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State/Territory Name: Maine

State Plan Amendment (SPA) #: 22-0004

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

April 15, 2022

Michelle Probert, Director
Office of MaineCare Services
Department of Health and Human Services
109 Capitol Street, 11 State House Station
Augusta, Maine 04333-0011

Re: Maine State Plan Amendment (SPA) 22-0004

Dear Ms. Probert:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) 22-0004. This amendment proposes to add language that details adherence with mandatory coverage of routine patient costs for services furnished in connection with qualifying clinical trials in accordance with the Consolidated Appropriations Act, 2021 (CAA).

We conducted our review of your submittal according to statutory requirements in Title XIX of the Social Security Act and implementing regulations that generally require states to assure necessary transportation for beneficiaries to and from covered services. This letter is to inform you that Maine Medicaid SPA 22-0004 was approved on April 13, 2022, with an effective date of January 1, 2022.

If you have any questions, please contact Gilson DaSilva at (617) 565-1227 or via email at gilson.dasilva@cms.hhs.gov.

Sincerely,

[redacted]

Ruth A. Hughes, Acting Director
Division of Program Operations

cc: Kristin Merrill, State Plan Manager, Office of MaineCare Services

DEPARTMENT OF HEALTH ANDHUMAN 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 0004

2. STATE: Maine (ME)

3. PROGRAM IDENTIFICATION: TITLE XIX OF THE SOCIALSECURITY 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
1905(gg)

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

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT
Attachment 3.1-A page 17 and Attachment 3.1-B Page 2

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 PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*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

9. SUBJECT OF AMENDMENT
Including language required for mandatory coverage of routine patient costs for services furnished in connection with qualifying clinical trials in accordance with the Consolidated Appropriations Act, 2021 (CAA).

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
Michelle Probert

13. TITLE
Director, MaineCare Services

14. DATE SUBMITTED
March 31, 2022

15. RETURN TO
Michelle Probert
Director, MaineCare Services
#11 State House Station
109 Capitol Street
Augusta, Maine 04333-0011

FOR CMS USE ONLY

16. DATE RECEIVED 03/31/2022

17. DATE APPROVED 04/13/2022

PLAN APPROVED - ONE COPY ATTACHED

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

19. SIGNATURE OF APPROVING OFFIC [redacted]

20. TYPED NAME OF APPROVING OFFICIAL
Ruth A. Hughes

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

22. REMARKS

State/Territory: _MAINE_____

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 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.

State/Territory: MAINE

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)

__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 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.