ALLIANCE for CONNECTED CARE

March 18, 2025

The Honorable Derek Maltz
Acting Administrator
U.S. Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

RE: Docket No. DEA-407 - Special Registrations for Telemedicine and Limited State Telemedicine Registrations

Dear Administrator Maltz:

The Alliance for Connected Care (the "Alliance") welcomes the opportunity to provide comments on the Drug Enforcement Administration ("DEA") proposed rule on special registrations for telemedicine and limited state telemedicine registrations.

The Alliance is dedicated to improving access to care through the reduction of policy, legal, and regulatory barriers to the adoption of telemedicine and remote patient monitoring. Our members are leading health care and technology organizations from across the spectrum, representing health systems, healthy payers, technology innovators, and patient and provider groups, including many types of clinician specialty and patient advocacy groups who wish to better utilize the opportunities created virtual care.

We appreciate the DEA's forward movement on telemedicine prescribing of controlled substances policy. However, the Alliance continues to be concerned to see language in the proposed rulemaking mandating in-person visits as this is not an appropriate guardrail for a telehealth service. Similarly, restricting the geography in which telemedicine can be offered undermines the value of creating virtual access for those patients who need it most. For these reasons, the Alliance encourages the Trump Administration to withdraw this proposal and work with stakeholders to ensure continued access to comprehensive medical care through telehealth, including when a controlled substance is required.

In our below comments, we discuss how the telemedicine access created on a temporary basis by DEA increased access to care, offer specific feedback on the proposed rule, and request the DEA to work with Congress and stakeholders to advance a safe and permanent pathway to ensure continued access to comprehensive medical care through telehealth, including when a controlled substance is required. We also request that the DEA consider holding another listening session to hear from health care practitioners, experts, advocates, patients, and other members of the public, including the Alliance, on the prescribing controlled substances via telemedicine.

Background

As you know, President Trump signed the bipartisan *SUPPORT for Patients and Communities Act* into law on October 24, 2018, which included a provision requiring the Attorney General – in consultation with the Secretary of Health and Human Services – to promulgate final regulations related to a Special Registration for Telemedicine. The special registration permits the Attorney General to issue a practitioner a special

registration to engage in the practice of telemedicine if the practitioner demonstrates a legitimate need for the special registration and meets other DEA requirements.

In 2020, the DEA acted swiftly under President Trump Administration's leadership, to ensure that adults and children could continue to access medically necessary controlled substances via telemedicine by waiving the requirement that the patient have a prior in-person visit, regardless of their location, for the duration of the public health emergency (and subsequently beyond). The expansion in access to crucial health services have made clear the importance of increased access to telemedicine services.

New restrictions on the remote prescribing of controlled substances would significantly impact patients who depend on these pathways to access essential medications. In 2024, across 258 organizations utilizing the Epic EMR and Cosmos, an estimated 44.6 million Schedule II - V controlled substances were prescribed to patients. Notably, around 16% of these prescriptions were issued without a prior in-person visit, accounting for more than 7 million prescriptions that could be at risk under such restrictions. Limiting remote prescribing would put a significant number of patients at risk, with a disproportionate impact on those already facing healthcare inequities.

For the last five years, telehealth has also been a crucial tool in providing a wide range of other important health services – particularly for those Americans who live in remote areas and locations with provider shortages. For example, as of December 2023, more than half (169 million) of the U.S. population lives in a Mental Health Professional Shortage Area (HPSA) and broader access to telehealth has been crucial in creating new access to care for these individuals as well as those with other conditions.

We strongly believe that the DEA should build on this experience to fully execute on the goals of President Trump's *Executive Order on Saving Lives Through Increased Support For Mental- and Behavioral-Health Needs*, which included a national call to action to increase access to telehealth. President Trump's commitment to the continuation of this care was further communicated in the Executive Order on Establishing the President's Make America Healthy Again Commission, which calls for action to address the estimated one in five United States adults living with a mental illness and cites Trump Administration leadership on expanding access to telehealth, especially in rural and underserved communities.

Specific Feedback on Proposals in the Proposed Rule

Broadly, the Alliance for Connected Care continues to reject the use of in-person care as a guardrail for telehealth. The Alliance and its members strongly believe that an in-person care requirement on either a patient or provider is never the right guardrail for a telehealth service. Requiring an in-person visit constrains telehealth from helping individuals that are homebound, have transportation challenges, live in underserved areas, and many more. It does not constrain those using telehealth for convenience. This creates a perversion by reducing access for those who need it most, while allowing access for others. We cannot create a guardrail that is an access barrier between patients and their clinicians – it will lead to harm the most vulnerable and access-constrained patients.

We are concerned that, rather than working to develop an evidence-based approach to identify and mitigate the risk of diversion, the DEA has designed overbroad restrictions on health care access that will have serious and detrimental implications for the hundreds of thousands of Americans who rely on

telehealth practitioners for care. 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 (that the DEA invested resources into investigating) and the normal provision of medical services through telehealth. We urge DEA to rescind or reissue this proposed rulemaking to ensure a more nuanced approach to diversion that allows ongoing, relationship-based care between patients and their virtual providers to continue.

Three Special Registration Pathways

The DEA proposes three types of special registration to accommodate the varying legitimate needs of practitioners, including clinician practitioners and covered online telemedicine platforms, in their capacity as platform practitioners. The Alliance is pleased to see the DEA propose a special registration pathway, as required by statute, to allow comprehensive medical care through telemedicine, including a proposal that includes Schedule II medications. These treatments are important in providing mental health, end-of-life care, substance use treatment, and many other services. Telemedicine has proven to be an effective tool in bridging the gap between patients and providers, reducing barriers to care, and supporting those most in need.

However, we note that the Ryan Haight Act requires only that DEA issue a singular Special Registration for Telemedicine (21 U.S.C.A. § 831(h)), while DEA proposes a concept that would see the creation of two Special Registrations for Clinicians, a new federal State Telemedicine Registration for each state in which a prescriber practices telemedicine, and Platform Registration and State Registration numbers for telemedicine platform providers. Such a concept is overly complex and unwieldy, imposing costly and unnecessary burdens on stakeholders. A single Special Registration for Telemedicine could be configured to allow for Schedule II prescribing or just Schedule III-V prescribing. In addition, a prescriber could obtain the current form of DEA registration for each state in which they intend to prescribe.

Advanced Telemedicine Prescribing Proposal

The Alliance is very concerned to see language in the Advanced Telemedicine Prescribing Proposal mandating what portion of patient care can be offered through telemedicine, as this is not an appropriate guardrail for the potential diversion of a controlled substance.

DEA proposes to require that the average number of special registration prescriptions for Schedule II controlled substances constitutes less than 50 percent of the total number of Schedule II prescriptions issued by the clinician special registrant in their telemedicine and non-telemedicine practice in a calendar month. The proposed places an arbitrary guardrail that would be difficult to track and would limit clinically appropriate prescriptions. This would require electronic health records to track the total number of controlled substances, the modality of prescription, and then to alert the provider when the arbitrary 50% threshold is met. For example, an oncologist seeing a cancer patient, needing to prescribe an opioid, could be restricted from doing so if that would mean that 51% of their prescriptions were delivered via telehealth. The clinical care a provider can deliver a patient should not depend on an arbitrary threshold of prescriptions prescribed to prior patients.

Additionally, defining a percentage of prescriptions over a period of time introduces operational hurdles that are not addressed in the rulemaking. If the limitation is on a monthly basis, is a provider expected to

anticipate the number of prescriptions they would prescribe in a month to determine if they have met the threshold? If on January 1st a provider prescribed 4 controlled prescriptions, 2 in person and 2 via telemedicine, are they then restricted from prescribing controlled substances until they prescribe more in person prescriptions? Situations like this could actually create pressure to prescribe more prescriptions in-person in order to provide necessary telemedicine prescriptions. The logistical barriers to operationalizing this without creating problematic barriers and incentives are significant.

There is no evidence supporting an in-person visit requirement as a guardrail for telemedicine services. In fact, studies have found that implementation of new in-person visit requirements would substantially change current standard mental health practice. Similarly, experts support the remove of in-person requirements for mental health services, with one expert stating that in-person visit requirements limit the ability of telehealth to expand access to mental health services for patients who live far from any mental health clinician and, therefore, cannot have in-person care. The Medicare Payment Advisory Commission (MedPAC) agreed that an in-person requirement for behavioral health services is a baseless provision for fraud concerns.

We remain concerned by the unclear language on practitioners with "legitimate need" for registration. DEA is not proposing regulations that delineate specific criteria, but is instead requiring clinician practitioners to furnish information on their Special Registration applications that demonstrates their specialized training. The list of practitioners outlined is arbitrary and creates unclear prescribing authority for a range of practitioners including primary care providers. Without clarity around who may and may not have legitimate need for the special registration, it is unlikely that any providers not explicitly listed will embark on the burdensome process to apply for a special registration.

Additionally, pharmacists do not currently have a way to know where the prescriber was physically located when treating the patient and no way to enforce a 50 percent prescribing limitation per calendar month since (a) PDMPs allow pharmacists to view data only by patient, not by prescriber; and (b) a pharmacist filling a Schedule II prescription from an Advanced Clinician Special Registrant has no way of knowing how many non-Schedule II prescriptions that prescriber will issue during the remainder of the calendar month.

Geographic Restrictions

Similarly, restricting the geography in which telemedicine can be offered undermines the value of creating virtual access for those patients who need it most. One study found that it was common for patients living in rural areas to receive mental health treatment from a neighboring state. Rural residents, in particular, have to travel 40 miles farther than their urban counterparts. In the college student population, approximately half a million college students lose access to psychiatric treatment each year due to unnecessary barriers related to state medical licensure. Three million students attend college outside of their home state, and many are not able to see their existing doctors while away at school, putting them at risk with limited and lack of care.

While requiring specific sites of care for telehealth may have made sense when technology was new and unreliable, clinicians today are effectively deploying telehealth nationwide. There is no reason for our most vulnerable populations to have less access to care. Restricting access to telemedicine will lead to

harsh consequences for many Americans relying on telehealth for mental health, substance use disorder, sleep disorders, terminal illness, and many other medical issues.

In addition to restrictions on where the patient can be located, we urge DEA to also consider variation in where the practitioner is located. The practice of a health is currently determined by the patient location at the time of care, not the location of the practitioner – but care could be disrupted for patients of clinicians that practice in multiple states. It is not uncommon for individuals to work in multiple locations while living in a different state or jurisdiction. Therefore, even with in-person care, it is not uncommon for practitioners to offer care to patients from multiple states. A restriction on the practice of telemedicine across a state border could create new and harmful barriers to treating a patient simply based on the location of the practitioner at the patients time of need.

Platform Registration

The Alliance appreciates the DEA's telemedicine platform registration as an attempt to consider the changing dynamic of the current day practices of telemedicine. However, we are concerned that under this registration, the DEA fails to take full advantage of the opportunity created by this registration capability. The telemedicine platform registration should be an opportunity to:

1. Reduce administrative burden of the special registration on practitioners operating on a platform – since their platform is taking some accountability for the provision of care and all of these individuals would have multiple special registrations.
2. Allow for some narrow platform-specific guardrails that focus on prescribing practices that DEA has identified and investigated as problematic.

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 the DEA, in exchange for greater flexibility to prescribe without in-person requirements and other arbitrary, overbroad restrictions on health care access. We recognize that there were some highly public instances of pandemic flexibilities being abused. We believe that those cases should inform the guardrails on exactly what types of business practices require additional oversight and monitoring. Those bad actors should allow the DEA to craft a nuanced regulation that targets questionable practices while allowing the practice of medicine to continue through telemedicine. We request that the DEA pursue a report, outlining the common characteristics of these questionable business practices, to inform its revised guardrails.

Finally, we are concerned by the DEA choice in outlining "direct-to-consumer" third party platforms as a "dispensing practitioner." The Controlled Substances Act (CSA) was not envisioned by Congress to encompass only the actual or constructive transfer of possession of a controlled substance. A technology platform that only facilitates communications between practitioner and patient, even if it provides some oversight of the practices of its associated prescriber, does neither. If the DEA wants to register these entities, it should develop a unique registration category for them as they are not "dispensers" under the current statutory definition.

Limited State Registration Pathway May Conflict Across State Laws

The proposed state registration pathway would require practices to be "in accordance" with Federal and state law. However, each state has its own laws and may conflict with one another – particularly when it comes to controlled substances. While not directly stated in this rule, there continues to be a misconception that telemedicine is separate and different from in-person care - when it is the same care, just provided through a different modality.

This proposal directly contradicts policy efforts to increase economic efficiency and encourage health care competition across state lines. We note that some policy voices, such as the authors of Project 2025, have called for actions to legally define the locus of service as where the provider is located during the telehealth visit, rather than where the patient is. Pursuing this definition would allow states to reserve their powers and ensure continuity and consistency of care from providers no matter where their patient might be.

Another area of concern is related to pharmacists, particularly with regard to the prescribing of buprenorphine. Currently, 13 states permit pharmacist-prescribing of buprenorphine. If finalized, DEA would need to provide additional clarification on this point.

We hope to work with the current Administration to encourage policies that increase telehealth access and interstate licensure, without these antique, outdated laws. We request the DEA offer additional clarity on how it will resolve conflicting state laws across the multi-state licensure pathway.

Application Process and Costs

We are concerned that the proposed regulation could create significant regulatory and financial burdens on practitioners. Many layers of registration create cost challenges for small providers and does not serve as an effective guardrail against potential bad actors, for whom the cost is not a barrier. For example, a typical primary care provider providing 18% of total telemedicine care out-of-state and would need at least four state registrations for the neighboring states, which studies have shown to be the most common out-of-state care, leading to a cost of $1,088.

For practitioners who only provide significant portions of care out-of-state, it would disincentivize providers from investing in out-of-state telemedicine care and further exacerbate the lack of mental health workforce available to patients.

Nationwide Prescription Drug Monitoring Program Check

While the idea of state-by-state checks are promising – they are not technically feasible with the infrastructure that exists today. Additionally, actions to implement this capability are beyond the scope of this rulemaking -- other federal government agencies/leadership may need to help states modernize PDMP capabilities to enable a seamless 50-state check. We request the DEA to provide additional clarity on how it could implement this nationwide PDMP program and consider its own capacity to help states and providers meet the requirements for implementing this program.

Creating a requirement that cannot be met, even with a three-year lead time is still a barrier to patient access to care. We request that DEA not create any barriers to patient care that are dependent on actions outside of its control, and instead work to facilitate the capability needed for this reporting.

Audio-Only Prescriptions

Audio-only telehealth should be an option, particularly for patients who lack access to the resources needed to participate in video-based telehealth. We collectively acknowledge that some patients do not have sufficient internet access, device access, or digital skills to connect with their clinicians over a stable video connection. In these instances, patients and providers should have the flexibility to choose when an audio-only telehealth visit is both clinically appropriate and preferred by the patient.

As recently as December 2024 Congress reaffirmed in law its desire to preserve access to audio-only telehealth services for those who need them. While audio-only telehealth may not always be the best format for care – this is a medical decision that should be left to the patient and practitioner offering the care, rather than be regulated by the DEA.

Rural populations already face higher barriers to accessing health care. For example, patients in remote areas may be unable to utilize visual telehealth, but, under this proposal, would be unable to request audio-only telehealth for their mental health treatment. There is also a double standard in the current regulatory proposal – DEA allows audio-only in the buprenorphine final rule in the use for treatment of opioid use disorder, but not for other important care.

Pharmacy Reporting

The DEA's proposal does not take into account changes necessary to electronic prescription standards and prescription drug monitoring program transmission standards. Prescribers issuing telemedicine prescriptions using their Special Registration would need to include on the prescription up to five DEA registration IDs:

1. DEA Registration,
2. Special Registration number
3. State Telemedicine number (unless they are DEA# exempt)
4. Telemedicine Platform Registration number (when applicable)
5. State Telemedicine Platform DEA Registration number (when applicable)

Current standards for electronic prescribing and PDMP transmission have no fields for any of these newly proposed registration numbers and the associated digital certifications. The standards also do not support the required use of other data elements that may be necessary for the pharmacy provider to identify the eRX being associated to a telehealth encounter (prescriber place of service, identification of a platform provider, etc.) Once new standards are adopted by these standards bodies, e-prescribing platforms, intermediaries, state PDMPs and pharmacies need to modify their systems to accommodate them.

If this proposal moves forward, we request the DEA to add a provision that none of these rules go into effect sooner than two years after the adoption of electronic prescribing and PDMP transmission standards that supports the inclusion of these new registration numbers as required data elements. The DEA should also consider requiring only the most restrictive DEA registration associated with a special registration prescriber rather than requiring cumbersome system standards to transmit all DEA registrations. Requiring the transmission for all DEA registrations could create conflict if prescribers with multiple registrations are not able to be validated by the DEA files.

The DEA and the prescriber should be responsible of management of all DEA registration numbers associated to a prescriber (rather than the pharmacy receiving the electronic prescription). Under corresponding responsibility, the pharmacist should only be responsible in validating the DEA registration submitted on the electronic prescription is active and valid for the prescribed drug.

Additionally, as noted above, it is only the actual or constructive transfer of possession of a controlled substance that is regulated by the Controlled Substances Act. A technology platform that only facilitates communications between practitioner and patient, even if it provides some oversight of the practices of its associated prescriber, does neither. If DEA wants to register these entities, it should develop a unique registration category for them as they are not "dispensers" under the current statutory definition.

It is unreasonable to expect pharmacists to have a corresponding responsibility related to the inclusion of the Platform Provider DEA number on a prescription, when in these rules DEA itself acknowledges that it might not always be clear to the platforms themselves whether such registration is warranted.

Restrictions on Opioid Use Disorder Prescriptions

The DEA continues to place arbitrary limitations on the care a telehealth provider is able to offer for many conditions, undermining that care in favor of in-person care which may or may not meet the patient's needs or offer the same quality of care. A day supply requirement is arbitrary. There will be some conditions for which an entire treatment regimen is less than 30 days, and other conditions – such as many mental health treatments —for which a 30-day restriction is an absolute barrier to high-quality care.

Additionally, clinical evidence has found:

- Long-term access to buprenorphine treatment can have improved clinical benefits.
- Risk of acute care service use and overdose were high following buprenorphine discontinuation irrespective of treatment duration.
- Patients who have their long-term opioid therapy discontinued or tapered have an increased risk of illicit opioid use

HHS guidance for clinicians notes the risk of sudden discontinuation of opioids may lead patients to seek other sources of opioids, potentially illicit opioids. The Department of Health and Human Services recognizes the clinical endangerment of suddenly cutting patients off from their treatment. DEA, a law enforcement agency, does not have the clinical expertise to recognize endangerment to patients.

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. There will be a risk of the patient being unable to receive continued access to their medications and the loss of access to a treatment that is working for the patient could be as harmful or even more harmful than the original condition being treated.

A time-based restriction is simply not a good approach to prevent diversion while causing many disruptions to the practice of medicine. DEA could consider many alternative options that may more directly address the risk of diversion – such as monitoring and audits of providers with unusually high-volumes or unusual treatment patterns when compared to peers in their specialty.

Thank you for your consideration of our comments. As you know, 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. We urge you to rescind or revise this regulation to better adhere to that standard – and to focus on specific steps that address the diversion DEA has investigated and documented. Please contact me at cadamec@connectwithcare.org with any questions.

Sincerely,

Alliance for Connected Care