Sample Buprenorphine Diversion Control Policy

XYZ Medical Practice

Office-Based Opioid Use Disorder Policy and Procedure Manual

Policy Title: Diversion Control for Patients Prescribed Transmucosal (Sublingual) Buprenorphine

Effective Date: _____ (Month, Day, Year)

This Diversion Control Policy is provided for educational and informational purposes only. It is intended to offer healthcare professionals guiding principles and policies regarding best practices in diversion control for patients who are prescribed buprenorphine. This policy is not intended to establish a legal or medical standard of care. Healthcare professionals should use their personal and professional judgment in interpreting these guidelines and applying them to the particular circumstances of their individual patients and practice arrangements. The information provided in this Policy is provided "as is" with no guarantee as to its accuracy or completeness.

Preamble: Healthcare professionals can now treat up to 275 patients with buprenorphine. This increased access may contribute to increased diversion, misuse, and related harms. Signs that a patient is misusing or diverting buprenorphine include (1) missed appointments; (2) requests for early refills because pills were lost, stolen, or other reasons; (3) urine screens negative for buprenorphine, positive for opioids; (4) claims of being allergic or intolerant to naloxone and requesting monotherapy; (5) nonhealing or fresh track marks; or (5) police reports of selling on the streets. Likewise, there are a range of reasons for diversion and misuse (e.g., diverting to family/friends with untreated opioid addiction with the intent of trying to "help" convince them to also get treatment; diverting to family/friends on a treatment waiting list; selling some or all of the medication to pay off old drug debts/purchase preferred opioid of misuse/pay for treatment in places where there are inadequate addiction treatment professionals taking private insurance or Medicaid for such reasons as inadequate reimbursement/no reimbursement/burdensome prior authorization process).

The safety and health of patients and others in the community could be at risk if misuse and diversion are not addressed proactively throughout treatment. The reputation of XYZ Medical Practice may also be put at risk.

Definitions: *Diversion* is defined as the unauthorized rerouting or misappropriation of prescription medication to someone other than for whom it was intended (including sharing or selling a prescribed medication); *misuse* includes taking medication in a manner, by route or by dose, other than prescribed.[377]

Purpose: Misuse and diversion should be defined and discussed with patients at the time of treatment entry; periodically throughout treatment, particularly when there have been returns to illicit drug use; and when suspected (e.g., incorrect buprenorphine pill/film count) or confirmed. These procedures will establish the steps to be taken to prevent, monitor, and respond to misuse and diversion of buprenorphine. The response should be therapeutic and matched to the patients' needs, as untreated opioid use disorder and treatment dropout/administrative discharges may lead to increased patient morbidity and mortality and further use of diverted medications or illicit opioids associated with overdose death.

Procedures for Prevention:

- Use buprenorphine/naloxone combination products when medically indicated and cost is not an issue. Reserve the daily buprenorphine monoproducts 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. Buprenorphine monoproducts are recommended for pregnant women.
- Counsel patients on safe storage of, and nonsharing of, medications. Patients must agree to safe storage of their medication. This is even more critical if there are children in the home where the patient lives. Counsel patients about acquiring locked devices and avoiding storage in parts of the home frequented by visitors (e.g., do not recommend storage in the kitchen or common bathrooms). Proactively discuss how medication should be stored and transported when traveling to minimize risk of unintended loss.
- Counsel patients on taking medication as instructed and not sharing medication. Explicitly explain to patients the definitions of diversion and misuse, with examples. Patients are required to take medication as instructed by the healthcare professional; for example, they may not crush or inject the medication.
- Check the prescription drug monitoring program for new patients and check regularly thereafter. Prescription drug monitoring program reports can be a useful resource when there is little history available or when there is a concern based on observation. Check for prescriptions that interact with buprenorphine and for other buprenorphine prescribers.

- Prescribe a therapeutic dose that is tailored to the patient's needs. Do not routinely provide an additional supply "just in case." Question patients who say they need a significantly higher dose, particularly when they are already at 24 mg per day of buprenorphine equivalents.
- Make sure the patient understands the practice's treatment agreement and prescription policies. The XYZ Medical Practice's treatment agreement and other documentation are clear about policies regarding number of doses in each prescription, refills, and rules on "lost" prescriptions. Review the policies in person with the patient. Offer an opportunity for questions. Patient and provider must sign the agreement. Review the policies again with the patient at subsequent appointments. See Sample Buprenorphine Treatment Agreement or Sample XR-NTX Treatment Agreement as needed.

Procedures for Monitoring:

- Request random urine tests. The presence of buprenorphine in the urine indicates that the patient has taken some portion of the prescribed dose. Absence of buprenorphine in the urine supports nonadherence. Testing for buprenorphine metabolites (which are present only if buprenorphine is metabolized) should periodically be included to minimize the possibility that buprenorphine is added directly to the urine sample. Dipstick tests can be subverted or replaced. A range of strategies can be used to minimize falsified urine collections, including (1) observed collection; (2) disallowing carry-in items (e.g., purses, backpacks) in the bathroom; (3) turning off running water and coloring toilet water to eliminate the possibility of dilution; (4) monitoring the bathroom door so that only one person can go in; and (5) testing the temperature of the urine immediately after voiding.
- Schedule unannounced pill/film counts. Periodically ask patients who are at high risk at initial or subsequent appointments to bring in their medication containers for a pill/film count.
- With unannounced monitoring (both pill/film counts and urine tests), the patient is contacted and must appear within a specified time period (e.g., 24 hours) after the phone call. If the patient doesn't show, then the provider should consider this as a positive indicator of misuse or diversion.
- Directly observe ingestion. Patients take medication in front of the healthcare professional or another qualified clinician and are observed until the medication dissolves in the mouth (transmucosal [sublingual or buccal] absorption). Patients who are having difficulty adhering to their buprenorphine can have their medication provided under direct observation in the office for a designated frequency (e.g., three times/week).
- Limit medication supply. When directly observed doses in the office are not practical, short prescription time spans can be used (e.g., weekly, 3 days at a time).

Procedures To Respond to Misuse or Diversion:

Misuse or diversion doesn't mean automatic discharge from the practice. However, it will require consideration of one or more of the following procedures:

- Evaluate the misuse and diversion. For instance, describe the incident of misuse (e.g., "the patient took the prescribed dose on three or more occasions by intravenous route immediately after starting treatment, stating that she believed the dose would not be adequate by sublingual route; she has just initiated treatment") or diversion ("the patient gave half of dose to his wife, who is still using heroin and was withdrawing, because he did not want her to have to buy heroin off the street; she is on a waiting list for treatment") and tailor the response to the behavior (e.g., reeducation of the patient on buprenorphine pharmacology in the first example above; assistance with treatment entry for the spouse in the second example). Reassess the treatment plan and patient progress. Strongly consider smaller supplies of medication and supervised dosing for any patient who is taking medication intravenously or intranasally or diverting, regardless of reason. Treatment structure may need to be increased, including more frequent appointments, supervised administration, and increased psychosocial support.
- Intensify treatment or level of care, if needed. Some patients may require an alternative treatment setting or pharmacotherapy such as methadone. The clinician will discuss these alternatives with the patient to ensure optimal patient outcome. This should be discussed at treatment onset so the patient is aware of the consequences of misuse and diversion.
- Document and describe the misuse and diversion incident. Also document the clinical thinking that supports the clinical response, which should be aimed at minimizing risk of diversion and misuse and treating the patient's opioid use disorder at the level of care needed.

Policy adapted from ASAM's *Office-Based Opioid Use Disorder Policy and Procedure Manual,* which is updated periodically; the most current version is available online (https://www.asam.org/docs/default-source/advocacy/sample-diversion-policy.pdf?sfvrsn=6).

Adapted with permission.[378]