

## **Table of Contents**

**State/Territory Name: South Dakota**

**State Plan Amendment (SPA) #: 22-0004**

This file contains the following documents in the order listed:

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

DEPARTMENT OF HEALTH & HUMAN SERVICES  
Centers for Medicare & Medicaid Services  
601 E. 12th St., Room 355  
Kansas City, Missouri 64106



**Medicaid and CHIP Operations Group**

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April 20, 2022

Sarah Aker, Medicaid Director  
Department of Social Services  
Richard F. Kneip Building  
700 Governors Drive  
Pierre, SD 57501-2291

RE: TN 22-0004

Dear Ms. Aker:

The Centers for Medicare & Medicaid Services (CMS) has completed its review of South Dakota's State Plan Amendment (SPA) Transmittal #22-0004, submitted on March 31, 2022. The SPA provides assurances that the State complies with federal requirements regarding coverage of routine patient care associated with participation in clinical trials as required by the Consolidated Appropriations Act, 2021.

CMS approved SPA #22-0004 on April 20, 2022, with an effective date of January 1, 2022. Enclosed is a copy of the CMS-179 summary form, as well as the approved pages for incorporation into the South Dakota State Plan.

If you have any questions regarding this amendment, please contact Mandy Strom at [mandy.strom@cms.hhs.gov](mailto:mandy.strom@cms.hhs.gov) or (303)844-7068.

Sincerely,

 Digitally signed by James  
G. Scott -S  
Date: 2022.04.20 15:53:14  
-05'00'

James G. Scott, Director  
Division of Program Operations

Enclosures

cc: Matthew Ballard, South Dakota Medicaid  
Renae Hericks, South Dakota Medicaid

<b>TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL</b> <b>FOR: CENTERS FOR MEDICARE &amp; MEDICAID SERVICES</b>	1. TRANSMITTAL NUMBER <u>2 2 - 0 0 0 4</u>	2. STATE <u>SD</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 <u>January 1, 2022</u>	
5. FEDERAL STATUTE/REGULATION CITATION <u>1905(gg)(1),(2),(3)</u>	6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars) a FFY <u>2022</u> \$ <u>0</u> b FFY <u>2023</u> \$ <u>0</u>	
7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT <u>Attachment 3.1-A, Page 12</u>	8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)	

9. SUBJECT OF AMENDMENT

Provides assurances that the State is in compliance with federal regulation regarding routine patient care and clinical trials.

10. GOVERNOR'S REVIEW (Check One)

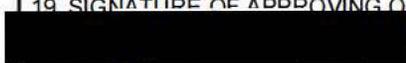
GOVERNOR'S OFFICE REPORTED NO COMMENT  OTHER, AS SPECIFIED:  
 COMMENTS OF GOVERNOR'S OFFICE ENCLOSED  
 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

11. SIGNATURE OF STATE AGENCY OFFICIAL 	15. RETURN TO DEPARTMENT OF SOCIAL SERVICES DIVISION OF MEDICAL SERVICES 700 GOVERNORS DRIVE PIERRE, SD 57501-2291
12. TYPED NAME <u>Laurie R. Gill</u>	
13. TITLE <u>Cabinet Secretary</u>	
14. DATE SUBMITTED <u>March 31, 2022</u>	

**FOR CMS USE ONLY**

16. DATE RECEIVED <u>March 31, 2022</u>	17. DATE APPROVED <u>April 20, 2022</u>
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**PLAN APPROVED - ONE COPY ATTACHED**

18. EFFECTIVE DATE OF APPROVED MATERIAL <u>January 1, 2022</u>	19. SIGNATURE OF APPROVING OFFICIAL  igitally signed by James G. Scott -S ate: 2022.04.20 15:53:53 -05'00'
20. TYPED NAME OF APPROVING OFFICIAL <u>James G. Scott</u>	21. TITLE OF APPROVING OFFICIAL <u>Director, Division of Program Operations</u>

22. REMARKS

**State/Territory: South Dakota****AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED****CATEGORICALLY NEEDY GROUP(S)**

## 30. Coverage of Routine Patient Cost in Qualifying Clinical Trials

\*The state needs to check each assurance below.

Provided:   X  

## I. General Assurances:

**Routine Patient Cost – Section 1905(gg)(1)**

  X   Coverage of routine patient cost for items and services as defined in section 1905(gg)(1) that are furnished in connection with participation in a qualified clinical trial.

**Qualifying Clinical Trial – Section 1905(gg)(2)**

  X   A qualified clinical trial is a clinical trial that meets the definition at section 1905(gg)(2).

**Coverage Determination – Section 1905(gg)(3)**

  X   A determination with respect to coverage for an individual participating in a qualified clinical trial will be made in accordance with section 1905(gg)(3).

PRA Disclosure Statement - This information is being collected to assist the Centers for Medicare & Medicaid Services in implementing Section 210 of the Consolidated Appropriations Act of 2021 amending section 1905(a) of the Social Security Act (the Act), by adding a new mandatory benefit at section 1905(a)(30). Section 210 mandates coverage of routine patient services and costs furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials effective January 1, 2022. Section 210 also amended sections 1902(a)(10)(A) and 1937(b)(5) of the Act to make coverage of this new benefit mandatory under the state plan and any benchmark or benchmark equivalent coverage (also referred to as alternative benefit plans, or ABPs). Under the Privacy Act of 1974 any personally identifying information obtained will be kept private to the extent of the law. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. The OMB control number for this project is 0938-1148 (CMS-10398 #74). Public burden for all of the collection of information requirements under this control number is estimated to take about 56 hours per response. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to CMS, 7500 Security Boulevard, Attn: Paperwork Reduction Act Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

TN:   22-0004  

Supersedes TN:   NEW  

Approval Date:   04/20/22  

Effective Date:   01/01/22