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State/Territory Name: Maryland

State Plan Amendment (SPA) #: 22-0007

This file contains the following documents in the order listed:

- 1) Approval Letter
- 2) CMS 179 Form/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 15, 2022

Ms. Tricia Roddy
Maryland Department of Health
201 W. Preston St., 5th Floor
Baltimore, MD 21201

Re: Maryland (MD) State Plan Amendment (SPA) 22-0007

Dear Ms. Roddy:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) 22-0007. This amendment proposes to update the State Plan language to comply with the amended section 1905(a)(30) of the Social Security Act, assuring coverage to eligible Medicaid participants for routine patient costs for otherwise covered items and services resulting from a qualifying clinical trial.

We conducted our review of your submittal according to statutory requirements in Title XIX of the Social Security Act. This letter is to inform you that Maryland Medicaid SPA 22-0007 was approved on April 15, 2022, with an effective date of January 1, 2022.

If you have any questions, please contact Talbatha Myatt at 215-861-4259 or via email at Talbatha.Myatt@cms.hhs.gov

Sincerely,

A large black rectangular redaction box covers the signature of Ruth A. Hughes.

Ruth A. Hughes, Acting Director
Division of Program Operations

cc: Alison Donley, Medicaid Provider Services Administration
Nina McHugh, Medicaid Provider Services Administration

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

1. TRANSMITTAL NUMBER

2 2 — 0 0 0 7

2. STATE

MD

3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT

XX XX

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(a)(30) 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 3.1A, pg. 35 (22-0007) (NEW)
Attachment 3.1B, pg. 11 (22-0007) (NEW)

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 PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)

9. SUBJECT OF AMENDMENT

This proposal updates the State Plan to align with the amended section 1905(a)(30) of the Social Security Act, providing coverage to Medicaid participants for routine patient costs for otherwise covered items and services resulting from a qualifying clinical trial.

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

12. TYPED NAME
Tricia Roddy

13. TITLE
Deputy Medicaid Director

14. DATE SUBMITTED
March 24, 2022

15. RETURN TO
Steven Schuh
Medicaid Director
Maryland Department of Health
201 W. Preston St., 5th Floor
Baltimore, MD 21201

FOR CMS USE ONLY

16. DATE RECEIVED **03/25/2022**

17. DATE APPROVED **04/15/2022**

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL
01/01/2022

19. SIGNATURE

20. TYPED NAME OF APPROVING OFFICIAL

Ruth A. Hughes

21. TITLE OF APPROVING OFFICIAL

Acting Director, Division of Program Operations

22. REMARKS

State/Territory:
Maryland

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#: 22-0007
Supersedes TN#: NEW

Approval Date: 04/15/2022

Effective Date: January 1, 2022

State/Territory:
Maryland

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:

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

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