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State/Territory Name: North Carolina

State Plan Amendment (SPA) #: 13-042

This file contains the following documents in the order listed:

- 1) RO Follow-Up Approval Letter
- 2) Pharmacy Approval Letter
- 3) CMS 179 Form
- 4) Approved SPA Pages



January 14, 2014

Aldona Z. Vos, M.D.
Secretary
Office of the Secretary
Department of Health and Human Services
2001 Mail Service Center
Raleigh, NC 27699-20014

Re: North Carolina Title XIX State Plan Amendment, Transmittal #13-042

Dear Dr. Vos:

This is to affirm approval of the above referenced State Plan Amendment which was submitted to the Regional Office on November 18, 2013. The State's requested effective date of October 1, 2013 has been accepted.

Enclosed for your records are:

1. a copy of the approval letter dated January 10, 2014 that was submitted to the State by Larry Reed, Director, Division of Pharmacy;
2. the original signed 179; and
3. the approved plan pages.

If you have any additional questions regarding this amendment, please contact Elaine Elmore, State Coordinator for North Carolina, at 404-562-7408.

Sincerely,

//s//

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

Enclosure(s)

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 & Elderly Health Programs Group**

January 10, 2014

Aldona Z. Wos, M.D.
Secretary
Office of the Secretary
Department of Health and Human Services
2001 Mail Service Center
Raleigh, NC 27699-20014

Dear Dr. Wos:

We have reviewed North Carolina State Plan Amendment (SPA) 13-042, Prescribed Drugs, received in the Regional Office on November 15, 2013. This amendment proposes to revise the National Medicaid Pooling Initiative (NMPI) Supplemental Rebate Agreement (SRA) previously submitted to CMS on December 30, 2009 to include definitions and structural changes that would provide the option of including Medicaid managed care utilization for accrual of supplemental rebates. We are pleased to inform you that the amendment is approved effective October 1, 2013.

We believe that the North Carolina NMPI SRA continues to be consistent with the objectives of the Medicaid program. Please note that this authorization extends only to the revised SRA, attachments and schedules included in this approval packet which will replace the current SRA packet submitted to CMS on December 30, 2009. Inclusion of the managed care organization (MCO) utilization under the Rhode Island NMPI SRA is optional and at the sole discretion of each member state.

If revisions are subsequently made to include MCO utilization for supplemental rebate collection or any other changes to the supplemental drug rebate agreement, attachments or schedules, all such documents should be submitted to CMS for review and approval. A separate SPA will be required if the state intends to exercise the option of including MCO utilization for supplemental rebates.

A copy of the CMS-179 form with the requested pen and ink change, as well as the pages approved for incorporation into the North Carolina state plan will be forwarded to you by the Atlanta Regional Office. If you have any questions regarding this amendment, please contact Jessica Walker at (410) 786-2457.

Sincerely,

/s/

Kim Howell
Acting Director
Division of Pharmacy

cc: Jackie Glaze, ARA, Atlanta Regional Office
Elaine Elmore, Atlanta Regional Office

**TRANSMITTAL AND NOTICE OF APPROVAL OF
STATE PLAN MATERIAL**1. TRANSMITTAL NUMBER:
13-0422. STATE
NC

FOR: HEALTH CARE FINANCING ADMINISTRATION

3. PROGRAM IDENTIFICATION:
TITLE XIX OF THE SOCIAL SECURITY ACT (MEDICAID)TO: REGIONAL ADMINISTRATOR
HEALTH CARE FINANCING ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES4. PROPOSED EFFECTIVE DATE
October 1, 2013

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:

Section 1927 of the Social Security Act (42 U.S.C. §1396r-8)

7. FEDERAL BUDGET IMPACT:

a. FFY 2014 \$0.00

b. FFY 2015 \$0.00

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:

Attachment 3.1-A.1, Page 14c

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

Attachment 3.1-A.1, Page 14c

10. SUBJECT OF AMENDMENT:

Supplemental Drug Rebate Agreement

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:

14. TITLE: Aldona Z. Wos, M.D.

15. DATE SUBMITTED: 11/15/163

16. RETURN TO:

Office of the Secretary
Department of Health and Human Services
2001 Mail Service Center
Raleigh, NC 27699-20014**FOR REGIONAL OFFICE USE ONLY**17. DATE RECEIVED:
11/18/13

18. DATE APPROVED: 01/10/14

PLAN APPROVED – ONE COPY ATTACHED19. EFFECTIVE DATE OF APPROVED MATERIAL:
10/01/1320. SIGNATURE OF REGIONAL OFFICIAL:
//s//21. TYPED NAME:
Jackie Glaze22. TITLE: Associate Regional Administrator
Division of Medicaid & Children Health Opns

23. REMARKS:

Approved with the following changes to item 6 as authorized by State Agency e-mail dated 01/06/14.

Blocked #6 changed to read: 42 CFR part 447

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.
- 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.

TN No.: 13-042
Supersedes
TN. No.: 10-003

Approval Date: 01-10-14

Effective Date: 10/01/2013