

### **Policy and Purpose:**

This policy is intended to ensure appropriate assessment, management and monitoring of patients receiving office-based medication for addiction treatment (MAT) for opioid and alcohol use disorders.

### **Overview**

The American Society of Addiction Medicine defines addiction as, “a treatable, chronic medical disease involving complex interactions among brain circuits, genetics, the environment, and an individual’s life experiences. People with addiction use substances or engage in behaviors that become compulsive and often continue despite harmful consequences.”<sup>1</sup> Many people are able to recover from substance use disorders (SUDs) without formal treatment; the purpose of engaging patients in MAT is the decrease the time it takes a patient to enter into recovery while decreasing the harm associated with substance use during that period.

To accomplish these outcomes, [name of FQHC] utilizes a harm-reduction model of care. Harm reduction refers to policies and programs that aim to reduce the harms associated with the management of a chronic disease. In SUD treatment, the harm reduction approach<sup>2</sup>:

- Avoids exacerbating the harm caused by the misuse of substances
- Identifies SUD as a chronic disease and treats patients with this disease with dignity
- Maximizes the intervention options
- Prioritizes achievable short-term goals, while working toward a long-term goal of abstinence

An essential component of harm-reduction programs includes the utilization of MAT to support symptom management and long-term engagement, a primary contributor decreasing opioid-overdose mortality and all-cause mortality<sup>3</sup>.

### **Patient Selection**

#### **Inclusion Criteria**

- Patient is at least 18 years old
- Patient meets DSM-5 criteria for Opioid Use Disorder or Alcohol Use Disorder

#### **Precautionary Criteria**

- Patient has serious uncontrolled/untreated psychiatric problems (suicidality, active psychosis, etc.)
- Patient misuses benzodiazepines, sedatives or hypnotics.
- Patient is pregnant or plans to become pregnant
- Patient has a known allergy/hypersensitivity to buprenorphine

### **Referral to Treatment**

Patients may enter into treatment one of 3 ways:

- SBIRT assessment within a continuity clinic identifies patient as meeting criteria for referral to treatment
  - All primary care patients are screened annually using the Drug Abuse Screening Tool (DAST) and Alcohol Use Disorder Inventory Test (AUDIT-C)

- Patients screening  $\geq 3$  on the DAST or  $\geq 6$  on the AUDIT-C are categorized as “high risk” and referral to treatment is appropriate.
- Established primary care patient self-refers into treatment. In this scenario, patients who identify as having an SUD may enter treatment without direct referral from their PCP. Chemical dependency providers engaging these patients in SUD treatment must remember to include SUD diagnosis into the problem list to ensure accuracy of patient care.
- Community member not established with [FQHC] self-selects into treatment
  - NOTE: Organization DOES accept non-PC patients
    - [FQHC] identifies no wrong door to accessing SUD treatment. For patients who are not established in primary care services, SUD and mental health services are open-access. However, [FQHC] believes care is best delivered within the health center by one centralized team. [FQHC] will support any patient who chooses to transition their care, but this will not be a requirement of ongoing treatment.
  - NOTE: Organization DOES NOT accept non-PC patients
    - [FQHC] believes care is best delivered within the health center by one centralized team. [FQHC] will support any patient who identifies a desire to transition the entirety of their care to [FQHC]. If a patient chooses to maintain their primary care externally to [FQHC], [FQHC] will provide resources to support engagement in alternative SUD treatment services.
- NOTE: If your FQHC has additional referral pathways, include these here. Examples may include:
  - Partner hospitals
  - Emergency Departments
  - On-call hospitalist services
  - Established relationships between community-based SUD providers

### **Initial Scheduling**

To support initial and ongoing engagement:

- Whenever possible, patient’s identifying desire for MAT should be started on medication same-day
- If this is not possible, patient’s should be scheduled within 24-48hrs of identifying desire for treatment with a DATA waived provider to begin MAT
- If appointments are not available to begin MAT within 48hrs, ongoing support should be provided by a member of the care team (Care Coordinator, Peer Support Specialist, and/or Behavioral Health Consultant) until completion of the initial appointment to ensure initial appointment attendance and ongoing treatment compliance.

Appointments will be scheduled with the prescribing provider. All efforts will be made to provide access to a behavioral health consultant (BHC) to complete psychosocial assessments of newly engaging MAT patients during the prescriber visit. To prevent delay of initiating medication, if an integrated BHC is not available on the day of medication induction, the patient will be scheduled for the next available BHC visit.

### **Initial Assessment of Opioid Dependence and Withdrawal**

#### **Patient History**

The care team should obtain medical history as below. It is recommended that the BHC or care manager (CM) engage the patient prior to the prescriber visit to obtain as much of the medical history

and ASAM assessment as possible. The prescriber visit will then augment the BHC or CM visit to maximize efficiency.

- Review current and past symptoms of opioid withdrawal.
- Review substance use, including age of initiation, length of use, amount used, method of use, treatment and treatment response for all substances used by patient.
- Review current substance use including type, method of administration, frequency of use, last use, recently hospitalizations related to use.
- Review past treatments including client response to treatment, and perceived effectiveness.
- Review concurrent medical/psychiatric problems, medications and labs.
- For female clients of childbearing age, address contraception.
- Review social factors including but not limited to: criminal justice involvement, support network, employment, food and/or housing insecurity
- ASAM Level of Care assessment. Note, patients should be maintained at the lowest level of care appropriate for the treatment of their SUD in order to minimize barriers to treatment. If a higher level of care is deemed necessary by the patient and care team, patient's should be maintained in outpatient treatment, if it is safe to do so, until the patient is able to be transitioned to that higher level of care.

### **Objective Data**

- Relevant components of the physical exam should be done at initial assessment: Provider should include:
  - Documentation of signs and symptoms of substance withdrawal.
  - Assessment of possible substance intoxication, including but not limited to alcohol odor, nystagmus, positive Romberg test, client disinhibition, or other altered mental status.
- Lab Results:
  - Urine toxicology screen
  - Pregnancy test (serum or urine HCG) for females with childbearing potential
  - Basic metabolic panel
  - Hepatic function profile
  - Complete blood count
  - HIV and Hep A,B, and C testing
- Review and documentation of prescription monitoring program results for prescriptions of opioids and benzodiazepines.

### **Prior to Initiation of Medication**

- Ensure that "MAT Treatment Agreement" is reviewed, signed, and scanned into patient record.
- Obtain release of information for any outside providers, including psychiatrists and relevant specialists.

- Provide patient with [FQHC] Induction Packet to include:
  - Information of chosen MAT
  - Contact information for care team
  - Community recovery and support resources
  - Relevant medication induction and planning instructions

### **Initiating Treatment with Buprenorphine**

- To maximize access and decrease barriers, many patients are appropriate for at home induction. The following procedure outlines the home induction process:
- Provide “Starting Buprenorphine at Home- Home Induction Instructions”
- Provide Patient Info Buprenorphine FAQ
- Prescribe no more than 7 days of medication when initiating treatment
  - For withdrawal symptoms, give Buprenorphine 4mg SL every 6 hours as needed
  - Total Buprenorphine dose for 1<sup>st</sup> 24 hours typically ranges between 8-16mgs
  - Total Buprenorphine dose for Day 2 is typically ranges from 8-16 mgs
  - Total Buprenorphine dose for Day 3 is typically ranges from 12-16 mgs
  - Most patients experience good control of withdrawal and cravings by the end of their first 3-5 days on buprenorphine.
  - Target dose: The dose that results in the optimal relief of objective and subjective opioid withdrawal symptoms. This is expected to be in the range of 12 to 20mg daily, though doses from 2 to 24 mg/day may be required to suppress opioid withdrawal effects. In most cases, the maximum daily dose is 24mg.
- Following home-induction, the patient should be scheduled within 7 days for follow-up.
- Within 48-hrs post home induction, a member of the care team will reach out to patient to assess symptoms and additional needs of the patient.

Patients who are buprenorphine naïve, report experiences of precipitated withdrawal, or who express other concerns related to home-induction protocols may be more appropriate for in-office initiation. The following procedure outlines the in-office initiation process:

- Prescribing provider assesses last use and experience of current withdrawal symptoms through administration of Clinical Opiate Withdrawal Scale (COWS). Patients experiencing mild to moderate withdrawal are appropriate for initiation of medication.
- NOTE:
  - For FQHC’s with on-site or partner pharmacies: DATA Waived prescriber send prescription for 8/2mg buprenorphine/naloxone to pharmacy for patient to pick up and bring back to observed dosing.
  - For FQHC’s without on-site or partner pharmacies: DATA Waived prescriber send 8/2mg Suboxone prescription to pharmacy 24hrs prior to initiation appointment. Patient is to bring to appointment for observed dosing.
- Provider administers 4/1mg buprenorphine/naloxone and observes patients for 20-30 minutes.
- After 20-30 minutes, provider assesses medication tolerance and experience of ongoing withdrawal symptoms.
  - At this time, provider may administer additional 4/1mg buprenorphine/naloxone or provide patient instructions as to appropriate timing for additional dosing.
- Provider prescribers next day dosing and patient is scheduling for second day of induction, at which point dosing may be titrated as appropriate, with stabilization often being obtained between 16-24mg buprenorphine.

Consider adjunctive medications for symptom management. These may include the following:

- Clonidine 0.1 to 0.3mg PO q4 to 6 hours PRN lacrimation, diaphoresis, rhinorrhea, piloerection
- Promethazine 25mg PO q4 to 6 hours PRN nausea/vomiting
- Ondansetron 4-8mg PO q4 to 6 hours PRN nausea, agitation
- Loperamide 4mg PO x 1 PRN diarrhea, then 2mg PO PRN each loose stool or diarrhea thereafter, NTE 16mg/24h;
- Ibuprofen 400 to 800 mg PO 4 to 6 hours with food prn myalgias/arthralgias, NTE 2400mg/24hours.
- Trazodone 50mg PO at bedtime prn insomnia

### **Buprenorphine Maintenance Therapy**

- **Provider Visit Frequency:** It is recommended that following initiation of buprenorphine, the frequency of provider visits be at least monthly for the first 3 months. Pending stability and adherence, provider visit frequency may increase or decrease.
- **Counseling:** It is recommended that patients on buprenorphine engage with an integrated BHC to support the treatment plan. Patients may choose to engage in additional support through scheduled BH visits or groups.
  - While engagement in counseling services is recommended and considered best-practice, patients will not be discharged from services for lack of engagement.
- **Prescription Drug Monitoring Program:** Physicians (or their surrogates) will check PMPs prior to each prescription of buprenorphine to ensure no additional opioid, benzodiazepine or other prescriptions were obtained from other sources.
- **Urine Toxicology:** Though there are no Federal or State regulations requiring toxicology screens for patients receiving buprenorphine, the provider might find it helpful to order toxicology screens weekly during the initiation period and then every 4-8 weeks to assess patient stability. If the provider has concerns about the patient, more frequent urine screens are encouraged. Tests for other alcohol screening can be added to the standard screen on a case-by-case basis. Assaying for buprenorphine is available and should be considered any time there is any suspicion of diversion, as this can confirm the patient's use of the medication by identifying metabolites in the urine.
- **After hours communication:** Patients will be provided with information as to how to reach a [FQHC] provider after hours. Patients will be informed as to the appropriate utilization of this resource and that medication refills will not be provided after hours.
- **Cross coverage:** Other providers with DATA 2000 waivers can be available to provide care if the treating provider is not available. This may or may not include prescribing of buprenorphine.
- **Patients transferring care:** Every effort will be made to avoid precipitated opioid withdrawal during transfer of care.
  - New patients presenting to the practice requesting continuation of maintenance buprenorphine will follow the guidelines for a signed contract
  - As deemed medically appropriate, when patients are referred to a higher level of care,

medication will be provided until that transition is able to occur.

### **Documentation and Compliance**

- Medical Staff Office and Pharmacy will keep on file a copy of the DEA DATA 2000 waiver for each provider prescribing buprenorphine.
- Care management staff will maintain a paper or electronic log of all patients they are treating who are receiving buprenorphine for opioid dependence, with close attention to the patient limits for each prescribing provider.
- All buprenorphine prescriptions should include both the physician's DEA number and the "X" DEA number which denotes buprenorphine provider status.
- If a DEA audit occurs, the audited physician should be prepared to present documentation of their waiver to prescribe buprenorphine, paper or electronic treatment log, and paper or electronic documentation of prescriptions they have written.
- In addition to standard HIPAA laws, federal regulations mandate strict confidentiality for information about patients being treated for substance use disorders (42 CFR Part 2). Additionally, the law requires written patient consent before information about substance abuse treatment can be disclosed to any other source review of outside records, PMP report, and urine toxicology screening.

### **Diversions Control**

Effective monitoring of adherence and response to treatment can increase the likelihood of positive clinical outcomes and reduce the possibility of diversion. The following steps will be taken with patients to prevent diversion:

- 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.
- Regular toxicology screening
- 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.
- 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:

- 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.
  - In this case, a send-out urine screen should be ordered to test for the presence of fentanyl
  - Other possible explanations include:
    - the individual is not using opioids at this time and is diverting the medication
    - The patient 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).
- 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.

### **Program Discharge**

The following may result in discharge from chemical dependency services:

1. Threatening behavior toward staff, patients, or facilities
2. Physically or verbally aggressive behavior toward staff, patients, or facilities
3. Illegal activities performed on [FQHC] premises
4. Diversion of MAT
  - a. In the case of diversion, discharge from chemical dependency services does not preclude the patient from continued engagement in primary care and behavioral health services.
  - b. Reengagement in chemical dependency services may be appropriate based on assessment of patient readiness and willingness to maintain adherence to treatment contract.
5. Need for a higher level of care than can be provided by [FQHC]
  - a. Any patient referred to a higher level of care must be formally discharged from outpatient treatment services. This formal discharge does not preclude the patient from reengaged in services in the future.

References:

1. American Society of Addiction Medicine. (September 15, 2019). *Short definition of addiction*. Retrieved from <https://www.asam.org/advocacy/find-a-policy-statement/view-policy-statement/public-policy-statements/2019/10/21/short-definition-of-addiction>
2. Hunt, N. (n.d.). A review of the evidence-base for harm reduction approaches to drug use. Retrieved from <https://www.hri.global/files/2010/05/31/HIVTop50Documents11.pdf>
3. Substance Abuse and Mental Health Services Administration. (2020). *Medications for opioid use disorder*. Treatment Improvement Protocol (TIP) Series 63. Publication No. PEP20-02-01-006. Rockville, MD: Author. Retrieved from <https://store.samhsa.gov/product/TIP-63-Medications-for-Opioid-Use-Disorder-Full-Document/PEP20-02-01-006>