

March 18, 2025

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

RE: ABHW Response to the <u>Special Registration for Telemedicine and Limited State Telemedicine Registrations Proposed Rule</u>; Docket No. DEA-407

Dear Acting Administrator Maltz,

The Association for Behavioral Health and Wellness (ABHW) appreciates the opportunity to provide feedback on the Drug Enforcement Administration (DEA)'s Special Registration for Telemedicine and Limited State Telemedicine Registrations Notice of Proposed Rulemaking (NPRM or proposed rule) that will establish special registrations for providers and telemedicine platforms to prescribe controlled substances II-IV without requiring an in-person visit.

ABHW is the national voice for payers managing behavioral health insurance benefits. ABHW member companies provide coverage to 200 million people in the public and private sectors to treat mental health (MH), substance use disorders (SUDs), and other behaviors that impact health and wellness.

Our organization aims to increase access, drive integration, support prevention, raise awareness, reduce stigma, and advance evidence-based treatment and quality outcomes. Furthermore, our policy work strives to ensure that physical and behavioral health care is integrated and coordinated. ABHW is focused on guaranteeing better outcomes for whole-person care for all individuals and communities.

We appreciate the thoughtfulness behind this proposed rule and the DEA's effort to balance expanded access while also maintaining the necessary safeguards to maximize patient safety. ABHW supports the creation of a special registration process without in-person requirements but encourages the DEA to make some adjustments to the proposal to enhance patient care and serve the broader public interest effectively.

Please see our specific concerns and recommendations below:

I. The Telemedicine Prescribing Registration



As discussed above, ABHW is grateful that the DEA has proposed a system that would authorize qualified practitioners to have less restrictive separate enhanced pathways for prescribing Schedule III -V controlled substances without the need for an in-person visit.

1) Requiring at Least One Audio-Video Encounter for Prescribing Medications for Opioid Use Disorder (MOUD)

This proposal also permits special registrants to prescribe schedule III-V controlled substances that are approved by the U.S. Food and Drug Administration (FDA) for the treatment of Opioid Use Disorder (OUD) via telemedicine via an audio-only visit without the need for an in-person evaluation. However, ABHW is concerned that the rule requires at least one audio-visual encounter before initiating or continuing care. As DEA notes, many OUD patients may lack the financial means to obtain treatment through audio-video telemedicine encounters. This is particularly true for patients living in areas with limited broadband access. We urge the DEA to defer to clinical decision-makers on whether audio-visual is needed to prescribe controlled substances, given the ongoing opioid crisis. At a minimum, we recommend that the DEA waive this requirement for the audio-visual encounter during the ongoing opioid public health emergency.

2) <u>Tiered Fee Structure for Special Registrations</u>

In addition to the existing DEA registration costs, the high cost of Special Registration may be a financial barrier to providers, especially solo practitioners. We suggest the DEA reduce the fee for special registration and consider charging providers a nominal fee instead of the current \$888.

II. The Advanced Telemedicine Prescribing Registration and Schedule II Controlled Substances

As proposed, the Advanced Telemedicine Prescribing Registration is available for certain health care providers who are board-certified in specific specialties, including psychiatry, and who need to be able to prescribe Schedule II controlled substances.

1) <u>Provision will Exclude Key Practitioners from Participating</u>

The proposed rule excludes primary care physicians and general medicine practitioners from the Advanced Telemedicine Prescribing Registration. Primary care physicians often serve as the first point of care for patients requiring controlled substances, whether for pain management 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. Additionally, there is momentum in integrating behavioral health with primary care, and where other government agencies are encouraging models like the collaborative care model. This preclusion limits the utility of deploying innovative integrated clinical models that aim to help meet the needs of society in a shrinking workforce.

Instead of listing specialties that qualify for advanced registration, ABHW recommends a standard that includes physicians and mid-level practitioners who, through their training, licensing or certification, and regular standard of care, are experienced with and regularly prescribe Schedule II medications during their everyday practice.

At a minimum, if the DEA does not alter its standard for who qualifies for special registration, ABHW recommends adding the following specialties: oncologists, surgeons, pulmonologists, general medicine, and primary care, and removing the need to be board-certified in psychiatric/psychological disorders, hospice care, etc., but rather to practitioners that routinely treat patients with those conditions. This is critical for integrated care systems and expanding integrated care models like the Collaborative Care Model.

2) Less than 50% Requirement and Pharmacist Verification

The proposed rule authorizes qualified, specialized practitioners to prescribe Schedule II-V controlled substances through telemedicine. 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 the ongoing treatment of many individuals.

First, the proposed requirement mandates that 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 the 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 also fails to account for the many counties nationwide that lack a single psychiatrist. Those counties rely on telemedicine to access psychiatry and

 $^{1}\, \underline{\text{https://www.commonwealthfund.org/publications/explainer/2023/may/understanding-us-behavioral-health-workforce-shortage}$



behavioral health services, particularly for children and adolescents. To impose an arbitrary quota on the modality of otherwise valid prescriptions would be tantamount to disrupting the continuity of care during a time of significant MH and SUD diagnoses. This requirement could arbitrarily prevent qualified practitioners from effectively serving patients via telemedicine.

While ABHW recognizes that in-person care may be necessary for some circumstances where it is a best clinical practice, we do not support mandating thresholds for in-person visits as it does not appropriately balance patient access with clinical necessity.

If the DEA proceeds to finalize this 50% requirement, ABHW requests additional operational time. Currently, systems are not configured to quickly identify whether a prescription is issued via telemedicine or an in-person visit. Additionally, the rule should clarify that pharmacies are not asked to validate whether a practitioner has exceeded their allotted telemedicine prescription amount.

3) Special Registrants Physically Located in the State Requirement

The rule requires that special registrants be physically located in the same state as a patient while prescribing Schedule II substances without clinical justification. This will once again disproportionately impact patients in states where providers are already in shortage, exacerbating health care for individuals in rural communities and defeating the purpose of telemedicine overall—expanding access to care. There are many reasons a patient may not be able or choose to visit a provider in person, including limited provider access where they live, childcare or transportation difficulties, physical difficulty traveling, provider preference, or concerns regarding stigma or privacy.

This also ignores the many situations where states' geographic borders are nearby, and patients often cross state lines to access care. ABHW recommends that the DEA modify the requirement that the prescriber of a Schedule C-II be in the same state as the patient; instead, the prescriber should be licensed to prescribe in the state where the patient is located.

III. State-specific Registration

We are concerned that requiring a practitioner to register with the DEA in every state that they are tele-prescribing controlled substances will increase the costs of health care without meaningfully controlling against diversion. The DEA waived this requirement during COVID-19 and is permitted to do so if it is consistent with public health and safety. We believe reinstating this requirement will increase health care costs and limit



legitimate access. ABHW asks the DEA to consider leveraging the existing flexibilities, which have been demonstrated over the last five years, to balance controlling against diversion with ensuring access. We urge the DEA to require the prescriber instead to maintain a special registration with the DEA in at least one state and permit the special registrant to prescribe controlled substances if authorized under and by state law in the state where the patient is located at the time of prescribing.

IV. Nationwide Prescription Drug Monitoring Program (PDMP) Check Operationally Unworkable

ABHW 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. States operate PDMP independently of one another, and not all states capture the same sets of information. While one state may capture all information from prescribing controlled substances, another may exclude the name of the controlled substance and the location of the patient receiving the prescription or fail to note whether the prescription was provided through telehealth or in person. The lack of uniformity across the states creates an untenable challenge for our members. There does not appear to be a feasible technical or operational means of achieving the PDMP check.

We recommend that the DEA take action to support PDMP interoperability across states. Also, it is unclear whether there are costs associated with checking multiple PDMPs, so we recommend that the DEA ensure that a national PDMP check will not come with excessive expenses and be an undue barrier. ABHW also suggests that the proposed three-year delayed start date be replaced with a start date that aligns with the availability and deployment of technology to support a nationwide PDMP check.

V. Exceptions for Integrated Care Systems

The DEA's Expansion of Buprenorphine Treatment via Telemedicine final rule exempts Veterans Affairs (VA) practitioners from special registration requirements. Once a patient has received an in-person medical examination from a VA medical practitioner, the provider-patient relationship is extended to all VA practitioners engaging in telemedicine with the patient. The rationales cited by the DEA for this rule at the VA include using an integrated electronic health record (EHR), established clinical guidelines, and extensive education on appropriate prescribing and misuse of prescriptions. These rationales apply to integrated systems as well.

ABHW supports seeking a similar exception for integrated health systems. These systems have similar features described in the rule exempting VA



practitioners from special registration, such as an integrated EHR, the use of established clinical guidelines, and education on appropriate prescribing and misuse of prescriptions, making it appropriate to waive the special registration requirements.

Alternatively, we support altering the definition of an in-person visit to extend the patient-provider relationship to all providers within the same health system rather than limiting it to an individual practitioner. Allowing an individual to be seen in person by one practitioner within the health system and permitting virtual prescribing by others allows for greater patient flexibility and is appropriate in a team-based system. This should apply to all practitioners with authority to prescribe, including pharmacists, not just physicians.

VI. Ensure Telehealth Access Doesn't Lapse

The current pandemic-era flexibilities for the remote prescribing of controlled substances expire at the end of the calendar year 2025. ABHW 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 and implements a safe, effective special registration process that strikes the right balance between access to care, patient safety, and diversion prevention.

Thank you for the opportunity to provide feedback on this NPRM. We are committed to engaging with the DEA and other partners to find opportunities to improve behavioral health access for all individuals. If you have questions, please contact Kathryn Cohen, Senior Director of Regulatory Affairs, at cohen@abhw.org.

Sincerely,

Debbie Witchey, MHA President and CEO

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