Table of Contents

State/Territory Name: California

State Plan Amendment (SPA) #: 22-0017

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

August 12, 2022

Jacey Cooper
Chief Deputy Director, Health Care Programs
California Department of Health Care Services
P.O. Box 997413, MS 0000
Sacramento, CA 95899-7413

Re: California State Plan Amendment (SPA) 22-0017

Dear Ms. Cooper:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) California 22-0017. This SPA proposes to add routine patient costs associated with participation in qualifying clinical trials as a Medi-Cal benefit effective July 1, 2022 to comply with the Consolidated Appropriations Act of 2021, which amended the Social Security Act to add a new section 1905(gg) to cover this item. The effective date of the SPA is July 1, 2022.

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 California Medicaid SPA 22-0017 was approved on August 12, 2022, with an effective date of July 1, 2022.

If you have any questions, please contact Cheryl Young at 415-744-3598 or via email at Cheryl.Young@cms.hhs.gov.

Sincerely,

[redacted] igitally signed by Ruth
ughes -S
ate: 2022.08.12
1:12:24 -05'00'

Ruth A. Hughes, Acting Director
Division of Program Operations

cc: Rene Mollow, California Department of Health Care Services (DHCS)
Lisa Murawski, DHCS
Jim Elliott, DHCS
Raquel Saunders, DHCS
Jennifer Dias, DHCS
Angeli Lee, DHCS
Amanda Font, DHCS

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: 22-0017

2. STATE: CA

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
July 1, 2022

5. FEDERAL STATUTE/REGULATION CITATION
SSA 1905(a)(30), 1905(gg)

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)
a. FFY 2022 $ 67,162
b. FFY 2023 $ 150,127

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT
Attachment 3.1-A, Page 14
Attachment 3.1-B, Page 12

8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT *(If Applicable)*
None

9. SUBJECT OF AMENDMENT
To add routine patient costs associated with participation in qualifying clinical trials as a Medi-Cal benefit.

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:
For Box 10 "Other, As Specified," Please note: The Governor's Office does not wish to review the State Plan Amendment.

11. SIGNATURE OF STATE AGENCY OFFICIAL
[redacted]

12. TYPED NAME
Jacey Cooper

13. TITLE
State Medicaid Director

14. DATE SUBMITTED
June 23, 2022

15. RETURN TO
Department of Health Care Services
Attn: Director's Office
P.O. Box 997413, MS 0000
Sacramento, CA 95899-7413

FOR CMS USE ONLY

16. DATE RECEIVED
June 23, 2022

17. DATE APPROVED
August 12, 2022

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL
July 1, 2022

19. SIGNATURE OF [redacted]
Digitally signed by Ruth Hughes - S
Date: 2022.08.12 11:12:51 -05'00'

20. TYPED NAME OF APPROVING OFFICIAL
Ruth A. Hughes

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

22. REMARKS

Instructions on Back

State/Territory: California

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: California

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.