Conflicts between Federal and State Regulations for Opioid Treatment Programs (OTP)

The California Society of Addiction Medicine believes Title 9 of the California Health and Safety Code needs to change to conform with the new Substance Abuse Mental Health Services Administration (SAMHSA) federal rule in order to improve access to treatment.

CSAM
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TITLE 9

SAMHSA

TITLE 9 SECTION 10120: PHYSICIAN EXTENDERS

10120(a) defines what they call "physician extenders" (Nurse Practitioners (NPs) and Physician Assistants (PAs)) can do in an OTP.

New 42 Code of Federal Regulation (CFR) 8.2 provides the Health and Human Services (HHS) definition of a "practitioner" who works in an OTP: "For purposes of this part, means a health care professional who is appropriately licensed by a State to prescribe and/or dispense medications for opioid use disorders and, as a result, is authorized to practice within an OTP."

WHY DOES THIS MATTER?

Expanding the range of activities NPs and PAs working in an OTP are allowed to perform will increase access to methadone for patients with opioid use disorder (OUD), particularly for clinics experiencing provider shortages.

TITLE 9 SECTION 10270: CRITERIAL FOR PATIENT SELECTION

10270(a) requires that the medical director (or designee) of the narcotic treatment program (NTP) "conduct a medical evaluation".

New CFR 8.12 "The full exam can be completed by a non-OTP practitioner, if the exam is verified by a licensed OTP practitioner as being true and accurate and transmitted in accordance with applicable privacy laws."

WHY DOES THIS MATTER?

One of the most frequently cited reasons for not admitting a patient to treatment at an OTP is the absence of sufficient medical providers at the OTP to complete the intake. This change can essentially expand the OTP medical staffing without cost to the OTPs.

10270(a)(2) requires laboratory tests for HCV, TB, and syphilis.

New CFR 8.12(f)(2)(i)(b) now states that a "patient's refusal to undergo lab testing should not preclude them from access to treatment, provided such refusal does not have the potential to negatively impact treatment with medications".

WHY DOES THIS MATTER?

Some prospective patients may be turned off by phlebotomy. Also, the steps required to assess which tests are indicated, complete the orders, send patient to complete phlebotomy, and confirm that phlebotomy was completed all take time. Postponing this step for people who are not ready for screening at the time they present for medications for opioid use disorder (MOUD) could make the admissions process more efficient and allow the OTP to admit more patients on a given day.

10270(a)(3) requires an "in-person" physical examination.

New CFR 8.12(f)(2)(i)(v) specifies that examination for intake to methadone treatment may be conducted by telehealth.

WHY DOES THIS MATTER?

As above, one of the most frequent reasons that patients cannot access treatment at an OTP is the absence of sufficient medical providers at the OTP to complete the medical portion of the intake process. Allowing remote medical providers to evaluate patients for treatment will expand access to methadone among patients with OUD.

Continued on reverse.

	TITLE 9	SAMHSA
TITLE 9 SECTION 10270: CRITERIAL FOR PATIENT SELECTION CONTINUED	**10270(d)(1)** requires "confirmed documented history of at least one year of addiction to opioids".	**New CFR 8.12(e)(1)** now states that "the person meets diagnostic criteria for a moderate to severe OUD; the individual has an active moderate to severe OUD or OUD in remission or is at high risk for recurrence or overdose."

WHY DOES THIS MATTER?

Many people have experienced nonfatal overdoses without a one-year history of addiction to opioids. People with non-fatal overdose are at extremely high risk of fatal overdose, but that risk is markedly decreased by MOUD.

TITLE 9 SECTION 10345: COUNSELING SERVICES IN MAINTENANCE TREATMENT	**10345(a)** requires a minimum of 50 minutes of counseling by an NTP counselor per calendar month.	**New CFR 8.12(f)(5)(i)** now includes the line "Patient refusal of counseling shall not preclude them from receiving MOUD".

WHY DOES THIS MATTER?

OTPs are chronically understaffed and the requirement to provide 50 minutes of counseling monthly leads to programs limiting the number of patients they serve. Furthermore, mandated counseling has not been demonstrated to improve outcomes in methadone treatment of OUD.

TITLE 9 SECTION 10355: MEDICATION DOSAGE LEVELS	**10355(d)(1)(a)** stipulates that the first dose a patient receives shall not be greater than 30 mg and 10355(d)(2) says that the total dose on first day shall not exceed 40 mg.	**New CFR 8.12(h)(3)** now states that the initial dose of methadone "should not exceed 50 mg unless the OTP practitioner...finds sufficient medical rationale...and documents that a higher dose was clinically indicated."

WHY DOES THIS MATTER?

Patients who use fentanyl have very high tolerance and require higher doses than in the past. When patients do not receive adequate relief of their withdrawal symptoms, they may continue to use fentanyl while in treatment on MOUD and have an increased risk of overdose and death.

TITLE 9 SECTIONS 10370-10400 CRITERIA FOR TAKE-HOME MEDICATION PRIVILEGES, STEP LEVEL SCHEDULES FOR METHADONE TAKE-HOME MEDICATION PRIVILEGES, RESTRICTING A PATIENT'S TAKE-HOME MEDICATION PRIVILEGES, AND RESTORING RESTRICTED TAKE-HOME MEDICATION PRIVILEGES	**10370(a)** lists the eight criteria that an OTP medical director must consider when determining a patient's eligibility for take-home doses of medication.	**New CFR 8.12(i)(2)** now provides five criteria that OTP medical practitioners shall consider.
	10375(a)(1)-(6) list the "time in treatment" required before patients are eligible to receive take-home doses of medication. Patients become eligible for take-home doses on days when the clinic is open on day 91 of treatment.	**New CFR 8.12(i)(3)** now allows for take-homes to be dispensed on day one of treatment. Eligible patients may come to clinic once a week immediately, once every two weeks after 15 days in treatment, and once a month after 31 days in treatment.
	10390(a)(1) requires NTP medical director to decrease the number of take-home medication schedule for any patient who tests positive for "illicit" drugs and 10400(a)(3) says that the patient must have three consecutive toxicology tests that are negative for "illicit" drugs.	**New CFR 8.12** (like the old CFR 8.12) has neither requirement.

WHY DOES THIS MATTER?

Patients frequently are turned off from methadone treatment due to the burden of having to report to a clinic daily for observed doses. Removing this barrier and placing the decision-making about safety to the community into the hands of the medical providers at the OTP increases the acceptability of this treatment among patients, particularly early in treatment and among patients who can stop using opioids with the help of MOUD but may still be using non-opioid (but "illicit") substances.