

U. S. Department of Justice

Drug Enforcement Administration 8701 Morrisette Drive Springfield, Virginia 22152

www.dea.gov

Dear Registrants,

In response to the public health emergency that has been declared as a result of the opioid crisis, the Drug Enforcement Administration (DEA) is exercising its authority under the Controlled Substances Act (CSA), in conjunction with the Department of Health and Human Services (HHS), to ensure patient's necessary access to medications for opioid use disorder (OUD). This guidance addresses the circumstances under which practitioners may continue to treat new patients—that is, patients a particular practitioner has not previously examined during an in-person visit—with OUD via telemedicine, to include audio-only telemedicine, without an in-person medical evaluation, consistent with the flexibilities in place during the COVID-19 public health emergency while DEA considers regulations to make such flexibilities permanent.

Background

A prescription for a controlled substance issued by means of the Internet (including telemedicine) must generally be predicated on an in-person medical evaluation (21 U.S.C. 829(e)), but the CSA contains certain exceptions to this requirement. One such exception for the use of telemedicine occurs when the Secretary of Health and Human Services (Secretary) has declared a public health emergency under 42 U.S.C. 247d, as set forth in 21 U.S.C. 802(54)(D). Under these circumstances, the Secretary and DEA Administrator are permitted to designate appropriate geographic areas and controlled substances subject to this telemedicine allowance.

Application of Section 802(54)(D) to the Opioid Crisis Public Health Emergency

The Secretary has declared such a public health emergency with regard to the continued consequences of the opioid crisis. This declaration was most recently renewed effective October 3, 2022. On November 30, 2022, the Secretary, with the concurrence of the DEA Administrator, designated that the telemedicine allowance under section 802(54)(D) applies to buprenorphine prescribed to patients with OUD for maintenance or detoxification treatment in all areas of the United States. This authorization is in effect from November 30, 2022, until the opioid crisis public health emergency declared by the Secretary ends, unless the Secretary and/or DEA Administrator specify an earlier date or otherwise first modify or withdraw this authorization.

Accordingly, while this authorization is in effect and subject to certain conditions described below, DEA-registered practitioners in all areas of the United States who meet all applicable requirements (discussed below) may issue buprenorphine prescriptions for the maintenance or detoxification treatment of OUD via telemedicine, to include audio-only telemedicine, to those patients for whom they have not conducted an in-person medical evaluation.

First, to use this authorization, a practitioner must comply with all otherwise applicable Federal and state laws and regulations, including the CSA and DEA regulations as well as state laws and regulations regarding under what circumstances a prescription can be predicated on telemedicine encounters. In particular, the CSA permits practitioners to prescribe buprenorphine for maintenance or detoxification treatment of OUD only if they first obtain an appropriate waiver, often referred to as "DATA waiver" (in reference to the Drug Addiction Treatment Act of 2000, which added 21 U.S.C. 823(g)(2) to the CSA). To qualify for such a waiver to dispense buprenorphine for maintenance or detoxification treatment, a practitioner must meet the qualifications set by the Substance Abuse and Mental Health Services Administration (SAMHSA) and obtain authorization from DEA. *See* 21 U.S.C. 823(g)(2); 21 CFR 1301.28.

Second, 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 professional practice. *See* 21 CFR 1306.04(a); *United States v. Moore*, 423 U.S. 122 (1975).

Third, the CSA requires a remote practitioner relying on a telemedicine exception to the inperson evaluation requirement to communicate with the patient (or health care professional treating the patient) using "a telecommunications system referred to in [42 U.S.C. 1395m(m)]." 21 U.S.C. 802(54). Subsection 1395m(m) references, but does not define, such telecommunications systems. The Centers for Medicare & Medicaid Services (CMS), however, has promulgated regulations implementing those provisions, and those regulations do define "telecommunications system" for Medicare payment purposes. Thus, it is to this CMS definition that the CSA's "telecommunications system" requirement referencing 42 U.S.C. 1395m(m) ultimately refers. Specifically, 42 CFR 410.78(a)(3) ("Special payment rules for particular items and service") states:

Interactive telecommunications system means, except as otherwise provided in this paragraph, multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. For services furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder to a patient in their home, interactive telecommunications may include two-way, real-time audio-only communication technology if the distant site physician or practitioner is technically capable to use an interactive telecommunications system as defined in the previous sentence, but the patient is not capable of, or does not consent to, the use of video technology.

CMS understands the prescription of buprenorphine for maintenance or detoxification treatment to qualify as the treatment of a mental health disorder under this regulation.² Thus, in addition to the use of an audio-video system, the use of two-way, real-time audio-only communication technology, such as a voice-only telephone call, is permitted under this telemedicine authorization if the

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¹ For additional information regarding HIPAA flexibilities under the COVID-19 PHE, please see OCR's Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency, https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html?msclkid=e3de2fa7b67711ecb528da62fec85fbe.

² See Medicare Program Final Rule, 86 FR 64996, 65061 (Nov. 19, 2021) ("We would like to clarify that [substance use disorder] services are considered mental health services for the purposes of the expanded definition of 'interactive telecommunications system' to include audio-only services under § 410.78(a)(3).").

practitioner and patient otherwise comply with the requirements of 42 CFR 410.78(a)(3) (e.g., the patient is located at home and the practitioner is technically capable of using audio-video technology).

A practitioner, however, may prescribe buprenorphine for OUD treatment based on an audioonly communication only after determining that an adequate evaluation of the patient can be accomplished via the use of an audio-only interaction. Additionally, practitioners should take steps to ensure that their use of this authorization does not lead to diversion of buprenorphine.³

Two additional points warrant clarification. The Secretary and DEA Administrator also have authorized the use of telemedicine under 21 U.S.C. 802(54)(D) for all schedule II–V controlled substances during the COVID-19 public health emergency and made certain other exceptions to normal regulatory requirements to address the COVID-19 emergency.⁴ These COVID-19 related authorizations include an allowance for the prescribing of buprenorphine for the maintenance or detoxification treatment of OUD via telemedicine, to include audio-only telemedicine, to those patients for whom they have not conducted an in-person medical evaluation. The authorization described in this letter operates independently of such COVID-19 related authorities, even if it authorizes some of the same actions. Accordingly, any changes to or rescission of the COVID-19 public health emergency allowances currently in effect that may occur in the future do not alter the authorization related to the opioid crisis public health emergency described here.

Additionally, this authorization is relevant only to practitioners who have never conducted an inperson evaluation of the patient. If the prescribing practitioner has previously conducted an in-person medical evaluation of the patient, the practitioner may issue a prescription for a controlled substance after having communicated with the patient via telemedicine, or any other means, pursuant to 21 U.S.C. 829(e)(2)(a)(i). This is true regardless of whether a public health emergency has been declared by the Secretary, so long as the prescription is issued for a legitimate medical purpose, the practitioner is acting in the usual course of professional practice, and the practitioner complies with applicable Federal and State laws (including, if applicable, the requirement to obtain a DATA waiver).

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

Sincerely,

Thomas W. Prevoznik Acting Assistant Administrator Diversion Control Division

EO-DEA250, DEA-DC-064, November 30, 2022

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³ For additional information regarding initiating buprenorphine treatment, including preventing diversion, please see SAMHSA Treatment Improvement Protocol 63, Medications for Opioid Use Disorder, https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document/PEP21-02-01-002.

⁴ See https://www.deadiversion.usdoj.gov/coronavirus.html.