Reducing Barriers to Medications for Opioid Use Disorder Commonwealth Guidance

This guidance is intended for prescribers, pharmacists, and other health professionals who help patients access medications for opioid use disorder (MOUD).

Since the end of 2022, the Pennsylvania Department of Health (PA DOH) has received an increase in complaints regarding controlled substance availability at pharmacies. Patients have reported:

- Difficulty in filling their prescriptions for controlled substances-particularly opioids for pain management, benzodiazepines, and buprenorphine.
- Having to call or visit multiple retail pharmacies to find one that had their medication in-stock.
- Receiving lower doses than their prescriptions called for or not a full supply.

In April 2024, PA DOH joined the U.S. Drug Enforcement Administration (DEA), Philadelphia Division to discuss best practices regarding prescribed controlled substances, specifically MOUD. PA DOH invited professional associations for both pharmacists and prescribers; local and chain pharmacies; health care systems and facilities; single county authorities; harm reduction organizations; and state and federal partners to attend this session.

During the session, the DEA Philadelphia Division and PA DOH answered a variety of questions across topics, including DEA investigation and enforcement practices, the different forms of MOUD, buprenorphine prescribing and diversion, continuity of care, and telehealth prescriptions.

In this document, Commonwealth agencies and boards including **PA DOH**, the **Pennsylvania Department of Drug and Alcohol Programs (PA DDAP)**, and the **Pennsylvania (PA) State Board of Pharmacy** answer a selection of prescribers' and pharmacists' most frequently asked questions.

Quick Access Resources

American Society of Addiction Medicine (ASAM) Criteria, Third Edition

- The ASAM Criteria provides comprehensive guidelines for assessing and treating individuals with substance use disorders, offering prescribers and pharmacists a valuable framework to enhance patient care through standardized criteria for placement, continued stay, and discharge decisions in addiction treatment.

ASAM National Practice Guideline for the Treatment of Opioid Use Disorder – 2020 Focused Update

- The ASAM National Practice Guideline offers evidence-based recommendations for the treatment of opioid use disorder, focusing on a comprehensive approach that integrates pharmacotherapy, psychosocial support, and individualized care to improve patient outcomes.

Distributor Settlement Agreement of July 2021 (PDF)

- The Distributor Settlement Agreement, dated July 21, 2021, outlines the terms for resolving claims among the Settling States, Settling Distributors, and Participating Subdivisions related to opioid misuse.

Electronic Prescribing of Controlled Substances FAQ

- This is an interim guidance from the Pennsylvania Department of Health on electronic prescribing of controlled substances until regulations are formalized by the Department, pursuant to Act 96 of 2018.

National Association of Boards of Pharmacy (NABP) Toolkits and Resources

- The NABP's medication treatment toolkits page provides pharmacists and prescribers with essential resources and guidelines to effectively implement medication-assisted treatment for opioid use disorder, enhancing patient care and accessibility to necessary treatments.

NABP's Buprenorphine Guidance Document (PDF)

- The NABP's buprenorphine guidance document assists pharmacists in navigating regulatory aspects of dispensing buprenorphine amid policy changes that promote accessibility, emphasizing the importance of verifying prescriptions to prevent misuse while ensuring patients with opioid use disorder receive timely treatment, ultimately aiming to balance the responsibilities of pharmacists with the urgent care needs of this population.

Pennsylvania Department of Health (PA DOH) Naloxone Resources

- The PA DOH's naloxone page provides essential information on naloxone as an opioid overdose reversal drug, detailing its availability, how to use it, and the importance of training for individuals to help combat the opioid crisis effectively.

Pennsylvania Prescription Drug Monitoring Program (PA PDMP) Dispenser Q&A

- The PA PDMP Q&A page offers detailed information for dispensers regarding their responsibilities, how to access the PDMP system, and the importance of monitoring prescription data to prevent opioid misuse and ensure patient safety.

U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) TIP 63 on MOUD (PDF)

- TIP 63 from the U.S. Substance Abuse and Mental Health Services Administration provides comprehensive guidelines on the use of medications for opioid use disorder, emphasizing evidence-based treatment approaches, patient-centered care, and the integration of pharmacotherapy with psychosocial support to improve outcomes for individuals with opioid dependence.

SAMHSA's Waiver Elimination (MAT Act) Resource

- The SAMHSA page on the waiver elimination under the MAT Act outlines changes that allow qualified healthcare providers to prescribe medications for opioid use disorder without needing a specific waiver, thereby increasing access to treatment for individuals suffering from opioid addiction.

SUBLOCADE® Risk Evaluation and Mitigation Strategy (REMS)

- The SUBLOCADE® website provides information about SUBLOCADE®, a once-monthly injectable medication for the treatment of opioid use disorder, highlighting its benefits, dosing information, and the importance of comprehensive treatment plans.

Acronyms

ASAM	American Society of Addiction Medicine
CDC	U.S. Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
DEA	U.S. Drug Enforcement Administration
FDA	U.S. Food and Drug Administration
MOUD	Medications for Opioid Use Disorder
NABP	National Association of Boards of Pharmacy
OBOT	Office-Based Opioid Treatment
ODSMP	Office of Drug Surveillance and Misuse Prevention
OTP	Opioid Treatment Program
OUD	Opioid Use Disorder
PA DDAP	Pennsylvania Department of Drug and Alcohol Programs
PA DOH	Pennsylvania Department of Health
PA PDMP	Pennsylvania Prescription Drug Monitoring Program
SAMHSA	U.S. Substance Abuse and Mental Health Services Administration
SCA	Single County Authority
SUBLOCADE® REMS	SUBLOCADE® Risk Evaluation and Mitigation Strategy
SUD	Substance Use Disorder
TIP	Treatment Improvement Protocol

Guidance

Ordering & Stocking

Can PA DOH help with the ordering thresholds put in place by pharmaceutical distributors? If not, what can prescribers and pharmacists do to overcome threshold issues?

PA DOH does not have the authority to establish or change distributor thresholds. According to the Distributor Settlement Agreement of July 2021, distributors must have a mechanism in place to detect suspicious orders that complies with federal and state laws, including injunctive relief terms established by opioid settlement agreements. Suspicious orders may be orders of unusual size, frequency, or pattern. PA DOH encourages pharmacies to communicate with their distributors and work collaboratively to adjust thresholds when patient volume necessitates.

If a group of new patients moves their care to a specific pharmacy after another pharmacy closes, how should that pharmacy handle the influx of patients?
Communication between pharmacies and distributors in advance of a suspected increase in patients is essential. PA DOH recommends that the pharmacy contact the distributor to notify them of the expected increase in new patients. The distributor should be able to use this information to supply the pharmacy with medications needed to meet the demand. If the distributor cannot be informed before the increase in patients, communicate with them as soon as possible to work out a solution.

What are the different forms of MOUD that pharmacies should stock?
Stocking is at the discretion of the pharmacies, and stocking may vary due to the supply and demand of an individual pharmacy's customers. However, the PA DOH encourages pharmacies to use their best judgment to ensure that patients receive the medications they need. Low barrier, uninterrupted access to MOUD is necessary to ensure a patient can continue their opioid use disorder treatment. Sudden or abrupt discontinuation of buprenorphine can lead to withdrawal and/or life-threatening symptoms such as physical and psychological distress, return to substance use, overdose, and overdose death.
For more information about the different types of MOUD and their functions, please see the SAMHSA's TIP 63 on MOUD.

Can controlled substances be stored at a pharmacy? Are pharmacies required to order and reorder controlled substances only when the refill is due?
Pharmacies licensed by the DEA can store/stock/order onsite any controlled substance if they are recorded and stored securely. PA DOH encourages pharmacies to stock what they need to support the needs of their patients – subject to proper maintenance of records and security.

Can controlled substances be stored at a correctional facility when ordered in advance or a refill?
Correctional facilities may order controlled substances in advance of when a refill is due, as long as they can provide the appropriate resources needed to store the products, such as a refrigerator if it is required for the product.

What was the DATA-2000/X-waiver removal and what is its impact on MOUD prescriptions?
In 2023, Section 1262 of the Federal Consolidated Appropriations Act removed the requirement for prescribers to apply for a DATA-2000 waiver (also known as the X-waiver) prior to prescribing buprenorphine for OUD. The Act also removed waiver requirements such as discipline restrictions, patient limits, and certification related to the provision of counseling.

Due to the elimination of the DATA-2000 waiver, some pharmacies may see more patients with prescriptions for buprenorphine. PA DOH encourages pharmacies to work with their distributors if they notice an increase in the number of patients and to adjust ordering thresholds accordingly. Pharmacies have an important role to fill buprenorphine prescriptions to ensure patients have access to timely, evidence-based treatment for OUD and avoid lapses in care.

For more information about the elimination of the DATA waiver, see SAMHSA's Waiver Elimination (MAT Act) resource.

Investigation & Enforcement

What are the steps for investigating concerns related to diversion of medications, and when should concerned parties involve law enforcement?

To help prevent prescription drug misuse and protect the health and safety of our community, the PA PDMP collects information on all filled prescriptions for controlled substances. This information helps health care providers safely prescribe controlled substances and helps patients get the treatment they need. The PA PDMP System is also a vital public health tool, providing critical data for planning, resource allocation, and evaluation efforts related to the overdose epidemic in Pennsylvania.

If you suspect suspicious activity involving prescription medication (i.e., fraudulent, stolen, or altered prescriptions; a suspicious doctor/pharmacy/individual obtaining prescription drugs for any purpose other than the treatment of an existing medical condition), please complete the Pennsylvania Office of Attorney General's Suspicious Activity Report.

Dispensation

What should pharmacists and prescribers do if a patient runs out of their medication early?

For more information about dispensation to patients who ran out of their medication early, please see the NABP's Medication for Opioid Use Disorder Guideline.

What are best practices for ordering and dispensing controlled substances for opioid withdrawal management through an inpatient hospital pharmacy for administration in an acute care hospital?

Having buprenorphine and or methadone available at inpatient hospital pharmacies to initiate OUD treatment is a best practice. For more information about medically supervised withdrawal, please see the SAMHSA's TIP 63 on MOUD.

What is the appropriate rule for how early pharmacists can fill a controlled substance?

Pharmacists and pharmacy teams are encouraged to use their best clinical judgment and consider the patient's clinical situation, functioning, and life context when making dispensing decisions. Abrupt discontinuation as a result of not having access to a prescribed controlled substance can present serious risks to patients, including withdrawal symptoms. Patients may consider other, non-prescribed sources to avoid withdrawal, which puts them at risk for overdose. Low barrier access to MOUD is necessary to ensure that a patient is able to continue their OUD treatment. Pharmacies and pharmacy staff have an important role to play in ensuring that patients have access to controlled substances that they are prescribed.

Can there be refills on prescriptions for controlled substances?
The guidelines for prescriptions and ordering for controlled substances are generally overseen by the DEA. According to the PA State Board of Pharmacy's regulations, Prescriptions for Schedule II controlled substances may not be refilled. A controlled substance in Schedule III, IV or V may not be filled or refilled more than five times in the 6-month period from the date of the prescription.

Pennsylvania Prescription Drug Monitoring Program (PA PDMP)

What is PA law regarding dispensing pharmacist updating the PA PDMP?
Pharmacies and dispensing prescribers must submit all controlled substance (Schedules II–V) dispensation information to the PA PDMP system no later than the close of the subsequent business day after dispensing a controlled substance. A business day is any day within the standard five-day business week beginning on Monday and ending on Friday. Dispensers are encouraged to submit every day as well as on weekends if they are open for business.
For more information, see PA PDMP's Dispenser Q&A.

Will the records of medications administered via outpatient OUD clinics be integrated into the PA PDMP in the future?
At this time, the PA PDMP does not have a mechanism to collect and document patient consent required by 42 CFR Part 2. Additionally, the PA PDMP does not currently have a mechanism to separate medical records related to substance use disorder from other dispensation records. This is necessary to ensure these records are not viewable by other users specific to PA's PDMP that are not covered under Part 2. DDAP and PA Department of Human Services to establish a mechanism to collect patient consent and relevant data.

Please note, any MOUD drug dispensed at a retail pharmacy is already collected by the PA PDMP. The above relates to medications dispensed in the context of a part 2 covered treatment program.

Are there any upcoming changes to electronic submissions of controlled substances?
Per Act 96 of 2018, practitioners, excluding those with statutory exceptions, are required to issue electronic prescriptions for Schedule II-V controlled substances as of October 24, 2019. PA DOH is in the process of promulgating electronic prescriptions for controlled substances regulations in accordance with Act 96.

Are pharmacists allowed to transfer an electronic prescription of a controlled substance to a different pharmacy?
Per the Pennsylvania Pharmacy Act, pharmacies cannot transfer Schedule II controlled substances but are allowed to transfer prescriptions for Schedule III-V drugs. However, pharmacies may have internal or corporate policies that may be different than the law.

DOH's FAQ about electronic prescribing of controlled substances may be helpful.

Buprenorphine

How common is the diversion and misuse of buprenorphine?
The National Institute on Drug Abuse (NIDA) recognizes "while there is some risk associated with misuse of buprenorphine, the risk of harms, such as fatal overdose, are significantly lower than those of full agonist opioids (oxycodone, hydrocodone, heroin)." (NIDA, 2021).

The U.S. Department of Health and Human Services Office of Inspector General published a report on the risk of misuse and diversion of buprenorphine for those enrolled in Medicare Part D which found that the risk of misuse and diversion is low (OIG, 2023).

Buprenorphine is a life-sustaining medication. Sudden or abrupt discontinuation of buprenorphine can lead to withdrawal and/or life-threatening symptoms such as physical and psychological distress, return to substance use, overdose, and overdose death. Access to buprenorphine is critical, and pharmacies are encouraged to work with patients to ensure buprenorphine is accessible.

For more information about the importance of buprenorphine access, see the joint letter written by the American Society of Addiction Medicine, the American Medical Association, American Pharmacists Association, and American Society of Health-System Pharmacists to the DEA, SAMHSA, U.S. Department of Health and Human Services, and White House Office of National Drug Control Policy.

What factors prompt an investigation of pharmacies for dispensing buprenorphine?
Pharmacies must follow the guidelines that comprise the Controlled Substance Act, including the assurance that there is a doctor/patient relationship, that the doctor and dispenser acted in good faith, and the patient needs the medication. For more information about best practices when dispensing buprenorphine, please see the NABP's Medication for Opioid Use Disorder Guideline.

Are there any concerns about using monotherapy buprenorphine over the buprenorphine/naloxone combination product?
SAMHSA's TIP 63 recommends the use of buprenorphine/naloxone combination products for patients when it is "medically indicated" and affordable for the patient. The monotherapy product should be considered for pregnant patients and patients who "could not afford treatment if the combination product were required, who have a history of stability in treatment and low diversion risk, or who have arrangements for observed dosing." (SAMHSA, p. 3-100).

For more information on monotherapy, please see the NABP's Medication for Opioid Use Disorder Guideline.

Would the PA DDAP recommend the prescription of SUBLOCADE® in long term care facilities? Would the PA DDAP recommend prescribing suboxone/vivitrol for people who do not use opioids?
PA DDAP does not direct the clinical decisions of prescribers, pharmacists, or pharmacy teams or policies of health systems and pharmacies. Prescribers, pharmacists, and pharmacy teams are encouraged to use

their best clinical judgment and consider the individual's clinical situation, functioning, and life context when making prescribing or dispensing decisions.

PA DDAP recommends prescribers review The ASAM Criteria, Third Edition and The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder – 2020 Focused Update to assist with clinical decision-making and utilize the ASAM criteria to determine the medication most appropriate for individuals with OUD. These guidelines address individuals in all settings.

Have there been considerations for Office Based Opioid Treatment programs (OBOTs) that have registered mobile clinics to transport SUBLOCADE® to treat and administer it to patients?
A facility does not have to be an Opioid Treatment Program (OTP) to order a stock supply of SUBLOCADE®. The only requirement is to be certified in the SUBLOCADE® REMS. PA DDAP does not license OBOTs that are engaged in the practice of medicine, so there would be no requirement to license a mobile OBOT unless that mobile component intends to provide substance use disorder treatment services in addition to MOUD, such as counseling.

Are there any concerns with out-of-state patients coming to Pennsylvania to fill prescriptions?

According to the PA State Board of Pharmacy, there is no concern with out-of-state patients filling prescriptions in Pennsylvania as long as the prescriptions comply with both federal and state regulations. The PA State Board of Pharmacy cannot comment on the requirements of other states.

Is there a list of SUBLOCADE® pharmacy vendors to compare rates?
Pharmacies should work with distributors regarding pricing. For more information, see the SUBLOCADE® REMS.

Telehealth

Are there Pennsylvania regulations specific to telehealth for pharmacists?
While telehealth regulations exist for various boards, there is no specific telehealth regulation by the PA State Board of Pharmacy for pharmacists. Pharmacists are permitted to conduct counseling and receive prescriptions via telephone.

Continuity of Care

Can a prescriber initiate a patient on methadone while the patient is admitted to an acute care hospital?
Hospitals have the authority to begin treatment for OUD under 21 CFR Part 1306 -- Prescriptions. The regulation states the hospitalist “may administer or directly dispense (but not prescribe).” The regulation further states, “not more than one day’s medication may be administered to the person or

for the person's use at one time. Such emergency treatment may be carried out for not more than three days and may not be renewed or extended."

PA DDAP recommends that hospitals have referral agreements with a local OTP, so the process is in place and streamlined for the hospital and the OTP. The SCA can work with the hospital to make these arrangements. See Pennsylvania Association of County Drug and Alcohol Administrators - Member Directory (pacdaa.org) for more information.

Could you speak to an emergency department dispensing a few doses of suboxone for outpatient use ("go pack")?
According to federal law, 21 CFR 1306.07(b) states, "Nothing in this section shall prohibit a physician who is not specifically registered to conduct a narcotic treatment program from administering (but not prescribing) narcotic drugs to a person for the purpose of relieving acute withdrawal symptoms when necessary while arrangements are being made for referral for treatment. Not more than one day's medication may be administered to the person or for the person's use at one time. Such emergency treatment may be carried out for not more than three days and may not be renewed or extended."

Please clarify the requirements in which a community pharmacy may dispense methadone for opioid use disorder in emergent/urgent scenario. Current rules allow hospitals to provide methadone for opioid use disorder but do not address pharmacies specifically?
There is no ability for a community pharmacy to dispense methadone for opioid use disorder without a prescription. Hospitals, namely physicians, can provide those medications for three days as noted in 21 CFR 1306.07(b). However, there is no allowance for a pharmacist to dispense these medications without a prescription from an appropriate medical professional.

Overdose Reversal & Harm Reduction

Can naloxone be used to combat fentanyl and xylazine overdoses?
Naloxone is a medication that can reverse an overdose that is caused by an opioid drug (i.e., prescription pain medication, heroin, or fentanyl). When administered during an overdose, naloxone blocks the effects of opioids on the brain and restores breathing within 2 to 3 minutes. One brand of naloxone is NARCAN™, which is now available over the counter.
PA DOH encourages the administration of naloxone for **any suspected overdose**. While there is no documented effective antidote for the effects of xylazine, naloxone should always be administered for all suspected overdoses, as xylazine is most often used in combination with opioids.
For more information about naloxone, visit the PA DOH's Naloxone page, or view the naloxone product fact sheet.

Currently, there are no FDA-approved medications for use in humans that reverse the effects of xylazine. However, xylazine is commonly found in combination with opioids, like fentanyl, and naloxone should be administered any time a drug-related overdose is suspected.

How will the Department of Health provide education on harm reduction?
Harm reduction is vital to reducing nonfatal and fatal overdoses. PA DOH's ODSMP is committed to bolstering best practices in harm reduction across the Commonwealth and developing funding opportunities to expand harm reduction services. ODSMP is committed to bolstering best practices in harm reduction across the Commonwealth and developing funding opportunities to expand harm reduction services.

ODSMP is using CDC Overdose Data to Action in States funding to provide grant funds to harm reduction organizations in Pennsylvania to provide linkage to care services via navigators and expand overdose education and naloxone distribution programs among people who use drugs. Additionally, current ODSMP activities geared towards harm reduction include: administering funding for emergency departments, harm reduction organizations, and community-based organizations to increase linkage to harm reduction resources via navigators; providing education to health care providers and care teams on the use of harm reduction principles and distribution of naloxone in clinical practice; providing education to public safety professionals on naloxone use and leave-behind; and distributing harm reduction supplies such as xylazine-associated wound care kits and naloxone leave-behind kits directly to organizations across the Commonwealth who provide services to people who use drugs..

Many patients receive methadone for MOUD at the same dose for years. Is the goal of methadone therapy to decrease dose and eventually become free of therapy? Or is the goal to remain on methadone therapy for life?
OUD is a **chronic**, **relapsing** illness. As such, medication for OUD is a clinical decision between the physician and the individual receiving services. **Like medication for other chronic illnesses**, medication for MOUD could be short-term, long-term, or for a lifetime.

CDC Prescribing Guidelines

Any guidance on patients who are prescribed a benzodiazepine and an opioid who clinically need both?
PA DOH does not dictate the clinical decisions of prescribers, pharmacists/pharmacy teams, or policies of health systems and pharmacies. Prescribers, pharmacists, and pharmacy teams are encouraged to use their best clinical judgment and consider the patient's clinical situation, functioning, and life context when making individual prescribing or dispensing decisions.
For more information, view the CDC's Clinical Practice Guideline for Prescribing Opioids for Pain. Recommendation 11 of the guidelines discusses prescribing opioid pain medication and benzodiazepines concurrently. These guidelines are intended to help clinicians improve patient outcomes and to supplement, but not replace, the individual clinician's judgment.

References

Substance Abuse and Mental Health Services Administration (SAMHSA). (2021). Medications for opioid use disorder for healthcare and addiction professionals, policymakers, patients, and families. *Treatment Improvement Protocol, 63*. https://store.samhsa.gov/sites/default/files/pep21-02-01-002.pdf

NIDA. 2021, April 13. What is the treatment need versus the diversion risk for opioid use disorder treatment? https://nida.nih.gov/publications/research-reports/medications-to-treat-opioid-addiction/what-treatment-need-versus-diversion-risk-opioid-use-disorder-treatment

U.S. Department of Health and Human Services Office of Inspector General (OIG). (November 2023). *The risk of misuse and diversion of buprenorphine for opioid use disorder in Medicare Part D continues to appear low: 2022*. https://oig.hhs.gov/documents/evaluation/2723/OEI-02-24-00130-Complete%20Report.pdf