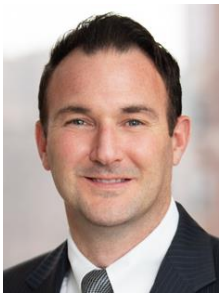
How Telemedicine Providers Can Adapt To Post-COVID Rules

By **Chris Eades and Mayo Alao** (June 2, 2023, 5:50 PM EDT)



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On May 10, just before the expiration of the federal COVID-19 public health emergency, the U.S. Drug Enforcement Administration and the Substance Abuse and Mental Health Services Administration — referred to jointly as the DEA — issued a rule temporarily extending the COVID-19 telemedicine flexibilities for prescribing controlled substances beyond the expiration of the public health emergency.[1]

Health care providers who have come to rely upon the flexibilities should understand the limitations set forth in the temporary rule and utilize this brief reprieve to prepare for what will likely be significant changes in the final permanent rules for prescribing through telemedicine.

In order to fully appreciate these considerations, it is important to understand the DEA's rules before the pandemic, during the public health emergency and what has been proposed post-public health emergency.

Prepandemic Regulation of Telemedicine Prescribing

Federally, the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 establishes the baseline requirements for prescribing controlled substances.[2]

The RHA generally requires that a provider perform at least one in-person medical examination of a patient prior to prescribing a controlled substance to that patient.

The RHA provides a few narrow exceptions for telemedicine; however, the primary exceptions are limited to scenarios when patients are physically treated within a DEA-registered hospital or clinic, in the physical presence of a DEA-registered provider.

These telemedicine exceptions do not generally capture treatment of the patient while that patient is at home or some other location.

Notably, though, the RHA also required the attorney general to promulgate regulations implementing a special registration for telemedicine to facilitate its expanded use to prescribe controlled substances without an in-person exam.[3]

When after several years this had not occurred, Congress subsequently enacted legislation requiring the DEA to issue final regulations for this special registration by October 2019.[4]

This date also came and went without any new rules — to the great dismay of providers and telemedicine stakeholders who eagerly awaited expansion of the RHA. Then, less than six months later, the world changed.

COVID-19 Public Health Emergency and Telemedicine Flexibilities

In March 2020, to aid in responding to the declared public health emergency, the DEA

invoked its emergency authority under Title 21 of the U.S. Code, Section 802(54)(D), to waive the requirement that telemedicine controlled substances prescriptions be predicated on an in-person physical examination of the patient.[5]

This permitted DEA-registered providers to issue controlled substance prescriptions to patients for whom they had not conducted an in-person medical evaluation during the public health emergency, so long as:

- The prescription was issued for a legitimate medical purpose by a provider acting in the usual course of his/her professional practice;

- The telemedicine communication was conducted using an audio-visual, real-time, two-way interactive communication system; and

- The provider was acting in accordance with applicable federal and state law.

Initially, providers utilized these flexibilities out of necessity due to the lockdowns, moratoria on elective procedures and other restrictions limiting in-person health care. But as the pandemic became more endemic, many providers looked to these flexibilities as a means to expand access to care more broadly, operationalizing and deploying telemedicine strategies that heavily relied on the flexibilities.

This has been especially true in particular clinical service areas, such as behavioral health and medication-assisted treatment, where the use of the telemedicine initiated prescriptions has, by nearly all accounts, dramatically increased access to critical health care services.

Thus, when the Biden administration announced that the public health emergency would end,[6] there was considerable angst among providers who had been relying on these flexibilities for more than three years.

At that point, the DEA had still not yet published any regulations to make the flexibilities permanent or otherwise expand the ability to use of telemedicine to prescribe controlled substances in the absence of a public health emergency.

Absent such rules, providers were faced with a return to the RHA, in its current form, which would represent a dramatic departure from the flexibilities and significant uncertainty in relation to the many patient relationships that had been established via telemedicine during the course of the pandemic.

Still, despite the benefits of expanded telemedicine prescribing, many stakeholders have expressed legitimate concerns regarding unsafe prescription practices, as well as potential fraud and abuse. This is particularly true in relation to business models where relevant clinical pathways fail to ensure that a bona fide medical evaluation is performed through telemedicine prior to issuing a controlled substance prescription.

Indeed, during the pandemic, the U.S. Department of Justice announced enforcement activity that resulted in charges involving over $1.4 billion in alleged losses, most of which

stemmed from false claims and fraudulent schemes involving telemedicine, sober homes, and illegal prescriptions and distribution of opioids.[7]

DEA Proposed Permanent Telemedicine Prescribing Rules

Ultimately, on March 1 this year, less than three months before the public health emergency was scheduled to expire, the DEA published two separate but related proposed permanent rules pertaining to controlled substance telemedicine prescriptions.

The proposed permanent rules, which were subject to an accelerated 30-day notice-and-comment period, are intended to expand the ability to prescribe controlled substances through telemedicine, but in a manner that is balanced against concerns relating to fraud, abuse and dangerous medical practices.

The first rule addresses telemedicine prescribing more generally,[8] while the second rule focuses on telemedicine prescriptions for buprenorphine used in medication-assisted treatment for substance use disorder.[9]

If implemented, these rules would expand the ability to prescribe controlled substances through telemedicine, subject to particular limitations related to type and quantity of medication, strict record-keeping practices and other related requirements. Stated differently, the proposed permanent rules are not a simple adoption of the DEA's flexibilities.

Specifically, the proposed permanent rules would effectively establish three new pathways to prescribe controlled substances through telemedicine: (1) telemedicine prescriptions following a qualifying telemedicine referral, (2) telemedicine prescriptions provided absent a qualifying referral and (3) telemedicine prescriptions provided to established patients during a 180-day transition period.

These pathways would be in addition to, and do not otherwise affect, the telemedicine exceptions currently set forth in the RHA. The proposed permanent rules establish general requirements relevant to all three pathways, as well as more specific requirements and limitations that are unique to each particular pathway.

By way of example, the following requirements would generally apply to all three pathways:

- All telemedicine prescriptions must comply with all other applicable state and federal laws and regulations, including all state-specific licensure requirements, CSR requirements, prescription limitations and scope of practice requirements.

- The prescription must be identified as a telemedicine prescription.

- The telemedicine prescription must follow a telemedicine encounter facilitated through an interactive telecommunication system — which generally requires the use of synchronous audio and video technology, with a limited exception made for mental health treatment.

- The telemedicine prescriber must maintain DEA registration where the prescriber is physically located when conducting the encounter.

- The telemedicine prescriber must be located in the U.S., or a U.S. territory, at the time of the encounter.

- The telemedicine prescriber must query the pertinent Prescription Drug Monitoring Program as directed in the rule.

- The telemedicine provider must comply with significant record-keeping obligations, which include particular content requirements. These records, and all associated detail, must then be available at the location where the telemedicine provider maintains DEA registration.

Additionally, the following requirements and limitations would apply to each respective permitted pathway:

Qualified Telemedicine Referral

A telemedicine prescription would be permitted following a qualifying telemedicine referral. A qualifying telemedicine referral involves a formal documented referral to a telemedicine provider that is predicated upon an existing relationship between a referring provider and a patient — where the referring provider has conducted at least one in-person physical evaluation of the patient.

Following a qualifying telemedicine referral, a prescribing provider would be permitted to prescribe any Schedule II-IV medication, without any particular quantity or refill limitations, subject to particular record-keeping and communication obligations related to the referral.

Telemedicine Prescription Without a Qualifying Referral or Prior In-Person Exam

Providers would be permitted to continue issuing prescriptions for controlled substances even when there has been no qualifying referral and no prior in-person exam subject to the following limitations:

- Strictly limited to a 30-day supply of only Schedule III-IV controlled substances;

- No prescriptions for opioids or Schedule II substances, except for buprenorphine prescriptions for opioid dependence if in compliance with other applicable state and federal law; and

- The prescribing provider would not be permitted to refill the medication, unless the patient subsequently undergoes a qualifying examination.

180-Day Transition Period

The proposed permanent rules would permit providers to continue issuing telemedicine prescriptions, for up to 180 days following the conclusion of the public health emergency, within the context of provider-patient relationships that were appropriately established during the public health emergency and that involved a prior controlled substance prescription via telemedicine, provided that the provider complies with all other applicable laws.

Note, however, this particular pathway has now been preempted by the DEA's temporary rule. It is nevertheless worth noting because, like the temporary rule that preempts it, it is preconditioned on a relationship having been appropriately established during, and not after, the defined time period.

DEA's Temporary Rule

In response to the proposed permanent rules, the DEA received more than 38,000 comments — all of this during the accelerated 30-day notice-and-comment period.

In order to permit the DEA additional time to consider these comments, and also to allow providers more time to realistically transition to a practice pattern more consistent with the proposed permanent rules, the DEA published a temporary rule to temporarily extend current flexibilities for prescribing controlled substances beyond the termination of the public health emergency.

The DEA published this temporary rule on May 10, just one day before the expiration of the public health emergency.

The temporary rule contains two key elements:

First, the temporary rule extends the flexibilities for an additional six months following the end of the public health emergency, through Nov. 11.

Second, the temporary rule permits the continued reliance upon those flexibilities for an additional 12 months thereafter. However, this grace period is strictly limited to provider-patient relationships that were appropriately established on or before Nov. 11.

Much like the proposed permanent rule's original 180-day transition period, in order to qualify, a provider-patient relationship must have been established through telemedicine and must have involved a prior controlled substance prescription during the qualifying period.

If a provider and patient have appropriately established such a relationship on or before Nov. 11, the same flexibilities that have governed the relationship will continue to be permitted until Nov. 11, 2024.

Following this date, however, the extended flexibilities will no longer be available.

Considerations for Telemedicine Providers

The temporary rule should provide the DEA with sufficient time to fully evaluate the extensive public comments to the proposed permanent rules and implement a final set of regulations permitting the practice of telemedicine under circumstances that are consistent with public health and safety, while maintaining effective controls against diversion.

Similarly, providers who have come to rely upon the flexibilities should take advantage of this additional time to consider implications for practice patterns potentially affected once the temporary extension expires. In particular, providers should consider the following:

Anticipate final rules and prepare for transition.

Given that the initial six-month grace period afforded by the temporary rule runs through Nov. 11, we expect that the DEA's final rules will be published before this date.

We also anticipate there is a high likelihood the final rules will retain many, if not all, of the requirements in the proposed permanent rules related to qualifying and nonqualifying telemedicine referrals.

As such, providers should utilize this additional time to digest the detailed requirements in the proposed permanent rules to determine how and which practice patterns may be affected.

Providers would also do well to proactively consider implementing certain of these requirements into regular practice — such as compliance with the detailed record-keeping requirements and Prescription Drug Monitoring Program query requirements.

Providers should also closely monitor for the DEA's final rules, once they are issued, as it will be critical that providers are situated to promptly comply with the same.

Consider state-specific prescribing limitations.

The RHA and its implementing regulations merely establish baseline requirements for controlled substance prescribing practices. It is also critical that providers ensure their prescribing practices comply with applicable state law, which in some instances may be more stringent than the DEA requirements.

For example, Arkansas does not permit providers to prescribe controlled substances without first seeing the patient for an in-person exam, except in certain limited circumstances,[10] and Indiana prohibits the use of telemedicine to prescribe opioids other than partial agonists used to treat opioid dependence.[11]

Given that telemedicine practice often involves the treatment of patients in different states, it will be critical for providers to be aware of, and comply with, state-specific prescription rules and prohibitions — in addition to the other variable telemedicine practice rules from state to state.

Establish appropriate patient visits.

To the extent it is medically appropriate and otherwise lawful, providers would do well to timely schedule patients during the extended period afforded by the temporary rule. As

noted above, establishing appropriate provider-patient relationships during this period will allow for additional flexibility moving forward.

Similarly, providers should consider the more general requirements of the RHA and proposed permanent rules in relation to the need for in-person examination. To the extent in-person examination will be required, providers should plan now for such a change in order to avoid any problematic lapses in care once the temporary flexibilities expire.

Develop broader virtual care compliance plans.

While the DEA's rules specifically apply to the practice of telemedicine as it relates to controlled substances, in many respects, the pandemic provided an opportunity for the industry to reevaluate how telemedicine is used and regulated, both on the state and federal levels.

We have seen significant legislation and rulemaking at all levels bearing on telemedicine practice. It is critical for telemedicine providers and entities to consider: (1) what telemedicine services they desire to provide and/or receive; (2) whether such clinical services can be provided within the requisite standard of medical care; (3) where patients and providers will be physically located when these services are provided; and (4) what federal and state rules, requirements, limitations and guidance may apply.

Once these essential concepts are vetted, telemedicine providers and entities should then develop legal compliance strategies, policies and procedures, incorporating appropriate guardrails, which account for these particulars.

Given that telemedicine prescribing is often material to these legal compliance considerations, it would be wise to develop these legal compliance strategies now — during the additional time period afforded by the temporary rule — and then modify as needed depending on any modifications to the proposed permanent rules.

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[1] Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Medications, 88 Fed. Reg. 30,037 (May 10, 2023).

[2] Ryan Haight Online Pharmacy Consumer Protection Act of 2008, Pub. L. No. 110-425, 122 Stat. 4820 (2008).

[3] 21 U.S.C. § 831(h) (2022).

[4] SUPPORT for Patients and Communities Act, Pub. L. No. 115-271, § 3231-32, 132 Stat. 3893, 3949-50 (2018).

[5] Letter from William T. McDermott, Assistant Adm'r, Diversion Control Div., to DEA Registrants (Mar. 25, 2020) (on file with the Dep't. of Justice Diversion Control Div.); Letter

from Thomas W. Prevoznik, Deputy Assistant Adm'r., Diversion Control Div., to DEA Qualifying Practitioners and DEA Qualifying Other Practitioners (Mar. 31, 2020) (on file with the Dep't. of Justice Diversion Control Div.).

[6] Letter from Xavier Becerra, Secretary, Dep't. of Health and Human Serv. to U.S. Governors (Feb. 9, 2023) (on file with the U.S. Dep't. of Health and Human Serv.).

[7] National Health Care Fraud Enforcement Action Results in Charges Involving over $1.4 Billion in Alleged Losses, Dept. of Just. (Sept. 17, 2021), https://www.justice.gov/opa/pr/national-health-care-fraud-enforcement-action-results-charges-involving-over-14-billion.

[8] Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation, 88 Fed. Reg. 12875 (proposed Mar. 1, 2023).

[9] Expansion of Induction of Buprenorphine via Telemedicine Encounter, 88 Fed. Reg. 12890 (proposed Mar. 1, 2023).

[10] Ark. Admin. Code § 007.29.1-38 (2022).

[11] Ind. Code Ann. § 25-1-9.5-8 (2022).