ConnectedHealthInitiative

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RE: Comments of the Connected Health Initiative in Response to the Drug Enforcement Agency's Requests for Input, *Special Registrations for Telemedicine and Limited State Telemedicine Registrations* (Docket No. DEA-407; 90 FR 6541)

The Connected Health Initiative (CHI) writes to provide input to the United States Drug Enforcement Administration (DEA) on its proposal to expand patient access to controlled substance medications via telemedicine by establishing a Special Registration framework and authorizing three types of Special Registration; and providing for heightened prescription, recordkeeping, and reporting requirements.[1]

I. Statement of Interest and General Views on Telemedicine Prescribing

CHI is the leading effort by stakeholders across the connected health ecosystem to responsibly encourage the use of digital health innovations and support an environment in which patients and consumers can see improvements in their health. We seek essential policy changes that will help all Americans benefit from an information and communications technology-enabled healthcare system. CHI is a longtime active advocate for the increased use of new and innovative digital health tools in both the prevention and treatment of disease. For more information, see www.connectedhi.com.

Digital and connected health tools, including those enabling virtual prescribing, have fundamentally improved and transformed American healthcare. Recognizing the essential role digital health has in care, during the COVID-19 public health emergency (PHE) DEA enabled adults and children to continue accessing medically necessary controlled substances via telehealth by waiving the requirement that the patient have a prior in-person visit, regardless of their location. The Centers for Disease Control (CDC) has acknowledged that "with expanded access and improved reimbursement policies in place, as well as ongoing acceptability by patients and healthcare providers, telehealth might continue to serve as an important modality for delivering during and after the pandemic."[2] Even more recently, data jointly released by the National Institute of Health, the Center for Disease Control, and the Centers for Medicare &

[1] 90 Fed. Reg. 6541.

[2] Lisa M. Koonin et al., *Trends in the Use of Telehealth During the Emergence of the COVID-19 Pandemic — United States, January–March 2020*, Centers for Disease Control and Prevention, Oct. 2020 (emphasis added).

Medicaid Services has established that patients receiving telehealth drug therapy for opioid use disorder had 33 percent lower adjusted odds of a fatal overdose than those receiving no medication treatment.[3] Moving forward, it is absolutely critical for DEA to provide support to the range of populations who have come to rely on telemedicine providers for necessary treatments and medications, particularly those in unserved and underserved communities that would otherwise be unable to establish necessary relationships and attain the treatment they need.

CHI welcomes the revisions in the current proposal addressing our concerns about the original 2023 draft. We appreciate the elimination of the requirement for in-person evaluations to prescribe Schedule III-V medications beyond 30 days via telemedicine. Furthermore, we generally support the introduction of a special registration process for Advanced Telemedicine Prescribing, allowing for Schedule II medication prescriptions in specific circumstances, such as hospice care, without mandating in-person evaluations. However, we make a range of recommendations on ways to improve DEA's proposed framework to support the continued delivery of essential care to patients, particularly those in underserved areas or with limited mobility, while addressing legitimate concerns about potential misuse, abuse, and diversion of controlled substances.

The federal flexibilities implemented in 2020, and in place through the end of 2025, have clearly demonstrated the efficacy of telemedicine in appropriately prescribing controlled substances. Telemedicine has proven effective for determining clinical appropriateness of prescriptions, conducting pill counts for adherence, monitoring toxicology testing, ensuring medication safety and efficacy, and identifying potential diversion risks. Further, telemedicine prescribing of controlled medications enhances access to care for remote and underserved communities; patients facing transportation challenges; individuals with physical or mental health impairments; caregivers and those requiring caregiver assistance; and patients with employment constraints. However, this extension alone does not resolve the long-term challenges facing telehealth services, particularly concerning the remote prescribing of controlled substances. As we approach this deadline, it is imperative that DEA develop sustainable, permanent solutions that balance patient access to care with necessary safeguards against misuse. There is a real risk that without a more nuanced and workable solution, we could face a policy lapse that would significantly disrupt patient care and access to necessary medications. To prevent such a scenario, it is crucial that the DEA consider further extending the current flexibilities beyond 2025. This extension would provide the necessary time for a comprehensive public-private sector dialogue to develop more refined and effective policies.

[3] Jones CM, Shoff C, Blanco C, Losby JL, Ling SM, Compton WM. Association of Receipt of Opioid Use Disorder–Related Telehealth Services and Medications for Opioid Use Disorder With Fatal Drug Overdoses Among Medicare Beneficiaries Before and During the COVID-19 Pandemic. JAMA Psychiatry. Published online March 29, 2023. doi:10.1001/jamapsychiatry.2023.0310.

II. Schedules III-V Telemedicine Prescribing Registration

We strongly support the DEA's assertion that practitioners must establish and maintain genuine doctor-patient relationships to prescribe within the bounds of "usual course of professional practice" and for "legitimate medical purposes." This aligns with CHI's position that state medical boards should retain primary authority in regulating medical practice.

The proposed Telemedicine Prescribing Registration for physicians registered to prescribe Schedule III-V controlled substances is a welcome development. This provision would apply to scenarios where in-person medical evaluations could significantly burden legitimate practitioner-patient relationships. CHI fully supports this proposal as it balances patient access with appropriate safeguards.

III. Schedules II-V Advanced Telemedicine Prescribing Registration

CHI commends the DEA for incorporating our previous recommendation to allow special registration for prescribing Schedule II medications to patients without in-person evaluations. We concur with the DEA's identified patient care circumstances where advanced telemedicine prescribing registration would be most beneficial, including psychiatric, hospice, palliative, long-term, pediatric, and neurologic care.

However, the proposed DEA rule contains several provisions that could inadvertently restrict patient access to necessary care and impede the practice of telemedicine, namely DEA's proposed requirement that a special registrant's Schedule II controlled substance prescriptions must average less than 50 percent of their total monthly prescriptions. This arbitrary limit may disproportionately impact providers who primarily practice telemedicine or help patients in underserved areas, potentially restricting legitimate prescribing practices and limiting patient access to needed medications. Further, we urge the DEA to consider expanding qualification criteria further to ensure that all relevant healthcare providers can participate. Many providers, such as those in primary care and general medicine (often the first line care to patients for which a prescription for a controlled substance may be clinically appropriate), geriatrics, and medical oncology, offer comprehensive care that may include palliative and hospice services, despite it not being their primary specialty. To prevent potentially harmful interruptions in patient care, especially for those reliant on telemedicine, the DEA should consider additional means for physicians to demonstrate their competence in these areas. This could involve a flexible process allowing physicians to showcase their relevant experience and expertise, even if it falls outside traditional specialty designations.

Additionally, the requirement that special registrants be physically located in the same state as patients receiving Schedule II prescriptions fails to account for the evolving nature of healthcare delivery, which increasingly spans geographic boundaries. This restriction could exacerbate existing disparities in access to care, particularly in areas near state borders or in regions with limited local healthcare resources. DEA guidance on "geographic red flags" for pharmacies could help mitigate some of these issues by clarifying how pharmacies should handle prescriptions from out-of-state providers.

Further, DEA's creation of separate regulations for Schedule II versus Schedule III-V controlled substances also lacks clear justification. This arbitrary distinction could interfere with providers' clinical decision-making processes and may not reflect the nuanced realities of patient care and medication management. To address these concerns, the DEA should consider revising or eliminating the 50 percent prescription ratio requirement, including primary care and general medicine practitioners in the special registration process, allowing for greater geographic flexibility in telemedicine prescribing, and providing a clear, evidence-based rationale for any differential treatment between controlled substance schedules.

Ultimately, the focus should remain on ensuring that patients have access to necessary care through telemedicine, particularly in underserved or remote areas where in-person specialty care may be limited. By adopting a more inclusive and flexible approach to advanced registration qualifications, the DEA can better serve diverse patient populations while maintaining high standards of care. This approach would align with the evolving landscape of medical practice and the increasing importance of telemedicine in delivering comprehensive healthcare services.

IV. Telemedicine Prescribing Frequency Limits

The proposed rule introduces two restrictive policies that would limit the frequency of controlled substance prescriptions issued through telemedicine encounters. First, in defining a “local in-person medical practice” for eligibility under the clinician special telemedicine registration, the DEA proposes that all offices within the practice must be located within 100 miles of each other and that no more than 50 percent of the total controlled substance prescriptions issued by the practice’s physicians and mid-level practitioners in any calendar month may be prescribed via telemedicine. Second, the rule stipulates that for Schedule II medications, prescriptions issued under special registration must constitute less than 50 percent of the clinician’s total Schedule II prescriptions across both telemedicine and in-person encounters within a given month.
CHI is deeply concerned about these arbitrary quantitative limits, which could have serious unintended consequences for patient care. Historical data shows that since 2012, opioid prescribing has declined by more than half, and this downward trend continued during the COVID-19 Public Health Emergency when telemedicine flexibilities were implemented. Importantly, allowing Schedule II medications to be prescribed via telemedicine has not led to an increase in prescribing rates. The harmful effects of imposing rigid prescribing limits are well-documented. For instance, the misapplication of the CDC’s 2016 opioid prescribing guideline caused significant patient harm by enforcing arbitrary dosage and duration limits. Although the CDC’s 2022 revision explicitly removed these metrics and emphasized individualized care based on patient needs, many restrictive policies imposed by state laws, pharmacies, and health plans remain in place, perpetuating barriers to appropriate care.

CHI strongly urges the DEA to withdraw these proposed metrics from the special registration policies. Once codified in regulation, such restrictions could lead to widespread disruptions in patient care that would be difficult, if not impossible, to reverse. Patients may face denial of necessary controlled substance prescriptions or be unable to access medically appropriate Schedule II medications due to practitioners’ fear of exceeding monthly percentage thresholds and risking their DEA registration. Furthermore, pharmacists may feel compelled to verify these

percentages as part of their corresponding responsibility, potentially resulting in inappropriate denials of medication at critical moments. While we recognize that the DEA does not intend to cause interruptions in care, past experience demonstrates how state legislatures, pharmacies, health plans, and healthcare professionals often misinterpret DEA policies out of fear of investigation or prosecution. This misinterpretation could exacerbate existing barriers to care for patients who rely on controlled substances for legitimate medical needs.

In addition to these concerns, CHI finds the first proposal unclear in its scope and application. Throughout the proposed rule and its accompanying flow charts, the DEA carefully explains that these regulations apply only when a clinician has not conducted an in-person evaluation of a patient prior to prescribing controlled substances via telemedicine. However, the proposed definition of a “local in-person medical practice” appears to apply the 50 percent telemedicine limitation to all controlled substance prescriptions issued via telemedicine—not just those requiring special registration due to the absence of an in-person visit. This lack of clarity could create significant confusion among physicians and others responsible for implementing or adhering to the rule. For example, if pharmacies or payers misinterpret this provision, patients could be denied access to necessary medications at the point of care, leading to undue pain and suffering.

CHI urges the DEA to provide greater clarity on this aspect of the proposal to prevent such misunderstandings. The potential for confusion underscores why arbitrary quantitative limits are not only unnecessary but harmful. Policymaking should prioritize patient-centered care while ensuring providers have clear guidance that supports safe and effective treatment without introducing fear-driven barriers or unintended consequences. By refining its approach and removing these restrictive metrics, the DEA can better align its policies with its stated goals of balancing access to care with appropriate safeguards against misuse.

V. Prescription Drug Monitoring Program (PDMP)

The DEA's proposal for nationwide Prescription Drug Monitoring Program (PDMP) checks before controlled substance prescribing could potentially serve as a valuable safeguard against inappropriate access to these medications. However, the current landscape of state PDMPs presents significant challenges to implementing this policy effectively. State PDMPs operate as independent entities with varying degrees of interstate connectivity and often require different data points that are not uniformly aligned. This lack of standardization across state programs makes the DEA's proposed nationwide check infeasible in its current form. The National Association of Boards of Pharmacy's (NABP) PDMP Interconnect represents the closest approximation to a nationwide system within the industry. However, even this initiative falls short of meeting the standards outlined by the DEA in the proposed rule. To make nationwide PDMP checks viable, significant efforts would be needed to standardize data requirements, improve interstate connectivity, and create a more uniform system across all states. Without these improvements, the proposed policy risks creating undue burdens on healthcare providers and potentially impeding legitimate patient access to necessary medications.

In the proposed rule, DEA proposes a phased approach to Prescription Drug Monitoring Program (PDMP) checks for clinician special registrants. Initially, for a three-year period, these registrants would be required to check PDMPs in the patient's state, the physician's state, and any states with reciprocity agreements. After this period, the requirement would expand to checking all 50 state PDMPs, contingent on the availability of a mechanism to do so. If such a comprehensive check is not feasible, the initial requirements would persist. Additionally, physicians with advanced special registration would be limited to issuing Schedule II prescriptions only to patients within their own state.

CHI acknowledges the importance of refining and utilizing state PDMPs, emphasizing the need for patient privacy protections and the role of these systems in supporting individualized clinical decision-making. We appreciate the DEA's recognition of the challenges posed by the fragmented nature of PDMPs across states and territories, and we concur with the need for enhanced interoperability. However, we strongly emphasize that PDMPs should serve as clinical information tools to identify uncoordinated patient care, not as law enforcement instruments. In considering these proposals, it is crucial to evaluate their impact on practice workflows and the feasibility of integrating new requirements without unduly burdening healthcare providers or impeding patient access to necessary care. The proposed requirement to check every state PDMP, in particular, warrants careful assessment before implementation. Healthcare providers already face significant administrative burdens, and adding new PDMP checking requirements could exacerbate these challenges.

Given these concerns, CHI recommends delaying the implementation of additional PDMP checking requirements until there is clear evidence that such checks improve patient outcomes and reduce drug-related mortality. This cautious approach would allow time for further refinement of PDMP systems, improvement of interoperability, and assessment of the real-world impact of expanded checking requirements on healthcare delivery and patient care. Furthermore, the proposal to restrict advanced special registration holders to prescribing Schedule II medications only within their state may limit access to care, particularly for patients in underserved areas or those who rely on interstate telemedicine services. This restriction should be carefully evaluated to ensure it does not create unintended barriers to legitimate medical care.

In summary, while CHI supports the thoughtful use of PDMPs to enhance patient care and safety, we urge the DEA to carefully consider the practical implications of these proposed requirements. A balanced approach that prioritizes patient care, respects provider workflows, and is grounded in evidence-based outcomes should guide the development and implementation of any new PDMP-related policies.

VI. Applicability of DEA Rules to Telemedicine Platforms and Direct-to-Consumer Companies

The DEA's proposed rule introduces a significant expansion of its regulatory scope by requiring telemedicine platforms and direct-to-consumer (DTC) companies to register with the agency, even if these entities do not directly prescribe or dispense controlled substances. This new requirement represents a departure from the DEA's current registration framework under the Controlled Substances Act (CSA), which primarily focuses on providers, pharmacies, and entities that directly handle controlled substances.

This proposed expansion raises several concerns and questions about its implementation and potential impact on the telehealth industry. Firstly, it's unclear how the DEA intends to define and categorize telemedicine platforms within its regulatory structure, given that these entities often serve as intermediaries or facilitators rather than direct healthcare providers. The lack of clarity in this regard could lead to confusion and potential overreach in regulation.

For DTC companies, the requirements are even more ambiguous. Many of these companies operate on diverse business models, some of which may only tangentially relate to the prescription or dispensing of controlled substances. The proposed rule does not provide clear guidelines on how these companies should comply or what specific aspects of their operations would fall under DEA scrutiny.

This regulatory expansion could have far-reaching consequences for the telehealth industry. It may impose significant administrative and financial burdens on companies that have not previously been subject to DEA oversight. There's also a risk that these new requirements could stifle innovation in the telehealth sector, potentially limiting the development of new platforms and services that could benefit patients.

Moreover, the inclusion of telemedicine platforms and DTC companies in the DEA registration process raises questions about DEA's capacity to effectively oversee and regulate these entities. The DEA's expertise has traditionally been in monitoring the direct handling of controlled substances, and it may face challenges in adapting its regulatory approach to the more complex and varied landscape of telehealth services.

As the healthcare industry continues to evolve, with telehealth playing an increasingly vital role, it's crucial that regulations strike a balance between ensuring patient safety and fostering innovation. The DEA should consider engaging in further dialogue with stakeholders in the telehealth industry to refine this aspect of the proposed rule to ensure that any new registration requirements are both practical and effective, without unduly burdening companies that are working to improve access to healthcare through technology.

VII. Patient Verification Photographic Record

The DEA's proposed rule introduces a new patient identity verification process for clinician special registrants conducting telemedicine encounters. This process would require patients to present a state or federal government-issued photo identification card via the audio-video telecommunications system's camera. During the initial telemedicine encounter, the clinician would be required to capture and store a photographic record of the patient presenting their identification, which would then be used to confirm the patient's identity in subsequent encounters.

While CHI acknowledges the DEA's efforts to address patient identity verification in telemedicine, we have several concerns about the proposed approach. Although testimony suggests that identity verification is common practice in telemedicine, it's unclear whether this specific method of photo capture and storage is widely used or feasible within current systems. The implementation of this new requirement raises questions about the readiness of electronic medical record (EMR) systems to accommodate such a photo verification process. We are uncertain about the technical feasibility and the potential impact on telemedicine practice workflows.

Given these unknowns, CHI encourages the DEA to engage with EMR vendors to gather and provide more comprehensive information about this aspect of the proposed policy to the registrant community. This would help clarify whether existing systems can support this requirement and what adjustments might be needed.

In light of these concerns, CHI proposes that the DEA consider more flexible alternatives that could achieve the same goal of identity verification while reducing administrative burdens and better accommodating patient needs. One such alternative could be allowing patients to self-register using an application of their choice, such as verifying their identity through a personal medical record app or uploading identification documents via an online portal prior to their telemedicine appointment. This approach would give patients more control over their personal information, reduce the administrative burden on healthcare providers, and potentially offer a more secure method of storing sensitive identification information.

This flexible approach could also be more easily integrated into existing digital health platforms, aligning with the evolving landscape of telemedicine and patient engagement. By offering patients the option to manage their own identity verification, the DEA could enhance patient autonomy while ensuring compliance with regulatory requirements.

At the very least, CHI urges the DEA to reconsider its current proposal and allow additional time for technology vendors to develop compliant solutions and for special registrants to integrate these new verification requirements into their practices. This extended timeline would help ensure a smoother transition and minimize disruptions to patient care.

VIII. Conclusion

CHI appreciates the opportunity to submit its comments to the DEA and urges its thoughtful consideration of the above input.

Sincerely,

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