American Hospital Association™
Advancing Health in America

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October 4, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

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 Brooks-LaSure,

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 Department of Health and Human Services (HHS) role in coordinating with the Drug Enforcement Administration (DEA) to support the safe prescribing of controlled substances via telehealth. Indeed, during the COVID-19 public health emergency (PHE), the DEA enacted certain flexibilities to ensure patients could continue to receive lifesaving medications via telehealth while minimizing exposure and preserving provider capacity. This included waiving the in-person visit requirement prior to the prescribing of controlled substances.

We applaud the quick actions that were taken in the midst of the pandemic. However, with the expiration date fast approaching, we are concerned that DEA in conjunction with HHS has not yet issued rules to either extend the current waiver or provide a permanent pathway to telemedicine prescribing of controlled substances as mandated by Congress. The current waivers will expire at the end of the year, and, without an extension of the current waiver or rules implementing a special registration for telemedicine prescribing, patients and their providers will experience profound negative impacts. **As such, we urge the agency to extend its waiver of the in-person visit requirement before the prescribing of controlled substances to provide the DEA**

additional time to develop a final rule (at a minimum an additional two years).[1] Crucially, this will prevent harmful interruptions in the delivery of necessary patient care dependent on continued virtual prescribing of controlled substances without a prior in-person evaluation and ensure adequate time for rulemaking to establish a permanent pathway.

STATUTORY REQUIREMENT FOR PERMANENT PATHWAY

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 seven categories where telemedicine could be utilized, including, but not limited to PHEs (the basis for the waiver during COVID-19), pursuant to a special registration obtained from the Attorney General, and other circumstances to be defined by regulation. The Ryan Haight Act went on in Sec. 311(h)(2) to specify that the Attorney General *shall* promulgate regulations specifying circumstances in which a special registration for telemedicine prescribing may be issued and the procedures for obtaining such a special registration.

The SUPPORT Act of 2018 again mandated that the DEA, in coordination with HHS, promulgate special registration final regulations specifying: (1) the circumstances in which a special registration for telemedicine may be issued that authorizes prescribing of controlled substances without an in-person evaluation; and (2) the procedure for obtaining a special registration. The COVID-19 pandemic offered an opportunity for the DEA to utilize lessons learned from the broad utilization of telemedicine prescribing to set forth policies and pathways for providers to continue to safely administer prescriptions virtually, even after the PHE period ended. **Unfortunately, despite the Ryan Haight Act requirement that the DEA establish a special registration process *nearly 16 years ago*, and subsequent reinforcement of this requirement over five years ago in the SUPPORT Act, the agency still has not created one.**

STATUS OF RULES

Last year, the DEA proposed two sets of rules for the telemedicine prescribing of controlled substances and the telemedicine prescribing of buprenorphine. However, these rules were overly restrictive and burdensome and established arbitrary timelines for when in-person visits would still be required. The inadequacy of these proposed rules was demonstrated by the groundswell of responses, with the agency receiving

[1] The agency extended waivers in 2023 for one year to provide time for new rulemaking but has yet to release new rules for comments. As such, stakeholders can surmise that one year was insufficient to develop, revise, finalize and operationalize rules. Also, previous iterations of rules generated over 38,000 comments, and therefore it is anticipated that there will be a significant volume of feedback again requiring additional time to process.

over 38,000 comments (including from the AHA).[2,3] The DEA in coordination with HHS extended existing waivers through 2024 to permit adequate time to review and address comments. **As such, there is precedent for extending the waivers to allow for appropriate rulemaking, and the DEA has the authority to extend waivers again.**

A related rule has been at OMB since June and has yet to be released. The AHA met with OMB to express the urgency of releasing rules expeditiously, given the timelines for rulemaking and the pending expiration of waiver flexibilities. Indeed, there is now a limited amount of time to finalize a path forward, as the in-person visit waivers expire in December. Specifically, there are less than 14 weeks until the end of the year, making a release of proposed and final rules untenable. This is especially true considering the time providers would need to make operational changes before the new year. Many specialty areas are already booking appointments in the new year, particularly in areas with provider shortages, further rendering implementation of new rules operationally unfeasible. **Therefore, we strongly urge the DEA in coordination with HHS to extend the waivers for the in-person visit requirement for prescribing controlled substances until it can, with appropriate stakeholder input, develop and propose a framework for a special registration process for prescribing controlled substances via telemedicine that fully addresses the comment letters it received.**

POTENTIAL ACCESS IMPLICATIONS

The progression to a permanent pathway for waiving in-person visits has been delayed by fears of diversion risk. We recognize and appreciate the important role that the DEA plays in mitigating the risk of diversion. However, there are no 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. This assumption not only overstates the risk of diversion but also fails to consider the millions of Americans who may be adversely impacted by an inability to access medically necessary medication through virtual prescribing. **In many cases, seeing a provider in person is simply not an option for some patients whether due to physician shortages, mobility issues, or transportation challenges.**

For example, there is a national shortage of psychiatrists and other behavioral health providers. Indeed, 123 million people live in a mental health provider shortage area according to Health Resources and Services Administration (HRSA), and the American Psychiatric Association (APA) projects a shortage of over 12,000 psychiatrists by

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[2] https://www.aha.org/lettercomment/2023-03-29-aha-comment-letter-dea-buprenorphine-telemedicine-prescribing-proposed-rule
[3] https://www.aha.org/lettercomment/2023-03-29-aha-comment-letter-dea-telemedicine-prescribing-controlled-substances-proposed-rule

2030.[4,5] Therefore, remote services are becoming increasingly important to link geographically dispersed patients to prescribers for medications like buprenorphine. There are other examples, for which virtual prescribing may be clinically appropriate and may support improved treatment adherence such as:

- A home-bound palliative care patient receiving opioids for pain management.
- A person with cancer who has transportation limitations receiving pain medications.
- A person with epilepsy living in a remote area receiving anti-seizure medication.
- A patient with MS receiving controlled substances for fatigue virtually due to mobility limitations.
- A child receiving ADHD medication virtually due to the lack of a pediatric psychiatrist in the immediate service area.

The potential harm in restricting access for patient populations such as these by not extending waivers for in-person visits very well may outweigh the potential risk for diversion from bad actors.

SPECIAL REGISTRATION PROCESS

As a solution, the AHA has supported — including most recently through formal comment letters to DEA and CMS — the statutory mandate that the DEA establish a special registration process to create a pathway to waive in-person evaluations prior to the prescribing of controlled substances for practitioners who register with the DEA.[6]

Notably, such a process could be included in the existing DEA registration process to enable prescribers to register as part of the existing licensure framework.

For example, practitioners, hospitals, clinics, pharmacies and others are currently required to complete applications for registration and renewal of registrations for prescribing controlled substances (namely forms 224 and 224a). This process has established guardrails that build upon state medical licensure processes and Medicare reporting. Rather than creating a novel and separate process or form, the DEA could add fields to those forms that providers already use. This way, the "special registration process" would include key elements that providers already report, such as practitioner contact information, employer, practice address, state medical licenses, liability history, etc., *and* could add unique attestations on patient identification verification via

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[4] https://data.hrsa.gov/topics/health-workforce/shortage-areas
[5] https://www.psychiatry.org/psychiatrists/advocacy/federal-affairs/workforce-development
[6] https://www.aha.org/lettercomment/2022-12-01-aha-letter-dea-regarding-request-release-special-registration-telemedicine-regulation

telemedicine, drug monitoring, diversion control and emergency protocols. We encourage the DEA and HSS to *not* require reporting of home addresses if practitioners are administering telehealth from their home addresses, due to privacy concerns, as we have expressed previously.[7]

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

[7] https://www.aha.org/lettercomment/2024-03-20-aha-urges-cms-remove-telehealth-provider-home-address-reporting-requirements