ConnectedHealthInitiative

February 28, 2025

The Honorable Robert Kennedy, Jr.
Secretary
Department of Health and Human Services
200 Independence Avenue Southwest
Washington, District of Columbia 20201

Mr. Derek S. Maltz
Acting Director
Drug Enforcement Administration
700 Army Navy Drive
Arlington, Virginia 22202

RE: Comments of the Connected Health Initiative in Response to the Department of Health and Human Services' and Drug Enforcement Agency's Final Rule and Request for Comments, *Expansion of Buprenorphine Treatment via Telemedicine Encounter and Continuity of Care via Telemedicine for Veterans Affairs Patients* (Docket No. DEA-948; DEA-407VA)

Dear Secretary Kennedy and Acting Director Maltz:

The Connected Health Initiative (CHI) writes to provide input to the Department of Health and Human Services (HHS) and the United States Drug Enforcement Administration (DEA) on its final rule, delay of effective dates, and request for comments addressing the circumstances under which (1) practitioners registered by DEA are authorized to prescribe schedule III-V controlled substances approved by the Food and Drug Administration for the treatment of opioid use disorder via a telemedicine encounter, including an audio-only telemedicine encounter[1] and (2) Department of Veterans Affairs practitioners acting within the scope of their Veterans Affairs employment are authorized to prescribe schedule II-V controlled substances via telemedicine to a Veterans Affairs patient with whom they have not conducted an in-person medical evaluation, if another VA practitioner has, at any time, previously conducted an in-person medical evaluation of the VA patient, subject to certain conditions.[2] HHS and DEA are soliciting comments on the extension of the effective date of these two final rules to March 21, 2025; and on whether there may be a need for their effective dates to be extended beyond that date, and address issues of fact, law, and policy raised by these rules, for consideration by officials of the two agencies.

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, fundamentally improve and transform American healthcare. Recognizing the essential role digital health has in

[1] 90 FR 6504.

[2] 90 FR 6523.

care, during the COVID-19 public health emergency (PHE) DEA enabled adults and children to continue to access 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."[3] Even more recently, data jointly released by the National Institute of Health, the Center for Disease Control, and the Centers for Medicare & 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.[4] As the PHE comes to an end, 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.

Given the widely demonstrated benefits of the PHE allowances made for telemedicine prescribing by DEA, supported by other federal expert agencies within HHS, we support DEA preserving as many PHE allowances for telemedicine prescribing as possible. It is vital that DEA policies reflect that innovators throughout the healthcare value chain have demonstrated the efficacy of telemedicine prescribing according to clinical, safety, and ethical guidelines. We appreciate the final rules taking steps to provide much-needed access to those receiving treatment of opioid use disorder, and urge that these allowances be maintained on a permanent basis.

We offer the following for HHS and DEA as they consider issues of fact, law, and policy raised by these rules:

- DEA has put into place an initial prescription limitation of six calendar months after which time either an in-person medical evaluation must be conducted or the practitioner can continue prescribing via another form of telemedicine, as such a time period provides adequate time for a patient to be stabilized on medication via audio-only medical encounter(s) without unduly increasing the risk of diversion. CHI supports this approach, which was updated based on concerns expressed with DEA's earlier proposals by CHI. This allowance provides a timeframe where it might be possible for patients to comply with the DEA's new rules. Indeed, in response to the DEA's proposed limitations, some clinicians have estimated that they "will not be able to see new patients for six to nine months to catch up with having to see patients who [they've] never seen face to face"

[3] 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).

[4] 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.

and that "this is going to be devastating and the cost will be significant, particularly for adolescent mental health."[5]

- If DEA rules are to restrict Schedule II prescriptions without a prior in-person visit, while Schedule III or higher medications (including buprenorphine) are able to be prescribed via telemedicine for 30 days' worth of the prescription, after which an in-person visit would be required for a refill, given the strong data, including in studies from the U.S. government, supporting the efficacy of telemedicine prescribing, DEA should provide a sufficient rationale for this arbitrary distinction that is clearly linked to a public benefit. DEA is strongly encouraged to remove the heightened restrictions on Schedule II medications and treat them the same as Schedule III medications.
- DEA should ensure that its telemedicine prescribing programs for both Schedule III, IV, or V non-narcotic controlled medications and buprenorphine as medication for opioid use disorder do not introduce new complexities and restrictions relative to the processes used during the PHE and do not institute extensive administrative/paperwork requirements that will be unreasonable to comply with. We strongly encourage DEA to identify and mitigate opportunities for reducing the administrative burden of compliance with both of its rule sets. Further, some proposed administrative requirements appear to have no link to a public benefit and simply discriminate against prescriptions accomplished via telemedicine, such as mandating that telemedicine prescriptions be labeled as such on the face of the prescription. Already, patients too often face improper denials of prescriptions based on the complexity of DEA requirements and liability concerns. DEA is encouraged to take all opportunities to streamline and ease compliance burdens while protecting patients.
- DEA rules should ensure that its rules account for patients who are unserved and underserved by brick-and-mortar healthcare options. Applying the DEA's rules in a one-size-fits-all manner will disenfranchise some of America's neediest patients who, without telemedicine prescription options, have no reasonable option to go through the steps required to get the treatment and medications they need. We support a DEA exception for those patients residing in healthcare professional shortage areas (HPSAs) and others in urban and suburban areas that face hardships getting to an in-person healthcare appointment. DEA should provide for this exception via either a new Ryan Haight Act "practice of telemedicine" exception, or clarify that such circumstances fall within its new exception proposed already.[6]
- DEA's rules should clearly recognize that the vast majority of providers and innovators developing and engaging in telemedicine prescribing adhere to standards of safety and ethics, and that its enforcement will focus on the minority of bad actors. DEA's enforcement of its rules against these bad actors should be paired with public education to ensure a broad understanding of expected behavior per its regulations.

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[5] Gabriel Perna and Brock E.W. Turner, *As PHE winds down, virtual prescribing of controlled substances is in limbo* (February 6, 2023) available at https://digitalhealth.modernhealthcare.com/digital-health/remote-prescribing-limbo-federal-covid-19-emergency-ends.

[6] 88 FR 12875

CHI appreciates the opportunity to submit its comments to HHS and DEA, and urge for their thoughtful consideration of the above input.

Sincerely,

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