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Scott A. Brinks
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Drug Enforcement Administration
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Submitted electronically via www.regulations.gov

RE: Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation (Docket No. DEA-407)

Dear Mr. Brinks:

On behalf of AHIP,[1] thank you for the opportunity to provide input on the proposed rule on Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation, published in the *Federal Register* on March 1, 2023.

Our collective experience has demonstrated that telemedicine is an important health care innovation. Telemedicine's value as a modality is supported by recent data —it is a cost-effective, convenient means of delivering high quality care, particularly to traditionally underserved areas,[2] and can expand access to care and reduce disparities, especially for rural populations where there is limited access to in-person care. Telemedicine can help eliminate barriers for patients such as transportation, childcare needs, time needed off work, and other challenges.[3]

AHIP strongly supports the use of telemedicine and our members are committed to expanding access to virtual care. While we appreciate the Drug Enforcement Administration's (DEA's) efforts to balance patient access with patient safety, we are concerned that the proposed rule may erect barriers to further innovation in health care and offer several recommendations for consideration.

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[1] AHIP is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to making health care better and coverage more affordable and accessible for everyone. We believe that when people get covered and get and stay healthy, we all do better. The best way to do that is to expand on the market-based solutions and public-private partnerships that are proven successes.

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8430850/

[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8898700/

Quality and Continuity of Care

The proposed rule allows for a patient to be prescribed a 30-day supply of schedule III through V non-narcotic controlled substances via telemedicine. To receive another prescription or refill beyond the 30-day supply would require that a person undergo an in-person examination, either with the prescribing provider or with a referring provider who is registered with the DEA to prescribe controlled substances. This requirement would apply to hundreds of medications with dramatically different safety concerns and risk of abuse or diversion. The application of a single, one-size-fits-all standard across all schedule III through V non-narcotic controlled substances fails to recognize these differences and does not align with clinical best practices.

We agree that there is a need to protect against inappropriate use of these medications and potential diversion. We also recognize that, in some cases, in-person evaluations are necessary to ensure adequate patient screenings and follow-up for higher risk medications. However, we are concerned that the proposed 30-day limit for all medications in these categories is not based on clinical best practice or evidence and is instead an arbitrary cutoff that could disrupt ongoing care for patients. Applying a one-size-fits-all requirement to a wide range of very different types of drugs will not necessarily alleviate the potential challenges associated with virtual prescribing of controlled substances.

Further, requiring in-person visits could be disruptive to patients who are already stable on a medication, particularly if they have limited ability to access in-person providers. Throughout the COVID-19 pandemic, patients and providers have been able to use telemedicine to manage a range of medications to address ongoing conditions. In fact, telemedicine played an outsized role in behavioral health during the pandemic, with nearly a third of behavioral health outpatient visits delivered over telehealth for opioid use disorder and substance use disorder (OUD/SUD) conditions, and with rural residents even more likely to use telehealth for behavioral health conditions.[4] That high level of telemedicine utilization for behavioral health continues even as the public health emergency comes to an end.[5]

We recommend that the need for and frequency of an in-person visit be evidence-based and clinically driven. We also recommend that the DEA consider allowing alternative safety measures, such as options for consistent, periodic visits with the same telemedicine provider or practice and/or urine drug screens to satisfy the in-person evaluation requirement, where clinically appropriate.

Equity Issues and the Social Determinants of Health

[4] https://www.kff.org/coronavirus-covid-19/issue-brief/telehealth-has-played-an-outsized-role-meeting-mental-health-needs-during-the-covid-19-pandemic/?utm_
[5] Ibid.

A one-size-fits-all approach to requiring in-person visits to receive a prescription for more than 30 days may exacerbate disparities in access to consistent ongoing care across communities. One key reason that many patients turn to telemedicine is because of the convenience in accessing high-quality, affordable care – especially if they have transportation or childcare issues, or difficulty getting time off from work to accommodate in-person visits. Eliminating telemedicine as a long-term option makes it more difficult for these patients to manage their health and access needed care. Moreover, in-person visits are not always available in certain communities, such as rural and underserved areas where providers may not be available or have long wait times for appointments. Even when there are sufficient in-person providers, appointments may not be available within the 30-day window required to continue a prescription.

The social determinants of health (SDOH) that impact many people are why telemedicine provides a lifeline. Transportation, childcare, work schedules, and other challenges, including concerns about stigma, may prevent people in certain communities from accessing in-person care. The convenience of telemedicine is often cited as the reason people in underserved communities choose virtual care.[6] We are concerned that the proposed rule shifts the burden of seeking care to the patient, which is counter to the goal of increasing access to needed care for underserved populations, especially given health care workforce shortages which can result in longer times to get in-person appointments.

Evidence-based and clinically driven flexibility in the 30-day window for an in-person visit will help account for the needs of underserved and rural populations and acknowledge the challenges presented in some communities with SDOH.

Administrative Burden

In the proposed rule, the DEA requests input on whether the administrative requirements would be excessively burdensome for providers. The rule proposes that providers maintain a written or electronic log for each prescription issued via a telemedicine encounter, stored at the provider's address registered with the DEA. The proposed rule also indicates that providers would be required to include a notation on the face of the prescription or within a prescription order (if prescribed electronically) that the prescription has been issued via a telemedicine encounter.

Providers may view the administrative burden as excessive if these requirements are vastly different from current requirements, fall outside of the clinical workflow, and require secondary documentation outside of the electronic health record (EHR). Additionally, it may be overly burdensome from technological and cost perspectives if "add-ons" are required to incorporate such record-keeping into the EHR.

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[6] https://www.ahip.org/news/press-releases/new-survey-americans-value-the-convenience-and-simplicity-of-telehealth-for-their-care

Pharmacists could face similar administrative burdens if they are responsible for validating an in-person visit prior to filling a prescription for a controlled substance ordered via telemedicine. Overly burdensome documentation or in-person visit validation requirements could inadvertently result in prescription delays and care disruption for impacted patients who need ongoing care.

Additional specifications to the telehealth label requirements will help avoid delays for patients to access medications, provide more clarity to prescribers on labeling, and assist pharmacies with operationalizing the new requirements.

We recommend that the DEA provide additional clarification on how telemedicine data would be required to be collected, recorded, and stored, how prescriptions would be required to be notated, and how the proposal differs from current practices. We further recommend that the DEA clarify whether and how pharmacies in retail settings would validate the in-person requirements in the proposed rule before dispensing a prescription.

Furthermore, while patients who established a telemedicine relationship during the public health emergency will have a 180 days transition period to meet the rules' new in-person medical evaluation requirement, prescribers, pharmacies, and new patients will need time to conform with the comprehensive list of new requirements, many of which involve clinical and business practice changes, technology updates, and patient education.

We recommend that the DEA set an effective date of six months from the date of the final rule, or allow enforcement discretion during this time, to provide patients, prescribers, and pharmacies sufficient time to understand and comply with the new rules.

Prescription Drug Monitoring Programs

Prescription Drug Monitoring Programs (PDMP) are powerful tools, typically accessed by prescribers and pharmacists, that have been used to protect patients from potential drug interactions, support coordination of patients' medications, and combat drug diversion and fraud, waste, and abuse within the system. PDMPs have been used to flag "doctor shopping," as well as "pill mill" providers who inappropriately prescribe medications to their patients. Throughout the opioid epidemic, AHIP and its members have supported the consistent use of PDMPs, including allowing health insurance provider access to these databases, and have advocated for improved interoperability across systems to enhance their oversight capabilities. These approaches would further promote patient safety and coordination of care.

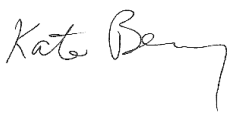
In the proposed rule, the DEA indicates that providers will be required to review the PDMP prior to prescribing a controlled substance via telemedicine. We support this requirement for providers, whether they deliver care via telemedicine or in-person, to help ensure safe

prescribing and coordinated patient care and to reduce potential diversion. However, not all state PDMPs include the same medications since what drugs are included and for what purposes is determined by each state. To improve coordination of care and protect patient safety, federal oversight should require that these medications be included in all state PDMPs, regardless of whether they are dispensed via telemedicine or in-person. Additionally, PDMPs should be accessible for providers to view across states since patients may seek care in multiple states.

AHIP supports continued use of PDMPs and recommends consistent inclusion and use criteria for PDMPs, regardless of whether medications are dispensed via telemedicine or in-person. Additionally, data in a PDMP should be accessible to providers viewing the information across states as well as health insurance providers.

Health insurance providers have a long history of working with federal and state governments, as well as other stakeholders, to promote patient access to health care, including via telemedicine. We look forward to continuing our partnership with the Administration and other stakeholders to promote affordable patient access to safe and effective treatment and reduce disparities.

Sincerely,



Kate Berry
Senior Vice President