SAMHSA
Substance Abuse and Mental Health Services Administration

SAMHSA/DEA Virtual Town Hall: Expanding Buprenorphine Access in Pharmacies to Treat Opioid Use Disorder

Note: This report represents the opinions of the participants in the Town Hall meeting and does not reflect an official position or policy of any federal or state agency.

As overdose deaths involving opioids remain at historically high levels in the United States and gaps in treatment for opioid use disorder (OUD) persist, the need to increase access to buprenorphine is critical. Pharmacists are well positioned to play a key role in expanding access to this life-saving treatment, but regulatory-, market-, and provider-level barriers hinder their potential. These barriers include manufacturer/distributor-imposed thresholds on pharmacists' ability to dispense buprenorphine, which became significantly stricter as a result of the opioid Multidistrict Litigation (MDL) settlement and other recent settlements with opioid manufacturers, wholesalers, and distributors;[1] financial and other disincentives for pharmacists to dispense buprenorphine; limitations on the role pharmacists can play as prescribers; and the tenacious influence of stigmatization at the individual, provider, and community levels.

Seeking to better understand the interconnected challenges with ensuring buprenorphine availability in pharmacies, in August 2022, the Substance Abuse and Mental Health Services Administration (SAMHSA) with the Office of the Assistant Secretary of Health convened pharmacy community members in a Policy Priority Roundtable on Buprenorphine Access and Availability in Pharmacy Settings. Among the views that emerged from that meeting was a call for continued opportunities for participants to bring concerns and solutions directly to the Drug Enforcement Administration (DEA) and other federal agencies.

As a step toward responding to feedback from that meeting, SAMHSA's Office of the Chief Medical Officer, the Office of the Assistant Secretary of Health, and the DEA hosted a virtual town hall on March 29, 2023, bringing together participants from the DEA and the U.S. Department of Health and Human Services (HHS), as well as from pharmacy organizations, and manufacturers/distributors. Town Hall participants discussed barriers to increasing the availability of buprenorphine in pharmacies, and they brainstormed solutions. Participants also shared their views on strengthening communication pathways. This report shares themes from the Town Hall discussions. To encourage participants to speak freely, participants were promised anonymity. Therefore, no names or specific organizations are associated with the opinions shared below.

1 . For an overview of the MDL and related settlements, see https://crsreports.congress.gov/product/pdf/LSB/LSB10365 and https://www.justice.gov/opa/pr/department-justice-files-motion-multi-district-opioid-case/

Barriers

Participant views related to barriers or challenges to buprenorphine supply are organized under the following topics:

- Unclear manufacturer/distributor thresholds.
- Supply and demand.
- Lengthy resolution processes.
- Pharmacist hesitation.
- Red flags/trigger alerts.

Unclear Manufacturer/Distributor Thresholds

Among the most important barriers identified by pharmacy participants concern limits on supply that threaten their ability to consistently order, receive, and dispense buprenorphine prescriptions.

Manufacturers/distributors establish supply thresholds as a part of their anti-diversion efforts, and pharmacies who surpass these thresholds have reported being cut off from ordering buprenorphine without warning.

Pharmacists attending the Town Hall meeting said they often do not know what their thresholds are or how close they are to approaching their thresholds with each order. Without this information, they can't take steps to mitigate a potential disruption in supply. Complicating the matter, each manufacturer/distributor may have a different threshold.

One participant reportedly asked a distributor directly about their pharmacy's threshold and was told that, because the information was a regulatory issue, the distributor was not allowed to share the specific threshold with the pharmacy. In the meantime, the participant said community members were dying from a lack of buprenorphine. In another case, a pharmacy had to undergo the expense and disruption associated with an audit triggered by a stop from the manufacturer, which took about a month to resolve.

Several pharmacy participants confirmed confusion around manufacturer/distributor thresholds. Although supply must be monitored, the DEA does not require manufacturers or distributors to establish thresholds or apply algorithms to trigger holds on buprenorphine.[2] However, in light of the MDL agreements in place, one participant suggested that distributors may be interpreting each manufacturer's guidance in an especially risk-adverse light. Another observed that guidance on suspicious monitoring programs may not be specific or direct enough to allow pharmacists to change a practice or to know exactly what they're allowed to do.

"We're dealing with a very frightened [buprenorphine] supply chain at this point."

2. For DEA guidance on reporting suspicious orders of controlled substances, go to https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-065)(EO-DEA258)_Q_A_SOR_and_Thresholds_(Final).pdf; A suspicious order Q&A is at https://www.deadiversion.usdoj.gov/faq/sors_faq.htm

Supply and Demand

Some pharmacy participants indicated they were concerned about thresholds in part because they anticipate an increased need for buprenorphine as a result of the removal of the DATA-waiver requirement (see box 1). If the repeal of the DATA-waiver works as intended, the number of buprenorphine prescribers could potentially increase. Such an increase could result in pharmacies needing to fill more buprenorphine prescriptions, which could trigger stops in supply.

Pharmacists in attendance noted that, in addition to filling scripts from new prescribers, other factors could significantly and suddenly influence the volume of buprenorphine they need, such as the closure of a nearby pharmacy, or the recently mandated access to medication-assisted treatment in correctional facilities in some states. Pharmacists question whether manufacturer/distributor thresholds have accounted for the anticipated increase in buprenorphine scripts and whether suppliers can adjust their thresholds rapidly to changing market circumstances.

Manufacturers/distributors, in contrast, said they have not seen a corresponding increase in buprenorphine orders to the degree it has challenged their threshold systems. Others noted that states may have their own limitations in place that affect buprenorphine supply, such as approving only the buprenorphine mono-product for pregnant women. While orders that are unusual in size, frequency, or pattern will raise a red flag, manufacturer/distributor participants said that there are systems in place for the legitimate expansion of thresholds, including requests from pharmacies to increase thresholds.

Box 1. Federal-Level Commitment to Increasing Access to Buprenorphine

Since its approval as a scheduled substance to treat OUD in 2002, regulatory barriers to accessing buprenorphine continue to be incrementally addressed. Most recently, in December 2022, the Biden Administration removed the need for providers to obtain a DATA-waiver (commonly known as an X-waiver) to prescribe buprenorphine to patients, a measure that had been in place since 2000. The removal of the DATA-waiver means there is no longer a federal limit on the number of patients a provider can treat with buprenorphine at any one time. While many challenges remain, federal agencies are seeking ways to address regulatory barriers to accessing buprenorphine while ensuring the system adequately discourages diversion.

Lengthy Resolution Processes

A pharmacy participant said that although there are indeed systems to request an increase in the threshold, it's a tedious, time-consuming process that doesn't necessarily result in a favorable outcome for patients. Other participants concurred that the process for resolving a stop in supply was lengthy. One participant said that manufacturers/distributors take months to respond to a request for a threshold increase, and often the request is still denied. Another agreed, saying that resolving an issue with the manufacturer/distributor took about 3 months of back-and-forth communication.

A pharmacy participant stated that, although pharmacists can ask for increases, the burden remains on the pharmacist to communicate with manufacturers/distributors when questions arise. For instance, pharmacists typically make a phone call to solve most pharmacy issues. But pharmacists may not know whom to call to resolve a threshold issue. Email processes set up by manufacturers/distributors are slower, and a pharmacist can't be sure if or when their email is read. Pharmacy participants said it would be helpful if pharmacists could call suppliers directly and let them know, for example, that they will have new buprenorphine prescriptions from a new provider and resolve the issue in real time. Pharmacy participants want a convenient, streamlined process for increasing thresholds that reduces the burden on pharmacists, such as a hotline to call to immediately resolve supply issues.

Another participant stated that pharmacists may feel that even if they did get a threshold increase, it would not be timely, and patients would still be without treatment. Several pharmacy participants noted the need for timely increases. As one participant said, pharmacists operate under a sense of urgency in providing medication, so "timely" means the same day or the next day, not months.

Likewise, if there is a need for an audit or investigation, pharmacy participants said patients on scheduled substances shouldn't have to pay the price. Pharmacists asked for a way to reach their supplier quickly to ensure patient medications continue to be supplied while the investigation is underway. This is particularly important in the context of buprenorphine treatment for OUD, where discontinuations in treatment are strongly linked to increased overdose risk.

A system that allowed a pharmacist to know where they are in relation to meeting their thresholds was also suggested, such as a green–yellow–red warning system if specific numbers cannot be provided. Better yet, some said, since buprenorphine is not commonly diverted, some stated it should not be subject to thresholds at all or be treated differently from stronger opioids that are used to treat pain.

"It's not about one pharmacy hitting a threshold; it's about one or more persons dying."

Manufacturer/distributor participants acknowledged the need to better understand pharmacy concerns around thresholds. The MDL holds signatories to strict provisions on how they handle suspicious orders and thresholds for controlled substances.

Manufacturers/distributors reflected on increasing thresholds by specific percentages. While that wouldn't solve all the issues, manufacturers/distributors in attendance said they would be more assured that they could increase access to buprenorphine while upholding their efforts to prevent diversion. Pharmacists agreed with the need to mitigate unintended consequences of the MDL.

Pharmacist Hesitation

Pharmacists in attendance offered some insights as to why manufacturers/distributors may not be seeing more requests for increased thresholds as a result of the DATA-waiver repeal. Many pharmacy participants said that pharmacists would like to dispense more

buprenorphine prescriptions but are concerned about the consequences of exceeding their thresholds. One participant said that, because reaching a threshold could threaten the pharmacy's ability to fill prescriptions for all scheduled substances for all the pharmacy's patients, pharmacists may be hesitant to take on new patients with buprenorphine prescriptions. One participant noted that since the MDL settlement, suspicious order monitoring programs have become much more stringent, to the point that manufacturers/distributors are looking at individual patient pharmacy records and doses prescribed. Others concurred, noting that the risk to pharmacists and pharmacies is significant, so some pharmacists choose to turn away patients.

Some participants said that the pharmacy profession in general is risk averse; pharmacists like to know exactly where the legal lines are so they can be sure to work inside them. Some participants suggested having guidelines and clear documentation to guide practice. Yet, as someone else pointed out, a pharmacist's knowledge of when they'll be cut off still doesn't help the patient get their life-saving medicine. If a pharmacy is cut off mid-month, it can be especially hard on under-resourced individuals.

Reimbursement is another reason that simply removing the DATA-waiver may not have resulted in an immediate increase in demand for buprenorphine. Pharmacists may lose money on dispensing buprenorphine due to low reimbursement rates. Participants suggested that reimbursement strategies could be adjusted to make dispensing buprenorphine profitable for pharmacists.

"With new legal and voluntary reductions in insulin costs, we should see increases in insulin orders and prescribing [for people with diabetes]. But unlike buprenorphine, [patients with diabetes] are unlikely to have gaps in care that may result in morbidity and mortality."

Red Flags/Trigger Alerts

One participant noted that their State Board of Pharmacy publishes a list of red flags that can trigger warnings or cut-offs, and some professional associations warn that dispensing buprenorphine in the presence of a red flag puts a pharmacist at risk of losing their license.

Pharmacy participants identified several factors associated with buprenorphine prescriptions that complicate how thresholds are met. One issue was how manufacturers/distributors differentiate between the single-entity buprenorphine and the combination product, as they are both ordered under the same drug code.

Macrodosing at induction is another confounding factor. As one participant noted, given the prevalence of illicit fentanyl and increasing threats of xylazine found in conjunction, inductions above the standard may be indicated. If providers increase the practice of macrodosing—say, inducing at 64 mg instead of 8 mg or 12 mg—from a threshold perspective, that is equivalent to four or five standard patients. Participants pointed out that, although macrodosing is not yet an evidence-based practice, high-quality research suggests benefits and minimal risk with higher dosages of buprenorphine for induction.

Another red flag is dispensing prescriptions for patients who live sometimes hundreds of miles away, as this may be interpreted as medication diversion/mis-monitoring. During the COVID-19 pandemic, this practice was regarded as a benefit, particularly for patients in rural areas. Public health emergency (PHE) flexibilities put in place during the COVID-19 pandemic allowed prescribers to initiate and prescribe buprenorphine without an in-person examination. The telehealth rules that will be in place following the end of the PHE are under review as of August 2023. Pharmacists expressed concern about their ability to confirm that in-person requirements have been met if they are mandated by law.

Patients who pay cash for their medicines may also raise a red flag because they may be perceived as trying to avoid having their case flagged as suspicious. However, in states that have not expanded Medicaid, underinsured patients who are not Medicaid eligible have no other choice. Other patients may prefer to pay cash for their OUD medication for privacy reasons. If their treatment is billed against a company insurance plan, they risk having their employer find out about it. Pharmacy participants suggested looking at payment systems and other data sources to avoid triggering audits from regulators based simply on cash payment.

A pharmacist said that flags may also be raised if the patient is also taking another controlled substance, such as Adderall, as this may elevate perception of co-occurring substance use disorders.

Summary of Barriers to Buprenorphine Access in Pharmacies

- Pharmacists' supply of buprenorphine may be cut off without warning when thresholds are reached.
- Manufacturers/distributors do not share their threshold algorithms and triggers with pharmacists.
- Interruptions in medications present lethal risks to patients.
- It may take weeks or months to resolve issues.
- Manufacturer/distributor thresholds may not be adjusted to keep up with increasing need.
- Pharmacists are concerned that increased dispensing could raise red flags that could stop orders.
- Supply concerns leave pharmacists hesitant to take on new buprenorphine patients.
- Pharmacists lose money because payment is tied to dispensing a medication, not to providing services.
- Manufacturers/distributors lack clear and transparent guidance from state regulators about their obligations under the MDL settlement and how they differ from existing requirements in the Controlled Substances Act.
- Pharmacists' potential to expand access to buprenorphine remains untapped.

"Perhaps the need for thresholds at all for buprenorphine products right now could be reassessed."

Potential Improvements

Participant views about ways to address barriers to buprenorphine access are presented under the following topics:

- Pharmacist scope of practice.
- State policies and practices.

Pharmacist Scope of Practice

One participant said that the current system has failed to meet patient needs, citing a December 2022 paper finding that 87 percent of individuals with OUD are not receiving evidence-based treatment.[3] Several participants identified the benefits of facilitating an expanded role for pharmacists in increasing access to buprenorphine.

One stated that pharmacists are arguably the most accessible healthcare providers in the nation. Pharmacies offer convenient hours and convenient locations: 90 percent of Americans live within 5 miles of a pharmacy. Accessibility is especially significant for rural and racial and ethnic minority communities, with whom pharmacists have built trusted relationships.

As the nation's medication experts, pharmacists are reimbursed for dispensing products rather than providing clinical services. Several participants noted that this may not be an optimal model for patient care. An alternative, they said, is to pay pharmacists for providing services, not dispensing products.

One strategy that was suggested by a participant would be to relax regulatory requirements and allow pharmacist to provide clinical services such as urine screening, as well as buprenorphine induction and management. A participant mentioned a recent pilot project that supports a role for pharmacists in buprenorphine induction and management (see box 2). Providing bridge therapy is another potential role for pharmacists.

By expanding the scope of practice to include clinical services, one participant stated, pharmacies would be recognized as effective care sites and not merely as dispensaries, and pharmacists would be reimbursed the same as other providers for providing the same services. However, expanded scopes of practice for pharmacists would need to be implemented in tandem with changes in payment policy so that pharmacists can be directly reimbursed for the provision of clinical services.

Against the backdrop of recent research showing that, despite regulatory changes, the number of providers prescribing buprenorphine and the number of buprenorphine prescriptions have not appreciably accelerated, one person said that providers have had two decades to expand access, and the only time access jumped is when prescribing rights were expanded to include nurse practitioners and physician assistants. The participant said that extending prescribing authority to pharmacists is a promising prescriber-level strategy to increase access.

3. Krawczyk, N., et al. (2022, December). Has the treatment gap for opioid use disorder narrowed in the U.S.?: A yearly assessment from 2010 to 2019. International Journal of Drug Policy, 110. doi:10.1016/j.drugpo.2022.103786

Box 2. Physician-Delegated Unobserved Induction With Buprenorphine in Pharmacies

In a 15-month randomized trial with 6 pharmacies and 21 pharmacists in Rhode Island, researchers sought to compare pharmacy-based medication for OUD with usual addiction care. In a collaborative practice arrangement, pharmacists assessed patient histories and, working with a physician, induced buprenorphine treatment in 100 patients. Following induction, 58 stabilized patients were randomly assigned to continue their follow-up at a pharmacy or with a typical addiction services provider. Patients visited the pharmacy once or twice a week and received counseling, monitoring, and other medical care. Findings showed that 89% of patients who received follow-up care in pharmacies continued care at 1 month, compared with 17% of those receiving usual care.

Source: Green, T., et al. (2023). Physician-delegated unobserved induction with buprenorphine in pharmacies. *New England Journal of Medicine, 388(2)*, 185–186. doi:10.1056/NEJMc2208055

State Policies and Practices

To tap the potential of pharmacists to help address the opioid crisis, participants called for supporting state policies such as those in Rhode Island, Kentucky, and Ohio that allow for an expanded role for pharmacists to connect patients to OUD treatment services and to prescribe buprenorphine. At the same time, participants said that policymakers should avoid passing laws and implementing regulations that impede pharmacists' ability to dispense buprenorphine. An expanded scope of practice would need to ensure that pharmacists were able to be adequately compensated for their services and to require public and private insurance coverage for OUD treatment services delivered by pharmacists.

Another person called for the National Alliance of State Pharmacy Associations (NASPA) to work with the DEA to expand the Mid-Level Practitioners lists so that more pharmacists are able to be licensed by the DEA. Currently it's allowed on a state-by-state basis, so federal leadership/NASPA may be required to meet with state Boards of Pharmacy.

Several participants said that red flags that are appropriate for other scheduled substances, such as oxycodone, are not necessarily appropriate for buprenorphine. Some participants felt that if buprenorphine were removed from the list of scheduled substances, the issue would be resolved.

While many participants saw an expanded scope of practice as an important strategy for addressing the opioid crisis, some participants noted that many pharmacists are already stretched thin in their current roles. One participant said that pharmacists need to be able to provide adequate care before thinking about expanding into new services. State policies have a large effect on pharmacy operations, and states may impose a variety of restrictions on pharmacists that can impede their ability to work efficiently. For instance, some

states severely limit the pharmacist-to-technician ratio. Such policies may not support an expanded role for pharmacists in addressing the opioid crisis, in their view.

Pharmacy participants suggested ways to reduce some of the administrative burden on pharmacists, such as the need to document the reason for dispensing buprenorphine. A simple solution would be for providers to indicate on the prescription whether it is for pain or OUD. More integrated electronic health records or other secure communication platforms would also help, they said.

Other participants raised the fact that buprenorphine care is part of a larger approach to care and harm reduction that includes access to fentanyl test strips where not prohibited by law; over-the-counter and behind-the-counter syringes; naloxone availability, including over-the-counter naloxone and other medicine to reverse opioid overdose; mental health services; and substance use navigators/peer recovery specialists.

A participant mentioned that Medicaid is the number one payer for substance use disorder and OUD and said that millions of people will lose insurance coverage this year as the COVID-19 public health emergency flexibilities related to Medicaid coverage come to an end. However, the participant felt the nation is still in a public health emergency—the opioid crisis—which is a sound reason to allow pharmacists to be prescribers and fill the gaps.

Strengthening Communication Pathways

Participant views in this area are organized into the following topics:

- Communication and education
- Stigmatization
- Communication channels

Communication and Education

Participants repeatedly noted the critical need for education within professions but also across disciplines. Suggested topics included educating industry members about thresholds and red-flag issues. Participants said that it's important for larger manufacturers/distributors to ensure that messaging about thresholds gets communicated to their distribution centers. Pharmacists and manufacturers/distributors iterated that clear and specific guidance from HHS and DEA would be a big help in easing concerns.[4]

Participants voiced a desire to hear more guidance from DEA. Some participants suggested that the agency could partner with professionals who have direct clinical and pharmacy experience to conduct education; learners could benefit from those with direct clinical and pharmacy experience as well as from trainers in the field of addiction medicine. Participants concurred that it would be beneficial for DEA and professionals to continue to provide joint educational opportunities to pharmacists. Education was also seen as a way to help pharmacists be less risk averse and take up new opportunities as they arise.

4 . This guidance was later published; see footnote 2.

Stigmatization

Several participants noted that even the best systems and policies can be rendered ineffective because of stigmatization. One participant said that access will remain a challenge unless stigmatization is addressed. For example, stigmatization can make it more difficult for pharmacies to become accessible care sites. At the same time, reducing stigmatization is a long-term effort; it can take generations. So, stigmatization has to be addressed concurrently with other educational activities.

Participants noted that one way to reduce stigmatization is to normalize the use of buprenorphine. A person noted that a study from Finland from 10 years ago suggested that pharmacists who dispensed buprenorphine had a matter-of-fact approach to it; it was viewed as just another part of their role. In the United States, a participant said, normalizing buprenorphine was hindered by the fact that, until very recently, providers needed a waiver, which gave it an aura of being difficult to manage. That requirement resulted in reluctance. Providers, in fact, can and routinely do manage buprenorphine like they manage other medications.

Communication was identified as a way to reduce stigmatization, and pharmacy participants noted that there are hundreds of ways to reach pharmacists, including through numerous professional meetings and webinars. To reduce stigmatization, a participant said, it's important to start normalizing early on, such as in pharmacy school. Participants noted that it's important to hear consistent messaging through several entities and events.

Communication Channels

Pharmacy participants said that messaging sources that carry authority with pharmacists include:

- State Boards of Pharmacies, since these boards license and regulate pharmacies and pharmacists.
- State public health organizations.
- DEA.
- National Association of Boards of Pharmacy.
- Pharmacy organizations and channels.
- Federal agencies and field offices.
- State-level associations.

Multidirectional communication was also raised by participants as a need. Participants stressed the importance of communication from pharmacy participants back to key entities, particularly DEA, Centers for Medicare & Medicaid Services, and SAMHSA. SAMHSA was encouraged to continue to find opportunities to keep the conversation going.

Summary of Participant Views on Potential Ways Forward

- Remove thresholds for buprenorphine.
- Develop a system to ensure pharmacists know their ability to order controlled substances in relation to thresholds.
- Create a system to allow continuation of service during an audit or investigation, including a real-time system to show thresholds and request approvals for increases.
- Expand types of prescribers to include pharmacists.
- Improve reimbursement strategies for dispensing and providing services.
- Allow for remote/telehealth prescribing beyond the COVID-19 emergency.
- Encourage collaborative care between prescribers and pharmacists.
- Increase multidisciplinary provider education to include pharmacists on medication for OUD as part of the Medication Access and Training Expansion Act.
- Establish efficient, bidirectional, real-time communication pathways across professions.
- Provide manufacturers/distributors with clear and specific guidance on thresholds and suspicious orders through DEA communication channels.
- Increase provider education on medication-assisted treatment expansion.
- Address stigmatization while addressing other needs.
- Invite payers into the conversation.
- Launch public informational campaigns to increase patient and provider knowledge about buprenorphine and normalize its use.