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Submitted via www.regulations.gov

March 17, 2025

The Honorable Derek S. Maltz
Acting Administrator
United States Drug Enforcement Administration
800 K Street, NW Suite 500
Washington, DC, 20001

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

Dear Acting Administrator Maltz:

The Association of American Medical Colleges (the AAMC) welcomes this opportunity to comment on the Drug Enforcement Administration (DEA) proposed rule "Special Registrations for Telemedicine and Limited State Telemedicine Registrations," 90 *Fed. Reg.* 6541 (January 17, 2025).

The AAMC (Association of American Medical Colleges) is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, biomedical research, and community collaborations. Its members are all 160 U.S. medical schools accredited by the Liaison Committee on Medical Education; 12 accredited Canadian medical schools; nearly 500 academic health systems and teaching hospitals, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools, academic health systems and teaching hospitals, and the millions of individuals across academic medicine, including more than 210,000 full-time faculty members, 99,000 medical students, 162,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Through the Alliance of Academic Health Centers International, AAMC membership reaches more than 60 international academic health centers throughout five regional offices across the globe. Learn more at aamc.org.

We recognize that the DEA plays an important role in preventing drug diversion and ensuring the legitimate prescribing of controlled substances. We are thankful for the DEA's willingness to consider stakeholder input, and we appreciate the Agency's use of the feedback from the previous proposals[1] on this topic in the development of this proposed rule. Although the new proposals address many of our previous concerns,[2] there are outstanding policies we wish to

[1] DEA, Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation, 88 FR 12890. (Mar. 1, 2023)
[2] AAMC, Comments to the DEA (Docket No. DEA-407). (Mar. 31, 2023)

address. We continue to urge the DEA, the Department of Health and Human Services (HHS), and Congress to work collaboratively to break down barriers to care while limiting drug diversion and preventing illegal drug sales.

GENERAL REGISTRY PROPOSALS

Allow Practitioners to Prescribe Controlled Substances via Telemedicine if the Patient Has Been Seen In-Person by Another Practitioner Within the Same Group Practice

We urge the DEA to amend the rules to allow a practitioner to prescribe controlled substances via telemedicine to a patient who has received an in-person medical evaluation from another practitioner who is in the same group practice without requiring the prescribing practitioner to participate in a special registry.

Under the Continuity of Care via Telemedicine for Veterans Affairs Patients Final Rule,[3] a Veterans Affairs (VA) practitioner who is acting within their scope of employment with the VA is permitted to prescribe controlled substances via telemedicine to a VA patient without an in-person medical evaluation if another VA practitioner has previously rendered an in-person visit with the patient.[4] Similar to the VA, practitioners in the same group practice have access to the patient's complete medical record in the electronic health record (EHR) system. Access to the EHR provides key information about the patient's condition, including the in-person medical evaluation, medical history, and medication history to allow practitioners in the same group practice to safely determine whether to prescribe the controlled substances or to conduct a telehealth or in-person visit for further evaluation. Additionally, practitioners in group practices often split duties to serve as an "on call" provider for the specialty, and cover emergency virtual consultations with patients across the practice. Practitioners on call or covering for colleagues must be able to prescribe controlled substances to assist with treatment plans. Therefore, if a practitioner in a group practice has seen a patient in-person, another practitioner in that group practice can use the patient's medical record to continue treatment virtually safely and effectively. Allowing practitioners to work collaboratively across the group practice improves the continuity of care.

Expand the Clinician Specialties Eligible to Participate in the Advanced Telemedicine Prescribing Registration for Schedule II Controlled Substances

The DEA proposes to limit the Advanced Special Registry to psychiatrists, hospice care physicians, palliative care physicians, physicians rendering treatment at long term care facilities, pediatricians, neurologists; and mid-level practitioners and physicians from other specialties who are board certified in the treatment of psychiatric or psychological disorders, hospice care,

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[3] DEA, Continuity of Care via Telemedicine for Veterans Affairs Patients, 90 FR 6523 (Jan. 17, 2025), further updated in Expansion of Buprenorphine Treatment via Telemedicine Encounter and Continuity of Care via Telemedicine for Veterans Affairs Patients, 90 FR 9841 (Feb. 19, 2025).
[4] 42 CFR §12.4(a).

palliative care, pediatric care, or neurological disorders unrelated to the treatment and management of pain. (pp.6549-50)

We urge the DEA to expand the Advanced Registry to allow family medicine practitioners, internists, oncologists, and infectious disease specialists to participate. We believe that these practitioners have received the appropriate training and are qualified to prescribe Schedule II substances to patients via telemedicine without an in-person visit. The past several years has provided a case study or trial period that has provided further evidence to support this recommendation. During the COVID-19 PHE and extended through CY 2025, the DEA used its emergency authority to waive the requirement that providers conduct an in-person evaluation prior to prescribing controlled substances via telemedicine.[5] As a result, many DEA-licensed practitioners, including family medicine practitioners, internists, oncologists, and infectious disease specialists have been permitted to prescribe controlled substances via telemedicine without an in-person visit. This waiver has increased access to clinically appropriate medications, including for mental health and substance use disorder treatment, by enabling providers to safely prescribe controlled substances remotely using telemedicine.

This telemedicine waiver has been especially important given the shortage of qualified behavioral health and primary care providers. According to data from the Health Resources and Services Administration (HRSA), as of March 17, 2025, 122 million people currently reside in a Mental Health Professional Shortage Area (HPSA) and there are 6,202 fewer practitioners than are needed.[6] Currently, 77 million people reside in a Primary Care Shortage Area and there are 13,364 primary care practitioners that are needed.[7] Additionally, a March 2024 report from the AAMC predicts a shortage of up to 86,000 physicians by 2036.[8]

These shortages have a real impact on patients, particularly those living in rural, frontier, island, or non-contiguous settings, and other communities with limited access to care. For example, in some rural areas communities may not have a psychiatrist within a commutable distance. In these cases, family medicine and primary care providers often fill the gap in the healthcare system by providing care via telemedicine. Oncologists often rely on prescribing Schedule II drugs via telemedicine because the severity of the illnesses that they treat often impact their patient's ability to travel to see a specialist in-person. Similarly, due to the communicable nature of the conditions treated by infectious disease specialists, it is also crucial that these practitioners can prescribe their patients Schedule II controlled substances via telemedicine when medically necessary, to limit the spread of infectious diseases. The AAMC is concerned that patients will be left without access to their medically necessary prescriptions due to the narrow scope of practitioners who can participate in the proposed Advanced Registry.

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[5] DEA, Third Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Substances, 89 FR 91253 (Nov. 19, 2024).
[6] HRSA, Data on Health Professional Shortage Areas by Discipline (last checked Mar. 2024).
[7] *Id.*
[8] AAMC, The Complexities of Physician Supply and Demand: Projections From 2021 to 2036 (Mar. 2024).

APPLICATIONS AND REPORTING PROPOSALS

The rule creates several requirements that a practitioner must satisfy to issue a prescription for a controlled substance following a telemedicine encounter. In addition, the rule imposes additional recordkeeping requirements for these telemedicine encounters to enhance the DEA's ability to detect and investigate the potential misuse of telemedicine to prescribe controlled substances. As discussed in more detail below, we believe that some of these requirements are overly burdensome and would interfere with access to care.

Allow a Five-Year Cycle for Both the Registry Application (Form 224S) and the DEA-Issued State Specific Registration to Mirror the Medicare Five-Year Renewal Cycle

The DEA proposes to require a three-year application cycle for each of the proposed registries. We believe that a three-year cycle is overly burdensome to providers and will not assist the DEA and its anti-diversion goals. (p. 6543) Administratively, a three-year application cycle is not cost-effective and is operationally challenging for potential participants, ranging from practitioners from large health systems to solo practitioners.

We recommend that DEA create a five-year registration cycle for both the Registry Application (Form 224S) and the DEA issues State Specific Registration to mirror the application cycle of the Medicare program. The Centers for Medicare & Medicaid Services (CMS) requires Medicare providers to revalidate or renew their enrollments every five years to maintain Medicare billing privileges.[9] This five-year cycle has allowed CMS to maintain updated records without creating additional costly administrative burden for participants. We believe that a similar five-year cycle would allow the DEA to effectively maintain up-to-date information necessary to achieve its anti-diversion and enforcement goals while limiting administrative burden.

CMS has also initiated certain procedures to promote efficiency and streamline the revalidation process. For example, Medicare practitioners can review current information on file, upload supporting documents, and electronically sign and submit the revalidation application.[10] CMS also sends a revalidation notice to providers and group practices before their revalidation due date.[11] We recommend that the DEA create similar procedures that allow for a streamlined revalidation process at the end of each cycle. Reducing administrative burden ultimately allows providers to spend more time with patients, improving access to care, and clinical outcomes.

Amend Form 224S—M Requirements to Allow Clinicians 30 Days to Report any Changes to the Information Provided in the Initial Application

The DEA proposes to require registrants to notify them of any changes to information provided in the application within 14 business days. (p. 6552) This includes information such as new

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[9] CMS, "Revalidations (Renewing Your Enrollment)" (webpage last modified Sep. 10, 2024), stating "In general, providers and suppliers revalidate every five years [.]"
[10] *Id.*, describing the Provider Enrollment, Chain, and Ownership System, or PECOS, as "the most efficient way [for providers] to submit [their] revalidation."
[11] *Id.*, describing that Medicare Administrative Contractors (MACs) send revalidation notices via email or U.S. postal mail about three to four months prior to the revalidation due date.

arrangements with direct-to-consumer platforms or prescribing in a new state. The proposed timeline is unreasonably expedited and may not be feasible for participants. CMS allows 30 days for Medicare participants to provide updates of any critical changes to the Medicare application.[12] Due to the novel nature of the special registries, we strongly recommend that the DEA allow a minimum of 30-days to report changes to a special registry application which mirrors the Medicare application requirements. We believe that a 30-day period, at a minimum, is necessary as providers develop new policies and procedures to promote efficient reporting compliance.

Remove the Requirement to Perform a Prescription Drug Monitoring Program (PDMP) Check for States or Territories with Reciprocity Agreements

The DEA proposes to require prescription drug monitoring program checks. For the first three years the DEA is proposing to require a PDMP check for (1) the state or territory where the patient is located; (2) state or territory where the clinician practitioner is located; and (3) any state or territory with PDMP reciprocity agreements with either the state or territory where the patient is located or the state or territory where the clinician practitioner is located. After three years the DEA will require a national PDMP check of all 50 states and any other U.S. district or territory that maintains its own PDMP, assuming a national registry is available. If after three years, there is no mechanism available to perform a nationwide check the DEA will require providers to return to the previous policy. (p. 6543)

The AAMC strongly supports the creation of a national PDMP. We believe a national PDMP check will effectively support the DEA's anti-diversion efforts for controlled substances. However, we are concerned that the implementation process will likely extend beyond three years. In the meantime, we are supportive of the proposal to require a PDMP check for the state or territory where the patient is located; and state or territory where the clinician practitioner is located. However, we recommend eliminating the third requirement, to perform a PDMP check-in any state or territory with PDMP reciprocity agreements with either the state or territory where the patient is located or the state or territory where the clinician practitioner is located, as it is overly burdensome.

Eliminate 50 Percent Threshold for Telemedicine Prescriptions of Schedule II Controlled Substances

The DEA proposes to require the average number of special registration prescriptions for Schedule II controlled substances must constitute 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. (p. 6556)

We urge DEA not to finalize this policy as it is overly burdensome, infeasible, arbitrary, will jeopardize patient care, and will not assist the DEA in its anti-diversion goals. Operationally, we

[12] CMS, Become a Medicare Provider or Supplier (website last modified Dec. 16, 2024) stating, "to avoid having your Medicare billing privileges revoked, be sure to report [critical changes] within 30 days"

do not believe that EHRs or other systems have the capability to proactively track this information, requiring a provider or their administrative staff to run retrospective reports for ongoing tracking. This policy would likely limit patient access to medically necessary medications depending on when a patient has a scheduled appointment, based on the prior prescription habits of the prescribing physician. If prescribers determine that their average telemedicine prescribing is greater than 50 percent during a given month, they will need to adjust future prescribing patterns for that month in a manner that is not based on medical decision making.

LOCATION PROPOSALS

Remove Requirement that Special Registrants be Licensed and Authorized Within the State and Territory Where the Practitioner is Located When the Telemedicine Encounter Occurs in Line with the Existing Waivers

The DEA is proposing to require special registrants to be licensed and authorized within the state and territory where the practitioner is located when the telemedicine encounter takes place, in addition to where the patient is located, which is already required by the DEA (p.6553) During the PHE, the DEA granted a temporary exception to its regulations to allow practitioners to prescribe controlled substances via telemedicine in states in which they are not registered if the practitioner is registered with the DEA in at least one state and has permission under state law to practice using controlled substances in the state where the dispensing occurs.[13] After the PHE, the DEA extended this waiver through CY 2025.[14] Beginning CY 2026, this rule would end this waiver and replace it with a requirement that the prescribing practitioner be DEA registered where they are located when the telemedicine encounter occurs and where the patient is located.

We urge the DEA to remove the requirement that the prescribing practitioner be registered in the state where they are located when they are issuing the prescription as it will limit access to care. Instead, current regulations that require that the prescriber be DEA registered and be legally authorized to practice in the state where the patient is located is a reasonable approach to ensuring patient protection[15]. If the DEA prescriber is traveling out of state temporarily when the patient needs a refill of their prescription, the practitioner would be unable to fill the prescription if the practitioner had to be DEA registered in their current location. Removing the proposed requirement that clinicians be registered in the state where they are located when issuing the prescription, would enable them to address urgent patient needs when they are temporarily in another state, helping to address provider shortages and improve access.

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[13] DEA, Diversion Control Division Guidance Document (DEA-DC-044), stating "In particular, during the COVID-19 public health emergency, DEA has granted a temporary exception to its regulations—Exception to Separate Registration Requirements Across State Lines (DEA067), issued March 25, 2020—to allow practitioners to prescribe controlled substances in states in which they are not registered if the practitioner is registered with DEA in at least one state and has permission under state law to practice using controlled substances in the state where the dispensing occurs."
[14] *Supra*, note 5.
[15] 21 U.S.C Sec 802(54)(A)(ii).

Eliminate the Requirement that Practitioners Must be Located in the Same State as the Patient When Prescribing a Schedule II Controlled Substance

The DEA proposes to require special registrants to be physically located in the same state as the patient when issuing a special registration prescription for Schedule II controlled substances. (p. 6556) This policy would prevent practitioners from prescribing Schedule II controlled substances via telemedicine to patients located in other states, despite being authorized and licensed to practice in the state where the patient is located. Once a practitioner is licensed and authorized to practice within a state, they are monitored by the medical licensing board within that state. They are required to abide by all state laws and requirements. State medical licensing boards have the authority to address any instances that may arise from the practitioners practicing telemedicine within their state. Practitioners are also required to perform a PDMP check in the state where the patient is located. Therefore, it is unnecessary to prevent practitioners who are engaging in telemedicine in a state where they are licensed and authorized to practice simply because they are not physically present within that state.

The audio-visual telecommunications technology that allows for care to be provided beyond the practitioner's physical location promotes expanded access to care, which is important given the provider shortages. Eliminating this requirement would make it more feasible for practitioners to expand access to medically necessary prescriptions by increasing the availability of practitioners. It will allow greater access to specialists, which will benefit patients in rural areas who do not have access to local specialists.

If a practitioner has a license to practice in a state and is in good-standing with the state medical boards, they should be permitted to prescribe schedule-II substances under the special registry within that state regardless of where they are physically located within the United States and its territories.

CONCLUSION

Thank you for the opportunity to comment on this proposed rule. The AAMC would be happy to work with the DEA on any of these issues discussed or other topics that involve the academic medicine community. Should you have any questions, please contact Ki Stewart at kstewart@aamc.org.

Sincerely,

Jonathan Jaffery, MD, MS, MMM
Chief Health Care Officer

cc: David Skorton, MD, AAMC President and CEO