



Addressing Issues at the Pharmacy with Buprenorphine Prescriptions

A Toolkit for Clinicians

Dispensing Buprenorphine at the Pharmacy

Although buprenorphine is an FDA-approved medication to treat opioid use disorder (OUD) that was dispensed <u>almost 16 million times in 2023</u>, practitioners prescribing it still encounter pharmacists with questions or concerns about the prescription. While pharmacists are expected to fill prescriptions issued for a legitimate medical purpose to a patient that is expected to benefit from the treatment, they also have a corresponding responsibility that gives them autonomy to decline to fill prescriptions in cases where the pharmacist is unable to resolve their concerns about the validity of the prescription. *In essence, a pharmacist is not legally required to dispense buprenorphine simply because it was prescribed.*

Additional context describing the issues behind dispensing declinations are highlighted here by ASAM, as well as in this buprenorphine-focused The Pharmacy Access to Resources and Medication for Opioid Use Disorder (PhARM-OUD) Guideline: A Joint Consensus Practice Guideline from the National Association of Boards of Pharmacy and the National Community Pharmacists Association

What should I do if the pharmacist has questions about or declines to fill my buprenorphine prescription?

Clinicians and pharmacists each have unique legal responsibilities when prescribing and dispensing controlled medications. This includes the pharmacist's legal responsibility to help ensure that prescriptions are issued for a legitimate medical purpose. It's possible that the pharmacist is asking questions to ensure they are meeting that responsibility.

If the pharmacist contacts your practice with questions about the prescription, consider the following:

• Answer the inquiry. Prescribing is only one part of getting the patient their medication. Like the legal prescribing responsibilities of registered practitioners, pharmacists similarly have legal responsibilities related to dispensing. It is in the patient's best interest for the prescriber and pharmacist to resolve any issues related to the prescription to ensure the patient has access to their medication. If the pharmacist is unable to resolve their concerns, they may decline to fill the prescription.

- Time is of the essence. Respond as promptly as possible to attempt to answer the questions and limit any delay in filling the prescription.
- **Pinpoint the issue.** Consult the chart below for common issues reported by buprenorphine prescribers. The chart provides information that may be helpful to resolve the pharmacist's concerns.
- The pharmacist may need to talk to the prescriber. While someone other than the prescriber may be able to answer some of the pharmacist's questions, that is not true of all their questions. To limit delays, the prescriber should make themselves available should the pharmacist need to resolve concerns that only the prescriber can address.
- Ask if the call resolves the concerns. Ask the pharmacist if your clarifications resolve their concerns or whether they have now decided not to dispense the prescription. If the latter, it is important to find another pharmacy willing to dispense.

If you discover that the pharmacist has <u>declined to fill</u> the prescription, consider the following:

- Contact the pharmacist. The pharmacist should always contact the prescriber before declining to fill the prescription for buprenorphine. If you have not talked to the pharmacist, contact them immediately to inquire about the reasoning behind the decision. Consult the chart below for common issues and guidelines about what should happen in these situations.
- Ask for the decision in writing. While not required, some pharmacies have issued written communications to prescribers documenting the decision not to dispense. Ask the pharmacist if you can get a copy and obtain it for your records and potential future advocacy.
- Contact the patient. In some instances, the patient may not be aware that their prescription has been declined. Let them know as soon as possible and let them know that you are working to address the issue.
- Ask if there is a process for appealing the decision. In some cases, there may be an avenue for you to appeal the pharmacist's decision. Consider this step if the pharmacist continues to decline to dispense.
- **Switch the patient's pharmacy.** Despite your best efforts, the pharmacist may ultimately decline to fill the prescription. In this case, you will need to find a pharmacy that will dispense the prescription to ensure your patient has their medications as soon as possible.
- Obtain copies of policies. If a pharmacist reports the use of a company policy in their decision to decline to fill, ask for a copy. This information can be helpful for future advocacy.

• Report the decision to ASAM. Data is important for observing emerging trends, and advocacy focused on resolving prescription filling declination decisions. If you are unable to resolve a dispute over a prescription, please <u>use this form</u> to report the instance to ASAM for each patient and occurrence.

The table below provides a list of common issues experienced by prescribers of buprenorphine for treatment of OUD, as well as associated recommendations that have been endorsed by ASAM, the National Association of Boards of Pharmacy, National Community Pharmacists Association, American Pharmacists Association, American Association of Psychiatric Pharmacists, American Society of Health Systems Pharmacists, and National Pharmaceutical Association. Consult this chart when communicating with the pharmacist about best practices for resolving each issue.

Category	What happened?	What the PhARM-OUD guidelines say:
Maintenance of pharmacotherapy	The pharmacist declined to dispense buprenorphine for maintenance treatment solely due to the duration of treatment.	Pharmacists should not decline to dispense buprenorphine solely due to the duration of maintenance treatment. OUD is a chronic medical condition and there is no recommended length of treatment. The duration of treatment depends on the treatment prescriber's clinical judgment and the patient's individual circumstances.
	 The pharmacist declined to dispense buprenorphine, even though: There are no contraindications; Pharmacist has verified prescriber is in good standing with DEA and is a registered prescriber; and There is no compelling evidence of diversion or misuse. 	Pharmacists should generally dispense buprenorphine in response to prescriptions issued by licensed prescribers with an active DEA registration, assuming the following conditions are met: • The patient has no known contraindications to buprenorphine. • The pharmacist can verify that the prescriber is in good standing with their state licensing board and maintains an active DEA registration. • There is no compelling evidence of misuse or diversion.

After a PDMP check performed by pharmacist, the pharmacist declined to fill because they expressed concern with any of the following: The presence of potential indicators of nontherapeutic dispensing Patient not filling most recent RX; on the prescription or in the PDMP profile does not always indicate · Patient has received or is receiving that a pharmacist should decline to dispense buprenorphine. In the buprenorphine from multiple scenarios described on the left, pharmacists should discuss their prescribers: concerns with the prescriber and patient and document the • PDMP data indicates multiple discussion before determining whether they should dispense. concurrent prescriptions; or • Patient has signs of CNS depression, hypotension, or other adverse effects attributed to buprenorphine. Indicators of misuse/diversion from PDMP Distance from either the patient's or prescriber's address to the checks pharmacy, particularly for patients receiving buprenorphine via telehealth, is **NOT** a reliable indicator of buprenorphine misuse or diversion. The pharmacist declined to dispense Pharmacies should immediately retire policies that prohibit because of: employee pharmacists from filling buprenorphine prescriptions Distance from patient's home to the solely due to the pharmacy's distance from prescriber or patient pharmacy; home address. · Prescription was for initial therapy and pharmacist declined to dispense due Distance-based algorithms may disproportionately impact persons to lack of a PDMP profile; or of color and low-income individuals who cannot access • Patient paid for prescription in cash. buprenorphine in their communities and perpetuate stigma toward persons in treatment. Pharmacists should dispense buprenorphine to patients initiating therapy with buprenorphine regardless of whether they have an established prescription drug monitoring program profile.

		Pharmacists should dispense buprenorphine to cash-paying patients. Cash payment alone is unlikely to indicate buprenorphine misuse or diversion. Patients may pay cash due to a lack of insurance, the use of manufacturer rebates, or to maintain privacy in self-insured employer group plans.
Early refills	The pharmacist declined to fill an early refill for a patient who has never made an early refill request at this pharmacy before.	A pattern of early refill requests for a single patient or among patients under the care of the same prescriber is more indicative of potential misuse or diversion than a single request for an early refill. Pharmacists should still discuss their decision to decline the prescription with the prescriber and document the nature and content of this discussion prior to deciding to dispense or decline the prescription.
	The pharmacist declined to fill an early refill for a patient who has made previous requests for early buprenorphine refills.	A pattern of early refill requests for a single patient or among patients under the care of the same prescriber is more indicative of potential misuse or diversion than a single request for an early refill. Pharmacists should still discuss their decision to decline the prescription with the prescriber and document the nature and content of this discussion prior to deciding to dispense or decline the prescription.
	The pharmacist described a pattern of early refills for patients under my care as a reason to decline to fill.	A pattern of early refill requests for a single patient or among patients under the care of the same prescriber is more indicative of potential misuse or diversion than a single request for an early refill. Pharmacists should still discuss their decision to decline the prescription with the prescriber and document the nature and content of this discussion prior to deciding to dispense or decline the prescription.

	The pharmacist cited early refill policy guidance in the decision to decline to fill.	Pharmacy chains and owners should provide guidance on early refills to staff pharmacists. Guidance should be tailored to patients receiving buprenorphine for the treatment of OUD rather than a general controlled substance refill policy. The early refill policy should be communicated to patients when they initiate buprenorphine pharmacotherapy. Pharmacists should be allowed to use their professional judgement to dispense buprenorphine earlier than allowed by employer policy.
Telemedicine	The pharmacist declined to fill because the prescription was issued via telemedicine.	Pharmacists should dispense buprenorphine prescriptions issued by virtual health, or telehealth prescribers if the prescription is legitimate, and the pharmacist can fulfill their corresponding responsibility. Pharmacists are encouraged to evaluate telehealth prescriptions in the same manner and to the same standard that they would prescriptions originating from in-person encounters. Pharmacists have the right to inquire about the nature of the patient-prescriber relationship formed regardless of the place of service. If pharmacists are concerned about the quality of the patient-prescriber relationship, they should contact the prescriber rather than deny the prescription.
	The telemedicine prescription was declined because the patient switched to a different telemedicine prescriber.	Pharmacists should continue to dispense buprenorphine to telehealth patients even if they change prescribers.

Buprenorphine monoproduct	The pharmacist declined to fill because the prescription was for buprenorphine monoproduct and the patient was not pregnant, did not have dental lesions, and did not present affordability issues with combination product. The pharmacist expressed a preference	Current clinical evidence supports the efficacy of buprenorphine monoproduct for the treatment of OUD. Buprenorphine monoproduct may be preferred for pregnant patients, those with dental lesions, and those who cannot afford combination products. Use should not be limited to these populations. Pharmacists may discuss the indication for monoproduct with the
	for the combination product over the monoproduct.	prescriber but should not prefer buprenorphine/naloxone combination products to buprenorphine monoproduct.
Prescriber communication	The pharmacist declined to fill the prescription because they could not reach the prescriber by phone, email, or pager.	If a pharmacist needs to clarify a buprenorphine prescription for whatever reason, they should make every effort to promptly contact the prescriber through direct communication via phone, email, or pager rather than fax while following state and federal privacy rules.
	The pharmacist was unable to reach the prescriber to clarify the prescription, and did not agree to a partial fill.	If pharmacists cannot promptly reach a prescriber to renew or clarify a buprenorphine prescription, they should consider dispensing a partial quantity of the prescription to prevent interruptions in care.

Stigma	The patient reported that the pharmacist made them feel stigmatized when interacting with them.	Pharmacists should model empathetic behavior and speech for other pharmacy staff when interacting with patients with OUD.
	The pharmacist appeared to rely on a patient interview to identify a patient suspected of misusing/diverting buprenorphine.	Pharmacists should not rely on a patient interview to attempt to identify patients who may misuse or divert buprenorphine.
	The pharmacist required the patient to transfer prescriptions for non-controlled substances to the pharmacy before they would dispense the prescription for buprenorphine.	Pharmacists should not require patients to transfer prescriptions for non-controlled substances to their pharmacy before dispensing buprenorphine.
Employer oversight	The pharmacist cited company policies on numerical thresholds, distance to prescriber/patient home, or days of medication supply as a reason to decline to fill the prescription for buprenorphine.	Pharmacy policies defined by numerical thresholds, such as distance to prescriber, distance to home, or days' supply, should not be used to guide clinical decision making. Numerical thresholds should not be used to deny buprenorphine prescriptions. Pharmacy corporations should prioritize appointing registered pharmacists to management positions responsible for establishing corporate controlled substance dispensing and purchasing policies.

What if the pharmacist says that they do not have enough stock of buprenorphine to dispense my prescription?

The stocking of buprenorphine is different from a pharmacist declination to dispense the prescription due questions about the legitimacy of it. If the pharmacist reports that there is not sufficient stock of the medication, consider the following:

- Ask the pharmacist when/if the stock of buprenorphine will be replenished. Work with the pharmacist to understand if the pharmacy intends to stock the medication and if so, how long until it will be available again. In some cases, you may need to consider switching the patient's pharmacy.
- Ask the pharmacist if there are therapeutic substitutions available in the interim. Sublingual buprenorphine/naloxone products may be used interchangeably, although bioavailability may differ between film and tablet preparations.
- Ask if the problem is distributor related. The Drug Enforcement Administration (DEA) has encouraged distributors to reevaluate their quantitative algorithms to ensure that they allow pharmacies to order sufficient supplies of buprenorphine. If the pharmacy is worried about crossing a specific numeric threshold, encourage them to consult with their distributor about their threshold modification process and possible adjustment for buprenorphine products for opioid use disorder. Consider working collaboratively with the pharmacy by providing your practice's anticipated monthly buprenorphine prescribing volume in the aggregate.
- Encourage the pharmacy to stock buprenorphine if they do not. If the pharmacy does not stock buprenorphine, use the opportunity to highlight the role of buprenorphine and encourage them to consider carrying the medication.

What if the pharmacist says that the issue is related to DEA concerns?

The DEA, US Department of Health and Human Services, and the US Department of Justice reinforced support for medications to treat OUD and urged distributors to reexamine any quantitative thresholds that may inhibit access to these medications in a March 2024 joint <u>letter</u>. DEA has also expressed that "neither the Controlled Substances Act (CSA) nor DEA regulations establish quantitative thresholds or limits on the amounts of controlled substances, including [medications for opioid use disorder] MOUD, that DEA registrants may order or dispense, nor do they require registrants to set such thresholds or limits."

However, the CSA does require DEA registrants (including distributors) to identify systems that identify "suspicious orders" such as orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. In response, these distributors may have monitoring systems that set thresholds that may in turn alert DEA to orders that have been identified as suspicious. As noted above, if the pharmacy is worried about crossing a specific numeric threshold that could trigger one of these suspicious order reports, they are encouraged to consult with their distributor about the availability of any threshold modification processes.

Is the pharmacists required to dispense my prescription?

No. A pharmacist may decline to fill a prescription for reasons including concerns about the legitimacy of a prescription that cannot be resolved, and if the patient exhibits signs of adverse effects from buprenorphine.

What if I am dealing with an issue not listed here?

Contact ASAM by emailing us about the issue at advocacy@ASAM.org.

About this document

This document is available to ASAM members as they navigate issues with prescriptions of buprenorphine for OUD treatment at the pharmacy. It is intended for informational and educational purposes only. ASAM does not warrant the accuracy or completeness of this document and assumes no responsibility for any injury or damage arising out of or related to any use of this document or for any errors or omissions.