



**U. S. Department of Justice**  
Drug Enforcement Administration  
8701 Morrissette Drive  
Springfield, Virginia 22152

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*www.dea.gov*

## DEA-Registered Narcotic Treatment Program

Dear Registrant:

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), the Drug Enforcement Administration (DEA) is exercising its authorities to provide flexibility in the delivery of controlled substances to ensure necessary patient therapies remain accessible. As part of this effort, DEA has partnered with the Substance Abuse and Mental Health Services Administration (SAMHSA) to develop temporary methods for Opioid Treatment Programs (OTPs) to provide their patients with necessary take-home doses of medication assisted treatment (MAT) during this emergency.<sup>1</sup>

Accordingly, DEA, following consultation with SAMHSA, is issuing this letter to provide OTPs with greater flexibility in how they deliver take-home doses of methadone to their patients. DEA is doing so by temporarily allowing OTPs to repeatedly use the same off-site location to deliver take-home methadone doses to their patients without separately registering that location with DEA, subject to certain conditions.

Patients that receive methadone through OTPs can be grouped into two categories: those who are authorized to take home doses of methadone to use on their own,<sup>2</sup> and those who are not so authorized and who must instead have individual doses of methadone administered or dispensed directly to them by the OTP each day. As discussed more fully below, the flexibility being announced in this letter applies to the first category of patients—that is, patients who are authorized to take home doses of methadone to use on their own.

As a result of the COVID-19 pandemic, some OTPs have had to close, placing increased demand on those OTPs that are still operational. Other OTPs have had to reduce their services due to staffing shortages. Because of this reduced staffing and other limitations imposed by COVID-19, some OTPs have had difficulty delivering take-home doses of methadone to patients.

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<sup>1</sup> 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).

<sup>2</sup> For the purposes of this letter, the category of patients authorized to receive take-home methadone includes patients temporarily authorized to take home doses of methadone pursuant to an exception granted during this public health emergency. See <https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf>. The CSA and DEA regulations refer to the dispensing of such take-home methadone as dispensing for "unsupervised use." See 21 U.S.C. 823(g)(1)(C); 21 CFR 1301.74(k).

In light of these challenges, some OTPs have inquired about setting up temporary off-site locations in the state in which the OTP is registered with DEA where patients could pick up their take-home doses of methadone from an OTP staff member. Doing so would potentially avoid disruptions in the OTPs' delivery of these take-home doses by allowing the OTPs to provide more services with fewer staff.

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. This is because, under the Controlled Substances Act, registrants, including OTPs, are generally required to separately register with DEA "at each principal place of business or professional practice where the [registrant] . . . dispenses controlled substances." 21 U.S.C. 822(e)(1); *see also* 21 CFR 1301.12(a). Under this standard, a registrant is generally required to separately register any location at which the registrant regularly dispenses controlled substances, even if the registrant does not intend to use the location on a long-term basis. This requirement normally would apply to off-site locations repeatedly used by OTPs to deliver take-home doses of methadone to their patients.

In view of the extraordinary circumstances that have arisen during this public health emergency, and in order to ensure adequate medical care for its duration, 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 methadone to their patients without separately registering those locations, subject to the following limitations:

- Before using the unregistered off-site location, the OTP must first contact its State Opioid Treatment Authority (SOTA), and receive the SOTA's approval to use the off-site location.
- Before using the unregistered off-site location, 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.<sup>3</sup> 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.
- Each day, the OTP may only transport those take-home methadone 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 methadone to the off-site location.
- Any methadone 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 methadone may be stored at the off-site location when an OTP staff member is not present.

The allowance set forth in this letter is granted to DEA-registered OTPs meeting these conditions from April 7, 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).

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<sup>3</sup> DEA's COVID-19 information webpage contains a link to the contact information of DEA local field offices.

Please note, however, that this allowance does *not* extend to any off-site locations regularly used by OTPs to provide daily doses of methadone directly to patients who are not authorized to receive take-home doses. Providing daily doses presents a heightened risk of diversion. 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.

We hope this information is helpful. For more information from SAMHSA please visit [www.samhsa.gov](http://www.samhsa.gov). For information regarding DEA's Diversion Control Division please visit [www.DEAdiversion.usdoj.gov](http://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.

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Sincerely,

Thomas W. Prevoznik  
Deputy Assistant Administrator  
Diversion Control Division