

Alliance for Connected Care 1100 H Street NW, Suite 740, Washington, DC 20005

Drug Enforcement Administration (DEA) Listening Session on "DEA's Regulations on Prescribing Controlled Substances via Telemedicine" September 12, 2023

The Alliance for Connected Care appreciates the opportunity to testify for this listening session on DEA's regulations of prescribing controlled substances via telemedicine.

The Alliance is dedicated to improving access to care through telemedicine and remote patient monitoring. Our members are leading health care and technology organizations from across the spectrum, representing health systems, health payers, and technology innovators. The Alliance works in partnership with an Advisory Board of approximately 50 patient and provider groups who wish to better utilize the opportunities created by telehealth.

We appreciate the DEA's quick response during the COVID-19 public health emergency (PHE) to allow prescribing via telemedicine. This was also a hugely meaningful expansion of access for Americans who had other barriers to accessing care. These include individuals who are frail, homebound or lack transportation, who live in areas with provider shortages, people of all kinds whose caregiving responsibilities serve as a barrier to care. We strongly support the development and implementation of a permanent policy for the prescribing of controlled substances though telemedicine to ensure these individuals do not lose access – as these are not challenges which will go away.

As I am sure many here today will discuss, mental health and substance use disorder visits continue to represent a growing share of all telehealth visits due to several factors, including growing needs for mental health services and well-documented workforce shortages in access across the nation. Americans rely heavily on telehealth for access to treatment for these mental health conditions, with it representing 62.5 percent of all telehealth treatment as of last year. While mental health is the most predominant condition represented, there are many others, such as end of life care for the frail and homebound.

We believe future DEA actions to preserve access to this care will be a crucial pillar supporting President Biden's Mental Health Strategy, which seeks to connect more Americans to mental health care through the widespread use of telehealth.

In our testimony today, the Alliance will discuss the importance of a special registration as the primary guardrail to identify and mitigate the risks of diversion in the prescribing of controlled substances through telehealth, and discuss implementation concerns for any proposed regulation.



We would like to begin by recognizing the importance of the DEA's work to prevent the diversion of controlled substances and zeroing in on exactly what needs to be accomplished in this rulemaking. As you know, the mission of DEA's Diversion Control Division is to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs.

We recognize that there were a couple public instances of inappropriate prescribing demonstrated during the public health emergency. These examples emphasize the need for a regulation that allows good actors to differentiate themselves from those engaging in questionable medical practices. They should also give the DEA very clear insights into exactly what types of practices may require additional oversight and monitoring – rather than a blanket restriction on telemedicine. As noted in its mission, it is crucial that the DEA balance their concerns around diversion with the huge number of Americans who are relying on leaders at the DEA for an uninterrupted supply of medication for legitimate medical needs. We believe the regulation proposed this spring did not strike this balance by failing to create a reasonable pathway for practitioners to treat patients via telemedicine without having had an in-person evaluation—effectively ending access to care for those with the highest health needs.

The special registration outlined by Congress laid the foundation for the right balance between empowering the DEA to identify and address diversion, while not inappropriately interfering in the practice of medicine and medical decision-making best left to a practitioner and patient, if implemented as envisioned.

For health care providers, this special registration process should be an opportunity to subject themselves to a higher level of scrutiny and appropriate data sharing with DEA, and in exchange have greater flexibility to prescribe without in-person referral requirements, prescribing time-limits, and the ability to prescribe a wider range of substances.

Having met these criteria, they should not be subject to other burdensome guardrails. We strongly believe that the registration itself should be the guardrail, and does not need to be accompanied by significant restrictions on the practice of medicine and medical decision making.

For the DEA, the special registration should be a tool that allows for the tracking and understanding of who is prescribing controlled substances, and in what manner, so that the DEA can act in its capacity as a law enforcement agency – and use this data to identify and investigate potential bad actors. As noted, we support data driven decision making based on documented abuses of controlled substances, where they exist. We believe that, rather than creating overbroad restrictions on the practice of medicine, DEA should be able to create tools that capture the data it needs to protect Americans from potential bad actors.



Turning to more specific recommendations, when considering a rigorous special registration process, that allows the prescribing through telehealth without an in-person visit, the DEA should consider:

- The ability to streamline implementation of the telemedicine registration process alongside existing DEA registration to limit additional burden on the DEA and practitioners. One example of this would be the use of a single special registration number in conjunction with the appropriate regular DEA registration number to prevent pharmacies and others from having to store multiple Special Registration numbers for prescribers.
- The ability to have the Special Registration clearly cited on prescriptions issued from a telehealth visit, along with the appropriate regular DEA# associated with the state where the patient is being treated would help address pharmacy-based barriers to medication access. There has been widespread documentation of pharmacies hesitating to fill controlled substance telemedicine prescriptions as the public health emergency came to an end. We believe consistent documentation, clearly endorsed by DEA will resolve many of the concerns that have led to additional barriers to patients receiving access to their medications.
- Maintaining the confidentiality of a telehealth prescriber's home address if that is their practice location, as release of this information could create a safety risk for that healthcare provider and any family. Prescribers should be allowed to include as the "prescriber address" element on a prescription the location of their physical practice if they have one, or if a prescriber is practicing for a telemedicine business the corporate address of that business.
- Partnering with the CDC, states, and others to obtain telemedicine-related data that may be reported to a state prescription monitoring program.
- With a strong registration system in place, we believe it would be appropriate for DEA to continue its flexibility when it comes to individual registrations for each state where a provider prescribes to patients. The Special Registration framework would be ideal for addressing multistate telemedicine provider registrations, and we request the DEA offer additional clarity and streamline how providers with a multi-state practice can meet registration requirements.
- Finally, DEA must allow an appropriate amount of time for the health care industry to make system updates to accommodate for the final rule and promote ongoing compliance. This is not only health care providers but also the many systems that support them such as electronic health records, pharmacy dispensing systems, licensure verification systems, and etc.



Additionally, we urge the DEA not to finalize requirements included in the proposed rule that limit the practice of medicine when offered through telehealth. We ask DEA;

- <u>Please do not finalize any provision that requires an in-person visit or referral prior to the delivery of a telehealth visit.</u> The primary challenge with an in-person referral mandate is the limitation on access it creates for the millions of Americans seeking treatment for a condition for which there are significant barriers to access. There is no reliable guarantee that patients who found access to care through telehealth over the past few years will be able to find and obtain a meeting with an in-person practitioner able to make an examination and referral.
- <u>Please do not omit Schedule IIN Non-Narcotic substances from the rulemaking.</u> The COVID-19 PHE has demonstrated almost three years of evidence for the prescription of Schedule IIN controlled medications via telemedicine. In the broader interest of continuing to prevent substance use disorder, we make specific note of the fact that treatment of a condition like ADHD with a controlled substance can be crucial to lowering the likelihood of a future substance use disorder.
- <u>Please do not add additional restrictions, such as 30-day limits on prescribing, which interfere with the practice of medicine and create additional barriers to high-quality care.</u> As an example, if we think about this restriction in practice – it means that a telehealth clinician will be pressured to prescribe a medication to a patient without clear knowledge of if that patient would be able to complete the full treatment regimen. Many other restrictions would have similar implications for proper patient care.

Thank you so much for this opportunity to comment. We continue to believe that it is both reasonable and possible for the DEA to protect Americans while differentiating between the higher-risk business practices and the normal provision of medical services through telehealth. We urge DEA to work with stakeholders, HHS, and others to find a more nuanced approach to diversion that allows ongoing, relationship-based care between patients and their virtual providers to continue.