February 14, 2025

The Honorable Derek Maltz
Acting Administrator
Drug Enforcement Administration
700 Army Navy Drive
Arlington, VA 22202

RE: ATA Action Responding to Special Registration for Telemedicine and Limited State Telemedicine Registrations Proposed Rule (Docket No. DEA-407)

Dear Acting Administrator Maltz,

On behalf of ATA Action, we appreciate the opportunity to provide feedback on the Drug Enforcement Administration (DEA)'s proposed rule to establish special registrations for providers and telemedicine platforms to prescribe controlled substances II-IV without requiring an in-person visit. 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. 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. This issue is a top priority for ATA Action and countless stakeholders nationwide. We have long advocated for the DEA to create a special registration process (see here for ATA Action's Special Registration recommendations), and we commend the agency for taking steps toward this goal.

We appreciate the thoughtfulness behind this proposed regulation and the DEA's effort to balance expanded patient access with necessary safeguards against diversion. While we support the creation of a special registration process without in-person requirements, key provisions require clarification and adjustment to ensure workability and effectiveness. Many aspects of the rule are workable for the telehealth community, but without meaningful changes, significant gaps will remain, leaving too many patients without access to necessary care.

ATA Action is committed to collaborate with the DEA in good faith to refine the rule and ensure no patient is left behind. **We urge the DEA to engage closely with telehealth community stakeholders to make the necessary improvements so that the final rule is both practical and effective in supporting providers, enhancing patient care, and serving the broader public interest.**

The following are our specific concerns and recommendations:

Clinical, Operational, and Technical Issues with the Telemedicine Special Registration Eligibility Requirements

The proposed rule authorizes qualified, specialized practitioners to prescribe Schedule II-V controlled substances through telemedicine by creating two distinct prescriber registration

frameworks. However, the proposal introduces several restrictive measures on prescribing Schedule II-V controlled substances that, while well-intended, may restrict access to care or interfere with ongoing treatment of many individuals. First, the proposed requirement mandates special registrant prescriptions for Schedule II controlled substances average less than fifty percent of the special registrant's prescriptions per month. This requirement does not account for unique needs of specialized providers such as psychiatrists and pain management specialists, both of whom routinely prescribe Schedule II substances within the course of their practice. This requirement could arbitrarily prevent qualified practitioners from effectively serving patients via telemedicine. Furthermore, the requirement fails to account for the many counties throughout the country that lack a single licensed psychiatrist. Without having a licensed psychiatrist, counties rely on telemedicine to provide access to psychiatry and behavioral health services, and imposing arbitrary quotas on otherwise valid prescriptions would be tantamount to disrupting continuity of care for numerous adults, adolescents, and children. ATA Action respectfully requests the DEA to disclose the methodology for selecting the fifty percent threshold over other potential percentages, as well as the data used to justify how the fifty percent threshold will mitigate or prevent diversion of controlled substances prescribed through telemedicine platforms.

Second, the proposed rule excludes primary care physicians and general medicine practitioners from the Advanced Telemedicine Prescribing special registration process unless they can meet the "most compelling use case" standard by demonstrating their "need warrants authorization of prescribing of Schedule II controlled substances." Primary care physicians often serve as the first point of care for patients requiring controlled substances, including Schedule II controlled substances, whether for pain management, ADHD, or other conditions. Excluding these providers from treating patients through telemedicine will create unnecessary barriers to care, particularly in rural and underserved communities where specialty care providers may be in shortage. At a time where medical practices are moving towards integrating behavioral health with primary care, this arbitrary exclusion limits the value in deploying innovative integrated clinical models which aim to meet the needs of society amongst a shrinking workforce. ATA Action requests the DEA make available data demonstrating that the selected specialties will have a greater impact on mitigating or preventing diversion of Schedule II controlled substances than permitting general medicine and primary care physicians utilizing telemedicine.

Third, the rule requires that special registrants be physically located in the same state as a patient while prescribing Schedule II controlled substances without any clinical justification. This will once again disproportionately impact patients in states where providers are already in shortage, exacerbating healthcare for individuals in rural communities, and defeating the purpose of telemedicine overall—expanding access to care. This also ignores the many situations where states geographic borders are in close proximity, and patients often cross state lines to access care. Primary examples of this are the "DMV" in the nation's capital area, the New York City metro area, Kansas City metro area, and St. Louis metro area. Respectfully, ATA Action requests the DEA provide data supporting the requirement for patients to reside in the same state as prescribing physicians as a more effective means of reducing or preventing diversion of controlled substances than allowing physicians to prescribe to patients across state lines.

Finally, the proposed rule also places additional hurdles for prescribers of Schedule II controlled substances versus Schedule III-V controlled substances. ATA Action believes clinical decision-making should be left to qualified medical professionals who can evaluate the appropriate level of care for each patient's needs. There is no clear justification for differentiating between Schedule II drugs in a way that could delay or limit patients receiving their necessary treatments. The role of the DEA should be to ensure patient safety and prevent misuse, not to dictate clinical decision-making of practitioners.

Telemedicine Platform Registration and Attestation Processes Warrant Clarity

The DEA's requirement that telemedicine platforms register under the proposed rule lacks clear authority under the Controlled Substances Act (CSA). The CSA grants registration authority to practitioners, pharmacies, and other entities engaging in the handling of controlled substances but does not explicitly provide for registration of technology platforms that do not themselves prescribe or dispense controlled substances. Without specific congressional authorization, the DEA's attempt to impose a registration framework for telemedicine platforms appears to exceed its regulatory authority under the CSA. ATA Action respectfully requests the DEA to provide their legal authority relied upon to register telemedicine platforms.

The proposed rule includes a provision requiring direct-to-consumer telemedicine platforms—rather than simply their affiliated prescribers—to obtain a special registration to prescribe Schedules II-V controlled substances to consumers online. This requirement leaves many logistical and compliance-related questions unanswered. One key concern is who must obtain the special registration? Would it be the management services organization who oversees the telemedicine platform, the affiliated medical practice, or both? Additionally, if a management services organization contracts to provide administrative support services with multiple affiliated medical practices, would each entity require its own registration, or would a single platform registration for the management services organization and all affiliated medical practices be sufficient?

In addition, the attestation process requirement also needs further explanation. The proposed rule indicates that telemedicine platforms seeking a special registration would need to attest to a legitimate need for the special registration but fails to detail to whom the attestation must be made. Moreover, if an individual practitioner working through a telehealth platform exceeds prescribing limitations under the Special Registration, who is subject to disciplinary action? Will it be the provider who made the attestation, the telehealth platform, an individual medical practice, or the management services organization? ATA Action requests more clarity on this component of the proposed Special Registration rule.

Also, the rule asks the platform to attest to all employment, contractual relationships, or professional affiliations with any clinician special registrant, online pharmacy, and their respective registration numbers on Form 224S. Would this operate as a notification requirement for telemedicine platforms or would telemedicine platforms be required to wait for approval from the DEA? If the latter, the approval process could slow down or interrupt care for patients

as new practitioners join or leave the telemedicine platform. Respectfully, ATA Action requests further clarity on this process.

Nationwide Prescription Drug Monitoring Program (PDMP) Check Operationally Unworkable

ATA Action is concerned that the proposed rule for a nationwide PDMP check across all states, districts and territories is not currently feasible due to technical and operational barriers. ATA Action appreciates that DEA has recognized this challenge and included language in the rule to provide for a three-year phase-in and, following the three-year phase-in, permit special registration to continue to perform PDMP checks as outlined for the phase-in period "if there is no means to perform this comprehensive nationwide check." ATA Action urges DEA to retain this flexibility in the final rule.

As DEA recognizes, states operate PDMP independent of one another and not all states capture the same sets of information. While Illinois may capture all information from the prescribing of controlled substances, Indiana may exclude the name of the controlled substance, the location of the patient receiving the prescription, or fail to note whether the prescription provided through telehealth or in-person. The lack of uniformity across the states creates an untenable challenge for our members.

As another example, while forty-eight states participate in the PDMP Interconnect, not all states share data with every other state or jurisdiction. Respectfully, ATA Action requests the DEA provide clear guidance in the final rule on how to achieve compliance with the PDMP check requirement if a state has not begun sharing information with every other state or jurisdiction prior to the proposed rule's three-year grace period lapsing.

ATA Action supports the idea of the PDMP check as a means of safeguarding against diversion and thanks the DEA for recognizing the current limitations that exist to establish a feasible technical or operational means of achieving the PDMP nationwide check.

Special Registration Application, Cycles, and Fees Are Overly Burdensome

During the COVID-19 public health emergency, DEA waived the requirement to register with the DEA in every state in which a practitioner is tele-prescribing controlled substances. ATA Action is deeply concerned that the cumulative costs of reimposing this requirement via the proposed Special Registration fees will create a significant financial burden for telemedicine platforms, individual practitioners, and our health care system—thereby potentially limiting access to affordable telehealth services for patients in need without meaningfully controlling against diversion.

In addition, the cumulative impacts of the fee amounts, as proposed, provides concern. The $888 Special Registration fee will quickly become an economic hardship for both telehealth providers and platforms alike, and adding additional per-state fees for providers serving patients in multiple states increases that economic burden further. For example, one psychologist treating patients via telehealth in 20 states would be required to pay $1,888 every three years, on top of

other licensing and compliance costs. Similarly, many independent practitioners and rural health providers rely on telehealth to reach patients in underserved areas.

Adding cumulative registration fees could create an economic disincentive for many providers and platforms alike to expand across state lines, reducing access to care in rural and medically underserved areas. While large health care systems may be able to absorb these costs, smaller practices may have difficulties in absorbing such additional fees, which will likely lead to passing through these added costs to patients, who may be unable to absorb the costs. Such a shift has the potential to drive up the costs of healthcare and increase healthcare disparities. ATA Action requests the DEA to provide details and assurances that, in the event this proposed rule is finalized, the agency has capacity to efficiently process and approve high volumes of applications without delay.

Concerns with Potential Delays in Granting of Special Registrations

If this proposal were finalized, ATA Action is concerned that the sheer number of new special registration applications could overwhelm the DEA's already limited administrative capacity, leading to significant processing delays. This could create bottlenecks that affect providers, telehealth platforms, and most importantly, patients who rely on timely access to care. Given the rise in telehealth usage, the proposed rule could result in tens of thousands, or even hundreds of thousands, of applications for special registrations in a short timeframe. If the DEA's processing infrastructure remains unchanged, delays could stretch for months, leaving many providers unable to prescribe controlled substances to their patients, and many patients unable to receive the care they desperately need.

ATA Action urges the DEA to extend existing flexibilities beyond the planned expiration date to allow for a gradual transition period to ensure patients do not experience disruptions in care while the registration system is developed. Rather than making an abrupt shift that applies to all providers, we recommend the DEA phase the implementation process by individual regions, provisional registration, or grandfathering period in a manner that allows practitioners to continue to treat patients throughout the process.

Additional DEA Verification Numbers Creates Administrative Burden for Pharmacists and Delays for Patients

ATA Action is concerned that requiring pharmacists to verify five different DEA numbers for prescribers will create an unnecessary and confusing administrative burden, increasing the time and complexity of prescription verification. Pharmacists are already responsible for ensuring compliance with DEA regulations, checking PDMP databases, and assessing the legitimacy of prescriptions. Adding multiple DEA numbers per provider will only exacerbate these challenges, leading to potential delays in dispensing medications and increasing the risk of error. This added complexity is particularly problematic in high-volume pharmacies, where efficiency is critical to ensuring patients receive medications without unnecessary delay. In addition, ATA Action is concerned that most widely used electronic prescribing software platforms would need time to implement additional data fields and integrations in order to facilitate compliance with the

proposed rule. ATA Action urges the DEA to streamline the verification process by considering a single, universal DEA number per provider or implementing an automated verification process that minimizes administrative burdens and maintains the integrity of controlled substances regulation. Congruently, ATA Action requests clarification on whether verifying all five DEA numbers on each prescription is considered part of pharmacists' corresponding responsibility.

The Proposed Rule Should Address Geographic Red Flag Issue

ATA Action has previously requested the DEA provide guidance to the general pharmacy community, clarifying that the geographic distance between a prescriber and patient should not automatically be considered a "red flag" when a prescription results from a legitimate telehealth visit. The lack of clear DEA guidance on the corresponding responsibilities of pharmacists has led to inconsistent pharmacy policies, causing some pharmacies to refuse to fill prescriptions from out-of-state providers, even when legitimately issued. Without clear direction, pharmacies may overcompensate out of fear of regulatory enforcement, resulting in delays, denials, or forced transitions to different medications. A prescription issued via telehealth by a DEA-registered, state-licensed practitioner following proper patient evaluation should not be subject to additional scrutiny due to geographic distances. ATA Action requests the DEA provide clear explanation on what constitutes a pharmacist's corresponding responsibility regarding telemedicine prescriptions.

To address this issue, ATA Action urges the DEA to issue clear guidance stating that the physical location of the prescriber in relation to the patient or pharmacy should not be an automatic red-flag, to clarify enforcement policies to reduce pharmacy uncertainty, and to collaborate with pharmacy organizations and state boards to align policies and prevent unnecessary prescription denials. Without this critical clarification, patients, particularly those in underserved areas, will continue to face unnecessary barriers to accessing essential medications through telehealth (See here for more details).

Patient Identity Verification

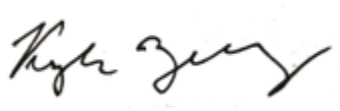
The proposed rule states that special registrants need to capture a photo of the patient and their identification during the initial encounter. There are technologies that many platforms utilize to capture and verify government-issued IDs before the encounter and the physician can verify the patient's identity during the encounter, but the registrant would not need to capture a photo of both the patient and the ID at the same time. Can the DEA clarify the goal of this requirement so that telemedicine platforms and special registrants can determine the least burdensome way to comply?

Looking Ahead: Ensure Access Does Not Lapse

The current pandemic-era flexibilities for the remote prescribing of controlled substances expires at the end of calendar year 2025. ATA Action urges the DEA to ensure that access to these critical prescriptions is not lost by either extending the flexibilities again or publishing a special registration rule that addresses all the concerns outlined above by working with ATA Action and other likeminded stakeholders to get this right.

Thank you for your attention to this important matter. We look forward to collaborating with you and your team to ensure we develop and implement a safe, effective special registration process that strikes the right balance between access to care, patient safety, and diversion prevention. Please reach out to me at kzebley@ataaction.org if you have any questions.

Kind Regards,



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