The Hospital + Healthsystem Association of Pennsylvania

Leading for Better Health

March 30, 2023

The Honorable Anne Milgram
Drug Enforcement Administration
Attention: DEA Federal Register Representative/DPW
8701 Morrissette Drive
Springfield, VA 22152

Re: Docket No. DEA-407, Proposed Rules on Expansion of Induction of Buprenorphine via Telemedicine Encounter and Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation

Dear Administrator Milgram:

On behalf of The Hospital and Healthsystem Association of Pennsylvania (HAP), which represents approximately 235 member hospitals, including 157 hospital emergency departments and nearly 85 inpatient behavioral health units, institutions for mental disease and standalone psychiatric hospitals, and 18 drug and alcohol detox or treatment units, we greatly value the opportunity to comment on the US Drug Enforcement Administration's (DEA) proposed rules to expand access to buprenorphine and critical medications classified as controlled substances via telemedicine. While we appreciate that the proposed rule expands the pre-pandemic prescribing landscape, it falls short of the stated goal of expanding access and ensuring continuity of care for patients.

The number of adults in Pennsylvania with mental illness and/or substance use disorders is increasing and surpassing the capacity of behavioral health providers.

In 2020, nearly 34 percent of non-elderly adults in Pennsylvania received care for a mental illness or substance use disorder, compared to 31 percent nationally[1]. The same year, it was estimated that 299,000 people in Pennsylvania met the criteria for a substance use disorder, and in 2021 approximately 5,224 Pennsylvanians fatally overdosed[2].

Across the commonwealth the demand for care outpaces the availability of mental health and substance use treatment services. In 2022, HRSA designated 58 percent of Pennsylvania counties as Mental Health Professional Shortage Areas and roughly 21 percent of counties as partial shortage areas[3]. Pennsylvania is home to rural communities with little or no access to evidence-based care as well as urban/sub-urban centers with access gaps.

[1] Kaiser Family Fund's "Demographics and Health Insurance Coverage of Nonelderly Adults With Mental Illness and Substance Use Disorders in 2020"
[2] PA Open Data Portal
[3] data.HRSA.gov, November 2022.

Pennsylvania hospitals and health systems see the impact of unmet care needs every day. Hospitals and health systems are the primary provider of mental health and substance use disorder care in many counties, offering a range of inpatient and outpatient behavioral health and substance use disorder treatments; and in every county, hospitals and health systems serve as the safety net for patients in acute crisis.

The limitations on prescribing buprenorphine via telemedicine will limit access to necessary and often life-saving treatment.

The proposed rule limits the prescribing of narcotic drugs approved by the FDA for maintenance or detoxification treatment (buprenorphine) based on a telemedicine encounter to a total 30-day supply. The rule requires a qualifying telemedicine referral or an in-person/telemedicine hybrid evaluation for ongoing prescribing beyond a seemingly arbitrary 30-days limit. While the proposal maintains some access to telemedicine prescribing, it stands to disrupt the continuity of care for many vulnerable patients.

For years, Pennsylvania hospitals and health systems have helped patients with substance use disorders navigate systemic and personal barriers to receive clinically appropriate and continuous care. The provider community deeply valued DEA's efforts to create flexibility during the Public Health Emergency (PHE) allowing providers to leverage telemedicine to bridge care gaps and extend access. Pennsylvania providers found that expanding access to buprenorphine, unlike other opioids, did not inherently result in diversion.

Our members, experts in their field, report that ease of use (access) is a principal goal in treating substance use disorder. Knowing that access to evidence-based, continuous treatment is essential for recovery, our members worry that any small change in practice may have unintended and fatal consequences. For some patients the provider's ability to observe the home environment via an audio/video telemedicine encounter is optimal; for others in-person observation can be more beneficial. By every measure, virtual care is always better than no care at all.

A reversion back to in-person visit requirements will affect most patients receiving treatment for substance use disorders but will disproportionally impact patients that have had traumatic experiences with social systems and institutions; have experienced breaches in trust with healthcare providers; and are often too easily lost to longitudinal care.

Limitations on prescribing critical medications used to treat mental illness will impact access to care and patient outcomes in a way that further disadvantages many patients who are already marginalized.

In the proposed rule addressing the prescription of controlled substances based on a telemedicine encounter, the agency requires an in-person evaluation prior to the prescribing of all schedule II drugs and all narcotics other than buprenorphine and within 30 days of an initial

prescription for schedule III-V non-narcotic drugs and buprenorphine. Again, this provision is more restrictive than warranted. HAP appreciates the agency's efforts to prevent diversion for controlled substances while making strides towards expanded access. However, these restrictions compromise so much of the progress made during the PHE towards treating patients with mental illness.

Telemedicine has provided access to patients who were untreated for a variety of reasons including geographic location, socio-economic status, and mental and emotional well-being. Patients that felt paralyzed by the symptoms of their mental illness connected with providers with greater ease. They established and maintained relationships with members of the medical community that they otherwise would not have had access to. Restricting that access by requiring an in-person evaluation prior to prescribing or imposing a requirement for an in-person evaluation within 30 days will undoubtedly have a negative impact on patient outcomes. Members of the physician community have also expressed that the requirement for in-person evaluation within 30 days feels arbitrary as there is no evidence linking that specific timeframe to lower rates of diversion or drug poisoning.

The proposed practice environment will deepen disparities in health based on income, location, access to transportation, access to childcare and many more factors. Patients that already have intermittent access to care are not likely to have relationships with a physician that can provide the required medical evaluation and, in light of the provider shortage, there may be none close by that are accepting patients or that have appointments available within the necessary window. Our experts all agree that once access to medication is compromised, the outcomes for patients with mental illness deteriorate.

HAP appreciates the flexibility offered through the schemes proposed to meet the requirement for a medical evaluation. However, the options only narrowly expand access and impose a great deal of administrative burden. For example, the requirement for the prescribing physician to participate in the medical evaluation through a simultaneous audio-video conference still requires a patient to be able to make it to an in-person appointment. It also requires not one, but two providers to dedicate time to the in-person evaluation making the whole process seemingly much less efficient. The second arrangement through which a prescribing provider can accept a telemedicine referral from the evaluating provider shows much more promise with regards to expanding access, but still presents administrative barriers if the two providers are from different health systems or are using different electronic medical record systems. There are limited mechanisms in place that would facilitate the transfer of this kind of information between providers with ease especially given the requirement for a copy of the medical record. Both options inadvertently create a burden on pharmacists who will feel compelled to ensure that the in-person requirement has been met—reducing the likelihood that they will fill prescriptions and further reducing pharmacy access to critical medications.

Pennsylvania communities need continuous access to effective mental health and substance use disorder treatment.

We view the proposed rule through a lens of access not law enforcement. The ability to prescribe critical medications classified as controlled substances via telemedicine is a key element of the broader effort to expand access to lifesaving treatment for individuals with substance use disorder and mental health diagnoses. Telemedicine providers acting in bad faith should be investigated in the same way that in-person providers acting in bad faith are. But, a 30 day limit does not account for the nuances in patient care needs. Furthermore, decisions regarding the most appropriate venue and mechanism for delivering care should be left to the provider to determine and document consistent with evidence-based practice recommendations and guidelines in their field. This will allow flexibility to ensure that patients have the care they need accounting for physical and behavioral health barriers and various social determinants that will impact their access while still recognizing and emphasizing that this would not be an endorsement of care that is not based on evidence, best practices, or could be dangerous or predatory. The application of a specific deadline to all individuals is much more problematic than the concept that patients should be connected to in-person care when available and appropriate. The timing of that connection cannot and should not be regulated or legislated.

We encourage the agency to align its rulemaking with the recent proposal from the Substance Abuse and Mental Health Services Administration that allows for fully virtual buprenorphine treatment and to consider feedback from key stakeholders including the American Hospital Association, the National Alliance on Mental Illness, the American Telemedicine Association, and many others calling for a special registration process that would expand access to critical medications classified as controlled substances and used to treat mental illness and substance use disorders while furthering the agencies efforts to avoid diversion and discourage or eliminate abhorrent prescribing patterns.

Thank you for the opportunity to submit our comments on the proposed rules on expansion of induction of buprenorphine via telemedicine encounter and telemedicine prescribing of controlled substances when the practitioner and the patient have not had a prior in-person medical evaluation. If you have any questions, please contact me at (215) 575-3741.

Respectfully,

Jennifer Jordan
Vice President, Regulatory, Behavioral Health and Equity Strategy