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**State/Territory Name: South Dakota**

**State Plan Amendment (SPA) #: 18-0006**

This file contains the following documents in the order listed:

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



**Center for Medicaid and CHIP Services**

**Disabled and Elderly Health Programs Group**

January 28, 2019

Ms. Lynne A. Valenti  
Cabinet Secretary  
South Dakota Department of Social Services  
Division of Medical Services  
700 Governors Drive  
Pierre, South Dakota 57501-2291

Dear Ms. Valenti:

We have reviewed South Dakota's State Plan Amendment (SPA) 18-0006, Prescribed Drugs, received in the Denver Regional Office on August 13, 2018. This SPA proposes to bring South Dakota into compliance with the reimbursement requirements in the Covered Outpatient Drug final rule with comment period (CMS-2345-FC).

SPA 18-0006 establishes reimbursement for covered outpatient drugs using an actual acquisition cost methodology and implements a professional dispensing fee of \$10.50. This SPA also includes reimbursement for physician-administered drugs, clotting factor, federal supply schedule, and drugs purchased at nominal price. In addition, the SPA states that drugs acquired through the federal 340B drug pricing program and dispensed by 340B covered entities and contract pharmacies are not covered.

In considering the proposed pharmacy reimbursement methodology, the state was required to provide adequate data, such as national or state surveys or studies, or other reliable data to demonstrate that the acquisition cost methodology and professional dispensing fees being paid are sufficient to ensure that South Dakota Medicaid beneficiaries will have access to pharmacy services. In keeping with the requirements of section 1902 (a)(30)(A) of the Social Security Act, we believe the state has demonstrated that their reimbursement is consistent with efficiency, economy, and quality of care, and are sufficient to ensure that care and services are available at least to the extent they are available to the general population in the geographic area.

We believe that there is evidence regarding the sufficiency of South Dakota's pharmacy provider network at this time to approve SPA 18-0006. Specifically, South Dakota has reported to CMS that 176 of the state's 180 licensed in-state retail pharmacies are enrolled in South Dakota's Medicaid fee-for-service program. With over a 97 percent participation rate, we can infer that South Dakota's beneficiaries will have access to pharmacy services at least to the extent available to the general population since Medicaid requires that beneficiaries be provided access to all covered outpatient drugs of participating drug manufacturers with a rebate agreement through a broad pharmacy network. In contrast, commercial insurers often have more limited drug formularies and a more limited pharmacy network.

Based on the information provided and consistent with the regulations at 42 CFR 430.20, we are pleased to inform you that SPA 18-0006 is approved with an effective date of August 1, 2018. A copy of the signed CMS-179 form, as well as the pages approved for incorporation into South Dakota's state plan will be forwarded by the Denver Regional Office.

If you have any questions regarding this amendment, please contact Lisa Shochet at (410) 786-5445 or [lisa.shochet@cms.hhs.gov](mailto:lisa.shochet@cms.hhs.gov).

Sincerely,



John M. Coster, Ph.D., R.Ph.  
Director, Division of Pharmacy

cc: Brenda Tidball-Zeltinger, Deputy Secretary, SD Department of Social Services  
William Snyder, Director, SD Medicaid  
Sarah Aker, Deputy Director, SD Medicaid  
Richard Allen, ARA, CMS, Denver Regional Office  
Kirstin Michel, CMS, Denver Regional Office  
Lisa Hughes, CMS, Denver Regional Office

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

1. TRANSMITTAL NUMBER:  
SD-18-006

2. STATE:  
South Dakota

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE  
SOCIAL SECURITY ACT (MEDICAID)

TO: REGIONAL ADMINISTRATOR  
CENTERS FOR MEDICARE & MEDICAID SERVICES  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE  
August 1, 2018

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:

42 CFR 447 Subpart I

7. FEDERAL BUDGET IMPACT:

a. FFY 2018: \$ 0.00  
b. FFY 2019: \$ 0.00

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT:

Attachment 4.19-B pages 20a and 20b, Attachment 3.1-A.1 page 1

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

Attachment 4.19-B page 20 and Attachment 3.1-A.1 page 1

10. SUBJECT OF AMENDMENT:

The proposed state plan amendment implements prescription drug reimbursement methodology changes required by the federal government including implementation of actual acquisition cost and a professional dispensing fee. The amendment removes obsolete drug coverage language. The amendment also allows the state to take appropriate action to maintain budget neutrality.

11. 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

12. SIGNATURE OF REGIONAL OFFICIAL:

13. TYPED NAME:

Lynne A. Valenti

14. TITLE:

Cabinet Secretary

15. DATE SUBMITTED:

August 13, 2018

16. RETURN TO:

DEPARTMENT OF SOCIAL SERVICES  
DIVISION OF MEDICAL SERVICES  
700 GOVERNORS DRIVE  
PIERRE, SD 57501-2291

FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED:

August 13, 2018

18. DATE APPROVED:

January 28, 2019

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL:

August 1, 2018

20. SIGNATURE OF REGIONAL OFFICIAL:

21. TYPED NAME:

Mary Marchioni

22. TITLE:

Acting ARA, DMCHO

23. REMARKS:

ATTACHMENT 4.19-B  
PAYMENTS FOR MEDICAL AND REMEDIAL CARE AND SERVICES

12a. Prescription Drugs

1. The State agency will reimburse prescribed drugs, including covered non-legend drugs that are prescribed by an authorized prescriber and legend drugs prescribed by an authorized prescriber, at the lowest of the following:
  - i. The pharmacy's usual and customary charge (U&C) to the general public for the drug; or
  - ii. South Dakota Medicaid's established State Maximum Allowable Cost (SMAC) for that drug plus the professional dispensing fee. (South Dakota Medicaid's SMAC is acquisition cost based and includes all types of medications, including specialty and hemophilia products); or
  - iii. The current National Average Drug Acquisition Cost (NADAC) for that drug plus the professional dispensing fee; or
  - iv. If there is no NADAC for the drug, the current wholesale acquisition cost (WAC) of the drug plus the professional dispensing fee.

In compliance with 42 CFR 447.512 and 447.514, reimbursement for drugs subject to Federal Upper Limits (FULs) may not exceed FULs in the aggregate.

2. All Indian Health Service and tribal pharmacies are paid the encounter rate by South Dakota Medicaid. Due to this, the logic described above and below does not apply to them regardless of their method of purchasing.
3. Federal Supply Schedule (FSS) purchased drugs are required to be billed and reimbursed at no more than their actual acquisition cost plus the professional dispensing fee.
4. Drugs not dispensed by a retail community pharmacy (such as a long-term care facility, or primarily through the mail) will be reimbursed by using the logic described above and below.
5. Clotting factor from specialty pharmacies, hemophilia treatment centers (HTC), and centers of excellence will be reimbursed through the logic described above and below. That is, in addition to the professional dispensing fee, they will be reimbursed the lowest of the U&C, SMAC, NADAC, or WAC if no NADAC price exists.
6. Drugs acquired at nominal price (outside of 340B or FSS) will be reimbursed at no more than the actual acquisition price plus the professional dispensing fee while using the logic described above and below.

ATTACHMENT 4.19-B  
PAYMENTS FOR MEDICAL AND REMEDIAL CARE AND SERVICES

7. South Dakota Medicaid requires physician administered drugs to be billed by the facility in which it was administered. Payment for physician administered drugs is limited to the lesser of the provider's U&C or South Dakota Medicaid's fee schedule. For physician administered drugs not listed in the fee schedule, payment is limited to 40 percent of the provider's U&C.
8. Where indicated that South Dakota Medicaid will reimburse a professional dispensing fee, the professional dispensing fee is \$10.50.
9. Drugs acquired through the federal 340B drug program and dispensed by covered entities as described in section 1927(a)(5)(B) of the Social Security Act are not covered.
10. Drugs acquired through the federal 340B drug pricing program and dispensed by 340B contract pharmacies are not covered.
11. Investigational drugs are not covered.
12. In the event that the above methodology is projected to result in expenditures that exceed the amount appropriated by the state legislature for the current state fiscal year the state may submit a state plan amendment to revise the reimbursement methodology.

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT  
State: South Dakota

REQUIREMENTS RELATING TO COVERED OUTPATIENT DRUGS FOR THE  
CATEGORICALLY NEEDY

Citation(s)	Provision(s)
Section 1935(d)(1) of the Act	The Medicaid agency does 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.
Sections 1927(d)(2) and 1935(d)(2)	<p>The Medicaid agency provides coverage 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.</p> <p>The following excluded drugs are covered:</p> <ul style="list-style-type: none"><li><u>X</u> (a) Agents when used for anorexia, weight loss, or weight gain, with limitations;</li><li>___ (b) Agents when used to promote fertility;</li><li><u>X</u> (c) Agents when used for the symptomatic relief of cough and colds;</li><li><u>X</u> (d) Prescription vitamins and mineral products, except prenatal vitamins and fluoride;</li><li><u>X</u> (e) Non-prescription drugs, with limitations;</li><li>___ (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 (see specific drug categories below);</li></ul>