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State/Territory Name: South Dakota

State Plan Amendment (SPA)#: 24-0008

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 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
Medicaid Benefits and Health Programs Group

July 30, 2024

Heather Petermann, Director
Department of Social Services
Division of Medical Services
700 Governors Drive
Pierre, SD 57501-2291

Dear Heather Petermann,

We have reviewed South Dakota's State Plan Amendment (SPA) 24-0008 received in the Centers for Medicare and Medicaid Services (CMS) OneMAC application on May 3, 2024. This amendment allows for coverage of select over-the-counter drugs manufactured by a firm that does not have a signed rebate agreement with the United States Department of Health and Human Services. Additionally, it allows South Dakota Medicaid to enter into value-based agreements with manufacturers on a voluntary basis.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SD-24-0008 is approved with an effective date of April 1, 2024.

We are attaching a copy of the signed CMS-179 form, as well as the page approved for incorporation into South Dakota state plan. If you have any questions regarding this amendment, please contact Michael Forman at 410-786-2666 or michael.forman@cms.hhs.gov.

Sincerely,



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

Cc: Renae Hericks, South Dakota Department of Social Services
Mike Jockheck, South Dakota Department of Social Services
Matthew Ballard, South Dakota Department of Social Services
Clarissa Barnes, South Dakota Department of Social Services
Tyler Deines, CMS Division of Program Operations

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

1. TRANSMITTAL NUMBER <u>2 4 — 0 0 0 8</u>	2. STATE <u>S D</u>
3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT <input checked="" type="radio"/> XIX <input type="radio"/> XXI	

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

4. PROPOSED EFFECTIVE DATE
April 1, 2024

5. FEDERAL STATUTE/REGULATION CITATION
Sec. 1927(d) of the Social Security Act

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)
a. FFY 2024 \$ 20,393
b. FFY 2025 \$ 27,214

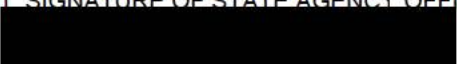
7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT
Supplement to Attachment 3.1-A , Page 20

8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)
Supplement to Attachment 3.1-A, page 20 (TN# 23-0010)

9. SUBJECT OF AMENDMENT
Allows for coverage of select over-the-counter drugs manufactured by a firm that does not have a signed rebate agreement with the United States Department of Health and Human Services and for South Dakota Medicaid to enter into value-based agreements with manufacturers on a voluntary basis.

10. GOVERNOR'S REVIEW (Check One)

GOVERNOR'S OFFICE REPORTED NO COMMENT OTHER, AS SPECIFIED:
 COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

11. SIGNATURE OF STATE AGENCY OFFICIAL


12. TYPED NAME
Heather Petermann

13. TITLE
Director


14. DATE SUBMITTED
May 3, 2024

15. RETURN TO
DEPARTMENT OF SOCIAL SERVICES
DIVISION OF MEDICAL SERVICES
700 GOVERNORS DRIVE
PIERRE, SD 57501-2291

FOR CMS USE ONLY

16. DATE RECEIVED May 3, 2024	17. DATE APPROVED July 30, 2024
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PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL April 1, 2024	19. SIGNATURE 
20. TYPED NAME OF APPROVING OFFICIAL Cynthia R. Denemark, R.Ph.	21. TITLE OF APPROVING OFFICIAL Director, Division of Pharmacy

22. REMARKS

SUPPLEMENT TO ATTACHMENT 3.1-A

12a. Prescribed Drugs

Any covered outpatient drug may be subject to prior authorization, and the agency maintains a list of drugs requiring prior authorization. Prescribing physicians, pharmacists, and/or designated representatives may contact the Medicaid Prior Authorization Unit via 1-800 phone or fax lines, mail or encrypted e-mail to request prior authorization. The program will issue responses within 24 hours of the request. Pharmacies may dispense a 72-hour supply of a prior authorized product in the event of an emergency. The program complies with requirements set forth in OBRA 1990 and 1993 pertaining to prior authorization programs.

Supplemental and Value-Based Rebates

Pursuant to Section 1927 of the Act, the State has the following policies for Medicaid supplemental rebates:

South Dakota participates in the Sovereign States Drug Consortium (SSDC) Medicaid multi-State purchasing pool. SSDC will negotiate supplemental rebates for South Dakota. The state retains all options to accept or reject offers. Drugs of manufacturers who do not participate in the supplemental rebate program will still be available to Medicaid recipients.

A model rebate agreement between the state and a drug manufacturer for drugs provided to the Medicaid population, submitted to the Centers for Medicare & Medicaid Services (CMS) with SPA TN # 22-0012, and entitled "SSDC South Dakota Medicaid Supplemental Drug Rebate Agreement" has been authorized by CMS. Any substantive modification to the agreement will be submitted to CMS for authorization.

CMS has authorized the state of South Dakota to enter into value-based agreements with pharmaceutical manufacturers, on a voluntary basis, for drugs provided to Medicaid beneficiaries using the value-based supplemental rebate agreement beginning April 1, 2024.

Savings recognized from value-based purchasing and supplemental rebate agreements 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.

All drugs covered by the value-based agreement, irrespective of a prior authorization agreement, will comply with the provisions of the national drug rebate agreement.

Per Section 1927 (b)(3)(D) of the Social Security Act the unit rebate amount is confidential and cannot be disclosed. Funds received from supplemental rebate agreements will be reported to CMS. The state will remit the federal portion of any supplemental rebates collected.

Over-the-Counter Drugs

Select over-the-counter (OTC) drugs are covered. The list of covered OTC drugs can be found in the Pharmacy Provider Manual.

Excluded Items

The program does not cover the following items:

1. Agents when used for the treatment of sexual or erectile dysfunction;
2. Drugs manufactured by a firm that has not signed a rebate agreement with the United States Department of Health and Human Services, Centers for Medicare and Medicaid Services except for select OTC dietary supplements;
3. Drugs and biologicals which the federal government has determined to be less than effective;
4. Experimental items.

The program does not cover any Medicare Part D drug for full-benefit dual eligible individuals who are entitled to receive Medicare benefits under Part A or Part B. (See **Attachment 3.1-A.1** for specific coverage.)