National Association of State
Controlled Substances Authorities

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Check out NASCSA's Youtube Channel

Did you know that many of our successful webinars are ultimately posted on our Youtube channel for future reference. All of our webinars are only available to members and sponsors however we do post them 6-8 weeks afterwards on our **Youtube channel**. Recent webinars on **Promethazine & Codeine** and **Regulator and Dispenser Preparation for the Drug Supply Chain Security Act** are now uploaded. More information about becoming a **member** or **sponsor**.

Speaking of membership, dues notices will be distributed in May for 2023-2024 so please be on the lookout for renewal notices.

Telemedicine and the Prescribing of Controlled Substances

February 27, 2023
By Karla L. Palmer, Hyman, Phelps & McNamara, PC (reprinted with permission)

The 2008 **Ryan Haight Online Pharmacy Consumer Protection Act** placed strict limits on online prescribing or the use of telemedicine encounters to prescribe controlled substances. The Ryan Haight Act was enacted to address the legal "grey area" in which prescribers and pharmacies operated via the creation of two new statutory requirements: 1) the at least one "in-person" medical evaluation requirement for prescribing practitioners, 21 U.S.C. § 829(e); and 2) the modified registration requirement for online pharmacies. 21 U.S.C. § 823(f). The Act also established new definitions for "Internet," "online pharmacy," "practice of telemedicine," among others. Notably, the Ryan Haight Act (and the later SUPPORT Act of 2018) also required DEA to promulgate regulations related to a "special registration" to engage in the practice of telemedicine, which now 15 years since the 2008 Act's passage, **DEA announced** on February 24th – likely as a result of the relaxation of telemedicine requirements during the COVID-19 public health emergency. 21 U.S.C. § 802(54)(D)(i). That emergency declaration is set to **expire on May 11, 2023**. While no "special registration" will yet be required to engage in telemedicine prescribing of controlled substances, DEA is proposing parameters to guide the practice of telemedicine encounters in a post-COVID world.

The Ryan Haight Act did not limit the ability to prescribe controlled substance medications by telemedicine so long as the patient and prescriber had a least one in-person visit. DEA's proposed rule when finalized would authorize telemedicine pursuant to the Controlled Substances Act, 21 U.S.C. § 802(54)(G), where: 1) the prescribing practitioner has not conducted an in-person medical evaluation with the patient; 2) the prescription was issued pursuant to a telemedicine encounter; and, 3) the telemedicine encounter results in a prescription for a controlled substance medication. Section 502(54)(G), unlike the other six "permissible" telemedicine encounters in the Ryan Haight Act, permits DEA to pass regulations to expand the use of telemedicine. See 21 U.S.C. § 503(54)(G) (specifically, telemedicine "being conducted under any other circumstances that the Attorney General and the Secretary have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.") The rule would require that the prescriptions be issued consistent with both state and federal law, and the practitioner to maintain an active DEA registration in the state in which the practitioner is located.

General Telemedicine Proposed Rule

One of the proposed rules, titled "Telemedicine prescribing of controlled substances when the practitioner and the patient have not had a prior in-person medical evaluation," linked **here**, addresses a practitioner's use of a defined "telemedicine encounter" to prescribe schedule III-V non-narcotic controlled substances and related parameters surrounding such prescribing when the patient and prescriber have not had a prior in-person evaluation.
The rule would permit a practitioner using a telemedicine encounter to prescribe controlled substances without an in-person visit under various situations involving both an audio-visual telehealth evaluation, or an in-person evaluation performed by a "referring" provider. Notably, for services furnished for purposes of diagnosis, evaluation, or treatment of a mental health disorder to a patient generally in their home, interactive telecommunications may include two-way, real-time audioonly communication technology, if the "distant site" physician or practitioner is technically capable to use an interactive telecommunications system, but the patient is not capable of, or does not consent to, the use of video technology. These audio-only encounters would seem to be an exception to DEA's stated preference for use of audio-video telemedicine encounters. The rule would also require enhanced recordkeeping requirements for both the referring practitioner (i.e., a prescriber that conducts an in-person visit) and prescribing practitioner (i.e., a prescriber that engages in telemedicine with the patient), including a review of PDMP data for the past year.

Importantly, if relying on a telemedicine visit, the prescription must be for an initial 30-day period, and only for schedule III-V non-narcotic controlled substances. If the patient seeks greater than the initial 30-day supply, then the telemedicine prescriber or referring prescriber must perform an in-person evaluation prior to prescribing additional controlled medications beyond the 30-day period. The visit may, however, include a patient's in-person visit with another practitioner while on an interactive video link with the prescribing practitioner.
If an in-person evaluation is performed by either a referring provider or the prescribing provider, the patient may also receive schedule II controlled substances, consistent with Ryan Haight requirements already in place.

Lastly, the proposal permits continued prescribing of controlled substances (schedules II-V) for a period of 180 days following the end of the COVID-19 emergency declaration (i.e., 180 days past May 11, 2023) for those telemedicine relationships established during the COVID-19 emergency.

DEA is Seeking Comments, But on a Short Fuse

The proposal lastly notes that DEA is seeking public comments on various topics, but on a short, 30-day timeline given the looming end of the pandemic emergency. Comment topics suggested by DEA include the following:

- Whether the rule should limit the issuance of prescriptions for controlled medications to FDA-approved indications contained in the labeling for those medications.
- Proposed practitioner recordkeeping obligations.
- Comments, including data from research and clinical practice, that provides evidence that an alternate maximum day supply (other than the proposed 30-day supply).
- Additional safeguards or flexibilities that should be considered with respect to the rule.
- Whether the proposed rule concerning the induction of buprenorphine via telemedicine (see below) should be combined with the general telemedicine rulemaking.

Telemedicine Prescribing of Buprenorphine for the Treatment of Opioid Use Disorder

DEA is also proposing regulations, linked **here** titled, "Expansion of induction of buprenorphine via a telemedicine encounter," which would expand the circumstances under which practitioners are authorized to prescribe any schedule III, IV, or V narcotic controlled substance — approved by FDA specifically for use in the maintenance or detoxification treatment of OUD — via a telemedicine encounter. The encounter may include an audio-only telemedicine encounter that meets the standards for the same set forth in CMS's telehealth services regulations at **42 C.F.R. § 410.78(a)(3),** provided certain requirements, including requirements under state laws and conditions are met.

Specifically, DEA notes that in those states where state law prohibits the prescription of a controlled substance based solely on an audio-only evaluation, the proposed regulation would

not authorize the audio-only prescription of buprenorphine for opioid-use disorder (OUD). Thus, the authorization of audio-only OUD telemedicine prescribing, and audio-video prescribing, would only apply in those states where such prescriptions are consistent with state law. The same is true with the general telemedicine proposed rule, above.
The only schedule III-V narcotic drug that is currently approved by the FDA for OUD treatment is buprenorphine. DEA notes that expanding a registered practitioner's authority to prescribe buprenorphine for the treatment for OUD via telemedicine, including an audio-only telemedicine encounter, would expand access to needed medical treatment. Relatedly, DEA states:

> Recent studies have revealed that, in some populations, upward of 94 percent of the unhoused community had a cell phone, while a limited amount owned or had access to computers, tablets, or internet access. Not only would this rulemaking make it easier for patients to obtain treatment, many practitioners have shown a willingness to treat patients using an audio-only telecommunications system.

The rule would require the practitioner to check and maintain PDMP data for patients prior to issuing the prescription, which DEA asserts will assist the practitioner in making clinical decisions.

The authority to prescribe buprenorphine by telemedicine is not unlimited, however. Not only must prescribing be consistent with state laws addressing use of telemedicine, but the patient must also receive a medical evaluation meeting certain requirements within 30 days of being prescribed buprenorphine via telemedicine for the induction of OUD treatment in order to obtain an additional supply of buprenorphine. Thus, the regulations would require that, within 30 days, the patient must either be examined in person by the prescribing practitioner or practice, or the prescribing practitioner would have to examine the patient remotely while the patient is in the physical presence of another DEA registered practitioner that is participating in an audio-video telemedicine encounter with the prescribing practitioner.

Alternatively, the requirement of a medical evaluation is satisfied when the prescribing practitioner receives a qualifying telemedicine referral for medication assisted treatment for OUD from a DEA-registered practitioner prior to issuing a prescription for controlled substances. Under this scenario, DEA notes the patient has already received the in-person medical evaluation from the referring practitioner, and thus the prescribing practitioner is authorized to prescribe beyond the 30-day limit.

For both proposed rules, the bottom line is that, while telemedicine is here to stay, circumstances permitting it are indeed not limitless. Remaining at the heart of any telemedicine encounter and controlled substances prescription is the need for an in-person medical examination – at some relatively early point (i.e. within 30 days) in the doctor-patient relationship.

And, as one who loves easy-to-follow charts… DEA has published one **here**, setting forth the various general parameters for prescribing via both telemedicine and in-person visits – and covering both the general and buprenorphine telemedicine proposed rules. Helpful practitioner prescribing guidance is set forth in a simplified document **here**. A complimentary webinar will be held on this issue on **March 23, 2023 at noon ET** which is open to all NASCSA members. To register click **here**.

Travel Scholarships Now Available

Travel scholarship applications and instructions to attend this year's 39th ***annual conference*** that will take place October 23-26, 2023 in Minneapolis, Minnesota are now available online.

In order to accommodate agencies that may require additional time to receive out of state travel approval, the Membership Committee with approval of the Executive Committee has changed the deadline to apply to June 2, 2023, with applicants to receive notification on or before July 14, 2023. We strongly encourage regular members to consider applying. Up to two (2) travel scholarships will be awarded.

More information is found **here**.

Upcoming Webinars

April 26, 2023 at 3 pm ET

ASAP PDMP Standards: Everything You Need to Know And What's in the Future

Speaker: Bill Lockwood, Executive Director, American Society for Automation in Pharmacy (ASAP)

Description: Bill Lockwood will cover the development of the ASAP standards — the reporting standard and the standard used to query PDMP data. He will discuss how it all started, the enhancements made over the years, the involvement in the process by PDMPs and other stakeholders, and more.

Register

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