

March 19, 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).