DCBA | Law & Policy

April 1, 2020

Via electronic communication

Karen A. Scott, MD, MPH
President
Foundation for Opioid Response Efforts
kscott@forefdn.org

Re: Prescribing Buprenorphine for Opioid Use Disorder During a Public Health Emergency

Dear Dr. Scott:

As you requested, we have analyzed four hypothetical scenarios for prescribing buprenorphine for opioid use disorder in the United States during the novel coronavirus outbreak. Our opinions are provided in detail on the attached pages.

In short, we conclude that the strategies described in Scenarios 1, 2, 3, and 4 may be implemented in a compliant manner under the federal Controlled Substance Act during the novel coronavirus public health emergency. Once such emergency declaration ends, however, practitioners must ensure that any use of telemedicine to prescribe buprenorphine or other controlled substances without first conducting an in-person exam meets one of the other telemedicine exceptions under the federal Controlled Substances Act.

Finally, upon your request, I have included at the end of this document information on DCBA Law & Policy and our experience advising clients in the addiction treatment field.

Sincerely,

Daniel C. McClughen
For the Firm

I. Background and Questions Presented

The U.S. Department of Health and Human Services ("HHS") has declared the novel coronavirus outbreak a public health emergency.[1] Due to the outbreak across the United States, concerns have been raised related to potential barriers to initiating or continuing treatment with buprenorphine for opioid use disorder.

Are the following three hypothetical scenarios permissible under federal controlled substance law?

Scenario 1

A patient presents to an outpatient clinic or emergency department and is seen by a Provider A, who is not X-waivered. Provider A completes a thorough in-person exam and determines that the patient meets criteria for treatment with buprenorphine for opioid use disorder. After reviewing the risks and benefits of treatment, the patient consents to treatment with buprenorphine. Using live audio-visual technology, Provider A communicates with an X-waivered colleague, Provider B, to consult on the patient's case. Provider B remotely discusses the patient's case with Provider A and evaluates the clinical information provided by Provider A without interviewing the patient directly. Once Provider B agrees that the patient is appropriate for treatment with buprenorphine for opioid use disorder, Provider B calls in the prescription for buprenorphine for the patient.

Scenario 2

A patient is in ongoing buprenorphine treatment at an outpatient clinic. The patient is treated by Provider C, who is X-waivered. The clinic is avoiding in-person visits to prevent transmission of the novel coronavirus. Provider C is not available, but Provider C's colleague in the same practice, Provider D, is cross-covering for Provider C until Provider C returns. Provider D, who is also X-waivered, remotely conducts a medical evaluation and confirms that it is necessary for Provider D to issue a new prescription. Provider D calls in a new buprenorphine prescription for the patient to ensure continuity of treatment.

Scenario 3

A patient who actively uses opioids is placed into home quarantine or isolation. The patient has not had any face-to-face encounter with a provider for the purposes of opioid use disorder evaluation. Provider E, who is X-waivered, contacts the patient by telephone and conducts a thorough evaluation of the patient's case. The patient screens positive for opioid withdrawal and Provider E determines that the patient is appropriate for treatment with buprenorphine and documents her rationale. Provider E then calls in a prescription for an oral buprenorphine product to be delivered to that patient to begin receiving treatment at home.

[1] U.S. Dep't of Health and Human Servs., *Determination that a Public Health Emergency Exists* (Jan. 31, 2020), https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.

Scenario 4

A new patient is seen by Provider F in an outpatient medical setting. Provider F conducts a thorough medical evaluation and determines that the patient is appropriate for buprenorphine treatment for opioid use disorder. Provider F subsequently refers the patient to Provider G, whose practice is not affiliated with Provider F's practice. Provider G discusses the patient's case with Provider F. Without first conducting an in-person medical exam, Provider G contacts the patient by telephone and conducts a medical evaluation. After determining that the patient is appropriate for buprenorphine treatment, Provider G issues a prescription. Provider G continues to conduct telephone visits in this manner during the public health emergency.

II. Analysis

A. The In-Person Exam Requirement for "Internet" Prescriptions

Under the federal Controlled Substances Act ("CSA"), all prescriptions for controlled medications, regardless of how they are dispensed, must be is issued for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice.[2] Additionally, the CSA sets forth specific requirements related to the dispensing of such medications via the Internet. Specifically, no "controlled substance that is a prescription drug . . . may be delivered, distributed, or dispensed by means of the Internet[3] without a valid prescription."[4] The term "valid prescription" means a "prescription that is issued for a legitimate medical purpose in the usual course of professional practice by— (i) a practitioner who has conducted at least 1 in-person medical evaluation of the patient; or (ii) a covering practitioner."[5]

The term "practitioner" means a "physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices . . . to . . . dispense . . . or administer . . . a controlled substance in the course of professional practice. . . ."[6]

The term "in-person medical evaluation" means a "medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals."[7]

[2] 21 C.F.R. § 1306.04 (2020).
[3] The term "Internet" means "collectively the myriad of computer and telecommunications facilities, including equipment and operating software, which comprise the interconnected worldwide network of networks that employ the Transmission Control Protocol/Internet Protocol, or any predecessor or successor protocol to such protocol, to communicate information of all kinds by wire or radio." 21 U.S.C. § 802(50) (2018).
[4] 21 U.S.C. § 829(e)(1) (2018).
[5] 21 U.S.C. § 829(e)(2)(A).
[6] 21 U.S.C. § 802(21).
[7] 21 U.S.C. § 829(e)(2)(B)(i).

The term "covering practitioner" means "a practitioner who conducts a medical evaluation (other than an in-person medical evaluation) at the request of a practitioner who (i) has conducted at least one in-person medical evaluation of the patient or an evaluation of the patient through the practice of telemedicine, within the previous 24 months; and (ii) is temporarily unavailable to conduct the evaluation of the patient."[8]

B. The Public Health Emergency Telemedicine Exception to the In-person Exam Requirement

The CSA contains several exceptions to the in-person exam requirement when a practitioner is engaged in the delivery, distribution, or dispensing of a controlled substance through the practice of telemedicine.[9] Telemedicine is the practice of medicine in accordance with all applicable federal and state laws by a practitioner (other than a pharmacist) who is (1) at a location remote from the patient and (2) communicating with the patient or the practitioner who is treating the patient, using multimedia communications equipment that includes, at a minimum, audio *and* video equipment permitting two-way, real time interactive communication.[10] Telephone, fax, and email systems do not meet this requirement.[11]

Most notably, an in-person exam is not required if the practice of telemedicine is being conducted during a public health emergency declared by the Secretary of HHS, and involves patients located in such areas, and such controlled substances, as the Secretary, with the concurrence of the Attorney General, designates.[12]

Consistent with this requirement, an information page published by the Drug Enforcement Administration ("DEA") states that for as long as the Secretary's designation of a public health emergency remains in effect, DEA-registered practitioners may issue prescriptions for controlled substances to patients for whom they have not conducted an in-person medical evaluation, provided all of the following conditions are met:

- The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice;
- The telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system; and
- The practitioner is acting in accordance with all applicable federal laws (e.g., the Health Insurance Portability and Accountability Act, "HIPAA") and state laws (e.g., state controlled substances acts, telemedicine laws and regulations, laws governing nurse practitioner and physician assistant prescriptive authority, patient privacy laws).[13]

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[8] 21 U.S.C. § 829(e)(2)(C).
[9] 21 U.S.C. § 802(54).
[10] 21 U.S.C. § 802(54)(A); 42 C.F.R. § 410.78(a)(3).
[11] U.S. Dep't of Justice Drug Enf't Admin., *Telemedicine and the Controlled Substances Act* (June 3-4, 2019), https://www.deadiversion.usdoj.gov/mtgs/pract_awareness/conf_2019/june_2019/arnold2.pdf.
[12] 21 U.S.C. § 802(54)(D).
[13] U.S. Dep't of Justice Drug Enf't Admin., *Covid-19 Information Page*, https://www.deadiversion.usdoj.gov/coronavirus.html (last visited Mar. 18, 2020).

"Provided the practitioner satisfies the above requirements, the practitioner may issue the prescription using any of the methods of prescribing currently available and in the manner set forth in the DEA regulations. Thus, the practitioner may issue a prescription either electronically (for schedules II-V) or by calling in an emergency schedule II prescription to the pharmacy, or by calling in a schedule III-V prescription to the pharmacy."[14] The practitioner should thoroughly document his or her rationale for the prescription in the patient's health record.

Notably, on March 31, 2020, DEA posted guidance on prescribing controlled substances approved to treat opioid use disorder during the novel coronavirus outbreak. Under this guidance, DEA has relaxed the audio-visual requirement under the CSA's public health emergency telemedicine exception. Specifically, DEA stated that for the duration of the public health emergency (unless DEA specifies an earlier date), X-waivered "practitioners have flexibility . . . to prescribe buprenorphine to new and existing patients with OUD via telephone . . . without first conducting an examination of the patient in person or via [audio-visual] telemedicine."[15]

The DEA's March 31 guidance is consistent with an FAQ document recently published by the Substance Abuse and Mental Health Services Administration ("SAMHSA") related to the provision of methadone and buprenorphine for the treatment of opioid use disorder during the public health emergency. There, SAMHSA states that it is permissible during the public health emergency for an X-waivered practitioner to treat new and existing patients with buprenorphine "via telehealth (including the use of telephone, if needed) . . ."[16]

C. Scenario 1

During the effective period of the public health emergency declared by HHS, Provider B may conduct a remote video consult with Provider A and issue a buprenorphine prescription without first conducting an in-person exam so long as:

- The prescription is issued for a legitimate medical purpose and in the usual course of professional practice;
- The telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system; and
- The practitioner is acting in accordance with applicable federal and state law.[17]

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[14] U.S. Dep't of Justice Drug Enf't Admin., *Covid-19 Information Page*, https://www.deadiversion.usdoj.gov/coronavirus.html (last visited Mar. 18, 2020).
[15] U.S. Dep't of Justice Drug Enf't Admin., *Dear Registrant Letter*, https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20%20(Final)%20+Esign.pdf (last visited April 1, 2020).
[16] Substance Abuse and Mental Health Services Administration, *FAQs: Provision of methadone and buprenorphine for the treatment of Opioid Use Disorder in the COVID-19 emergency*, https://www.samhsa.gov/sites/default/files/faqs-for-oud-prescribing-and-dispensing.pdf (last visited Mar. 25, 2020).
[17] U.S. Dep't of Justice Drug Enf't Admin., *Covid-19 Information Page*, https://www.deadiversion.usdoj.gov/coronavirus.html (last visited Mar. 18, 2020).

D. Scenario 2

The practice of telemedicine exception does not apply under the scenario when Provider D cross-covers for Provider C's existing patient, given that Provider C has already conducted an in-person exam and the patient has been in ongoing treatment with buprenorphine for OUD under Provider C's care. As such, Scenario 2 is permissible given that the covering provider, Provider D, is X-waivered and has independently evaluated and verified that the buprenorphine prescription is medically necessary for the patient.[18] While use of an audio-visual, real-time, two-way interactive communication system could be beneficial under these circumstances, it is not required.

Notably, when a covering practitioner fills a buprenorphine prescription for a patient, that patient is counted against the covering practitioner's patient limit for the duration of the prescription.[19]

E. Scenario 3

During the effective period of the public health emergency declared by HHS, Provider E may conduct a telephone evaluation of a quarantined new patient and then issue a prescription for buprenorphine for OUD without first conducting an in-person exam if:

- Provider E verifies that the prescription is issued for a legitimate medical purpose and in the usual course of professional practice; and
- The practitioner is acting in accordance with applicable federal and state law.[20]

F. Scenario 4

During the effective period of the public health emergency declared by HHS, Provider G may accept a referral from Provider F, conduct a telephone examination, and prescribe buprenorphine to the referred patient for OUD if:

- Provider G verifies that the prescription is issued for a legitimate medical purpose and in the usual course of professional practice; and
- The practitioner is acting in accordance with applicable federal and state law.[21]

[18] Medication Assisted Treatment for Opioid Use Disorders, 81 Fed. Reg. 44716-17 (July 8, 2016).
[19] However, if a cross-covering practitioner is merely available for consult but does not dispense or prescribe buprenorphine while the prescribing practitioner is away, the patients being covered do not count toward Provider D's patient limit. Medication Assisted Treatment for Opioid Use Disorders, 81 Fed. Reg. 44716-17 (July 8, 2016).
[20] U.S. Dep't of Justice Drug Enf't Admin., *Covid-19 Information Page*, https://www.deadiversion.usdoj.gov/coronavirus.html (last visited Mar. 18, 2020).
[21] *Id.*

G. Telemedicine Using Mobile Apps

The Office of Civil Rights ("OCR") at HHS is responsible for enforcing federal regulations set forth under HIPAA. OCR recently issued a notice stating that it will exercise enforcement discretion and not impose penalties for noncompliance with such regulatory requirements "by covered health care providers in connection with the good faith provision of telehealth during the COVID-19 nationwide public health emergency." This exercise of discretion applies to any telehealth service, including those unrelated to the diagnosis and treatment of the virus.[22]

Under the OCR notice, "covered health care providers may use popular applications that allow for video chats, including Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, or Skype, to provide telehealth without risk that OCR might seek to impose a penalty for noncompliance with the HIPAA Rules related to the good faith provision of telehealth during the COVID-19 nationwide public health emergency."[23]

OCR requires that the app to provide telehealth services be non-public facing. "Facebook Live, Twitch, TikTok, and similar video communication applications are public facing, and should not be used in the provision of telehealth by covered health care providers."[24]

H. Other Exceptions to the In-Person Exam Requirement Once the Novel Coronavirus Public Health Emergency Ends

A public health emergency declaration lasts for 90 days or until the Secretary declares that the emergency no longer exists, whichever occurs first.[25] A declaration can be renewed for subsequent 90-day periods.[26] HHS declared the novel coronavirus a public health emergency on January 31, 2020. Additionally, HHS has renewed several times the declaration of a public health emergency related to the opioid crisis, with the most recent renewal on January 24, 2020.[27]

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[22] U.S. Dep't of Health and Human Servs., Notification of Enforcement Discretion for telehealth remote communications during the COVID-19 nationwide public health emergency (Mar. 17, 2020), https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html.
[23] *Id.*
[24] *Id.*
[25] U.S. Dep't of Health and Human Servs., Public Health Emergency Declaration Q&As (Sept. 5, 2019), https://www.phe.gov/Preparedness/legal/Pages/phe-qa.aspx.
[26] *Id.*
[27] U.S. Dep't of Health and Human Servs., Public Health Emergency Declarations (Jan. 31, 2020), https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.

Unlike the public health emergency related to the novel coronavirus, we are not aware of any opioid-crisis emergency designation by HHS, with concurrence of the Attorney General, related to the prescribing of controlled medications via telemedicine without an in-person medical exam. As explained above, such a designation is required under the CSA's telemedicine exception. Therefore, once the coronavirus public health emergency ends, practitioners likely cannot rely on the public health emergency telemedicine exception even if the opioid crisis declaration is subsequently renewed.

Once the novel coronavirus public health emergency ends, practitioners can still rely on other distinct scenarios provided under the CSA telemedicine exception. For example, an in-person exam is not required if the practice of telemedicine is being conducted (i) while the patient is being treated and is physically located in a DEA-registered hospital or clinic; and (ii) by a remote practitioner acting in the usual course of professional practice and in accordance with state law, who is DEA-registered in the state where the patient is located.[28] All other telemedicine requirements (e.g., audio-visual requirements) also apply. Similarly, an in-person exam is not required if the practice of telemedicine is being conducted while the patient is being treated by, and in the physical presence of, a practitioner acting in the usual course of professional practice and in accordance with state law, who is DEA-registered in the state where the patient is located.[29] All other telemedicine requirements (e.g., audio-visual requirements) also apply.

III. Conclusion

Under the federal CSA, Scenarios 1, 2, 3, and 4 can be implemented in a compliant manner during the novel coronavirus public health emergency. Once such emergency declaration ends, however, practitioners must ensure that any use of telemedicine to prescribe buprenorphine or other controlled substance without first conducting an in-person exam meets one of the other telemedicine exceptions under the CSA.

Importantly, practitioners must continue to adhere to their legal obligations not only under the federal CSA, but also under all other applicable federal and state laws, such as HIPAA, state controlled substances acts, state telemedicine laws and regulations, state laws and regulations governing nurse practitioner and physician assistant prescriptive authority, and state patient privacy laws. We recommend that practitioners and health care organizations consult with and follow the advice of their own legal counsel, including interpretations of state law.

[28] 21 U.S.C. § 802(54)(A).
[29] 21 U.S.C. § 802(54)(B).

About DCBA Law & Policy

DCBA Law & Policy is a Washington, DC-based law firm that provides legal, legislative, and regulatory counsel on matters involving health care access, opioids and other controlled medications, drug diversion and abuse prevention, addiction treatment, pain management, and drug testing. Our clients include addiction treatment providers; biopharmaceutical, biotech, and medical device companies; hospitals; laboratories; medical researchers; and recovery residences. Our attorneys' recent publications include:

- *Warm Handoffs: The Duty of and Legal Issues Surrounding Emergency Departments in Reducing the Risk of Subsequent Drug Overdoses*, 48 U. Mem. L. Rev. 1100 (2019);
- *Potential Impact of Texas et al v United States on Persons with Substance Use Disorder*, ABA Health eSource (Oct. 2018); and
- *Diligence and Documentation: Managing the Risks of Prescribing Controlled Substances*, 5 PainWeek J. 52 (2017).

Daniel C. McClughen is an associate attorney at DCBA Law & Policy. Mr. McClughen provides research, analysis, and strategic insight to DCBA's clients on matters of health care and business law and policy. He advises health care practitioners, addiction treatment programs, recovery residences, and clinical laboratories on transactional matters; marketing and lead generation; drug testing; controlled substance prescribing; and compliance with federal and state laws, including anti-kickback, patient brokering, physician self-referral, and patient privacy laws.