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Understanding the Implications of Federal Remote Prescribing Laws on Telemedicine's Role in Behavioral Health Treatment


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I. Introduction

The urgency of increasing access to mental health care and behavioral health treatment cannot be overstated. Access to these services has begun to increase slightly within recent years, sparked by an increased discussion about mental health, and the continued removal of the stigma surrounding mental health treatment. While the discussion at least provided a boost in visibility of the need to improve mental health treatment access, the opioid epidemic is now making the country acutely aware of the horrors of substance abuse disorders and the limited means of treating the individuals suffering from addiction. It is no coincidence that the places hit hardest by opioid addiction are also those with limited access to mental and behavioral health providers: rural America.

Rural regions in the United States are those with some of the lowest populations of psychiatric providers and addiction treatment counselors, but with some of the highest prevalence of opioid and alcohol addiction. Opioid and alcohol addiction have a high comorbidity with other mental health disorders, such as depression and anxiety. The combination has proven to overwhelmingly impact rural communities, with few options for treatment in the surrounding area.

However, telemedicine offers a viable solution to provider shortages, particularly with an eye towards mental health-care professionals. Telemedicine alone will not remedy the shortage of psychiatrists in the United States, but the technology does possess the capability of greatly increasing access to them. However, although there is not a substantial barrier to increasing access to therapy through telemedicine, a large driver of psychiatric care is provided through pharmaceutical treatments. The ability for providers to prescribe pharmaceuticals, particularly 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 enacted on Oct. 15, 2008 and was effective April 13, 2009. (The DEA issued interim final regulations on April 6, 2009, effective April 13, 2009.) The term "internet" is sufficiently broad under the Haight Act that it would be implicated under any fact pattern involving remote encounters between health-care providers and patients who are using telemedicine technologies.

The relevance of the Haight Act, a law that went into effect almost nine years ago, has been revitalized, but the opioid epidemic and advances in psychiatric treatment are now demonstrating the law requires clarification through amendment to improve access to pharmaceutical treatments and, in turn, increase access to mental health care.

II. Use of Telemedicine to Address Certain Key Issues

A. What Is Telemedicine?

"Telemedicine" is defined as "the use of medical information exchanged from one site to another via electronic communications to improve a patient's clinical health status." Telemedicine is not a separate medical specialty, but rather a tool in the delivery of care. Telemedicine includes three broad categories of technologies for the provision of patient care: 1) "Interactive Services," which refers to real time interaction between physician and patient, via phone, video chat or text for diagnosis, consultation, treatment, education and care management; 2) **"**Remote Patient Monitoring" captures the use of devices to remotely collect and send data to medical professionals for interpretation; 3) **"**Store-and-forward" refers to the collection and transmission of medical data, such as images, to a medical professional for assessment.

B. What Issues can Telemedicine Help to Address?

The U.S. is set to face a widespread shortage of physicians across specialties at a time when demand is continually rising. The lack of primary care physicians has been the center of discussion for years in the move to clinically integrated medicine, but the overall shortage is likely to particularly impact geriatric populations at a time when the US population is aging. Recent political developments are likely to further complicate physician supply.

Nearly 20% of Americans live in rural areas, but only 9% of physicians practice in rural settings. With such a shortage, nearly a fifth of the country must travel a substantial distance to get the care they need. Telemedicine offers nearly on-demand access to physicians, providing convenience and access to needed care. The technology is continuously being recognized for its ability to mitigate the shortage of providers in rural health markets, particularly within the field of primary care.

However, telemedicine's benefits may yet be best applied within the mental and behavioral health field. Psychiatrists are one of the most in-demand specialists in the country, and their shortage is likely to only increase with infrequent matches into residency programs. Psychologist prescribing laws remain scattered, with no consensus on how to proceed with giving various mental health providers access to prescribing psychiatric medications. Rural areas particularly suffer from the shortage of psychiatric providers, further increasing both non-reporting of mental health issues, and the lack of treatment.

The shortage in psychiatric providers in rural areas has only further complicated the resolution of the opioid epidemic sweeping the United States. Rural areas are amongst the hardest hit by opioid addiction. The aforementioned lack of providers makes it extremely difficult for those suffering from addiction to receive addiction treatment and counseling. When considering the comorbidity between mental illness and substance abuse disorders, this leaves rural areas particularly exposed to the challenges faced by the shortage of psychiatrists.

Telemedicine could play a substantial role in solving the shortage in mental health practitioners. Telemedicine offers the opportunity to pair the pool of psychiatrists in urban areas with individuals in need of treatment in rural areas. However, providing access to cognitive behavioral therapy may not be enough for those suffering from common mental health conditions such as bipolar disorder, general depression, and Generalized Anxiety Disorder. The need for pharmaceutical treatment is a foregone conclusion in cases as severe as schizophrenia and as common as attention deficit disorder, and prescription drugs are frequently a key component in the treatment of opioid addiction. Thus, the ability for telemedicine to be most beneficial as a tool and resource for the communities it is designed to help is dependent on the ability of a provider to remotely prescribe pharmaceuticals. However, the ability to remotely prescribe is limited at both the state and Federal level.

III. State and Federal Limitations on Remote Prescribing

A. Overview State Scope of Practice Restrictions on Prescribing

While the Haight Act is often the focus of compliance programs, in reality remote prescribing regulation is largely left to the states. Remote prescribing restrictions can be commonly found in telemedicine-specific statutes or regulations, pharmacy practice acts, medical practice acts, and in controlled substances acts themselves.

For example, Oklahoma requires a face-to-face encounter prior to prescribing any medication or using telemedicine to treat a patient. However, Oklahoma has become more of an exception than the rule, particularly in light of the substantial amount of progress telemedicine programs have made with legislatures in the past two years. Even Texas, whose Medical Board was embroiled in litigation with Teladoc for years concerning its telemedicine regulations, had an exception allowing for remote prescribing for mental health services without an in-person encounter throughout the time it restricted the use of telemedicine more generally. Overall, the state restrictions on telemedicine practice have generally eased, providing more navigable space to practice medicine using digital means.

B. Federal Controlled Substance Laws

1. Haight Act Requirements

a) Brief History

In 2001, Ryan Haight bought Vicodin through an online pharmacy via a prescription from a doctor he never met; he later overdosed on the opioid. Haight's overdose came at a time when online pharmacies were completely unregulated and the rampant abuse of pharmaceutical medications was beginning to come to light. The Haight Act sought to limit the use of the internet to obtain controlled substances—Schedule II substances like Vicodin—without a valid prescription.

The Haight Act specifically states that "no controlled substance that is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act may be delivered, distributed, or dispensed by means of the Internet without a valid prescription." The Haight Act defines a valid prescription as "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." 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 a portion of the evaluation is conducted by other health professionals.

b) Understanding the Actual Implications of the Haight Act

The Haight Act was written at a time when the modern application of telemedicine was still in its early stages and was intended to address online pharmacies that were prescribing medications in response to short questionnaire responses. Today, providers interact with patients using various kinds of advanced, interactive communication technologies and there is an enhanced focus on prescription drug monitoring to avoid abuse. That said, the Haight Act does not present a barrier to most telemedicine programs becoming a key part of the efforts to provide mental health treatment. The majority of pharmaceutical products for major depression, bipolar disorder, and Generalized Anxiety Disorder—the most common mental health issues in the US—are not controlled substances. This means that the prescription of an SSRI to treat depression using telemedicine, for example, is not subject to any restriction under Ryan Haight. There are a limited number of antipsychotics used in the treatment of schizophrenia that are Schedule IV drugs, but otherwise the Haight Act will not be the main barrier to prescribing pharmaceutical treatments for a wide range of mental illnesses.

c) Telemedicine Defined and Haight Act Exceptions

The Haight Act provides exceptions from the in-person examination requirements for the "the delivery, distribution, or dispensing of a controlled substance by a practitioner engaged in the practice of telemedicine." For an activity to qualify as the "practice of telemedicine," the following facts and circumstances must apply:

1. The practitioner is at a location remote from the patient;

2. The practitioner is communicating with the patient using a telecommunications system referred to in section 1395m(m) of title 42;

3. The telemedicine activity constitutes the practice of medicine and the practitioner is acting in the usual course of professional practice, in accordance with applicable Federal and State laws;

4. The practitioner is not a pharmacist and is authorized to prescribe controlled substances in the state in which the patient is located; and

5. One or more of the following facts and circumstances applies:

a. Covering Practitioner. The prescription is written by a "covering practitioner," which is a practitioner who has been invited by the patient's treating physician to treat the patient because the treating physician, who initially conducted an in-person medical evaluation or an evaluation of the patient through the practice of telemedicine within the previous 24 months, is "temporarily unavailable" to conduct the evaluation of the patient.

b. Physical Presence in DEA-Registered Facility. The telemedicine service is being conducted while the patient is being treated by, and physically located in, a DEA-registered hospital or clinic.

c. Physical Presence of DEA-Registered Practitioner. The telemedicine service is being conducted while the patient is being treated by, and in the physical presence of, a practitioner who is acting in the usual course of professional practice, acting in accordance with applicable state law and is DEA-registered to prescribe controlled substances in the state in which the patient is located. Some have argued that this is an expensive addition to the consultation and may be unnecessary for patient care.

d. Indian Health Service. The telemedicine service is being conducted by an employee or contractor of the Indian Health Service, or is working for an Indian tribe or tribal organization under its contract or compact with the Indian Health Service under the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450 et seq.), and such individual is acting within the scope of the employment, contract, or compact, has been designated as an Internet Eligible Controlled Substances Provider by the Secretary under Section 831(g)(2) of the Controlled Substances Act.

e. Public Health Emergency. The telemedicine service is being conducted during a public health emergency declared by the Secretary under Section 247d of Title 42, and such telemedicine activity involves patients who are located in such areas, and such controlled substances, as the Secretary, with the concurrence of the Attorney General, designates.

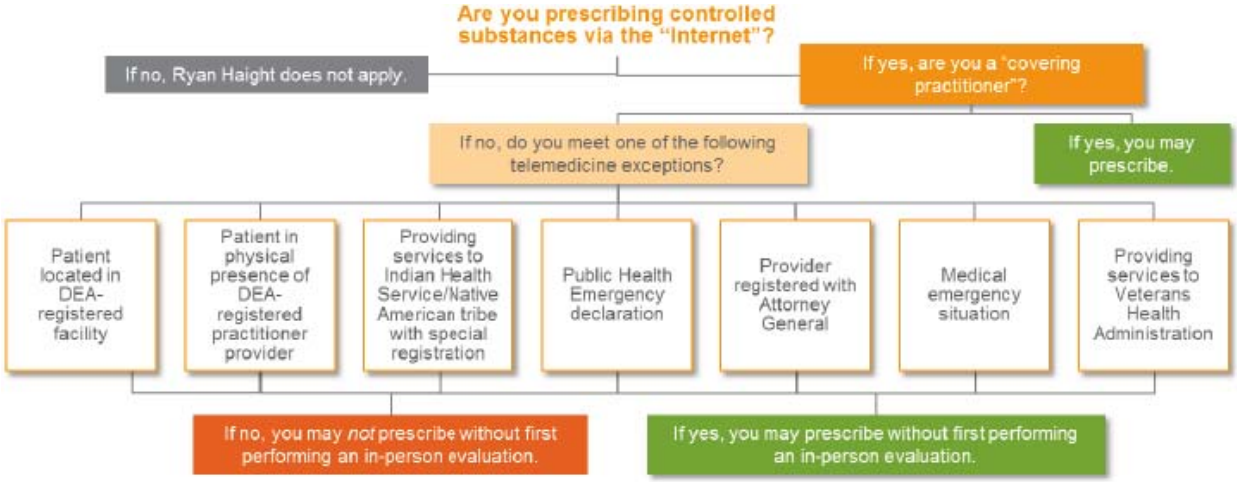
f. Special Registration. The telemedicine service is being conducted by a practitioner who has obtained from the Attorney General a special registration under Section 831(h) of the Controlled Substances Act. This exception has not been implemented, but the DEA has announced plans to develop and implement this telemedicine registration provision to practitioners to use telemedicine to prescribe controlled substances without performing an in-person examination in the spring of 2018.

g. Veterans Administration Medical Emergency. The telemedicine service is being conducted during a medical emergency situation that (i) requires immediate intervention by a health-care practitioner who is an employee or contractor of the Veterans Health Administration, (ii) who is using controlled substances to prevent what the practitioner reasonably believes in good faith will be imminent and serious clinical consequences, such as further injury or death, (iii) the medical emergency prevents the patient from being in the physical presence of a practitioner acting in the usual course of business and employment and within the scope of the official duties or contract of that employee or contractor.

h. Public Health and Safety. The telemedicine service is being conducted under any other circumstances that the Attorney General and the Secretary have jointly, by regulation, determined to be consistent with ensuring effective controls against diversion and otherwise consistent with the public health and safety.

The Haight Act's requirements make it nearly impossible for a practitioner to treat a new patient in his or her home, place of employment or at a clinic that lacks a pharmacy without first performing an in-person visit. In addition, the Haight Act makes it very difficult for medical groups to rotate patients between the different members of the practice or provide regular coverage for one another.

A decision tree can assist providers to determine whether an in-person examination is required.



2. Drug Addiction Treatment Act of 2002 ("DATA")

Opioid addiction is one of the few psychiatric disorders that requires a provider to "fight fire with fire." In looking specifically at the opioid epidemic, and the continued abuse and overdose prevalence of heroin, controlled substances play a significant role in treatment. Buprenorphine and naltrexone are two key pharmaceutical products used in the treatment of addiction; both are opioid derivatives. Buprenorphine is a Schedule III substance; naltrexone is a Schedule II substance. Under the Haight Act, neither substance can be prescribed without a physician-patient interaction first taking place in person. Further complicating prescribing of these two drugs through telemedicine is the Drug Addiction Treatment Act of 2002 ("DATA"). DATA importantly limits the number of patients to whom a practitioner can prescribe opioid-based medications for drug addiction treatment, specifically buprenorphine-based treatments such as Suboxone (buprenorphine plus naloxone), which means that even if a telemedicine program could adequately navigate the Haight Act and the state law requirements, supply limitations will continue to pose a problem.

These medications may be prescribed, administered, or dispensed for maintenance or detoxification treatment only by a practitioner who meets the definition of a "qualifying physician" as set forth in 21 U.S.C. § 823(g)(2) and who has applied for, and obtained from the DEA, a waiver under DATA 2000, with an assigned unique identification number (sometimes referred to as an "X-waiver" as the unique identification number consists of the physician's DEA number with an X appended to the end).

Under the waiver, qualified practitioners who file an initial Notification of Intent ("NOI") may prescribe certain of these key addiction treatment drugs for a maximum of 30 patients at a time. After one year, the practitioner may file a second NOI indicating his or her intent to prescribe buprenorphine for up to 100 patients at a time. Notably, on July 9, 2016, the Department of Health and Human Services promulgated a new final rule that modifies the regulations governing buprenorphine prescribing under the Section 303(g) "X-waiver" program (81 FR 44712). Effective August 8, 2016, under the new rule, practitioners who have had a waiver to treat 100 patients for at least one year could obtain approval to prescribe buprenorphine for up to 275 patients after submitting a "Request for Patient Limit Increase" to the Substance Abuse and Mental Health Services Administration, if they meet certain new heightened eligibility requirements. Allowing practitioners to prescribe anti-addiction medications to a higher number of patients has enabled practitioners to take on more patient cases, which has helped to meet patient demand; however, the strict rules surrounding the X-waiver program have intimidated some practitioners from submitting requests for limit increases.

IV. Compliance Considerations for Telemedicine Programs

Telehealth providers must design their programs to take into account the myriad state and federal laws and regulations that apply to the operation of a telemedicine program that involves the prescribing of controlled substances. Until the Haight Act is amended or the "special registration" pathway is implemented, telemedicine providers must continue to: (1) identify other potential prescription medications that are not classified as controlled substances to treat patients, if such option is available and appropriate; (2) partner with DEA-registered facilities to allow for patients to visit the facility in-person to receive telemedicine servicies; (3) arrange for DEA-registered providers to be physically present with patients during the telemedicine encounter; (4) arrange for the telemedicine provider to visit with the patient in-person before using telemedicine to provide future care; or (5) identify other potential solutions that provide patients with access to care.

Given the array of different state and federal rules that apply, telemedicine providers should continue to develop and implement a compliance program that includes policies, procedures and protocols that address compliance with the state and federal laws and regulations governing telemedicine programs, including remote prescribing rules. These policies, procedures and protocols should take into account the specific facts and circumstances applicable to the

telemedicine program, the patients who will receive telemedicine services, the types of telemedicine providers participating in the program, and the physical location of the patients.

V. Key Takeaways

- Remote prescribing laws are generally governed at the state level, not through the Haight Act, but in the event of a conflict between them, the stricter of the two controls.
- The Haight Act restricts the prescription of controlled substances using the "internet," which is broadly defined to encompass telehealth and its related technologies.
- While most psychiatric treatments using pharmaceuticals will not involve the use of a controlled substance, the treatment of addiction frequently requires the use of one.
- Telehealth providers should keep in mind the limited utility of the Haight Act exceptions in designing a compliance program, and remember that as it pertains to mental and behavioral health treatment, the majority of treatment options will be regulated at the state level, not through the Haight Act.
- The Haight Act would benefit from amendment to provide freedom for telemedicine providers to prescribe controlled substances in the appropriate circumstances, particularly for addiction treatment.

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