American Hospital Association™
Advancing Health in America

Washington, D.C. Office
800 10th Street, N.W.
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100

March 29, 2023

The Honorable Anne Milgram
Administrator
Drug Enforcement Administration
Submitted Electronically

Re: 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 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 a Drug Enforcement Administration (DEA) proposed rule for the telemedicine prescribing of controlled substances when there has not been a prior in-person medical evaluation. We are submitting separate comments on the DEA's related proposed rule regarding the expansion of the induction of buprenorphine via a telemedicine encounter.

We recognize and appreciate the DEA's continued efforts to support the safe prescribing of controlled substances via telehealth during the COVID-19 public health emergency (PHE). Indeed, during the COVID-19 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 required initial in-person visits prior to prescribing controlled substances via telehealth and allowing the use of telephone evaluations to initiate buprenorphine prescribing, have proved critical in ensuring patients' access.

The Ryan Haight Act of 2008 outlined specific requirements for in-person evaluations prior to the prescribing of controlled substances. However, this law also outlined several categories where an in-person evaluation could be waived, including, but not limited to PHEs (as was the case during COVID-19) and other circumstances to be defined by regulation. This category of "other circumstances" was an opportunity for the DEA to, in this rule, utilize lessons learned from the pandemic to set forth policies and pathways for providers to continue to safely administer prescriptions virtually, even after the PHE

period ends. **Instead, this proposed rule would impose burdensome restrictions and additional administrative requirements on providers and patients, which we are concerned will adversely impact patient access to medically necessary treatments.** Therefore, we have several recommendations, outlined below, that we urge the DEA to adopt, each supporting improved access while continuing to ensure the safe prescribing of controlled substances.

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 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 the agency, 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 several categories of exception for the in-person exam prior to the prescribing of controlled substances, 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 public health emergency as declared by the Secretary of Health and Human Services;
(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 mentioned above 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 virtually do so safely and securely, without any in-person visits. Therefore, it would act as a streamlined process to advance access to care without unnecessary regulatory tasks. **Unfortunately, despite a Ryan Haight Act requirement that the DEA establish a special registration process nearly 14 years ago, and a subsequent reinforcement of this requirement over three years ago in the SUPPORT Act, the agency still has not created one.**

In the rule, the DEA asserts that since this proposed rule includes certain circumstances under which telemedicine encounters may result in prescription of controlled

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

substances, it fulfills the DEA's obligation to create a special registration process. However, we disagree; the statute clearly delineates the special registration process separately from other circumstances to be specified by regulation.

In addition, the DEA also states that it *considered* adopting a special registration process but determined it would be overly burdensome. However, it is unclear in the rule what aspects of a special registration process would be more burdensome than many of the policies that the DEA already proposes. For example, the rule 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 additional supplies of medication, which would impose a burden on both the prescriber and the patient. As such, we disagree that a special registration process would necessarily be overly burdensome.

Indeed, there is an opportunity to establish a streamlined process, tied to the existing DEA registration process. This also could provide a tracking mechanism to monitor which providers are virtually prescribing. **Therefore, we urge the agency to create a special registration process regulation to identify a pathway to waive in-person evaluations prior to the prescribing of controlled substances for practitioners who register with the DEA. We would welcome the opportunity to assist in developing a proposed special registration process.**

However, we now face a limited amount of time to develop a potential alternative to a return to pre-pandemic telemedicine practices as the COVID-19 PHE waivers will expire in May. **Therefore, we strongly urge the DEA 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.**

We will note that 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 COVID-19 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 beyond the PHE's end of the in-person exam waiver for patients who began treatment during this period. **DEA should exercise this same authority to create an additional provision that would allow for extensions of this waiver for telemedicine prescribing of controlled substances without an in-person evaluation for *all* patients, including those who did not begin their treatment during the COVID-19 PHE, until the special registration process, as required by the Ryan Haight Act and SUPPORT Act, is formalized.**

PROPOSED 30-DAY REQUIREMENT FOR IN-PERSON EVALUATION IS OVERLY BURDENSOME AND ARBITRARY

In the proposed rule, the DEA suggests that the prescribing of controlled substances via telemedicine be time limited. Specifically, it proposes that prescriptions administered via telemedicine 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. In addition, 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 enforced through a general requirement that ignores case-by-case needs. For example, 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 scheduling of additional appointments that otherwise are not clinically necessary and interfere with the clinician-patient relationship in determining the best course of care delivery.

More importantly, inserting 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, patients who need childcare, and patients with challenges accessing or using transportation (including patients with disabilities). Indeed, many patients likely sought virtual care in the first place due to an 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 recommend removing the 30-day supply limit and 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 neither of these address circumstances where several practitioners participate in team-based care. For example, a practitioner who is part of a care team 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 return 30 days later for an in-person follow-up 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, the clarification should be made that 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 providers or other providers physically present with the patient during a telemedicine visit. For example, practitioners would be required 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 would also need to keep records of the written referral.

The DEA states that these 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 telemedicine poses an increased risk for diversion nor rationale for how the data points collected would reduce risk for misuse.

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 be to support investigations or audits, we believe this information could instead be collected or reviewed using medical records. Physician and staff shortages exist 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

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

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.**

LIMITING SCOPE OF CONTROLLED SUBSTANCES ALSO RESTRICTS ACCESS

During the COVID-19 pandemic, the use of virtual prescribing via telemedicine for narcotic and non-narcotic schedule II-V controlled substances has supported patients with a variety of clinical needs in receiving medically necessary medications. Some examples include anti-seizure medications for epilepsy patients; pain medication for cancer patients; sleep medications for patients with sleep disorders; and medication for children and adults with ADHD.

However, the proposed rule would limit telehealth prescribing of controlled substances without a prior in-person visit to schedule III-V non-narcotic medications only. The rule states that prescribing any schedule II or narcotic substances via telemedicine would pose too great a risk to public health and safety. Yet, the agency does not provide any actual data demonstrating that access to these substances for medically appropriate treatment via telemedicine poses an increased risk for diversion, or any other increased risk for that matter. Rather, the agency relies on a general assumption that because controlled substances can be misused, an increase in access results in increased risk.

We are concerned that this assumption, and the DEA's proposal, fails to consider the millions of Americans who may be adversely impacted from an inability to access medically necessary medication through virtual prescribing. It also interferes with clinicians' ability to leverage tools and resources to administer medically necessary treatment. **Therefore, we recommend that the DEA add circumstances under which schedule II and narcotic medications can be eligible for telemedicine prescribing without a prior in-person exam. Circumstances which would warrant waiving the in-person requirement could include certain diagnoses/disease burdens (like hospice) and/or inability to travel to in-person appointments (whether due to transportation limitations, physical disability, or geographic distance).**

For example, patients with Multiple Sclerosis may have significant disability or disease burden that limits their ability to travel for in-person appointments; providing an exemption to waive in-person requirements for virtual prescribing of schedule II drugs, such as Adderall and or Ritalin for fatigue or improving alertness, in those circumstances can greatly improve access to care.

SIX-MONTH TRANSITION PERIOD ONLY ACCOUNTS FOR RELATIONSHIPS ESTABLISHED DURING THE COVID-19 PHE

The proposed rule states that for relationships established during the COVID-19 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 period to the requirements set forth in the proposed rule. 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 PHE (whichever is later) to either complete an in-person evaluation *or* receive a qualified telemedicine referral as defined by the proposed regulation *or* 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 is scheduled to end. 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 two-to-three months out (in the May-June timeframe). By the time a final rule is published, many visits 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 or providers may be operating on hybrid schedules. 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 request. 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
Senior Vice President
Public Policy Analysis and Development