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State/Territory Name: Oklahoma

State Plan Amendment (SPA) #: 22-0021

This file contains the following documents in the order listed:

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

CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICAID & CHIP SERVICES

Medicaid and CHIP Operations Group

May 13, 2022

Melody Anthony
Oklahoma Health Care Authority
4345 N. Lincoln Blvd.
Oklahoma City, OK 73105

Re: Oklahoma State Plan Amendment (SPA) 22-0021

Dear Ms. Anthony:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) 22-0021. This amendment proposes comply with new mandatory Medicaid coverage and reimbursement of routine patient costs furnished in connection with participation in qualifying clinical trials.

We conducted our review of your submittal according to statutory requirements in Section 1905(gg) of the Social Security Act (SSA). This letter is to inform you that Oklahoma Medicaid SPA 22-0021 was approved on May 12, 2022, with an effective date of January 1, 2022.

If you have any questions, please contact Stacey S. Steiner at (214) 767-6479 or via email at stacey.steiner@cms.hhs.gov .

Sincerely,

[redacted]
Digitally signed by James G. Scott -S
Date: 2022.05.13 16:00:16 -05'00'

James G. Scott, Director
Division of Program Operations

Enclosures

cc: Traylor Rains, OHCA
Sandra Puebla, OHCA
Kasie McCarty, OHCA

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

FORM APPROVED
OMB No. 0938-0193

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL

FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES

1. TRANSMITTAL NUMBER: 22 — 0021

2. STATE: OK

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

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
Section 1905(a)30 and Section 1905(gg) of the SSA

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)
a. FFY 2022 $ 0
b. FFY 2023 $ 0

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT
Attachment 3.1-A Page 12
Attachment 4.19-B Page 45

8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*
Attachment 3.1-A Page 12; NEW
Attachment 4.19-B Page 45; NEW

9. SUBJECT OF AMENDMENT

State Plan amendment to comply with new mandatory Medicaid coverage and reimbursement of routine patient costs furnished in connection with participation in 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. SIGNATURE OF STATE AGENCY OFFICIAL
[redacted]

12. TYPED NAME
Melody Anthony

13. TITLE
State Medicaid Director

14. DATE SUBMITTED
March 16, 2022

15. RETURN TO
Oklahoma Health Care Authority
Attn: Traylor Rains
4345 N. Lincoln Blvd.
Oklahoma City, OK 73105

FOR CMS USE ONLY

16. DATE RECEIVED
March 16, 2022

17. DATE APPROVED
May 12, 2022

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL
January 1, 2022

19. SIG[redacted]ROVING OFFICIAL
Digitally signed by James G. Scott -S
Date: 2022.05.13 16:01:02 -05'00'

20. TYPED NAME OF APPROVING OFFICIAL
James G. Scott

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

22. REMARKS

Instructions on Back

AMOUNT, DURATION AND SCOPE OF MEDICAL AND REMEDIAL CARE SERVICES PROVIDED TO THE CATEGORICALLY NEEDY

30. Coverage of Routine Patient Cost in Qualifying Clinical Trials

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.

METHODS AND STANDARDS FOR ESTABLISHING PAYMENT RATES
ROUTINE PATIENT COST IN QUALIFYING CLINICAL TRIALS

30. Coverage of Routine Patient Cost in Qualifying Clinical Trials

Reimbursement for routine patient costs associated with qualified clinical trials follows the existing rate methodology approved within the Oklahoma State Plan for the individual service/item provided.