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State/Territory Name: ND

State Plan Amendment (SPA) #: 15-0012

This file contains the following documents in the order listed:

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICAID & CHIP SERVICES

Center for Medicaid and CHIP Services
Disabled and Elderly Health Programs Group

December 4, 2015

Maggie D. Anderson, Executive Director
North Dakota Department of Human Services
600 East Boulevard Avenue, Department 325
Bismarck, ND 58505-0250

Dear Ms. Anderson:

We have reviewed North Dakota State Plan Amendment (SPA) 15-0012 received in the Denver Regional Office on September 30, 2015. This amendment provides the terms upon which the state will collect supplemental rebates from drug manufacturers. North Dakota entered into a supplemental drug rebate agreement (SRA) with the Sovereign States Drug Consortium (SSDC) Medicaid multi-state purchasing pool on May 29, 2015. The intent of the SRA affords the Department to receive a supplemental rebate from drug manufacturers, in addition to rebates received under the CMS Rebate Agreement, pursuant to Section 1927 of the Social Security Act, for the manufacturer's covered product(s) quarterly utilization in the North Dakota Medicaid Program. The parties also intend for this Agreement to meet the requirements of federal law at Section 1927 of the Social Security Act. We are pleased to inform you that the SPA is approved, effective July 1, 2015.

Based upon the information provided, we believe this amendment is consistent with the objectives of the Medicaid program, is designed to increase the efficiency and economy of the Medicaid program and benefits Medicaid beneficiaries. Approval of North Dakota SPA 15-0012 extends only to the North Dakota SRA and attachment templates submitted to the Centers for Medicare & Medicaid Services (CMS) on September 30, 2015. If changes are subsequently made to the SRA or its attachments, a new SPA and any required documents should be submitted to CMS for review and authorization.

A copy of the CMS-179 form, as well as the pages approved for incorporation into the North Dakota state plan, will be forwarded by the Denver Regional Office. If you have any questions regarding this amendment, please contact Renee Hilliard at (410) 786-2991.

Sincerely,

[redacted]

John Coster
Director,
Division of Pharmacy

cc: Richard Allen, ARA, Denver 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: **15-0012**	2. STATE **North Dakota**
	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 **July 1, 2015**	

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:	7. FEDERAL BUDGET IMPACT:
Section 1927 of the SSA	a. FFY **2015** **$ 0** b. FFY **2016** **$ (633,333)**
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:	9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*:
Attachment to Page 5 of Attachment 3.1-A **Attachment to Page 4 of Attachment 3.1-B**	**Attachment to Page 5 of Attachment 3.1-A** **Attachment to Page 4 of Attachment 3.1-B**

10. SUBJECT OF AMENDMENT:

Amends the North Dakota State Plan to provide for Medicaid supplemental rebates.

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:
Delegated to Single State Medicaid agency

12. SIGNATURE OF STATE AGENCY OFFICIAL: [redacted]	16. RETURN TO:
13. TYPED NAME: **Maggie D. Anderson**	**Maggie D. Anderson, Executive Director** **ND Department of Human Services** **600 East Boulevard Avenue Dept 325** **Bismarck ND 58505-0250**
14. TITLE: **Executive Director, ND Dept. of Human Services**	
15. DATE SUBMITTED: **September 30, 2015**	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED: September 30, 2015	18. DATE APPROVED: December 4, 2015
PLAN APPROVED – ONE COPY ATTACHED	
19. EFFECTIVE DATE OF APPROVED MATERIAL: July 1, 2015	20. SIGNATURE OF REGIONAL OFFICIAL: [redacted]
21. TYPED NAME: Richard C. Allen	22. TITLE: ARA, DMCHO

23. REMARKS:

FORM HCFA-179 (07-92)

ON AMOUNT, DURATION AND SCOPE

Services

12a. In compliance with Section 1902(a)54 and Section 1927 of the Social Security Act the Medical Services Division of the Department of Human Services will cover drugs supplied by those manufacturers participating in the drug rebate program with the federal Centers for Medicare & Medicaid Services (CMS) with the following limitations as defined by the Medical Services Division of the Department of Human Services:

1. Drug Efficacy Study Implementation (DESI) Study drugs as determined by the Food and Drug Administration to be less-than-effective and items that are identical, related, or similar (IRS) will not be allowed for payment.

2. Experimental or investigational drugs will not be allowed for payment, with the exception of stiripentol (generic, if available; brand if generic is not available) for children if the coverage has been ordered by the child's physician, determined medically necessary by the Department of Human Services, and has been authorized for the specific child's use by the U.S. Food & Drug Administration.

3. Drugs dispensed in quantities of more than a 34-day supply will not be allowed for payment with the exception of:

   a. Claims received in which a third party liability has been processed; or
   b. Claims for unit of use products where the directions are such that the supply will last longer than 34 days.

4. Drugs identified by the Medical Services division as requiring prior approval and listed in the Pharmacy Provider Manual will not be allowed for payment except in accordance with SSA 1927(d). The following prior authorization requirements, found in section 1927(d)(5) of the Act, are met: The prior authorization program provides a response by telephone of other telecommunication device within 24 hours of a request and the prior authorization program provides for the dispensing of at least a 72-hour supply of a covered drug in an emergency situation.

   a. Supplemental Rebate Agreements: Certain covered products in accordance with Section 1927 of the Social Security Act may not be among the baseline preferred drugs identified by the State of North Dakota's Drug Use Review Board for various therapeutic classes. The state may negotiate supplemental rebate agreements that would reclassify any drug not designated as preferred in the baseline listing for as long as the agreement is in effect.

      In addition, the State has the following policies for the supplemental rebate program for the Medicaid Population:

      The state of North Dakota has entered into an agreement with the "Sovereign States Drug Consortium (SSCD)" Medicaid multi-State purchasing pool. Funds received from supplemental rebate agreements will be reported to CMS. The state will remit the

federal portion of any supplemental rebates collected. Manufacturers with supplemental rebate agreements are allowed to audit utilization data.

A rebate agreement between the state and a drug manufacturer for drugs provided to the Medicaid program, submitted to the Centers for Medicare & Medicaid Services (CMS) on September 30, 2015 and entitled, "SSDC North Dakota Medicaid Supplemental Rebate Agreement" has been authorized by CMS.

This Agreement may not be amended or modified without the mutual written consent of the parties. Any modification or amendment must be authorized by CMS.

The unit rebate amount is confidential and cannot be disclosed in accordance with Section 1927 (b)(3)(D) of the Social Security Act.

The Medical Services Division may require prior authorization for covered outpatient drugs. Non-preferred drugs are available with prior authorization.

The prior authorization process for covered outpatient drugs will conform to the provisions of Section 1927 (d)(5) of the Social Security Act.

5. Erectile dysfunction drugs will not be allowed for payment.

6. The early refill threshold for non-controlled substance prescriptions is 80%. This can be over-ridden by the pharmacist if:

   a. They determine it is medically necessary to over-ride the early refill edit; and
   b. The previous prescription is 50% utilized or more; and
   c. The pharmacist submits the necessary over-ride codes.

   The early refill threshold for controlled substance prescriptions is 85%. Pharmacists must contact Medical Services to discuss medical necessity for controlled substance prescription early refills as well as any non-controlled substance prescriptions that don't meet all three of the above conditions.

   Accumulation edits allow a maximum of 10 days of supply accumulation in a rolling six month period for controlled substances and a maximum of 15 days of supply accumulation in a rolling six month period for non-controlled substances. Pharmacists must contact Medical Services to discuss medical necessity for over-rides for accumulation edits.

7. To increase the cost-effectiveness of dispensing habits, quantities of medication may be restricted if the Medical Services Division or the Drug Utilization Review (DUR) Board determines (a) an alternate method of dispensing would be medically appropriate and more cost-effective, or (b) the dose is not a medically accepted dose supported by citations in the compendia described in Section 1927(g)(1)(B)(i) of OBRA '93.

8. Effective January 1, 2006, the Medicaid agency will not cover any Part D drug for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B.

   The Medicaid agency provides coverage (as specified below) for the following excluded or otherwise restricted drugs or classes of drugs, or their medical uses to all Medicaid

recipients, including full benefit dual eligible beneficiaries under the Medicare Prescription Drug Benefit – Part D.

a. Agents when used for anorexia, weight loss, weight gain are only covered for orlistat when used for morbid obesity.

b. Agents when used to promote fertility are not covered.

c. Agents when used for cosmetic purposes or hair growth or hair loss are not covered.

d. Agents when used for the symptomatic relief of cough and colds are only covered for cough syrups.

e. Prescription vitamins and mineral products are only covered for vitamin B-12 injection, folic acid, renal failure multi-vitamins, multi-vitamins typically used in cystic fibrosis, and iron.

f. Non-prescription drugs are only covered for analgesics, antacids, artificial tears, and iron. These are covered for full benefit dual eligible beneficiaries through prior authorization if a therapeutically equivalent Part D prescription drug is determined not effective by the physician (e.g. ibuprofen prescription versus non-prescription ibuprofen).

g. Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee are not covered.

9. Active Pharmaceutical Ingredients (APIs) will not be allowed for payment except select APIs used in extemporaneously compounded prescriptions when dispensed by a participating pharmacy provider pursuant to a prescription issued by a licensed prescriber following all state and federal laws. The select APIs will only include those that are determined by the State to be cost effective compared to other covered alternatives. APIs that have been identified as being cost effective are identified at http://www.nd.gov/dhs/services/medicalserv/medicaid/docs/covered-APIs.pdf.

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