

Table of Contents

State/Territory Name: California

State Plan Amendment (SPA) #: 20-0006-B

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

December 20, 2021

Jacey Cooper
Chief Deputy Director, Health Care Programs
California Department of Health Care Services
P.O. Box 997413, MS 0000
Sacramento, CA 94899-7413

Re: California State Plan Amendment (SPA) 20-0006-B

Dear Ms. Cooper:

The Centers for Medicare & Medicaid Services (CMS) reviewed your Medicaid State Plan Amendment (SPA) submitted under transmittal number (TN) 20-0006-B. This amendment proposes to add medication-assisted treatment (MAT) as a mandatory benefit in the Medicaid state plan. This letter is to inform you that California Medicaid SPA Transmittal Number 20-0006-B is approved effective October 1, 2020 until September 30, 2025, pursuant to 1905(a)(29) of the Social Security Act and Section 1006(b) of the SUPPORT Act.

Section 1006(b) of the SUPPORT for Patients and Communities Act (SUPPORT Act), signed into law on October 24, 2018, amended section 1902(a)(10)(A) of the Act to require state Medicaid plans to include coverage of MAT for all eligible to enroll in the state plan or waiver of state plan. Section 1006(b) also added a new paragraph 1905(a)(29) to the Act to include the new required benefit in the definition of “medical assistance” and to specify that the new required benefit will be in effect for the period beginning October 1, 2020, and ending September 30, 2025.

Section 1006(b) of the SUPPORT Act also added section 1905(ee)(1) to the Act to define MAT, for purposes of the new required coverage, as:

. . . all drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), including methadone, and all biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) to treat opioid use disorders; and[,] . . . with respect to the provision of such drugs and biological products, counseling services and behavioral therapy.

CMS conducted our review of your submittal according to statutory requirements in Title XIX of the Act and implementing regulations.

If you have any questions, please contact Cheryl Young at 415-744-3598 or by email at Cheryl.Young@cms.hhs.gov.

Sincerely,



Digitally signed by
James G. Scott -S
Date: 2021.12.20
9:31:21 -06'00'

James G. Scott, Director
Division of Program Operations

Enclosure

cc: Dr. Kelly Pfeifer, Department of Health Care Services (DHCS)
Lindy Harrington, DHCS
Tyler Sadwith, DHCS
Jacob Lam, DHCS
Shaina Zurlin, DHCS
Chuck Anders, DHCS
Angeli Lee, DHCS
Amanda Font, DHCS

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

1. TRANSMITTAL NUMBER
2 0 — 0 0 06 -B

2. STATE
California

3. PROGRAM IDENTIFICATION:
Title XIX of the Social Security Act (Medicaid)

TO: REGIONAL ADMINISTRATOR
CENTERS FOR MEDICARE & MEDICAID SERVICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES

4. PROPOSED EFFECTIVE DATE
~~July 1, 2020~~ October 1, 2020

5. TYPE OF PLAN MATERIAL (*Check One*)

- NEW STATE PLAN AMENDMENT TO BE CONSIDERED AS NEW PLAN AMENDMENT

COMPLETE BLOCKS 6 THRU 10 IF THIS IS AN AMENDMENT (*Separate transmittal for each amendment*)

6. FEDERAL STATUTE/REGULATION CITATION
42 CFR 440.130 and 42 CFR Part 447
Sec. 1905(a)(29) of the Social Security Act &

7. FEDERAL BUDGET IMPACT
a. FFY ~~2020~~ 2021 \$ ~~112~~ (in thousands) \$0
b. FFY ~~2021~~ 2022 \$ ~~448~~ (in thousands) \$0

8. PAGE NUMBER OF THE PLAN SECTION OR ATTACHMENT
~~Supplement 3 to Attachment 3.1-A, pages 3-6a~~
~~Supplement 3 to Attachment 3.1-B, pages 1-4a~~
~~Limitations on Attachment 3.1-A, pages 20-20a~~
~~Limitations on Attachment 3.1-B, pages 20-20a~~
Attachment 4.19-B, pages 38-41g^{4u}

9. PAGE NUMBER OF THE SUPERSEDED PLAN SECTION OR ATTACHMENT (*If Applicable*)
~~Supplement 3 to Attachment 3.1-A, pages 3-6a~~
~~Supplement 3 to Attachment 3.1-B, pages 1-4a~~
~~Limitations on Attachment 3.1-A, pages 20-20a~~
~~Limitations on Attachment 3.1-B, pages 20-20a~~
~~Attachment 4.19-B, pages 38-41f~~

10. SUBJECT OF AMENDMENT See Box 23 for revised description

~~Counseling via telehealth and telephone, FDA approved drugs to treat opioid use disorder, add Medication Assisted Treatment, remove LAAM, remove Early and Periodic Screening, Diagnosis, and Treatment services prior authorization, accurately define Naltrexone as a component of service, and technical changes to Provider Qualifications.~~

11. GOVERNOR'S REVIEW (*Check One*)

- GOVERNOR'S OFFICE REPORTED NO COMMENT OTHER, AS SPECIFIED
 COMMENTS OF GOVERNOR'S OFFICE ENCLOSED
 NO REPLY RECEIVED WITHIN 45 DAYS OF SUBMITTAL

12. SIGNATURE OF STATE AGENCY OFFICIAL

16. RETURN TO
Department of Health Care Services
Attn: Director's Office
P.O. Box 997413, MS 0000
Sacramento, CA 95899-7413

13. TYPED NAME
Jacey Cooper

14. TITLE
State Medicaid Director

15. DATE SUBMITTED
September 30, 2020

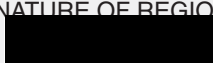
FOR REGIONAL OFFICE USE ONLY

17. DATE RECEIVED
September 30, 2020

18. DATE APPROVED
December 20, 2021

PLAN APPROVED - ONE COPY ATTACHED

19. EFFECTIVE DATE OF APPROVED MATERIAL
October 1, 2020

20. SIGNATURE OF REGIONAL OFFICIAL
 Digitally signed by James G. Scott -S
Date: 2021.12.20 19:31:59 -06'00'

21. TYPED NAME
James G. Scott

22. TITLE
Director, Division of Program Operations

23. REMARKS

For Box 11 "Other, As Specified," Please note: The Governor's Office does not wish to review the State Plan Amendment.

CMS made pen/ink changes on 12/16/21 to Box 1: SPA number modification. Box 7: Revision per discussion with state on 12/16/21. Box 8: Page revisions per RAI response on 12/13/21: Delete old pages and add new Supplement 7 to Att. 3.1-A, pages 1-8 and new Supplement 7 to Att. 3.1-B, pages 1-8.

Box 10: Revise description as "Adds the new mandatory section 1905(a)(29) Medication-Assisted Treatment (MAT) benefit in compliance with section 1006(b) of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act."

State of CALIFORNIA

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

Citation: 3.1(a)(1) Amount, Duration, and Scope of Services: Categorically Needy (Continued)

1905(a)(29) X MAT as described and limited in Supplement 7 to Attachment 3.1-A.

ATTACHMENT 3.1-A identifies the medical and remedial services provided to the categorically needy.

State of CALIFORNIA

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

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

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.

“Assessment for MAT for OUD” consists of activities to evaluate or monitor the status of a beneficiary’s behavioral health and determine the appropriate level of care and course of treatment for that beneficiary. Assessments for MAT for OUD shall be conducted in accordance with applicable State and Federal laws, and regulations, and standards. Assessments for MAT for OUD may be initial and periodic, and may include contact with family members or other collaterals if the purpose of the collateral’s participation is to focus on the treatment needs of the beneficiary. Assessment for MAT for OUD services may include one or more of the following components:

- Collection of information for assessment used in the evaluation and analysis of the cause or nature of the OUD.
- Diagnosis of OUDs utilizing the current DSM and assessment of treatment needs for medically necessary treatment services. This may include a physical examination and laboratory testing (e.g., body specimen screening) necessary for treatment and evaluation conducted by staff lawfully authorized to provide such services and/or order laboratory testing (laboratory testing is covered under the “Other laboratory and X-ray services” benefit of the California Medicaid State Plan).
- Treatment planning, a service activity that consists of development and updates to documentation needed to plan and address the beneficiary’s needs, planned interventions and to address and monitor a beneficiary’s progress and restoration of a beneficiary to their best possible functional level.

“Group Counseling for MAT for OUD” consists of contacts with multiple beneficiaries at the same time. Group Counseling shall focus on the needs of the participants.

“Individual Counseling for MAT for OUD” consists of contacts with a beneficiary. Individual Counseling for MAT for OUD can include contact with family members or other collaterals if the purpose of the collateral’s participation is to focus on the treatment needs of the beneficiary by supporting the achievement of the

beneficiary's treatment goals. Individual Counseling for MAT for OUD also includes preparing the beneficiary to live in the community and providing linkages to services available in the community.

"Medical Psychotherapy for MAT for OUD" is a counseling service conducted by the medical director of a Narcotic Treatment Program/Opioid Treatment Program on a one-to-one basis with the beneficiary.

"Medication Services for MAT for OUD" includes prescription or administration of non-MAT medications related to OUD services, or the assessment of the side effects or results of the medication.

"Patient Education for MAT for OUD" is education for the beneficiary on addiction, treatment, recovery and associated health risks.

"Prescribing and monitoring of MAT for OUD" consists of prescribing, administering, dispensing, ordering, monitoring, and/or managing the medications used for MAT for OUD.

"Crisis Intervention Services for OUD" consists of contacts with a beneficiary in crisis. A crisis means an actual relapse or an unforeseen event or circumstance which presents to the beneficiary an imminent threat of relapse. OUD Crisis Intervention Services shall focus on alleviating the crisis problem, be limited to the stabilization of the beneficiary's immediate situation, and be provided in the least intensive level of care that is medically necessary to treat their condition.

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

See section iii.c below.

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.

PRACTITIONER QUALIFICATIONS

Provider Entities

All MAT for OUD services are provided by DMC certified providers. DMC certified providers providing MAT for OUD services must: 1) be licensed, registered, enrolled, and/or approved in accordance with all applicable state and federal laws and regulations; 2) abide by the definitions, rules, and requirements for stabilization and rehabilitation services established by the Department of Health Care Services; and 3) sign a provider agreement with a county or the Department of Health Care Services, if applicable.

Practitioners

MAT for OUD Services							
Practitioner Qualifications	Assessment*	Crisis Intervention	Counseling (Individual and Group)	Medical Psychotherapy	Medication Services	Patient Education	Prescribing and monitoring of MAT for OUD
	C, L *	C,L	C, L	M	L	C, L	L**

C = Counselors

An Alcohol or other drug (AOD) counselor that is either certified or registered by an organization that is recognized by the Department of Health Care Services and accredited with the National Commission for Certifying Agencies (NCCA).

L = Licensed Practitioner of the Healing Arts

A Licensed Practitioner of the Healing Arts (LPHA) include any of the following: Physician, Nurse Practitioner (NP), Physician Assistant (PA), Registered Nurse, Registered Pharmacist, Licensed Clinical Psychologist (LCP), Licensed Clinical Social Worker (LCSW), Licensed Professional Clinical Counselor (LPCC), and Licensed Marriage and Family Therapist (LMFT), and licensed-eligible practitioner working under the supervision of a licensed clinician.

M = Medical director of a Narcotic Treatment Program. The medical director of a Narcotic Treatment Program is a licensed physician in the State of California.

Notes

*The physical examination shall be conducted an LPHA in accordance within their scope of practice and licensure. An OUD diagnosis may only be made by an LPHA.

** May be provided by an LPHA within their scope of practice. Providers must be a waived prescriber of buprenorphine to prescribe or order buprenorphine.

State of CALIFORNIA

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

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

- Generic first policy
- Preferred drug lists
- Clinical criteria
- Quantity limits

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.

State of CALIFORNIA**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.

State of CALIFORNIA

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

Citation: 3.1(a)(1) Amount, Duration, and Scope of Services: Medically Needed (Continued)

1905(a)(29) X MAT as described and limited in Supplement 7 to Attachment 3.1-B.

ATTACHMENT 3.1-B identifies the medical and remedial services provided to the medically needy.

State of CALIFORNIA

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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State of CALIFORNIA

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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Clinical criteria

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State of CALIFORNIA**1905(a)(29) Medication-Assisted Treatment (MAT)**

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State/Territory: California

REIMBURSEMENT FOR 1905(a)(29) MEDICATION ASSISTED TREATMENT FOR OPIOID USE DISORDERS

1. Payment for a) unbundled and bundled services; and b) bundled services and prescribed drugs and biologicals administered by a provider for the treatment of opioid use disorders are reimbursed per the Drug Medi-Cal Program methodology described in Attachment 4.19-B, starting on page 38.
2. Payment for unbundled prescribed drugs and biologicals used for the treatment of opioid use disorders are reimbursed per the methodology described in Supplement 2 to Attachment 4.19-B, Pages 1-10 for drugs that are dispensed or administered.