Telehealth and Prescribing Controlled Substances: Where are we now?

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The telehealth landscape has changed drastically during the COVID-19 pandemic. One of the most fundamental changes for longtime telehealth stakeholders has been practices around prescribing controlled substances virtually. This article provides an overview of that landscape, and outlines the pivotal questions that remain unanswered in this area of law as the U.S. begins to contemplate a post-COVID 19 public health emergency ("PHE") world.

In particular, it focuses on three issues: 1) federal and state-level requirements to perform a prior in-person examination of the patient before prescribing controlled substances; 2) federal and state-level requirements for state-specific controlled substances registrations; and 3) the status of federal efforts to establish a new "telemedicine registration" exception to the in-person examination requirement under federal law.

In-Person Examination Requirements for Prescribing Controlled Substances

As amended by the Ryan Haight Act, the Controlled Substances Act has long prohibited prescribing controlled substances via telehealth without a prior in-person examination unless one of a number of exceptions is satisfied.

Congress enacted the Ryan Haight Act in 2008. The legislation was named after an 18-year old who tragically overdosed on Vicodin prescribed by a doctor he had never met through the internet. In response, Congress amended the Controlled Substances Act to prohibit prescribing controlled substances by means of the internet without the prescribing physician first examining the patient in-person.

The Ryan Haight Act contains seven "telemedicine" exceptions which allow controlled substances to be prescribed via telehealth without a prior in-person exam. To briefly summarize, they involve: 1) a patient being treated in a hospital or clinic that is registered with the Drug Enforcement Administration ("DEA") at the time of the telemedicine examination; 2) a patient being treated in the physical presence of a DEA-registered practitioner; 3) services provided by a practitioner employed by the Indian Health Service or a tribal organization; 4) during a public health emergency declared by the Department of Health and Human Services; 5) a patient being treated by a practitioner who has obtained a special telemedicine registration from the Administrator of the DEA; 6) a patient being treated during a medical emergency by an employee or contractor of the Department of Veterans Affairs; or 7) other circumstances specified by regulation. The fourth "telemedicine" exception applies for the duration of the PHE.

Critically, while the DEA has repeatedly been called upon (including by Congress in the SUPPORT Act of 2018, and more recently by more than 70 stakeholder

organizations and Senator Mark Warner in recent months) to establish the special telemedicine registration listed above, to date, it has failed to do so. In the early days of the COVID-19 PHE, the DEA announced that it would not enforce the Ryan Haight Act's prohibition on prescribing controlled substances via telehealth without a prior in-person examination, in reliance on the PHE telemedicine exception referenced above.

Neither the CSA as amended by the Ryan Haight Act nor, to the best of our knowledge, any sub regulatory guidance issued by the DEA imposes any restrictions on where a prior in-person examination must be conducted to satisfy the Ryan Haight Act.

In-Person Examination Requirements Under State Law

While states also have laws addressing prescribing controlled substances via telehealth, the Ryan Haight Act requirements serve as a federal "floor", i.e., less restrictive state laws are superseded by the Ryan Haight Act, but the federal law does not supersede state laws which contain stricter requirements. The Ryan Haight Act specifically requires practitioners prescribing controlled substances to do so in accordance with applicable state law, i.e., the laws of the state in which the patient is located.

Some states expressly prohibit prescribing certain schedules of controlled substances medication to patients without first performing an in-person examination.[1] Other states allow controlled substances to be prescribed without a prior in-person examination, as long as such prescribing satisfies the requirements of the Ryan Haight Act.[2] And some states are silent, and neither permit nor prohibit prescribing controlled substances via telehealth without a prior in-person examination.

Controlled Substances Registration Under Federal Law

The Controlled Substances Act requires every person who prescribes any controlled substance to hold a registration issued by the DEA, and a separate DEA registration for each state in which the practitioner prescribes controlled substances, based on the location of the patient. This means that, for a telemedicine physician licensed in all fifty states who wishes to prescribe controlled substances to patients in such states, the practitioner must hold fifty state-specific DEA registrations.

Importantly, however, in March 2020, the DEA announced that, for practitioners with a DEA registration in the state in which the provider is located, the state-specific DEA registration requirement in the state in which the patient is located would be waived for the duration of the PHE. However, like the waiver of the in-person examination requirement referenced above, to date there is no indication that the federal registration requirement will be waived after the PHE terminates.

Despite the unprecedented growth of telehealth services in recent years, to date, the DEA has not issued guidance indicating how virtual medical practices whose practitioners treat patients via telehealth can obtain state-specific controlled substances registrations.

Critically, many DEA field offices only approve applications which include a physical address in the state at issue, so that DEA agents can perform site visits. To date, DEA has not issued guidance indicating how virtual medical practices whose practitioners treat patients via telehealth can satisfy the "physical address" requirement.

Controlled Substances Registration Under State Law

Many states also require practitioners to hold a state-issued controlled substances registration to prescribe controlled substances to patients in that state. This requirement is independent of the state-specific DEA registration requirement referenced immediately above, meaning that in practice, many states require practitioners to hold two controlled substances licenses to prescribe controlled substances to patients. The DEA posted a list of the 25 "second controlled substance license" states earlier in 2022.

Special Registration

For many telehealth stakeholders, one of the most frustrating legal issues in this space has been the DEA's repeated refusal to enact a special registration process that would enable physicians to be approved to prescribe controlled substances via

telehealth without a prior in-person exam, similar to the DATA 2000, or "X-Waiver," process which exists for prescribing buprenorphine without an in-person exam. As enacted, the "practice of telemedicine" definition for purposes of the Controlled Substances Act was meant to be temporary until the special telemedicine registration process was established by regulation, which is expressly acknowledged in preamble commentary published by the DEA and the Department of Justice in 2009.

What's Next?

Providers have grown accustomed to mass confusion regarding the healthcare regulatory landscape during the pandemic. But there is perhaps no area of health care law more perplexing than controlled substances prescribing, if only because of the DEA's almost complete silence on its intentions moving forward.

In a March 2022 press release, DEA Administrator Anne Milgram announced the agency's plans to expand access to medication-assisted treatment ("MAT") to help patients suffering from substance use disorder, including by allowing such medication to be prescribed via telehealth.[3] The press release states, "in response to the COVID-19 public health emergency, DEA implemented temporary regulations allowing medication-assisted treatment to be prescribed by telemedicine. DEA is working to make those regulations permanent." As of October 2022, the scope DEA envisions for those regulations has yet to be communicated to industry.

In contrast, the Centers for Medicare & Medicaid Services ("CMS") within the U.S. Department of Health and Human Services has communicated its plans to create a post-pandemic "off-ramp" to give industry time to reorient and prepare for a return to the pre-pandemic landscape (with some changes) in successive rulemakings, describing a 151 day transition period to allow pandemic flexibilities to sunset. That off-ramp period applies to the majority of pandemic-specific federal waivers and flexibilities relevant to the telehealth industry, but not the controlled substances prescribing issues discussed herein.

Congress has also begun to contemplate telehealth changes post-pandemic. The House of Representatives passed H.R. 4040 in August, which also has the support of the Biden administration, and calls to extend flexibilities involving the Medicare program through the end of calendar year 2024. However, as passed by the House, H.R. 4040 did not address controlled substances prescribing.

Conclusion and Takeaways

Historically, telehealth advocacy involving the DEA has focused on the capacity for telehealth to expand access to care in medically underserved communities, delivering clinically necessary care to patients in need of treatment. What makes the current situation different is that significant numbers of Americans have received care via telehealth relying on the regulatory flexibilities adopted during the pandemic. As a result, the ability to prescribe controlled substances via telehealth is now necessary for continuity of care purposes. As it stands, absent intervention by the DEA, whenever the COVID-19 public health emergency ends, patients who have established care virtually involving controlled substances will lose access to treatment.

HLB's Digital Health Practice actively monitors digital health regulatory developments, including controlled substances prescribing at the federal and state levels. If you have any questions, please contact Jeremy Sherer in Boston, or any other member of our Hooper, Lundy & Bookman team.

[1] See, e.g., Mont. Admin. R. 24.156.813(4).
[2] See, e.g., Ind. Code Ann. § 25-1-9.5-8.
[3] See DEA Press Release, "DEA's Commitment to Expanding Access to Medication-Assisted Treatment," (March 23, 2022).

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