Rebalancing Controlled Substance Regulations in Telemedicine
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Regulations for prescribing controlled medications via telehealth, established by the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (Ryan Haight Act), were relaxed to improve access to care in the setting of the COVID-19 pandemic. The Ryan Haight Act—in most circumstances—requires patients to have at least 1 in-person medical evaluation before they can be prescribed controlled substances via telehealth. Flexibilities, established during the Public Health Emergency (PHE) by federal entities, particularly the Drug Enforcement Agency (DEA) and the Department of Health and Human Services (DHHS), allowed prescribing of controlled substances based on telehealth evaluation without any in-person evaluation. In anticipation of the PHE's expiration on May 11, 2023, the DEA released 2 proposed rules in March 2023 that received a robust public response. Consequently, the DEA and DHHS issued a 6-month extension of PHE flexibilities—now set to expire on November 11, 2023—and a subsequent 1-year grace period for compliance with the new rules.

Although re-enforcement of the Ryan-Haight Act is unsurprising, the DEA confronts new realities: many patients, clinicians, and insurers have embraced telemedicine to expand access to care, but others have raised concerns. Practices at some telehealth companies, which as an industry in 2021 acquired nearly $18 billion of equity funding, have produced reason for mistrust, including reports of overly liberal prescribing at Cerebral and Done Health, leading to US Department of Justice investigations for possible violations of the Controlled Substances Act, and distribution of private health information to advertisers by BetterHelp, resulting in Federal Trade Commission intervention. In this article, we aim to elucidate major components of the proposed rules, highlight evolving considerations with the DEA's approach, and offer potential improvements before finalization.

Reviewing the DEA's Approach

One of the proposed rules ("the first rule" for conciseness) specifically addresses in-person patient visit requirements for prescribing nonnarcotic Schedules III through V controlled medications. In summary, it requires that patients complete an in-person evaluation by the telemedicine practitioner or another DEA-registered practitioner (ie, nurse practitioner, physician assistant, and others permitted to obtain a registration under Form 224). Most important, it states that on initial encounter, telemedicine practitioners may prescribe patients up to a 30-day supply of nonnarcotic Schedules III through V controlled medications. Beyond this point, the practitioner must see the patient for an in-person medical evaluation, complete a surrogate in-person medical evaluation via simultaneous observation of another DEA-registered practitioner conducting the patient's examination, or have the patient receive a face-to-face evaluation from a DEA-registered practitioner who subsequently writes a qualifying telemedicine referral. The DEA explains that narcotics and Schedule II controlled medications, including stimulants, are not covered in the rule because they pose undue risks to public safety. Thus, they cannot be prescribed on the basis of an initial telemedicine encounter but could be prescribed after receipt of a qualifying telemedicine referral.

The other proposed rule ("the second rule" for conciseness) imposes in-person evaluation requirements identical to those in the first rule (eg, 30-day limited supply) for buprenorphine for the strict purpose of opioid use disorder (OUD) treatment, specifically, maintenance or detoxification treatment. An exception is made for buprenorphine because of its considerable effectiveness in OUD
treatment, setting it apart from other narcotics. In both rules, the DEA mandates review of Prescription Drug Monitoring Program information and strict recordkeeping requirements.2

Challenges and Considerations

Balancing the need for access with the need for appropriate prescribing and consideration of medical comorbidities is a complex challenge. Controlled substances, by their nature, present increased risks of misuse and dependence and, like all medications, can cause serious and fatal adverse effects. In-person medical examination can reduce risks with controlled substances by ruling out medical causes of symptoms, assessing risks from potential adverse effects, and augmenting assessment beyond audio or video conferencing alone. There are many circumstances in which telemedicine and in-person care have been considered comparable, but this assessment is still an active area of study.

In keeping with its directive to protect public health, the DEA seeks to limit diversion resulting from inappropriate prescribing. The DEA's published rationale for the temporary extension of PHE flexibilities cites concerns over disruption of care continuity and inadvertent spurring of telehealth companies to engage in problematic practices.3 Overall, the DEA's approach represents an earnest effort to rebalance regulations, although further refinements should be considered.

The requirement for an in-person evaluation may inadvertently exacerbate care disparities: many patients living in rural and underserved areas who are prescribed controlled substances are forced into an environment similar to that before prescribing requirements under the PHE were relaxed. Nonetheless, ensuring patients receive physical consideration for symptoms and potential adverse effects may also improve care quality. The extension of PHE flexibilities and the subsequent 1-year grace period help mitigate concern over disrupting care continuity.

Survey data from 2022 indicate that the average appointment wait time for family medicine physicians across major US metropolitan areas is 20.6 days, with the longest being 136 days,5 but the data do not include wait times from all possible DEA-registered practitioners. Thus, the proposed transition period length seems acceptable; however, only 59% of surveyed offices accept Medicaid.5 In light of this, the DEA could consider adapting the transition period depending on key patient characteristics—for example, insurance status and residence in rural or underserved areas.

More generally, the first rule dictates that telemedicine referrals must indicate a specific practitioner to whom the patient is being referred. For patients already being prescribed controlled substances through telemedicine, a clinician who conducts an in-person evaluation can provide a referral back to the clinician who currently manages a patient's conditions. However, for patients who are newly seeking to connect with a telemedicine practitioner, it is unclear how determination of a specific practitioner will work operationally. Oftentimes, only after patients complete the company's screening procedures are they assigned to a clinician. The extent to which in-person practices have developed adequate telemedicine referral networks or that telehealth companies are willing to adapt their internal procedures accordingly is unknown. Discrepancy between clinical practice and this part of the requirement poses a care-continuity risk. The DEA should issue practical guidance to help facilitate a straightforward transition for patients.

The second rule attempts to strike a balance between the risk of buprenorphine diversion and the benefits of its appropriate use. However, the DEA's argument for limiting access primarily cites examples of physicians unscrupulous in their medical practice. Simultaneously, the nation is in the midst of an opioid crisis, with a more than 6-fold increase in opioid-use deaths since the turn of the century6 and with far too few clinicians who are able and willing to treat OUD with lifesaving medications such as buprenorphine.7 As a result of telehealth flexibilities under PHE, many patients with OUD were, fortunately, able to initiate or maintain treatment with medications. Benefits of these policies were demonstrated in a study of Medicare beneficiaries that found receipt of OUD-related telehealth services was associated with lower odds of medically treated overdose and higher odds of improved medication retention.8 Moreover, illicit use of buprenorphine is more common for managing opioid withdrawal (related to inadequate dosing or difficulty connecting with
a buprenorphine-prescribing clinician) and maintaining abstinence from other opioids rather than for abuse. Thus, the rule’s requirement for in-person evaluation within 30 days of initial telemedicine encounter may place patients at potential risk of treatment lapse. We recommend that the DEA amend the second rule, increasing allowed prescription length and further reducing barriers to buprenorphine access.

As the DEA takes critical steps to minimize risks to patients with safeguards for prescribing controlled substances, it also works to maintain gains achieved by accessible care during the expansion of telemedicine. The DEA may be setting a precedent for how other departments reinforce their policies and adapt to innovations in the post-COVID-19 PHE era as it prudently pursues balance in the ever-evolving landscape of digital health care.

ARTICLE INFORMATION
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REFERENCES