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State/Territory Name: Missouri

State Plan Amendment (SPA) #: 22-0011

This file contains the following documents in the order listed:

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

June 21, 2022

Robert Knodell
Acting Director
Missouri Department of Social Services
Broadway State Office Building
P.O. Box 1527
Jefferson City, Missouri 65102

Re: Missouri State Plan Amendment (SPA) 22-0011

Dear Mr. Knodell:

On March 29, 2022, the Centers for Medicare & Medicaid Services (CMS) received Missouri State Plan (SPA) No. 22-0011. This State Plan Amendment adds coverage of the routine patient costs furnished in connection with participation in clinical trials as outlined in Section 1905(gg) in the Social Security Act.

We are pleased to inform you that SPA 22-0011 was approved on June 21, 2022, with an effective date of January 1, 2022 as requested by the state. Enclosed is a copy of the CMS 179 summary form, as well as the approved pages for incorporation into the Missouri State Plan.

If you have any questions regarding this matter you may contact Deborah Read (816) 426-5925 or by e-mail at Deborah.read@cms.hhs.gov.

Sincerely,

James G. Scott, Director
Division of Program Operations

Enclosures

cc: Todd Richardson, SMD, MHD
Glenda Kremer MHD
Sophia Hinojosa, Program Branch Manager

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 — 0011
2. STATE: MO
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
1905(gg) of the Social Security Act

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 3.19 A, Page 22*~~
~~Attachment 3.1 B, Page 10**~~
Attachment 3.1 A, Page 22
Attachment4.19 B, Page 56

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 PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*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

9. SUBJECT OF AMENDMENT
This amendment adds coverage of routine patient costs furnished in connection with participation in qualifying clinical trials as required by the Centers for Medicare & Medicaid Services (CMS). MHD already covers these services.

10. GOVERNOR'S REVIEW *(Check One)*
(●) GOVERNOR'S OFFICE REPORTED NO COMMENT SLV
( ) COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
( ) NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL
( ) OTHER, AS SPECIFIED:

11. SIGNATURE OF STATE AGENCY OFFICIAL

12. TYPED NAME
Robert J. Knodell

13. TITLE
Acting Director

14. DATE SUBMITTED
3-25-22

15. RETURN TO
MO HealthNet Division
P.O. Box 6500
Jefferson City, MO 65102

FOR CMS USE ONLY

16. DATE RECEIVED
3/29/2022

17. DATE APPROVED
June 21, 2022

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL
1/1/2022

19. SIGNATURE OF APPROVING OFFICIAL

20. TYPED NAME OF APPROVING OFFICIAL
James G. Scott

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

22. REMARKS

* pen and ink change to 3.1 A authorized by the state via e-mail 6/21/2022 and ** pen and ink change authorized to remove 3.1B page per e-mail 6/21/2022.

State __Missouri___

Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials

Except as otherwise noted in the plan, state developed fee schedule rates are the same for both public and private providers who provide routine services in connection with qualifying clinical trials. The agency's fee schedule rate was set as of January 24, 2022, and is effective for services provided on or after that date. All rates are published at https://dss.mo.gov/mhd/providers/pages/cptagree.htm.

State/Territory:
Missouri

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 notconduct or sponsor, and a person is not required to respond to, a collection of information unlessit 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 SecurityBoulevard, Attn: Paperwork Reduction Act Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.