this request, please contact Angel Davis at (410) 786-4693.

Sincerely,

/s/

Larry Reed
Director
Division of Pharmacy

cc: Jackie Glaze, Acting ARA, 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: **10-024**

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: **September 1, 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:
42 CFR 447.331

7. FEDERAL BUDGET IMPACT:
a. **FFY 2010 -- 2011 ($3,258,949)**
b. **FFY 2011 -- 2012 ($3,519,665)**

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:
Attachment 3.1-A.1 Pages 14 and 14a

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:
Attachment 3.1-A.1 Pages 14 and 14a

10. SUBJECT OF AMENDMENT:
PRESCRIBED DRUGS

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:
[redacted]

13. TYPED NAME:
Lanier M. Cansler

14. TITLE:
Secretary

15. DATE SUBMITTED:
8/23/10

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: 09/01/10

18. DATE APPROVED: 03/21/11

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: 10/01/10

20. SIGNATURE OF REGIONAL OFFICIAL:
[redacted]

21. TYPED NAME: Jackie Glaze

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

23. REMARKS:

Approved with the following changes to item 7a and 7b

Block # 7a changed to read: FFY 2011 ($2,108,866) and **7b Changed to read**: FFY 2012 ($2,277,575)

12.a. Prescribed Drugs *(continued)*

(3) The Department may establish authorizations, limitations, and reviews for specific drugs, drug classes, brands, or quantities in order to manage effectively the Medicaid pharmacy program. This may include limitations on monthly brand-name and generic prescriptions as well as restrictions on the total number of medications, except that the Department may not impose limitations on brand-name medications for which there is a generic equivalent in cases where the prescriber has determined at the time the drug is prescribed, that the brand-name drug is medically necessary and has written on the prescription order the phrase "medically necessary". The Department may impose prior authorization requirements on brand-name drugs for which the phrase "medically necessary" is written on the prescription.

The Division of Medical Assistance (DMA) has a prescription limit of eight (8) prescriptions per recipient per month for recipients age twenty-one (21) and older. This limitation does not apply to EPSDT eligible children. A pharmacist may override the monthly limitation with three (3) additional prescriptions per recipient per month based on the assessment of the recipient's need for additional medications during the month of service. The Division requires additional review for greater than three additional prescriptions. Recipients who reside in nursing facilities and intermediate care facilities/mental retardation centers are exempt from the prescription limitation.

(4) Drugs for which Medical Assistance reimbursement is available are limited to the following:

Covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under Section 1927(a) of the Act which are prescribed for a medically accepted indication.

A preferred drug list or other restrictions such as Prior Authorization (PA) must permit coverage of participating manufacturers' drugs. In addition, prior authorization must be obtained from the Medicaid agency or its authorized agent for any drug on the prior authorization list before Medicaid reimbursement is available. The state provides for response by telephone or other telecommunication device within twenty-four (24) hours of a request for prior authorization. The state also provides for the dispensing of at least a seventy-two (72) hour supply of a covered outpatient prescription drug in an emergency situation (effective July 1, 1991).

12.a. Prescribed Drugs

(1) Limited to rebateable legend drugs, Insulin and selected rebateable over the counter (OTC) drugs designated per the North Carolina Division of Medical Assistance policy on Over the Counter Medications, criteria listed in General Clinical Coverage Policy No. A2. Prior authorization is required for certain high-cost drugs which are subject to overutilization or abuse per the North Carolina Division of Medical Assistance Policy for Prior Authorization, General Clinical Coverage Policy No. A3.

(2) For Non MAC (Maximum Allowable Cost) drugs, a prescription designated by a brand or trade name for which one or more equivalent drugs are available shall be considered to be an order for the drug by its generic name, except when the prescriber personally indicates in their own handwriting on the prescription order brand name "medically necessary". For MAC drugs, the prescriber must write in their own handwriting on the face of the prescription brand name "medically necessary". The Department may prevent substitution of a generic equivalent drug when the net cost to the State of the brand-name drug, after consideration of all rebates, is less than the cost of the generic equivalent. The Department will ensure that the preferred brand-name name drug is not on the Federal Upper Limit or State Maximum Allowable Cost lists in order to maintain lesser of logic pricing of prescription drug claims.