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ALERT

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Telemedicine Prescribing of Controlled Substances and the Ryan Haight Online Pharmacy Consumer Protection Act of 2008

Attorneys
Timothy M. McCrystal
Elizabeth M. Whitkin
Bessie Frías

As the COVID-19 federal public health emergency and its subsequent pandemic restrictions are set to end in May 2023, the future of telemedicine prescribing has become a central question for many physicians and consumers. The importance of this topic was recently highlighted on February 24, 2023 when the Drug Enforcement Agency (the "DEA") announced its proposed rules for post COVID-19 telemedicine prescription practices for controlled substances.

The backdrop for these regulations is the Ryan Haight Act Online Pharmacy Consumer Protection Act of 2008 (the "Ryan Haight Act"), which amended the Controlled Substances Act to establish guidelines for physicians prescribing controlled substances via online platforms and the practice of telemedicine. The Act imposes requirements on practitioners to engage in at least one in-person medical evaluation with a patient prior to providing an online prescription for a controlled substance, subject to certain exceptions.

How Did the COVID-19 Public Health Emergency Alter Telemedicine Prescribing Practices?

One such exception to the requirement for an in-person medical evaluation is when a federal public health emergency has been declared, such as the ongoing COVID-19 public health emergency. In response to the declaration of the public health emergency, on March 16, 2020, the Department of Health and Human Services provided that all practitioners authorized to dispense controlled substances in the United States would be allowed to prescribe Schedule II-V controlled substances to patients without having first conducted an in-person medical evaluation. To do so, practitioners would be required to satisfy the following conditions: (1) the prescription is issued for a legitimate medical purpose; (2) the telemedicine communication is conducted using an audio-visual, real-time, two-way, interactive communication system; and (3) the practitioner is acting in accordance with applicable federal and state laws. This exception or "waiver" remains in effect through the end of the COVID-19 public health emergency. These exceptions proved critical for providing continuity of care during mandated state lockdowns, as health care professionals could continue prescribing needed medication virtually uninterrupted.

Controlled Substance Prescribing after COVID-19

There has been widespread industry concern over what the expiration of the COVID-19 public health emergency would mean for telemedicine prescribing of controlled substances as the in-person medical evaluation requirement of the Ryan Haight Act would again apply to most telemedicine encounters. Specifically, there has been concern that the expiration of the waiver will lead to disruptions in care, particularly for vulnerable populations who have come to rely on telemedicine prescribing of controlled substances for behavioral health and substance use disorder treatment.

The DEA's proposed rules of February 24, 2023, seek to address this concern and would add increased flexibility to the current telemedicine prescribing regime under the Ryan Haight Act in certain circumstances, though the rules are significantly more restrictive than current practices under the COVID 19 waiver.

The Proposed Rules

The proposed rules apply to telemedicine prescribing of Schedule III-V non-narcotic controlled medications (88 FR 12875) and Schedule III-V narcotic controlled medications approved by the Food and Drug Administration for the maintenance or detoxification treatment of opioid use disorder, which, at this time, includes only buprenorphine (88 FR 12890). The proposed rules apply only in "limited circumstances when the prescribing practitioner wishes to

prescribe controlled medications via the practice of telemedicine and has not otherwise conducted an in-person medical evaluation prior to the issuance of the prescription" and would allow for the prescription of a 30-day supply of such controlled medications without an in person evaluation, provided that the prescription otherwise complies with applicable state and federal law. Importantly, the personal performance of an in-person medical evaluation by the prescribing practitioner or the receipt of a qualifying telemedicine referral (described in more detail below) is required *before* any prescription of Schedule II controlled substances or narcotic controlled substances other than buprenorphine may be issued.

To prescribe Schedule III-V non-narcotic controlled medications or buprenorphine beyond the initial 30 days, an in-person medical evaluation must be completed in one of three ways: 1) the prescribing practitioner may personally perform an in-person medical evaluation of the patient (*i.e.*, in the physical presence of the patient); 2) through a virtual process whereby a different DEA-registered practitioner acting in the usual course of his or her professional practice conducts an in-person medical evaluation of the patient while participating in a two-way, simultaneous, audio-visual teleconference with the prescribing practitioner; or 3) through a "qualifying telemedicine referral" whereby a different DEA-registered referring practitioner who has performed an in-person evaluation of the patient then refers the patient to the prescribing practitioner, communicating the results of the medical evaluation—including any diagnosis, evaluation, or treatment—to the prescribing practitioner prior to the prescribing practitioner issuing a prescription. The proposed rules also contemplate a six-month transitional period to facilitate the adjustment of doctor–patient telemedicine relationships established during the COVID-19 public health emergency to the telemedicine relationships that would be required under the new proposed rules.

The proposed rules also require prescribing practitioners, prior to issuing a prescription, to review recent prescription drug monitoring program ("PDMP") data regarding controlled mediation prescriptions issued to the patient in the prior year. Several recordkeeping requirements would also apply to prescribing and referring practitioners.

The proposed rules are open to public comment for 30 days (through March 26, 2023).