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State/Territory Name: Missouri

State Plan Amendment (SPA) #: 22-0011

This file contains the following documents in the order listed:

1) Approval Letter
2) CMS 179 Form/Summary Form
3) Approved SPA Pages
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
TRANSMITTAL AND NOTICE OF APPROVAL OF
STATE PLAN MATERIAL
FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES

TO: CENTER DIRECTOR
CENTERS FOR MEDICAID & CHIP SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

1. TRANSMITTAL NUMBER 22-0011
2. STATE MO
3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT XIX
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 3.1 A, Page 22 *
   Attachment 4.19 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 PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)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)
   SLV
   ○ GOVERNOR’S OFFICE REPORTED NO COMMENT
   ○ COMMENTS OF GOVERNOR’S OFFICE ENCLOSED
   ○ NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

11. SIGNATURE OF STATE AGENCY OFFICIAL

12. TYPED NAME Robert J. Knodell
13. TITLE Acting Director
14. DATE SUBMITTED 3-25-22

FOR CMS USE ONLY
15. RETURN TO MO HealthNet Division
   P.O. Box 6500
   Jefferson City, MO 65102
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.

Instructions on Back
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.
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: 22-0011

Approval Date: 06-21-2022

Supersedes TN: New

Effective Date: 01-01-2022