

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

Version for Public Comment

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Introduction

Barriers to buprenorphine access:

Buprenorphine is a partial opioid agonist indicated for the treatment of opioid use disorder (OUD). Unlike methadone and extended-release naltrexone, buprenorphine can be dispensed in community pharmacies pursuant to a prescription issued by any provider with a valid Drug Enforcement Administration (DEA) registration. Patients receiving treatment with buprenorphine are upwards of 60% less likely to die of an opioid overdose than those not in treatment.^{1,2} Retaining individuals in OUD treatment is necessary to maximizing the benefits of buprenorphine-based pharmacotherapy for OUD. Pharmacists, therefore, have a critical role to play in protecting the health and safety of persons with OUD by stocking and dispensing buprenorphine.

Still, around half of all pharmacies in the United States are unable to dispense buprenorphine products for the treatment of OUD.^{3,4} Buprenorphine availability is limited for a variety of reasons, however, administrative barriers to supply remain persistent.⁵ The US opioid overdose epidemic created an imminent need to curtail inappropriate opioid prescribing. Available public health surveillance data provides evidence that these efforts have been at least somewhat successful.⁶ In 2010, there were 6.8 opioid overdose deaths per 100,000 US residents, 4.8 of these involved prescription opioids. By 2021, this had increased to 24.7 opioid overdose deaths per 100,000 US residents with 4.9 deaths per 100,000 attributable to prescription opioids indicating stabilization in prescription opioid related mortality rates. The bulk of the difference in overdose deaths can be attributed to the introduction of fentanyl and its analogues to the US drug supply. In 2010, 1 death per 100,000 residents was attributed to synthetic opioids, including fentanyl. By 2021, that number had risen to 21.8 deaths per 100,000 residents.^{6,7}

Rising synthetic opioid related mortality has created a pressing need to make treatment accessible. Unfortunately, efforts taken to limit opioid misuse and diversion have inadvertently and adversely impacted access to buprenorphine. As a partial opioid agonist and DEA Schedule III controlled substance, buprenorphine is subject to federal and state limitations on opioid supply. In 2019, the SUPPORT Act required that all DEA registrants that distribute controlled substances report suspicious orders to DEA. To comply with the terms of the SUPPORT Act, DEA created the Suspicious Order Reporting System (SORS), a platform that allowed individual wholesalers to report orders that they viewed as unusually large, deviating from a normal ordering pattern, or deviating from a normal ordering frequency.⁸ Effectively, the SUPPORT Act tasks pharmaceutical wholesalers with defining the parameters that constitute a suspicious order from each pharmacy in their distribution network and reporting these orders directly to DEA through SORS. Of note, very little public guidance is provided on what defines a suspicious order.

In an effort to comply with the terms of the SUPPORT Act and to avoid liability, pharmacy organizations and wholesalers regulate wholesale purchase and dispensing of buprenorphine as they do other opioid analgesics.^{5,9-12} The regulatory treatment of buprenorphine by these agencies is reasonable in light of the financial liability pharmacy organizations and pharmaceutical wholesalers have faced through multidistrict opioid litigation.^{13,14} In total, US pharmacy organizations and pharmaceutical wholesalers will pay over \$30 billion to states for their role in the US opioid crisis. This

regulatory position, however, adversely impacts access to buprenorphine in community pharmacies. If buprenorphine is subjected to the same limits on controlled substance purchase as other medications, then pharmacies will be forced to limit the amount of buprenorphine they dispense to avoid wholesaler “caps” on controlled substance supply established by SORS.

Policy intended to ease access to buprenorphine:

Rising opioid overdose mortality has created a pressing need for treatment to be more accessible placing the onus on policy makers to take action to remove longstanding barriers to treatment. In March 2020, DEA and the Department of Health and Human Services overturned provisions of the Ryan Haight Act that previously prevented prescribers from initiating buprenorphine without an in-person office visit. This policy change allows providers to initiate buprenorphine and continue patients on treatment through a virtual health, or telehealth, encounter.^{15,16} In December 2022, the Mainstreaming Addiction Treatment (MAT) Act and Medication Access and Training Expansion (MATE) Acts were signed into law. This legislation allows any DEA registered practitioner with prescribing authority, including Advanced Practice Registered Nurses and Physicians Assistants, to prescribe buprenorphine for the treatment of OUD. The MAT and MATE acts, therefore, eliminated the need to register under the Drug Abuse Treatment Act of 2000 (DATA-2000) and obtain an X-Waiver from DEA to prescribe buprenorphine.^{17,18} Recognizing that the MAT and MATE acts would increase buprenorphine prescribing and increase demand for treatment, DEA released a letter to registrants in March of 2024 asking wholesalers to reexamine quantitative thresholds for buprenorphine orders to ensure that pharmacies could purchase a sufficient quantity of buprenorphine to meet the needs of patients with OUD.^{11,19}

Rationale for the Creation of this guidance:

As policy changes, pharmacies and pharmacists should expect to dispense more buprenorphine. DEA, the Substance Abuse and Mental Health Services Administration (SAMHSA), and the broader US Department of Health and Human Services have all endorsed support for this approach to care. The advent of virtual health for persons with OUD, the elimination of the X-Waiver, and recent guidance on buprenorphine wholesale all change the practice paradigm for persons with OUD. Current practice guidelines for the management of OUD do not address these unique changes to pharmacy practice. This guidance for pharmacists directly addresses these areas and more in an attempt to help pharmacists make dispensing decisions that optimize the quality of care for individuals prescribed buprenorphine.

Controlled substance dispensing is difficult and requires that pharmacists make deliberate efforts to verify the legitimacy of prescriptions prior to dispensing. Fulfillment of the pharmacist’s corresponding responsibility is critical to ensuring that controlled substances, including buprenorphine, are not used inappropriately or diverted.²⁰ Conversely, assuming that buprenorphine is being prescribed inappropriately and wrongly denying care for persons with OUD can have disastrous consequences for patients. Delaying the initiation of care or refusing care to an established patient dramatically increases a patient’s risk of death due to opioid overdose.²¹ This document seeks to help pharmacists balance the risks and benefits to themselves, their employer, and, most importantly, their patients that accompany each buprenorphine dispensing decision. The overarching recommendation of this document is that pharmacists should make a good faith effort to provide high

quality care to persons with OUD by always maintaining an adequate supply of buprenorphine and filling legitimate prescriptions in a timely manner. If a pharmacist can verify that a buprenorphine prescription is legitimate and fulfill their corresponding responsibility, they should dispense. Doing so ensures that patients with OUD, a chronic medical condition, can receive the treatment that they need.

Note, that this document is not a clinical practice guideline. High quality, evidence based clinical practice guidelines are publicly available from SAMHSA (*TIP 63: Medications for OUD*) and the American Society of Addiction Medicine (*The ASAM National Practice Guideline for the Treatment of OUD*). While this document does provide clinical context for community pharmacists, pharmacists are encouraged to refer to guidance from ASAM and SAMHSA for more detailed clinical information. The intent of this guidance is to inform pharmacists' decision making at the point of care in community pharmacies not to supplant evidence based clinical guidance from other sources.

Intended Audience

This guidance is intended to be used by pharmacists involved in the dispensing of medication for OUD in the community pharmacy setting. The contents may also be useful for educators and pharmacy preceptors involved in training pharmacy students or residents in colleges of pharmacy or affiliated experiential programs. Finally, the recommendations of this document should be used by pharmacy owners and pharmacy corporations to guide the development of patient-centered policy for persons with OUD in community pharmacies.

Interpreting the Recommendations:

At many points in this document, pharmacists are recommended to dispense medication for OUD if they are able to verify that a prescription is legitimate and fulfill their corresponding responsibility. In the context of this document, corresponding responsibility is defined as the pharmacist's obligation to ensure that a prescription has been issued for a legitimate medical purpose consistent with the usual course of a practitioner's professional practice.²⁰ If the pharmacist cannot verify, and document, that these criteria have been met, then they have not fulfilled their corresponding responsibility. Pharmacists are, first and foremost, autonomous practitioners and should be encouraged to use their professional judgement in a way that most effectively addresses the health needs of their patients. In the rare case that a pharmacist feels that dispensing buprenorphine would not benefit their patient, would not be appropriate, or would otherwise cause harm, pharmacists should carefully document their decision and explain their rationale to the patient and prescriber as appropriate. In general, however, if the prescription is legitimate and the patient is expected to benefit from treatment, pharmacists should dispense buprenorphine in a manner that is consistent with the recommendations of this guidance as long as, in their professional judgement, the prescription was issued for a legitimate medical purpose.

Development of this Guidance

This document was developed through a multi-stage process that involved practicing pharmacists, physicians, and experts from a variety of professional settings. In the first phase, investigators held focus groups with community pharmacists in Texas, California, and West Virginia to

identify barriers to buprenorphine dispensing in community pharmacies. In the second phase, a panel of 22 experts was recruited to develop and refine recommendations to directly address barriers elicited through the preliminary focus groups.

The expert panel consisted of present and former members of State Boards of Pharmacy, individuals with expertise in drug enforcement, individuals with expertise in pharmaceutical wholesale, addiction medicine physicians, psychiatric pharmacists with expertise in substance use disorder treatment, and community pharmacists. These individuals participated in a four-round, Delphi panel using a modified version of the RAND Appropriateness Method.²² Prior to the first round of the Delphi panel, participants were provided an evidence packet consisting of relevant clinical trials, observational studies, policy documents, and white papers to support the formation of their recommendations. The evidence packet may be reviewed [at this link](#).

In the first round of the Delphi panel, panelists were first asked to evaluate a series of sixteen vignettes describing barriers to buprenorphine access. Panelists then responded to a series of open-ended questions providing recommendations to address that barrier. Members of the steering committee then reviewed the panel's suggestions and aggregated similar recommendations. In the second round, panelists reviewed each statement developed in the first round, rated the appropriateness of that statement on a nine-point scale anchored from 1: "Not at All Appropriate" to 9: "Extremely Appropriate." In this context, an appropriate recommendation was defined as a recommendation that, if followed, would confer greater benefit than harm to patients and the surrounding community. Recommendations that at least 75% of responding participants rated as seven or higher were deemed to have reached consensus. In round three, statements that did not reach consensus were modified based on panelist feedback and subjected to another round of appropriateness rating. Finally, on March 8, 2024, panelists were provided the opportunity to participate in a live meeting to discuss, modify, and re-rate the remaining recommendations that had not yet reached consensus.

The final recommendations were organized into seventeen main recommendations and 23 supporting recommendations. Members of the steering committee then drafted detailed rationale, grounded in the available evidence, policy, and statute, to support the formation and implementation of each recommendation and supporting recommendation. Panelists and all members of the steering committee were provided the opportunity to review and suggest edits to the rationale sections. The consensus statements were not modified at this phase as they had already been accepted by the panel. Of note, this document is the first in a planned series of statements emanating from the work of this expert panel. Future releases will include guidance to boards of pharmacy, a statement on wholesale buprenorphine purchase, and a statement on pharmacist/prescriber communication and collaboration. All releases, including the current, will be reviewed and accepted by the National Association of Boards of Pharmacy (NABP) and the National Community Pharmacists Association (NCPA) prior to final publication. The protocol for the development of this guidance was registered with Open Science Framework in April of 2023.²³

Public Comment Period and Review of Public Comments

Pharmacies are the most accessible providers in the US healthcare system. Most Americans live within five miles of a community pharmacy and patients visit pharmacies more frequently than they do primary care providers.^{24,25} Because pharmacies are accessible to the public, it is important that the public be able to weigh in on how services are provided in community pharmacies. For this reason, members of the public are encouraged to provide feedback on this guidance between now and June 1, 2024. Other stakeholders including prescribers, private organizations, regulatory agencies, patient advocacy organizations, and professional associations are also encouraged to provide input. Comments will be reviewed for appropriateness by a member of the steering committee and displayed on this page for public viewing on a weekly basis. Insensitive and stigmatizing comments will not be displayed. Consistent with the recommendations in this guidance, commenters should refer to recommendations for avoiding stigma toward people who use drugs provided by the National Institute on Drug Abuse when drafting their comments.²⁶ On June 11, 2024, the National Association of Boards of Pharmacy will host a review meeting with a separate panel of experts to review the public comments and make any necessary modifications to the final document. The final guidance will be published no later than July 1, 2024.

Executive Summary:

A summary of the panel's recommendations and supporting recommendations is below. Rationale supporting each recommendation is available within the document.

Recommendation 1 | Maintenance Pharmacotherapy with Buprenorphine:

Declining to dispense buprenorphine can lead to interruptions in opioid use disorder (OUD) treatment, force patients into withdrawal, and increase risk of recurrent opioid use. Pharmacists should maintain a sufficient supply of buprenorphine in their pharmacies and be willing to dispense buprenorphine to patients with OUD.

Supporting Recommendations

- OUD is a chronic medical condition and there is no recommended length of treatment. The duration of treatment depends on the treatment provider's clinical judgement and the patient's individual circumstances. Pharmacists should not decline to dispense buprenorphine solely due to the duration of maintenance treatment.
- Pharmacists should generally dispense buprenorphine in response to prescriptions issued by licensed physicians, physician assistants, or nurse practitioners with an active Drug Enforcement Administration (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 medical board and maintains an active DEA registration.
 - There is no compelling evidence of misuse or diversion.
- Declining to dispense buprenorphine is a measure of last resort and should only be considered after discussion with the patient and their prescriber when the pharmacist strongly suspects prescription forgery, prescription alteration by the patient, misuse, or diversion.
- Concerns about buprenorphine's regulatory status should not deter pharmacists from stocking and dispensing it.

- The implementation of the MAT and MATE acts extends prescribing authority for buprenorphine to all DEA registered providers. All physicians, physician assistants, and advanced practice nurses with prescriptive authority can issue valid prescriptions for buprenorphine.

Recommendation 2: Red Flags and Prescription Drug Monitoring Programs:

Prescription Drug Monitoring Programs (PDMP) are useful decision support tools that can help pharmacists identify controlled substance misuse and diversion. Pharmacists should use the information in the PDMP profile to supplement, rather than as a substitute for, their clinical judgement when making dispensing decisions. Pharmacists should query the PDMP prior to dispensing all buprenorphine prescriptions.

Supporting Recommendations:

- The presence of red flags on prescription or PDMP review does not always indicate that a pharmacist should decline to dispense buprenorphine. Rather, pharmacists should discuss their concern with the patient and provider prior to making a dispensing decision. The following scenarios should lead to a discussion on appropriate use:
 - a. An increase in a patient's maintenance buprenorphine dose of more than 50% between prescriptions.
 - b. If a patient is attempting to fill a new prescription issued more than 30 days ago or if the pharmacist suspects the patient is not filling their most recent prescription.
 - c. A patient has received or is receiving buprenorphine from multiple providers with no consistent plan of care.
 - d. A patient's PDMP profile or the pharmacy's prescription database indicate multiple concurrent buprenorphine prescriptions.
 - e. The pharmacist suspects that the patient is experiencing medical complications of buprenorphine pharmacotherapy.
- The limited availability of buprenorphine in community pharmacies and a shortage of buprenorphine prescribers may cause patients to travel further to access buprenorphine than other medications. Distance from the patient's address or the provider's address to the pharmacy alone is not a sufficient reason to decline to dispense buprenorphine.
- Chain pharmacies and pharmacy owners should immediately retire policies that prohibit employee pharmacists from filling buprenorphine prescriptions solely due to the pharmacy's distance from provider or patient home address.
- As buprenorphine access is diminished in areas of socioeconomic vulnerability, distance-based algorithms may disproportionately impact persons of color and low-income individuals who cannot access buprenorphine in their communities and perpetuate stigma toward persons in treatment.
- Cash payment, in the absence of other indicators, is unlikely to represent 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. Pharmacists should dispense buprenorphine to cash-paying patients.
- If a pharmacist declines to dispense buprenorphine to a new or existing patient, they should first discuss this with the prescriber and clearly document their rationale for refusing to fill.

- In addition to "red flags", pharmacists should review the PDMP for potential "green flags", or indicators that a patient is actively engaged in therapy and using their medication as directed. These may include a history of timely buprenorphine refills, receiving sequential prescriptions from the same prescriber or prescriber group, the absence of concurrent opioid agonist prescriptions, and a long-term history of buprenorphine pharmacotherapy.

Recommendation 3 | Early Refills:

Occasional requests to refill buprenorphine early are unlikely to indicate misuse of buprenorphine but may instead indicate that a patient has been asked to change their dose, lost or damaged a dosage unit, or is attempting to refill their medication in advance of a change in home address or insurance benefits. Before making a dispensing decision, pharmacists should discuss the context of the request with the patient, contact the prescriber, and document their rationale for dispensing or declining the prescription.

Supporting Recommendations:

- 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.
- 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.

Recommendation 4 | Telehealth:

Pharmacists should dispense buprenorphine prescriptions issued by telehealth providers if the prescription is legitimate, and the pharmacist can fulfill their corresponding responsibility.

Supporting Recommendations:

- Telehealth prescriptions received via electronic prescribing platforms are not more likely to be fraudulent or illegitimate than prescriptions from face-to-face encounters and should not be subjected to a higher level of scrutiny than other buprenorphine prescriptions.
- Pharmacists have the right to inquire about the nature of the patient/provider relationship and should contact the telehealth provider to fulfill their corresponding responsibility if necessary.
- Pharmacists should continue to dispense buprenorphine to telehealth patients who are adherent to a stable plan of care even if they change providers.

Recommendation 5 | Buprenorphine Monotherapy:

Current clinical evidence supports the efficacy of buprenorphine monotherapy for the treatment of OUD. There are clear indications for buprenorphine monotherapy, including cost, pregnancy, and dental lesions. Pharmacists may discuss the indication for monotherapy with the provider but should not prefer buprenorphine/naloxone combination products to buprenorphine monotherapy.

Recommendations 6-10 | Recommendations to Protect Patient Safety:

- Pharmacists should discuss potential adverse effects of buprenorphine pharmacotherapy with patients at each refill and inquire about their experiences with the medication.
- Pharmacists should offer to dispense naloxone to patients prescribed buprenorphine for the management of OUD.
- As with any medication, pharmacists should educate patients about the dangers of certain drug combinations (particularly full opioid agonists, benzodiazepines, and sedative hypnotics) and the risks associated with alcohol use while taking buprenorphine.
- Pharmacists should provide counseling on the safe storage and disposal of buprenorphine products.
- Pharmacy technicians can provide valuable support to the process of care. Where not otherwise prohibited by state law, technicians can improve the efficiency of care by extracting information from prescription monitoring programs, contacting providers, reminding patients to refill their prescriptions, and assisting with reimbursement issues.

Recommendations 11-15 | Care Coordination and Provider Communication:

- Pharmacists should extend the same level of medication therapy management, immunization, and point-of-care testing services to patients with OUD as they do to other patients.
- Implementing collaborative practice agreements could potentially enable pharmacists to monitor buprenorphine pharmacotherapy, provide supportive care, and potentially create opportunities to bill for cognitive services provided.
- Pharmacists can promote adherence to treatment for OUD by being willing and able to refer patients in treatment to local primary care, mental health, and peer support providers upon patient request.
- If a pharmacist needs to clarify a buprenorphine prescription for whatever reason, they should make every effort to promptly contact the prescriber through direct phone communication rather than fax. Additionally, the pharmacist should keep the patient informed about their efforts and the status of the prescription.
- To prevent unnecessary delays, pharmacists may consider dispensing a minimal partial quantity of the prescription while awaiting additional information from the provider regarding the plan of care.

Recommendation 16 | Stigma Toward Persons with OUD:

Pharmacists, pharmacy technicians, and all pharmacy staff should approach persons living with OUD with empathy, compassion, and support, recognizing and addressing how their biases may impact their ability to provide care and make appropriate, patient centered decisions.

Supporting Recommendations:

- Requiring patients to transfer prescriptions for non-controlled substances to a pharmacy to access buprenorphine is an unethical process that interferes with patient autonomy and potentially constitutes medical coercion. This practice should be abandoned.
- Requiring a patient interview prior to dispensing buprenorphine is an unusual, stigmatizing, and discriminatory practice that would not be employed in other contexts. This practice should be discontinued.

- Pharmacy personnel often mirror pharmacists' behavior in their interactions with patients. Pharmacists should be cautious in how they address patients with OUD as this may impact the way that other pharmacy staff react toward persons with OUD.

Recommendation 17 | Employer Oversight:

Employer policies governing buprenorphine dispensing should prioritize flexibility, allowing individual pharmacists to exercise their professional judgment when deciding whether to dispense a prescription for buprenorphine.

Supporting Recommendations:

- Pharmacy corporations should clarify that numerical thresholds, such as distance to provider, distance to home, or days' supply, should be applied to guide inquiry and documentation, rather than as reasons to deny the dispensing of buprenorphine.
- Pharmacy corporations should utilize their purchasing power to renegotiate wholesale purchasing agreements, ensuring continued ability to purchase buprenorphine.
- Pharmacy corporations should prioritize appointing registered pharmacists to management positions responsible for establishing corporate controlled substance dispensing and purchasing policies.

Maintenance Pharmacotherapy with Buprenorphine

Recommendation: Declining to dispense buprenorphine can lead to interruptions in opioid use disorder (OUD) treatment, force patients into withdrawal, and increase risk of recurrent opioid use. Pharmacists should maintain a sufficient supply of buprenorphine in their pharmacies and be willing to dispense buprenorphine to patients with OUD.

Supporting Recommendations

- OUD is a chronic medical condition and there is no recommended length of treatment. The duration of treatment depends on the treatment provider's clinical judgement and the patient's individual circumstances. Pharmacists should not decline to dispense buprenorphine solely due to the duration of maintenance treatment.
- Pharmacists should generally dispense buprenorphine in response to prescriptions issued by licensed physicians, physician assistants, or nurse practitioners with an active Drug Enforcement Administration (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 medical board and maintains an active DEA registration.
 - There is no compelling evidence of misuse or diversion.
- Declining to dispense buprenorphine is a measure of last resort and should only be considered after discussion with the patient and their prescriber when the pharmacist strongly suspects prescription forgery, prescription alteration by the patient, misuse, or diversion.
- Concerns about buprenorphine's regulatory status should not deter pharmacists from stocking and dispensing it.
- The implementation of the MAT and MATE acts extends prescribing authority for buprenorphine to all DEA registered providers. All physicians, physician assistants, and advanced practice nurses with prescriptive authority can issue valid prescriptions for buprenorphine.

Rationale:

Long-term Maintenance Pharmacotherapy:

Buprenorphine is widely accepted as safe and effective for the treatment of OUD and is the only medication for OUD that can be dispensed directly to patients in community pharmacies in all fifty states. Prevailing practice guidelines from the American Society of Addiction Medicine (ASAM) and the Substance Abuse and Mental Health Services Administration (SAMHSA) recognize buprenorphine as a first line treatment for OUD. Importantly, there is no maximum known safe duration of buprenorphine pharmacotherapy and no known minimum effective duration of treatment.^{27,28} Patients progress through OUD treatment at varying rates and the duration of pharmacotherapy for any given patient cannot be predicted at baseline. What is known is that risk of morbidity and mortality increase significantly for treatment episodes shorter than 180 continuous days.²⁹ In no way should a treatment duration of 180 days be misconstrued as a maximum duration of treatment. High quality, observational research suggests that treatment durations of 365 days or longer confer additional reduction in mortality. In a cohort of patients with OUD, those who remained in treatment for 91-180 days had a significantly higher risk of all-cause mortality (aHR: 2.94, 95% CI: 1.11-7.79) than those who remained in treatment for 365 days or longer.³⁰ Other observational work indicates that durations of fifteen months or longer are associated with relative reductions in risk of overdose (173%), opioid related hospitalization (128%), and all cause inpatient admission (52%) compared to those in treatment for 6-9 months.³¹

Maintaining Access to Buprenorphine:

There is sufficient evidence to support long-term, maintenance pharmacotherapy with buprenorphine yet patients struggle to access medication for OUD in community pharmacies. A 2022 telephone audit of pharmacies in 5,734 pharmacies in eleven states, only 48% of community pharmacies reported that they were able to dispense a one-week supply of buprenorphine in response to patient request.³ In a more recent telephone audit of 5,283 pharmacies, 57.9% of pharmacies reported buprenorphine availability.³² Failure to maintain supply of buprenorphine is a significant barrier to continuity of pharmacotherapy for OUD. If established patients are forced to identify a new pharmacy due to lapses in inventory, their odds of a gap in medication possession of seven days or longer increase by 1.67 times.³³ In the first two weeks after patients discontinue treatment for OUD, their immediate risk of mortality is eight times higher than it is while receiving treatment.²¹ Even short interruptions in treatment, therefore, can prove fatal to persons with OUD.

In light of this evidence, it is reasonable to recommend that pharmacists maintain buprenorphine in their inventory and that they dispense buprenorphine upon receipt of a valid prescription from a DEA registered provider as long as the patient has no known medical contraindications to buprenorphine, the pharmacist can verify that the prescriber is in good standing with their state medical board and the DEA, and that there is no compelling evidence of misuse or diversion. OUD is a chronic disease, and abruptly disrupting pharmacotherapy for a patient with a chronic condition is insensible. Similarly, failing to dispense buprenorphine in a timely manner to patients with OUD could result in adverse clinical sequelae including overdose or death.³⁴

These recommendations apply to all points during care, from buprenorphine initiation through long term maintenance. Patients ready to initiate treatment with buprenorphine, particularly those recently discharged from the inpatient or emergency setting following an opioid overdose, are often in active withdrawal and need treatment expeditiously.³⁵ Despite the risks associated with gaps in medication possession, only 28.5% of patients who receive buprenorphine in the emergency department setting fill a subsequent buprenorphine prescription post-discharge.³⁴ A first prescription for any medication should be viewed as a critical transition of care. When a patient with no known history of pharmacotherapy for OUD presents to a community pharmacy with a new buprenorphine prescription, this is an opportunity for a pharmacist to provide, rather than deny, care. In most circumstances, pharmacists should favor dispensing buprenorphine to patients new to their pharmacy. Before declining to dispense buprenorphine, a pharmacist should first discuss their decision with the prescriber and the patient. If the pharmacist declines due to limited medication availability, they should make a good faith effort to help the patient identify a pharmacy that can dispense.

Standards for Enforcement of the Controlled Substance Act:

Given the risks of morbidity and mortality associated with buprenorphine discontinuation, there are very few circumstances in which the potential benefits to the patient of refusing to dispense outweigh the risks of early discontinuation. Buprenorphine is classified as a DEA Schedule III controlled substance. While it is recognized that the regulatory status of buprenorphine may make it difficult to purchase and dispense buprenorphine, the risks of filling legitimate prescriptions is minimal. The federal Controlled Substance Act authorizes pharmacists to dispense controlled substance prescriptions issued for a legitimate medical purpose. The treatment of opioid use disorder is a legitimate, and necessary, medical purpose. Furthermore, enforcement usually requires a sustained pattern of aberrant prescribing or dispensing behavior for DEA or other enforcement agencies to be able to demonstrate that pharmacists have violated the Controlled Substance Act.³⁶

In July of 2022, in their decision on *Ruan vs United States*, the Supreme Court found that controlled substance prescribing is authorized unless the prescribers have “knowingly and

intentionally” acted in an unauthorized manner.³⁷ In brief, although DEA may continue to use investigative findings (e.g., a review of the pharmacy or provider’s financial practices, disregard of red flags, and failure to assess medical necessity) to prove a prescriber or pharmacist’s subjective intent, Ruan places the burden of proof on DEA to demonstrate that the provider or pharmacist knowingly issued or dispensed a controlled substance prescription written for an illegitimate medical purpose before the controlled substance act can be enforced.³⁸ Assuming that the pharmacist fulfills their corresponding responsibility and is able to verify that a buprenorphine prescription was issued for a legitimate medical purpose, dispensing buprenorphine in the routine course of care for persons with OUD is highly unlikely to result in investigation, adverse action against the pharmacist’s license, or liability to the pharmacy or pharmacist. An excellent lay summary of the implications of *Ruan vs United States* for practicing pharmacists may be found here:

- <https://www.uspharmacist.com/article/dea-must-prove-knowing-and-intentional-violations-of-the-controlled-substances-act>

The Mainstreaming Addiction Treatment Act:

More positively, buprenorphine is now more available than ever. The Mainstreaming Addiction Treatment (MAT) Act and the Medication Access and Training Expansion (MATE) Act were signed into law in December of 2023. The MAT act allows all prescribers with an active DEA registration and Schedule III prescriptive authority to prescribe buprenorphine for the treatment of OUD. The MATE act requires that all DEA registrants complete a one-time, eight-hour training on OUD treatment prior to renewing their DEA license. The provisions of the MAT and MATE acts therefore eliminate the need for providers to complete requisite training and obtain a Drug Abuse Treatment Act of 2000 waiver, commonly known as an X-waiver, to dispense buprenorphine.¹⁷ Pharmacists, therefore, should no longer expect an X-DEA number on buprenorphine prescriptions as the MAT act eliminates the X-waiver. The passage of this legislation creates a clear need for community pharmacists to provide reliable access to medication for OUD.

Buprenorphine’s Regulatory Status:

Pharmacists often refuse to order buprenorphine due to concerns surrounding wholesaler suspicious order monitoring systems.³⁹ Pharmacists report that ordering buprenorphine will cause them to breach wholesaler “caps” on controlled substance purchase, leading their wholesaler to bar them from purchasing controlled substances.^{9,39} On March 8, 2024, the DEA released guidance to registrants clarifying that wholesalers should monitor buprenorphine separately from other controlled substances.¹¹ In this letter, DEA directly stated that the passage of the Mainstreaming Addiction Treatment act would result in a higher volume of buprenorphine dispensing and, thus, buprenorphine wholesale orders. This document provides a direct signal of DEA’s support for accessible OUD treatment. With that, it is encouraged that pharmacists and pharmacies work closely with their wholesale suppliers to enable them to continue to provide access to treatment for OUD. Concerns surrounding suspicious order monitoring programs should no longer be a barrier to buprenorphine supply in community pharmacies.

Red Flags and Prescription Drug Monitoring Programs

Recommendation:

Prescription Drug Monitoring Programs (PDMP) are useful decision support tools that can help pharmacists identify controlled substance misuse and diversion. Pharmacists should use the information in the PDMP profile to supplement, rather than as a substitute for, their clinical judgement when making dispensing decisions. Pharmacists should query the PDMP prior to dispensing all buprenorphine prescriptions.

Supporting Recommendations:

- The presence of red flags on prescription or PDMP review does not always indicate that a pharmacist should decline to dispense buprenorphine. Rather, pharmacists should discuss their concern with the patient and provider prior to making a dispensing decision. The following scenarios should lead to a discussion on appropriate use:
 - a. An increase in a patient's maintenance buprenorphine dose of more than 50% between prescriptions.
 - b. If a patient is attempting to fill a new prescription issued more than 30 days ago or if the pharmacist suspects the patient is not filling their most recent prescription.
 - c. A patient has received or is receiving buprenorphine from multiple providers with no consistent plan of care.
 - d. A patient's PDMP profile or the pharmacy's prescription database indicate multiple concurrent buprenorphine prescriptions.
 - e. The pharmacist suspects that the patient is experiencing medical complications of buprenorphine pharmacotherapy.
- The limited availability of buprenorphine in community pharmacies and a shortage of buprenorphine prescribers may cause patients to travel further to access buprenorphine than other medications. Distance from the patient's address or the provider's address to the pharmacy alone is not a sufficient reason to decline to dispense buprenorphine.
- Chain pharmacies and pharmacy owners should immediately retire policies that prohibit employee pharmacists from filling buprenorphine prescriptions solely due to the pharmacy's distance from provider or patient home address.
- As buprenorphine access is diminished in areas of socioeconomic vulnerability, distance-based algorithms may disproportionately impact persons of color and low-income individuals who cannot access buprenorphine in their communities and perpetuate stigma toward persons in treatment.
- Cash payment, in the absence of other indicators, is unlikely to represent 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. Pharmacists should dispense buprenorphine to cash-paying patients.
- If a pharmacist declines to dispense buprenorphine to a new or existing patient, they should first discuss this with the prescriber and clearly document their rationale for refusing to fill.
- In addition to "red flags", pharmacists should review the PDMP for potential "green flags", or indicators that a patient is actively engaged in therapy and using their medication as directed. These may include a history of timely buprenorphine refills, receiving sequential prescriptions from the same prescriber or prescriber group, the absence of concurrent opioid agonist prescriptions, and a long-term history of buprenorphine pharmacotherapy.

Rationale:

Prescription Drug monitoring Programs:

PDMPs are clinical decision support tools that allow clinicians to monitor all controlled substance prescriptions dispensed to a patient from all community pharmacies within a state regardless of payment source. Several state PDMPs allow providers to see dispensing activity in other states that share the same operating interface. In the context of OUD treatment, it is important to note that federal law prevents Opioid Treatment Programs (e.g., methadone clinics) from reporting dispensation to PDMPs.⁴⁰ Furthermore, while all states except Missouri require dispensers to report data to the PDMP, most states do not require emergency departments and inpatient facilities to report data to the PDMP.⁴¹ Despite these limitations, PDMPs have been shown to effectively reduce drug diversion⁴² and lead to reductions in potentially inappropriate opioid prescribing.⁴³ When interpreting a patient's PDMP profile, prescribers and pharmacists often search for "red flags" to determine if a patient's controlled substance use is for a legitimate medical purpose.²⁰ Consistently dispensing prescriptions with red flags may increase a pharmacy's risk of inspection by the Drug Enforcement Administration (DEA) and state regulatory authorities, and expose the pharmacy to liability. Red flags, however, are neither defined by statute nor guidance by the DEA but through a series of enforcement action levied against pharmacies over the past three decades.³⁶ Common red flags cited by pharmacists include the presence of overlapping opioid prescriptions, long travel distances to the pharmacy, cash payment, extended durations of non-buprenorphine opioid treatment, or the co-prescribing of certain combinations of controlled substances. The uncertainty surrounding enforcement and the lack of direct guidance from DEA may potentially lead to overly conservative clinical decision making at the point of care and cause pharmacists to decline to dispense legitimate prescriptions when any red flags are present.^{9,44}

In no circumstance should the presence of red flags immediately disqualify a patient from filling a prescription for medication for OUD. Rather, red flags should lead to a patient centered discussion on the appropriateness of the course of therapy with both the patient and the provider. Both parties should be provided the opportunity to explain the presence of red flags. To fulfill their corresponding responsibility, the pharmacist should carefully document the details of this discussion in the patient's pharmacy record in a manner that can substantiate the medical legitimacy of the prescription.^{20,38} Only then, should they decide to dispense or refuse the prescription. In all circumstances, the pharmacist should weigh the risks of declining to dispense (e.g., withdrawal, return to illicit opioid use, and overdose) against the benefits of this action. In other words, after discussing their concerns with the patient and prescriber, if the prescription is otherwise legitimate, the pharmacist should dispense if they can fulfill their corresponding responsibility. Failing to do so may lead to harmful, and potentially fatal, gaps in care.²¹

Dose escalation and the use of high dose buprenorphine:

There are certain indicators observable in the PDMP profile that should be discussed with both the patient and the provider before a pharmacist dispenses buprenorphine. A significant increase in the buprenorphine dose for a patient in maintenance may indicate the need for a discussion with the provider. Early in treatment, patients may titrate their dose upwards rapidly.⁴⁵ In the first few weeks of treatment, as the patient's dose is stabilized, doses of 24 mg or higher may be required.⁴⁶ This is particularly true for patients with a history of fentanyl use which contributes to increased opioid tolerance.^{46,47} For this reason, ASAM and the Center for Substance Abuse Treatment (CSAT) both support the use of buprenorphine at daily doses of up to 32 mg for maintenance treatment of opioid use disorder.^{46,48,49} It is worth noting that buprenorphine's package insert was developed and approved by FDA before prevalent use of fentanyl.⁵⁰ Current consensus guidance from ASAM and CSAT should be used to guide clinical decision making rather than the package insert alone. After the patient's dose is stable, a substantial increase in the total daily dose should lead the pharmacist to

clarify the reason for the dose increase with the treatment provider, particularly if the change in dose occurred simultaneously with a change in provider as this may indicate a lapse in care coordination. Additionally, if a pharmacist observes that the patient is experiencing sedation or other adverse effects at any point in treatment or is concerned that buprenorphine may lead to drug-drug or drug-disease interactions, the pharmacist should contact the prescriber prior to dispensing.

Filling potentially outdated buprenorphine prescriptions:

To ensure that patients in treatment remain adherent to their plan of care, it is critical that they fill their most recent prescription. Patients prescribed buprenorphine often visit their treatment provider at least monthly. If a patient presents a prescription written more than 30 days ago, this may not be their most recent prescription. The pharmacist should contact the prescriber to clarify before dispensing.

Multiple provider episodes:

Furthermore, multiple concurrent buprenorphine prescriptions or prescriptions from multiple buprenorphine prescribers from different practice groups may indicate potential misuse or diversion. Patients prescribed buprenorphine may, occasionally, receive prescriptions from different prescribers due to the organizational structure of telehealth or community-based treatment programs. If the plan of care appears to be consistent, this is not necessarily a cause for concern. Because buprenorphine is not universally available in community pharmacies, patients may frequently change pharmacies to maintain access to treatment.³³ When multiple provider use or multiple pharmacy use is detected, pharmacists may fulfill their corresponding responsibility by contacting the treatment organization or patient to clarify the reason that the patient has changed providers and documenting their discussion.

Travel Distance to Provider

Patients with OUD often struggle to identify a local source of care. West Virginia Medicaid enrollees residing in metropolitan areas lived an average of 7.1 miles from their nearest buprenorphine provider.⁵¹ Those in non-metropolitan areas lived an average of 14.5 miles from their nearest provider.⁵¹ Distance to nearest provider, however, is likely an under-estimate of distance to actual provider. In Pennsylvania, persons prescribed buprenorphine lived a median of 4.2 miles from their nearest potential provider but traveled 48.8 miles to their actual treatment provider.⁵² Locating a buprenorphine provider is difficult, particularly in socioeconomically disadvantaged areas.^{53,54} The Mainstreaming Addiction Treatment (MAT) Act, signed into law in December 2022, enables all prescribers with an active DEA registration to prescribe buprenorphine for the treatment of OUD.¹⁷ Whether this legislation will reduce travel burden, however, remains unknown.

The scarcity of buprenorphine prescribers means that patients may need to travel further to access treatment for OUD. Limited availability of buprenorphine in community pharmacies may also mean that patients have to range further from their homes to fill their prescription.³ In either case, distance may be interpreted as a red flag at the point of dispensation. Within the context of substance use disorder treatment, however, the evidence suggests that this is more an indicator of limited and inequitable access to care than an indicator of diversion. Pharmacists should not rely on traditional distance-based decision rules to determine whether a buprenorphine prescription should be dispensed. Rather, pharmacists should discuss concerns about travel distance with the patient and provider before deciding to decline to dispense buprenorphine. In any case, travel distance alone should not dictate whether a pharmacist decides to dispense. If a prescription is otherwise legitimate, the pharmacist can fulfill their corresponding responsibility, and the patient has no known contraindications to buprenorphine, the pharmacist should dispensing regardless of how far the patient traveled to receive the prescription, how far they traveled to fill the prescription, or how far the prescriber is from their pharmacy. Accordingly, corporate policy that dictates that pharmacists cannot fill prescriptions issued to patients or by prescribers further than a certain distance from their

pharmacy should be abandoned. These policies diminish access for patients with OUD and potentially more so for patients living in disadvantaged areas.

Self-Payment

Patients in treatment for OUD may not use insurance to purchase their medication for several reasons. In the 2019 National Survey on Drug Use and Health, 15.9% of all patients with OUD^{55,56} and 20% of adolescent patients in need of treatment for OUD were uninsured.⁵⁷ If approximately one in five patients do not have insurance, it is unreasonable to expect that all patients prescribed buprenorphine use insurance at the pharmacy counter. Even for patients with insurance, insurance coverage of substance use disorder treatment services is not always adequate. Simply put, cash prices for buprenorphine may be lower than the patient's copay or co-insurance. Patients with OUD are regularly exposed to stigma from providers, employers, and even friends and family members.^{58–60} Fear of stigma in the workplace is an often cited outcome of stigma toward persons with OUD.^{61–63} Patients in treatment may be concerned that their employer will terminate their employment should they use their employer sponsored health insurance to pay for substance use disorder treatment services or medication.^{63–65}

Concerns of workplace exposure are not unwarranted. First, plan services may provide aggregate, deidentified summaries of utilization to employer sponsors. Employees of smaller companies may feel threatened by the sharing of sensitive information, even if deidentified. Additionally, the Coronavirus Aid, Relief, and Economic Security (CARES) Act of 2020 diminished the effectiveness of measures laid out in 42 CFR Part 2 intended to protect the privacy of persons receiving treatment for substance use disorder.^{40,66} Although 42 CFR Part 2 requires that patients in treatment must approve of all information transmittal between Health Information Privacy and Portability Act (HIPPA) covered entities, a provision of the CARES Act, the Protecting Jessica Grubb's Legacy Act, permits an initial consent to apply to future disclosures.^{66,67} This means that if patients consent to share their information once, future disclosures do not require consent. Finally, if the Affordable Care Act were amended to remove protection for pre-existing conditions, a history of addiction treatment would likely disqualify individuals from receiving future coverage.⁶⁸

Other patients may need to purchase buprenorphine out of pocket due to unexpected changes in therapy. In the first several weeks of treatment, a patient's daily buprenorphine dose is likely to change frequently as their provider attempts to find the dose that most effectively limits cravings without causing adverse effects.⁴⁵ If a patient fills their initial prescription using their employer sponsored prescription benefit for a seven-day's supply and is then asked to titrate their dose upwards, they may deplete their supply earlier than expected leading to an early refill. This refill would not necessarily be eligible for reimbursement under the patient's prescription benefit. Efforts to amend the previous claim or to obtain authorization for an early refill may delay care. If patients are traveling an extended distance to the pharmacy, they may be unable to return the next day. This is an example of a circumstance when it may be perfectly rational for a patient to wish to pay for their prescription out of pocket. With these circumstances in mind, pharmacists should consider allowing patients to purchase buprenorphine out of pocket particularly if no other red flags are present, the provider is informed, there is sufficient documentation to support the medical legitimacy of an early refill, and the patient is not experiencing adverse effects of treatment.

General Approach to Red Flags:

Note that in each of these circumstances, pharmacists should contact the prescriber and patient before making a dispensing decision rather than denying the prescription outright. The pharmacist's priority in each case is to fulfill their corresponding responsibility while establishing the legitimacy of the prescription and the appropriateness of continuing or initiating treatment with buprenorphine. If the prescription is legitimate and the pharmacist can fulfill their corresponding responsibility, they

should dispense. In each scenario, the pharmacist should weigh the risks of delaying treatment against the benefits of waiting for the provider to respond to the pharmacist's query. If the provider is not available to clarify, the pharmacist may consider dispensing a partial fill to avoid unnecessary, and potentially harmful, disruptions in treatment.

Regardless of their decision, it is critical that pharmacists openly and transparently discuss the rationale for their decision with the patient. Dismissing the patient without explanation or telling the patient that the medication is not in stock without offering to order it is not ethical. Patients with OUD should be treated with the same level of dignity or respect afforded to others living with non-substance related chronic diseases. Along these lines, patients should also have the opportunity to explain the presence of red flags and pharmacists should be receptive to their explanation. Stigma from health professionals, including pharmacists, often leads individuals to use diverted buprenorphine to sustain their recovery.^{69,70} Addressing stigma in the pharmacy most fundamentally means fostering an environment of mutual trust and respectability between pharmacy staff and patients.

Green Flags

Like any clinical decision support tool, PDMPs may also be used to monitor indicators of treatment success. As patients with OUD enter maintenance treatment with buprenorphine, their PDMP profile will provide the pharmacist with a concise overview of their commitment to maintaining their recovery. Patients who consistently fill their prescriptions on time, who have an established relationship with a single provider or practice, and who avoid the concomitant use of full opioid agonists should be commended. Declining to dispense to an established patient because the PDMP demonstrates a long and established treatment history is an unethical and irrational clinical practice. It is therefore recommended that the pharmacists' approach to reviewing the PDMP be expanded to support the inclusion of "green flags" in the decision-making process. The presence of any of these indicators should reaffirm the pharmacist's decision to dispense buprenorphine to the patient.

Early Refills

Recommendation: Occasional requests to refill buprenorphine early are unlikely to indicate misuse of buprenorphine but may instead indicate that a patient has been asked to change their dose, lost or damaged a dosage unit, or is attempting to refill their medication in advance of a change in home address or insurance benefits. Before making a dispensing decision, pharmacists should discuss the context of the request with the patient, contact the prescriber, and document their rationale for dispensing or declining the prescription.

Supporting Recommendations:

- 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.
- 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.

Rationale:

Considerations for early refills during induction and stabilization:

Buprenorphine pharmacotherapy is subject to frequent modification. In the first two weeks of treatment, buprenorphine is rapidly titrated as the treatment provider and patient work to find the lowest effective dose that controls cravings and minimizes withdrawal symptoms.⁴⁵ Guidance from the SAMHSA recommends that patients be titrated to no more than 8 mg of buprenorphine on day one of treatment and no more than 16 mg on day two.²⁷ Steady state plasma concentrations are reached after approximately 7-days.^{71,72} At a daily buprenorphine dose of 16 mg, approximately 80-85% of Mu opioid receptors are bound.⁷³ Patients with a history of fentanyl use may benefit from higher doses. In a cohort of 6,499 patients initiating buprenorphine between 2016 and 2020, patients prescribed 16 mg of buprenorphine were found to have a greater risk of treatment discontinuation within 180 days of initiation (aHR: 1.20, 95% CI: 1.06-1.37) than those prescribed 24 mg daily.⁴⁷

Prevailing guidelines recommend that patients are seen frequently early in the course of buprenorphine treatment to ensure that withdrawal symptoms are adequately managed and to modify the buprenorphine dose as needed.^{27,45} For patients who are capable of assessing their own withdrawal symptoms or those with experience with buprenorphine, at home induction may be considered.^{27,45,74} In some cases, unobserved induction is performed by issuing the patient a prescription for an approximate one week supply of buprenorphine (e.g., a quantity of 14, 8 mg/2mg buprenorphine/naloxone tablets).⁷⁴ The duration and intensity of the initial prescription for unsupervised home induction may vary depending on the patient's expected treatment needs, provider preference, and the patient's treatment history.⁷⁵ In either case, it is difficult to predict buprenorphine needs early in treatment. It is conceivable, however, that patients may deplete their initial prescription earlier or later than expected causing the pharmacist to perceive their next refill as early or delayed, respectively. Refusing to dispense buprenorphine early in treatment significantly increases the patient's risks of withdrawal as described previously. Rather than refuse to dispense

due to early or delayed refill requests, the pharmacist is strongly recommended to contact the treatment provider, explain their concerns about the patient's refill timing, and ask for clarification. They should document this discussion to fulfill their corresponding responsibility and make their dispensing decision accordingly.

Considerations for early refills during maintenance pharmacotherapy:

Short gaps in medication possession at any point in treatment have been shown to markedly increase risk of mortality.^{21,30} Any number of reasonable scenarios may lead patients to request an early buprenorphine refill. Persons prescribed buprenorphine are generally like those living with other chronic conditions in that they have other obligations and circumstances that may require them to refill a prescription early. They may need to travel for work, leave town for a funeral, or may wish to take a vacation. Most pharmacists would work to refill insulin for a patient with diabetes in each of these cases, patients living with substance use disorder deserve the same level of care. If the patient occasionally requests an early refill, the pharmacist should generally comply. Concerns should be addressed through discussion with the provider and documentation. In most cases, however, occasional requests for an early refill should not constitute cause for concern.

Patient Reports of Damaged Dosage Units:

Additionally, patients at any point in therapy⁷⁴ may need to cut sublingual buprenorphine/naloxone films into sections.⁷⁶ While this is not recommended in the product labeling, prescribers may recommend cutting films to achieve the patient's needed dose efficiently. Despite the current labeling, Suboxone[®] films may be safely cut with a ruler and a razor blade and doing so has been shown to yield sections with 97.7% dose stability relative to initial strength.⁷⁶ It is reasonable to observe, however, that this process may lead to error. A patient may incidentally damage a film while cutting, misplace the reserved half, or expose the reserved half to moisture damaging the film. In this case, the patient may need an early refill to avoid disruptions in treatment.

Considerations to Prevent Misuse and Diversion:

Pharmacists should, in these scenarios, be mindful of patients stockpiling buprenorphine or accumulating a surplus of medication through sustained early refill requests as this may be a sign of non-medical use or diversion.^{77,78} There is no evidence to guide the operationalization of a general early refill policy. Rather, pharmacists should consider allowing sporadic, early buprenorphine refills if the circumstances necessitating an early refill are reasonable, the prescriber is informed, and the pharmacist documents their decision and rationale for dispensing. If the patient continues to routinely request early refills, appears to be stockpiling buprenorphine, or frequently reports theft, loss, or damage of medication, the pharmacist should consider declining to fill. Prior to making their dispensing decision, however, the pharmacist should discuss their rationale with the prescriber and patient and document the discussion. In any case, refusal to fill should only be considered if the pharmacist has reason to believe that the patient's prescription was not issued for a legitimate medical purpose, the patient is not using buprenorphine as directed, or that the patient is diverting their medication. In each case, the pharmacist should cautiously weigh the risks and benefits of declining to dispense buprenorphine.

Pharmacy Policy on Early Buprenorphine Refills:

From the above, it follows logically that corporate policies that prohibit pharmacists from using their clinical judgement to dispense buprenorphine early are unacceptable. While the impact of these policies on treatment outcomes remains unknown, it is highly unlikely that they are beneficial to patients with OUD. Furthermore, pharmacy owners and pharmacy corporations would be hard pressed to demonstrate that these policies are aligned with the priorities of the Department of Justice and the DEA.¹¹ In a March 8, 2024 letter to registrants, DEA reiterated that registrants should prioritize uninterrupted access to medication for OUD. Arbitrary restrictions on the timeliness of refills

are far from patient centered and likely contribute to harmful interruptions in buprenorphine pharmacotherapy. For this reason, it is strongly recommended that pharmacy owners and pharmacy corporations abandon restrictions on early buprenorphine refills and allow pharmacists to use their clinical judgement when determining if a buprenorphine prescription should be dispensed before the scheduled date of refill. As long as a pattern of early refill requests is not present, pharmacists should carefully weigh the risks of an early refill against the risks of an interruption in access and ensure that the patient's access to medication for OUD is not interrupted.

Providing Care to Persons Utilizing Telehealth

Recommendation: Pharmacists should dispense buprenorphine prescriptions issued by virtual health, or telehealth, providers if the prescription is legitimate, and the pharmacist can fulfill their corresponding responsibility.

Supporting Recommendations:

- Telehealth prescriptions received via electronic prescribing platforms are not more likely to be fraudulent or illegitimate than prescriptions from face-to-face encounters and should not be subjected to a higher level of scrutiny than other buprenorphine prescriptions.
- Pharmacists have the right to inquire about the nature of the patient/provider relationship and should contact the telehealth provider to fulfill their corresponding responsibility if necessary.
- Pharmacists should continue to dispense buprenorphine to telehealth patients who are adherent to a stable plan of care even if they change providers.

Rationale:

Quality and Cost Effectiveness of Telehealth Services for People with OUD

In March of 2020, DEA, along with the department of Health and Human Services (HHS), temporarily suspended provisions of the Ryan Haight act allowing providers to initiate patients on buprenorphine products indicated for the treatment of OUD through an audio only or audio-visual telehealth encounter. After initiation, providers may continue to prescribe buprenorphine without an in-person encounter as allowed by state law. Though these flexibilities were initially temporary, DEA and HHS have repeatedly extended telehealth flexibilities. Under their current extension, telehealth flexibilities will not expire until December 31, 2024.^{16 15}

Emerging evidence suggests that access to telehealth has led to improved treatment outcomes for persons with OUD. Among individuals with OUD, receipt of telehealth services has been shown to significantly reduce risk of overdose mortality (aOR, 0.67; 95% CI, 0.48-0.92).⁷⁹ Telehealth encounters are both more convenient, and potentially less stigmatizing, than in person encounters for persons with OUD. Patients are 3.34 times more likely to complete a scheduled telehealth encounter compared to a scheduled in-person encounter.⁸⁰ As discussed in earlier sections, travel distance to care is a salient barrier to OUD treatment, particularly in rural and socioeconomically disadvantaged areas.^{52,54} Telehealth effectively addresses distance to prescriber as a barrier to care.

Pharmacists may legitimately question the patient provider relationship developed or the quality of care delivered in telehealth encounters. The evidence, however, suggests that telehealth encounters are non-inferior to in-person visits. In a comparative analysis of patients treated by clinicians with low, moderate, and high use of telemedicine in their practice, there was no difference in the rate of MOUD initiation, days' supply of MOUD, or OUD related clinical events between patients treated within high and low telemedicine practices.⁸¹ Furthermore, buprenorphine has been shown to improve patient satisfaction, accessibility, and treatment adherence.^{82,83} Widespread implementation of substance use disorder telehealth programs is expected to avert upwards of 20,000 overdose deaths annually. Implementing telehealth programs as a part of a comprehensive approach to buprenorphine treatment is expected to contribute to a total gain of 517,045 quality adjusted life

years and a total cost savings of over \$621,000,000 annually providing evidence of the cost effectiveness of telehealth interventions for OUD.⁸⁴

Considerations for the legitimacy of telehealth prescriptions:

The first three and a half years of buprenorphine treatment via telehealth have provided sufficient evidence to support the quality and cost effectiveness of treatment through this modality. Still, pharmacists report reluctance to dispense buprenorphine prescriptions issued by telehealth prescribers.⁸⁵ In particular, pharmacists report that distance from the pharmacy or patient to the telehealth prescriber, the perceived legitimacy of the physician/patient relationship, and concerns that filling telehealth prescriptions will interrupt their ability to order other controlled substances by triggering supply restrictions through suspicious order monitoring programs. First, distance to prescriber is not a legitimate reason to avoid filling a telehealth prescription. The DEA has not only endorsed the legitimacy of telehealth prescribing but has repeatedly extended the suspension of the Ryan Haight Act that allows for the issuance of buprenorphine prescriptions without an in-person encounter. It is highly unlikely that DEA expected patients to only use local telehealth providers as this would defeat the practicality of the legislation and limit access. Of note, most telehealth agencies will use secure, electronic prescribing systems to transmit prescriptions. The likelihood of prescription forgery is, therefore, extremely minimal.⁸⁶ Second, there is no reason to suspect that telehealth encounters are of inferior quality when compared to in-person visits. While additional evidence is still emerging, that which is available to date indicates that patients prescribed buprenorphine via telehealth experience similar outcomes to those who have received in-person care. Finally, concerns that dispensing telehealth prescriptions may cause pharmacists to breach wholesaler limits or “caps” on buprenorphine purchase should not deter pharmacists from filling legitimate telehealth prescriptions. As mentioned earlier in this document, DEA has clarified their support for wholesale of buprenorphine products indicated for the treatment of OUD.¹¹ If pharmacists do see an influx of buprenorphine patients from a single telehealth practice and are concerned that extending access may interfere with wholesale acquisition, they should work closely with their wholesaler to ensure that monitoring parameters are amended to allow their pharmacy to continue purchasing buprenorphine.^{10,87}

If pharmacists are concerned about the legitimacy, appropriateness, or veracity of a telehealth prescription, they should contact the prescriber and document their discussion to alleviate their concerns. When evaluating the legitimacy of a prescription, pharmacists are encouraged to rely on the definitions of legitimacy established by the DEA and their state board of pharmacy.²⁰ Rarely will a state have separate standards for medically necessary telehealth and in person prescriptions issued by prescribers in good standing with DEA and their state medical board. 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. The evidence available suggests that buprenorphine treatment is likely to benefit patients with OUD regardless of the patient’s source of care. Use of a telehealth prescriber is not a sufficient reason to be denied care if the prescription is otherwise legitimate.

Evaluating multiple provider use in telehealth patients

Patients who use telehealth may change providers occasionally due to the organizational structure or process of care in the telehealth practice. If the patient's plan of care remains unaltered or does not drastically change under a new provider, a provider change alone is not cause for concern. Once again, the risks of abruptly discontinuing treatment greatly outweigh the potential benefits to the pharmacy or pharmacist of refusing to fill the prescription. If a pharmacist is concerned due to a change in provider, they should contact the telehealth provider and ask them to verify the reason for the change in provider. The nature and outcome of the call should be documented in the patient profile before dispensing the prescription to fulfill their corresponding responsibility.

Buprenorphine Monotherapy

Recommendation:

Current clinical evidence supports the efficacy of buprenorphine monotherapy for the treatment of OUD. There are clear indications for buprenorphine monotherapy, including cost, pregnancy, and dental lesions. Pharmacists may discuss the indication for monotherapy with the provider but should not prefer buprenorphine/naloxone combination products to buprenorphine monotherapy.

Rationale:

Indications for Buprenorphine Monotherapy:

There are several indications for buprenorphine monotherapy, or buprenorphine products formulated without naloxone, for the treatment of OUD. For pregnant and breastfeeding individuals with OUD seeking treatment, buprenorphine formulations without naloxone are preferred to combination products due to concerns about naloxone's potential to cross the placenta and cause harm to the developing fetus.²⁷ The emergence of oral carries or dental lesions provides another compelling reason to transition patients away from sublingual buprenorphine/naloxone preparations. Transdermal, or long acting injectable products should be considered in patients suffering from dental carries or other oropharyngeal adverse effects associated with the use of buprenorphine/naloxone sublingual products.⁸⁸ Additionally, buprenorphine monotherapy may be less costly than combination products.⁸⁹ Some pharmacies only stock brand name formulations of sublingual combination products due to Medicaid formulary management practices. In those states, locating generic sublingual combination products may be difficult leading to delays in care.

Safety and appropriateness of buprenorphine monotherapy:

Buprenorphine monotherapy and naloxone combination formulations have comparable clinical safety profiles in patients with OUD in that there is no difference in the risk of mortality between patients treated with buprenorphine monotherapy and those treated with buprenorphine/naloxone.⁹⁰ Additionally, there is conflicting evidence regarding the ability of naloxone coformulation to prevent parenteral misuse.^{91,92} Though buprenorphine users may be less likely to use naloxone containing products parenterally,⁹¹ pharmacodynamic evaluations show no difference in buprenorphine bioavailability if buprenorphine is administered with or without naloxone.⁹² This is potentially because buprenorphine has up to 10-fold greater binding affinity for the Mu opioid receptor than naloxone which diminishes the ability of naloxone to act as an antagonist in the presence of buprenorphine.⁹³ Finally, patients with a history of buprenorphine insufflation reported no difference in preference for buprenorphine products formulated with or without naloxone in a blinded experiment.⁹² Still, evidence based practice guidelines from ASAM recommend the use of buprenorphine/naloxone combination products for the first-line management of OUD.⁴⁵ If a patient cannot afford combination products, combination products are not available, or if the patient is experiencing adverse effects related to combination therapy, transitioning to buprenorphine monotherapy is a reasonable clinical action. Pharmacists should work closely with physicians and patients to ensure that the most appropriate buprenorphine product is used to support the patient's recovery. These discussions should be guided by the principle that the option that is available and affordable to the patient is preferable to delays or disruptions in care.

Recommendations to Protect Patient Safety

At the point of care, pharmacists should do the following to ensure that buprenorphine pharmacotherapy is delivered safely to persons with OUD:

- Pharmacists should discuss potential adverse effects of buprenorphine pharmacotherapy with patients at each refill and inquire about their experiences with the medication.
- Pharmacists should offer to dispense naloxone to patients prescribed buprenorphine for the management of OUD.
- As with any medication, pharmacists should educate patients about the dangers of certain drug combinations (particularly full opioid agonists, benzodiazepines, and sedative hypnotics) and the risks associated with alcohol use while taking buprenorphine.
- Pharmacists should provide counseling on the safe storage and disposal of buprenorphine products.
- Pharmacy technicians can provide valuable support to the process of care. Where not otherwise prohibited by state law, technicians can improve the efficiency of care by extracting information from prescription monitoring programs, contacting providers, reminding patients to refill their prescriptions, and assisting with reimbursement issues.

Rationale:

Routine Therapeutic Monitoring:

The Omnibus Budget Reconciliation Act of 1990 required that pharmacists provide counseling to Medicaid patients in all 50 states.⁹⁴ Shortly thereafter, all 50 states and the District of Columbia enacted policy requiring that pharmacists provide counseling to all patients, regardless of insurance status. Pharmacists are obligated to counsel patients prescribed buprenorphine. They should not, however, limit their counseling to the patient's index encounter but should continue to monitor therapy with buprenorphine by regularly assessing patient wellbeing and safety at all points in treatment. Although the adverse event profile of buprenorphine resembles that of other opioids (constipation, sedation, nausea, etc.), some adverse events of buprenorphine therapy may not appear acutely. Dental carries, for instance, may take months to appear. For this reason, pharmacists should routinely monitor patients for adverse events at each refill. If adverse events occur, the pharmacist should inform the prescriber as soon as possible and work with the patient and prescriber closely to modify the plan of care to avoid harm. A full explanation of the adverse events associated with buprenorphine may be found in the medication labeling:

<https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=8a5edcf9-828c-4f97-b671-268ab13a8ecd>.

In addition to monitoring for the incidence of adverse events, pharmacists should take steps to educate patients on the prevention of adverse events. Pharmacists should discuss oral hygiene at the time of treatment initiation and should consider referring patients to dental care if oral lesions or dental carries emerge. Patients should be informed that dental carries or oral lesions may emerge regardless of their oral health history. Patients receiving buprenorphine should receive routine dental care.⁵⁰ Pharmacists can assist in this by inquiring as to whether or not patients prescribed buprenorphine have a source of dental care at the time of treatment initiation and by referring those without dental care to a local dentist.

Access to Naloxone:

Pharmacists should also counsel patients prescribed buprenorphine on steps to prevent overdose. The Federal Food and Drug Administration recommends that all individuals in treatment for OUD be prescribed naloxone.⁹⁵ While filling a naloxone prescription should not be a prerequisite to receive buprenorphine, pharmacists should encourage patients to purchase naloxone. Prescription only and over the counter naloxone preparations are effectively interchangeable. It should be noted

that there are currently no known benefits to higher dose, 8 mg, naloxone preparations compared to conventional 4 mg preparations.⁹⁶ Higher doses of naloxone may increase the severity of precipitated withdrawal symptoms, including severe acute pain.⁹⁶ Pharmacists should counsel patients and others in the home on overdose detection and appropriate use of naloxone. Pharmacists should be able to clearly describe how to differentiate overdose from intoxication to avoid inappropriate naloxone administration which may lead to unnecessary precipitated withdrawal. Pharmacists are encouraged to consult training materials and guidance available from the SAMHSA if they are unclear on naloxone administration or use.⁹⁷

Concomitant use of buprenorphine and CNS Depressants

Overdoses involving buprenorphine are rarely due to the use of buprenorphine alone. In a series of 2,369 post mortem examinations of opioid overdose victims, buprenorphine was only involved in 55 (2.3%).⁹⁸ Of these, 51 involved another substance.⁹⁸ Like any other opioid, buprenorphine may interact synergistically with benzodiazepines, alcohol, other opioids, and other central nervous system (CNS) depressants. Patients should, therefore, be counseled to avoid using buprenorphine with non-prescribed CNS depressants, including alcohol. It should be noted that the supervised, medical use of benzodiazepines and sedative hypnotics is not contraindicated with buprenorphine.⁹⁹ Guidance from ASAM, SAMHSA, and FDA all agree that use of CNS depressants alone should not be a reason to withhold or discontinue treatment with buprenorphine.^{27,45,99} Withholding treatment due to concomitant use of CNS depressants will not prevent patients from using illicit opioids leaving them at a substantially increased risk of overdose. Rather, pharmacists should work closely with prescribers to ensure that patients are using CNS depressants as prescribed. Pharmacists should also educate patients on the risk of overdose associated with the use of both agents and, conversely, the potential risks associated with abrupt disruption of long-term benzodiazepine treatment.

Buprenorphine storage and disposal:

Pharmacists should also discuss buprenorphine storage and disposal at the point of care. Approximately 56% of individuals who misuse prescription drugs obtain them from a friend or family member.¹⁰⁰ Improperly stored medications pose a significant risk to others and the home, including children and older adults. Poor storage may also increase risk of theft and diversion. Pharmacists should, therefore, counsel all patients prescribed buprenorphine on safe medication storage and disposal. Buprenorphine should be stored in a secure, preferably locked, location out of reach of children or others susceptible to harm. Where available, pharmacists should provide a single use drug disposal system to patients prescribed buprenorphine. In 2022, the Federal Food and Drug Administration announced the planned implementation of a Risk Evaluation and Mitigation Strategy (REMS) requiring pharmacists to provide a mail-back drug disposal system with each opioid medication dispensed.^{101,102} A REMS program is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. The REMS program is expected to be fully implemented in calendar year 2024 with financial support from opioid manufacturers. Until that time, it is highly recommended that pharmacists consider supplying a drug disposal system to patients or, when not available, advising on safe disposal. Several compliant disposal products exist and may be available through publicly funded state or federal programs.¹⁰³ In the absence of availability, pharmacists should recommend that patients deposit unused medication in a public medication takeback box (locations available here: <https://safe.pharmacy/drug-disposal/>) or return medications through an organized, local drug takeback event. If neither option is available, pharmacists may recommend removing buprenorphine products from their packaging, placing them in a sealable plastic bag, and mixing with unpalatable substances (coffee grounds, saw dust, or dirt) before

disposing of them in the household trash.¹⁰⁴ Flushing unused medication, including buprenorphine, down the toilet is environmentally deleterious and should be avoided.

Involving pharmacy technicians in the care of persons with OUD

Pharmacists are well equipped to ensure that patients prescribed buprenorphine receive appropriate counseling and supportive care in the community setting. To ensure that pharmacists have ample time to counsel patients prescribed buprenorphine, it is highly recommended that pharmacists work closely with pharmacy technicians to ensure that they can focus on the cognitively demanding aspects of care delivery outlined above. Pharmacy technicians can play a key role in promoting adherence and safety for persons prescribed buprenorphine. At the most fundamental level, pharmacy technicians may improve efficiency of access by proactively working to address reimbursement issues, monitoring pharmacy inventory, and contacting providers for prescription renewals. In many states, pharmacy technicians may act as PDMP delegates and assist pharmacists in downloading the patient's PDMP profile for review.⁴¹ Finally, pharmacy technicians are capable of communicating directly with patients to remind them to refill or retrieve prescriptions from the pharmacy. In addition to improving efficiency, involving pharmacy technicians in the process of team-based care for persons with OUD fosters a cooperative culture of compassion in the pharmacy thus limiting stigma toward persons in treatment.

Care Coordination and Provider Communication

Recommendation: The following recommendations are intended to optimize the quality and efficiency of care for persons with OUD in community pharmacies:

- Pharmacists should extend the same level of medication therapy management, immunization, and point-of-care testing services to patients with OUD as they do to other patients.
- Implementing collaborative practice agreements could potentially enable pharmacists to monitor buprenorphine pharmacotherapy, provide supportive care, and potentially create opportunities to bill for cognitive services provided.
- Pharmacists can promote adherence to treatment for OUD by being willing and able to refer patients in treatment to local primary care, mental health, and peer support providers upon patient request.
- If a pharmacist needs to clarify a buprenorphine prescription for whatever reason, they should make every effort to promptly contact the prescriber through direct phone communication rather than fax. Additionally, the pharmacist should keep the patient informed about their efforts and the status of the prescription.
- To prevent unnecessary delays, pharmacists may consider dispensing a partial quantity of the prescription while awaiting additional information from the provider regarding the plan of care.

Rationale:

Access to pharmacist delivered supportive care

Seamless transitions of care from provider to pharmacy and a focus on comprehensive care delivery are critical to ensure that patients prescribed buprenorphine receive high quality pharmaceutical care without unnecessary interruptions. Patients with OUD stand to benefit from the same suite of services that pharmacists provide their other patients, including vaccination. In a 2015 review of electronic medical records, 67.9% of individuals with OUD were found to lack immunity to Hepatitis B. Of those, 43.5% had no documentation of completing their primary Hepatitis B vaccine series prior to presenting with OUD.¹⁰⁵ In another cohort of 1,127 syringe exchange participants, only 57.1% reported having received an MMR vaccine, 45.9% Hepatitis A, 47.5% Hepatitis B, and 47.6% seasonal influenza.¹⁰⁶ Pharmacists are prolific vaccinators. As of 2024, more than 60% of influenza vaccines in the United States are administered in community pharmacies.¹⁰⁷ Given the relative accessibility of community pharmacies and the frequency with which patients prescribed buprenorphine visit community pharmacies, pharmacists should routinely assess vaccination status and offer to vaccinate patients with OUD. This would unquestionably benefit patients, particularly those without a routine source of primary care.¹⁰⁸ In addition to vaccination, eligible individuals prescribed buprenorphine may be expected to benefit from Medication Therapy Management (MTM) and point-of-care testing services in the same way as individuals without problematic opioid use.

In a cohort of 12,179 individuals prescribed buprenorphine and at least one other medication for a non-substance related chronic disease state, adherence to buprenorphine was associated with adherence to other maintenance medications.¹⁰⁹ Adherence to buprenorphine is also associated with both lower healthcare utilization and lower healthcare expenditures among individuals in treatment.^{110,111} Pharmacy based interventions aimed at improving medication adherence are, therefore, highly likely to be beneficial for patients in treatment. In the United States, over 140,000

Medicare enrollees received treatment with buprenorphine in 2022.¹¹² While this represents a small fraction of the total number of Medicare enrollees with OUD, these individuals would likely be eligible for, and benefit from, MTM services delivered by the pharmacist. Of note, this service is eligible for reimbursement by the patient's Part D prescription drug benefit. The complexity of buprenorphine pharmacotherapy, the prevalence of comorbidities in patients with OUD, and the risks associated with non-adherence all suggest that MTM services should be provided to patients with OUD. Pharmacists interested in providing MTM Services should consult resources provided by the Centers for Medicare and Medicaid Services as well as the individual patient's Part D drug plan.¹¹³ More resources may be found here:

- <https://www.cms.gov/medicare/coverage/prescription-drug-coverage-contracting/medication-therapy-management>

Collaborative practice models

In most states, pharmacists may enter into collaborative practice agreements with providers that enable them to supervise and potentially modify therapy, provide point-of-care testing, or potentially order laboratory tests and prescribe therapy according to their results.¹¹⁴ Patients with OUD are expected to benefit from these services in the same way as those without problematic substance use and should be offered these as allowed by state law. More uniquely, however, emerging collaborative pharmacy practice models tailored to patients prescribed buprenorphine promise significant improvements in convenience of care, medication adherence, cost effectiveness, and potentially health outcomes for patients with OUD.^{75,115-117} Most recently, results of a clinical trial published in the *New England Journal of Medicine* demonstrated that patients prescribed buprenorphine for unobserved induction by pharmacists working under a physician protocol were significantly more likely to remain adherent to treatment one-month later compared to those receiving standard of care (89% vs 5%).⁷⁵

Other successful practice models involve leveraging frequent pharmacist contact to minimize the cost of care.¹¹⁷ In a small, single-arm analysis of 12 patients enrolled in a health department based collaborative drug therapy management program, patients prescribed buprenorphine received follow-up care from an outpatient pharmacist. The physician consulted as needed and reviewed the pharmacist's care plan. Involvement of a community pharmacist was shown to result in a \$22,000 cost savings and yield 100% treatment retention at six-months.¹¹⁷ In another example, community pharmacists entered into an Operational Care Agreement with buprenorphine prescribers. Under the agreement, patients visited the pharmacist monthly and as needed for medication reconciliation and to complete a clinical assessment. The physician was responsible for initiating buprenorphine, issuing maintenance prescriptions, and reviewing the care notes taken by the pharmacist. In this sample, 88% of patients were retained at six-months.¹¹⁶ In patient satisfaction screenings completed after the six-month follow-up, 86% of participants reported that treatment delivered under the pharmacist/physician collaborative care model was better than their past healthcare experiences.¹¹⁶

Evidence to support components of collaborative care models is emerging, however, that which is available suggests that involving the pharmacist in care can maximize convenience and promote long-term retention in treatment. In states where collaborative practice agreements are allowed by law, incident-to-billing practices may be used to ensure that pharmacists are compensated

for non-dispensing services delivered to patients with OUD. Pharmacy professional organizations should continue to advocate for expansion of payment models that support pharmacists motivated to provide services to patients with OUD while simultaneously educating the pharmacy workforce on the implementation of best practices in this area. Accessible templates for collaborative practice agreements and guidance on billing and reimbursement are needed to promote the widespread dissemination of collaborative practice agreements for OUD treatment.

Practical steps to improve the efficiency and quality of buprenorphine pharmacotherapy:

The widespread dissemination and adoption of pharmacist collaborative practice models may not occur in the immediate future. There are, however, several things that pharmacists can do to work more closely with local treatment providers to improve access to buprenorphine. First, patients prescribed buprenorphine may see their pharmacist more frequently, or at least as frequently, as their treatment provider. Pharmacists have a tremendous opportunity to be a resource for individuals prescribed buprenorphine. Outside of being a source of medication information, pharmacists can help refer patients to care in their immediate community. This may be more important for persons receiving treatment with telehealth. Pharmacists should consider inquiring as to whether their patients have a local source of care and be prepared to refer them to, or help them locate, accessible physical and mental health providers. Community pharmacists are uniquely well positioned to do this as they are often familiar with providers in their area, see patients from a multitude of providers, and are often afforded a unique perspective on an individual's care needs in their role as medication use expert.

Finally, pharmacists can directly improve the quality of care for persons with OUD by simply leveraging patient-centered communication approaches. Communication barriers between provider and pharmacist are a salient barrier to buprenorphine access.¹¹⁸ Community pharmacists are often distrustful of buprenorphine prescribers and tend to rely on communication through the patient as a way of reaching prescribers.¹¹⁸ This places burden directly on the patient and is an inefficient and error prone approach to clinical communication. Pharmacists, and prescribers alike, should be willing to communicate directly to avoid unnecessary delays in care. Rather than delaying care through the use of inefficient forms of communication, refill requests and prescription modifications should be managed telephonically as much as possible. Delays in care due to the inability of a pharmacist to quickly reach a prescriber are unacceptable in the current era of communication and are a direct threat to continuity of pharmacotherapy for OUD. If a pharmacist cannot reach a prescriber quickly, it is strongly recommended that, where possible, the pharmacist consider dispensing a partial quantity of buprenorphine (1-3 days, as appropriate) to ensure that the patient is not without medication possession. The risks of therapy interruption to the patient outweigh the minor administrative risks to the pharmacist and pharmacy associated with dispensing a partial quantity of buprenorphine to an established patient. This is especially important for patients without access to personal transportation as these individuals may be more burdened by returning to the pharmacy later in the day or the next day to pick up their prescription.

Stigma Toward Persons with OUD

Recommendation: Pharmacists, pharmacy technicians, and all pharmacy staff should approach persons living with OUD with empathy, compassion, and support, recognizing and addressing how their biases may impact their ability to provide care and make appropriate, patient centered decisions.

Supporting Recommendations:

- Requiring patients to transfer prescriptions for non-controlled substances to a pharmacy to access buprenorphine is an unethical process that interferes with patient autonomy and potentially constitutes medical coercion. This practice should be abandoned.
- Requiring a patient interview prior to dispensing buprenorphine is an unusual, stigmatizing, and discriminatory practice that would not be employed in other contexts. This practice should be discontinued.
- Pharmacy personnel often mirror pharmacists' behavior in their interactions with patients. Pharmacists should be cautious in how they address patients with OUD as this may impact the way that other pharmacy staff react toward persons with OUD.

Rationale:

The Oath of a Pharmacist and Stigma Toward Persons with OUD:

The way that patients are treated at the point of care can determine whether or not persons with OUD continue treatment. The first line of the American Pharmacists Association *Oath of a Pharmacist* is “*I will consider the welfare of humanity and relief of suffering my primary concerns.*” The second line is “*I will promote inclusion, embrace diversity, and advocate for justice to advance health equity.*”¹¹⁹ Denying to fill legitimate prescriptions for persons in treatment violates both of these standards. Denying a legitimate prescription would violate this ethical premise and be directly damaging to persons with OUD. For very practical reasons, grounded in the roots of pharmacy practice, it is therefore recommended that pharmacists fully embrace their role as relievers of human suffering and promoters of health equity by dispensing medication for OUD whenever possible. Stigma experienced in the pharmacy is a significant barrier to treatment. Upwards of 34% of persons who resorted to the use of diverted buprenorphine report adverse interactions with pharmacy staff as a primary reason for leaving traditional care.¹²⁰ In all settings of care, regardless of corporate policy and pressure, pharmacists alone are responsible for determining how they treat the patients in their practice.

Requiring Patient Interviews:

In the formative focus groups used to lay the groundwork for this guidance, participants reported that they felt the need to interview persons with OUD prior to dispensing buprenorphine to ensure that their intentions in filling buprenorphine were legitimate. There is no evidence to support this practice or to guide the interpretation of a patient interview in this manner. Any interpretation is likely to be biased by the interviewing pharmacist's preconceived negative assumptions, otherwise known as stigmatic beliefs, toward the person wishing to fill the prescription. Furthermore, this practice is completely abnormal in other chronic disease states. There are very few scenarios in which a pharmacist would feel the need to interview a person with diabetes prior to dispensing insulin, buprenorphine is no different.

Forced Prescription Transfer:

Pharmacists often require persons filling buprenorphine to transfer other prescriptions to their pharmacy prior to dispensing buprenorphine. This practice is burdensome, discriminatory, and unnecessary. It is burdensome in that patients may already have a routine source of care and not wish to disrupt their relationship with their current pharmacist. Alternatively, patients may be un- or under-insured and, thus, shop around for their medication at the lowest cost.¹²¹ Finally, patients prescribed buprenorphine may not have other maintenance medications to transfer. This practice is discriminatory in that patients in low-income areas may have reduced access to buprenorphine in otherwise convenient pharmacies.⁵⁴ A patient may wish to maintain their usual, convenient source of care even if their routine pharmacy does not stock buprenorphine.

Wholesale restrictions are not a reason to force prescription transfer:

Pharmacists often cite concerns about wholesale controlled substance purchase, or “caps”, as a reason to require patients to transfer non-controlled prescriptions with buprenorphine.^{9,39,85} Pharmacists may feel that requiring a patient to transfer prescriptions for non-controlled substances “offsets” their ratio of controlled substance to non-controlled substance orders. This practice is unnecessary in light of recent clarification from the DEA encouraging pharmaceutical wholesalers to disentangle buprenorphine from other opioid medications in suspicious order monitoring programs.¹¹ Regardless of the reasons for why a patient cannot or will not transfer their medication, it is the patient, not the pharmacist who should dictate their source of care.¹²² Pharmacists have an ethical obligation to preserve patient autonomy within reasonable limits.¹¹⁹ The freedom to choose a pharmacy is the most fundamental choice that a pharmacist can provide a patient. Why a patient chooses their pharmacy is unimportant. New patients, regardless of what they are prescribed, represent an opportunity for pharmacy growth and for pharmacists to provide care.

Creating a welcoming pharmacy environment:

It cannot be overstated that all patients including those prescribed buprenorphine deserve to be treated with dignity and respect by all staff in community pharmacies. Persons prescribed buprenorphine report that they more frequently feel stigmatized from pharmacists and pharmacy technicians than other care providers.¹²³ Stigma is a learned pattern of behavior developed through the transmission of ritualized practices from members within a group.¹²⁴ Furthermore, power gradients, such as those formed between pharmacists and pharmacy technicians, may serve to perpetuate stigma in the workplace.^{125,126} In brief, pharmacy technicians and other pharmacy personnel may begin to mirror the stigmatizing behavior of pharmacists toward other groups in an effort to avoid being the object of stigma themselves. Pharmacists have an ethical obligation to treat all patients equitably.¹¹⁹ Fulfilling this obligation entails creating a practice environment where patients are accepted regardless of their medical, demographic, or socioeconomic status. If pharmacists treat patients with OUD negatively, other pharmacy employees are likely to follow suit to preserve their status within the power hierarchy of the pharmacy. Simply put, if pharmacists address persons with OUD with dignity, respect, and trust as they would any other patient, their staff are likely to do the same.

Fostering a caring environment for persons with substance use disorder is no different than the approach pharmacists use toward persons with other chronic disease states. Pharmacists should be cautious of the language they use when communicating with persons with substance use disorder.

Avoiding using terms such as “addict” and “substance abuser” in favor of person first terms such as “person with substance use disorder” has been shown to directly impact the perceptions of providers toward patients in their care.¹²⁷ Being able to promptly fill buprenorphine prescriptions, rather than ordering buprenorphine or making patients unnecessarily wait in the pharmacy, has also been shown to make persons with substance use disorder feel more accepted in the pharmacy environment.¹²³ Finally, pharmacists and pharmacy owners should consider providing their staff opportunities to participate in stigma reduction training. An institutional commitment to developing staff to more effectively provide care for persons with substance use disorder sends a strong signal to staff that the pharmacy is committed to providing equitable access to effective treatment.¹²⁸

Employer Oversight

Recommendation: Employer policies governing buprenorphine dispensing should prioritize flexibility, allowing individual pharmacists to exercise their professional judgment when deciding whether to dispense a prescription for buprenorphine.

Supporting Recommendations:

- Pharmacy corporations should clarify that numerical thresholds, such as distance to provider, distance to home, or days' supply, should be applied to guide inquiry and documentation, rather than as reasons to deny the dispensing of buprenorphine.
- Pharmacy corporations should utilize their purchasing power to renegotiate wholesale purchasing agreements, ensuring continued ability to purchase buprenorphine.
- Pharmacy corporations should prioritize appointing registered pharmacists to management positions responsible for establishing corporate controlled substance dispensing and purchasing policies.

Rationale:

Impact of Corporate Policy on Patient Care

Multidistrict opioid litigation has led to an accumulated \$13 billion in financial damages to community pharmacies nationwide, a number that is expected to grow as cases continue to enter settlement.¹³ As prosecutors continue to settle cases with community pharmacies, pharmacy corporations, and pharmaceutical wholesale distributors all have reacted by enacting increasingly severe restrictions on controlled substance supply within community pharmacies. Corporate policy has become a salient barrier to buprenorphine and controlled substance dispensing in community pharmacies.^{9,85} As reviewed elsewhere in this document, there is almost no evidence supporting the utility of algorithmic dispensing rules in preventing buprenorphine misuse or diversion.^{9,36} Policies that limit a pharmacist's ability to dispense a buprenorphine prescription due to the distance between the patient's home and their provider, the distance between their home and the pharmacy, or the distance between provider and pharmacy are arbitrary and highly likely to lead to adverse and discriminatory decisions against rural and minoritized patients. Similarly, restrictions on the duration of a buprenorphine prescription may eliminate any potential adherence benefit that accompanies providing longer duration prescriptions.²⁷ As patients enter maintenance treatment, longer duration buprenorphine prescriptions (e.g., 30 vs 14 days) may be used to limit travel to pharmacy, thereby optimizing the convenience of care. Policy limiting pharmacists to dispensing a fixed duration of buprenorphine for ambulatory use would directly defy the provider's plan of care.

Effective Employer Guidance on Buprenorphine Dispensing

Any policy that does exist should be guiding rather than dictatory. It is reasonable for pharmacy organizations to set clear expectations and to provide standard operating procedures for pharmacists at the point of care. This may include guidance on reimbursement, guidance on the use of PDMPs, guidance on naloxone dispensing, and guidance on documentation to ensure that pharmacists fulfill their corresponding responsibility. Such guidance from the organization may play a role in limiting liability to the corporation and employee pharmacists. Pharmacy corporations may also be able to make care more accessible by signaling their support for buprenorphine dispensing. Any guidance on buprenorphine dispensing developed by pharmacy corporations should be grounded in valid, clinical

evidence and should allow pharmacists to use their clinical judgement to make dispensing decisions that optimize the safety and effectiveness of care. The autonomy and the expertise of practicing pharmacists must be maintained. Corporate policy is blind to individual patient circumstance and must, therefore, not interfere with the pharmacists' ability to provide care.

Improving Wholesaler Relationships

Rather than creating inhibitory policy, large pharmacy corporations should leverage their wholesaler relationships and purchasing power to negotiate the terms of suspicious order monitoring programs with wholesalers to ensure that pharmacies under their management can continuously be able to purchase buprenorphine. Doing so may eliminate "caps" on buprenorphine purchase. Individual wholesalers, rather than the DEA, are responsible for establishing the terms of suspicious order monitoring programs.¹² DEA has also signaled their support for flexibility in suspicious order monitoring programs to improve access to medication for OUD.¹¹ Pharmacy corporations, especially those that command significant market share, may be able to work closely with wholesalers to amend the terms of suspicious order monitoring programs to better serve the needs of persons with OUD.

Engaging Pharmacists In Corporate Decision Making

The creation of flexible, patient centered corporate policy; clinically meaningful guidance for pharmacists and renegotiating the terms of suspicious order monitoring programs would allow for pharmacy corporations to serve persons with OUD more effectively. Appointing pharmacists to lead these initiatives within pharmacy corporations would ensure applicability to employee pharmacists and potentially lead to the creation of more practical corporate initiatives.

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