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State/Territory Name: **District of Columbia**

State Plan Amendment (SPA) #: **22-0002**

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

May 2, 2022

Melisa Byrd
Medicaid Director
Department of Health Care Finance
441 4th Street, N.W., 9th Floor, South
Washington, D.C. 20001

Re: State Plan Amendment (SPA) DC-22-0002

Dear Director Byrd:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) DC-22-0002. This amendment proposes to effectuate the coverage of routine patient costs incurred during qualified clinical trials from January 1, 2022 forward, as required by the Consolidated Appropriations Act, 2021, Division CC, Title II, Section 210.

We conducted our review of your submittal according to statutory requirements in Title XIX of the Social Security Act and Consolidated Appropriations Act, 2021. This letter is to inform you that DC Medicaid SPA 22-0022 was approved on May 2, 2022, with an effective date of January 1, 2022.

If you have any questions, please contact LCDR Frankeena McGuire via email at Frankeena.McGuire@cms.hhs.gov

Sincerely,

A handwritten signature in blue ink that reads 'James G. Scott'.

Digitally signed by
James G. Scott -S
Date: 2022.05.02
21:07:20 -05'00'

James G. Scott, Director
Division of Program Operations

cc: Mario Ramsey, DHCF

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES	1. TRANSMITTAL NUMBER: 22-0002	2. STATE: District of Columbia
	3. PROGRAM IDENTIFICATION: TITLE <u>XIX</u> OF THE SOCIAL SECURITY ACT	
TO: CENTER DIRECTOR CENTERS FOR MEDICARE & MEDICAID SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE: January 1, 2022	
5. FEDERAL STATUTE/REGULATION CITATION: Section 1905(a)(30) of the Social Security Act	6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars): a. FFY 2022: <u>\$0</u> b. FFY 2023: <u>\$0</u>	
7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT: Attachment 3.1A, pp 12 Attachment 3.1B, pp 10 Attachment 4.19B, pp 35	8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable): N/A.	

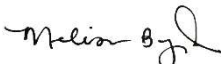
9. SUBJECT OF AMENDMENT:

Coverage of routine patient costs associated with qualified 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


OTHER, AS SPECIFIED:
D.C. Act: 22-434

11. SIGNATURE OF STATE AGENCY OFFICIAL 	15. RETURN TO Melisa Byrd Senior Deputy Director/Medicaid Director Department of Health Care Finance 441 4 th Street, NW, 9 th Floor, South Washington, DC 20001
12. TYPED NAME Melisa Byrd	
13. TITLE Senior Deputy Director/Medicaid Director	
14. DATE SUBMITTED March 28, 2022	

FOR CMS USE ONLY

16. DATE RECEIVED March 28, 2022	17. DATE APPROVED 05/02/2022
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PLAN APPROVED – ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL January 1, 2022	19. SIGNATURE OF APPROVING OFFICIAL  Digitally signed by James G. Scott -S Date: 2022.05.02 21:07:55 -05'00'
20. TYPED NAME OF APPROVING OFFICIAL James G. Scott	21. TITLE OF APPROVING OFFICIAL Director, Division of Program Operations
22. REMARKS	

**State/Territory: District of
Columbia**

AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED

CATEGORICALLY NEEDY GROUP(S)

27. 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: DC-22-0002
Supersedes TN: **NEW**

Approval Date: **05/02/2022**
Effective Date: **01/01/2022**

**State/Territory: District of
Columbia**

AMOUNT, DURATION AND SCOPE OF SERVICES PROVIDED

MEDICALLY NEEDY GROUP(S)

26. 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: DC-22-0002
Supersedes TN: NEW

Approval Date: **05/02/2022**
Effective Date: January 1, 2022

32. Service providers of certain items and services furnished in connection with participation in qualifying clinical trials may be reimbursed to the extent the items and services are otherwise covered through the State Plan, waivers, or 1115 demonstration programs. Reimbursable items or services include:

- A. Items or services provided to an individual during a qualified clinical trial; and,
- B. Items or services provided to prevent, diagnose, monitor, or treat complications associated with participation in a qualified clinical trial.