

XYZ Medical Practice

Guidance 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 physicians 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. Physicians 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. ASAM will strive to update this Policy from time to time, but cannot ensure that the information provided herein is current at all times.

Preamble: With physicians having the ability to treat up to 275 patients with buprenorphine, there is concern that this increased access may contribute to increased diversion, misuse and related harms. There are a range of signs that a patient is misusing or diverting buprenorphine including but not limited to: (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 of naloxone, and requesting monotherapy; (5) non-healing or fresh track marks; or (5) police reports of selling on the streets. Likewise, there are a range of reasons of diversion and misuse (e.g., diverting to family/friends with untreated opioid addiction with patient trying to be “help” convince them to also get into treatment or get through time on a waiting list, selling some or all of medication in order to pay off old drug debts/purchase preferred opioid of abuse/pay for treatment in places where there are inadequate addiction work force taking private insurance or public Medicaid for multiple reasons [e.g., inadequate reimbursement/no reimbursement/burdensome PA process]).

The safety and health of the patient and others in the community could be at risk, if misuse and diversion are not addressed proactively and 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).¹

¹ Lofwall, Michelle, and Walsh, Sharon. “A Review of Buprenorphine Diversion and Misuse: The Current Evidence Based and Experiences from Around the World.” *Journal of Addiction Medicine*, Volume 8, Number 5. P. 316.

Misuse includes taking medication in a manner, by route or by dose, other than prescribed.²

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 lapses or relapses 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 matched to the patients' needs as untreated opioid use disorder and treatment drop-out/administrative discharges may lead to increased patient morbidity, mortality and further use of diverted medications or illicit opioids associated with overdose death.

Procedures for Prevention:

- **Use buprenorphine/naloxone combination products when cost is not an issue and medically indicated.** Reserve the daily buprenorphine mono-products for pregnant patients and patients who otherwise could not afford treatment if the combination product (i.e., buprenorphine/naloxone) was required, who have a history of stability in treatment and low diversion risk, or with arrangements for observed dosing. Buprenorphine-only products are recommended for pregnant women.
- **Counsel patients on safe storage of, and non-sharing 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 where visitors frequent (e.g., do not recommend storage in kitchen or common bathrooms). Proactively discuss how medication should be stored / transported when traveling to minimize risk of unintended loss.
- **Counsel patients on taking medication as instructed and not sharing medication. Explicitly explain to patients definitions of diversion and misuse with examples.** Patients are required to take medication as instructed by the physician, for example, they may not crush or inject the medication.
- **Check PDMP for new patients and check regularly thereafter.** PDMP 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 or if there are other buprenorphine prescribers.
- **Prescribe a therapeutic dose that is tailored to the patient's needs.** Don't 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/daily of buprenorphine equivalents.
- **Make sure the patient understands the practice's treatment agreement and prescription policies.** The XYZ Medical Practice's treatment agreement and/or other documentation is clear about the practice's policies regarding number of doses in each prescription, refills and rules regarding "lost" prescriptions. Review the policies in person

² Ibid, p. 316.

with the patient. Offer an opportunity for questions. The patient and provider must sign the agreement. Review the policies again with the patient at subsequent appointments. See Sample Treatment Agreement.

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 non-adherence. Testing for buprenorphine metabolites (only present if buprenorphine is metabolized) may 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 (purses, backpacks) into the bathroom; (3) turning off running water and coloring toilet water to eliminate 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 the initial or subsequent appointments to bring in their bottles 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 they do not show, then the provider should consider this as a positive indicator of misuse/diversion.

- **Directly observe ingestion.** In this kind of monitoring, the medication is taken in front of the physician or another qualified clinician and is 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, for example, weekly or three days at a time.

Procedures to Respond to Misuse or Diversion:

Misuse or diversion does not mean automatic discharge from the practice. However, it will require consideration of one or more of the procedures listed below.

- **Evaluate the misuse and diversion** – for instance, describe the incident of misuse (patient took prescribed dose on 1, 2, 3 or more occasions by intravenous route immediately after starting treatment stating believed dose would not be adequate by SL route; has just initiated treatment) or diversion (patient gave half of dose to wife who is still using heroin and was withdrawing because didn't want her to have to go out and buy heroin off the street and she is on a waiting list for treatment) and tailor the response to the behavior (e.g., re-education of patient on buprenorphine pharmacology in first case, assistance with treatment entry for spouse in second case). **Reassess treatment plan and patient progress. Strongly consider smaller supplies of medication and supervised dosing for any patient who is using medication intravenously and intranasally and 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 assure optimal patient outcome. This should be discussed at treatment onset so that patient is aware of consequences of misuse/diversion.
- **Document and describe the misuse and diversion incident, clinical thinking that supports the clinical response that should be aimed at minimizing risk of diversion and misuse and treating the patients opioid use disorder at the level of care needed.**