

State of California—Health and Human Services Agency Department of Health Care Services



DATE: January 10, 2018

MHSUDS INFORMATION NOTICE NO.: 18-004

TO: COUNTY BEHAVIORAL HEALTH DIRECTORS

COUNTY DRUG & ALCOHOL ADMINISTRATORS

COUNTY BEHAVIORAL HEALTH DIRECTORS ASSOCIATION OF

CALIFORNIA

CALIFORNIA COUNCIL OF COMMUNITY BEHAVIORAL HEALTH

AGENCIES

COALITION OF ALCOHOL AND DRUG ASSOCIATIONS

CALIFORNIA ASSOCIATION OF ALCOHOL & DRUG PROGRAM

EXECUTIVES, INC.

CALIFORNIA ALLIANCE OF CHILD AND FAMILY SERVICES

CALIFORNIA OPIOID MAINTENANCE PROVIDERS

SUBJECT: IMPLEMENTATION OF ASSEMBLY BILL (AB) 395 FOR NARCOTIC

TREATMENT PROGRAMS (NTPs)

PURPOSE

The purpose of this Department of Health Care Services' (DHCS) Information Notice is to summarize and implement the provisions of AB 395, which went into effect on January 1, 2018.

BACKGROUND

Prior to the passage of AB 395, Health and Safety Code Section 11839.2 permitted licensed Narcotic Treatment Programs (NTPs) to provide federally approved controlled substances to patients with an opioid use disorder (OUD) for the purpose of Narcotic Replacement Therapy (NRT). These NRT controlled substances include full agonist medication (methadone) and partial agonist medication (buprenorphine products).

However, the federal Food and Drug Administration (FDA) has approved medications that are not controlled substances for the purpose of providing Medication Assisted Treatment (MAT) to patients with Substance Use Disorders (SUD). These MAT medications include Naltrexone, Disulfiram, Acamprosate, and Naloxone. Naltrexone is a medication approved for the treatment of OUDs and alcohol use disorders. Disulfiram and Acamprosate are approved to treat alcoholism. Naloxone is approved to reverse an opioid overdose in an emergency situation.

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AB 395 amends the language in Health and Safety Code Section 11839.2, among other sections, to specify that a licensed NTP may provide non-controlled medications approved by the FDA for providing MAT to patients with a SUD. Any new medications approved by the FDA in the future would also be allowed to be utilized by NTPs.

SUMMARY OF CHANGES MADE BY AB 395

Expanded MAT Services

AB 395 amends the language in Health and Safety Code Section 11839.2 to state that a licensed NTP may provide all non-controlled medications approved by the FDA for providing MAT to patients with a SUD (Expanded MAT), in addition to the previously allowable FDA approved NRT medications. However, AB 395 does not add funding for Expanded MAT services.

<u>Drug Medi-Cal Service Claim Submission Timeframe</u>

AB 395 also amends Welfare and Institutions Code Section 14021.6 to extend the timeframe for service claim submission by Drug Medi-Cal treatment providers from 30-days from the date of service to six-months from the date of service. DHCS may receive and authorize the processing of late claims upon review of substantiating documentation justifying good cause for late submittal of the claim in accordance with Title 22, California Code of Regulations (CCR), Section 51008.5.

DHCS IMPLEMENTATION OF AB 395 PROVISIONS

AB 395 authorizes DHCS to implement, interpret, or make specific the provisions of the legislation through provider bulletin, until regulations are adopted on or before January 1, 2021. NTPs electing to provide Expanded MAT services remain subject to all of the regulatory requirements contained in Title 9, CCR Division 4, Chapter 4.

DHCS' promulgates the following additional requirements upon NTPs electing to provide Expanded MAT services through this Information Notice:

Protocol Amendment to Include MAT Services

NTPs electing to provide Expanded MAT services are required to submit an amended protocol in writing to DHCS in accordance with Title 9, CCR 10035(a) prior to providing Expanded MAT services.

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In addition to the requirements set forth in Title 9, CCR 10035(c), protocol amendments that add Expanded MAT services shall include:

- A written statement of the estimated impact of the addition of Expanded MAT services upon the population and area served, funding and budget, staff, facilities, and upon any other portion of the protocol affected by the addition of Expanded MAT;
- 2. The patient selection criteria for each Expanded MAT medication;
- 3. The patient orientation information to be provided to patients regarding nature, purpose, hazards, risks, and effects of Expanded MAT medications;
- 4. Other treatment and support services to be provided, including counseling and case management;
- The procedures for dosing and/or administration of each Expanded MAT medication; and
- The Expanded MAT medication storage procedures for each Expanded MAT medication.

Administration of medications for Expanded MAT services shall be the responsibility of the medical director or appropriately licensed program personnel under the direction of the medical director.

Licensed Patient Capacity

The licensed patient capacity of an NTP is the total number of patients receiving NRT services. This includes patients who receive both NRT and Expanded MAT services. Patients who only receive Expanded MAT services are not included in the licensed patient capacity of an NTP. Furthermore, NTPs are not subject to additional licensing fees stemming from the provision of Expanded MAT services to patients.

Expanded MAT Patient Selection and Orientation

NTPs providing Expanded MAT services shall meet the selection criteria set forth in Title 9, CCR 10270. In addition to the patient orientation requirements set forth in Title 9, CCR 10280, NTPs shall also advise all Expanded MAT patients of the nature, purpose, hazards, risks, and effects of the specific MAT medications provided to the individual patients.

Expanded MAT Program Requirements

Administration of medications for Expanded MAT services shall be the responsibility of the medical director or appropriately licensed program personnel under the direction of the medical director. NTPs are subject to existing laws and regulations governing documentation, medication, and record keeping at treatment facilities. Specifically, each NTP providing Expanded MAT shall:

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- Maintain accurate records of medications used in Expanded MAT traceable to specific patients, showing dates and quantities dispensed, prescribed, and/or administered:
- 2. Maintain adequate security over stocks of medications used in Expanded MAT to guard against theft; and,
- 3. Develop and maintain procedures that require administering and/or dispensing all medications associated with Expanded MAT in accordance with the approved product labeling for each medication.

Inspection and Monitoring

NTPs providing Expanded MAT services are subject to the same inspection and monitoring visits by DHCS as described in Title 9, CCR 10080 and 10085.

If you have questions regarding this Information Notice, please contact the Counselor and Medication Assisted Treatment Supervisor, Pelumi Abimbola at pelumi.abimbola@dhcs.ca.gov or (916) 552-9642.

Sincerely,

Original signed by

Karen Baylor, Ph.D., LMFT, Deputy Director Mental Health & Substance Use Disorder Services