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State/Territory Name: North Dakota

State Plan Amendment (SPA) #: ND-11-015

This file contains the following documents in the order listed:

1) Approval Letter
2) 179
3) Approved SPA Pages

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

Center for Medicaid and CHIP Services

October 31, 2011

Ms. Maggie D. Anderson
Director
Division of Medical Services
ND Department of Human Services
600 East Boulevard Avenue Dept 325
Bismarck, ND 58505-0250

Dear Ms. Anderson:

We have reviewed North Dakota State Plan Amendment (SPA) 11-015, received in the Regional Office on August 2, 2011. This amendment proposes to add coverage of Stiripentol, add coverage of active pharmaceutical ingredients (APIs) that are compounded in a prescription and adds language regarding coverage of smoking cessation products for pregnant women to the pharmacy section of the State plan. In addition, this amendment makes changes regarding the drug quantity dispensed and the early refill threshold.

We are pleased to inform you that the amendment is approved, effective July 11, 2011. 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 Terry Simananda at (410) 786-8144.

Sincerely,

/s/

Larry Reed
Director
Division of Pharmacy

cc: Richard Allen, ARA, Denver Regional Office
Diane Dunstan-Murphy, 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: **11 – 015**	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 11, 2011**	

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: **1927 of the Act**	7. FEDERAL BUDGET IMPACT: a. FFY 2011 $ 1,100.00 b. FFY 2012 $ 4,000.00
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: **Attachment to Page 5 of Attachment 3.1-A** **Attachment to Page 4 of Attachment 3.1-B**	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**

10. SUBJECT OF AMENDMENT:

Amends the State Plan to clarify limits for prescription drug coverage.

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: Maggie D. Anderson, Director, Medical Services Division

12. SIGNATURE OF STATE AGENCY OFFICIAL:	16. RETURN TO:
13. TYPED NAME: **Maggie D. Anderson**	**Maggie D. Anderson, Director** **Division of Medical Services** **ND Department of Human Services** **600 East Boulevard Avenue Dept 325** **Bismarck ND 58505-0250**
14. TITLE: **Director, Division of Medical Services**	
15. DATE SUBMITTED: 8/2/2011	

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:	18. DATE APPROVED: 10/31/11

PLAN APPROVED – ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL: 9/11/11	20. SIGNATURE OF REGIONAL OFFICIAL:
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 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. North Dakota Medicaid will accept voluntary supplemental rebates offered by manufacturers. The presence or absence of these rebates will not determine or otherwise influence prior authorization status of the medications. All rebates collected will be shared per the FFP Match Rate in effect at the time of collection of the rebates.

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. Drugs when used to promote smoking cessation will not be allowed for payment with the exception of nicotine gum with a two year limitation of 1,164 pieces per recipient, bupropion hydrochloride sustained release tablets with a two year limitation of 180 tablets per recipient, nicotine transdermal patches with a two year limitation of 90 days of therapy (any combination of strengths), nicotine lozenges with a two year limitation of 1,164 lozenges per recipient, and varenicline tartrate with a two year limitation of 336 tablets per recipient. Also, the recipient must be enrolled with the North Dakota Tobacco Quit Line to receive smoking cessation drugs. If the recipient is to receive patches, lozenges, or gum, then the recipient must have used their allotment from the North Dakota Tobacco Quitline. The Medicaid agency will provide coverage of prescription and over-the-counter (OTC) smoking/tobacco cessation covered outpatient drugs for pregnant women as recommended in "Treating Tobacco Use and Dependence – 2008 Update: A Clinical Practice Guideline" published by the Public Health Service in May 2008 or any subsequent modification of such guideline.

8. 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.

9. 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.

h. Barbiturates are covered (all).

i. Benzodiazepines are covered (all).

j. Agents when used to promote smoking cessation. (Restricted to the prescription drugs, bupropion and varenicline, and over-the-counter nicotine patches, lozenges, and gum. Prescription drugs are covered for Medicaid recipients who are not full-benefit dual eligible individuals. Over-the-counter drugs are covered for all populations. Coverage of all prescription and over-the-counter agents is available to only those Medicaid recipients that are enrolled with and actively participating in the North Dakota Tobacco Quitline.)

10. 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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