March 18, 2025

Mr. Derek S. Maltz, Acting Administrator
Drug Enforcement Administration
Attn: DEA Federal Register Representative/DPW
8701 Morrissette Drive
Springfield, VA 22152

RE: RIN 1117-AB40

Submitted electronically via regulations.gov

Dear Acting Administrator Maltz:

The Health Innovation Alliance (HIA) is pleased to submit comments to the 2025 proposed rule entitled *Special Registrations for Telemedicine and Limited State Telemedicine Registrations*. While HIA supports safeguards to ensure that controlled substances are prescribed appropriately, we believe there are several concerns and shortcomings with the current proposal that warrant revision in some instances and recission in others.

HIA is a diverse coalition of patient advocates, healthcare providers, consumer organizations, employers, technology companies, and payers working together to improve health care through the commonsense use of data and technology. Founded in 2007, HIA has been a stalwart supporter of health information technology and interoperability, having worked on key legislation ranging from the HITECH Act to the 21st Century Cures Act.

General Comments

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 during the COVID-19 pandemic, from five million encounters in 2019 to over 53 million encounters in 2020.[1] While that number has since stabilized since the pandemic, 12.7 percent of visits by Medicare beneficiaries from October through December 2023 were still conducted via telehealth, representing a sizeable increase from pre-pandemic levels.[2]

Given this widespread adoption, it is important that new rulemaking strikes a balance between maintaining appropriate safeguards while minimizing burdens on providers and patients. COVID-era flexibilities will expire December 31, 2025, and all affected parties need predictability in order to plan for the future. A lapse in policy would have wide-reaching consequences for patients, who have become accustomed to accessing virtual care. We recognize the need for a special registration framework to monitor and maintain appropriate virtual prescribing and provide that clarity to patients, providers, and business partners. The current proposal comes short of this balance in several ways. In particular, a 50-state PDMP check is infeasible and the policies it requires would place undue operational constraints on business partners. Short of major revisions to the NPRM,

[1] https://www.gao.gov/products/gao-22-104454
[2] https://www.kff.org/medicare/issue-brief/what-to-know-about-medicare-coverage-of-telehealth/

we believe an alternative path forward would be to rescind the proposed rule and convene a working group of public and private sector stakeholders to craft a new, more workable rule that would provide a stable path forward for all parties. While we recognize that this would further delay complete implementation of a law that was passed 16 years ago, it is crucial that the DEA finalizes policies that provide the appropriate balance of the various priorities. If that balance is not achieved, it will negatively impact patient access to care, further burden providers, and require further regulatory action.

PDMP Check

> *After three years, however, the* individual special registrant *would be required, before issuing any* special registration prescription *for controlled substances to a patient, to check the PDMPs of all 50 states of the United States and any other U.S. district or territory that maintains its own PDMP. This requirement for a broader, nationwide PDMP check would not begin until three (3) years after the final rule's effective date, to allow registrants and industry sufficient time to comply with the new requirement. If, however, there is no mechanism to perform such a nationwide check after these three years, then* individual special registrants *would remain required to continue performing PDMPs checks of the states in the three categories described above, and* individual special registrants *would only be able to issue* special registration prescriptions *for Schedule II controlled substances to patients located within the same state as the* individual special registrant, i.e., *where there is an intra-state practitioner-patient relationship.*[3]

The proposal includes language modifying current regulation to require a practitioner to, three years following the effective date of the final rule, check the PDMPs of all 50 states and U.S. territories that maintain such a system. PDMPs are incredibly useful tools and have improved greatly in response to the opioid epidemic. Documented challenges with PDMPs create issues for mandating PDMP checks on providers, making the regulation unworkable in many places. For example, the proposals for the various types of registrants covers prescription of either Schedule III-V or Schedule II-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.[4] Under this proposal, practitioners in those states 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 need 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, some, like New Hampshire, Idaho, and Delaware, have less than twenty-five percent integration or unknown levels.[5] If the DEA wants to require practitioners to check PDMPs, then they need to first ensure that the system works as intended and does not create useless tasks for clinicians. Even the existing industry systems that come close to capturing nationwide data still would not meet the standards set out by DEA in the NPRM.

Any discussions of new requirements on providers to check state PDMPs must account for the additional burden created by a lack of data sharing infrastructure. The administration has made it a priority to reduce undue regulatory burden, and reducing burden in the healthcare system is particularly important given the vast amount of time and money that already goes toward compliance in health care. We suggest revisions to ensure

[3] 90 F.R. *at* 6554
[4] https://www.pdmpassist.org/Policies/Maps/PDMPPolicies
[5] https://www.pdmpassist.org/State

that this proposal does not run against the administration's burden reduction goals. Specifically, the DEA should work with states and private sector actors to support PDMP interoperability efforts, with the goal of a 50-state PDMP check being feasible. The DEA must also ensure that running a national PDMP check does not create significant financial burden on practices before moving to require such a check. Finally, a national check should not be required until some period of time after that capability has been developed, to give practices time to acquire access to and deploy such a solution.

Balancing Burden and Safeguards

Any permanent rulemaking related to the remote prescribing of controlled substances (without in-person requirements) should appropriately support the continued delivery of essential care to patients while addressing concerns around misuse/abuse/diversion and operational burdens levied on clinicians. While we appreciate the considerations for patient safety and diversion control, many of these proposals could prove problematic for providers given the specific conditions outlined in the proposed rule resulting in decreased patient access to needed care.

For example, a subset of clinicians will likely be adversely impacted by the proposed requirement that a special registrant's prescriptions for Schedule II drugs must average less than half of their total monthly prescriptions. This will inadvertently impact clinicians whose practice is not based in a brick-and-mortar clinic—or patients that reside in care deserts—and could prevent some providers from prescribing certain medications via telemedicine. In addition, DEA has not explained its methodology for the 50 percent threshold. While we understand there need to be guardrails against pill mills or other unscrupulous activity, we are concerned there could be unintended consequences, including disrupted patient care in certain specialties where Schedule II substances are prescribed more often.

Primary care and general medicine practitioners are excluded from the special registration process. In many instances, these providers provide first line care to patients where a controlled substance prescription may be clinically appropriate. The proposed rule would require telemedicine platforms and direct-to-consumer companies to register even if they themselves do not prescribe or dispense a controlled substance. Operationally, this creates a considerable regulatory burden for special registrants. Pharmacists will be tasked with navigating the proposed verification processes, and it's unclear whether DEA has the administrative capacity to handle an influx of tens of thousands of applications without delaying or impeding access to care. Overall, we are concerned that these proposals are not workable given the highly complex nature of existing relationships between patients, providers, and supporting business partners, and we suggest revisiting the proposals. Specifically, DEA should ensure primary care providers and other qualified prescribers are included in the development of any proposal to match current clinical practices. Secondly, registration should focus on the prescriber rather than the platform that facilitates the patient-provider interaction. We again suggest that a working group may be the appropriate avenue to collect stakeholder feedback and revise current proposals to more carefully balance safety concerns with patient access needs.

We thank DEA for the opportunity to comment on this proposed rule, and we look forward to working with the Administration and other agencies to promote continued access to virtual care.

Sincerely,

Brett Meeks
Executive Director