



U. S. Department of Justice
Drug Enforcement Administration
8701 Morrissette Drive
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www.dea.gov

DEA-Registered Narcotic Treatment Program

Dear Registrant:

The Drug Enforcement Administration (DEA) previously issued a guidance document (Doc. No. DEA078), posted on our website and dated April 7, 2020, providing greater flexibility in how Opioid Treatment Programs (OTPs) may deliver take-home doses of methadone to their patients. In light of the nationwide public health emergency declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, as a result of the Coronavirus Disease 2019 (COVID-19), DEA is now extending the same flexibility to OTPs in how they deliver take-home doses of buprenorphine.¹ As with methadone, DEA is temporarily allowing OTPs to regularly use the same off-site location to deliver take-home buprenorphine doses to their patients without separately registering that location with DEA, subject to the same conditions as expressed in the April 7 methadone guidance document.

Under normal circumstances, such off-site locations would have to be separately registered with DEA if used regularly by the OTP to deliver take-home doses of controlled substances, as more fully described in the April 7 methadone guidance document. However, during the public health emergency or until this guidance document is withdrawn or modified by DEA (whichever comes first), DEA is granting additional flexibility to permit OTPs to dispense take-home doses of buprenorphine without obtaining a separate registration for the locations at which such deliveries occur.

In the same manner as described in the April 7 methadone guidance document, DEA will exercise its authorities to permit OTPs to regularly use off-site locations located in the same state in which the OTP is registered with DEA to deliver take-home doses of buprenorphine to their patients without separately registering those locations. The same limitations as applied to methadone will also apply to off-site locations to dispense buprenorphine, and are as follows:

- Before using the unregistered off-site location to dispense buprenorphine, the OTP must first contact its State Opioid Treatment Authority (SOTA), and receive the SOTA's approval to use the offsite location.

¹ For additional information regarding DEA's and SAMHSA's responses to COVID-19, please see <https://www.deadiversion.usdoj.gov/coronavirus.html> and <https://www.samhsa.gov/coronavirus>. The Controlled Substances Act (CSA) and DEA regulations refer to OTPs as Narcotic Treatment Programs (NTPs).

- Before using the unregistered off-site location to dispense buprenorphine, the OTP must receive approval from the local DEA field office. Once the SOTA approves the location, it should contact the local DEA field office. If the SOTA does not contact the DEA field office, the OTP must contact the field office itself.² The DEA field office may have additional questions about the off-site location and may need to inspect it to ensure that it does not present an unacceptable risk of diversion. Note, however, that if the DEA field office has already approved the off-site location for dispensing methadone, it may also be used to dispense buprenorphine without further approval from DEA.
- Each day, the OTP may only transport those take-home buprenorphine doses to the unregistered off-site location that the OTP reasonably anticipates will be delivered to patients that day. That is, the OTP should never transport a reserve of buprenorphine to the off-site location.
- Any buprenorphine not delivered to patients by the OTP at the off-site location must be returned to the OTP's DEA-registered location the same day. No buprenorphine may be stored at the off-site location when an OTP staff member is not present.

Please note that this guidance only applies to take-home doses of buprenorphine directly dispensed by OTPs. This guidance is not intended for use by individual DEA-registered DATA-waivered practitioners when prescribing buprenorphine to patients for dispensing from a pharmacy.³ In addition, this allowance does *not* extend to any off-site locations regularly used by OTPs to provide daily doses of buprenorphine directly to patients who are not authorized to receive take-home doses. Thus, DEA has concluded that such locations must continue to be separately registered with DEA to ensure that they do not become sources of diversion.

The allowance set forth in this letter is granted to DEA-registered OTPs meeting these conditions from April 28, 2020, through the duration of this public health emergency as declared by the Secretary of HHS (unless this allowance is first modified or withdrawn by DEA).

We hope this information is helpful. For more information from SAMHSA please visit www.samhsa.gov. For information regarding DEA's Diversion Control Division please visit

² DEA's COVID-19 information webpage contains a link to the contact information of DEA local field offices. See <https://www.deadiversion.usdoj.gov/coronavirus.html>.

³ The Controlled Substances Act permits practitioners to dispense narcotic drugs for opioid use disorder without separately registering as an OTP by providing a waiver of this separate registration requirement for practitioners dispensing schedule III, IV, or V narcotic controlled substances approved by the Food and Drug Administration specifically for the use in maintenance or detoxification treatment. 21 U.S.C. 823(g)(2); 21 CFR 1301.28. Currently, the only controlled substance meeting these criteria is buprenorphine. To qualify for such waiver to dispense buprenorphine for maintenance or detoxification treatment outside of an OTP, the practitioner must meet the qualifications set by the Substance Abuse and Mental Health Services Administration (SAMHSA). Practitioners who have met these SAMHSA qualifications and obtained authorization from DEA to dispense buprenorphine for maintenance or detoxification treatment are often referred to as "DATA-waived practitioners" (in reference to the Drug Addiction Treatment Act of 2000, which added 21 U.S.C. 823(g)(2) to the CSA). The guidance in this document does not apply to such buprenorphine prescribing pursuant to a DATA waiver.

www.DEAdiversion.usdoj.gov. Please contact the Diversion Control Division, Policy Section at (571) 362-3260 if you seek additional assistance regarding this or any other matter.

Guidance documents, like this document, are not binding and lack the force and effect of law, unless expressly authorized by statute or expressly incorporated into a contract, grant, or cooperative agreement. Consistent with Executive Order 13891 and the Office of Management and Budget implementing memoranda, the Department will not cite, use, or rely on any guidance document that is not accessible through the Department's guidance portal, or similar guidance portals for other Executive Branch departments and agencies, except to establish historical facts. To the extent any guidance document sets out voluntary standards (e.g., recommended practices), compliance with those standards is voluntary, and noncompliance will not result in enforcement action. Guidance documents may be rescinded or modified in the Department's complete discretion, consistent with applicable laws.

Sincerely,

Thomas W. Prevoznik
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Diversion Control Division

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