# **Table of Contents**

# State/Territory Name: Puerto Rico

# State Plan Amendment (SPA) #: 21-0002

This file contains the following documents in the order listed:

- Approval letter
  CMS-179 form
  Assume of SDA set
- 3) Approved SPA pages



Medicaid and CHIP Operations Group

June 11, 2021

Edna Marin Ramos Medicaid Director Puerto Rico Medicaid Program Puerto Rico Department of Health P.O. Box 70184 San Juan, PR 00936-8184

Re: Puerto Rico State Plan Amendment 21-0002

Dear Ms. Marin Ramos:

The Center for Medicare & Medicaid Services (CMS) has reviewed Puerto Rico's State Plan Amendment (SPA) 21-0002, Coverage of Mandatory Medication Assisted Treatment (MAT).

This amendment proposes to address the newly added mandatory benefit for coverage and reimbursement of medication-assisted treatment (MAT) in opioid treatment programs (OTPs) and office-based opioid treatment settings in compliance with Section 1006(b) of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, HR 6, and, Section 1905(a) (29) of the Social Security Act. The purpose of the SPA is to provide necessary treatment for Medicaid beneficiaries with OUD and help address the national opioid epidemic

Pursuant to section 1135(b)(5) and/or 1135(b)(1)(C) of the Act, due to the COVID-19 public health emergency (PHE), CMS issued an approval letter on March 12, 2021 allowing Puerto Rico to modify the SPA submission requirements at 42 C.F.R. 430.20, to allow the territory to submit a SPA implementing section 1905(a)(29) of the Act by March 31, 2021 that would take effect on October 1, 2020.

Pursuant to section 1135(b)(5) and/or 1135(b)(1)(C) of the Act, due to the COVID-19 PHE, CMS issued an approval letter on March 12, 2021 allowing Puerto Rico to modify the public notice time frames set forth at 42 C.F.R. 447.205, in order to obtain an effective date of October 1, 2020 for its SPA implementing statewide methods and standards for setting payment rates for the benefit described at section 1905(a)(29) of the Act. The territory will issue public notice as soon as possible.

We conducted our review of your submittal according to statutory requirements in Title XIX of the Social Security Act and implementing regulations. This letter is to inform you that Puerto Rico's Medicaid SPA Transmittal Number 21-0002 is approved effective October 1, 2020 until

September 30, 2025, pursuant to Section 1006(b) of the SUPPORT Act. Enclosed are the approved SPA pages and signed CMS-179 form.

If you have any questions concerning this information, please contact Ivelisse Salce at 212-616-2411 or by email at <u>Ivelisse.Salce@cms.hhs.gov.</u>

Sincerely,

James G. Scott, Director Division of Program Operations

Enclosures cc: Jorge Galva

17. DATE RECEIVED 03/24/2021	18. DATE APPROVED    06/10/2021      - ONE COPY ATTACHED    20. SIGNATURE OF REGIONAL OFFICIAL      20. SIGNATURE OF REGIONAL OFFICIAL    22. TITLE      Director    Division of Program Operations	
17. DATE RECEIVED 03/24/2021 PLAN APPROVED 19. EFFECTIVE DATE OF APPROVED MATERIAL	- ONE COPY ATTACHED	
17. DATE RECEIVED 03/24/2021 PLAN APPROVED	- ONE COPY ATTACHED	
17. DATE RECEIVED 03/24/2021	06/10/2021	
17. DATE RECEIVED	18. DATE APPROVED 06/10/2021	
FOR REGIONAL		
15. DATE SUBMITTED March 24, 2021	San Juan PR 00936-8184	
14. TITLE EXECUTIVE DIRECTOR	Puerto Rico Dept of Health PO Box 70184	
13. TYPED NAME EDNA Y. MARIN RAMOS	Medicaid Program	
	EDNA Y. MARIN RAMOS	
12. SIGNATURE OF STATE AGENCY OFFICIAL	16. RETURN TO	
GOVERNOR'S OFFICE REPORTED NO COMMENT	OTHER, AS SPECIFIED	
11. GOVERNOR'S REVIEW (Check One)		
10. SUBJECT OF AMENDMENT Coverage of Medication Assisted Treatment (MAT) in a manne Prevention that Promotes Opioid Recovery and Treatment (SU	r compliant with Section 1006(b) of the Substance Use- Disorder PPORT) for Patients and Communities Act	
Description for Attachment 3.1 A, pages 14-18 Attachment 3.1 B, page 11 Description for Attachment 3.1 B, pages 14-18 Attachment 4.19-B, Page 3		
Attachment 3.1 A, page 12	OR ATTACHMENT (If Applicable)	
8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT	b. FFY2022 \$ 0.00 9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION	
6. FEDERAL STATUTE/REGULATION CITATION Title 19 of the Social Security Act Section 1905(a)(29)	7. FEDERAL BUDGET IMPACT a. FFY2021 \$ 0.00	
	AMENDMENT (Separate transmittal for each amendment)	
NEW STATE PLAN AMENDMENT TO BE C	CONSIDERED AS NEW PLAN AMENDMENT	
5. TYPE OF PLAN MATERIAL (Check One)		
TO: REGIONAL ADMINISTRATOR CENTERS FOR MEDICARE & MEDICAID SERVICES DEPARTMENT OF HEALTH AND HUMAN SERVICES	4. PROPOSED EFFECTIVE DATE October 1, 2020	
FOR: CENTERS FOR MEDICARE & MEDICAID SERVICE	SECURITY ACT (MEDICAID)	
TRANSMITTAL AND NOTICE OF APPROVAL O STATE PLAN MATERIAL	DF      21-0002       Puerto Rico	
TRANSPORTER AND MORIOR OF ADDROVAL O		
APPROVED CENTERS FOR MEDICARE & MEDICAID SERVICES	1. TRANSMITTAL NUMBER 2. STATE	

## 1905(a)(29) Medication-Assisted Treatment (MAT)

- Citation: 3.1(a)(1) Amount, Duration, and Scope of Services: Categorically Needy (Continued)
- 1905(a)(29)  $\boxtimes$  MAT as described and limited in Supplement 2 to Attachment 3.1-A.

TN No. 21-0002

Approval Date: 06/10/2021

### **State of Puerto Rico**

### 1905(a)(29) Medication-Assisted Treatment (MAT)

Amount, Duration, and Scope of Medical and Remedial Care Services Provided to the Categorically Needy

i. General Assurance

MAT is covered under the Medicaid state plan for all Medicaid beneficiaries who meet the medical necessity criteria for receipt of the service for the period beginning October 1, 2020, and ending September 30, 2025.

- ii. Assurances
  - a. The state assures coverage of Naltrexone, Buprenorphine, and Methadone and all of the forms of these drugs for MAT that are approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and all biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).
  - b. The state assures that Methadone for MAT is provided by Opioid Treatment Programs that meet the requirements in 42 C.F.R. Part 8.
  - c. The state assures coverage for all formulations of MAT drugs and biologicals for OUD that are approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 and all biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).
- iii. Service Package

The state covers the following counseling services and behavioral health therapies as part of MAT.

a. Please set forth each service and components of each service (if applicable), along with a description of each service and component service.

From October 1, 2020, through September 30, 2025, the state assures that MAT to treat OUD as defined at section 1905(ee)(1) of the Social Security Act (the Act) is covered exclusively under section 1905(a)(29) of the Act.

### **State of Puerto Rico**

## 1905(a)(29) Medication-Assisted Treatment (MAT)

Amount, Duration, and Scope of Medical and Remedial Care Services Provided to the Categorically Needy (continued)

Service	Description	Provider Type(s)
Individual Counseling	Individual counseling, insight oriented,	Physician,
	behavior modifying and/or supportive.	Medical
		Psychiatrist,
		Psychologist,
		Social Worker
Group Counseling	Group counseling, insight oriented,	Physician,
	behavior modifying and/or supportive.	Medical
		Psychiatrist,
		Psychologist,
		Social Worker
Mental Health	Mental health assessment is provided by	Psychologist,
Assessment by Non-	someone other than a physician who is a	Social Worker
Physician Professional	trained staff member. The assessment	
	identifies factors of mental illness,	
	functional capacity, and gathers	
	additional information used for the	
	treatment of mental illness.	
Treatment Plan	Development of a treatment plan and/or	Psychologist,
Development and	its modification, in relation to opioid use	Social Worker
Modification	disorder.	

b. Please include each practitioner and provider entity that furnishes each service and component service.

See table in section iii.a. above.

#### **State of Puerto Rico**

### 1905(a)(29) Medication-Assisted Treatment (MAT)

Amount, Duration, and Scope of Medical and Remedial Care Services Provided to the Categorically Needy (continued)

c. Please include a brief summary of the qualifications for each practitioner or provider entity that the state requires. Include any licensure, certification, registration, education, experience, training and supervisory arrangements that the state requires.

Provider Type	Qualifications
Physician	A person with a license to practice medicine as an M.D. or a D.O. in Puerto Rico, whether as a Primary Care Physician (PCP) or in the area of specialty under which he or she will provide medical services through a contract with the Contractor (MCO); and is a Provider enrolled in the Puerto Rico Medicaid Program; and has a valid registration number from the Drug Enforcement Agency and the Certificate of Controlled Substances of Puerto Rico, if required in his or her practice
Medical Psychiatrist	A person who possesses a license to practice medicine and a psychiatrist specialty license issued by the licensing agency of Puerto Rico and is enrolled in the Puerto Rico Medicaid Program or a properly trained person who practices psychiatry under the direct supervision of a licensed Provider
Psychologist	A person who possesses a Doctoral or Master's Degree in clinical or counseling psychology and a license issued by the licensing agency of Puerto Rico and is enrolled in the Puerto Rico Medicaid Program or a properly trained person who practices psychology under the direct supervision of a licensed Provider
Social Worker	A person who possesses a Master's Degree in social work and a current license issued by the licensing agency of Puerto Rico and is enrolled in the Puerto Rico Medicaid Program or a properly trained person who practices social work under the direct supervision of a licensed Provider

### **State of Puerto Rico**

### 1905(a)(29) Medication-Assisted Treatment (MAT)

Amount, Duration, and Scope of Medical and Remedial Care Services Provided to the Categorically Needy (continued)

iv. Utilization Controls

 $\boxtimes$  The state has drug utilization controls in place. (Check each of the following that apply)

- $\boxtimes$  Generic first policy
- $\boxtimes$  Preferred drug lists
- $\boxtimes$  Clinical criteria
- $\boxtimes$  Quantity limits

 $\Box$  The state does not have drug utilization controls in place.

#### v. Limitations

Describe the state's limitations on amount, duration, and scope of MAT drugs, biologicals, and counseling and behavioral therapies related to MAT.

MAT drugs and biologicals are covered so long as use is consistent with the FDA label in terms of indication, dose, duration, and patient age.

#### 1905(a)(29) Medication-Assisted Treatment (MAT)

Amount, Duration, and Scope of Medical and Remedial Care Services Provided to the Categorically Needy (continued)

PRA Disclosure Statement - This information is being collected to assist the Centers for Medicare & Medicaid Services in implementing section 1006(b) of the SUPPORT for Patients and Communities Act (P.L. 115-271) enacted on October 24, 2018. Section 1006(b) requires state Medicaid plans to provide coverage of Medication-Assisted Treatment (MAT) for all Medicaid enrollees as a mandatory Medicaid state plan benefit for the period beginning October 1, 2020, and ending September 30, 2025. 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 # 60). Public burden for all of the collection of information requirements under this control number is estimated to take about 80 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.

## 1905(a)(29) Medication-Assisted Treatment (MAT)

- Citation: 3.1(b)(1) Amount, Duration, and Scope of Services: Medically Needy (Continued)
- 1905(a)(29)  $\boxtimes$  MAT as described and limited in Supplement 2 to Attachment 3.1-B.

### **State of Puerto Rico**

### 1905(a)(29) Medication-Assisted Treatment (MAT)

Amount, Duration, and Scope of Medical and Remedial Care Services Provided to the Medically Needy

vi. General Assurance

MAT is covered under the Medicaid state plan for all Medicaid beneficiaries who meet the medical necessity criteria for receipt of the service for the period beginning October 1, 2020, and ending September 30, 2025.

- vii. Assurances
  - d. The state assures coverage of Naltrexone, Buprenorphine, and Methadone and all of the forms of these drugs for MAT that are approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) and all biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).
  - e. The state assures that Methadone for MAT is provided by Opioid Treatment Programs that meet the requirements in 42 C.F.R. Part 8.
  - f. The state assures coverage for all formulations of MAT drugs and biologicals for OUD that are approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355 and all biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262).
- viii. Service Package

The state covers the following counseling services and behavioral health therapies as part of MAT.

d. Please set forth each service and components of each service (if applicable), along with a description of each service and component service.

From October 1, 2020, through September 30, 2025, the state assures that MAT to treat OUD as defined at section 1905(ee)(1) of the Social Security Act (the Act) is covered exclusively under section 1905(a)(29) of the Act.

### **State of Puerto Rico**

## 1905(a)(29) Medication-Assisted Treatment (MAT)

Amount, Duration, and Scope of Medical and Remedial Care Services Provided to the Medically Needy (continued)

Service	Description	Provider Type(s)
Individual Counseling	Individual counseling, insight oriented, behavior modifying and/or supportive, in an office or outpatient facility.	Physician, Medical Psychiatrist, Psychologist, Social Worker
Group Counseling	Group counseling, insight oriented, behavior modifying and/or supportive.	Physician, Medical Psychiatrist, Psychologist, Social Worker
Mental Health Assessment by Non- Physician Professional	Mental health assessment is provided by someone other than a physician who is a trained staff member. The assessment identifies factors of mental illness, functional capacity, and gathers additional information used for the treatment of mental illness.	Psychologist, Social Worker
Treatment Plan Development and Modification	Development of a treatment plan and/or its modification, in relation to opioid use disorder.	Psychologist, Social Worker

e. Please include each practitioner and provider entity that furnishes each service and component service.

See table in section iii.a. above.

### **State of Puerto Rico**

### 1905(a)(29) Medication-Assisted Treatment (MAT)

Amount, Duration, and Scope of Medical and Remedial Care Services Provided to the Medically Needy (continued)

f. Please include a brief summary of the qualifications for each practitioner or provider entity that the state requires. Include any licensure, certification, registration, education, experience, training and supervisory arrangements that the state requires.

Provider Type	Qualifications
Physician	A person with a license to practice medicine as an M.D. or a D.O. in Puerto Rico, whether as a PCP or in the area of specialty under which he or she will provide medical services through a contract with the Contractor; and is a Provider enrolled in the Puerto Rico Medicaid Program; and has a valid registration number from the Drug Enforcement Agency and the Certificate of Controlled Substances of Puerto Rico, if required in his or her practice
Medical Psychiatrist	A person who possesses a license to practice medicine and a psychiatrist specialty license issued by the licensing agency of Puerto Rico and is enrolled in the Puerto Rico Medicaid Program or a properly trained person who practices psychiatry under the direct supervision of a licensed Provider
Psychologist	A person who possesses a Doctoral or Master's Degree in clinical or counseling psychology and a license issued by the licensing agency of Puerto Rico and is enrolled in the Puerto Rico Medicaid Program or a properly trained person who practices psychology under the direct supervision of a licensed Provider
Social Worker	A person who possesses a Master's Degree in social work and a current license issued by the licensing agency of Puerto Rico and is enrolled in the Puerto Rico Medicaid Program or a properly trained person who practices social work under the direct supervision of a licensed Provider

### **State of Puerto Rico**

### 1905(a)(29) Medication-Assisted Treatment (MAT)

Amount, Duration, and Scope of Medical and Remedial Care Services Provided to the Medically Needy (continued)

ix. Utilization Controls

 $\boxtimes$  The state has drug utilization controls in place. (Check each of the following that apply)

- $\boxtimes$  Generic first policy
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 $\Box$  The state does not have drug utilization controls in place.

### x. Limitations

Describe the state's limitations on amount, duration, and scope of MAT drugs, biologicals, and counseling and behavioral therapies related to MAT.

MAT drugs and biologicals are covered so long as use is consistent with the FDA label in terms of indication, dose, duration, and patient age.

#### 1905(a)(29) Medication-Assisted Treatment (MAT)

Amount, Duration, and Scope of Medical and Remedial Care Services Provided to the Medically Needy (continued)

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#### 29. Medication-Assisted Treatment (MAT)

a. Drugs and Biologicals to Pharmacy Providers

Coverage is provided for all formulations of MAT drugs and biologicals through Puerto Rico's managed care program and its associated pharmacy benefit manager. Reimbursement for these medications is consistent with all other drugs provided through this mechanism.

b. Opioid Treatment Programs

All OTPs licensed in Puerto Rico are operated by the Puerto Rico Mental Health & Anti-Addiction Services Administration. Reimbursement for these services is established as the lesser of the negotiated rate with these public providers, the Medicare reimbursement rate for the same service, or the charge for the services to the general public.

c. Counseling and Behavioral Health Services

All counseling and behavioral health services are provided through Puerto Rico's managed care program and based on the rate negotiated between the provider and managed care plan.