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State/Territory Name:  New Jersey

State Plan Amendment (SPA) #: 22-0007

This file contains the following documents in the order listed:

1) Approval Letter
2) Summary Form (with 179-like data)
3) Approved SPA Pages
April 7, 2022

Jennifer Langer Jacobs
Assistant Commissioner
NJ Department of Human Services
Division of Medical Assistance and Health Services
PO Box 712, Mail Code #26
Trenton, NJ 08625-0712

Re: New Jersey State Plan Amendment (SPA) #NJ-22-0007

Dear Ms. Jacobs:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) #NJ-22-0007. This amendment proposes to include assurances that the state covers routine patient costs for items and services furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials.

We conducted our review of your submittal according to statutory requirements in sections 1905(a)(30) and 1905(gg) of the Social Security Act. This letter is to inform you that New Jersey Medicaid SPA #NJ-22-0007 was approved on April 7, 2022 with an effective date of January 1, 2022.

If you have any questions, please contact Terri Fraser at 410-786-5573 or via email at Terri.Fraser@cms.hhs.gov.

Sincerely,

James G. Scott, Director
Division of Program Operations

cc: Nicole McKnight
Terri Fraser
Sheri Gaskins
Michael Tankersley
Ryan Tisdale
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 22-0007  
2. STATE NJ

3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT  
   - XIX  
   - XXI

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 3.1-A Page 15  
   ATTACHMENT 3.1-B Page 13c

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 PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable)  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

9. SUBJECT OF AMENDMENT  
   Routine Patient Costs Associated with Participation in Qualifying Clinical Trials

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

11. TYPED NAME  
    Sarah Adelman

12. TITLE  
    Commissioner, Department of Human Services

13. DATE SUBMITTED  
    3/29/22

14. DATE RECEIVED  
    3/29/22

15. RETURN TO  
    Jennifer Langer Jacobs, Assistant Commissioner  
    Division of Medical Assistance and Health Services  
    P.O. Box 712, Mail Code #26  
    Trenton, NJ 08625-0712

FOR CMS USE ONLY

16. DATE APPROVED  
    4/7/22

17. PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL  
    1/1/22

19. TYPED NAME OF APPROVING OFFICIAL  
    James G. Scott

20. TITLE OF APPROVING OFFICIAL  
    Director, Division of Program Operations

21. REMARKS

Instructions on Back
State/Territory: New Jersey

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: April 7, 2022
Effective Date: January 1, 2022
State/Territory: **New Jersey**

**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)**

___ 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)**

___ A qualified clinical trial is a clinical trial that meets the definition at section 1905(gg)(2).

**Coverage Determination – Section 1905(gg)(3)**

___ 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).

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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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