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State/Territory Name: North Carolina

State Plan Amendment (SPA) #: 22-0010

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) Summary Form (with 179-like data)
- 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

April 12, 2022

Dave Richard
Deputy Secretary, NC Medicaid
North Carolina Department of Health and Human Services
2501 Mail Service Center
Raleigh, NC 27699-2501

Re: North Carolina State Plan Amendment (SPA) 22-0010

Dear Mr. Richard:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) 22-0010. This amendment complies with section 210 of the Consolidated Appropriations Act of 2021 by adding a new mandatory benefit of routine patient services and costs furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials.

We conducted our review of your submittal according to statutory requirements in Title XIX of the Social Security Act (the Act) and implementing regulations at section 1902(a)(30) of the Act. This letter is to inform you that North Carolina Medicaid SPA 22-0010 was approved on April 08, 2022, with an effective date of January 1, 2022.

If you have any questions, please contact William Pak at (404) 562-7407 or via email at William.Pak@cms.hhs.gov.

Sincerely,

A solid black rectangular box redacting the signature of Ruth A. Hughes.

Ruth A. Hughes, Acting Director
Division of Program Operations

cc: Melanie Bush
Emma Sandoe
Betty Staton
Cecilia Williams

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

1. TRANSMITTAL NUMBER

2 2 — 0 0 1 0

2. STATE

NC

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, 2022

5. FEDERAL STATUTE/REGULATION CITATION

Division CC, Title II, Section 210 of the Consolidated Appropriations

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)

a. FFY 22 \$ 0
b. FFY 23 \$ 0

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT

Attachment 3.1-A, Page 12
Attachment 3.1-B, Page 10

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 PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)

Attachment 3.1 A, Page 12
Attachment 3.1 B, Page 10

9. SUBJECT OF AMENDMENT

Qualifying Clinical Trials

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:

11. TYPED NAME OF APPROVING OFFICIAL

12. TYPED NAME
Kody H. Kinsley

13. TITLE
Secretary

14. DATE SUBMITTED
March 29, 2022

15. RETURN TO

Office of the Secretary
Department of Health and Human Services
2001 Mail Service Center
Raleigh, NC 27699-20014

FOR CMS USE ONLY

16. DATE RECEIVED
March 29, 2022

17. DATE APPROVED
April 8, 2022

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL
January 1, 2022

20. TYPED NAME OF APPROVING OFFICIAL
Ruth A. Hughes

21. TITLE OF APPROVING OFFICIAL
Acting Director, Division of Program Operations

22. REMARKS

Pen and ink change made to Box 8 with approval of the state on April 8, 2022.

State/Territory: North Carolina

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: 22-0010
Supersedes TN: NEW

Approval Date: 04/08/2022
Effective Date: 01/01/2022

State/Territory: North Carolina

AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED

MEDICALLY 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:

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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.

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