

## **Table of Contents**

**State/Territory Name: Nebraska**

**State Plan Amendment (SPA) #: 22-0003**

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  
601 E. 12th St., Room 355  
Kansas City, Missouri 64106



Medicaid and CHIP Operations Group

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June 17, 2022

Kevin Bagley  
Director  
Division of Medicaid & Long-Term Care  
Nebraska Department of Health & Human Services  
301 Centennial Mall South  
Lincoln, NE 68509

Re: Nebraska State Plan Amendment (SPA) 22-0003

Dear Mr. Bagley:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) NE-22-0003. This amendment proposes Consolidated Appropriations Act (CAA) Coverage of Routine Costs Associated with Qualifying Clinical Trials.

We conducted our review of your submittal according to statutory requirements in Title XIX of the Social Security Act and implementing regulations. 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. This letter is to inform you Nebraska SPA 22-0003 was approved on June 16, 2022, with an effective date of January 1, 2022.

If you have any questions, please contact Tyson Christensen at (816) 426-6440 or via email at [Tyson.Christensen@cms.hhs.gov](mailto:Tyson.Christensen@cms.hhs.gov).

Sincerely,

Ruth A. Hughes, Acting Director  
Division of Program Operations

Enclosures

cc: Dawn Kastens  
Catherine Gekas-Steeby

<b>TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE &amp; MEDICAID SERVICES</b>		1. TRANSMITTAL NUMBER <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="border: 1px solid black; padding: 2px 5px;">2</div> <div style="border: 1px solid black; padding: 2px 5px;">2</div> <div style="border: 1px solid black; padding: 2px 5px;">—</div> <div style="border: 1px solid black; padding: 2px 5px;">0</div> <div style="border: 1px solid black; padding: 2px 5px;">0</div> <div style="border: 1px solid black; padding: 2px 5px;">0</div> <div style="border: 1px solid black; padding: 2px 5px;">3</div> </div>	2. STATE <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="border: 1px solid black; padding: 2px 5px;">N</div> <div style="border: 1px solid black; padding: 2px 5px;">E</div> </div>
TO: CENTER DIRECTOR CENTERS FOR MEDICAID & CHIP SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES		3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT <input checked="" type="checkbox"/> XIX <input type="checkbox"/> XXI	
5. FEDERAL STATUTE/REGULATION CITATION 42 US 1396(d)(gg)(1-3) // [Section 1905(gg)(1-3) of the Act]		4. PROPOSED EFFECTIVE DATE January 1, 2022	
7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT Click or tap here to enter text. Att. 3.1-A, pg 13 (new) Att. 3.1-B, pg 10 (new)		6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)  a. FFY <u>2022</u> \$ <u>0</u> b. FFY <u>2023</u> \$ <u>0</u>	
9. SUBJECT OF AMENDMENT CAA Coverage of Routine Costs Associated with Qualifying Clinical Trials		8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable) Click or tap here to enter text.	
10. GOVERNOR'S REVIEW (Check One) <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 45%;"> <input type="radio"/> GOVERNOR'S OFFICE REPORTED NO COMMENT  <input type="radio"/> COMMENTS OF GOVERNOR'S OFFICE ENCLOSED  <input type="radio"/> NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL         </div> <div style="width: 45%;"> <input checked="" type="radio"/> OTHER, AS SPECIFIED:            Governor has waived review         </div> </div>			
11. SIGNATURE OF STATE AGENCY OFFICIAL  12. TYPED NAME Kevin Bagley 13. TITLE Director, Division of Medicaid & Long-Term Care 14. DATE SUBMITTED March 28, 2022		15. RETURN TO Dawn Kastens Division of Medicaid & Long-Term Care Nebraska Department of Health and Human Services 301 Centennial Mall South Lincoln, NE 68509	
<b>FOR CMS USE ONLY</b>			
16. DATE RECEIVED    March 28, 2022		17. DATE APPROVED    June 16, 2022	
<b>PLAN APPROVED - ONE COPY ATTACHED</b>			
18. EFFECTIVE DATE OF APPROVED MATERIAL January 1, 2022		19. SIGNATURE OF /	
20. TYPED NAME OF APPROVING OFFICIAL Ruth A. Hughes		21. TITLE OF APPROVING OFFICIAL Acting Director, Division of Program Operations	
22. REMARKS			

State/Territory: Nebraska

**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: ☒

**I. General Assurances:**

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

☒ 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)**

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

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

☒ 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: NE 22-0003  
Supersedes TN: New

Approval Date: June 16, 2022  
Effective Date: January 1, 2022



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