HEALTHCARE
LEADERSHIP COUNCIL

March 18, 2025

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

RE: Docket No. DEA-407 – Special Registrations for Telemedicine

Dear Acting Administrator Maltz:

On behalf of the Healthcare Leadership Council (HLC), we appreciate the opportunity to provide comments on the Drug Enforcement Administration (DEA) proposed rule, "Special Registrations for Telemedicine and Limited State Telemedicine Registrations."[1]

HLC is an association of CEOs and C-suite executives from all sectors of healthcare working to shape the future of the U.S. healthcare system. HLC is the exclusive forum for the nation's healthcare industry leaders to lead on major, sector-wide issues, generate innovative solutions to unleash private sector ingenuity, and advocate for policies to improve our nation's healthcare delivery system. Members of HLC – hospitals, academic health centers, health plans, pharmaceutical companies, medical device manufacturers, laboratories, biotech firms, health product distributors/wholesalers, post-acute care providers, homecare providers, group purchasing organizations, and information technology companies – advocate for measures to increase the quality and efficiency of healthcare through a patient-centered approach.

HLC and our member companies champion the role of telehealth in expanding patient access to comprehensive medical care and improving convenience, while also helping to mitigate workforce shortages, particularly in rural areas. Ensuring patients can receive necessary treatments – including controlled substances – through telehealth is critical to maintaining continuity of care and addressing gaps in provider availability.

Overview

HLC appreciates the DEA's efforts to establish a long-overdue special registration framework, as mandated by the Ryan Haight Act of 2008, to allow practitioners to prescribe controlled substances via telemedicine without an initial in-person medical evaluation. This framework is intended to balance clinically appropriate access to care while mitigating threats of misuse, abuse, and diversion. We support the overall intent of the proposed special registration process which enables access to care without in-person requirements. However, we have concerns with some of the proposals and seek revisions, outlined below, to help ensure operational feasibility for all impacted parties. These revisions will alleviate unnecessary barriers to care while supporting appropriate access to care and advancement of these important public health goals.

We strongly urge the DEA to consider the healthcare community's feedback on the proposed rule and closely collaborate with stakeholders to design a more balanced special registration framework

[1] https://www.govinfo.gov/content/pkg/FR-2025-01-17/pdf/2025-01099.pdf.

– one that ensures appropriate safeguards against drug misuse and diversion, preserves patient access to critical care, and minimizes unnecessary operational burdens.

With the current pandemic-era flexibilities set to expire at year end, we encourage DEA to either revisit the current extension or work quickly to ensure promulgation of a final rule that reflects stakeholder feedback and can be implemented by all impacted entities. This will help ensure patients and providers do not lose access to legitimate pathways for evidence-based, clinically appropriate care.

Access Barriers and Operational Challenges

A viable special registration process to govern remote prescribing of controlled substances (without any in-person requirements) must be practical for providers to implement while maintaining appropriate safeguards against diversion, misuse, and abuse. Unfortunately, the current proposal falls short of achieving this balance, instead introducing complex, burdensome requirements that will harm patient access, disproportionately impacting vulnerable populations, rural communities, and patients with behavioral health or chronic conditions.

The following are examples of provisions in the proposed rule that create significant barriers to access and impose impracticable operational requirements. We request that the DEA revisit these proposals to minimize patient and provider burdens to ensure a final rule is both implementable and effective.

- **The 50% Prescribing Limitation Is Arbitrary and Operationally Impracticable.** The proposed rule disqualifies clinicians from special registration if more than 50% of their Schedule II (CII) prescriptions are issued via telemedicine, yet DEA offers no evidence to support this threshold or that such policy would prevent diversion. This arbitrary cap disregards telemedicine's role in rural areas, behavioral health, and care deserts. It could inadvertently impact clinicians whose practices are not based in a brick-and-mortar clinic (or operate in a hybrid modality) and could force specialists to limit prescriptions or turn patients away in order to comply. Additionally, the requirement is unenforceable, as pharmacists have no way to verify whether a prescriber has exceeded the 50% threshold when filling a prescription. Instead of imposing ineffectual restrictions, DEA should focus on targeted enforcement of bad actors rather than limiting legitimate providers who use telemedicine to expand patient access to clinically appropriate care. Additionally, DEA seeks to impose additional hurdles for CII prescriptions that are not otherwise required of Schedule II through V. Healthcare providers should be responsible for making appropriate, evidence-based decisions for the unique needs of a given patient. Moreover, the addition of arbitrary guardrails on CIIs could needlessly delay or impede access to timely care.
- **Excluding Primary Care and General Medicine Practitioners Ignores Patient Needs.** The proposed rule's exclusion of primary care providers (PCPs) and general medicine practitioners from the special registration process undermines patient access to care. PCPs often serve as the first point of contact for patients requiring controlled substances to address a variety of clinical needs. Communities nationwide lack specialized providers and patients often rely on their PCP for both acute and chronic needs. Arbitrarily limiting the types of providers eligible for special registration may significantly disrupt legitimate access.

- **Geographic Restrictions on CII Prescribing Undermine Telemedicine Access.** The proposed rule requires a special registrant to be physically located in the same state as the patient when prescribing CII medications via telemedicine, a restriction that undermines telemedicine's core purpose – expanding access to care. While site-based restrictions may have been relevant when telehealth technology was less advanced, today's clinicians effectively provide high-quality virtual care nationwide. This geographic limitation disproportionately impacts patients in rural areas, where access to behavioral health providers often depends on out-of-state clinicians, as well as college students, who may lose access to established providers when attending school away from home. It also fails to account for situations in which patients and providers are located in close proximity to one another albeit across state lines. Many individuals who travel across state lines to receive services and treatments would see dramatic changes to their ability to access care. HLC would appreciate clarification from DEA as to the anticipated impact on misuse, abuse, or diversion by limiting teleprescribing to a specific geographic area.
- **Nationwide PDMP Check Requirement is Operationally Unworkable.** The proposed rule requires clinician special registrants to check all 50 state Prescription Drug Monitoring Programs (PDMPs), as well as any U.S. district or territory maintaining a PDMP, before issuing a special registration prescription for a controlled substance. While this nationwide PDMP check would be phased in over three years, the DEA acknowledges that no mechanism currently exists to perform such a check. Nationwide PDMP checks have the potential to serve as a helpful tool to safeguard against patients or providers seeking inappropriate access to controlled substances; and we appreciate DEA's recognition of that value. However, it is not technically feasible with the infrastructure that exists today. Additionally, PDMPs do not leverage uniform data sets, and many are not integrated with electronic health records, requiring providers to exit clinical workflows, manually log into multiple systems, and conduct redundant queries – a time-consuming and inefficient process. The lack of uniformity in both access and content presents a significant challenge for HLC members and the broader community.
- **Unnecessary Registration Requirement for Telemedicine Platforms and Direct-to-Consumer Companies.** The proposed rule expands DEA registration requirements to certain telemedicine platforms and direct-to-consumer companies, even if they do not directly prescribe or dispense controlled substances. Expanding the entities subject to these requirements is a significant shift in DEA's interpretation of the Controlled Substances Act, which has traditionally applied registration requirements only to prescribers, pharmacies, and entities that physically handle controlled substances. Under the proposed rule, telemedicine platforms would be required to register with the DEA if they exert control over clinical decision-making, influence prescribing practices, or manage prescription or medical records. This broad and ambiguous new classification creates uncertainty about which entities will be subject to registration, particularly for technology-driven healthcare companies that facilitate telemedicine access but do not directly prescribe or dispense controlled substances. Additionally, DEA has not provided sufficient clarity on how it will process and oversee these new registrants, raising concerns about potential administrative delays and unintended disruptions to virtual care access.

Conclusion

Thank you for the opportunity to provide comments on the proposed rule. Given its substantial shortcomings, we urge the DEA to collaborate with entities in the healthcare value chain to develop a more effective, patient-centered framework that preserves access while preventing diversion. HLC and our members stand ready to partner with the DEA to ensure that any final rule supports high-quality, accessible, and clinically appropriate care. If you have any questions, please do not hesitate to contact me at kmahoney@hlc.org or (202) 449-3442.

Sincerely,

Katie Mahoney
Executive Vice President and Chief Policy Officer