Publisher: Day Pitney Alert
February 26, 2025

New Telehealth Controlled Substances Rules Released

March 18 deadline for comments on state registration for telehealth controlled substances prescribing remains unchanged in newly released DEA and HHS rules

Overview

Less than a month after the Drug Enforcement Administration (DEA) and Department of Health and Human Services (HHS) published two final rules and one proposed rule regulating the remote prescribing of controlled substances via telemedicine, they have already announced changes. On February 19, the DEA and HHS decided to delay the effective date of the final rules from February 18 to March 21, due to the change in presidential administrations and President Donald Trump's "Regulatory Freeze Memorandum." The February 19 publication, however, does not affect other rules and proposals in this space that have been previously published, including the DEA and HHS' newly proposed special registration system for telemedicine prescribers and companies — whose comment period is open until March 18 — or the "Third Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications," which has been in effect since May 10, 2023, and whose extension permits practitioners to prescribe controlled substances via telemedicine through the end of 2025.

Regulatory Update

First, the effective date of the final rules "Expansion of Buprenorphine Treatment via Telemedicine Encounter" and "Continuity of Care via Telemedicine for Veterans Affairs Patients," published under the Biden administration on January 17, has been delayed from February 18 until at least March 21, or the end of the 60-day regulatory freeze. In the interim, the DEA and HHS also announced a new comment period, ending February 28, "to allow interested parties to provide comments about issues of fact, law and policy raised by the [postponed] rules…and allow Department of Justice and [HHS] officials further opportunity to review any potential questions of fact, law and policy raised by those two final rules."

As a reminder, the buprenorphine rule provides patients with remote access to buprenorphine, the medicine used to treat opioid use disorder, and implements a change that allows patients to receive a six-month supply of buprenorphine through a telephone consultation with a provider before needing an in-person visit to their own buprenorphine provider. The other final rule released on January 17 was "Continuity of Care via Telemedicine for Veterans Affairs Patients," which exempts U.S. Department of Veterans Affairs (VA) practitioners from any future requirements of the proposed special registration system. Instead, the continuity of care rule says that once a VA patient has received an in-person medical exam from a VA medical practitioner, their provider-patient relationship is extended to all VA practitioners, including those who engage in telemedicine with the patient.

While the buprenorphine treatment expansion has generally been seen as a positive change, some of the virtual-only providers who have proliferated over the past few years say the rule doesn't make a lot of sense without the DEA and HHS finalizing the special telehealth registration framework for prescribing all controlled substances via telemedicine that they

proposed on January 17. Without that system, a buprenorphine telemedicine patient other than a VA patient being treated by a VA provider is still required to have an in-person visit with their provider after six months, at which point the DEA and HHS' special registration proposal may not yet be finalized.

Second, and as alluded to, the access to buprenorphine and VA patient final rules were part of a set of three rules released on January 17, which included as its third component a proposed special telemedicine registration framework, whose first DEA proposal dates to March 2023. The DEA and HHS received more than 38,000 comments on that rule, which has led them to rework the proposed special registration system. It also led to their peeling the buprenorphine rule and VA patient rule off as rules for which significant work had been done — work that Biden's DEA did not want to lose before it handed over the agency on January 20. Now, with the January 17 publication of the "Special Registrations for Telemedicine and Limited State Telemedicine Registrations" proposed rule, the new special registration system was reformed by the DEA to allow more comprehensive prescribing of Schedule II and narcotic and non-narcotic controlled substances via telemedicine. It will permit a patient to receive prescribed medications through telemedicine visits without ever having an in-person evaluation from a medical provider. And it contains protections to prevent and detect diversion of those substances while introducing three types of special registrations for telemedicine:

- *Telemedicine Prescribing Registration*, which authorizes clinician practitioners qualified to prescribe Schedule III-V controlled substances via telemedicine;
- *Advanced Telemedicine Prescribing Registration*, which authorizes qualified, specialized clinician practitioners to prescribe Schedule II-V controlled substances via telemedicine (when the medical practitioner is board-certified as a psychiatrist, hospice care physician, physician rendering treatment at a long-term care facility or pediatrician for the prescribing of medications identified as the most addictive and prone to diversion to the illegal drug market); and
- *Telemedicine Platform Registration*, which authorizes covered online telemedicine platforms ("online platforms that facilitate connections between patients and medical providers that result in the prescription of medications") to dispense Schedule II-V controlled substances.
    - This is the first time such telemedicine platforms will be required to register with the DEA and is the direct result of the DEA's observations during the pandemic that "some unscrupulous medical providers on online platforms have used flexible telemedicine rules to put profit ahead of the well-being of patients."

Falling into any of these categories makes a person or an entity a "special registrant," with special registrants being required by the proposal to maintain a *State Telemedicine Registration* for each state in which the registrant provides services. Those state registrations would be issued by the DEA via a "streamlined" application process and would be valid for three years. Any medication prescribed through such a special registrant would have new recordkeeping requirements, including that they be prescribed through electronic prescribing for controlled substances and only after an identity and a nationwide prescription monitoring program check becomes required three years into the program. Until then, registrants have other administrative legwork to do to confirm the patient's state and any other state with a prescription monitoring program reciprocity agreement with either the patient's or registrant's state. Under each iteration of the system, individual and platform registrants will be assigned identifying numbers for both their special and state registrations, both of which must be included when writing and fulfilling a "special registration prescription." Pharmacies will use those identifying numbers to confirm whether the prescribing clinician and the facilitating platform practitioner are authorized to prescribe and dispense controlled substances under this special registration framework.

The DEA is seeking public comment on additional medical specialists who should be authorized to issue Schedule II medications; additional patient protections for the prescribing of Schedule II medications by telemedicine, including whether

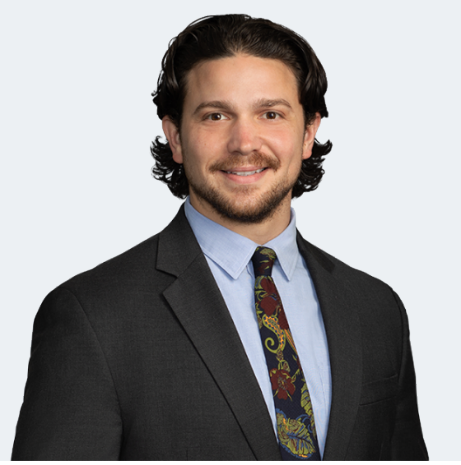
the special registrant should be physically located in the same state as the patient being prescribed the Schedule II medication; whether to limit Schedule II medications by telemedicine to medical practitioners whose practice is limited to less than 50 percent of prescriptions by telemedicine; and the appropriate duration needed for the rules' provisions to be enacted. Comments are due on this proposed special registration system on or before March 18, a date that is unchanged by the February 19 announcement.

Third and finally, although the February 19 announcement does reference the DEA and HHS' third extension of the "Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications," it does so to underscore that the extension is unchanged by the February 19 announcement, and thus notwithstanding a delay in the implementation of the buprenorphine treatment telemedicine rule, with the announcement stating that the "new effective dates will not delay or limit the ability of the practitioners covered by these two rules to prescribe via telemedicine, because the [extension…is] in effect [and] permits practitioners to prescribe via telemedicine through December 31, 2025."

Conclusion and Takeaways

These interrelated developments in this long-standing effort to make permanent the pandemic public health emergency's telemedicine flexibilities underscore not only the evolving regulatory landscape for telemedicine prescribing but also how that landscape has been and may continue to be affected by the change in presidential administrations. That landscape, of course, also includes state laws and their interactions with federal telehealth rules, particularly around what is necessary to establish a patient-provider relationship via telemedicine, as is generally necessary to prescribe, regardless of treatment modality, or state scope of practice limitations. If you provide telehealth services that include prescribing controlled substances, we encourage you to review the revised deadlines, consider submitting comments, and conceptualize or begin to implement compliance actions where appropriate. Day Pitney's healthcare attorneys are actively advising clients in this area and are available for questions.

Authors



Damian J. Privitera

Counsel

Hartford, CT | (860) 275-0200

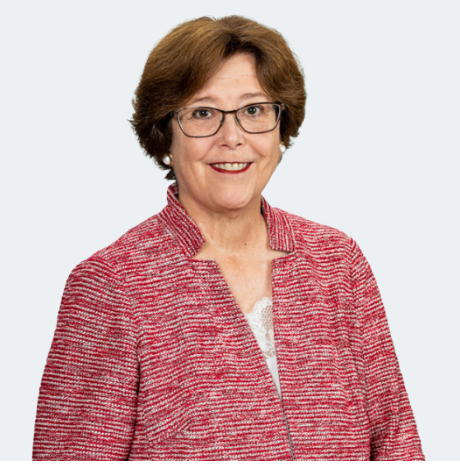
dprivitera@daypitney.com

William J. Roberts

Partner

Hartford, CT | (860) 275-0184

wroberts@daypitney.com



Susan R. Huntington

Partner

Hartford, CT | (860) 275-0168

Washington, D.C. | (202) 218-3909

shuntington@daypitney.com