



September 5, 2023

Anne Milgram
Administrator
Drug Enforcement Administration
700 Army Navy Drive
Arlington, VA 22202

Re: DEA Public Listening Sessions on Telemedicine Regulations; Recommendations on Special Registration Process

Dear Administrator Milgram:

Thank you for DEA's efforts to hear stakeholder feedback by hosting public listening sessions to receive comments from healthcare practitioners, experts, advocates, patients, and other members of the public to inform DEA's regulations on prescribing controlled substances via telemedicine. We appreciate the opportunity to expand upon our comments^{1,2} to the March 2023 proposed rules^{3,4} to include recommendations around how to create a Special Registration process for telemedicine prescribing of controlled substances.

ATA Action, the American Telemedicine Association's affiliated trade association focused on advocacy, advances policy to ensure all individuals have permanent access to telehealth services across the care continuum. ATA Action supports the enactment of state and federal telehealth coverage and fair payment policies to secure telehealth access for all Americans, including those in rural and underserved communities. The ATA represents a broad coalition of health care providers, including those that exclusively practice telemedicine and those blending virtual and traditional in-person care. It is a guiding principle of the ATA that telehealth is health and health care practice should be regulated on a level playing field regardless of whether in-person or virtual, and regardless of type of virtual platform. ATA Action recognizes that telehealth and virtual care have the potential to truly transform the health care delivery system – by improving patient outcomes, enhancing safety and effectiveness of care, addressing health disparities, and reducing costs – if only allowed to flourish.

Research supports our statements about the importance of prescribing controlled substances via telehealth. A national study showed that utilizing telehealth for medications for opioid use disorder (MOUD) during the pandemic increased odds of treatment receipt and retention as well as decreased odds of overdose when compared to in-person care.⁵ Dr. Shoff, a social science research analyst at the Centers for Medicare & Medicaid Services (CMS), worked on the study, and stated "*the findings showed that telehealth improved the receipt and retention of MOUD, suggesting that this method of healthcare delivery may address common barriers to OUD-related treatment such as transportation and perceived stigma associated with OUD.*"⁶ Results of a study in Southwestern Ohio showed that patients who received video-based telehealth services within 14 days of a substance use diagnosis did not drop out as frequently when compared to patients who received in-person services only.⁷ Retention also has been shown to be higher in underserved communities when telehealth is used. Findings of a study conducted in Pennsylvania and New York that used a virtual-first telehealth OUD treatment platform indicated

that regardless of race/ethnicity and geography, retention for buprenorphine use was high:⁸ *“The limited number of buprenorphine prescribers also makes telemedicine a particularly attractive option for reaching patients in rural and other low treatment access areas.”*⁹ Instead of embracing modern care that eases access to potentially life-saving treatment, in-person requirements do the opposite.

With Attention-Deficit/Hyperactivity Disorder (ADHD) on the rise, it is critical to look at the impacts of telehealth on prescribing practices. Researchers analyzed over 1 million initial patient visits from more than 200 large health systems for ADHD and anxiety to compare potential differences in prescribing practices for telehealth and in-person visits. The data were from Jan. 1, 2020 through March 31, 2023. Eighty-four percent (84%) of the initial telehealth visit prescriptions were for stimulants, which was similar to 87% for patients seen in person.¹⁰

More than 150 million Americans reside in a federally designated mental health desert.¹¹ Thirty percent (30%) of patients lack local access to mental health care.¹² The issue is more pronounced within rural, low-income, and Black or Brown communities.¹³ To compound the problem, our country has a mental health care provider shortage with more than 50% of counties in the country not having a psychiatrist.¹⁴ The importance of telehealth laws for controlled substances goes beyond mental health. Cancer patients who are receiving palliative care may encounter significant challenges with attending outpatient appointments for reasons such as pain, shortness of breath, lack of energy, and the use of assistive devices.¹⁵ These factors make in-person visits even more difficult for end-of-life cancer patients: *“the rapid adoption of telemedicine in response to the COVID-19 pandemic has proven to be highly beneficial for advanced cancer patients and caregivers.”*¹⁶

We appreciate DEA’s responsibility to write rules that provide effective controls against diversion and protect public health and safety, but the requirement that a patient see a clinician in-person is not an effective control against diversion and, instead, simply limits access to legitimate health care. ATA Action’s comments to DEA’s March 2023 proposed rules specifically detail why in-person mandates restrict access to care and how restricted access to telemedicine will increase patient harm and diversion risk. We appreciate DEA’s efforts to review and incorporate stakeholder feedback on those comments, including considering the creation of a Special Registration process.

We maintain that in-person requirements are not a clinically appropriate or effective way to limit diversion and our first preference would be to permanently waive the in-person requirement as was done during the COVID-19 public health emergency. However, practitioners are willing to take extra steps to further demonstrate their legitimacy when practicing via telemedicine and make themselves available to DEA scrutiny in order to root out bad actors. Thus, we respond directly to DEA’s questions regarding the creation of a Special Registration process for that purpose.

We recommend that DEA’s approach to regulating the telemedicine prescribing of controlled substances balance the need to ensure patient access to care with the need to prevent diversion by considering the following two principles:

1. Clinical practice should not be limited by non-clinical decisionmakers.
2. Telehealth is not a type of care, but a modality of care. Rules should take into account the unique nature of the use of technology as a modality without arbitrarily restricting its use.
 - a. Minimum expectation of clinical standards, best practices, and quality should not vary across modalities for the same service.
 - b. However, differences in operations by modality should be taken into account – just as there are advantages and disadvantages to receiving a service in a hospital versus a doctor’s office, there are advantages and disadvantages to receiving a service remotely.
 - c. Advantages of receiving a service remotely include more standardized care across a national practice which may result in higher quality, more convenience and accessibility for both the patient and the provider, and potentially reduced infrastructure costs. Increased access to care is critical given current provider shortages and geographic maldistribution of providers.
 - d. The countering disadvantage to increased access to care via the use of technology is the increased reach that bad actors may have using technology, which speaks to DEA’s concerns of diversion and overprescribing.
 - e. We must ensure that DEA has the tools it needs to prevent diversion without limiting the ability of legitimate prescribers to practice.

Therefore, to create a Special Registration process for telemedicine providers seeking to prescribe controlled substances via telemedicine as a part of their clinical practice, we make the **attached recommendations**. These recommendations seek to strike the balance between ensuring legitimate prescribers can practice, thereby expanding access to needed health care services using the telehealth modality, with preventing diversion. Our recommendations are also designed to fit into DEA’s current infrastructure without creating undue burdens for providers.

Lastly, we urge DEA to consider realistic timelines when implementing these new processes. We appreciate the ability for stakeholders to comment on proposed rules and the allowance of adequate time for DEA to consider such comments. We also emphasize that following a final rule, DEA should allow adequate time for the healthcare industry to accommodate new clinical and administrative procedures and update systems – such as electronic health records, pharmacy management systems, and license verification systems – to promote compliance.

We are pleased to share these recommendations with the DEA. We also look forward to commenting once again on any new or modified proposed rules that DEA puts forth to address telemedicine prescribing post-pandemic. Please do not hesitate to contact us at any time with questions or for further discussion.

Sincerely,

Kyle Zebley
Executive Director
ATA Action

ATA Action’s Recommendations to DEA for a Special Registration Process for Telemedicine Prescribing of Controlled Substances Without a Prior In-Person Visit

September 2023

1. The Special Registration process should work in conjunction with the existing registration process.

Anyone prescribing, dispensing, or administering a controlled substance must register with the DEA under the Controlled Substances Act using form 224 or form 224a for renewals. Form 224 registration is available to practitioners (MD, DO, DDS, DMD, DVM, DPM), “mid-level practitioners” (NP, PA, OD, RPh, and other entities as recognized by their state)¹⁷, pharmacies, hospitals, clinics, and military practitioners. Currently, DEA requires registration in each state where the practitioner practices.

Special registration should be an optional supplemental form associated with the existing registration process and should result in a modifier on a practitioner’s DEA number, such as a “T” at the end, to indicate that the provider has a special telemedicine registration. Providers should use the modified DEA number when issuing a prescription via telemedicine. Thus, a provider will have the same registration number whether they prescribe in person or via telemedicine, but will be able to indicate *both* that they have gone through the special registration process and that the specific prescription was issued via telemedicine when the DEA number on the prescription includes the modifier. We encourage DEA to ensure that this type of information can be transmitted in e-prescribing platforms.

2. Telemedicine providers should not be required to maintain local addresses in every state where they practice.

The value of telemedicine by nature is only fully captured through the ability to practice across state lines. Improving access to care in remote areas or areas lacking specific services or providers will only occur when technology is able to be used to bridge gaps in geography. The Special Registration process should help realize the potential of telehealth to address health access issues while maintaining appropriate oversight of providers.

Providers are already required to obtain state licenses and authority in the states where they practice. Thus, many telehealth providers hold multiple state licenses. However, the most significant limiting factor to a multi-state practice, and the most counter-intuitive, is the requirement to have a physical location in every state where you practice. Having a physical address in each state defeats the purpose of serving patients remotely. Medical boards do not require physicians to have an in-state brick-and-mortar address in order to obtain a medical license, and DEA should follow that same approach for applicants with multistate telemedicine footprints.

In order to obtain a DEA registration, DEA requires applicable state controlled substances licenses and registrations. During the COVID-19 public health emergency, the requirement to have state authority from each state where you practice was waived and prescribers could operate

nationwide using one DEA from one state registration. If DEA deems it necessary to maintain the pre-pandemic requirement that applicable controlled substances authority or registration be obtained in every state where the provider practices, the Special Registration process should allow for such authority to be obtained without the need for a physical address in each state. For prescribers who are not dispensing, administering, or otherwise handling or storing a controlled substance in a state, a physical address in that state should not be necessary. Practitioners should follow all applicable state laws in states where they practice, but it is not necessary for a telemedicine provider to maintain a physical presence in a state where they practice. The Special Registration process for telemedicine prescribing should recognize and account for that.

3. Special Registration should include the elements DEA needs to monitor for illegitimate practitioners and illegal prescribing practices.

- Personal/business information
 - *Address, Phone, and Email:* This is collected in the standard registration process. Practitioners should be able to list the site where they practice in person, the site where they conduct their telehealth practice, or the location of their practice group office. The purpose of this is not to have a physical location in each state, but for the practitioner to be easily contacted by authorities as needed. Thus, the location must include a phone number and email address at which the practitioner can be directly reached. It may be a corporate headquarters if the corporate headquarters has the ability to directly reach the individual practitioner within a reasonable timeframe. Practitioners should NOT be required to publicly list their home address or phone number, even if it is the location where they practice most often. Limiting the physical locations will have the added benefit of making it easier for DEA to monitor an ever-more diverse and mobile prescriber workforce.
 - *Provider identification number:* prescribers should register for telemedicine as individuals using their NPI number.
- State authority
 - *State practice licenses:* Consistent with DEA registration, practitioners should provide valid and active State medical or other clinical licenses to practice, including supervisory agreement or other authorities, as required by the state. Practitioners should provide this information for every state where they have authority to practice.
 - *State controlled substances registration:* should be provided as applicable, but there should not be a requirement that providers maintain a physical presence in each state (see recommendation #2).
 - *States of practice:* In addition to and consistent with state license and controlled substances authority provided, providers could indicate the states in which they

intend to practice. This would need to be easily updatable without re-registration as providers obtain authority to expand into new states.

- *Proof of malpractice insurance:* practitioners could provide proof of malpractice insurance.
- Background check
 - Clinicians currently undergo a standard federal FBI background check as a part of the process to obtain their clinical licenses. If DEA also requires a background check, it should utilize a streamlined process to obtain the necessary information with limited burden on the provider. The DEA should either access the existing federal background check information or request a copy from the practitioner.
- Attestations – we recommend that the DEA include a list of required practices that an applicant should attest to adhering to, potentially including:
 - *Description of practice and clinical protocols:* similar to the information that practitioners provide when applying for malpractice insurance, DEA could require a brief description of a practitioner’s practice, including patient population served and internal and external clinical and quality assurance protocols in place.
 - *Prescription drug monitoring programs:* practitioners should attest that they will utilize the prescription drug monitoring program as required by state law.
 - *Diversion control protocol:* similar to provider responsibility under HIPAA around maintaining privacy of protected health information, practitioners could attest to having practices in place to prevent diversion. Such practices could include the assignment of a clinical or non-clinical Diversion Prevention Officer (similar to a HIPAA Privacy Officer) who is responsible for training staff on identifying and preventing inappropriate practices and periodically reporting any violations to DEA using existing suspicious activity reporting processes. The attestation could include the question “does your medical practice have an internal reporting and investigation process for activity suspicious for diversion or inappropriate prescribing?”.
 - *Patient identification verification protocol:* practitioners could attest to utilizing protocols that ensure patient identity is verified before prescriptions are issued.
 - *Emergency protocols:* practices could attest to protocols and procedures they have in place to address medical emergencies during the course of practice.
- Training requirement
 - *For all registrants:* Starting July 2023, all new and renewed DEA registrants must complete an 8-hour training course on addiction medicine, per Substance Abuse

and Mental Health Services Administration (SAMHSA) guidelines.¹⁸ Special Registration could reiterate the required proof of this training.

- *Special Registration training:* DEA could add a one-hour training requirement in order to obtain Special Registration. This training should not be specific to addiction services, but should be related to preventing diversion of all controlled substances and any unique considerations related to the practice of telemedicine. For example, Washington state now requires healthcare professionals offering telemedicine services to complete telemedicine training, which can either be approved publicly available training or training developed internally by the practice that meets certain guidelines.¹⁹ Mechanics of the training could also be pulled from current HIPAA training requirements.

DEA asks what data is already reported to federal and state authorities, insurance companies, and other third parties. Practitioners report prescribing information to state PDMPs as required by state law or policy. When practitioners contract with insurance companies, they are often required to report licensing and other information. It would not be feasible for either practitioners to report, or for the DEA to receive, data on every prescription at the patient level as a national system for reporting such information does not exist and would trigger significant patient health information privacy and security concerns. It would also be administratively burdensome to create a system redundant to the PDMP.

Potentially feasible actions to provide DEA with more visibility into the prescribing and dispensing landscape and more tools to pursue bad actors could include:

- Requiring that prescribers retain records and share with DEA upon request.
 - Requested information could include aggregated, non-patient-specific, data around prescribing trends over a set time period.
- Requiring that practices proactively report suspicious activity, including based upon their protocols attested to above.
 - In one example, a telehealth provider had a sophisticated system for tracking and verifying patient identity and was able to identify a “patient” illegally submitting identification for multiple identities. Catching such an actor would be more difficult in a brick-and-mortar setting without the use of technological tracking. The suspicious activity was voluntarily reported to the local DEA, but there was not a streamlined mechanism to easily share such information with the DEA.

When reviewing prescribing patterns, it is important for DEA to consider the population that the telemedicine prescriber serves; telemedicine prescribers are often specialized into a treatment area and patients with specific conditions seek them out, so trends may vary from a provider who sees every type of patient in a geographic area. Put more directly, the mere fact that a specialized telehealth practitioner has a high volume of prescriptions of a specific medication should not, on its own, trigger suspicion.

4. Special Registration should not be limited to any specific specialty or treatment condition. Schedule II prescribing could involve additional oversight but should not have additional restrictions.

A wide range of disciplines, including family medicine, internal medicine, pediatrics, child and adolescent psychiatry, endocrinology, emergency medicine, and substance use disorder care rely on appropriately prescribing controlled substances and, therefore, should not be excluded from the Special Registration process.

ATA Action believes that telehealth is health and that clinical judgment should be left to the clinician. There are not distinctions for prescribing of controlled substances for different conditions or treatments for in-person providers, nor should there be for telemedicine providers. It would also further restrict access to certain medications if providers had to obtain another separate registration to prescribe them.

However, we understand that schedule II medications are classified as more dangerous than schedule III-V medications and recognize DEA's interest in particularly limiting diversion of those medications. Therefore, we recommend the same general Special Registration process for schedule II-V medications, but with some additional information required, on the same form, of registrants who indicate interest in prescribing schedule II medications. We would envision the process mirroring DEA's current form which distinguishes between narcotics and non-narcotics. The additional information required could be drawn from the suggestions in recommendation #3, should not be overly burdensome, and should maintain clinicians' ability to practice good clinical judgment.

5. Dispensers (pharmacies and pharmacists) should be able to identify legitimate prescribers who have a current Special Registration.

Traditional practice of pharmacy often relied on pharmacist-prescriber relationships in local areas. Especially in the fallout of the opioid epidemic, pharmacists have been trained to be suspicious of any "red flags" in prescribing patterns and are thus suspicious of prescribers they are not familiar with or not in their geographic area. This has resulted in denials to dispense legitimate prescriptions simply because they were issued via telemedicine, which has negatively impacted patient care. The Special Registration process should be used to help dispensers identify legitimate telemedicine prescribers and have confidence in the legitimacy of prescriptions issued by a prescriber with a Special Registration, even if from a remote location.

We note that the March 2023 DEA proposed rules contemplated requiring the prescriber to include a notation on the face of the prescription that the prescription has been issued via a telemedicine encounter, which we refer to as a telemedicine "stamp." Clinically, a valid prescription is a valid prescription and the fact that one was issued via telemedicine makes it no less so. If the stamp simply indicates that the prescription was done via telemedicine, we anticipate that dispensers would simply see it as an additional "red flag," which would result in further denials to dispense legitimate prescriptions.

If DEA chooses to maintain this prescription “stamp,” we recommend utilizing it to help dispensers identify prescribers who have undergone the Special Registration process to prescribe controlled substance via telemedicine, thereby giving the dispenser confidence that the telemedicine prescription is indeed valid. We recommend that DEA should make clear that the addition of the “T” modifier to the registration number should explicitly indicate to the pharmacist that the geographic red flag should not be considered. If possible, we recommend that DEA create some manner of safe harbor for pharmacists who ignore the geography red flag based on the prescriber’s verified Special Registration status. Pharmacists still have the corresponding responsibility to ensure that they fill legitimate prescriptions, but geography should not be a “red flag” in that process when a prescription is sent by a telehealth provider that has gone through the Special Registration process.

6. The location of the patient should not require any registration unless otherwise required because controlled substances are dispensed or administered at that site.

Patients should be able to receive telemedicine services from their home or any other location, to include clinics, residential treatment facilities, halfway houses, jails, juvenile detention centers, prisons, group homes, rehabilitation centers, schools, qualified hospice programs, and assisted living facilities. Those locations where the patient is during the visit should not be required to have any controlled substances authority. The prescriber prescribing the controlled substance (and the dispenser dispensing it) should hold the controlled substances authority, not the location of the patient when they see the prescriber remotely.

7. The Special Registration process should not place any arbitrary limits on a clinician’s ability to practice within the scope of their authority.

- Prescribers should NOT be limited to treating an arbitrary number of patients.
- Prescribers should NOT be limited to issuing prescriptions for an arbitrary time period.
- DEA should not arbitrarily limit which clinician types have which authorities or privileges – that is governed by state clinical practice laws and boards.
- Prescriptions should NOT be limited to FDA-approved indications. It is legal and common for clinicians to use their clinical judgment to prescribe medications “off-label.”

¹ ATAAction. (2023, March 27). Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation (Docket No. DEA-407).

https://www.americantelemed.org/wp-content/uploads/2023/03/ATA-Action_DEA-telehealth-Docket-No.-DEA-407_March-2023.pdf

² ATAAction. (2023, March 27). Expansion of Induction of Buprenorphine via Telemedicine Encounter (Docket No. DEA-948). https://www.americantelemed.org/wp-content/uploads/2023/03/ATA-Action_DEA-bup-via-telehealth-Docket-No.-DEA-948_March-2023.pdf

³ DEA proposed rule “Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation” on March 1, 2023.

<https://www.regulations.gov/document/DEA-2023-0029-0001>

⁴ DEA proposed rule “Expansion of Induction of Buprenorphine via Telemedicine Encounter” on March 1, 2023.

<https://www.regulations.gov/document/DEA-2023-0028-0001>

⁵ Jones, C.M.; Shoff, C.; Hodges, K.; Blanco, C.; Losby, J.L.; Ling, S.M.; Compton, W.M. (2022). Receipt of Telehealth Services, Receipt and Retention of Medications for Opioid Use Disorder, and Medically Treated Overdose Among Medicare Beneficiaries Before and During the COVID-19 Pandemic. *JAMA Psychiatry*. 79(10):981-992.

⁶ National Institute on Drug Abuse (2022, August 21). Increased Use of Telehealth for OUD Services During COVID-19 Pandemic Associated with Reduced Risk of Overdose. <https://nida.nih.gov/news-events/news-releases/2022/08/increased-use-of-telehealth-for-opioid-use-disorder-services-during-covid-19-pandemic-associated-with-reduced-risk-of-overdose>

⁷ Gainer, D.M., Wong, C., Embree, J.A., Sardesh, N., Amin, A., & Lester, N. (2023, January 29). Effects of Telehealth on Dropout and Retention in Care among Treatment-Seeking Individuals with Substance Use Disorder: A Retrospective Cohort Study. *Substance Use & Misuse*. v 58(4), Pages 481-490.

<https://www.tandfonline.com/doi/full/10.1080/10826084.2023.2167496>

⁸ Williams, A.R., Aronowitz, S.V., Rowe, C., Gallager, R., Behar, E., & Bisaga, A. (2023, March 24). Telehealth for opioid use disorder: retention as a function of demographics and rurality. *The American Journal of Drug and Alcohol Abuse*, v49(2), Pages 260-265.

<https://www.tandfonline.com/doi/full/10.1080/00952990.2023.2180382?src=recsys>

⁹ Lin LA, Fernandez AC, Bonar EE. Telehealth for Substance-Using Populations in the Age of Coronavirus Disease 2019: Recommendations to Enhance Adoption. *JAMA Psychiatry*. 2020 Dec 1;77(12):1209-1210.

¹⁰ Bartelt, K., Barkley, E., Butler, S., & Sandberg, N. (2023, June 27). ADHD Medications Prescribed at Similar Rates During Telehealth and In-Person Visits. *Epic Research*. <https://epicresearchblob.blob.core.windows.net/cms-uploads/pdfs/adhd-medications-prescribed-at-similar-rates-during-telehealth-and-in-person-visits.pdf>

¹¹ DEA Telehealth Proposal Brings Risks, Not Patient Protections. *Health Affairs Forefront*, March 23, 2023.

<https://www.healthaffairs.org/content/forefront/dea-telehealth-proposal-bring-risks-not-patient-protections>

¹² *ibid*

¹³ *ibid*

¹⁴ *ibid*

¹⁵ Aldana, G. L., Onyinyechi, V. E., & Reddy, A. (2023). Best Practices for Providing Patient-Centered Tele-Palliative Care to Cancer Patients. *Cancers*, 15(6), 1809. <https://doi.org/10.3390/cancers15061809>.

¹⁶ *ibid*

¹⁷ Mid-Level Practitioners Authorization by State. (n.d.).

https://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf

¹⁸ Substance Abuse and Mental Health Services Administration. Training Requirements (MATE Act) Resources.

<https://www.samhsa.gov/medications-substance-use-disorders/training-requirements-mate-act-resources>

¹⁹ Washington State Hospital Association. (n.d.). Washington State Telehealth Training Information.

<https://www.wsha.org/policy-advocacy/issues/telemedicine/washington-state-telemedicine-collaborative/telemedicine-training/>