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STATE/TERRIORITY NAME: MINNESOTA

STATE PLAN AMENDMENT (SPA)#: 22-0025

This file contains the following documents in the order listed:

- 1) Approval Letter**
- 2) CMS 179 Form**
- 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

October 5, 2022

Cynthia MacDonald, Medicaid Director
Minnesota Department of Human Services
P.O. Box 64983
St. Paul, MN 55164-0983

Re: Minnesota State Plan Amendment (SPA) 22-0025

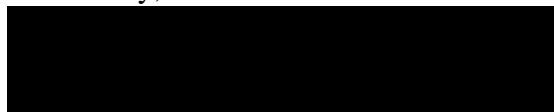
Dear Ms. MacDonald:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) 22-0025. This amendment assures the Federally-required coverage of routine patient costs associated with participation in qualifying clinical trials.

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 Minnesota Medicaid SPA 22-0025 was approved on October 5, 2022, with an effective date of July 1, 2022.

If you have any questions, please contact Sandra Porter at 312-353-8310, or via email at Sandra.Porter@cms.hhs.gov.

Sincerely,



James G. Scott, Director
Division of Program Operations

Enclosures

cc: Alexandria Zoellner, MN DHS
Melorine Mokri, MN DHS
Patrick Hultman, MN DHS

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

1. TRANSMITTAL NUMBER

2 2 — 0 0 2 5

2. STATE

MN3. 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

Section 1905(a)(30) of the Act

6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars)

a. FFY 2022 \$ 0b. FFY 2023 \$ 0

7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT

3.1-A Page 72b3

3.1-B Page 78b3

4.19-B Page 86

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 PAGE NUMBER OF THE SUPERSEDED PLAN SECTION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

same

9. SUBJECT OF AMENDMENT

Clinical Trial Coverage Attestation

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

Patrick Hultman

13. TITLE

Deputy Medicaid Director

14. DATE SUBMITTED

July 13, 2022

15. RETURN TO

Alley Zoellner

Minnesota Department of Human Services

Federal Relations Unit

540 Cedar Street, PO Box 64983

Saint Paul, MN 55164

FOR CMS USE ONLY

16. DATE RECEIVED

July 13, 2022

17. DATE APPROVED

October 5, 2022

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL

July 1, 2022

20. TYPED NAME OF APPROVING OFFICIAL

James G. Scott

21. TITLE OF APPROVING OFFICIAL

Director, Division of Program Operations

22. REMARKS

State/Territory: Minnesota**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: 22-25
 Supersedes TN: NEW

 Approval Date: October 5, 2022
 Effective Date July 1, 2022

State/Territory: Minnesota**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**II. 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.

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 Approval Date: October 5, 2022
 Effective Date: July 1, 2022

STATE: Minnesota

Attachment 4.19-B

Effective: July 1, 2022

Page 86

TN: 22-25

Approved:

Supersedes: NEW

30. Routine patient costs for items and services furnished in connection with participation in a qualifying clinical trial

Routine Patient Costs Furnished in Connection with Participation in Qualifying Clinical Trials Reimbursement for services is the lesser of charges or the Medicaid fee schedule amount. A maximum allowable fee is established by procedure code regardless of provider location. All public and private providers are reimbursed according to the same fee schedule. Providers may access the fee schedule at https://mn.gov/dhs/assets/mhcp-fee-schedule_tcm1053-294225.pdf.

TN: 22-25
Supersedes TN: NEW

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