SAMHSA
Substance Abuse and Mental Health Services Administration

Policy Priority Roundtable Summary Report

Improving Buprenorphine Access in Pharmacy Settings

Note: The roundtable report represents the opinions and recommendations of the pharmacy stakeholder participants in the roundtable and does not reflect an official position, policy, or set of recommendations from any federal or state agency

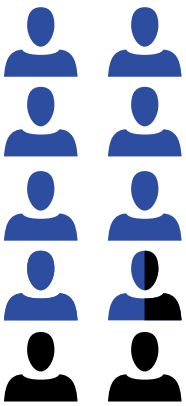
The overdose crisis has worsened over the past several years and is on track to claim over 100,000 lives this year. This crisis affects all communities and has been fueled by heroin, illicit fentanyl, and prescription opioids. Buprenorphine treatment is associated with reduced risk of overdose death. The federal government has eliminated outdated rules that can limit access to this life-saving treatment, while increasing awareness and understanding of the medication.[1] Despite these efforts, barriers to buprenorphine continue to persist in many settings. This roundtable was convened by the U.S. Department of Health and Human Services (HHS) consisting of pharmacy stakeholders from both retail and independent pharmacies, pharmacy associations, academics, and state and local public health partners to address barriers associated with buprenorphine access and availability in pharmacies.

Buprenorphine is a U.S. Food and Drug Administration (FDA)-approved medicine used to treat opioid use disorder (OUD) that can diminish the effects of opioid dependency, such as withdrawal symptoms and cravings; increase safety in cases of overdose; and lower the potential for opioid misuse, when taken as prescribed. Buprenorphine is the first medication to treat OUD that can be prescribed or dispensed in physician offices, which significantly increases access to treatment.[2] Studies have shown that buprenorphine cuts the risk of overdose in half[3] and doubles the likelihood of patients engaging in long-term treatment.[4] According to the Controlled Substances Act, buprenorphine is classified as a Schedule III substance based on its lower abuse potential than Schedule I or II substances such as full opioid agonists.

Despite the value and evidence supporting the safety and effectiveness of buprenorphine, recent reports reflect limited access to buprenorphine in many pharmacies, with buprenorphine availability in some areas ranging from 42 to 73 percent, depending on a number of factors.[5–11] Characteristics include independent pharmacies that are less likely to stock buprenorphine (compared to chain pharmacies);[5–7, 10] locations within non-Medicaid expansion states; locations within non-metropolitan counties;[5] locations within Southern states;[6] and locations within neighborhoods with lower health insurance rates.[8] While these findings suggest that there are barriers to accessing buprenorphine, there is a need to understand what the barriers are and which measures[11] might improve access.

The Toll of the Opioid Epidemic

5.6M



In 2020, **5,600,000** people had an opioid use disorder.[18]

In 2020, 80,411 out of 106,699, or **75.4%**, of total overdose deaths involved opioids.[19]

To better understand barriers and associated challenges with access to buprenorphine, the Office of the Chief Medical Officer at the Substance Abuse and Mental Health Services Administration and the Office of the Assistant Secretary of Health, on behalf of HHS, convened a ***Policy Priority Roundtable on Buprenorphine Access and Availability in Pharmacy Settings.***

This meeting was supported and facilitated by representation from many operational divisions of HHS, including the Centers for Disease Control and Prevention, Centers for Medicare & Medicaid Services, FDA, the Health Resources and Services Administration, the Immediate Office of the Secretary, Indian Health Service, Office of the Assistant Secretary of Health, Office of the Assistant Secretary of Planning and Evaluation, National Institutes of Health, and National Institute on Drug Abuse. Other federal partners included the U.S. Drug Enforcement Administration (DEA) and the Office of National Drug Control Policy.

This meeting occurred virtually on August 11, 2022, and August 12, 2022, with participants that included distributors, pharmacy executives from the major chains, individual pharmacists, practitioners, and individuals with lived experience with OUD. The purpose of this meeting was to identify barriers associated with buprenorphine access and availability in pharmacies and develop solutions to address the barriers.

This report is based on stakeholder input from the August 11–12, 2022, ***Policy Priority Roundtable on Buprenorphine Access and Availability in Pharmacy Settings.***

Barriers and Challenges to Buprenorphine Access in Pharmacies

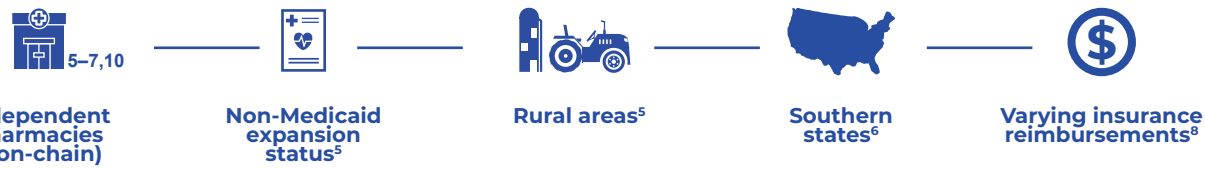
It is not fully understood why there are such widespread limitations on access to buprenorphine in pharmacies. Pharmacy mandates, bureaucratic procedures, biases, gaps in care coordination for patients with OUD, mistrust, and fears of DEA enforcement may all contribute to limited availability.[12]

Some studies highlight pharmacists' reluctance to provide buprenorphine to certain individuals, especially those that they suspect are seeking buprenorphine from far away or out of state.[10-12] Furthermore, the increase of telehealth in response to the COVID-19 pandemic, which was intended to increase access, may have inadvertently added new barriers with pharmacists seeing prescriptions from unfamiliar geographic areas. This in turn has influenced pharmacies to create gatekeeping measures such as geographic restrictions, telephone prescription "confirmations," prescription cancellations, and refusals.[12]

Additionally, some pharmacists report rejecting new prescriptions due to historical utilization that does not account for new providers and patients. This limits the quantity that can be ordered or the number of prescriptions that can be filled.[13] The confusion appears to stem from a misunderstanding of DEA regulations.[14,15,16] Many pharmacies limit ordering of buprenorphine out of caution.[17] Finally, self-reports indicate pharmacists' stigmatization of people who need buprenorphine.[10,14-16,18]

1985	Buprenorphine marketed as Schedule V narcotic analgesic[20]
2000	DATA 2000 enabled X- waivered physicians to treat OUD with FDA-approved narcotic medications[21]
2002	Buprenorphine approved by FDA for treatment of OUD[20]
2006	Maximum number of patients to whom physicians could prescribe buprenorphine increased from 30 to 100[22]
2016	Maximum number of patients to whom physicians could prescribe buprenorphine increases to 275[23]
2018	SUPPORT Act expanded privilege of prescribing buprenorphine to other qualifying practitioners, including nurses and physician assistants[23]
2020	Federal legislation allowed for telehealth prescriptions of buprenorphine in wake of COVID–19 Public Health Emergency[12]
2021	Updated HHS guideline exempted certain providers from waiver required to prescribe buprenorphine[24]
2023	Removal of the DATA 2000 (X) Waiver

Lack of Access Factors as Identified by Research



Framework for the Roundtable Discussions

During the ***Policy Priority Roundtable on Buprenorphine Access and Availability in Pharmacy Settings***, meeting participants were asked to consider challenges and barriers (day 1) and solutions (day 2) across the buprenorphine supply chain. Participants were divided into three breakout groups based on their interest and expertise. The three groups—manufacturing & distribution; pharmacy; and prescriber & patient—were asked to describe the most relevant actions that HHS and other federal departments could consider to increase buprenorphine access.

Buprenorphine Supply Chain

Summary of Barriers Associated With Buprenorphine Access and Availability in Pharmacies

Meeting participants identified barriers across the manufacturing, pharmacy, provider, and patient levels. Throughout the buprenorphine supply chain, five underlying themes emerged: (1) stigmatization; (2) patient burden; (3) classification of buprenorphine in the same category as other opioids; (4) fear of violating understood threshold rules; and (5) pharmacies losing money on dispensing buprenorphine prescriptions due to low reimbursement rates

Stigmatization	Stigmatization around OUD creates barriers for people to seek treatment and access care. Stigmatization can be defined as projecting negative attitudes against an identifiable group of people. It perpetuates fear or anger toward individuals with OUD, directing attention away from understanding the disease and treating the problem. Stakeholders noted the following common misconceptions: ● Buprenorphine has high value as a street drug. ● Patients are selling their buprenorphine on the street. ● Providers are prescribing buprenorphine as a substitution for other opioids. ● Dispensing buprenorphine will attract undesirable clientele to the pharmacy. ● The pharmacy will get a bad reputation for attracting undesirable individuals to the community and distributing opioids into the community. ● Prescribers of buprenorphine prescribe too much and may not know if it will be diverted for recreational use.
Patient Barriers	● There are not enough buprenorphine prescribers, and individuals need to travel long distances to get treatment. ● Telehealth has expanded the number of individuals who can receive a prescription, but pharmacies are suspicious of prescriptions from outside of the community. ● Sometimes dosages will have to be increased or decreased as a part of treatment, but pharmacies will not allow, and insurance may not pay for, changes in buprenorphine dosages within the same month. ● Patients taking buprenorphine cannot request to fill their prescription early for any reason, even if they are about to travel. ● When patients or prescribers call pharmacies to see where to fill prescriptions, pharmacies are trained to not disclose which controlled medications they have on premises. ● Some pharmacies carry only certain forms of buprenorphine, forcing patients to search around for a different pharmacy or request that their prescriber change their prescription.

Summary of Barriers (continued)

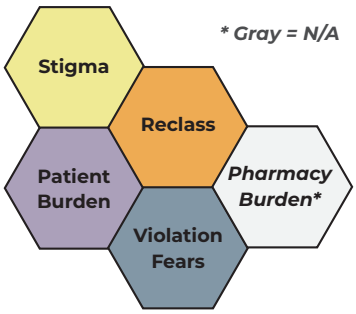
Classification in the Same Category as Other Opioids	A controlled substance is one that is tightly controlled by the government because it may be misused, diverted, or cause addiction. The control applies to the way the substance is made, used, handled, stored, and distributed. Controlled substances include opioids, stimulants, depressants, hallucinogens, and anabolic steroids. Although buprenorphine is a Schedule III drug, it is treated similarly as Schedule II opioid medications by distributors. ● Because pharmacies and distributors cap the total amount of controlled substances distributed, this limits the amount of buprenorphine that can be distributed. ● This classification may be the reason why some pharmacists are reluctant to fill prescriptions. They may see it as a further misdistribution of opioids. Source: National Cancer Institute; https://www.cancer.gov/publications/dictionaries/cancer-terms/def/controlled-substance
Fear of Violating Rules	Many stakeholders feared that they would violate rules against thresholds. Others feared being named in multidistrict litigations as contributing to the opioid pandemic. Examples of perceived violations included: ● Filling prescriptions from people who live more than 20–25 miles from the pharmacy. ● Filling too many prescriptions for buprenorphine at the same pharmacy. ● Requesting a high quantity of buprenorphine from the distributor. ● Accepting telehealth prescriptions without knowing whether the patient had seen the prescriber face-to-face within the last 24 months. ● Impending end to COVID-19 emergency rules, such as the allowance of telehealth prescriptions. ● A large number of new buprenorphine prescriptions from the same prescriber.
Pharmacies Losing Money on Every Prescription	Dispensing buprenorphine can be expensive because there are significant regulations regarding storage, the need to ensure legitimacy, and paperwork, combined with low reimbursement. Stakeholders noted the following: ● Pharmacies often report losing $10 for each buprenorphine prescription they fill. This is due to pharmacy staff labor hours combined with low reimbursement rates. ● Prior authorization is often required by private insurance payers, and this is a hurdle that takes pharmacy staff significant time to assess. ● Pharmacists are not allowed to modify the quantity or doses prescribed because the FDA label on the medications warns against it.

Recommendations To Increase Buprenorphine Access and Availability in Pharmacies

Meeting participants identified specific actions that may be taken by HHS and other federal agencies to increase access to buprenorphine at pharmacies. The list of recommendations appears below and is organized into three categories: (1) short-term action items for messaging considerations; (2) long-term action items for funding consideration; and (3) regulatory and legislative actions. The left column denotes the barriers that are addressed by each category of recommendations. (This roundtable report represents the opinions of the participants only; no inference should be made concerning the position or policy of any federal or state agency).

Short-Term Action Items

Barriers Addressed



Recommendations

1. Create opportunities where HHS and the U.S. Department of Justice come together to ensure consistent and clear messaging around the importance of increasing buprenorphine access in pharmacies. Messaging should clarify that buprenorphine is a life-saving medication as a component of treatment and harm reduction and that buprenorphine is different from other opioids. Denying buprenorphine access, in certain cases, may violate laws prohibiting disability rights discrimination.

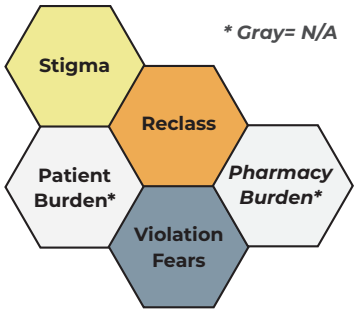
1a. HHS and DEA should provide opportunities for stakeholders to talk directly to them about their concerns and to clarify what the regulations are. Ideas include convening a "road show" across the country where pharmacists can talk directly with DEA staff; and convening a "de-mystifying regulations day" that includes individuals from DEA and HHS providing clarification and opportunities for discussion with leadership at pharmacies, pharmaceutical companies, and big corporations that are part of the supply chain. [Note: A town hall with DEA occurred in March 2023.]

1b. DEA could offer clear and written documentation to address fears and clarify points of misunderstanding regarding buprenorphine policy and investigations. Topics could include when COVID-19 public health emergency measures, such as telehealth prescriptions, will end. Ideas referenced in the meeting include developing a "Myth vs. Fact" document; and ensuring that regional DEA offices are all using the same regulations, which are clearly written and can be shared with pharmacies. [DEA has favorably responded to this action item.]

1c. HHS should continue to consult with its Office for Civil Rights (OCR) and Office of the General Counsel regarding denials of prescribed medication, to a person with OUD, such as buprenorphine, as possible violations of federal civil disability rights and federal civil rights laws governing other protected classes (e.g., race, color and national origin), including the Americans with Disabilities Act, Section 504 of the Rehabilitation Act of 1993, Section 1557 of the Affordable Care Act, the Civil Rights Act of 1964, and other federal nondiscrimination laws to better inform providers of their obligations and duties under the law. Specifically, a request for written technical assistance guidance about the responsibilities of chain pharmacies by OCR should be considered.

1d. HHS and DEA should enhance messaging that buprenorphine is a Schedule III medication and should be considered differently from other opioids which are Schedule II. Efforts should be considered to ungroup buprenorphine from the safeguards implemented as part of manufacturer-controlled safety procedures, algorithms used for opioid distribution to pharmacies, and pharmacies' automated checks.

Recommendations for U.S. Government Actions To Increase Buprenorphine Access and Availability in Pharmacies

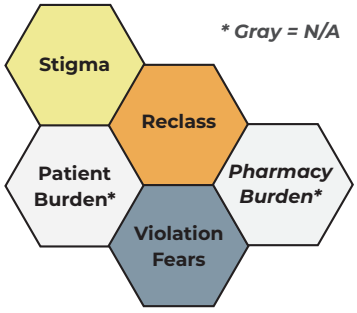


2. HHS could consider enhancing partnerships with non-governmental organizations to further disseminate clear and consistent messaging about buprenorphine. Many of the meeting participants noted they could help disseminate the message through communications channels such as boards of pharmacies; state pharmacy associations; pharmacy professional organizations; state regulatory and licensing boards; state attorney generals; HHS regional administrators; and pharmacy student organizations.

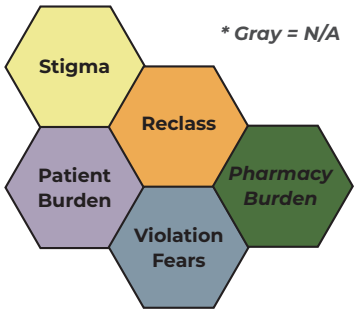
Long-Term Action Items

Barriers Addressed

Recommendations



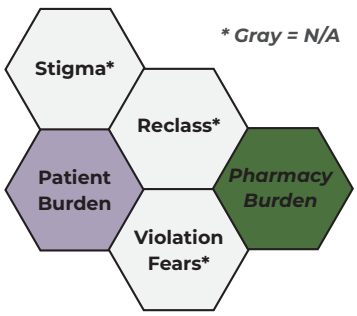
3. HHS should consider additional investments to fund educational opportunities for the health care and pharmacy workforce to reduce stigmatization and clarify misperceptions about buprenorphine. There should be emphasis that buprenorphine is a life-saving treatment for OUD, much like insulin is for diabetes. Ideas included education modules at university and medical residency programs; during initial licensure and renewals for doctors, nurses, and pharmacists; during pharmacy residency programs; as part of eligibility process to be on state boards of pharmacy; and within student pharmacist groups.



4. HHS should consider providing technical assistance for studies or expert panels to explore expanded formularies for buprenorphine and whether the reimbursement rates are adequate. There are some state Medicaid agencies that still utilize prior authorizations. [Meetings with some of these state agencies have begun.]

5. Consider funding models for treatment expansion pilot studies.

5a. Consider expanding the types of prescribers to include pharmacists. Consider conducting a pilot study to look at viable and effective models. [Note: Outside of research studies, this requires federal activity.]



5b. HHS should explore demonstration projects for providing financial or other incentives for pharmacies to dispense buprenorphine. A pilot grant program could be used to test this model.

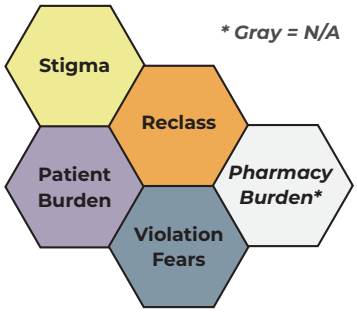
5c. Consider a study to look at models of prescriber and pharmacist collaborations that are likely to increase access and safety.

Recommendations for U.S. Government Actions To Increase Buprenorphine Access and Availability in Pharmacies (continued)

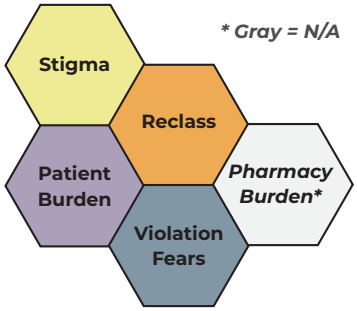
Regulatory and Legislative Actions

Barriers Addressed

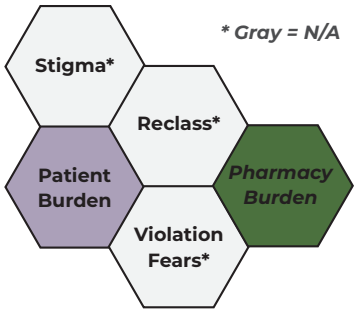
Recommendations



6. Remove the X-waiver for buprenorphine, recognizing that it is a treatment for OUD, as cases of diversion often involve seeking relief from withdrawal symptoms. [Note: This occurred following the convening with the passage of the 2023 Appropriations Bill.]



7. FDA should consider modifying the dosing guidance on buprenorphine medication packaging so that providers and pharmacists may have greater flexibility in terms of dosage, such as being able to halve films or tablets as needed.



8. Consider expanding the types of locations where a prescription can be filled. For example, allow community behavioral health centers, federally qualified health centers, and other community providers to dispense buprenorphine. This might be especially helpful in rural communities with few pharmacies. [This would require federal approval from DEA.]

Meeting Participants

This report is based on the thoughtful input of many stakeholders who were present for the ***Policy Priority Roundtable on Buprenorphine Access and Availability in Pharmacy Settings***, held virtually on August 11 and August 12, 2022. The meeting participants are listed in alphabetical order by first name. Federal employees listed below participated as subject matter experts or as administrative support for the roundtable convening.

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