March 31, 2023

Anne Milgram, Administrator
Drug Enforcement Agency
8701 Morrissette Drive
Springfield, VA 22152

RE: Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation (DEA – 407)

Expansion of Induction of Buprenorphine via Telemedicine Encounter (DEA – 948)

Submitted Electronically via regulations.gov

Dear Administrator Milgram:

Thank you for the opportunity to comment on the proposed rules regarding the prescribing of certain controlled substances via telemedicine.

The Health Innovation Alliance (HIA) is a diverse coalition of patient advocates, healthcare providers, consumer organizations, employers, technology companies, and payers who support the adoption and use of technology and data to improve health outcomes and lower costs. We appreciate the work of the Drug Enforcement Agency (DEA) in releasing these proposals for comment. We hope you will consider our comments as you work to finalize these policies.

HIA acknowledges the difficulty the DEA faces in balancing these rules with the serious issues Americans face with drug diversion, prescription drug abuse, and medication overdoses. We address several provisions of the proposals below including in-person requirements, blanket limits on day supply, requiring Prescription Drug Monitoring Program (PDMP) checks, and limiting access through qualifying referrals. We also make recommendations, including:

- Removing the 30-day prescribing limit in favor of allowing practitioners to prescribe the courses of treatment indicated for the diagnosed condition, based on clinical guidelines;
- Extending the current flexibilities available under the COVID-19 Public Health Emergency (PHE) until a final rule is released and providing a clear and adequate transition period (of at least six months) after the final rule is released; and
- Replacing provisions like those defining qualifying referrals with commonsense policies that maintain access to care and medications without causing delays in patient care.

<u>General Comments</u>

HIA and our members have long recognized the tremendous benefits of telehealth including increasing access to healthcare services and practitioners, especially those with transportation issues or those who live far away from the care they need. The Government Accountability Office (GAO) found that

telehealth utilization for Medicare beneficiaries skyrocketed, from five million encounters in 2019 to over 53 million encounters in 2020.[1] For the last three years, technology has allowed patients to be evaluated, counseled, diagnosed, and treated while keeping them at a lower risk of contracting COVID-19. The benefits of telehealth will not expire along with the COVID-19 public health emergency (PHE) declaration. Patients and providers should be able to continue to use telehealth beyond the PHE when it makes sense for them.

More than half of Americans will be diagnosed with a mental health disorder at some point in their lives.[2] Mental and behavioral health disorders are difficult to diagnose and treat, and many effective treatments require the use of controlled substances. The DEA claims that the proposed rules will impact a "narrow subset of telemedicine consultations" where there is both a remote consultation and controlled substance prescription.[3] Given the tremendous increase in the need for behavioral health services in the last few years and that the use of virtual care for behavioral health has increased 45-fold since before the pandemic, HIA believes the DEA is downplaying the impact these proposals will have on patients. The types of prescriptions affected by these rules treat a wide variety of conditions in addition to medication-assisted treatment (MAT) for Opioid Use Disorder (OUD) like depression, anxiety, insomnia, epilepsy, and attention deficit hyperactivity disorder. Many of these conditions would be severely impacted by any disruption in care should the patient not be able to be seen in person, especially psychiatric care, and chronic disease management.

HIA strongly believes that in-person requirements are not necessary prior to telehealth visits, and we defer to clinicians and patients to determine the best method for them to deliver and receive care. Should the DEA maintain in-person requirements as the rule is finalized, HIA recommends the DEA hold an annual review of both the efficacy and the burden of the requirement. This review should be published in the Federal Register and include an opportunity for public comment. Additionally, the DEA should hold in-person meetings with stakeholders, including patients, to inform future iterations of these rules.

A well-documented provider shortage in the United States has made it difficult for patients to be physically seen by a practitioner, particularly in rural and underserved areas. According to a report published by the Association of American Medical Colleges, the nation is facing a shortage of up to 48,000 primary care physicians and more than 77,000 non-primary care physicians by 2034.[4] The report also highlights, "If underserved populations had health care use patterns like populations with fewer access barriers, demand would rise such that the nation would be short by about 102,400 (13 percent) to 180,400 (22 percent) physicians relative to the current supply."[5] Now is not the time to unnecessarily restrict access to safe, effective, and efficient modalities of care. Instead, we should ensure that technologies are in place to expand access to telehealth for all populations, specialties, and services appropriate for virtual care.

HIA also supports expanded access to the use of buprenorphine to treat OUD via telehealth which will improve access to needed care, especially during the ongoing opioid PHE. According to data published by the National Institute on Drug Abuse, just under 107,000 Americans died of a drug-involved overdose in 2021 – the highest number of deaths ever recorded in this category.[6] There is no doubt that the pandemic

[1] https://www.gao.gov/products/gao-22-104454
[2] https://www.cdc.gov/mentalhealth/learn/index.htm
[3] https://www.dea.gov/press-releases/2023/02/24/dea-announces-proposed-rules-permanent-telemedicine-flexibilities
[4] https://www.aamc.org/media/54681/download
[5] https://www.aamc.org/media/54681/download
[6] https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates

has exacerbated opioid and substance use disorders. MAT using buprenorphine, when administered and monitored in accordance with best practices established by the medical community, has shown to be an effective treatment for OUD. The Substance Abuse and Mental Health Services Administration states that there are no significant differences between telemedicine and in-person buprenorphine prescriptions for continued substance use treatment, retention in treatment, or engagement in services.[7] For buprenorphine-based MAT, HIA recommends increasing the time a patient is eligible to receive the medication via telemedicine (to at least six months) prior to being required to be seen in person. The risk identified by the DEA for telehealth prescribing can be mitigated with appropriate guardrails, such as patient monitoring. Where possible, flexibilities should be preserved to ensure the most vulnerable continue to have access to treatment.

Specific Comments

Timing and Implementation

HIA appreciates that the DEA, in consultation with the U.S. Department of Health and Human Services (HHS), has addressed some of the requirements under the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 (P.L. 110-425) within these proposals prior to the expiration of the PHE. However, the timing of these rules does not give sufficient opportunity for either the agency to be responsive to stakeholder comments or for the provisions to be implemented effectively. A 30-day comment period is too short for many organizations to review, analyze, and prepare comprehensive comments on a complex rule, especially if those organizations are membership-driven and need to go through a process for approval.

Additionally, the comment period closes six weeks prior to the end of the PHE, leaving little time for the rule to be finalized and implemented prior to May 11. The issues and policies discussed in the rule affect far too many lives for this to be rushed and risk confusing patients and providers. Providers in particular need sufficient time to implement the required changes to avoid disruptions in patients' care.

Finally, the DEA has had nearly 15 years to implement the provisions in the Ryan Haight Act, including establishing a special registration process. However, even that process has not been implemented or even proposed in this rulemaking. It is clear that these policies will impact patients directly, and the DEA should give patients and their caregivers ample time to respond. HIA does not suggest the healthcare community needs 15 years to respond, but 90 days is reasonable.

HIA suggests the DEA establish a transition period of at least six months from the final rule's publication date for all policies that differ from the flexibilities allowed under the PHE. If the final rule is not published by May 11, HIA believes that the current flexibilities should be extended while the final rule is under consideration. Alternatively, the flexibilities could be kept in place until the expiration of the opioid PHE, allowing for continuity of care for patients and preventing whiplash for practitioners needing to implement different sets of rules.

30-Day Supply Limit

Practitioners could prescribe controlled medications to a patient using telemedicine only for a period of 30 days before a medical evaluation of the nature described below would be required, starting from the date of issuance of the first prescription pursuant to a telemedicine encounter. The prescribing

[7] https://public-inspection.federalregister.gov/2022-27193.pdf

practitioner would be permitted to issue multiple prescriptions for the patient, provided, however, that the prescriptions do not authorize the dispensing of more than a total quantity of a 30-day supply of the controlled medication. Once that prescribing period ends, if the patient does not receive a medical evaluation as described below, the practitioner would no longer be able to prescribe any controlled medication to that patient as a result of a telemedicine encounter until the medical evaluation has taken place. (88 FR 12881)

The DEA is attempting to control the practice of medicine in its proposal to limit providers to a 30-day supply, and this limit is not based on clinical guidelines which differ by medication. The agency is not qualified to provide clinical decision support to prescribers. Prescribers who have the training, experience, and qualifications required by the DEA to be a DEA-registered provider need to be able to prescribe the medication they believe necessary in their professional judgment based on their clinical evaluation of the patient. Many of the conditions requiring non-narcotic medications that are Schedule III-V are chronic and require consistent medication adherence to mitigate symptoms and for any improvement in symptoms to be sustained.

The 30-day prescribing limit should be removed in favor of allowing practitioners to prescribe the courses of treatment indicated for the diagnosed condition, based on clinical guidelines.

Qualifying Referral

This definition would require the referring practitioner to have conducted at least one medical evaluation of the patient in the physical presence of the referring practitioner, without regard to whether portions of the evaluation are conducted by other practitioners. This means that if multiple practitioners were physically present during the medical evaluation, they would all have the ability to issue a qualifying telemedicine referral under this section as long as they otherwise complied with DEA regulations. Any other referrals, such as those predicated on a telemedicine visit exclusively, would not constitute a qualifying telemedicine referral. Both the referring practitioner and the prescribing practitioner would be required to maintain records of the referral. (88 FR 12879)

To receive a prescription greater than a 30-day supply, the DEA offers an in-person visit or a qualified referral. HIA is concerned with two specific parts of this proposal:

1. The referral has to be connected to a personal National Provider Identifier (NPI); and
2. The referring prescriber must be DEA-registered.

These two provisions create significant access and continuity of care issues. For example, medical groups and practices do not have an NPI, but a practitioner who has examined a patient in person should be able to refer that patient to a practice or medical group. The referrals themselves do not result in a prescription of medication. Therefore, the referring provider should not need to be DEA-registered. The prescription authority in these cases still resides with the DEA-registered practitioner. This unnecessarily restricts access to patients who are initially seen by a licensed, non-DEA-registered provider and then referred by that licensed provider to a DEA-registered provider to be seen via telehealth.

HIA recommends that both provisions be removed from the final rule in favor of policies as described above that maintain access to needed medications.

Required PDMP Checks

Proposed paragraph (e) would require practitioners to review available information about past prescriptions to a particular patient. Proposed paragraph (e)(1) would require the practitioner, if employed by the Department of Veterans Affairs, to review the Department of Veterans Affairs' internal prescription database for data regarding any controlled medication prescriptions issued to the patient in the last year, or, if less than a year of data is available, in the entire available period. Proposed paragraph (e)(1) would require all practitioners prescribing pursuant to § 1306.31 to review the PDMP data for the State in which the patient is located, where available, for the last year. (88 F.R. 12882)

The proposal includes language modifying statute to require a practitioner to not only check the state PDMP but also record all attempts at checking the PDMP. PDMPs are incredibly useful tools and in response to the opioid epidemic have improved greatly. Documented issues with PDMPs create issues for mandating PDMP checks on providers. Requiring PDMP, specifically for items such as MAT, may be viable, but these issues should be addressed and resolved before placing a blanket requirement tied to the ability to prescribe.

For example, one of the proposals covers Schedule III-V drugs. According to the Prescription Drug Monitoring Program Training and Technical Assistance Center – a project that receives federal funding and is published in collaboration with the Bureau of Justice Assistance – several states (AK, KS, ME, MO, NH, OR, SC, VT) do not have PDMPs that collect information on Schedule V drugs.[8] Under this proposal, in those states, practitioners would be required to check the PDMP prior to prescribing a medication that the system does *not* track. Not only is this a waste of time, but any hope of catching duplicate, overlapping, or prescription interaction with other drugs that may be Schedule V would not be possible.

Checking PDMPs can also be very time-consuming for providers, especially when they have to exit their electronic health record (EHR) to log in to the PDMP, run the query, and then switch back. While many states do report some level of PDMP integration into their EHR, many, like Tennessee, Virginia, and New Hampshire have less than ten percent integration or unknown levels.[9] If the DEA wants to require practitioners to check PDMPs, then they need to first ensure that the system works as intended and is not overly burdensome.

Any discussions regarding a new requirement for providers to check the state PDMP need to consider the additional burden created by a lack of seamless data sharing infrastructure.

We thank the DEA and those collaborating agencies for their work on these proposals and for the opportunity to comment.

Sincerely,

Brett Meeks
Executive Director

[8] https://www.pdmpassist.org/Policies/Maps/PDMPPolicies
[9] https://www.pdmpassist.org/State

CC:

The Honorable Merrick Garland, Attorney General

The Honorable Xavier Becerra, Secretary
US Department of Health and Human Services