XYZ Medical Practice

Sample 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 providers 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. Providers should use their personal and professional judgment in interpreting these guidelines and applying them to the specific 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 always current.

Preamble: As the availability of buprenorphine treatment for opioid use disorder has increased, so have reports of diversion, misuse, and related harms. In addition to potential harms in the community, diversion indicates medication non-adherence and should be proactively addressed by healthcare providers. 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 to or intolerant of naloxone, and requesting monotherapy; (5) non-healing or fresh track marks; or (5) police reports of selling on the streets. There are a range of reasons for diversion and misuse including diverting to family/friends with untreated opioid addiction to 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 debts/purchase preferred opioid/pay for treatment in places where there are inadequate providers 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 for whom it was not intended (including sharing or selling a prescribed medication).[1] *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, when the patient has returned to use, and when suspected (e.g., incorrect buprenorphine pill/film count) or confirmed (e.g. police report).

These procedures will establish steps to prevent, monitor, and respond to misuse and diversion of buprenorphine. The providers' response should be therapeutic and 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 increased risk for overdose death.

Procedures for Prevention:

- **Use buprenorphine/naloxone combination products when cost is not an issue and medically indicated.** Reserve the daily buprenorphine monoproducts for pregnant patients, patients who otherwise could not afford treatment if the combination product (i.e., buprenorphine/naloxone) was required, patients who have a history of stability in treatment and low diversion risk, or patients with arrangements for observed dosing. While the evidence on the safety and efficacy of naloxone in pregnant women remains limited, the combination buprenorphine/naloxone product is frequently used, and the consensus of ASAM's National Practice Guideline for the Treatment of Opioid Use Disorder committee is that the combination product is safe and effective for this population. Naloxone is minimally absorbed when these medications are taken as prescribed. If the patient encounters cost issues (e.g. loses medical insurance), consider utilizing prescription savings and discount programs to find the most affordable option available to the patient.

- **Counsel patients on safe storage 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 locking devices and avoiding storage in parts of the home where visitors frequent (e.g., recommend against 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 the definitions of diversion and misuse with examples.** Patients are required to take medication as instructed by the provider, 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 patient history available or when there is a concern for the patient based on observation. Check for prescriptions that interact with buprenorphine or if there are other providers currently treating your patient with buprenorphine or other medications.

- **Prescribe a therapeutic dose that is tailored to the patient's needs.** One patient may need a total dose of 24mg while another may only need 16mg. Do not routinely provide an additional supply "just in case." Have a discussion with patients who say they need a significantly higher dose, particularly when they are already at 24 mg/daily of buprenorphine equivalents. Evidence suggests that 16 mg per day or more may be more effective than lower doses. There is limited evidence regarding the relative efficacy of doses higher than 24 mg per day, and the use of higher doses may increase the risk of diversion.

- **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 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 may indicate 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 for misuse/diversion 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 period (e.g., 24 hours) after contact. If they do not appear, then the provider should consider this as a positive indicator of misuse/diversion.

  In rural areas or where access to treatment is limited, providers may consider partnering with local pharmacies to conduct pill/film counts to reduce potential transportation burdens for patients.

- **Directly observe ingestion.** In this kind of monitoring, the medication is taken in front of a 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 treatment plan 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 indicated but not practical, short prescription timespans can be used, for example, weekly or three days at a time.

Procedures to Respond to Misuse or Diversion:

Misuse or diversion should never mean automatic discharge from the practice. However, it will require a therapeutic response and consideration of one or more of the procedures listed below.

- **Evaluate the misuse and diversion** – for instance, describe the incident of misuse (e.g., patient took prescribed dose on 1, 2, 3 or more occasions by intravenous route immediately after starting treatment stating that they believed the 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) 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 observed dosing for any patient who is misusing or diverting their medication regardless of reason.** Treatment structure may need to be increased, including more frequent appointments, observed dosing, and increased psychosocial support.

- **Intensify treatment or level of care, if needed.** Some patients may require an alternative treatment setting or change in pharmacotherapy, such as methadone. The clinician should 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/diversion incident, clinical thinking that supports the clinical response that should be aimed at minimizing risk of diversion and misuse and treating the patient's opioid use disorder at the level of care needed.**

[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.

[2] Ibid, p. 31