



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

DEA Qualifying Practitioners
DEA Qualifying Other Practitioners

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 prescribing and dispensing 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 ensure authorized practitioners may admit and treat new patients with opioid use disorder (OUD) during the public health emergency. DEA has already announced that practitioners may prescribe controlled substances to patients using telemedicine without first conducting an in-person evaluation during this public health emergency under 21 U.S.C. 802(54)(D).¹ Today, DEA notes that practitioners have further flexibility during the nationwide public health emergency to prescribe buprenorphine to new and existing patients with OUD via telephone by otherwise authorized practitioners without requiring such practitioners to first conduct an examination of the patient in person or via telemedicine.² This additional flexibility under which authorized practitioners may prescribe buprenorphine to new patients on the basis of a telephone evaluation is in effect from March 31, 2020, until the public health emergency declared by the Secretary ends, unless DEA specifies an earlier date.

The Controlled Substances Act (CSA) allows practitioners to dispense narcotic drugs, including buprenorphine, to individuals with OUD for maintenance or detoxification treatment if the practitioners separately register with DEA as an opioid treatment program (OTP). *See* 21 U.S.C. 823(g)(1). The CSA also permits practitioners to dispense narcotic drugs for OUD by providing for 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. *Id.* at 21 U.S.C. 823(g)(2); 21 CFR 1301.28. Currently, the only controlled substance meeting these criteria is buprenorphine. To qualify for the waiver to dispense buprenorphine for maintenance or detoxification treatment, the practitioner must meet the qualifications set by 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).

¹ *See* <https://www.deadiversion.usdoj.gov/coronavirus.html>.

² This letter only addresses the topic of prescribing buprenorphine for maintenance and detoxification treatment. The dispensing of methadone for maintenance and detoxification treatment is addressed in a separate letter.

Under the CSA, all prescriptions for controlled substances, including those issued for maintenance or detoxification treatment, must be issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice. *See* 21 CFR 1306.04(a). As noted above, despite the CSA's limitations on issuing prescriptions for controlled substances by means of the Internet, for the duration of the public health emergency, a practitioner may prescribe a controlled substance to a new patient via telemedicine—using a real-time, two-way, interactive audio-visual communication—without first conducting an in-person examination.³ *See* 21 U.S.C. 802(54)(D).

Independently, SAMHSA's regulations also require that an OTP conduct an in-person medical evaluation of a patient before prescribing or directly dispensing controlled substances, including buprenorphine, for maintenance treatment or detoxification. *See* 42 CFR 8.12(f)(2). On March 19, 2020, however, SAMHSA exempted OTPs from the requirement that they perform such an in-person physical evaluation 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 the use of a telephone. SAMHSA also announced that it was allowing DATA-waived practitioners to prescribe buprenorphine for maintenance or detoxification treatment to do so via telephone, "while complying with all applicable standards of care."⁴

Under normal circumstances, DEA would not consider the initiation of treatment with a controlled substance based on a mere phone call to be consistent with the framework of the CSA given that doing so creates a high risk of diversion. However, in light of the extraordinary circumstances presented by the COVID-19 public health emergency, and being mindful of the exemption issued by SAMHSA, DEA likewise advises that, only for the duration of the public health emergency (unless DEA specifies an earlier date), OTPs should feel free to dispense, and DATA-waived practitioners should feel free to prescribe, buprenorphine to new patients with OUD for maintenance treatment or detoxification treatment following an evaluation via telephone voice calls, without first performing an in-person or telemedicine evaluation. This may only be done, however, if the evaluating practitioner determines that an adequate evaluation of the patient can be accomplished via the use of a telephone. The prescription also must otherwise be consistent with the practitioner's aforementioned obligation under the CSA and DEA regulations to only prescribe controlled substances for a legitimate medical purpose while acting in the usual course of professional practice.

³ Where a prescription for a controlled substance is issued by means of the Internet, the CSA (as amended by the Ryan Haight Act) requires that such prescription involve at least one in-person medical evaluation, with limited exceptions. After conducting one in-person medical evaluation, a practitioner may thereafter prescribe controlled substances by means of the Internet or via telephone. Except where an exception applies, however, a new patient must ordinarily be examined in-person prior to a practitioner prescribing or dispensing a controlled substance to the patient. One such exception is an examination via telemedicine conducted pursuant to 21 U.S.C. 802(54)(D).

⁴ <https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf>.

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

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Thomas W. Prevoznik
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DEA068 – March 31, 2020