## The Ins and Outs of Opioid Treatment Programs (OTPs)

Jason Kletter, PhD, Joseph Mott, MD, Dan Hymas, MBA, and Javier Moreno

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- We respectfully acknowledge that we live and work in territories where Indigenous nations and Tribal groups are traditional stewards of the land.
- Please join us in supporting efforts to affirm Tribal sovereignty across what is now known as California and in displaying respect, honor and gratitude for all Indigenous people.

#### Whose land are you on?

Option 1: Text your zip code to 1-855-917-5263 Option 2: Enter your location at <u>https://native-land.ca</u> Option 3: Access Native Land website via QR Code:





Addiction Technology Transfer Center Network Funded by Substance Abuse and Mental Health Services Administration What we say and how we say it inspires the hope and belief that recovery is possible for everyone.

Affirming, respectful, and culturally-informed language promotes evidence-based care.

## **PEOPLE FIRST**

### Language Matters

in treatment, in conversation, in connection.





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CALIFORNIA OPIOID MAINTENANCE PROVIDERS

# OPIOID TREATMENT PROGRAMS

JASON KLETTER, PHD

BAYMARK HEALTH SERVICES

BOARD PRESIDENT, CALIFORNIA OPIOID MAINTENANCE PROVIDERS

## OPIOID TREATMENT PROGRAMS (OTP/NTP)

WHAT DO THEY DO?

HOW DO THEY FIT INTO THE CONTINUUM OF CARE?

JOSEPH A. MOTT, M.D., J.D., FASAM

ACADIA HEALTHCARE

### WHAT IS AN OTP?

- Opioid Treatment Programs (OTPs) are highly structured, highly-regulated, comprehensive substance use disorder treatment programs.
- OTPs employ a multi-disciplinary team of medical providers (MDs, NPs, and PAs), nurses, and counselors to deliver evidence-based treatment of opioid use disorder.
- OTPs <u>dispense</u> both buprenorphine and methadone for the treatment of opioid use disorder. The medication is dispensed to the patient by a nurse, who directly observes the patient ingest the medication at the dispensing window. OTPs also conduct regular, ongoing urine drug screening for every patient (usually at least monthly for the duration of treatment), along with counseling and treatment planning.
- "Take-home" doses of medication are available only after patients have achieved "stability."

#### **OTPs ARE HIGHLY REGULATED**

- Certified by Substance Abuse and Mental Health Services Administration (SAMHSA)
- Licensed by the Drug Enforcement Agency (DEA)
- Accredited by SAMHSA-approved organization (i.e.: CARF)
- Licensed by California Department of Health Care Services (DHCS)
- Certified by Medi-Cal (DHCS)
- Contracted with Counties for DMC and other funding
- Ongoing audits by all entities

#### MEDICATION-ASSISTED TREATMENT IS THE MOST EFFECTIVE TREATMENT FOR OPIOID USE DISORDER

Medications for the treatment of opioid use disorder include opioid agonist treatments (OAT: methadone, buprenorphine) and extended-release naltrexone (Vivitrol).

#### National Institutes of Health (NIH):

"The safety and efficacy of MAT has been unequivocally established. <u>Methadone maintenance coupled with</u> relevant social, medical and psychological services has the highest probability of being the most effective of all treatments for opioid addiction."

#### Substance and Mental Health Services Administration (SAMHSA):

"MAT has been shown to improve patient survival, increase retention in treatment, decrease illicit opioid use & other criminal activity; increase patients' ability to gain/maintain employment, improve birth outcomes among women who have substance use disorders and are pregnant, and lower a person's risk of contracting HIV or hepatitis C by reducing the potential for relapse."

### THE ROLE OF OTPs IN THE HUB AND SPOKE MODEL

- "The primary aim of the MAT Expansion Project is to implement the Hub and Spoke model to increase access to opioid use disorder (OUD) treatment. This includes developing OTPs as regional subject matter experts and referral resources."
- The goal of the hub and spoke model is to create a seamless system of care where patients can move through the various stages of treatment accessing the services that are most likely to support recovery.
- The continuum of care ensures individualized treatment and optimal outcomes.
- Clients may be enrolled in OTP <u>and</u> another level of care <u>simultaneously</u> (e.g., OTP + residential treatment).

#### The ASAM Criteria: Adult Level of Care Placement

Adult Levels of Care	DIMENSION 1 Acute Intoxication and/or Withdrawal Potential	DIMENSION 2 Biomedical Conditions and Complications	DIMENSION 3 Emotional, Behavioral, or Cognitive Conditions and Complications	DIMENSION 4 Readiness to Change	DIMENSION 5 Relapse, Continued Use, or Continued Problem Potential	DIMENSION 6 Recovery/Living Environment
LEVEL 0.5 Early Intervention	No withdrawal risk	None or very stable	None or very stable	Willing to explore how current alcohol, tobacco, other drug, or medication use, and/or high-risk behaviors may affect personal goals	Needs an understanding of, or skills to change, current alcohol, tobacco, other drug, or medication use patterns, and/or high risk behavior	Social support system or significant others increase the risk of personal conflict about alcohol, tobacco, and/or other drug use
TP - LEVEL 1 noid Treatment Program	Physiologically dependent on opioids and requires OTP to prevent withdrawal	None or manageable with outpatient medical monitoring	None or manageable in an outpatient structured environment	Ready to change the negative effects of opioid use, but is not ready for total abstinence from illicit prescription or non-prescrip- tion drug use	At high risk of relapse or continued use without OTP and structured therapy to promote treatment progress	Recovery environment is supportive and/or the patient has skills to cope
LEVEL 1 Outpatient Services	Not experiencing significant with- drawal, or at minimal risk of severe withdrawal. Manageable at Level 1-WM (See withdrawal management criteria)	None or very stable, or is receiving concurrent medical monitoring	None or very stable, or is receiving concurrent mental health monitoring	Ready for recovery but needs motivating and monitoring strate- gies to strengthen readiness. Or needs ongoing monitoring and disease management. Or high severity in this dimension but not in other dimensions. Needs Level 1 motivational enhancement strategies	Able to maintain abstinence or control use and/or addictive behaviors and pursue recovery or motivational goals with minimal support	Recovery environment is supportive and/or the patient has skills to cope
LEVEL 2.1 Intensive Outpatient Services	Minimal risk of severe withdrawal, manageable at Level 2-WM (See withdrawal management criteria)	None or not a distraction from treatment. Such problems are manageable at Level 2.1	Mild severity, with potential to distract from recovery; needs monitoring	Has variable engagement in treatment, ambivalence, or a lack of awareness of the substance use or mental health problem, and requires a structured program several times a week to promote progress through the stages of change	Intensification of addiction or mental health symptoms indicate a high likelihood of relapse or continued use or continued problems without close monitoring and support several times a week	Recovery environment is not supportive, but with structure and support, the patient can cope
LEVEL 2.5 Partial Hospitalization Services	Moderate risk of severe withdrawal manageable at Level 2-WM (See withdrawal management criteria)	None or not sufficient to distract from treatment. Such problems are man- ageable at Level 2.5	Mild to moderate severity, with potential to distract from recovery, needs stabilization	Has poor engagement in treatment, significant ambivalence, or a lack of awareness of the substance use or mental health problem, requiring a near-daily structured program or intensive engage- ment services to promote progress through the stages of change	Intensification of addiction or mental health symptoms, despite active participation in a Level 1 or 2.1 program, indicates a high likelihood of relapse or continued use or continued problems without near-daily monitoring and support	Recovery environment is not supportive, but with structure and support and relief from the home environment, the patient can cope
LEVEL 3.1 Clinically Managed W-Intensity Residential Services	No withdrawal risk, or minimal or sta- ble withdrawal. Concurrently receiving Level 1-WM (minimal) or Level 2-WM (moderate) services (See withdrawal management criteria)	None or stable, or receiving concurrent medical monitoring	None or minimal; not distracting to recovery. If stable, a co-occurring capable program is appropriate. If not, a co-occurring enhanced program is required	Open to recovery, but needs a structured environment to main- tain therapeutic gains	Understands relapse but needs structure to maintain therapeutic gains	Environment is dangerous, but recovery is achievable if Level 3.1 24-hour structure is available
LEVEL 3.3 Clinically Managed pulation Specific High sity Residential Services	At minimal risk of severe withdrawal. If withdrawal is present, manageable at Level 3.2-WM (See withdrawal management criteria)	None or stable, or receiving concurrent medical monitoring	Mild to moderate severity; needs structure to focus on recovery. Treatment should be designed to address significant cognitive deficits. If stable, a co-occurring capable program is appropriate. If not, a co-occur- ring enhanced program is required	Has little awareness and needs interventions available only at Level 3.3 to engage and stay in treatment. If there is high severity in Dimension 4 but not in any other dimension, motivational enhancement strategies should be provided in Level 1	Has little awareness and needs interventions available only at Level 3.3 to prevent continued use, with immi- nent dangerous consequences, because of cognitive deficits or comparable dysfunction	Environment is dangerous and patient needs 24-hour structure to learn to cope
LEVEL 3.5 Clinically Managed High-Intensity Residential Services	At minimal risk of severe withdrawal. If withdrawal is present, manageable at Level 3.2-WM (See withdrawal management criteria)	None or stable, or receiving concurrent medical monitoring	Demonstrates repeated inability to control impulses, or unstable and dangerous signs/symptoms require stabilization. Other functional defi- cits require stabilization and a 24-hour setting to prepare for community integration and continuing care. A co-occurring enhanced setting is required for those with severe and chronic mental illness	Has marked difficulty with, or opposition to, treatment, with dan- gerous consequences. If there is high severity in Dimension 4 but not in any other dimension, motivational enhancement strategies should be provided in Level 1	Has no recognition of the skills needed to prevent con- tinued use, with imminently dangerous consequences	Environment is dangerous and the patient lacks skills to cope outside of a highly structured 24-hour setting
LEVEL 3.7 Medically Monitored nsive Inpatient Services	At high risk of withdrawal, but manageable at Level 3.7-WM and does not require the full resources of a licensed hospital (See withdrawal management criteria)	Requires 24-hour medical monitoring but not inten- sive treatment	Moderate severity; needs a 24-hour structured setting. If the patient has a co-occurring mental disorder, requires concurrent mental health services in a medically monitored setting	Low interest in treatment and impulse control is poor, despite negative consequences; needs motivating strategies only safely available in a 24-hour structured setting. If there is high severity in Dimension 4 but not in any other dimension, motivational enhancement strategies should be provided in Level 1	Unable to control use, with imminently dangerous con- sequences, despite active participation at less intensive levels of care	Environment is dangerous and the patient lacks skills to cope outside of a highly structured 24-hour setting
LEVEL 4 Medically Managed Angive Inpatient Services		Requires 24-hour medical and nursing care and the full resources of a licensed hospital	Because of severe and unstable problems, requires 24-hour psychiatric care with concomitant addiction treatment (co-occurring enhanced)	Problems in this dimension do not qualify the patient for Level 4 services. If the patient's only severity is in Dimension 4, 5, and/ or 6 without high severity in Dimensions 1, 2, and/or 3, then the patient does not qualify for Level 4	Problems in this dimension do not qualify the patient for Level 4 services. See further explanation in Dimension 4	Problems in this dimension do not qualify the patient for Level 4 services. See further explana- tion in Dimension 4

### ADMISSION CRITERIA: FEDERAL vs. CALIFORNIA (most OTPs have the 2+2 exception)

	Meet DSM Criteria for Moderate to Severe Opioid Use Disorder	Current Physical Dependence	Duration of moderate-severe OUD	Failed Detoxification Attempts	Treatment Voluntary
Federal Regulations	Required	Not required	One year	Only required for minors	Required
California Regulations	Required	Required	Two years	Required; must document failure of two or more attempts	Required
With "Two + Two" Programmatic Exception from California	Required	Required	All or most of the past year – defined as six months plus one day	Not required	Required

### EXCEPTIONS TO REQUIREMENT FOR CURRENT PHYSICAL DEPENDENCE AT TIME OF ADMISSION

	Incarcerated Patients	Pregnant Patients	Former MMT Patients
Federal Regulations	If admitted within six months of release	If document previous history of moderate-severe OUD and current risk of relapse	If admitted within two years of discharge from MMT
California Regulations	If admitted within one month of release, AND if incarcerated for at least one month, AND if eligible for admission to MMT when incarcerated	Requires current physical dependence and duration of OUD as above	If admitted within 6 months of discharge from an MMT episode of at least 6 months, AND if voluntarily discharged

### WHAT IS METHADONE?

- Methadone binds to and activates opioid receptors in the brain.
- Methadone is categorized as a "full opioid agonist" (in contradistinction to buprenorphine, which is a "partial opioid agonist"). Other examples of "full opioid agonists" include oxycodone, heroin, and fentanyl.
- Methadone works to treat opioid use disorder because it is oral, legal, and long-acting. Because it has a slow onset and a long half-life, and the "right dose" of methadone can suppress or prevent withdrawal symptoms for 24 hours when taken once a day, without producing intoxication.

### METHADONE DIFFERS FROM OTHER OPIOIDS IN SEVERAL IMPORTANT WAYS

- The "right dose" of methadone for any individual patient depends on that patient's pre-existing opioid tolerance (their level of physical dependence), and how their body handles methadone. There can be significant variability in methadone metabolism among patients, requiring a highly individualized approach to dosing.
- Special caution is required during treatment initiation. The half-life of methadone in most individuals already taking it is approximately 24 hours, but in the first week of treatment, the half-life can be much longer (up to 55 hours).
- Because it takes about five half-lives of a drug in order to achieve steady state, methadone doses are normally titrated upwards no more frequently than once a week, and it can take weeks (or even months) to find the right dose for a patient.

#### DIFFERENCES BETWEEN METHADONE AND BUPRENORPHINE

- Buprenorphine is a "partial opioid agonist," with a "ceiling effect" in causing respiratory depression. It is virtually impossible for an opioid-dependent patient to overdose on buprenorphine (unless it is taken along with a sedative or with alcohol).
- Buprenorphine is a Schedule III narcotic and can be prescribed in all treatment settings.
- Buprenorphine can cause "precipitated withdrawal" if induction is not timed correctly. This is a particular challenge in patients who use fentanyl. However, dosing is otherwise straightforward, and even maximum doses can be achieved in one to two weeks.
- For about half of patients who inject heroin, buprenorphine may not be adequate to suppress withdrawal symptoms and cravings sufficiently to permit sustained abstinence. In the case of patients who use fentanyl, that fraction is likely higher. Such patients require methadone instead.
- Methadone is a "full opioid agonist" with no ceiling effect in causing respiratory depression. Patients can overdose on methadone in the exact same way they can with other full opioid agonists like heroin or fentanyl, if they take too much.
- Methadone is a Schedule II narcotic and for the treatment of opioid use disorder, is only available in the OTP setting.

Methadone does not cause "precipitated withdrawal," but achieving an effective dose can take weeks to months.



### JOSEPH A. MOTT, M.D., J.D., FASAM

Medical Director

Desert and Riverside Comprehensive Treatment Centers

Joseph.Mott@ctcprograms.com

#### MOBILE MEDICATION UNITS DANIEL HYMAS

#### **OTP Mobile Components**

- June 2021 DEA announced final published rule:
  - DEA registrants who are authorized to dispense methadone for opioid use disorder would be authorized to add a "mobile component" to their existing registration – eliminating the separate registration requirement for these mobile narcotic treatment programs (NTPs). The rule also outlined the reports and records that shall be maintained for NTPs that wish to expand the reach of their treatment programs by use of mobile components.

#### **OTP Mobile Component Overview**

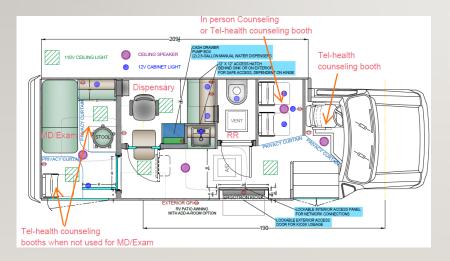
Mobile components facilitate expanded access to medication assisted treatment in rural and underserved areas. They operate as "extensions" of the existing brick and mortar OTP, adhering to the same federal, state and DEA regulations, and limited to providing the exact same services and medications.

#### Each mobile component :

- has its own DEA compliant medication safe and security alarm system
- has clearly defined operational hours
- drives to and parks in the same location to deliver services each day. The location is leased and appropriately zoned for such use
- returns to the brick-and-mortar OTP daily to re-inventory & securely store medication overnight
- has specific mobile component additional policy and procedures and emergency preparedness plans

#### **Mobile Component Photos**







#### Acadia's Experience With Mobile Medication Units

• Successes

- Greatly increases the availability of life-saving medications to those in rural areas.
  - Reduces the cost of transportation to the patient
  - Increases likelihood that they can consistently dose
- Many communities have been supportive of the mobile units and work with providers to develop guidelines around their use.
- Many states are offering grants/incentives to help increase the number of mobile units available.
- Challenges
  - Mobile units, while not a new concept, are new to many communities and they do not know how to classify them for zoning purposes
    - Food Truck vs Mobile Mammogram vs Mobile Harm Reduction



## Expanding MAT Access Through Medication Units

Javier Moreno, MBA

**Director of CA Government Relations** 

Aegis Treatment Centers, LLC

A Subsidiary Company of Pinnacle Treatment Centers







#### Definition

"Medication unit" means a facility established as part of, but geographically separate from, a narcotic treatment program, from which licensed private practitioners or community pharmacists dispense or administer an opioid agonist treatment medication or collect samples for drug testing or analysis.

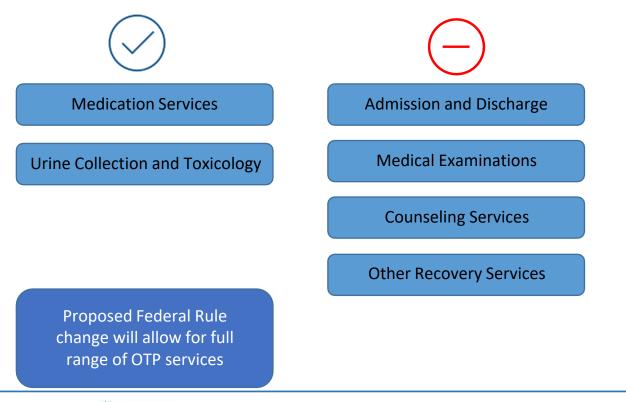
§ 10000. Definitions. (a)(16)

















### **Potential Locations**

- Free Standing Building
- Medical Office
- Pharmacy
- Emergency Room
- Correctional Setting
- Behavioral Health Department

#### Requirements

- Adequate Space
- Ability to adhere to the same rules and guidelines as NTPs
- Meet DEA Security Requirements
- Subject to regulatory inspections







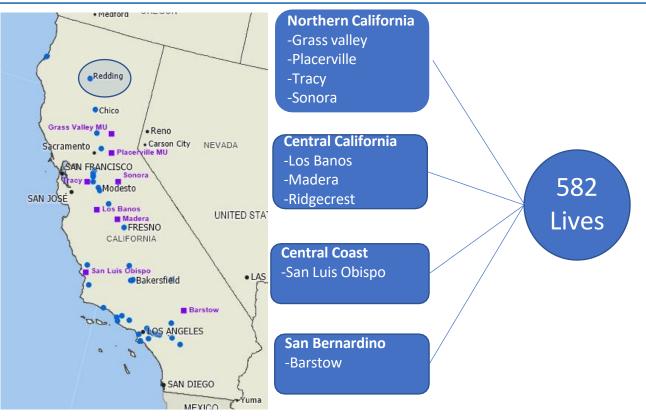
Save More Lives	Removing access barriers such a transportation (e.g., Rural) or provider shortages
Lower Costs	Smaller communities may not sustain a full clinic
Stigma Reduction	Stigma and NIMBYism exist - smaller footprint allow a community to acclimate
Test New Markets	Test new markets for potential full treatment program without significant investment





#### Medication Units Work











#### Process

- SAMHSA Certification
  - Form- SMA 162 Completed (Online)
- DHCS Initial Application
  - DHCS 5014 Narcotic Treatment Program Initial Application
  - DHCS 5025 Facility Requirements
  - DHCS 5026 Staff Hours
  - DHCS 5028 Letters of Cooperation
  - DHCS 5030 Geographical Area
  - DHCS 5031 Organizational Responsibility
- DEA Registration Number application
- DEA Inspection
- DHCS Inspection

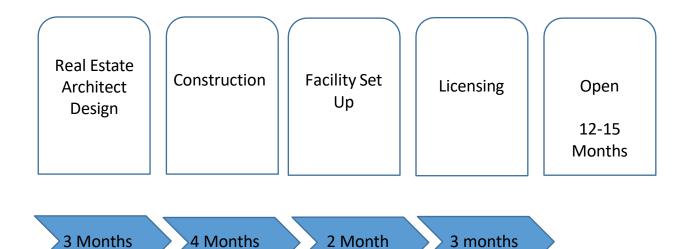
#### **PINNACLE** TREATMENT CENTERS



#### References

- SAMHSA
  - Certification of Opioid Treatment Programs
- Department of Health Care Services
  - Frequently Asked Questions: Narcotic Treatment Programs Medication Unit Application
  - MHSUDS INFORMATION NOTICE NO.: 17-015 Medication Unit (MU) Overview











Contact Information Javier Moreno Javierm@Pinnacletreatment.com





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