Foundation *for* Opioid Response Efforts

'COVID-19 National Emergency Response' Webinar Series

MOUD and the COVID-19 National Emergency Response
March 19, 2020
Webinar Questions and Answers

Disclaimer: We have asked our webinar panelists to address questions from the webinar and are providing responses below, to the best of our current knowledge, given the rapidly evolving circumstances. These answers are informational in nature and are not intended as legal or medical advice.

1. **Is there a legal opinion on the Ryan Haight Act's requirement for an in-person medical exam prior to prescribing controlled substances? Does the telemedicine exception to the in-person exam requirement under the Ryan Haight Act permit the initial exam to be conducted by phone call without video?**

   FORE engaged a Washington D.C.-based health law and policy firm to draft an opinion letter regarding the use of telemedicine to prescribe buprenorphine during the public health emergency declared by the U.S. Department of Health and Human Services (HHS). The opinion letter can be found here. It explains how the federal Controlled Substances Act (CSA), as amended by the Ryan Haight Act, requires that an in-person exam be conducted prior to issuing a prescription for a controlled substance by means of the "Internet," unless the prescriber is engaged in the practice of telemedicine.

   The CSA contains several distinct "practice of telemedicine" exceptions to the in-person exam requirement, including the use of telemedicine during a public health emergency declared by HHS. This exception requires, among other things, that the telemedicine encounter occur using "audio-visual, real-time, two-way interactive" communications. Therefore, the exception itself does not permit the initial exam to be conducted by telephone in lieu of an in-person exam. (Please see responses to Questions 2 and 3 for related discussion.)

   However, on March 31, 2020 (after the date of the webinar), the Drug Enforcement Administration (DEA) published guidance on prescribing controlled substances approved to treat opioid use disorder during the COVID-19. Under this guidance, DEA has temporarily 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" as long as the "evaluating practitioner determines that an adequate evaluation of the patient can be accomplished via the use of a telephone."

As always, prescribers must only prescribe controlled medications for a legitimate medical purpose while acting in the usual course of professional practice.

2. **May a licensed provider who is not X-waivered but located at a DEA-registered health care location (e.g., a hospital) perform the in-person evaluation for a new patient, determine that the patient is appropriate for treatment with buprenorphine, consult with an X-waivered provider at a remote location by phone, and request that the X-waivered provider issue a buprenorphine prescription? Where would I learn more about this?**

   As explained under Question 1 above, the CSA requires the X-waivered provider to communicate with the other provider or patient using an audio-visual, real-time, two-way interactive communications system prior to issuing an initial prescription for a controlled substance.

   At the same time, recent guidance from the DEA temporarily relaxes this audio-visual requirement during the COVID-19 public health emergency. Specifically, a qualified practitioner may conduct an evaluation of a new patient by phone before prescribing buprenorphine, if the practitioner determines it is appropriate to do so.

   Given that the guidance does not directly address provider-to-provider communications, it is unclear whether such communication can be done by telephone under this example. The approach that would provide the prescriber the greatest assurance of compliance is to either communicate with the other provider using audio-visual technology, or to speak directly with the patient by phone.

   The legal opinion letter prepared for FORE provides an analysis of several hypothetical clinical scenarios like this one. The letter can be found here. Additionally, the DEA has published a COVID-19 information page explaining how telemedicine may be used during the public health emergency to prescribe controlled substances in general. The information page links to the DEA's guidance on prescribing buprenorphine during the public health emergency.

   DEA published this guidance on March 31, 2020, after the date of this webinar.

3. **When you say 'audio-visual,' what if a patient only has a phone but no access to a smartphone or webcam and cannot be seen in person? This is frustrating because many vulnerable patients often do not have access to smartphones or computers with audio-visual capabilities. Is there any indication that the visual requirement maybe lifted?**

   Health care providers are being faced with tremendous challenges during the COVID-19 outbreak. In recognition of the challenges many practitioners have faced in prescribing buprenorphine via telemedicine using audio-visual technology, as required under the CSA, DEA has issued guidance temporarily relaxing the audio-visual requirement. As explained above, the guidance provides 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" as long as the "evaluating practitioner

determines that an adequate evaluation of the patient can be accomplished via the use of a telephone."

DEA published this guidance on March 31, 2020, after the date of this webinar.

4. **Do we need to register or do an application to start telehealth services?**

   No, we are not aware of any federal law that requires such registration to begin providing services through telehealth. Providers should be aware of any requirements under state law specific to telemedicine, however.

   As mentioned above, the CSA includes several distinct telemedicine exceptions to the requirement that an in-person exam be conducted prior to issuing a prescription for a controlled substance. One of these exceptions is when the practice of telemedicine is conducted by a practitioner who has obtained a special registration from the DEA. The SUPPORT for Patients and Communities Act of 2018 required the DEA to establish rules setting forth how and under what circumstances the special registration for telemedicine can be obtained. To date, DEA has not done so.

   Additionally, Medicare, state Medicaid programs, and private payers have specific conditions that must be met to be eligible for reimbursement for telemedicine services covered by such payers.

5. **I know non-HIPAA compliant audio-visual platforms are being allowed now, but could you give us a short list of the most common platforms that are HIPAA compliant?**

   HHS Office of Civil Rights (OCR) recently published a statement explaining that it will exercise enforcement discretion and will not impose penalties for HIPAA noncompliance in connection with a good faith provision of telemedicine during the public health emergency. Therefore, covered health care providers temporarily "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." However, OCR explained that platforms such as "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."

   In addition, the statement issued by HHS provides the following examples of vendors that represent they **are** HIPAA-compliant: Skype for Business/Microsoft Teams, Updox, VSee, Zoom for Healthcare, Doxy.me, Google G Suite Hangouts Meet, Cisco Webex Meetings/Webex Teams, Amazon Chime, and GoToMeeting.

6. **How do we document no face to face visits?**

   DEA requires that all prescriptions for controlled substances, regardless of whether they are issued after an in-person or a telehealth exam, must be issued for a legitimate medical purpose

and in the usual course of professional practice. Therefore, thorough documentation is imperative to show that this standard has been met. You can find a template from to CA Bridge's EPIC dotphrase for telehealth visit documentation here.

7. **What are the drug testing requirements or recommendations for prescribing buprenorphine remotely? How would you suggest addressing urine drug screening (UDS) needs during this time? Can you clarify how often we should be doing UDS on higher risk patients? Should we provide a patient during the first appointment with buprenorphine via telemedicine who is in need, yet when there are no labs or urine?**

   There are no federal requirements or specific guidance for drug testing. Some state Medicaid programs do have requirements, but these may be modified at this time. ASAM provides clinical guidance on testing. Our panelists describe clinical judgement along with good documentation as the approach they would take- weighing the risks of infection exposure versus risk level of the patient.

8. **Is there more information on telehealth best practices as far as providing counseling for OTP clients?**

   SAMHSA has published an FAQ document related to the provision of methadone and buprenorphine for the treatment of opioid use disorder during the public health emergency. The FAQ focuses primarily on OTP settings and provides valuable information.

9. **Can buprenorphine and stimulants (schedule II) be mailed to people's homes from pharmacies?**

   Yes. United States Postal Service regulations permit the mailing of controlled substances by pharmacies when distribution is lawful under DEA regulations (i.e., pursuant to a valid prescription) and if the mailer is registered with DEA or exempt from DEA registration as permissible by law.

10. **Does federal law allow me to prescribe more than one month's worth of buprenorphine? What about methadone delivery?**

    Unlike schedule II medications, there is no 30-day limit for schedule III-controlled substances under the federal CSA. Therefore, unless prohibited by state law, more than one month's worth of buprenorphine may be prescribed. However, buprenorphine and other schedule III drugs cannot be filled or refilled more than six months after the date on which such prescription was issued. And if refills are authorized on the original prescription, the medication cannot be refilled more than five times during the six-month period. State law may be more restrictive. Prescribing more than 30 days and authorizing refills on the initial prescription is not typical in office-based opioid treatment settings, however, and the prescriber should exercise great caution before doing so and thoroughly document his or her medical rationale.

As a general rule, OTPs may only dispense methadone directly to a patient. Take home doses are permitted in limited circumstances. SAMHSA addresses take home doses during the public health emergency in its FAQ document and in its OTP guidance document. Additionally, in a recent letter to HHS, DEA stated that in certain circumstances an OTP may make a "doorstep" delivery of take home doses of narcotic medications in an approved lockbox to a quarantined patient.

11. **Is buprenorphine allowed to be dispensed off site during the novel coronavirus public health emergency if it is normally delivered to a clinic. If the clinic closes, can the pharmacy dispense and have the clinic deliver it to someone in the community?**

    X-waivered practitioners may prescribe buprenorphine that can be dispensed by a community pharmacy. The pharmacy may deliver the medication to the patient.

    If the clinic is registered as an OTP but does not have an X-waivered practitioner to prescribe buprenorphine, then the OTP generally must dispense the medication on-site directly to the patient. Take home doses are permitted in limited circumstances. SAMHSA addresses take home doses during the public health emergency in its FAQ document and in its OTP guidance document. Additionally, in a recent letter to HHS, DEA stated that in certain circumstances an OTP may make a "doorstep" delivery of take home doses of narcotic medications in an approved lockbox to a quarantined patient.

12. **I'm curious to know if there have been any recommendations on staggering the provision of take-home doses to reduce the number of patients attending an OTP at the same time.**

    We have not seen any official guidance on this, but several states are recommending programs enact steps to decrease clinic traffic, such as staggering appointment times and identifying those patients appropriate for extended take home doses.