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State/Territory Name: **Puerto Rico**

State Plan Amendment (SPA) #: **24-0012**

This file contains the following documents in the order listed:

- 1) DPO Approval Letter
- 2) Approved SPA pages
- 3) CMS-179 form
- 4) Decision Memo

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



April 8, 2025

Luz E. Cruz Romero
Medicaid Director
Department of Health
P.O. Box 70184
San Juan, PR 00936-8184

Re: State Plan Amendment (SPA) PR-24-0012

Dear Director Cruz:

The Centers for Medicare & Medicaid Services (CMS) has completed our review of the proposed amendment submitted under transmittal number (TN) 24-0012. This plan amendment was submitted to enable Puerto Rico to enter into direct arrangements with pharmaceutical manufacturers for supplemental rebates and value-based or outcomes-based agreements.

This letter informs you that Puerto Rico's Medicaid State Plan Amendment, TN 24-0012, was approved on April 7, 2025 and will be effective on January 1, 2025. Enclosed are copies of Form CMS-179 and the approved State Plan Amendment pages that should be incorporated into the Puerto Rico State Plan.

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

Sincerely,

A large black rectangular box redacting the signature of Ruth A. Hughes.

Ruth A. Hughes,
On Behalf of Courtney Miller, MCOG Director

cc: Charlotte Hammond
Lisa Shochet

TRANSMITTAL AND NOTICE OF APPROVAL OF STATE PLAN MATERIAL FOR: CENTERS FOR MEDICARE & MEDICAID SERVICES		1. TRANSMITTAL NUMBER <div style="text-align: center;"> <u>2</u> <u>4</u> — <u>0</u> <u>0</u> <u>1</u> <u>2</u> </div>	2. STATE <div style="text-align: center;"> <u>PR</u> </div>
TO: CENTER DIRECTOR CENTERS FOR MEDICAID & CHIP SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES		3. PROGRAM IDENTIFICATION: TITLE OF THE SOCIAL SECURITY ACT <div style="text-align: center;"> <input checked="" type="radio"/> XIX <input type="radio"/> XXI </div>	
5. FEDERAL STATUTE/REGULATION CITATION Section 1927(b)(1) of the Social Security Act		4. PROPOSED EFFECTIVE DATE <div style="text-align: center;"> January 1, 2025 </div>	
7. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT Description for Attachment 3.1-A, p. 9		6. FEDERAL BUDGET IMPACT (Amounts in WHOLE dollars) a. FFY <u>2024</u> \$ <u>0</u> b. FFY <u>2025</u> \$ <u>0</u>	
9. SUBJECT OF AMENDMENT Prescribed drugs update to enter into a direct agreement with pharmaceutical manufacturers for a supplemental drug rebate program.		8. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (If Applicable) Description for Attachment 3.1-A, pp. 9	
10. GOVERNOR'S REVIEW (Check One) <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;"> <input type="radio"/> GOVERNOR'S OFFICE REPORTED NO COMMENT <input type="radio"/> COMMENTS OF GOVERNOR'S OFFICE ENCLOSED <input type="radio"/> NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL </div> <div style="width: 45%;"> <input checked="" type="radio"/> OTHER, AS SPECIFIED: Designated to State Medicaid Director </div> </div>			
11. SIGNATURE OF STATE AGENCY OFFICIAL <div style="background-color: black; height: 20px; width: 100%;"></div>		15. RETURN TO PUERTO RICO MEDICAID PROGRAM PUERTO RICO DEPARTMENT OF HEALTH PO BOX 70184 SAN JUAN PR 00936-8184	
12. TYPED NAME Dinorah Collazo-Ortiz, Esq., CHC		13. TITLE Program Executive Director	
14. DATE SUBMITTED 9/26/2024		16. DATE RECEIVED 09/26/2024	
FOR CMS USE ONLY			
18. EFFECTIVE DATE OF APPROVED MATERIAL 01/01/2025		17. DATE APPROVED 04/07/2025	
PLAN APPROVED - ONE COPY ATTACHED			
20. TYPED NAME OF APPROVING OFFICIAL Ruth A. Hughes		19. SIGNATURE <div style="background-color: black; height: 20px; width: 100%;"></div>	
21. TITLE OF APPROVING OFFICIAL On Behalf of Courtney Miller, MCOG Director		22. REMARKS <div style="height: 100px;"></div>	

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
STATE / TERRITORY: COMMONWEALTH OF PUERTO RICO

AMOUNT, DURATION, AND SCOPE OF MEDICAL AND REMEDIAL CARE AND
SERVICES PROVIDED TO THE CATEGORICALLY NEEDY

Description of Limitation

11.a. Physical therapy and or chiropractor services as determined medically necessary.

- a. Initial 15 sessions available without prior authorization.
- b. Additional sessions require prior authorization.
- c. The physical therapy treatment limit is combined with the limit for chiropractic care.

12.a. Prescribed drugs

Puerto Rico will provide coverage and reimbursement for covered outpatient drugs consistent with prior authorization and other requirements as set forth under Section 1927 of the Social Security Act.

Based on the requirements for Section 1927 of the Act, Puerto Rico has the following policies for the supplemental drug rebate program for the Medicaid population:

- a. CMS has authorized Puerto Rico to enter into a direct agreement with pharmaceutical manufacturers for a supplemental drug rebate program. The supplemental rebate agreement, titled "The Puerto Rico Medicaid Supplemental Rebate Agreement," is effective January 1, 2025.
- b. If the agreement changes, it will be submitted to CMS for approval.
- c. Supplemental rebates received by Puerto Rico under this agreement that are in excess of those required under the national drug rebate agreement will be shared with the federal government on the same percentage basis as applied under the national drug rebate agreement.
- d. All drugs covered by the program, irrespective of a supplemental agreement will comply with provisions of the national drug rebate agreement.
- e. CMS has authorized Puerto Rico to enter into voluntary value/outcomes-based contracts with manufacturers. The conditions of the value/outcomes-based contract would be agreed upon by both the state and manufacturer.