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State/Territory Name: **Puerto Rico**

State Plan Amendment (SPA) #: **23-0011**

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 11, 2023

Dinorah Collazo Ortiz
Puerto Rico's Medicaid Director
Puerto Rico Department of Health
P.O. Box 70184
San Juan, PR 00936-8184

Re: Puerto Rico State Plan Amendment (SPA) 23-0011.

Dear Ms. Collazo:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) 23-0011. This amendment establishes compliance with the mandatory coverage and reimbursement of routine patient costs furnished concerning participation in qualifying clinical trials under Section 1905(gg) of the Social Security Act.

We reviewed your submittal according to statutory requirements in Title XIX of the Social Security Act and implementing regulations section 1905(a)(30) and 1905(gg) of the Act. This letter informs you that Puerto Rico Medicaid SPA 23-0011 was approved on May 11, 2023, effective January 1, 2022.

If you have any questions, please contact Ivelisse Salce at 212-616-2411 or via email at Ivelisse.Salce@cms.hhs.gov.

Sincerely,

James G. Scott, Director
Division of Program Operations

cc: Dinorah Collazo

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

1. TRANSMITTAL NUMBER

2 3 — 0 0 1 1

2. STATE

PR

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

January 1, 2022

5. FEDERAL STATUTE/REGULATION CITATION

Sections 1905(a)(30) and 1905(gg) of the 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 1
Attachment 3.1-B, Page 1
Attachment 4.19-B, Page 1

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 PAGE NUMBER OF THE SUPERSEDED PLAN SECTION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

New
New
New

9. SUBJECT OF AMENDMENT

This amendment proposes to cover routine patient costs 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

OTHER, AS SPECIFIED:
Delegated to State Medicaid Director

11. SIGNATURE OF STATE AGENCY OFFICIAL

DocuSigned by:
Dinorah Collazo Ortiz

12. TYPED NAME

Dinorah Collazo-Ortiz, Esq., CHC

13. TITLE

EXECUTIVE DIRECTOR

14. DATE SUBMITTED

04/05/2023

15. RETURN TO

Dinorah Collazo-Ortiz, Esq., CHC
Medicaid Program
Puerto Rico Dept of Health
PO Box 70184
San Juan PR 00936-81814

FOR CMS USE ONLY

16. DATE RECEIVED

04/05/2023

17. DATE APPROVED

05/11/2023

PLAN APPROVED - ONE COPY ATTACHED

18. EFFECTIVE DATE OF APPROVED MATERIAL

01/01/2022

19. SIGNATURE OF APPROVING OFFICIAL

20. TYPED NAME OF APPROVING OFFICIAL

James G. Scott

21. TITLE OF APPROVING OFFICIAL

Director, Division of Program Operations

22. REMARKS

State/Territory Puerto Rico

**AMOUNT, DURATION, AND SCOPE OF SERVICES PROVIDED
CATEGORICALLY NEEDY GROUP(S)**

30. Coverage of Routine Patient Cost in Qualifying Clinical Trials

Provided: X

I. General Assurances:

Routine Patient Cost – Section 1905(gg)(1)

X Coverage of routine patient costs 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.

State/Territory Puerto Rico

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Qualifying Clinical Trial – Section 1905(gg)(2)

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

Coverage Determination – 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.

State/Territory Puerto Rico**4.19B Payment for Services****30. OTHER TYPES OF CARE**

Coverage of Routine Patient Costs Associated with Participation in Qualifying Clinical Trials Pursuant to Section 1905(a)(30) of the Social Security Act, Medicaid reimburses routine patient costs for items and services furnished in connection with participation in a qualifying clinical trial (pursuant to section 1905(a)(30) of the Social Security Act), according to the state plan reimbursement methodology for the item or service provided.

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: PR-23-0011
 Supersedes TN: New

Approval Date: 05/11/2023
 Effective Date 01/01/2022