Telehealth Promises and Pitfalls: Remote Prescribing of Controlled Substances, the SUPPORT Act, and Remaining Risks

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The healthcare industry is in the midst of a historic transformation, as the ongoing proliferation of technological advancements continues to improve the quality of medical care, increasing patient access, and revolutionizing the practice of medicine in the United States. In the context of telemedicine, more specifically in relation to remote prescribing of controlled substances, the ability to capitalize on innovation has, thus far, been stifled in certain respects by the Ryan Haight Online Consumer Protection Act of 2008 ("Haight Act"). However, more recently, the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act ("SUPPORT Act") was signed into law with the promise to reduce the obstacles imposed by the Haight Act and better equip the medical community to fight the opioid epidemic. While the SUPPORT Act will likely give providers more flexibility in prescribing controlled substances via telemedicine, it is important to understand the regulatory barriers and risks that remain.

The Haight Act and the SUPPORT Act:

In 2008, Congress passed the Haight Act, named after an 18 year old who died after overdosing on prescription painkillers that he obtained online from a physician he had never met.[1] The Haight Act makes it "unambiguous that it is a *per se* violation of the CSA [(Controlled Substances Act)] for a practitioner to issue a prescription for a controlled substance by means of the internet without having conducted at least one in-person medical evaluation, except in certain specified circumstances."[2] One of the exceptions to the Haight Act allows the DEA to activate a "special registration" for certain providers who: (i) demonstrate a legitimate need for special registration; (ii) are registered to deliver, distribute, dispense, or prescribe controlled substances in the state where the patient is located; and (iii) maintain compliance with state and federal laws when delivering, distributing, dispensing and prescribing a controlled substance.[3]

Before providers could utilize the Special Registration exception to prescribe controlled substances over the internet, however, the DEA was required to promulgate regulations, establishing the limited circumstances in which a provider would be issued a special registration and the procedure for obtaining such special registration.[4] The language under the Haight Act did not mandate a deadline for the DEA to enact the Special Registration regulations, and, as a result, such action was never taken. The SUPPORT Act seeks to remedy this issue by requiring the Attorney General to issue the Special Registration regulations by October 24, 2019.[5]

Further, the SUPPORT Act, namely Section 3232 (the Special Registration for Telemedicine Clarification Act of 2018), was enacted to address the growing concern of access to mental health services, with an estimated 111 million Americans living in areas with limited access to mental health professionals.[6] Relatedly, legislators behind the SUPPORT Act believe that authorizing the remote prescribing of controlled substances could add one more tool to fight the opioid epidemic,

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as certain controlled substances are known to play a vital role in the treatment of opioid addiction, and the rural parts of the country with some of the highest incidence rates of opioid addiction are among the regions with the fewest mental health practitioners.[7] While it is nearly certain that by October 24, 2019, practitioners will have greater freedom to prescribe controlled substances to patients treated via telemedicine, the specific scope and limitations remain to be seen and may be dependent upon more than just the DEA's Special Registration regulations.

Interplay with State Laws:

While compliance programs often focus on the Haight Act in relation to prescribing policies, remote prescribing regulation is largely left to the states. Applicable prescribing restrictions may be found in telemedicine statutes and regulations; state examining board rules and regulations, including, but not limited to, pharmacy practice acts and medical practice acts; and state controlled substances acts. The federal CSA stipulates that state laws on the same subject matter (that would otherwise be within the authority of the state) are not preempted "unless there is a positive conflict between that provision of this subchapter and that State law so that the two cannot consistently stand together."[8] In other words, if challenged, state laws that prohibit remote prescribing of controlled substances altogether (or without a prior in-person examination) are likely to be preempted. Also subject to preemption, if challenged, are state laws that expressly authorize remote controlled substance prescribing without requiring the provider to meet, *at least*, the requirements set forth under the DEA's Special Registration regulations (once implemented). However, states that impose additional or different requirements on providers' ability to prescribe controlled substances online are likely to be upheld, so long as such laws and regulations may consistently stand together. For example:

- Most states prohibit controlled substance prescriptions based solely on the patient's completion of a medical questionnaire online or by telephone
- Numerous states authorize online prescribing of controlled substances if a valid physician-patient relationship has been formed (and some states further list the elements of a valid physician-patient relationship)
- Some states require a provider to obtain separate authorization from the state licensing board before such provider may prescribe controlled substances over the internet
- Many states place additional restrictions, depending on the condition for which the controlled substance is being provided (e.g., acute or chronic pain) or its intended effect (e.g., to cause an abortion)

Accordingly, after the issuance of the Special Registration regulations, providers must still ensure that their prescribing practices comply with state laws and regulations like those listed above, among others, as applicable. Further, it is important to understand that inconsistent state laws will only be subordinated to federal law to the extent related to online prescribing of *controlled substances*. States will retain control over all other prescribing practices. In other words, it may ultimately be the case that, depending on the state laws to which a provider is subject, the provider may prescribe controlled substances in accordance with the Special Registration regulations and other non-conflicting state laws, but such provider may not prescribe *other (non-controlled) prescription drugs* via telemedicine without a prior in-person examination, if at all. Provider practices and other healthcare entities must, therefore, maintain comprehensive compliance policies, incorporating not only the Haight Act (and Special Registration regulations, once effective),

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but also applicable state laws and regulations, noting, among other things, the different restrictions and requirements based on whether the prescription is for a controlled substance.

Remaining Risks:

In addition to the requirements of the to-be-issued Special Registration regulations and applicable state laws, healthcare providers must account for a number of other potential areas of risk—some of which may be heightened in the telemedicine/remote prescribing context, including, but not limited to, the following:

1. **Payor Coverage/Reimbursement:**

   Although states are increasingly enacting parity rules, whether in relation to Medicaid or commercial payors, and CMS has recently expanded the scope of coverage for certain telemedicine practices under the Medicare program and (potentially) Medicare Advantage plans, beginning in 2022, there are still serious limitations as to what telehealth practices are covered by a given plan and substantial variation among payors. Accordingly, in addition to the type of prescription drug, the drug's intended effect, and the condition at-issue, among the many other circumstances that may further restrict a provider's ability to prescribe controlled substances via telemedicine under federal and state law, providers must also consider the patient's insurance and the ever-changing conditions of coverage/reimbursement with respect to telemedicine.

2. **Malpractice:**

   Malpractice concerns may be heightened when prescribing controlled substances via telemedicine because, depending on the particular technology used, the provider may not be able to develop as much insight into the patient's condition and other relevant information when conducting telemedical consultations to the same extent as s/he may be able in person. However, most, if not all, states specify that providers are held to the same standard of care in relation to treatment via telemedicine as that of traditional, in-person treatment. Certain controlled substances may further heighten liability concerns, as providers could face liability for under-prescription, over-prescription, overdoses, and addiction. For example, in 2017, a St. Louis jury awarded $17.6 million to plaintiffs who brought a malpractice suit against a physician for overprescribing pain medication between 2008 and 2012.[9] Importantly, in addition to maintaining thorough documentation of patient monitoring and risk assessments, providers seeking to prescribe controlled substances remotely should confirm that their professional liability insurance coverage extends to what many policies describe as "distant care" and that coverage applies in every state in which the provider's patients are located.

3. **Fraud and Abuse:**

   It is projected that the global market value of telemedicine, currently at $29.6 billion, will continue to increase at a rate of 19% per year until 2022.[10] Such increased spending and the ever-evolving regulatory scheme governing telehealth and remote prescribing make such practices ripe for heightened fraud and abuse scrutiny. The first false claims case involving telehealth was brought in 2016 in connection with a mental health practice that allegedly submitted false claims to Medicare for certain services provided to patients via telemedicine.[11] The government alleged that the providers improperly submitted claims to Medicare for services rendered over the phone, explaining that, at the time:

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> Medicare permit[ted] certain types of "telehealth" services where the patient is in a rural health professional shortage area and where the provider uses an interactive audio and video communications system that permits real-time communication between the provider and the patient. However, the patients treated over the phone by DR. FRY and CPC ASSOCIATES were not located in rural health professional shortage areas and DR. FRY and CPC ASSOCIATES did not use interactive audio and video communications.[12]

Accordingly, it is important to understand the limits of Medicare's coverage and payment policies when providing services via telemedicine. Additionally, providers may be subject to false claims liability in connection with telehealth services provided in contravention of state and/or federal law, such as those described in the preceding sections. Finally, among many others, the practices described below have been identified by the DOJ as particularly suspect:

- Providing free or discounted telehealth equipment or software to individuals who may become patients or consumers of telehealth services
- Providing or offering telehealth-related funding or equipment to organizations that are actual or potential referral sources
- Offering telehealth services to organizations that are potential or actual referral sources and agreeing to refer telehealth patients preferentially to providers within these organizations for non-telehealth services

Conclusion:

Telemedicine's ability to truly reduce access barriers and allow mental health professionals to treat underserved populations suffering from opioid use disorder is dependent, at least in part, on a provider's ability to remotely prescribe controlled substances. We will likely continue to see further state and federal legislation in this space beyond the October 2019 Special Registration regulations mandated by the SUPPORT Act. Due to the potential lack of clarity and uniformity with such additional legislation, before introducing remote prescribing into provider practices, such providers must develop and implement compliance policies incorporating the applicable laws, regulations, and rules at both the state and federal level and highlighting areas of increased risk.

We will continue to monitor these issues at the state and federal level and will provide updates as needed. In the meantime, any questions may be directed to the Haynes Boone Healthcare and Life Sciences Practice Group.

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[1] 21 U.S.C. § 802(54).

[2] 21 U.S.C. § 829(e); DEA, Implementation of the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, 74 FR 15599-15603 (April 6, 2009).

[3] *Supra*, note 1.

[4] Congressional Research Service, *The Special Registration for Telemedicine: In Brief*, (December 7, 2018).

[5] *Id.*

[6] Congressional Research Service, *The Special Registration for Telemedicine: In Brief*, (December 7, 2018).

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[7] Medication-assisted treatment (MAT) combines behavioral therapy with one of three Food and Drug Administration (FDA)-approved medications—buprenorphine, methadone, or naltrexone— for the treatment of opioid use disorder (OUD). *See, e.g.*, American Society of Addiction Medicine, *The ASAM National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use* (2015); U.S. Department of Health and Human Services (HHS), *Addressing Prescription Drug Abuse in the United States: Current Activities and Future Opportunities* (2013); Substance Abuse and Mental Health Services Administration (SAMHSA), *In Brief, Rural Behavioral Health: Telehealth Challenges and Opportunities* (2016).

[8] 21 U.S.C. § 903.

[9] *Koon v. Walden*, 539 S.W.3d 752 (Mo. App. E.D. 2017).

[10] Reuters, *Global Telemedicine Market Size, Share, Major Players, Strong Application, Top Region, Industry Investment Analysis and 2022 Forecast Research Study*, (Accessed January 28, 2019).

[11] Press Release, United States Department of Justice, *Danbury Physician and Mental Health Practice Pay $36,000 to Settle False Claims Act Allegations,* (July 27, 2016).

[12] *Id.*

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