Treating Substance Use Disorders via Telemedicine

The federal Ryan Haight Act remains a barrier to allowing physicians to prescribe medication-assisted treatment via telemedicine without an in-person appointment. But that could change if the DEA activates a special registration.

By Daniel Zinsmaster, Esq., and Margaret Power, Esq.

N OCT. 26, 2017, the opioid epidemic was officially declared a national public health emergency by the U.S. Department of Health and Human Services (HHS). Despite the significant attention being given to the crisis, data shows that the problem has yet to peak, as the prevalence rate for overdoses continues to rise. The Centers for Disease Control and Prevention (CDC) recently released data showing that overdose deaths in the United States increased by 29.7% between July 2016 and September 2017, rising on average 5.6% per quarter. While many options are being explored to determine how to effectively treat the spectrum of health issues related to substance use disorders, leveraging telehealth and telemedicine as a treatment modality in the addiction medicine field has only begun to be explored as a viable option.

"A handful of states have amended their controlled substance prescribing laws so that medication-assisted treatment (MAT) may be delivered through telemedicine."

Treating Addiction

One of the three goals of HHS' Opioid Initiative, part of the federal response to the opioid epidemic, is expanding access to Medication-Assisted Treatment (MAT) to reduce opioid use disorders and overdoses. The Substance Abuse and Mental Health Services Administration (SAMHSA), a division of HHS, defines MAT as "the use of FDA-approved medications, in combination with counseling and behavioral therapies, to provide a 'whole-patient' approach to the treatment of substance use disorders." These medications include antagonist, agonists, and partial agonist medications such as naloxone, methadone, and Suboxone, respectively. For reference, an antagonist prevents opioids from binding to the brain's mu receptors, also known as morphine receptors. Such medications block the receptor sites and have no potential for abuse. Agonists and partial agonists bind to the mu receptor in the same way as an opioid, preventing cravings and withdrawal, but do not cause a euphoric feeling.

While the efficacy of MAT has been demonstrated, the U.S. Surgeon General estimates that only one in ten individuals with a substance use disorder receive any type of specialty treatment. This problem is compounded by a lack of practitioners. Physicians who want to treat opioid addicted patients with Schedule III-V Controlled Substances that have been approved by the FDA for that indication (which is presently limited to buprenorphine-containing products such as Suboxone and Subutex) must apply for a waiver under the *Drug Addiction Treatment Act of 2000 (DATA 2000)*. And while physician extenders became eligible in late 2016 under the Comprehensive Addiction and Recovery Act to obtain DATA 2000 waivers, all approved providers are restricted to seeing only 30 patients for their first certification year, with the opportunity to increase to 100 and 275 patients in the subsequent years if certain criteria are met.

Beyond the number of patients a provider may treat at any given time, additional barriers exist as a consequence of the primary medications used to treat opioid use disorder being classified as controlled substances, including Methadone and Suboxone. As a result, state and federal laws and regulations limit a provider's ability to prescribe such medications via telemedicine.

Federal Law and the Ryan Haight Act

For a prescription for a controlled substance to be valid, federal law requires that the prescription be issued for a legitimate medical purpose by a practitioner acting in the usual course of his or her professional practice. The practitioner is responsible for the proper prescribing and dispensing of controlled substances. Failure to prescribe in accordance with regulatory mandates can expose a practitioner to administrative, civil, and criminal sanctions. The Drug Enforcement Administration (DEA) is the agency within the U.S. Department of Justice responsible for carrying out the functions assigned to the agency under the Controlled Substances Act.

Telemedicine has been shown to improve access to care, reduce costs, and increase efficiency and patient satisfaction. However, restrictive federal regulations have prevented providers from using telemedicine to its full capabilities. For example, the ability for practitioners to prescribe controlled substances to patients the provider has not seen in person is limited

by the *Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Haight Act)*. The Haight Act was passed by Congress in response to an overdose death by a teenager who purchased prescription painkillers from an online pharmacy without ever meeting a physician. Although the Haight Act was intended to stop the proliferation of internet pharmacies that were selling controlled substances online, its effects are more widespread by preventing any provider from prescribing a controlled substance via telemedicine unless one in-person exam has already been conducted.

While there are exceptions from this in-person examination requirement if a provider is engaged in the "practice of telemedicine," the scope of activities permitted is narrow and largely excludes most modern telemedicine practices. Arguably the most widely applicable of these exceptions is that a physician practicing telemedicine may prescribe controlled substances absent an in-person evaluation if the patient is treated by and physically located in a hospital or clinic which has a valid DEA registration and the telemedicine practitioner is treating the patient in the usual course of professional practice and in accordance with state law. Even so, because few practices meet these narrow exceptions, in most cases it is likely that for a practitioner to comply with federal law, one in-person exam must be conducted before prescribing controlled substances to a patient using telemedicine technologies.

State Developments

States have also taken action in response to the opioid epidemic. A handful of states have amended their controlled substance prescribing laws so that MAT may be delivered through telemedicine. For example, in 2017 the State Medical Board of Ohio promulgated new regulations that allow providers to issue a prescription for both non-controlled and controlled substances via telemedicine. Ohio's regulations allow for the prescribing of controlled substances without a concurrent in-person examination if, among other requirements, one of the following requirements is met:

- The person is an active patient of the physician or an active patient of a colleague whom the physician is seeing as part of an on call or cross-coverage arrangement. "Active patient" is defined as having conducted one in-person examination or evaluation through telemedicine within the last 24 months.
- The person has been admitted as an inpatient to or is a resident of an institutional facility.
- The prescribing physician is a hospice practitioner and the patient is hospice-enrolled.
- The patient is being treated by, and in the physical presence of, an Ohio-licensed physician or other DEA-registered provider and provides services in accordance with the current standards of practice; *or*
- The physician has received a special DEA registration to provide controlled substances in the particular situation.

"Even if state law requirements appear less stringent, the federal Haight Act prevents practitioners from prescribing controlled substances via telemedicine unless one in-person exam has already been conducted."

Similarly, in 2016 Indiana began allowing controlled substances to be prescribed via telemedicine without an in-person examination; however, it is restricted to partial agonists such as Suboxone. West Virginia amended its telemedicine laws in 2016 and allows for the prescribing of controlled substances to a remote patient so long as the physician-patient relationship isn't based "solely based upon a telemedicine encounter." Delaware also allows for the prescribing of controlled substance via telemedicine if a physician-patient relationship is established. Notably, in March 2018, the Delaware Board of Medicine issued proposed regulations that would limit the prescribing of opioids via telemedicine to addiction treatment programs offering MAT pursuant to a waiver issued by the Delaware Division of Substance Abuse and Mental Health.

However, because federal law preemptively sets the floor for prescribing activities, typically one in-person encounter must occur before controlled substances may be prescribed in order to comply with the Haight Act, even if state law requirements appear less stringent.

DEA Special Registration and Legislation

The Haight Act contains an exception from the in-person examination requirement for those providers and entities that obtain a "special registration" from the U.S. Attorney General or the DEA Administrator. A similar exception is found in the Ohio regulation discussed above. Yet, despite the Haight Act being enacted in 2008, the DEA has never set forth a regulation to implement this special registration, and consequently, this registration has never been created.

On Jan. 30, 2018, Senators Claire McCaskill (D-MO), Lisa Murkowski (R-AK), and Dan Sullivan (R-AK) sent a letter to Robert Patterson, the Acting Administrator for the DEA, urging him to expedite the rule making process for this special registration. The letter specifically addresses the senators' concerns that rural Americans who live far from treatment centers and lack access to mental health professionals in their communities are adversely impacted by the one in-person examination requirement of the Haight Act, and would benefit from this special registration.

“The Haight Act allows an exception from the in-person exam requirement for providers who obtain a ‘special registration’ from the U.S. Attorney General or the DEA Administrator. Yet the DEA has never set forth a regulation to implement this special registration.”

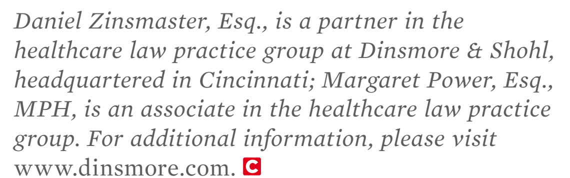
The U.S. House of Representatives has also proposed legislation to require the Attorney General to promulgate the special registration regulations and allow for more entities to qualify as a clinic under the Haight Act. One bill, entitled *Improving Access to Remote Behavioral Health Treatment Act of 2018*, would allow community health centers and addiction treatment centers to obtain a DEA registration as a clinic, which would allow providers to prescribe controlled substances to patients at these sites without the need for an in-person visit. Another, entitled *Special Registration for Telemedicine Clarification Act of 2018,* directs the Attorney General to promulgate special registration regulations within 30 days of its passage.

In the other chamber, on April 4, 2018, the Senate Committee on Health, Education, Labor, and Pensions (HELP) released a discussion draft of the *Opioid Crisis Response Act of 2018*. Among other things, the Act would “clarify DEA’s ability to develop a regulation to allow qualified providers to prescribe controlled substances in limited circumstances via telemedicine.” Similar to the *Improving Access to Remote Behavioral Health Treatment Act of 2018*, it would also “allow community mental health and addiction treatment centers to register with the DEA to treat patients through the use of telemedicine.” A full committee hearing on the Act was held on April 11, 2018, and the bill was introduced on April 16.

As to the executive branch, the White House released a fact sheet to accompany the public health emergency declaration that states that the president intends for the declaration to “allow for expanded access to telemedicine services, including services involving remote prescribing of medicine commonly used for substance abuse or mental health treatment.”

Conclusion

As new options continue to be explored for how best to address the opioid epidemic, delivering MAT through telemedicine is a practical option that should be considered. Nonetheless, many states seeking to expand access will likely need to enact reforms so that care may be delivered through telemedicine technology. Federal reforms are also necessary so that major barriers can be removed and thus provide patients with access to much needed treatment.



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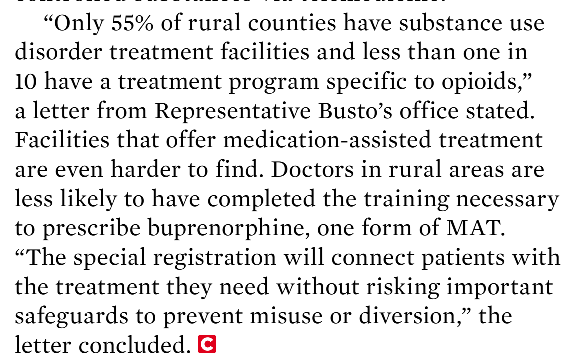
Legislative Update

ON JUNE 12, the U.S. House of Representatives passed HR 5483, the *Special Registration for Telemedicine Clarification Act of 2018*. Illinois Reps. Cheri Bustos and Bobby Rush were coauthors of the legislation, along with two other House members. The bill passed during the two-week long consideration of dozens of bills to combat the opioid crisis, and it was slated for the U.S. Senate as this magazine went to press. As of June 12, the House had approved 25 other opioid-related bills.

HR 5483, the *Special Registration for Telemedicine Clarification Act of 2018,* will clarify telemedicine waivers. Federal law permits the Attorney General to issue a special registration to health care providers to prescribe controlled substances via telemedicine in legitimate emergency situations, such as a lack of access to an in-person specialist. However, the waiver process has never been implemented through regulation, and some patients do not have the emergency access they need to treatment. This bipartisan bill directs the Attorney General, with the Secretary of HHS, to promulgate interim final regulations within one year of passage of the law. Such action will improve flexibility in the practice of telemedicine. Specifically, the bill requires DOJ to allow for the prescription of medication-assisted treatment (MAT) and other controlled substances via telemedicine.



“Only 55% of rural counties have substance use disorder treatment facilities and less than one in 10 have a treatment program specific to opioids,” a letter from Representative Busto’s office stated. Facilities that offer medication-assisted treatment are even harder to find. Doctors in rural areas are less likely to have completed the training necessary to prescribe buprenorphine, one form of MAT. “The special registration will connect patients with the treatment they need without risking important safeguards to prevent misuse or diversion,” the letter concluded.