American Hospital Association™
Advancing Health in America

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The Honorable Anne Milgram
Administrator
Drug Enforcement Administration
Submitted electronically

Re: Proposed Rule for Expansion of Induction of Buprenorphine via Telemedicine Encounter

Dear Administrator Milgram,

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to provide feedback on the Drug Enforcement Administration's (DEA's) proposed rule for expansion of induction of buprenorphine via telemedicine encounter. We are submitting separate comments on the proposed rule regarding telemedicine prescribing of controlled substances when there has not been a prior in-person evaluation.

Buprenorphine is an opioid partial agonist used to treat individuals with opioid use disorder (OUD). It is the only Schedule III narcotic approved by the U.S. Food and Drug Administration for treatment of OUD; because it is an opioid, albeit of lower strength than other opioids like heroin, there is potential for misuse. However, data from the past several years demonstrates that increased access to buprenorphine — for example, via prescriptions issued by medical professionals using telehealth modalities — not only increases likelihood of recovery from OUD, but it also does not increase the likelihood of diversion (for misuse) of the substance.

We recognize and appreciate the DEA's continued efforts to support the safe prescribing of controlled substances, including via telehealth and including during the COVID-19 public health emergency (PHE). Indeed, during the PHE, the DEA enacted certain flexibilities to ensure patients could continue to receive lifesaving medications via telehealth while minimizing exposure and preserving provider capacity. These flexibilities, including waiving the required initial in-person visit prior to prescribing

controlled substances via telehealth and allowing the use of telephone evaluations to initiate buprenorphine prescribing, have proved critical in providing access to patients.

The Ryan Haight Act of 2008 outlined several categories where an in-person evaluation could be waived including but not limited to during PHEs (as was the case during COVID-19) and for other circumstances to be defined by regulation. Because the DEA waived the in-person evaluation criterion during the PHE, the agency now can integrate lessons learned from the pandemic to provide pathways for providers to continue to safely administer prescriptions, particularly buprenorphine for the treatment of OUD, virtually beyond the end of the PHE. **Instead, the DEA proposes to impose burdensome restrictions and additional administrative requirements on providers and patients, which we are concerned will adversely impact patient access to medically necessary OUD treatment.** Therefore, we have several recommendations, outlined below, that we believe would better maintain secure but accessible prescriptions for buprenorphine. **Most importantly, we urge the DEA to expeditiously set forth a special registration process regulation to identify a pathway to waive in-person evaluations prior to the prescribing of controlled substances, especially buprenorphine, for practitioners who register with the DEA. Further, we strongly urge the DEA to extend the waivers for the in-person visit requirement for prescribing of controlled substances until it, with significant stakeholder input, develops and proposes such a process for prescribing controlled substances via telemedicine.**

Proposed Rules Do Not Set Forth Statutorily Mandated Special Registration Process

As mentioned above, there are seven categories of exception for the in-person exam requirement for the prescription of controlled substances via telemedicine, including:

(1) treatment in a hospital or clinic;
(2) treatment in the physical presence of a DEA-registered practitioner;
(3) treatment by Indian Health Service or Tribal practitioners;
(4) treatment during a PHE as declared by the Secretary of Health and Human Services (HHS);
(5) treatment by a practitioner who has obtained a "special registration;"
(6) treatment by Department of Veterans Affairs practitioners during a medical emergency; and
(7) other circumstances specified by regulation.[1]

The option for a special registration process was viewed as a key part of the Ryan Haight Act. Specifically, it would set forth the circumstances under which a practitioner already licensed to prescribe controlled substances could do so safely and securely

[1] https://www.congress.gov/110/plaws/publ425/PLAW-110publ425.pdf

virtually, without unnecessary in-person visits. Therefore, it would be a streamlined process to advance access to care without unnecessary regulatory tasks. **Unfortunately, although the Ryan Haight Act required that the DEA establish this special registration process nearly 14 years ago and the SUPPORT For Patients and Communities Act re-enforced this requirement (and applied a clear timeline for the process's development by 2019), the agency still has not done so.** In the rule, the DEA asserts that since this proposed rule includes certain circumstances under which telemedicine encounters may result in prescription of controlled substances, it fulfills the DEA's statutory obligations. However, we disagree that the DEA has met this legal requirement. The statute clearly and specifically directs the agency to develop a special registration process separately from the other circumstances specified by regulation.

The DEA also states that it considered adopting a special registration process, but determined such a process would be overly burdensome. It is unclear what aspects of a special registration process would be more burdensome than many of the policies that the DEA already proposes in this rule. For example, it sets forth proposals for providers to engage in a significant amount of recordkeeping with unclear value; it also would require an in-person exam within 30 days of the initial telehealth visit to secure ongoing prescriptions of buprenorphine. As such, we disagree that a special registration process would be overly burdensome. Indeed, there is an opportunity to establish a streamlined process, tied to the existing DEA registration process. This could also provide a tracking mechanism to monitor which providers are virtually prescribing. **Therefore, we urge the agency to create a special registration process as stated above.**

However, we now face a limited time to develop a potential alternative to a return to pre-pandemic telemedicine practices when waivers expire in May. **Therefore, we strongly urge the DEA to find way to extend the waivers for the in-person visit requirement for prescribing of controlled substances until it can, with significant stakeholder input, develop and propose a framework for a special registration process for prescribing controlled substances via telemedicine.**

Indeed, the agency has the authority to extend the waiver of the in-person visit requirement further. Because the Controlled Substances Act does not have a feature allowing patients to be grandfathered from the in-person exam requirement waiver at the conclusion of the PHE, DEA proposes to use its authority to create a new term — "telemedicine relationship established during the COVID-19 public health emergency" — to apply a further extension of the in-person exam waiver for initiation of buprenorphine beyond the end of the PHE for patients who began this specific treatment during the PHE. **DEA should exercise this same authority to create an additional provision that would allow for extensions of this waiver for prescribing of buprenorphine for all patients, including those who did not begin their OUD treatment during the PHE.** Buprenorphine is a unique substance used for a specific, lifesaving purpose; the agency has the authority to extend PHE-era waivers to ensure continued access to this treatment while we work to develop a permanent framework.

Alternatively, the DEA can use authority granted under the opioid PHE to extend these waivers. This opioid PHE has been renewed over a dozen times, most recently Dec. 22, 2022, by HHS Secretary Xavier Becerra (effective Jan.1, 2023). Just as the DEA used its authority to allow for the initial evaluation to be conducted via telemedicine during the COVID-19 PHE, the agency has the discretion to use the same authority under the opioid PHE to allow the "practice of telemedicine" when it is being "conducted during a public health emergency declared by the Secretary under section 247d of title 42." We urge the DEA to act under this PHE as intended: to innovate and implement a variety of actions to combat the opioid epidemic.

Proposed 30-day Requirement for In-person Evaluation Is Overly Burdensome and Arbitrary

In the proposed rules, the DEA suggests that the prescribing of controlled substances via telemedicine be time limited. Specifically, it proposes that initial prescriptions would not be able to exceed a 30-day supply. To receive additional quantities, the patient would need to be examined in-person by the prescribing practitioner; be examined remotely by the prescribing practitioner while in the physical presence of another DEA-registered practitioner participating in an audio-video telemedicine encounter; or receive a qualifying telemedicine referral from a DEA-registered practitioner prior to issuing a prescription. The referring practitioner would also need to complete a face-to-face evaluation.

We are concerned that these limits are arbitrary, unnecessarily burdensome and will reduce access to critical care. While some patients may benefit from a periodic in-person evaluation, the need for in-person evaluation should be left to clinical judgment, rather than an overarching general requirement. Indeed, some patients may need to be seen sooner than 30 days, others may not need to be seen in person for several months. Adding a requirement for an in-person visit at specific cadences that do not reflect the case-by-case needs of specific patients may lead to unnecessary appointments and interfere with the clinician-patient relationship.

More importantly, an in-person evaluation requirement that is not otherwise clinically necessary would adversely impact access, particularly for patients who are, for example, in rural or remote geographic areas, who need childcare and who have challenges accessing or using transportation (including patients with disabilities). Indeed, many people likely sought virtual care in the first place due to inability to access services or the distance required to see a provider in person. In addition, significant workforce shortages mean that seeing a provider within 30 days of an initial visit for non-medically necessary reasons could pose significant challenges and may not be operationally feasible. **Therefore, we would recommend removing the 30-day supply limit instead allowing clinicians to determine the frequency of in-person exams.**

In addition, the proposed rule provides only two alternatives to the in-person evaluation by the prescribing practitioner, both of which require other types of in-person evaluations. We are concerned that none of these exceptions address circumstances where several practitioners participate in team-based care. For example, a practitioner who is part of a team of practitioners may have seen a patient in-person and prescribed a controlled substance. However, the rule does not address whether other practitioners who are part of that care team would *also* need to see the patient in person, or whether the in-person visit by the original practitioner fulfills the requirement. For example, a cancer patient may be seen by a care team comprised of multiple practitioners and specialists. The patient may see one practitioner virtually, be prescribed a controlled substance, and follow-up 30 days later in-person for a refill. However, they subsequently may see multiple practitioners on the same care team virtually. Based on the current rule, it is unclear if each of those practitioners could again refill their prescription (because another member of the team satisfied the in-person visit requirement), or whether each of them would also need to conduct an in-person visit. However, requiring patients to see each practitioner on the care team in-person poses barriers (e.g., travelling for multiple in-person appointments that could otherwise be completed virtually), and reduces the benefit of continuity provided from a clinical team who are closely coordinating on care plans. **Therefore, we urge the DEA to clarify that exceptions to in-person requirements can be made when providers are participating in team-based care delivery. Specifically, if a patient is being treated by a care team, they may be seen in-person by one practitioner on the care team and not need to be seen in-person by all other practitioners on the care team.**

Recordkeeping Poses Potential Additional Administrative Burden

The proposed rule would impose significant administrative burden on prescribing practitioners, and where applicable, the referring provider or provider physically present with the patient during a telemedicine visit. For example, it would require practitioners to keep written or electronic logs of each prescription issued. It also states that in instances where the prescribing practitioner is virtually connected to another DEA practitioner who is physically with a patient for the medical evaluation, both the prescribing practitioner and the practitioner physically with the patient would have to maintain logs of the visit and prescription. If a practitioner makes a referral for a telemedicine prescription, the referring provider will also need to keep records of the written referral.

The DEA states that these additional recordkeeping barriers, in addition to the in-person visit requirement for ongoing prescriptions, are necessary to mitigate the risk of diversion. However, the agency did not provide any data demonstrating that access to medications via telemedicine poses an increased risk for diversion. Rather, the agency relies on the assumption that because controlled substances can be misused, an increase in access could result in increased risk of misuse. The data the DEA does cite actually demonstrates that misuse of buprenorphine was highest among those who did

not have their own prescription, underscoring the need for expanded access to buprenorphine treatment.

In addition, these recordkeeping requirements pose additional and unnecessary administrative burden for providers and staff. For example, while the purpose of the log requirements seems to support investigations or audits, we believe this information could be collected or reviewed from medical records instead. Physician and staff shortages are prevalent across the country and most acutely in rural and underserved communities. The Association of American Medical Colleges projects shortages will only get worse with "an estimated shortage of between 37,800 to 124,000 physicians by 2034."[2] A contributing factor to shortages are burnout and overburden of administrative tasks. With such time-consuming — and largely redundant — administrative tasks to complete, practitioners who are already stretched thin would have even less time for patient care. **Therefore, we urge the DEA to reconsider what type of information is truly necessary and whether it can be gleaned more easily from other sources before imposing these burdens on the already overburdened behavioral health workforce.**

Finally, data from the National Institute on Drug Abuse and the Centers for Disease Control and Prevention demonstrate that the proportion of opioid overdose deaths involving buprenorphine did not increase in the months after prescribing flexibilities were put in place during the COVID-19 pandemic. Further, investigators found that most people who died of an overdose involving any opioid had no evidence of current treatment for substance use disorders. This information not only emphasizes the need to improve access to treatment for SUD and remove — or at least not erect additional — barriers to care, but also shows that there is little danger associated with these flexibilities.

Six-month Transition Period Only Accounts for Relationships Established During the COVID-19 PHE

As mentioned above, we believe that the DEA should develop a special registration process for prescribing buprenorphine without an in-person evaluation in lieu of the proposed provisions in this rule; to do so, we believe that the agency must extend COVID-19 PHE waivers to ensure that people who need access to buprenorphine prescribed via telehealth can get it, regardless of whether they have already established a relationship with a prescriber during the PHE. However, if the DEA declines to consider this alternative, the proposed rule states that for relationships established during the PHE where a provider has not conducted an in-person evaluation, but has prescribed Schedule II-V substances, there will be a six-month transition period from the flexibilities provided during the PHE to the requirements set forth in the proposed rule.

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[2] https://www.aamc.org/news-insights/press-releases/aamc-report-reinforces-mounting-physician-shortage

This means that if a provider-patient relationship was established during the state of emergency, then providers will have 180 days from the effective date of a final rule or end of the PHE (whichever is later) to either complete an in-person evaluation, receive a qualified telemedicine referral as defined by the proposed regulation, complete a remote evaluation where another DEA practitioner is physically with the patient during the audio-video encounter, or stop prescribing.

However, this process does not provide an "on-ramp" for new provider-patient relationships established after the COVID-19 PHE ends. That is, it appears that new provider-patient relationships will be subject to the rule's requirements on May 12, immediately after the PHE ends. Given that comments are due March 31, the most amount of time providers would have to come into compliance with the final policies is 41 days — and that is only if a final rule is published on April 1, the day after comments are due. Yet, many practices are already scheduling new patient visits 2-3 months out (May-June). By the time a final rule is published, many may be scheduled well into the summer. Complying with the DEA's policies is not as simple as flipping appointments from virtual to in-person. For example, patients may have issues arranging transportation to appointments, providers may be operating on hybrid schedules, etc. Hospitals, health systems and practices need adequate time to determine the best way to incorporate any new requirements into clinical practice. **Therefore, we recommend that the six-month window also apply to new relationships.**

We thank you for considering our requests. If you have any questions concerning our comments, please feel free to contact me, or have a member of your team contact Jennifer Holloman, AHA's senior associate director of policy, at jholloman@aha.org or Caitlin Gillooley, AHA's director of behavioral health and quality policy, at cgillooley@aha.org.

Sincerely,

/s/

Ashley Thompson
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