

Table of Contents

State/Territory Name: North Dakota

State Plan Amendment (SPA) #: ND-23-0006

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 Form/Summary Form
- 3) Approved SPA Pages

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 and Elderly Health Programs Group

May 16, 2023

Krista Fremming
Interim Director
Medical Services Division
ND Department of Health and Human Services
600 East Boulevard Avenue Dept. 325
Bismarck, ND 58505-0250


Dear Krista Fremming,

The CMS Division of Pharmacy team has reviewed North Dakota's State Plan Amendment (SPA) 23-0006 received in the CMS Medicaid & CHIP Operations Group on March 7, 2023. This SPA proposes to amend the State Plan to implement a value-based supplemental rebate agreement.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 23-0006 is approved with an effective date of January 1, 2023. Our review was limited to the materials necessary to evaluate the SPA under applicable federal laws and regulations.

We are attaching a copy of the signed CMS-179 form, as well as the pages approved for incorporation into North Dakota's state plan. If you have any questions regarding this amendment, please contact Omar Alemi at (720) 853-2724 or omar.alemi@cms.hhs.gov.

Sincerely,



Cynthia R. Denemark, R.Ph.
Acting Director
Division of Pharmacy

cc: LeeAnn G. Thiel, ND Department of Health and Human Services
Tyson Christensen, CMS, North Dakota State Lead

**TRANSMITTAL AND NOTICE OF APPROVAL OF
STATE PLAN MATERIAL
FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES**

1. TRANSMITTAL NUMBER

2 3 — 0 0 0 6

2. STATE

ND

3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT

XIX XXI

TO: CENTER DIRECTOR
CENTERS FOR MEDICAID & CHIP SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE

January 1, 2023

5. FEDERAL STATUTE/REGULATION CITATION

Section 1927 of the Social Security Act

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)

a. FFY 2023 \$ 0
b. FFY 2024 \$ 0

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT

Attachment to Page 5 of of Attachment 3.1-A
Attachment to Page 4 of of Attachment 3.1-B

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 PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)

Attachment to Page 5 of of Attachment 3.1-A (TN 18-0018)
Attachment to Page 4 of of Attachment 3.1-B (TN 18-0018)

9. SUBJECT OF AMENDMENT

Amends the State Plan to implement a value-based supplemental rebate agreement.

10. 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:
Caprice Knapp, Director
Medical Services Division

11. SIGNATURE OF STATE AGENCY OFFICIAL

12. TYPED NAME
Krista Fremming

13. TITLE
Interim Medical Services Director

14. DATE SUBMITTED
March 7, 2023

15. RETURN TO

Krista Fremming, Interim Director
Medical Services Division
ND Department of Health and Human Services
600 East Boulevard Avenue Dept 325
Bismarck ND 58505-0250

FOR CMS USE ONLY

16. DATE RECEIVED
03/07/2023

17. DATE APPROVED
05/16/2023

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL
01/01/2023

19. SIGNATURE OF APPROVING OFFICIAL

20. TYPED NAME OF APPROVING OFFICIAL
Cynthia R. Denemark, R.Ph.

21. TITLE OF APPROVING OFFICIAL
Acting Director, Division of Pharmacy

22. REMARKS

12.a Drugs (continued)

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 not covered.
 - b. Agents when used to promote fertility are not covered.
 - c. Agents when used for the symptomatic relief of cough and colds are covered.
 - d. Prescription vitamins and mineral products are only covered for vitamin B-12, folic acid, renal failure multi-vitamins, multi-vitamins typically used in cystic fibrosis, and iron.
 - e. Certain Over-The-Counter drugs are covered as outlined in the pharmacy provider manual. The drugs 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).
 - f. 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>
10. The State may enter into value-based contracts with manufacturers on a voluntary basis. These contracts will be executed on the model agreement entitled "Value-Based Supplemental Rebate Agreement" submitted to CMS on March 7, 2023 and authorized for use beginning January 1, 2023.

12.a Drugs (continued)

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 not covered.
 - b. Agents when used to promote fertility are not covered.
 - c. Agents when used for the symptomatic relief of cough and colds are covered.
 - d. Prescription vitamins and mineral products are only covered for vitamin B-12, folic acid, renal failure multi-vitamins, multi-vitamins typically used in cystic fibrosis, and iron.
 - e. Certain Over-The-Counter drugs are covered as outlined in the pharmacy provider manual. The drugs 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).
 - f. 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>
10. The State may enter into value-based contracts with manufacturers on a voluntary basis. These contracts will be executed on the model agreement entitled "Value-Based Supplemental Rebate Agreement" submitted to CMS on March 7, 2023 and authorized for use beginning January 1, 2023.