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Advancing Health in America

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March 18, 2025

Acting Administrator Derek Maltz
Drug Enforcement Administration
ATTN: DEA Federal Register Representative
8701 Morrissette Dr.
Springfield, VA 22152

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

Dear Acting Administrator Maltz:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations; our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to share our comments regarding the Drug Enforcement Administration's (DEA's) proposed rule for Special Registrations for Telemedicine and Limited State Telemedicine Registrations.

The AHA continues to support the concept of a special registration process to waive in-person evaluations prior to the prescribing of controlled substances. However, we are concerned that the proposed process would be inefficient and unnecessarily burdensome. We recommend the agency adopt a more streamlined process that would enable prescribers to register as part of the existing licensure framework. This approach would achieve the agency's crucial goal of mitigating diversion while minimizing excessive burdens on our already overtaxed clinical workforce. Specifically, we urge the agency to:

- Expand the existing DEA registration forms to collect the information sought instead of creating separate registration forms and fees.
- Expand the list of providers eligible for advanced telemedicine prescribing.
- Remove the requirement for Prescription Drug Monitoring Program (PDMP) reviews for every state and territory.
- Remove the requirement for Schedule II prescribers to be physically located in the same state as the patient.
- Remove the requirement for Schedule II prescribers to have less than 50% of Schedule II prescriptions issued as special registration prescriptions.
- Remove certain recordkeeping and reporting requirements, including the requirement to maintain a photographic record of patient identity verification.

Given the scope of the proposed changes, we also encourage the DEA to extend the timeline for implementation, which we recognize would also require extension of the relevant waiver flexibilities until the final rule is published and in effect. Patients, practitioners, platforms, pharmacies and other stakeholders must have adequate pre-implementation periods to prepare for changes in process.

Below are our detailed comments.

Background

The Ryan Haight Act of 2008 established specific requirements for in-person evaluations prior to the prescribing of controlled substances. This law also outlined seven categories of instances in which telemedicine, rather than in-person evaluations, could be utilized. One of these categories was a special registration process, and the law specified that the Attorney General *shall* promulgate regulations specifying circumstances in which a special registration for telemedicine prescribing may be issued as well as the procedures for obtaining such a special registration. The SUPPORT Act of 2018 again mandated that the DEA, in coordination with the Department of Health and Human Services (HHS), promulgate special registration regulations. The law specified: (1) the circumstances in which a special registration for telemedicine may be issued that authorizes prescribing of controlled substances without an in-person evaluation; and (2) the procedures for obtaining a special registration.

The AHA has continuously supported a special registration process to waive in-person visit requirements for those prescribers who register. Indeed, a streamlined special registration process that ensures appropriate tracking of virtual prescribers would help safely ensure access to critical services. As such, we have recommended that the DEA establish such a process based on the existing registration process.[1] Over the last five years, waivers of in-person visits and broad utilization of virtual prescribing have demonstrated significant benefits to patients in accessing lifesaving medication. Meanwhile, data have indicated no increased risk for diversion. **As such, we support the agency's pursuit of a permanent pathway for practitioners to waive in-person visit requirements. However, we have both concerns with and recommendations to improve the agency's proposed special registration process.**

TYPES OF SPECIAL REGISTRATION

The DEA proposes three types of special registration:

- Telemedicine prescribing registration, which would authorize qualified clinician practitioners to prescribe Schedule III-V controlled substances via telemedicine.

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[1] https://www.aha.org/system/files/media/file/2023/03/aha-comment-letter-to-dea-on-telemedicine-prescribing-of-controlled-substances-proposed-rule-3-29-23.pdf.

- Advanced telemedicine prescribing registration, which would authorize certain practitioners to prescribe select Schedule II-V controlled substances via telemedicine.
- Telemedicine platform registration, which would authorize online telemedicine platforms to dispense Schedule II-V controlled substances.

Under the proposed framework, clinician practitioners would be considered clinician special registrants, and platform practitioners would be considered platform special registrants.

In general, we urge the agency to issue clarifying guidance on how post-graduate hospital trainees (also known as residents) would register under this scheme. Residents typically utilize a hospital DEA registration number when prescribing controlled substances in accordance with their residency program. The proposed rules did not address applications in training settings, and therefore we request clarifying.

Additional feedback on the proposed registration types follows.

Advanced Telemedicine Prescribing Registration. In addition to demonstrating a legitimate need for this type of special registration, the DEA proposes that only certain clinician practitioners would be eligible. These include:

- Psychiatrists.
- Hospice care physicians.
- Palliative care physicians.
- Physicians rendering treatment at long-term care facilities.
- Pediatricians.
- Neurologists.
- Mid-level practitioners and physicians from other specialties who are board-certified in the treatment of psychiatric or psychological disorders, hospice care, palliative care, pediatric care, or neurological disorders unrelated to the treatment and management of pain.

The list does not include other specialties or clinical applications that serve patients who would benefit from virtual prescribing flexibilities. For example, a geographically remote patient with cancer receiving pain medications from an oncologist and a home-bound patient with a sleep disorder receiving sleep medication from a pulmonologist could both benefit greatly from access to these services. In these instances, seeing a practitioner in person is simply not an available option. As such, virtual prescription pathways should also be available to these practitioners and patients. **Therefore, we urge the agency to expand the list of eligible providers able to register for advanced telemedicine special registration to include all practitioners who can prescribe these medications in person.** Doing so also would include, for example, oncologists or pulmonologists registered with the DEA.

Telemedicine Platform Registration. The DEA proposes a separate process for telemedicine platform registration, which would authorize virtual practitioners practicing only on telemedicine platforms (as opposed to seeing some patients in person and some via telemedicine) to prescribe controlled substances. **While we agree that it would be beneficial to track these practitioners separately, we urge the agency to issue clarification on this registration process.** We agree that platform providers should maintain certain records of clinicians who enter into a platform relationship (including disciplinary actions and complaints). However, we disagree that the threshold for clinical need should be lower for this category. Specifically, in the proposed rule, platform providers under this designation would be able to prescribe Schedule II-V drugs, the same as advanced registration clinicians; however, the requirements to demonstrate need are aligned instead with the standard telemedicine registration clinicians who are able to prescribe only Schedule III-V drugs. It is unclear why platform special registrants would be held to a different, less rigorous standard than advanced special registrants. This essentially penalizes clinicians leveraging hybrid models of care (in-person and virtual appointments). **If the intent was for platform practitioners to also register as either general or advanced telemedicine prescribers in addition to platform registrants, then we request that the DEA issue such a clarification. Otherwise, we encourage the agency to adopt parallel requirements based on the schedule of drug prescribed.**

STATE REGISTRATION

In addition to the aforementioned special registration categories, the DEA proposes that practitioners would need to complete a state registration for every state in which they treat a patient. The agency proposes that the state registration would be a novel, separate and ancillary credential administered by the DEA (not the states). **We are concerned that this additional layer of licensure is overly burdensome without providing clear benefit, particularly considering existing licensure standards.** Specifically, to require practitioners to submit separate registration forms for each state in which a patient is located is redundant, since the same information is already provided on other forms. That is, the existing general DEA registration process already asks for information on state medical licenses; the proposed process would duplicate efforts without providing additional safeguards.

It is unclear what purpose registering for each individual state would serve given the existing DEA registration process, the proposed special registration questions and state medical licensure processes. If the purpose is to track the states that a telemedicine practitioner is not only licensed in but also wishes to prescribe certain controlled substances to, then a question about this could be added to the general registration form. For example, the DEA could add a question to the existing general registration form such as, “In which states do you have patients that you will virtually prescribe special-registration controlled substances? (check all that apply).” **To avoid unnecessary and duplicative administrative burden, we urge the DEA to remove**

the requirements for practitioners to complete state-specific registration forms and adopt this approach instead.

If the agency does move forward with this proposal, we request it provide guidance on state responsibility for enforcement as the proposed rule also does not address the notification and enforcement process for state registrations. Specifically, it does not address enforcement responsibilities in states where practitioners are licensed and in good standing through state medical boards, are registered and in good standing with the DEA, and have completed the general special registration process but are not registered for an individual state. **Enforcement activities are often complex, involving the DEA, state medical boards and state law enforcement. If this policy is adopted, we request further guidance on both agency and state responsibilities for enforcement.**

SPECIAL REGISTRATION AND STATE REGISTRATION APPLICATIONS

The DEA proposes two new forms (224S and 224S-M for modifications) that practitioners completing special registration and state registration would need to submit. However, as we previously noted, the establishment of a separate form would be redundant, creating undue administrative burden for both practitioners and the DEA, which would need to develop separate systems for processing and tracking the new forms. Specifically, practitioners, hospitals, clinics, pharmacies and others are already required to complete applications for registration and renewal of registrations for prescribing controlled substances through forms 224 and 224a. This process has established guardrails that build upon state medical licensure processes and Medicare reporting. State medical boards screen applicants for education and training as part of licensure processes and are responsible for investigating complaints, monitoring compliance and disciplining providers when necessary. Given the DEA's unique role in mitigating risk of diversion for controlled substances, the registration process complements existing state-based processes. The DEA collects supporting information from physicians about state licensure, locations and adverse actions on the existing applications. **Therefore, rather than creating a novel and separate process or form, we urge the DEA to add any additional information it needs on special registration to the forms 224 and 224a that are already in use.** This way, the special registration process would include both key elements that providers already report — such as practitioner contact information, employer, practice address, state medical licenses, liability history, etc. — and providers could add unique attestations. Indeed, the proposed rule highlighted that the special registration would be contingent on good standing of other DEA registrations and that the special registration location would need to already be registered with the DEA. As such, it would make sense to link special registration questions to the existing form.

SPECIAL REGISTRATION PRESCRIPTIONS

In addition to abiding by state laws where the provider is located, the patient is located and the practitioner is registered with the DEA, under the agency's proposal, providers also would need to follow several provisions related to the prescriptions administered under special registration.

Nationwide PDMP Review. The DEA proposes that for the first three years after the rule is finalized, providers would need to complete PDMP checks for the states where the patient is located, the clinician is located and for any state with a reciprocity agreement to the patient/clinician locations. After three years, the DEA proposes that providers would need to review the PDMPs of all 50 states and territories when prescribing a controlled substance via telemedicine for each patient.

While PDMPs can provide useful information on patients' prescription histories, the proposal to perform PDMP reviews for all 50 states and territories is simply operationally infeasible and is unlikely to offer additional protection against diversion. Performing a PDMP check for all 50 states is not as easy as visiting one website, entering a patient's name and receiving a list of results. First, interoperability infrastructure does not currently exist to support providers reviewing information across all 50 states and territories from a single platform. Interstate data-sharing partnerships vary, with some states limiting data sharing to noncontiguous states. Additionally, "ownership" of the PDMP within state health departments or other agencies (like law enforcement) can also hinder accessibility and data transfer across state lines. According to the Assistant Secretary for Technology Policy, only 31 states reported sharing data with more than 30 states through data-sharing systems like RxCheck or PMP InterConnect.[2] This lack of data sharing means that physicians would have to maintain separate logins for different state PDMP portals, which is incredibly burdensome. In addition, 10 territories do not have PDMPs. There also are large gaps in integration with electronic health records (EHRs). Interfaces between state PDMP databases and EHRs minimize resource requirements, since physicians can seamlessly access prescription histories while reviewing the patient's medical record. However, building PDMP/EHR interfaces can be resource intensive and requires providers to leverage an EHR of sufficient size and scope to support multi-state PDMP interfaces or interfaces with data-sharing systems (like the ones mentioned above). This lack of interoperability means that most physicians would need to manually check individual state PDMP portals, which would, in effect, negate their ability to use this waiver.

Second, PDMP reviews themselves are often time consuming and administratively burdensome. Research (which typically involved just one state) shows that these reviews vary based on specialty. Using psychiatrists as an example, the estimated amount of time used to retrieve PDMP reports is around 22 hours annually.[3]

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[2] https://www.healthit.gov/buzz-blog/health-it/physicians-have-widespread-access-to-state-pdmp-data-but-data-sharing-varies-across-states.

[3] https://pmc.ncbi.nlm.nih.gov/articles/PMC6176751/.

Extrapolating to all 50 states and 14 territories means that the physician would need over 1,400 hours annually just to perform PDMP reviews. That equates to 1,400 fewer patient hours and a cost of over $174,000 per year per prescriber to retrieve this information (using the Bureau of Labor Statistics' average hourly rate for psychiatrists of $124).[4] It is unlikely any provider could absorb this level of burden, especially given the already high degree of burnout among physicians.

Finally, barriers to accessing and interpreting PDMP data are not limited to data interoperability and time challenges. Indeed, the specific data elements, standards and formats also vary from state to state. For example, while there are some common reporting elements, specific data elements are dictated by state-level statute and regulation. This variation hampers the ability of physicians to have a holistic view across all PDMP reports. Also, some states have the ability to create aggregate and custom reports to summarize data longitudinally, whereas others do not and the onus is on the physician to manually aggregate the data. Again, this highlights the cumbersome nature of PDMP review in the current environment.

To be clear, PDMPs are helpful state-level interventions that can improve surveillance on inappropriate prescriptions; however, as we noted in our response to the Assistant Secretary for Planning and Evaluation's Request for Information on Ensuring Patient Access and Effective Drug Enforcement, there is significant room for improvement in each state's PDMP and serious limitations on interoperability across state programs**. As such, we once again urge DEA to coordinate with HHS and other agencies to develop strategies to enhance the data interoperability of PDMPs. This will maximize the utility of PDMP data in the long term and better support physicians in mitigating risk of diversion. In the meantime, we urge the DEA to remove the requirements for additional PDMP reviews beyond current standards for in-person prescribing of controlled substances and limit the requirement to the state where the provider and patient are located.**

Special Registration Audio-Video. In the proposed rule, the DEA would mandate that a clinician special registrant utilize both audio and video components of an audio-video telecommunications system to prescribe under the special registration framework. This unnecessarily restricts patients' access to virtual prescribing when video technology may not be available. CMS has identified the services that are eligible for audio-only encounters. **Similarly, we encourage the DEA to provide parameters or exceptions where audio-only prescribing may be appropriate.**

Schedule II Special Registration Prescriptions. The agency proposes two additional requirements for special registration prescriptions of Schedule II drugs. First, the agency proposes that clinician special registrants prescribing Schedule II drugs be physically located in the same state as the patient. However, this arbitrary requirement defeats the

[4] https://www.bls.gov/oes/2023/may/oes291223.htm.

purpose of virtual prescribing flexibilities and limits patient choice. Physician shortages are impacting some states and specialties more acutely than others. For example, Texas has over 13 million people living in mental health care provider shortage areas and would need 614 additional practitioners to remove that designation.[5] Restricting special registration practitioners to prescribing these drugs only to patients in their state would not help with existing shortages such as these. Often practitioners are simply not available in some communities, and telemedicine provides options for patients to access geographically dispersed practitioners located in other states. So long as practitioners are abiding by federal and state statute and conforming to standards issued by state licensing boards, we urge the DEA to not arbitrarily limit access to services. **As such, we ask that the DEA remove the requirement for providers and patients to be located in the same state for prescribing of Schedule II drugs.**

Additionally, the agency proposes to require that the number of special registration Schedule II drugs constitute less than 50% of the total number of Schedule II drugs issued by the clinician in their telemedicine and non-telemedicine practice in a calendar month. **We are unclear from the discussion in the rule why the agency proposed this standard, and without further rationale, we recommend removing it.** There is no evidence to suggest that requiring practitioners to prescribe less than 50% of drugs virtually would mitigate risk of diversion. Rather, the agency relies on a general assumption that because controlled substances can be misused, an increase in access results in increased risk.

RECORDKEEPING AND REPORTING

The DEA also proposes additional recordkeeping and reporting requirements. For example, it proposes that clinician special registrants be required to capture a photographic record of the patient presenting federal- or state-issued identification cards. If the patient does not feel comfortable with the clinician taking a picture, the patient could provide a copy of their ID. **We are concerned that this requirement could raise fair concerns by patients about their privacy, while at the same time not adding additional protection against diversion.** Telehealth providers generally document in the medical record an attestation that patient identification was verified. There are also standards at the state level on types of data fields required for identity verification, some of which may not be on a state or federal ID card. Therefore, having photographic evidence of identity presentation is unnecessary and adds administrative burden to take and preserve a photo in the medical record. This detracts from the clinical time that the practitioner is engaging with the patient, is costly to maintain and poses unnecessary risk (i.e., capture and maintenance of additional sensitive data). Just as a practitioner would not be expected to take a picture of a patient in an exam

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[5] https://www.kff.org/other/state-indicator/mental-health-care-health-professional-shortage-areas-hpsas/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Practitioners%20Needed%20to%20Remove%20HPSA%20Designation%22,%22sort%22:%22desc%22%7D.

room to verify identity, the same standard applies to virtual appointments. Finally, there is no evidence to suggest that this added requirement would minimize risk of diversion. **As such, we urge the DEA to defer to state requirements for identity verification and not impose additional requirements.**

We also are concerned that additional reporting requirements, like the requirement for pharmacies to generate monthly reports of special registration prescriptions filled and the requirement for practitioners to generate annual special registrant reports, are overly burdensome and will not lead to reduced risk of diversion. According to the proposed rule, the DEA would require pharmacies to report aggregate data within the first seven days of every month on the special registration prescriptions filled during the preceding month for each Schedule II controlled substance and certain Schedule III-V controlled substances. These requirements could result in further limiting access since providers may simply elect to no longer virtually prescribe medications or fill telemedicine prescriptions since it is too burdensome to keep up with the recordkeeping and reporting requirements. This has already been an issue with "red flags" for prescriptions issued in remote geographies, where pharmacists have declined filling prescriptions for controlled substances from outside states. There are many reasons a virtual prescription may be filled in a remote state or geography: a patient is on vacation, a student is in college, a patient is maintaining the same provider after moving out of state, a patient is seeing a specialist in a different state when they cannot find a doctor locally, etc. Nonetheless, distance from the prescriber and patient has been identified as a "red flag" and has hampered access as many pharmacies are simply opting to not fill virtual prescriptions. The potential risk to access in these cases may outweigh potential risk of diversion. **In addition to removing the requirements for additional annual and monthly reports, we urge the agency to also remove reference to geography as a red flag for risk of diversion.**

Given the scope of a new special registration process and breadth of potential changes, we also urge the agency to delay implementation to allow adequate time for stakeholders to prepare. Specifically, we request that the DEA provide at least a one-year pre-implementation period after rules are finalized to ensure that practitioners can appropriately prepare for changes. Simultaneously, we urge the agency to extend the current in-person visit waivers to avoid gaps in access until rules are finalized.

We thank you for considering our comments on this proposed rule. If you have any questions concerning our comments, please feel free to contact me or have a member of your team contact Jennifer Holloman, AHA's senior associate director of policy, at jholloman@aha.org or Caitlin Gillooley, AHA's director of behavioral health and quality policy, at cgillooley@aha.org.

Sincerely,

/s/

Ashley Thompson
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