



March 31, 2023

[Submitted electronically via regulations.gov]

The Honorable Anne Milgram
Administrator
Drug Enforcement Agency
600 Army Navy Dr.
Arlington, VA 22202

RE: Docket No. DEA-948 for “Expansion of Induction of Buprenorphine via Telemedicine Encounter.”

Dear Administrator Milgram,

ASHP is pleased to submit comments to the Drug Enforcement Administration (DEA) regarding the proposed rule, “Expansion of Induction of Buprenorphine via Telemedicine Encounter” (the “proposed rule”). ASHP is the largest association of pharmacy professionals in the United States, representing 60,000 pharmacists, student pharmacists, and pharmacy technicians in all patient care settings, including hospitals, ambulatory clinics, and health-system community pharmacies. For over 80 years, ASHP has championed innovation in pharmacy practice, advanced education and professional development, and served as a steadfast advocate for members and patients. In addition, ASHP is the accrediting body for pharmacy residency and technician training programs, and provides comprehensive resources to support pharmacy professionals through every stage of their careers. For more information, visit [ashp.org](https://www.ashp.org) and ASHP’s consumer website, [SafeMedication.com](https://www.SafeMedication.com).

ASHP appreciates the opportunity to provide our input on the proposed rule. We share DEA’s commitment to addressing the opioid epidemic, but urge the agency to balance enforcement priorities with ensuring continued patient access to critical telehealth services. Recent studies demonstrate that telehealth is a safe and effective means to prescribe controlled substances to treat opioid use and substance use disorders (SUD), even with regards to diversion prevention.¹ We strongly urge DEA to reconsider the proposed requirement that new telemedicine patients prescribed buprenorphine receive an in-person evaluation within 30 days of the initial fill. Providers are already struggling to meet patient demand for appointments, and many patients encounter difficulties juggling medical appointments with childcare and job responsibilities.

We are concerned that certain elements of DEA’s proposed rule could adversely impact patient care:

- **Use PHE Authority to Protect Patient Access to Buprenorphine: Rather than instituting a hard limitation now, we urge DEA to consider a second option: using the opioids-related public health emergency (PHE) to extend the flexibility to prescribe buprenorphine via telemedicine without an in-person evaluation for at least another year.** Given that the Mainstreaming Addiction Treatment Act, which removed federal X-waiver requirements, was only recently passed, there will still be considerable flux in the substance use disorder treatment space even after the COVID-19 PHE ends. Using the opioids-

¹ See, e.g., Tanz LJ, Jones CM, Davis NL, et al. Trends and Characteristics of Buprenorphine-Involved Overdose Deaths Prior to and During the COVID-19 Pandemic. *JAMA Netw Open*. 2023;6(1):e2251856. doi:10.1001/jamanetworkopen.2022.51856 (Finding that increased telehealth access to buprenorphine during the COVID-19 PHE did not result in elevated levels of substance misuse or buprenorphine-involved overdose deaths).

related PHE to extend regulatory flexibility would allow the healthcare system time to adapt to the X-waiver changes, without enacting regulatory parameters that may prove unnecessarily restrictive.

- Practice of Telemedicine Definition: As a preliminary matter, it is imperative that DEA address the exclusion of pharmacists from its definition of the “practice of telemedicine.” Specifically, § 1300.4 defines the term to mean the “practice of medicine in accordance with applicable Federal and State laws by a practitioner (other than a pharmacist),” thereby specifically excluding pharmacists. Prohibiting pharmacists from prescribing buprenorphine via telemedicine will significantly and unnecessarily limit patient access to care by a key member of the healthcare team. Pharmacists have more medication training and expertise than any other clinician, and studies show that utilizing pharmacists in the provision of medications for opioid use disorder (MOUD) increases access to treatment and improves treatment retention rates.² Even after removal of the X-waiver, patients are still struggling to access buprenorphine and effective policy solutions will require full engagement of every clinician on the healthcare team.

The exclusion of pharmacists from telemedicine creates an unnecessary barrier to care at the federal level. As written, the telemedicine definition appears to bar any pharmacists from prescribing buprenorphine (or any controlled substance) via telemedicine, potentially even within a collaborative practice agreement or state protocol that is overseen by a physician. In a number of states, pharmacists, as part of the healthcare team and in conjunction with patients’ physicians, have prescriptive authority for controlled substances.³ Utilizing pharmacists to initiate medications is becoming standard practice throughout the states. Perpetuating an outdated and artificial federal limit on the ability of pharmacists to participate in the practice of telemedicine for buprenorphine will unnecessarily limit care, adversely affecting patient outcomes and potentially threatening lives. Meeting the goal of increasing buprenorphine access will require systemic effort that engages every single member of our nation’s healthcare teams.

We recognize that the “practice of telemedicine” definition is statutory, which limits regulatory options for removing the barrier. ASHP strongly urges DEA to support a potential legislative fix to this outdated statutory text. In the interim, for the purposes of buprenorphine access, we urge DEA to work with the U.S. Department of Health and Human Services and the Administration for Preparedness and Response to utilize the opioids-related PHE to access flexibilities under the Public Readiness and Preparedness (PREP) Act to temporarily remove the bar on pharmacist prescribing of buprenorphine until a permanent fix is in place.⁴

² See, e.g., Dipaula B, Menachery E. Physician-pharmacist collaborative care model for buprenorphine-maintained opioid-dependent patients. *J Am Pharm Assoc.* 2015;55:187-192; Suzuki J, Matthews ML, Brick D. Implementation of a collaborative care management program with buprenorphine in primary care: A comparison between opioid-dependent patients and chronic pain patients using opioids non-medically. *J Opioid Manag.* 2014;10(3):159-168.

³ ASHP has developed a model state legislation (see Attachment A) and a model state protocol (see Attachment B) for pharmacist prescribing of MOUD. While neither is telehealth-focused, the model legislation and protocol may help DEA understand how pharmacists are currently engaged in MOUD and how they could be further utilized to expand access to buprenorphine.

⁴ Please see ASHP’s February 13, 2023 letter to the White House with recommendations for expanding MOUD access: <https://www.ashp.org/news/2023/02/13/ashp-calls-on-biden-administration-to-utilize-pharmacists-to-expand-access-to-opioid-treatments?>

- Extend the Timelines for In-Person Evaluations: Requiring an in-person evaluation within 30 days for a new telehealth prescription of buprenorphine may threaten continuity of care. Under the proposed rule, outside of the telehealth referral option, the prescriber must see the patient within 30 days before issuing a refill. Given the current demands on clinicians, many of whom have long wait times for appointments, particularly those who specialize in mental health and/or substance use treatment, patients may struggle to get an appointment within that timeframe. Further, because DEA is proposing to extend the timeframe to 180 days for those patients who received a telehealth prescription without an in-person evaluation during the COVID-19 public health emergency, there is no pressing clinical need to shorten the timeframe for new patients to only 30 days. We urge DEA to extend the timelines for new patient in-person evaluations to a minimum of 180 days.

As noted below, if DEA expects that an in-person evaluation, even for the purposes of referral, include certain elements beyond a standard visit (i.e., height, weight, blood pressure, medication history) that can only be provided by a mental health or substance use disorder expert, these timeframes may need to be further extended to at least 180 days to ensure patients can actually be seen in time to receive medically necessary refills.

- Clarification of Proposed Reporting and Recordkeeping Requirements: ASHP has concerns about the feasibility of compliance with certain elements of the proposed rule. Specifically, we urge DEA to clarify the following issues:
 - In-Person Evaluation: Pursuant to the proposed rule, a prescriber must see a new telehealth patient for an in-person evaluation within 30 days of the initial prescription to issue any refills, but the same provider will have no such limitations for a patient they have previously evaluated. While we appreciate that DEA was likely trying to provide regulatory flexibility by not specifying timeframes for previous evaluations or providing details about the type of evaluation that is considered acceptable, providers may be hesitant to move forward without additional clarity regarding DEA's expectations.

Specifically, we urge DEA to clarify whether there is a timeframe within which the prescriber must have previously seen the patient in person in order to avoid the 30-day limitation. For instance, can the visit have occurred more than 5 years in past? Additionally, we urge DEA to clarify that the in-person visit requirement can be satisfied if the patient meets with a clinician within the prescriber's health system, practice, or collaborative practice arrangement. Similarly, does DEA have any expectations regarding the clinical elements (e.g., the provider type, the examination or labs required, etc.) of the in-person evaluation, or will the agency defer to the Centers for Medicare & Medicaid Services (CMS), insurers, or other stakeholders (e.g., medical societies) about what constitutes an appropriate in-person evaluation for the purposes of telemedicine prescribing?

- Reporting and Recordkeeping: The proposed rule includes a fairly extensive list of elements that DEA expects a prescribing clinician to maintain for each telemedicine prescription issued. However, not all clinicians and practices will have electronic health records systems that accommodate the information fields required. Dispensing pharmacies may not have access to the full details of telemedicine prescriptions, particularly pharmacies that do not share a medical records system with a prescriber. Beyond checking for the notation that a prescription was

made via a telemedicine encounter, do dispensers have specific elements they must document on the prescription before it can be filled? In particular, does DEA expect that a dispenser would be required to somehow verify that in-person requirements were met before filling a telemedicine prescription? Because the X-waiver had specific documentation requirements, dispensers are accustomed to checking for certain notations on controlled substance prescriptions and without clarity regarding the requirements for verifying a telemedicine prescription, dispensers may be hesitant to fill prescriptions out of fear of liability and/or DEA enforcement.

Thank you for your consideration of our comments. As noted above, we share DEA's commitment to addressing the opioid epidemic, and we urge the creation of a telemedicine framework that safeguards and enhances patient access to critical MOUD services. Please do not hesitate to contact me at 301-664-8698 or jschulte@ashp.org if ASHP can provide any further information or assist the agency in any way.

Sincerely,

A handwritten signature in black ink that reads "Jillanne Schulte Wall". The signature is written in a cursive, slightly slanted style.

Jillanne Schulte Wall, J.D.
Senior Director, Health & Regulatory Policy

Attachment A: ASHP Model State Legislation

Executive Summary

Congress recently eliminated the X-waiver, a federal barrier to pharmacists prescribing medications for opioid use disorder (MOUD). States can now use pharmacists to improve access to MOUD. This model legislation was developed to help states expand access to MOUDs and curb the opioid crisis in their communities.

Explanation of Key Elements:

1. Provide clear authority for pharmacists to initiate MOUD

The model legislation establishes clear authority for physicians and institutions to establish agreements with pharmacists to manage medication therapy to treat opioid use disorder. It should provide flexibility for these agreements to include a statewide protocol, collaborative practice agreement, or institutional protocol.

2. Establish a timeline for board of pharmacy action on buprenorphine

The elimination of the X-waiver was intended to expand access to buprenorphine. Legislation should direct the board of pharmacy to establish a model statewide protocol for pharmacist initiation and management of buprenorphine therapy for opioid use disorder. A model protocol is available [here](#).

3. Ensure pharmacists comply with federal registration and training requirements

Federal law requires that pharmacists register with the DEA and complete certain training requirements prior to prescribing controlled substances to treat opioid use disorder. State law should align with these federal prescribing requirements.

4. Remove any pre-existing state barriers to MOUD prescribing

Most MOUDs, including buprenorphine, are controlled substances. Some state Controlled Substances Acts or Pharmacy Practice Acts may legacy prohibitions against pharmacists prescribing controlled substances. These must be removed to allow prescribing of MOUD.

5. Create a mechanism for Medicaid to pay for these pharmacist services

If the state does not have an existing Medicaid payment mechanism for clinical services provided by pharmacists, add this authority to the Medicaid statute to allow reimbursement of pharmacist services related to MOUD management.

6. Create a mechanism for commercial insurance to pay for these pharmacist services

If the state does not have an existing commercial insurance payment mechanism for clinical services provided by pharmacists, add this authority to the insurance statute, to allow reimbursement of pharmacist services related to MOUD management. Some states may have separate statutes governing group health plans, HMOs, or other plan types. Replicate this language in those statutes.

Model legislative text:

Pharmacist-Supported Access to Medications for Opioid Use Disorder

- (a) A pharmacist may initiate, modify, discontinue, or administer medications for the treatment of opioid use disorder, opioid withdrawal symptoms, overdose prevention, and opioid side effects, and taper or discontinue opioids, pursuant to a protocol, collaborative practice agreement, or institutional privileging agreement, to the extent authorized by federal law.
- (b) The Board of Pharmacy shall establish a statewide protocol for pharmacist treatment of opioid use disorder, including but not limited to initiation of buprenorphine-containing treatments, not later than 180 days after the date of enactment of this provision.
- (c) A pharmacist authorized to issue an order to initiate or adjust a medication assisted treatment that is a controlled substance shall register with the federal Drug Enforcement Administration and complete the training required by Section 303 of the Controlled Substances Act (21 U.S.C. 823).
- (d) [If applicable] Delete any language in the State Pharmacy Practice Act and State Controlled Substances Act prohibiting pharmacists from ordering controlled substances and clarify that the state shall permit a pharmacist to register with the federal Drug Enforcement Administration to provide services outlined in the Controlled Substances Act.
- (e) Medicaid [and its Medicaid managed care issuers] shall provide direct payment to a pharmacist providing covered health care services authorized in this legislation to a Medicaid beneficiary at a rate no less than that of other health care providers for providing the same service.
- (f) For health plans, policies, contracts, or agreements issued, amended, adjusted, or renewed on or after [insert date of next plan year]:
- (1) Benefits may not be denied for any health care service performed by a licensed pharmacist if:
 - (A) The service performed was within the lawful scope of the pharmacist's license;
 - (B) The plan would have provided benefits if the service had been performed by another health care provider; and
 - (2) Health benefit plans or issuers, policies, contracts, or agreements that delegate credentialing to contracted health care facilities shall accept credentialing for pharmacists employed or contracted by those facilities. Health plans or issuers shall reimburse facilities for covered services provided by network pharmacists within the pharmacists' scope of practice per negotiations with the facility.

Attachment B: ASHP Model State Protocol

Executive Summary

Congress recently eliminated the X-waiver, a federal barrier to pharmacists prescribing medications for opioid use disorder (MOUD). States can now use pharmacists to improve access to MOUD. This model protocol was developed to help health care providers and boards of pharmacy utilize pharmacists to expand access to MOUDs and help curb the opioid crisis in their communities.

1. Purpose: To formally identify the function that pharmacists, licensed in [insert state], may perform in providing drug therapy management to patients with opioid use disorder (OUD).
2. Authority: [Insert reference to state pharmacy practice act]
3. Pharmacist registration and training
 1. A pharmacist authorized to issue an order to initiate or adjust a medication assisted treatment that is a controlled substance shall register with the federal Drug Enforcement Administration and complete the training required by Section 303 of the Controlled Substances Act (21 U.S.C. 823), as well as any future education needed to maintain registration.
4. Referral criteria:
 1. Patients with a known or suspected opioid use disorder are referred by a provider, patient care team member, or
 2. By patient self-referral.
5. Prior to undertaking drug therapy management authorized under this protocol, the pharmacist shall:
 1. Conduct an interview and physical assessment of the patient for signs and symptoms of opioid use and opioid use disorder sequelae.
 2. Review the patient's medical records and perform medication reconciliation, if available.
 3. Order and interpret any laboratory tests necessary to support patient assessment.
 4. Query the state prescription drug monitoring program (PDMP) to obtain controlled substance prescription history.
6. The pharmacist may perform the following authorized functions in accordance with this protocol and the standards of care for the treatment of opioid use disorder:
 1. Drug Therapy Management
 1. Initiate, modify, discontinue, and administer formulations of buprenorphine, naltrexone, or other medications FDA approved for treatment of opioid use disorder.

2. Initiate, modify, discontinue, and administer naloxone or other medications FDA approved for overdose prevention.
 3. Initiate, modify, discontinue, and administer medications for the treatment of opioid induced side effects.
 4. Initiate, modify, discontinue, and administer medications for the treatment of opioid withdrawal symptoms including but not limited to alpha-2 agonists, antiemetics, antihistamines, anticonvulsants, antidiarrheal agents, analgesics, and sedative hypnotics.
 5. Initiate, modify, discontinue, and administer medications for the purpose of opioid tapering.
2. Develop a treatment plan for opioid use disorder including referral to medical services, case management, psychosocial services, substance use counseling, and residential treatment as indicated.
 1. For patients who self-refer to the pharmacist for treatment, the pharmacist will have direct communication with a collaborating physician to review the treatment plan by a method and frequency determined by the physician.

7. Documentation and Reporting

1. The pharmacist's assessment, clinical findings, and plan of care will be documented in a health record mutually accessible by the referring provider, collaborating physician, and/or primary care provider. If a mutually accessible health record is not available documentation will be shared via facsimile or other secured communication platform.
2. Pharmacists shall report prescribing and dispensing of any controlled substance or any other required medications to the state prescription drug monitoring program, as required by state law.