



Updated April 21, 2020

## FAQs: Provision of methadone and buprenorphine for the treatment of Opioid Use Disorder in the COVID-19 emergency

1. Can a practitioner working in an Opioid Treatment Program (OTP), admit a **new** patient with opioid use disorder (OUD) to an OTP using telehealth (including use of telephone, if needed)?

Answer: Federal law requires a complete physical evaluation before admission to an OTP.

Under 42 C.F.R. § 8.12(f)(2):

(f) Required services— . . .

(2) Initial medical examination services. OTPs shall require each patient to undergo a complete, fully documented physical evaluation by a program physician or a primary care physician, or an authorized healthcare professional under the supervision of a program physician, before admission to the OTP. The full medical examination, including the results of serology and other tests, must be completed within 14 days following admission.

**However, under 42 C.F.R. § 8.11(h), SAMHSA has the authority to grant exemptions to OTPs from certain requirements of the OTP regulations.**

With respect to new patients treated with **buprenorphine**, SAMHSA has made the decision to pre-emptively exercise its authority to exempt OTPs from the requirement to perform an in-person physical evaluation (under 42 C.F.R. § 8.12(f)(2)) for any patient who will be treated by the OTP with buprenorphine if a program physician, primary care physician, or an authorized healthcare professional under the supervision of a program physician, determines that an adequate evaluation of the patient can be accomplished via telehealth. This exemption will continue for the period of the national emergency declared in response to the COVID-19 pandemic, and applies exclusively to OTP patients treated with buprenorphine. **This exemption does not apply to new OTP patients treated with methadone.** In addition, treatment of OTP buprenorphine patients must be done in accordance with SAMHSA's OTP guidance issued on March 16, 2020. See <https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf>. The OTP provider caring for the buprenorphine patient under these circumstances must be a licensed healthcare practitioner who can, in his or her scope of practice prescribe or dispense medications and have a current, valid DEA registration permitting prescribing or dispensing of medications in the appropriate Controlled Substances Schedule.

For **new** OTP patients that are treated with **methadone**, the requirements of an in-person medical evaluation will remain in force. SAMHSA has made this determination on the basis that eliminating the in-person physical examination requirement for new methadone patients could present significant issues for a patient with OUD. Patients with OUD starting methadone are not permitted to receive escalating doses for induction as take home medication. This means that a person starting methadone for OUD would get a maximum dose of 30 mg/d and may be on this dose, which for most people with OUD would be a low dose that will potentially be inadequate, for extended periods (up to 14 days if the clinic is using a blanket exception during the current medical emergency). The methadone dose could only be increased by a small amount (e.g., 5 mg/d) meaning that the person would be on what are considered to be subtherapeutic doses of methadone to treat OUD for an extended period. An initial in-person physical evaluation is needed in order for OTP providers to address such risks in each **newly** admitted methadone patient.

2. Can a practitioner working in an Opioid Treatment Program continue to treat an **existing** OTP patient using **methadone** via telehealth (including use of telephone, if needed)?

Answer: Yes, a practitioner may continue treating an existing patient of the OTP with methadone via telehealth and in accordance with SAMHSA's OTP guidance issued on March 16, 2020, assuming applicable standards of care are met. See <https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf>. The OTP provider caring for the methadone patient under these circumstances must be a licensed healthcare practitioner who can, in his or her scope of practice prescribe or dispense medications and have a current, valid DEA registration permitting prescribing or dispensing of medications in the appropriate Controlled Substances Schedule.

3. Can a practitioner working in an Opioid Treatment Program, continue to treat an **existing** OTP patient using **buprenorphine** via telehealth (including use of telephone, if needed)?

Answer: Yes, a practitioner may continue treating an existing patient of the OTP with buprenorphine via telehealth assuming applicable standards of care are met, and the patient's buprenorphine treatment is in accordance with SAMHSA's OTP guidance issued on March 16, 2020. See <https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf>. The OTP provider caring for the methadone patient under these circumstances must be a licensed healthcare practitioner who can, in his or her scope of practice prescribe or dispense medications and have a current, valid DEA registration permitting prescribing or dispensing of medications in the appropriate Controlled Substances Schedule.

4. Can a practitioner with a DATA 2000 waiver, and working outside the context of an OTP, treat **new and existing** patients with **buprenorphine** via telehealth (including use of telephone, if needed)?

Answer: Yes, if a practitioner, has a DATA 2000 waiver, the practitioner may prescribe buprenorphine under the practitioner's DATA 2000 waiver while complying with all applicable standards of care. In such a case, the patient will count against the practitioner's patient limit and must treat the patient in accordance with any rules that apply to practicing with a waiver under 21 U.S.C. § 823(g)(2), and 42 C.F.R. Part 8, as applicable.

5. Can an OTP dispense medication (**either methadone or buprenorphine products**) based on telehealth (including telephone, if needed) evaluation?

Answer: Yes. Under the current national health emergency, OTPs can provide medication under blanket exception: up to 14 doses for clinically less stable patients and 28 doses for clinically stable patients (clinical stability and ability to safely manage medication must be determined by the clinical team and documented in the patient's medical record). See <https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf>.

6. Can OTP mid-level practitioners continue to dispense and administer MAT medications at an OTP in the event that their supervising provider can no longer provide supervision regarding the administration or dispensing of MAT medications?

Answer: OTP regulations under 42 C.F.R. § 8.12(h)(1) provide that:

OTPs must ensure that opioid agonist treatment medications are administered or dispensed only by a practitioner licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense opioid drugs, or by an agent of such a practitioner, supervised by and under the order of the licensed practitioner. This agent is required to be a pharmacist, registered nurse, or licensed practical nurse, or any other healthcare professional authorized by Federal and State law to administer or dispense opioid drugs.

Therefore, a mid-level practitioner can administer and dispense MAT medication within an OTP, absent the direct supervision of an OTP physician, if the mid-level practitioner is "licensed under the appropriate State law and registered under the appropriate State and Federal laws to administer or dispense opioid drugs." Please

note, however, that this flexibility does not negate the OTP medical director's obligation to "assume responsibility for administering all medical services performed by the OTP." See 42 C.F.R. § 8.12(b).

7. Is an OTP required to send an exemption request when any provider other than the medical director assumes responsibility for performing a medical director's functions under 42 CFR § 8.12(i)(2) regarding unsupervised take home medications?

Answer: Yes. 42 CFR § 8.12(i)(2) states that, "[t]reatment program decisions on dispensing opioid treatment medications to patients for unsupervised use beyond that set forth in [42 CFR § 8.12(i)(1)], shall be determined by the medical director." Therefore, OTPs must request an exemption when any practitioner other than the medical director assumes responsibility for making decisions regarding unsupervised take home medication orders or dosing changes. Medical directors may assign tasks related to these functions to an appropriately trained and licensed practitioner, including mid-level providers, but such tasks must be performed under the supervision of the medical director. The medical director must remain responsible for all medical services delivered at the corresponding OTP.

8. Does an OTP need to submit an exemption request when an OTP wishes to change its medical director, assuming the new medical director is an appropriately licensed physician?

Answer: No, OTPs do not need to submit an exemption request when simply changing medical directors. However, the OTP does need to notify SAMHSA when a medical director change has occurred pursuant to 42 C.F.R. § 8.11(f)(5).

9. Will SAMHSA approve exemptions for mid-level providers to be designated as medical directors?

Answer: No. Under 42 CFR § 8.2, a medical director must be a physician, and therefore, mid-level providers cannot be a medical director of an OTP.

10. May an OTP request an exemption to allow mid-level practitioners to perform functions that are required to be performed by an OTP physician or the medical director (under 42 C.F.R. § 8.12) in the event the medical director or physician cannot perform the regulatory functions?

Answer: Yes, an OTP may request an exemption from the requirements of 42 CFR § 8.12 in order to have mid-level providers perform functions related to admitting patients, ordering unsupervised take home medication, or changing medication doses during the COVID-19 emergency if consistent with applicable state law and the mid-level provider's scope of licensure.

11. Should OTP's specifically identify by name the mid-level practitioner to take on these functions?

Answer: No, The names of the individual practitioners are not required for these exemption requests.

12. What OTP medical director or program physician functions require an exemption in order to be independently performed by a mid-level practitioner?

Answer: Mid-level providers acting under the direct supervision of a medical director or program physician do not require an exemption to perform functions under 42 C.F.R. § 8.12. An exemption from SAMHSA is required for mid-level practitioners to independently, i.e., without the supervision of the medical director or a program physician, perform the following medical director or physician functions in an OTP based on the Federal opioid treatment standards under 42 C.F.R. § 8.12:

**§ 8.12(b) Administrative and organizational structure.**

- Assuming responsibility for administering all medical services performed by an OTP (a function of the medical director).

- Assuming responsibility for ensuring that the OTP is in compliance with all applicable Federal, State, and local laws and regulations (a function of the medical director).

**§ 8.12(e) Patient admission criteria -**

- Ensuring that each patient voluntarily chooses maintenance treatment and that all relevant facts concerning the use of the opioid drug are clearly and adequately explained to the patient, and that each patient provides informed written consent to treatment (a function of a program physician).
- Waiving, when clinically appropriate, the requirement of a 1-year history of addiction under 42 C.F.R. § 8.12(e)(1), for patients released from penal institutions (within 6 months after release), for pregnant patients, and for previously treated patients (up to 2 years after discharge). (A function of a program physician.)
- Certifying pregnancy for purposes of the above bullet point (a function of a program physician.)
- Assessing patients with two or more unsuccessful detoxification episodes within a 12-month period for other forms of treatment (a function of a program physician).

**§ 8.12(h) Medication administration, dispensing, and use.**

- Documenting in a patient's record that 40 milligrams did not suppress opioid abstinence symptoms when providing an initial dose of methadone in excess of 30 milligrams or 40 milligrams in the first day (a function of a program physician).
- Making dosing and administration decisions (a function of a program physician that is “familiar with the most up-to-date product labeling.”)

**§ 8.12 (i) Unsupervised or “take-home” use.**

- Making OTP decisions on dispensing opioid treatment medications to patients for unsupervised use beyond that set forth in 42 C.F.R. § 8.12(i)(1) (a function of the medical director).
- Considering the take-home criteria listed in 42 C.F.R. 8.12(i)(2) when determining which patients may be permitted unsupervised use (a function of the medical director).

13. If the OTP has received an exemption from SAMHSA for a mid-level practitioner to perform designated functions of the medical director or program physician and subsequently that mid-level practitioner becomes unavailable, does the OTP need to submit another exemption request identifying the new midlevel by name?

Answer: No, if the mid-level exemption request has been approved, but the mid-level practitioner is no longer able to perform the designated duties, for instance due to illness, the OTP is not required to submit another request identifying the new mid-level practitioner during the exemption timeframe.

Practitioners may request an OTP Extranet account at <http://otp-extranet.samhsa.gov/request/>