Diversion Control Protocol Template for Opioid Use Disorder Treatment Providers

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Background

Pharmacotherapy for opioid use disorder (OUD) is an evidence-based intervention that uses Food and Drug Administration (FDA)-approved medications (i.e., buprenorphine, methadone, and oral and extended-release injectable naltrexone). Pharmacotherapy combined with counseling and behavioral therapies as well as social, peer, and recovery support services may be referred to as medication-assisted treatment (MAT).[1] The expansion of access to pharmacotherapy for OUD, including the introduction of office-based treatment with buprenorphine is a critical and life-saving element of the national and community-level response to illicit and nonmedical opioid use and overdose. In view of the known diversion of prescribed opioids pain relievers, it is natural that concerns about the diversion of legally prescribed or dispensed buprenorphine or methadone should arise. Surveillance data and published literature indicate the risk for diversion of buprenorphine, and to a much lesser extent methadone, is real.[2]

Addressing buprenorphine diversion risk is complex, given the motivations for diverting it and the resulting personal, program, and public safety issues. It is essential to consider these complexities when developing or expanding approaches to expanding access to pharmacotherapy.

Opioid treatment programs (OTPs) are required to have diversion control plans (DCPs), as per Federal and in some cases State regulations. DCPs should be implemented in substance use disorder (SUD) treatment settings for which such regulations may not exist, such as office-based buprenorphine treatment, federally qualified health centers, and community mental health centers.

Purpose and Audience

This Substance Abuse and Mental Health Services Administration (SAMHSA)-recommended template is intended to provide guidance for the development and implementation of DCP protocols and procedures across OUD treatment settings that are not OTPs.

This template combines adaptations of diversion control strategies for OTPs described in the *Federal Guidelines for Opioid Treatment Programs* and adherence monitoring approaches that address diversion in SAMHSA's *Sublingual and Transmucosal Buprenorphine for Opioid Use Disorder: Review and Update* to support positive patient outcomes while minimizing risks associated with buprenorphine diversion.

Diversion and Public Safety

Misuse of diverted buprenorphine is associated with less severe medical emergencies and outcomes than misuse of diverted methadone.[3] There are several reports of buprenorphine being used to successfully treat heroin overdose.[4, 5] While, nonmedical use seems to be associated with a risk for nonfatal overdose among people who only occasionally use opioids.[6]

Moreover, when a legally prescribed medication enters an illicit market, there are public safety concerns, including the following:

- There is a risk for pediatric exposure, which is often more dangerous than accidental exposure in adults.[7]
- Intravenous buprenorphine use[8] contributes to injection-related public safety risks such as discarded injection equipment and blood-borne virus transmission.
- Medication taken without medical oversight could have deleterious interactions with other medications or illicit substances.

A final and important negative public safety impact of buprenorphine diversion is its effect on community, treatment systems, and provider perceptions of buprenorphine treatment. Treatment of an OUD with buprenorphine is associated with a wide array of individual- and community-level improvements as well as cost savings. However, providers, drug courts, and others adopt negative views of buprenorphine overall when exposed to diverted buprenorphine.[9, 10, 11]

Diversion and Patient Outcomes

Treatment adherence as-prescribed is an important contributor to positive clinical outcomes. Negative or dangerous implications of diversion include the following:[12]

- Prescribers could make inaccurate decisions about medication safety, assessment of dose efficacy, tapering buprenorphine or transitioning to another treatment agent because the prescriber assumes the patient is taking the prescribed dose, which would not be the case if the patient diverts buprenorphine.
- If an individual reduces or changes their dose of buprenorphine in favor of diverting it, withdrawal symptoms and increased cravings can occur. Withdrawal symptoms and cravings can put the individual at increased risk for resumed use of illicit opioids.
- Consistent (i.e., no diversion) versus inconsistent (i.e., possible diversion) consumption of the prescribed dose may affect the successes of behavioral treatment.[13]
- Patients engaged in buprenorphine diversion, risk involvement with the legal system, which can negatively influence treatment attendance and outcomes.

Clearly communicate to patients that patient safety and resolved OUD symptoms are major reasons for implementing and enforcing strategies to minimize diversion.

Why Do People Divert Buprenorphine?

There are two main reasons why a patient treated with buprenorphine might divert their medication:

- Some individuals sell or trade some or all their buprenorphine for money or goods.[14] Knowing this information is important because it might represent a missed case management opportunity to support patients in accessing employment, housing, food or other services.

- Others might be diverting all or some buprenorphine to nonmedically treat the OUD of a family or friend who is unable or unwilling to access OUD treatment.[15, 16, 17] Knowing this information is important because helping family and friends access treatment can improve the patient's outcomes.

The goal of a DCP should be to protect the health of the public by minimizing diversion, maximizing positive patient outcomes, and preserving therapeutic engagement around possible risks and motivations for diversion.

How to Use This Template

There are two parts to this template:

Part I. Program focuses on the environmental, logistical, and staff-related diversion prevention strategies at the program level.

Part II. Patient relates directly to patient variables such as dosing, schedule, unsupervised use of medication, comorbid substance use and seeing multiple providers.

Both parts include sample procedures drawn from existing DCPs. For each part, you should determine the risk factors and strategies most appropriate for your treatment setting and enter them in the fillable PDF section. List the staff title/position responsible for each procedure that you are implementing. Both parts of this template also include a section for strategies to minimize negative impacts on the therapeutic relationship with the patient—sample strategies are provided for this. For additional information and guidance, please review the list of resources on page 9.

Part I. Program

SAMHSA's guidelines for OTPs state: "Diversion in the program environment can be deterred and detected by regular surveillance and monitoring of areas in and around the program, where opportunities for diversion may exist."[18] Buprenorphine may be provided in many different venues outside of OTPs. For this reason, some of the procedures that are critical for OTPs may not apply or might need to be adapted for non-OTP settings. For example, OTPs store and dispense medication, thus DCPs for OTPs involve considerable attention to secure medication storage and inventory control. An example of a modification for office-based buprenorphine where medication is not stored for administration to patients might focus on securing prescription pads, developing a relationship with a pharmacy where most patients fill prescriptions, and checking the prescription drug monitoring program (PDMP). Each procedure should be considered based on the likelihood of reducing diversion risk and balanced against any possible negative impact on the therapeutic environment of the program. Policies and procedures adopted to reduce diversion risk should include strategies to mitigate this risk.

Use the template below to plan your diversion control policies and procedures and accompanying steps to prevent compromising the program's therapeutic milieu. Be sure to list the staff person responsible for each policy or procedure by title or position.

These are examples of procedures related to program, environment, and staff:

- Maintain secure storage and strict inventory of all medications stored on site.
- Use tamper resistant prescription pads and secure them when not in use.
- Be responsive to calls from pharmacies or pharmacists and other treating providers.
- Prescribe the buprenorphine/naloxone combination versus buprenorphine mono-product, except during pregnancy or other clinically justified situations.
- Maintain tidy and well-lit facilities both inside and out.
- Create a recovery-oriented program environment so that patients struggling with poly-substance use or return to substance use receive respectful support rather than conceal their substance use to avoid consequences.
- Develop policies to formally welcome and include family members, friends, and the community in program activities.

These are examples of strategies to mitigate the risk for damaging the provider-patient relationship:

- Provide specific voluntary opportunities for patients to convene, socialize, and informally support each other, if desired, and minimize ad hoc gatherings.
- Provide staff sensitivity training related to SUD and other mental health conditions; include front desk and administrative staff.
- Design and staff your program to assure appropriately trained professionals and peers are responsive to the needs of patients.
- Use recovery support services and peers to respond promptly to individual- or community-level stressors associated with risk of return to substance use.

Part I. Program	
Procedure	**Staff Responsible (Title/Position)**
Strategies to minimize damage to therapeutic alliance	

Part II. Patient

Effective monitoring of adherence and response to treatment can increase the likelihood of positive clinical outcomes and reduce the possibility of diversion. Each procedure should be evaluated for capacity to reduce diversion and examined for risk of creating an atmosphere of mistrust or otherwise damaging a therapeutic relationship. When possible, indicate strategies to mitigate this risk.

Insert your patient-related diversion control procedures in the box below. Use the template below to plan your diversion control policies and procedures and accompanying steps to prevent compromising the program's therapeutic milieu. List the staff title/position responsible for each procedure.

These are examples of procedures related to patients:

- Inform patients that the program regularly checks the State PDMP and routinely reviews the PDMP findings with the patient.
- Obtain consent to coordinate care with other treating providers.
- Conduct medication counts and require observed dosing at unpredictable intervals.
- Obtain specimens for toxicology testing any unpredictable intervals. Use appropriate strategies to limit specimen tampering (i.e., use a variety of testing procedures such as urine, breathalyzer, and saliva testing; monitor the temperature of urine specimens; and consider measuring specific gravity or other values to help detect dilution or falsification).
- Test for substances based on the individual patient's history, substances and pharmaceutical commonly abused in your area, and expected metabolites of prescribed medications.
- Respond to unexpected toxicology results with increased therapeutic engagement and services rather than punishment.
- Use quantitative testing methods to confirm positive screening test results.
- Provide prescribed medications through a single, agreed upon pharmacy.
- Abide by a predictable set of rules regarding steps required to refill medication (i.e., treatment compliance, provider communication, toxicology testing, and medication inventory).
- Make sure patients fully understand the risks and benefits of the chosen treatment and the need to participate in behavioral therapy and recovery support services for treatment success.
- Address or coordinate care for the patient's comorbid medical and psychiatric conditions including pain.
- Address a return to substance use as an exacerbation of the underlying substance use disorder rather than as a failure and provide intensified services including recovery support services and, when appropriate, referral to a higher level of care to support achieving disease remission and engagement in recovery.
- Discuss proper storage of medications, including lockable boxes. Discuss storage plan for patients who are homeless or unstably housed.

These are examples of strategies to mitigate the risk for damaging the provider-patient relationship:

- If diversion is suspected discuss the concern with the patient and identify motivation for diversion.
- Mitigate wherever possible drivers and motivations associated with diversion.
- Make sure staff are available to assist patients in times of stress to prevent relapse and promote prompt stabilization if relapse occurs.
- Foster an attitude of personal stewardship of pharmacotherapy for opioid use disorder and a sense of social accountability for consequences of diversion as part of recovery.

Interpretation of unexpected drug screen results is important to retaining patients in care. Consider including some additional components in the DCP:

- In the case of diversion, the most concerning finding in a urine drug screen is one that is negative for buprenorphine. Most urine drug screens will be positive for buprenorphine/norbuprenorphine for 2–3 days after last dose.
- If the patient has a urine drug screen negative for buprenorphine and positive for other types of opioids, this is consistent with continued opioid use and cessation of buprenorphine. In these cases, a conversation with the patient about goals for treatment is warranted. If the patient is interested in continuing treatment, re-induction is warranted. It is possible that the original dose of buprenorphine might be too low, or that psychosocial supports may need to be increased.
- If the patient has a urine drug screen that is negative for buprenorphine and negative for other types of opioids, it implies that the patient has not taken buprenorphine or opioids that are captured in your screen for 2–3 days. It is important to know which types of opioids the urine drug screen you are using captures. For example, many drug screens do not include fentanyl, so if a patient had stopped using buprenorphine but is using illicit fentanyl, the urine drug screen will appear negative for opioids on the standard opioid screen. Other possible explanations include: (1) the individual is not using opioids at this time and is diverting the medication, or (2) the individual brought in urine from someone else who is not taking any substances (in which case checking the temperature reading on the urine at the time of collection is helpful). Talk to the patient about their current treatment goals, and if they are interested in continuing treatment—re-induction is warranted. It is possible that the original dose of buprenorphine might be too low, or that psychosocial supports may need to be increased.
- It is considered best practice to document awareness/confirmation of any unexpected urine drug screen results in the chart and to discuss them with the patient and the care team, and when appropriate to include adjustments to the treatment plan (e.g., increased medication dose, increased frequency of visits, increased psychosocial support).
- Consider dosing adjustments that maintain the patient on a dose that is effective for the reduction of craving while having the least potential for diversion.

Part II. Patient	
Procedure	**Staff Responsible (Title/Position)**
Strategies to minimize damage to therapeutic alliance	

Summary

OUD treatment providers are well-positioned to provide vital education to patients and family members regarding the importance of using medications as prescribed, to identify potential diversion activity, and to intervene in the case of confirmed diversion. Systems and protocols for prescribing, monitoring, dispensing, and safely disposing of MAT medications need to be implemented by all OUD treatment providers regardless of treatment setting to mitigate the risk of nonmedical use and diversion of the medications. OUD treatment providers that are not OTPs can utilize this DCP template to develop formal diversion control protocols and procedures. OUD treatment providers can supplement this template by reviewing the existing resources listed below.

Resources

- Substance Abuse and Mental Health Services Administration. *Federal guidelines for opioid treatment programs.* HHS Publication No. (SMA) PEP15-FEDGUIDEOTP. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2015. https://store.samhsa.gov/shin/content/PEP15-FEDGUIDEOTP/PEP15-FEDGUIDEOTP.pdf. Accessed October 18, 2016.
- Technical Assistance Publication (TAP) 30: Buprenorphine: A Guide for Nurses
- TAP 32: Clinical Drug Testing in Primary Care
- Treatment Improvement Protocol (TIP) 40: Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction
- TIP 43: Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs
- Prescription Drug Monitoring Program Center of Excellence www.pdmpexcellence.org
- Prescription Drug Monitoring Program Training and Technical Assistance Center www.pdmpassist.org
- Providers' Clinical Support System for Medication Assisted Treatment www.pcssmat.org
- Centers for Medicare & Medicaid Services. *Partners in Integrity: What is a Prescriber's Role in Preventing the Diversion of Prescription Drug*. Baltimore, MD. Centers for Medicare & Medicaid Services; 2014. https://www.cms.gov/medicare-medicaid-coordination/fraud-prevention/medicaid-integrity-education/provider-education-toolkits/downloads/prescriber-role-drugdiversion.pdf. Accessed August 29, 2017.
- National Alliance for Model State Drug Laws www.namsdl.org/prescription-monitoring-programs.cfm
- Poison Help Line 1-800-222-1222 (24 hours a day, 7 days a week) www.aapcc.org
- Lowfall MR, Martin J, Tierney M, Fatséas M, Auriacombe M, Lintzeris N, Buprenorphine diversion and misuse in outpatient practice. *Journal of Addiction Medicine.* 2014; 8(5): 327-332.
- European Monitoring Centre for Drugs and Drug Addiction. *Perspectives on drugs: strategies to prevent diversion of opioid substitution treatment medications.* Lisbon, Portugal: European
- Monitoring Centre for Drugs and Drug Addiction; 2016. http://www.emcdda.europa.eu/system/files/attachments/2638/OST%20medications_POD2016.pdf. Accessed October 18, 2016.

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