ConnectedHealthInitiative

March 31, 2023

U.S. Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

RE: Comments of the Connected Health Initiative in Response to the Drug Enforcement Agency's Requests for Input, *Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation* (Docket No. DEA-407); and *Expansion of Induction of Buprenorphine via Telemedicine Encounter* (Docket No. DEA-407)

The Connected Health Initiative (CHI) writes to provide input to the United States Drug Enforcement Administration (DEA) on its proposed rules addressing the circumstances under which a practitioner is allowed to prescribe controlled substance via telemedicine,[1] and under which individual practitioners are authorized to prescribe schedule III-V narcotic drugs or combinations of such drugs that have been approved for use in continuous medical treatment (also referred to as maintenance) or withdrawal management treatment (also referred to as detoxification) via a telemedicine encounter, including an audio-only telemedicine encounter.[2]

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 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

[1] 88 FR 12875.

[2] 88 FR 12890.

[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).

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.

The CHI community is deeply concerned about the impacts of the DEA's proposals, both in the context of prescribing Schedule III, IV, or V non-narcotic controlled medications as well as prescribing buprenorphine as medication for opioid use disorder, and the unintended consequences of the DEA's proposed rule changes. Unless altered, countless American patients will face a flash cut of availability for needed treatment and medications. Given the widely demonstrated benefits of the PHE allowances made for telemedicine prescribing by DEA, supported by other federal expert agencies within the Department of Health and Human Services, we call on DEA to (1) preserve all PHE allowances for telemedicine prescribing permitted by its existing authority and (2) further study the impact of its PHE allowances and the impacts on American patients before instituting changes that would disenfranchise American patients. As part of this study, DEA should conduct further consultations with innovators throughout the healthcare value chain who have demonstrated the efficacy of telemedicine prescribing according to clinical, safety, and ethical guidelines; and further consider the impact of its proposals on the prescribing of controlled substances via telemedicine more broadly. With this augmented evidence base and perspective, DEA should then propose rules to support the continued responsible leveraging of telemedicine prescribing of Schedule III, IV, or V non-narcotic controlled medications as well as buprenorphine as medication for opioid use disorder. Further, at this stage, DEA should combine its two rule proposals to reduce confusion.

DEA should make a number of critical changes that will mitigate the negative impact the rules would have on American patients. For example, DEA can, and should, create an exception to continue to allow telehealth prescribing of buprenorphine without an in-person visit. Further, DEA should consider the following proposals:

- DEA proposes to eliminate the ability to prescribe controlled substances via telemedicine in instances where the patient did not have an in-person exam, with the exception of an initial prescription period of no more than a 30 days' supply of the prescription; and that patients requiring Schedule II medication or Schedule III-V narcotic medications, with the exception of buprenorphine for opioid use disorder (OUD) treatment, first undergo an initial in-person exam before the prescription can be issued. At a minimum, it is critical that DEA revisit this 30 day limitation, which, unless altered, would rapidly shift countless patients into vulnerable positions that too often lead to drug diversions and related harmful outcomes. At a minimum, DEA should revise the exception to this provision to be for an initial prescription period of a minimum of six months' supply of the prescription. Such an allowance would provide a timeframe where it might be possible for patients to

[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.

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

- DEA's rules propose that Schedule II prescriptions cannot be permitted 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's rationale for this arbitrary distinction is insufficient and is not 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's proposed telemedicine prescribing programs for both Schedule III, IV, or V non-narcotic controlled medications and buprenorphine as medication for opioid use disorder introduce new complexities and restrictions relative to the processes used during the PHE and would institute extensive administrative/paperwork requirements that will be arduous 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 must revise its proposals to 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. Accordingly, DEA should create an 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]

[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

- 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.

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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