Office-Based Opioid Treatment Policy and Procedure Manual

Adult Medicine Clinic
Harborview Medical Center

UW Medicine

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Disclaimer

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INTRODUCTION

Purpose of the Manual

The purpose of this manual is to provide detailed policies and protocols of the Harborview Medical Center (HMC) Office-Based Opioid Treatment (OBOT) program for the use of buprenorphine and buprenorphine/naloxone in the treatment of opioid use disorder (OUD) in the primary care clinics at HMC. This program was first developed at HMC's Adult Medicine Clinic (AMC) and then implemented in other HMC primary care clinics.

Introduction to the OBOT Buprenorphine Program

Buprenorphine/naloxone is an effective treatment for OUD. It is the first OUD medication available for prescription from a physician's office or clinic outside a traditional opioid treatment program (OTP). Before the advent of buprenorphine/naloxone, methadone was the only Food and Drug Administration (FDA)-approved medication to treat OUD in the United States. A major limitation of methadone is that it is available only at licensed methadone maintenance OTP clinics. Providing buprenorphine/naloxone medication in a doctor's office or community clinic—such as through HMC's AMC—is an important step toward expanding access to addiction treatment in traditional medical settings.

Many HMC inpatients and primary care patients have OUD, which has significant negative consequences on their medical and mental health and care. Multiple ambulatory physicians have obtained Drug Addiction Treatment Act of 2000 (DATA 2000) waivers to qualify for providing buprenorphine/naloxone treatment in their clinics. The HMC OBOT program was established to promote, coordinate, and support opioid addiction treatment in outpatient settings.

Treatment Philosophy

The HMC OBOT team believes that substance use disorder (SUD) is a chronic medical condition that requires ongoing, comprehensive, patient-centered care directed at improving health outcomes. The HMC OBOT team's priorities are patient engagement, patient retention in care, and patient progress in one or more life domains. The program's philosophy relies less on rule-based protocols and more on a team-based model to make important and difficult treatment decisions. The team comprises DATA 2000-waivered physicians (MDs) and providers, nurse care managers (NCMs), program managers, mental health and addiction counselors, and pharmacists.

OBOT PROGRAM STAFFING

Waivered Physicians and Providers

- HMC OBOT physicians have obtained DATA 2000 waivers to prescribe Schedule III, IV, and V controlled substances and FDA-approved medications to treat patients during medically supervised opioid withdrawal or OUD maintenance treatment. Each physician has a current state medical license and a valid Drug Enforcement Administration (DEA) registration number. These physicians have completed either 8 hours of an approved training course on the management of patients with OUD or board subspecialty certification for addiction psychiatry or addiction medicine.
- Advanced registered nurse practitioners (ARNPs) and physician assistants (PAs) may also obtain DATA 2000 waivers to prescribe buprenorphine/naloxone. The requirements for these waivers include 24 hours of training from a certified organization such as the American Society of Addiction Medicine, American Academy of Addiction Psychiatry, American Medical Association, and any other organization that the Secretary of Health and Human Services determines is appropriate.
- For the first year after receiving a waiver, physicians, ARNPs, and PAs are limited to treating 30 active patients at any given time; after the first year, they can apply to the Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Treatment (CSAT) for an extended waiver to treat up to 100 patients.
- Physicians who have treated 100 patients for at least 1 year can apply to expand their treatment limit to 275 patients if they also meet other criteria as outlined by CSAT. ARNPs and PAs are not eligible to apply for an extension to the 275- patient limit.

Nurse Care Managers

- Hold a state registered nurse license.
- Complete an initial 8-hour training curriculum covering OBOT with buprenorphine/naloxone, including the use of buprenorphine/naloxone for OUD treatment in office settings based on CSAT's Technical Assistance Publication 30: *Buprenorphine—A Guide for Nurses*, or an equivalent training.
- Attend periodic booster trainings on topics relevant to the HMC OBOT program (e.g., hepatitis C treatment and management, urine toxicology screening, relapse prevention, motivational interviewing, treatment retention, harm reduction techniques, compassion fatigue), participate in case discussions, review current materials, and network with other NCMs.
- Are responsible for:
  - Overseeing buprenorphine/naloxone intake assessment, induction, stabilization, maintenance, and relapse prevention.
  - Ensuring that state and federal guidelines are followed.

  - Collaborating with HMC OBOT physicians, social workers/counselors, psychiatrists, pharmacists, primary care physicians, and specialty care physicians to whom the patient has been referred.
  - Coordinating between HMC OBOT physicians and pharmacists and assisting with prescription handling and refill requests.

Program Managers

- Provide administrative support to the team by addressing insurance issues, assisting with patient scheduling, and managing physician files (e.g., DEA numbers, state licensure).
- Manage incoming referrals and complete initial telephone screening with potential HMC OBOT patients.
- Collaborate with outside agencies to foster relationships with the HMC OBOT program and to better serve patients.
- Manage lists of patients per provider to ensure compliance with DEA requirements (i.e., provider limits of 30, 100, or 275 patients).
- Ensure adherence to CSAT's administrative requirements, including:
  - Obtaining certification, accreditation, and waiver approval.
  - Ensuring accurate physician records (e.g., keeping records on prescription and dispensation of medications for OUD detoxification and maintenance treatment in accordance with DEA regulations 21 CFR 1304.03(c)).
  - Making sure that electronic health record systems comply with federal regulations.
  - Maintaining accurate records of patient identifier, name, dose, quantity of drug prescribed/dispensed, and visits.
  - Providing DEA with records to ensure compliance with DATA 2000 regulations. Because DEA reviews only medications used in OUD treatment, program managers are encouraged to keep separate records for these medications to facilitate the review.

Mental Health and Addiction Counselors

- Mental health and addiction counseling is integrated into the HMC OBOT program through the Behavioral Health Integration Program (BHIP). Licensed clinical social workers (LICSW) provide supportive counseling, behavioral activation counseling, cognitive behavioral therapy, and other forms of therapy. Psychiatrists are available for consultation and for direct patient evaluation as needed.
- Patients participating in OBOT may meet with BHIP counselors any time before induction, during therapy, or after discharge whether voluntary or involuntary.
- Some patients participating in OBOT prefer outside counseling or may already be assigned to other settings for mental health treatment. To ensure seamless coordination with outside counselors, patients sign a release of information form at their NCM intake visit so that providers can communicate with one another.

- Although mental health and addiction counseling is strongly encouraged, engagement in counseling is not required to continue receiving OUD medication. Patients struggling with continued substance use or mental health stability are offered counseling as a way to intensify treatment in the office-based setting.

Pharmacists

- AMC's clinical pharmacists assist with answering questions regarding medication dosing, drug–drug interactions, and other pharmacologic issues.

PROGRAM PROCEDURES

Referrals

Referrals are accepted from a variety of sources including primary care physicians, needle syringe exchange programs, hospital emergency rooms, inpatient units, and self-referrals. OBOT staff consider the following when evaluating a referral:

- Patient must meet *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.; DSM-5) criteria for a moderate to severe OUD.
- Patient must be in stable mental and physical health or engaged in appropriate treatment to address these issues.
- Patient must be willing to comply with program requirements.
- Patient must agree with the goals of the HMC OBOT program, which are to:
  - Prevent or reduce withdrawal symptoms and cravings for opioids through use of medications.
  - Restore normal physiological functions that may have been disrupted by drug use and improve quality of life.
  - Address any psychiatric problems.
  - Address other medical issues, including preventive health and co-morbidities that may be the results of substance use.
- Patient must be able to meet the following logistic requirements:
  - Can attend required visits during hours of office operation.
  - Has access to transportation options.
  - Can comply with visit and counseling recommendations.
- Patient must not have chronic pain issues requiring additional opioid management beyond buprenorphine/naloxone. Patients with co-occurring OUD and chronic pain can often obtain adequate pain relief with buprenorphine, in conjunction with other non-opioid therapies.
- Patient must not need higher levels of care with more intensive management (e.g., daily monitoring and assessment, medication administration because of advanced psychiatric illness).
- Patient must be willing to work toward not using other illicit substances and not drinking alcohol. Discontinuation of other substances before induction is not typically required, although inpatient medical detoxification may be necessary for patients with heavy alcohol or nonprescribed benzodiazepine use.

Program Manager Screening

Screening is completed by the program manager either by phone or in person and includes the following components:

- Medical, social, and substance use histories, as well as current use, are reviewed. Demographics, living situation, insurance coverage, safety issues, and treatment goals are also examined (see *Appendix 1: Telephone or In-Person Screening for Buprenorphine/Naloxone*).
- Patients prescribed controlled substance, especially benzodiazepines and stimulants, must agree to consider alternative treatments and sign a release allowing coordination of care between the HMC OBOT team and the prescribing provider. Users of alcohol or illicit benzodiazepines who are at risk of significant withdrawal will need assessment by the treating physician or provider to determine whether medical detoxification needs to be coordinated with OBOT treatment initiation.
- Program expectations are briefly reviewed, and patients determine whether they can meet these expectations.
- Intake appointments with the NCM and waivered provider are scheduled.
- Urine drug screen (UDS) testing can be completed during the in-person screening with the patient's permission.

NCM Intake

Intake is completed by a NCM at a scheduled in-person visit. The intake appointment with the NCM can occur on the same day as the patient's visit with the waivered physician or provider. It includes the following elements:

- Patients' medical histories, medications, addiction histories, and results from physical exams, if needed, are assessed. The NCM also confirms the DSM-5 diagnosis of moderate to severe OUD and assesses appropriateness of buprenorphine/naloxone treatment in the office-based setting (see *Appendix 2: Nurse Care Manager Intake Tool*).
- Patients who are not currently physically dependent on opioids (e.g., those who have been released from incarceration) must have a prior moderate to severe OUD diagnosis that can be documented through medical or addiction treatment records or physical exam findings.
- UDS and other laboratory tests are completed, if clinically indicated. These tests include complete blood count; comprehensive metabolic panel (including AST/ALT); pregnancy test (required on all people who could become pregnant, unless not clinically indicated); hepatitis A, B, and C serologies; and HIV testing.
- Patients complete a behavioral health screening including the Patient Health Questionnaire (PHQ9), Generalized Anxiety Disorder Screener (GAD7), and PTSD Checklist for DSM-5 (PCL5). BHIP services are also discussed, if indicated.
- Patients receive education on buprenorphine/naloxone: what it is, how it works, medication administration, interactions, safety, storage, self-care, induction, maintenance, detoxification, tapering, and withdrawal. They also review and sign treatment consent forms (see *Appendix 3: Sample Consent Forms*).

- The NCM explains program expectations. Patients review these expectations and sign treatment agreements (see *Appendix 4: Buprenorphine Treatment Agreement*).
- The NCM checks the state prescription drug monitoring program (PDMP) database to find out what controlled substances patients have been prescribed and how often they have been prescribed these medications.
- The NCM makes a plan for induction. This entails determining whether the patient can begin treatment through home induction or whether in-office induction is warranted. In-office induction is preferred when the patient's diagnosis must be confirmed, when the patient is transitioning from methadone, or when the patient has experienced previous adverse reactions.
- The NCM educates patients on overdose prevention, including how to use naloxone and where to access naloxone kits.

Visit With Waivered Physician or Provider

- The first visit with the waivered provider includes conducting medical, mental health, and SUD histories; completing other appropriate screening (e.g., physical exam, lab tests); and confirming a moderate to severe OUD diagnosis.
- If the patient is a good candidate for OBOT, the physician writes a 1-week script for buprenorphine and gives it to the NCM for the induction appointment.
- If the patient has completed the NCM intake and has been cleared to safely start medication at home, the physician arranges with the nurse for the patient to begin same-day home induction.
- Before leaving the clinic, the patient receives education on overdose prevention and a prescription for naloxone.

BHIP Intake Appointment

- BHIP services can be initiated at any phase of treatment.
- BHIP services are optional but strongly encouraged. Patients may also choose to engage in counseling outside AMC.
- The BHIP care coordinator visits with the patient for 60 minutes to establish rapport, understand the patient's mental health and addiction histories, and assess mental health needs. At the end of the session, a follow-up BHIP visit is scheduled.
- After the visit, the mental health counselor generally discusses the patient's plan of care with the consulting psychiatrist.
- The BHIP care coordinator informs the physician of any concerns about candidacy for the HMC OBOT program.

Induction

Induction is performed by the NCM either in the office or at home with support by phone. Home induction is preferred to avoid delay in starting medication. An office induction may be indicated

if withdrawal needs to be documented for diagnostic reasons, the patient is transitioning from methadone, the patient has experienced a previous adverse reaction (e.g., an allergic reaction or precipitated withdrawal), or the patient prefers to be at the clinic.

- **Day 0: Office Induction**
  - The NCM sends the prescription to the pharmacy, and the patient picks it up immediately before the scheduled appointment.
  - The patient arrives at the clinic in early withdrawal, with medication in hand.
  - The NCM assesses symptoms with the Clinical Opiate Withdrawal Scale (COWS). If the COWS score is higher than 8, the NCM instructs the patient to take an initial buprenorphine/naloxone 4/2 mg dose as prescribed (see *Appendix 5: Induction Protocols*).
  - The patient removes the initial buprenorphine/naloxone dose from the medication bottle and takes the dose sublingually (i.e., places it under the tongue). The nurse observes the patient and provides additional administration instructions if necessary.
  - After 30–60 minutes, the NCM reassesses the patient using COWS, instructs the patient to take a second 4/2 mg dose sublingually if needed, and again observes and supervises the patient for proper administration. The second dose is not needed if the patient shows improvement in the COWS score or feels subjectively better. The second dose may be reserved to take at home later in the day when symptoms of withdrawal worsen or return.
  - The NCM provides the patient with written instructions and a follow-up plan that includes the clinic's telephone number and a list of scheduled clinic visits.
  - The NCM telephones the patient later in the afternoon, the following day, and as needed and schedules a return clinic visit in 1 week.
- **Day 0: Home Induction**
  - The NCM reviews instructions for home induction, including signs and symptoms of withdrawal, dosing, and safe storage. The patient is given written instructions and a copy of the COWS. This can be done at NCM intake if the patient is a candidate for home induction.
  - The NCM and patient agree on a start date and time and develop a phone follow-up plan.
  - The NCM sends the prescription to the pharmacy for the patient to pick up.
  - The patient assesses symptoms with the COWS. If the COWS score is greater than 8, the patient administers an initial buprenorphine/naloxone 4/2 mg dose as prescribed (see *Appendix 5: Induction Protocols*).
  - The NCM telephones the patient later in the afternoon, the following day, and as needed and schedules a return clinic visit in 1 week.

- **Day 1:** The patient checks in with the NCM by telephone. The medication is taken per prescription instructions and until symptoms stabilize.
- **Day 2 through Day 5:** The NCM may check in with the patient as needed during the week. The patient is instructed to return to the clinic as needed and no later than 1week following induction.

Stabilization

Stabilization involves weekly appointments with the NCM and follow-up with the prescribing provider within the first month after starting medication.

- Goal: Stabilize medication dose and engage patient in the treatment plan.
- The target buprenorphine/naloxone dose is 16 mg/day or less. BID dosing (i.e., twice daily dosing) is especially helpful for patients with chronic pain to maximize the analgesic effect of the medication.
- Daily doses higher than 16 mg can be considered to address persistent opioid use, craving, or withdrawal symptoms, but usually not until after week 3 or 4.
- The patient returns to clinic after taking the medication for 1 week. The NCM repeats a UDS, assesses symptoms of withdrawal and craving, and refills the prescription as appropriate. Prescriptions are limited to a 1-week supply during this phase. Because symptoms of withdrawal and craving are common in the first week or two and lessen over time, usually the dose is not increased before week 3 or 4.
- The patient sees the NCM weekly for 4 to 6 weeks or until stable. If UDS results are appropriate and the patient attends weekly visits, then the patient generally progresses to the maintenance phase.
- If the patient has an alcohol use disorder history and is currently drinking, consider additional monitoring with breathalyzer and/or urine ethyl glucuronide UDS.
    - Alcohol use disorder medications (e.g., gabapentin, topiramate, acamprosate, or disulfiram) may be offered to patients.
    - Patients managed on buprenorphine/naloxone cannot simultaneously be treated with naltrexone.

Treatment Agreement Review (see *Appendix 4: Buprenorphine Treatment Agreement*)

- Goal: Engage the patient in the treatment plan and individualize treatment to meet the patient's needs.
- Because the initial focus is on medication adherence and adjustment, other elements of the treatment plan may need reinforcement.
- The NCM and patient review the treatment agreement several times during treatment to reinforce expectations and answer questions: at intake, a few weeks after treatment is initiated, and annually thereafter or more frequently as needed. This review includes several components:

- Make clear that the rules and expectations are reviewed with all patients being treated with buprenorphine/naloxone and that they apply to all patients equally. Patients who cannot comply with the treatment agreement may be better served in other treatment settings.
- Set clear expectations and guidelines. In addition to specific items, the rules and expectations can include general items such as the physician's philosophy of treatment for substance use.
- Encourage patients to ask questions.
- Review the treatment agreement together and provide it in written form. After they sign and date the form, patients should be given a copy of it to take home. The original is filed in the patient's record. An abbreviated "Friendly Reminders" version of the treatment agreement may be given to patients at their third or fourth follow-up visit.
- Reassure patients about common issues that others have experienced. Patients may have concerns about entering treatment or changing from other medication treatment settings (e.g., methadone). Ambivalence about these changes should be addressed. Patients should understand that treatment is maintenance and should be continued for at least 6 months.
- Ensure patients can contact a member of the HMC OBOT team during business hours.

Maintenance

Maintenance involves visits with the NCM every 2 to 4 weeks and with the waivered physician or provider every 3 months.

- Goal: Establish a stable dose of buprenorphine with sustained abstinence from opioids and less frequent clinical monitoring.
- Initially, clinic visits are scheduled with the physician or NCM every 2 weeks with refills that coincide with visits.
- Each decrease in visit frequency requires consensus of the treatment team.
- No routine follow-up lab testing is recommended other than age-appropriate screening and follow-up testing for medical or mental health issues (e.g., hepatitis C). These conditions are managed through the patient's primary care provider.
- Follow-up clinic visits include (see *Appendix 6: Nurse Care Manager Follow-up Form*):
  - UDS testing.
  - Assessment of status. This involves a discussion of recovery, relapse, and relevant medical issues.
  - Review of current buprenorphine/naloxone dose, adherence, correct administration techniques, side effects, and any difficulties obtaining or taking buprenorphine/naloxone.

  - Review of the treatment plan. This may include counseling, meetings, need for further psychiatric treatment, and other recovery supports.
  - Review of contact information, including pharmacy information to ensure prescriptions are faxed to the correct pharmacy.
  - Medication refills. Prescription should last until the next scheduled appointment. Refills are faxed to the patient's preferred pharmacy at the end of the visit.
  - Check of the PDMP database every 3 months and as needed. Unexpected results are discussed with the patient.
- Visits with the waivered HMC OBOT physician occur at least every 3 months. These visits include a review of medical and mental health issues, lab test results, recovery status, and UDS results.
- The NCM is available for treatment support and planning by phone in between scheduled visits. The treatment plan may be affected by medical issues, pregnancy status, medication changes, pending needs for surgery, acute/chronic pain management, or need for psychiatric assessment.
- The intervals between appointments can be decreased and prescription quantity adjusted if more treatment support is indicated because of relapse to opioid use, medical needs, or psychiatric destabilization.

Tapering and Relapse Prevention

Maintenance therapy is the recommended course of treatment. Risk of relapse during or after taper should be carefully considered with the patient. Tapering may be initiated voluntarily by the patient or given to the patient as an alternative when discussing referral to another treatment program. In the event of a taper, review the following with the patient:

- Upon abrupt discontinuation, a mild to moderate withdrawal syndrome will occur.
- Subjective withdrawal symptoms begin within the first 3 days, peak between 3 and 5 days, and return to baseline usually within 10 to 14 days, maybe longer. Post-acute withdrawal symptoms or craving often persist for months.
- Autonomic withdrawal signs (e.g., lacrimation, rhinorrhea, tremors, chills, gooseflesh) may occur.
- General complaints include restless legs, insomnia, anxiety, and abdominal distress.
- Buprenorphine/naloxone should be tapered over days, weeks, or months, depending on patient tolerance of symptoms.
- Following a taper, the provider and patient should consider treatment with intramuscular naltrexone for relapse prevention.
- If the taper is voluntary, the NCM maintains periodic contact with the patient. The treatment team should observe a low threshold for restarting buprenorphine if the patient identifies a need to restart medication.

Prescription Procedure

- Specific protocols are followed when handling prescriptions.
  - Prescriptions are ordered by the waivered physicians through the electronic medical record, printed, signed, and given to the HMC OBOT NCM or program manager.
  - The NCM faxes the prescription to the pharmacy on record following a scheduled visit or phone encounter.
  - After the prescription has been faxed, the NCM attaches the fax confirmation and places it in a confidential locked file for at least 6 months (in case of fax error or the need to review the prescription).
  - After 6 months, prescriptions are destroyed in a secure recycle bin.
  - Prescription records are maintained in the electronic health record system for review by clinicians as needed and for DEA regulatory purposes.
- Patients must keep scheduled appointments to obtain prescription refills. Occasional exceptions for unavoidable circumstances (e.g., transportation issues) are permitted but should be rare.
- Special precautions should be taken when a patient reports that the buprenorphine/naloxone medication has been lost, stolen, or destroyed.
  - Lost, stolen, or destroyed prescriptions and medications are generally not replaced. Patients are informed of this at the time of intake. This notification is stated verbally and included in writing in the treatment agreement.
  - Cases are reviewed individually by the HMC OBOT team, if requested by the patient, and a decision will be rendered. The team may decide to replace the medication one time only. The patient should be told that lost or stolen prescriptions will not be replaced in the future should this occur again.
  - If a patient loses the medication and the prescription is for more than 1 week, the prescription amount will go back to weekly prescriptions until the team thinks it is safe for the patient to be given a larger quantity of medication.
  - Recurrence of lost, stolen, damaged, or destroyed medications may lead to referral to a more structured treatment setting.
  - All reports of lost, stolen, or destroyed medication are tracked in a log that includes patient name, quantity of lost medication, and recommendations of the treatment team regarding replacement.

UDS Procedure

- UDS samples are generally required at each visit.
- All belongings (e.g., coats, bags) are left in the office of the medical assistant or outside the bathroom door. Patients may keep their wallets and cell phones with them.
- The patient hands the UDS sample to the gloved medical assistant in a biohazard bag.

TREATMENT DECISION-MAKING

Decisions to change the treatment plan, setting, or structure are guided by the program treatment philosophy.

- Priority is placed on continuation of medication treatment, whether in the office-based setting or elsewhere.
- Decisions should be based on patterns of patient behavior rather than on single data points (e.g., one UDS result, a missed appointment).
- Patients may make progress in one or more domains of addiction severity (i.e., social, family, legal, employment, mental, or physical health) before full discontinuation of substance use; progress in any area may be rationale for continuation of treatment in the office-based setting, at least temporarily.
- Challenging situations or decisions about changing the treatment setting should be addressed by the treatment team.

Central to treatment is the support and consistency provided for patients and all providers by the HMC OBOT team, which meets weekly when most or all team members are available. This process becomes the foundation of a consistent and fair treatment milieu.

- By discussing difficult clinical situations and clinic policies, team members develop consistent practices, shared knowledge, and confidence that clinical backup is close at hand, thus minimizing staff stress and burnout.
- Attention to unintentional bias in clinical decision-making can be facilitated in an open and supportive group setting.
- Even team members who cannot regularly attend team meetings benefit from the support and shared decision-making that occur during these meetings.

ADDRESSING SUBSTANCE USE DURING TREATMENT

Persistent illicit drug use during the stabilization period is common, and relapse of varying severity can occur during the maintenance phase. Illicit drug use is generally reported by the patient and confirmed by UDS results, but illicit use can also be initially identified by UDS.

- Patterns of drug use and resulting effects on recovery vary considerably, at times making treatment decisions difficult or ambiguous.
- Getting the patient's perspective on progress in treatment and any challenges to recovery is the first step in evaluating evidence of persistent substance use. Each story is different, and identifying key details requires assessment of evolving patient circumstances.

Self-Report vs. UDS Results

When ongoing illicit substance use is reported by the patient, a collaborative plan can be developed. The plan should pay particular attention to whether the home environment is conducive to recovery or includes key social supports who are actively using substances.

- In general, working toward patient-identified goals is preferred over provider admonitions to stop illicit substance use. When a patient is allowed to lead changes in the treatment plan and is not successful, collaborative agreement on a transition to a different treatment setting is more likely.
- In spite of reassurance that disclosure of use will not threaten continuation of treatment in the office-based setting to the same extent as persistent use without disclosure, patients can be embarrassed by or not recognize the severity of their substance use. Recognizing that disclosure of use is difficult for patients at times and requires considerable trust in the treatment team can provide perspective for providers and the team.

Strategies for assessing differences between patient self-report and UDS results depend on the specific UDS testing strategies of the clinic.

- Knowledge of the characteristics of the UDS test being used and any laboratory protocols for reflexive testing of positive tests is important in creating clinic policies.
- Some programs await confirmation of positive tests before making treatment decisions, whereas other programs call patients back within 24–48 hours to repeat the testing if self-report and UDS results differ.

Buprenorphine Adherence and Diversion

Buprenorphine adherence is crucial to successful treatment. Nonadherence can occur for a variety of reasons and may be self-reported or found on a UDS that is negative for buprenorphine metabolite (norbuprenorphine).

- Early in buprenorphine treatment, patients who relapse may be afraid to continue buprenorphine, for fear of precipitated withdrawal. Patients need reassurance that once they have been through induction, they are not at risk for precipitated withdrawal even if they relapse and that they should continue with their buprenorphine medication.

- Incarceration can also disrupt buprenorphine adherence. If patients have completed detoxification while incarcerated, their opioid tolerance will be lower. Consider reinitiating buprenorphine/naloxone at a lower dose or transitioning to extended-release injectable naltrexone.
- Finally, buprenorphine adherence can be disrupted when patients raise their dose without prior discussion with their providers. In this situation, patients should be urged not to change their dose ("don't be your own doctor") and returned to scheduled weekly visits so that they can be accurately assessed on the prescribed dose.
- If pain is involved with buprenorphine dose escalation, efforts should be made to provide alternative pain treatment strategies.

Despite careful discussion of what the program considers diversion, patients may feel pressure to lend or give medication as a way of "helping out" a member of their social group.

- If patients who report taking buprenorphine regularly are found to have a UDS result without buprenorphine metabolites, diversion and/or submission of a false urine specimen are possibilities.
- An observed urine specimen collection can be considered.
- Some urine screening tests may not be adequately sensitive to detect buprenorphine doses less than 4–6 mg, requiring a confirmatory test.

Providers can call the patient back between dispensing visits to be sure the patient has the medication. Diversion is usually grounds for changing the treatment setting to an OTP for daily buprenorphine dispensing or methadone maintenance.

Ongoing Illicit Opioid Use

Ongoing or recurrent opioid use during treatment should lead to maintaining or returning to weekly visits.

- Buprenorphine adherence needs to be addressed and ensured.
- Craving and signs and symptoms of opioid withdrawal should be assessed, and a buprenorphine dose increase considered.
- A PDMP check is indicated.

An increase in treatment intensity is often the best response, but if the patient does not respond positively to buprenorphine, consideration should be given to switching to methadone or naltrexone.

Ongoing Illicit Non-Opioid Substance Use

Because no medications are available to treat SUDs other than opioid and alcohol use, progress in treatment of illicit non-opioid substance use is usually tied to improvement in social support, formal or informal.

- Ongoing or recurrent non-opioid illicit substance use usually leads to maintaining or returning to weekly visits and intensification of treatment. Positive UDS results for methamphetamine should be confirmed by a more specific test if the patient does not admit to use, because false-positive test results are common.
- Illicit benzodiazepine use should prompt a PDMP check, consideration of the possibility of serious benzodiazepine withdrawal, and, for those with significant anxiety, consideration of an underlying psychiatric condition.
- Alcohol use may necessitate breathalyzer testing and consideration of alcohol use disorder treatment, including medications (other than naltrexone).
- More severe presentations of alcohol or benzodiazepine problems (e.g., emergency room visits, clinical intoxication or sedation) require prompt consideration of alternative treatment settings.

UDS Tampering

- If a urine sample is deemed questionable by clinic staff (e.g., specimen is cold), the test should be repeated the same day. Random observed urine tests can be conducted by same-sex personnel if absolutely necessary; however, this is not routine. Some programs may have access to alternative clinical laboratories with chain-of-custody procedures for observing and ensuring accurate results.
- A UDS found to have high levels of buprenorphine and no buprenorphine metabolite is consistent with adding buprenorphine directly to the urine sample.
- Patients suspected of taking illicit opioids instead of prescribed buprenorphine could be asked to take a buprenorphine dose under supervision to assess for precipitated withdrawal.
- UDS tampering reduces available clinical information, questions the therapeutic alliance, and makes collaborative treatment planning difficult. Thus, if urine tampering is identified more than once, a transfer to a difference treatment setting should be strongly considered. Programs where alternative medication treatment is not available will have to make difficult decisions about the risks and benefits of continuation of buprenorphine in this situation.

Relapse During the Maintenance Phase

- Exploring changes in mental health, relationships, employment, and other circumstances is important to identify possible triggers for relapse. Patients may be embarrassed and not disclose promptly, so care should be taken to encourage disclosure as a strategy that allows continued treatment more readily than discrepancy between self-report and drug testing results. Often such patients can return to better function by addressing a previously ignored trigger.
- Patients with substantial treatment success may be the best judge of the response to relapse, so treatment staff should trust patients' judgment on the best way to proceed.

Revision of the Treatment Plan

The treatment plan may need revision to address ongoing clinical instability. A collaborative and patient-centered plan to intensify treatment in a supportive environment is ideal. Revisions to the treatment plan may include:

- More frequent visits and urine testing.
- Shortened prescriptions.
- Loss of refill privileges.
- Addition or increased intensity of group or individual psychosocial treatment or sober support.
- Increased intensity of mental or physical healthcare.
- Changes in the recovery environment.

Evaluation of OBOT Effectiveness

Situations in which the HMC OBOT team may recommend a higher level of care include:

- Ongoing opioid use despite adequate buprenorphine/naloxone dosing (as evidenced by the absence of cravings and withdrawal and adequate opioid blockage).
- Negative UDS results for buprenorphine/naloxone.
- Ongoing abuse of higher doses of benzodiazepines or barbiturates causing impairment, sedation, overdose, medical events, or hazardous behaviors despite interventions by the HMC OBOT team.
- Use of alcohol causing sedation, impairment, or hazardous behaviors despite interventions by the HMC OBOT team.
- Continued use of cocaine or other stimulants despite intensification of treatment with more frequent HMC OBOT visits and monitoring.
- Threatening or abusive behavior.

Changing the Care Plan

All decisions to refer patients to a higher level of care are made by consensus of the treatment team. Continuation of medication treatment is a priority, and patients are encouraged to continue primary care services in the clinic whether or not buprenorphine prescribing is continued.

The NCM or physician reviews treatment options with the patient and asks the patient to consider these options until the next scheduled clinic appointment, ideally in 1 week. At that time, the patient is asked to select the treatment option that meets their needs. Medication is continued while the patient considers options. Treatment options include:

- Directly observed treatment with buprenorphine.
- Inpatient or residential addiction treatment (preferably with buprenorphine).

- Methadone maintenance.
- Dual diagnosis/addictions clinic admission.
- Intensive outpatient treatment (preferably with buprenorphine).
- Detoxification.
- Discontinuing buprenorphine prescribing (“taking a break from treatment”).

At the next visit, the team initiates a referral based on the patient’s decision. Medication is continued until the patient connects with the alternative treatment setting. Patients who can be stabilized at a higher level of care may be eligible to return to OBOT at a later date. Patients may also choose to discharge from treatment, in which case they are given a 1-week prescription with which to taper.

SPECIFIC POPULATIONS

Methadone Transfers

Transition is difficult, and rationale for change in treatment should be carefully considered. There is significant risk of relapse when tapering methadone from the usual maintenance dose (80–120 mg) to a dose where buprenorphine transition is possible (30 mg or less). In addition, precipitated withdrawal is more likely when transitioning from methadone compared with short-acting opioids. It is difficult to anticipate which patients will feel better on buprenorphine. Because of these risks, the OBOT team usually suggests that patients on methadone maintenance seek additional take-home methadone doses as a way to make treatment less burdensome.

Patients may prefer a less structured treatment environment and a setting where care can be integrated. If patients are considering a methadone taper to prepare for buprenorphine transition, the OBOT team recommends that the taper be slow enough to avoid craving and other withdrawal symptoms. If craving or withdrawal occurs, holding the methadone dose constant for a specified period may be prudent. Working collaboratively with the patient and the methadone treatment provider allows for safe and appropriate methadone dose titration or return to prior dosing. Returning to a stable methadone dose should be an option at any stage of the transition.

Once a stable methadone dose of approximately 30 mg has been achieved, transition to buprenorphine can occur. Staff should advise the patient to arrange for time off work during the transition and seek family support with childcare and other responsibilities as discomfort may last 1 to 2 weeks. The last methadone dose should be approximately 36 hours before the patient visits the OBOT clinic to accurately assess the level of withdrawal. Because timing between the last methadone dose and safe administration of the first buprenorphine/naloxone dose is difficult to predict, buprenorphine administration should be guided by withdrawal symptoms objectively documented with a COWS score between 13 and 15. Clonidine, anxiolytics (including benzodiazepines), and NSAIDs may be used to manage distressing withdrawal symptoms and continued during induction. Inpatient detoxification is another option to assist a patient in the transition from methadone to buprenorphine/naloxone.

Pregnancy and OUD

Untreated OUD during pregnancy is high risk for spontaneous abortion, withdrawal-induced fetal distress, premature labor, and intrauterine death. Medication treatment is associated with major reductions in these risks and is recommended for all pregnant patients with OUD. Methadone has been used successfully in this patient population for decades, and increasing evidence also supports the use of buprenorphine.

Buprenorphine is associated with less severe neonatal abstinence syndrome (NAS) compared with methadone, resulting in less need for medication and shorter hospital stays. However, buprenorphine is also associated with lower treatment retention compared with methadone. Pregnant patients taking buprenorphine should be counseled on the importance of switching to methadone if buprenorphine treatment is not going well.

Patients already maintained on stable buprenorphine doses who become pregnant should be encouraged to continue treatment throughout pregnancy to achieve the best outcomes for them

and their baby. Many pregnant patients have concerns about remaining on medication treatment because of the risk for NAS, which occurs in about half of babies regardless of which medication is being taken. The risk of NAS, which can be successfully treated in nearly all cases, is clearly outweighed by the risk to both the pregnant woman and the baby of tapering buprenorphine. Treatment providers should be prepared to counsel a patient throughout the pregnancy on the importance of maintaining adherence to medication.

Pregnant patients who present for treatment should be cared for by providers with experience treating this population if at all possible. Close coordination of prenatal care and OUD treatment is crucial, with a priority on maintaining medication adherence, whether using buprenorphine or methadone.

Breast feeding should be encouraged as usual, and patients encouraged to continue their buprenorphine (or methadone) treatment after delivery. Very little buprenorphine is passed to the infant through breast milk.

Patients With Dual Diagnoses

Patients with dual diagnoses can be treated with buprenorphine/naloxone in an office-based setting. It can be difficult to determine whether psychiatric symptoms represent a primary disorder or a substance-induced disorder until patients are stable on buprenorphine/naloxone and not using other substances. A careful history may establish a prior primary psychiatric diagnosis during a period of abstinence, in which case resumption or initiation of appropriate psychiatric medication can be considered. The HMC OBOT team recommends screening for psychiatric symptoms at intake and when patients are more stable.

Patients Requiring Surgery

Few evidence-based studies are available on the management of patients on buprenorphine/naloxone maintenance in the peri-procedure period. Experts have developed some guidelines based on pharmacological principles that avoid under treatment of acute pain, the potential of opioid withdrawal, and disruption of opioid addiction treatment.

- The appropriate treatment of acute pain in patients on buprenorphine/naloxone maintenance includes continuing the patient's baseline opioid requirements to avoid increased pain sensitivity associated with opioid withdrawal. Thus, daily opioid maintenance treatment requirements must be met before attempting to achieve analgesia.
- Patients have been shown to have increased pain sensitivity and cross-tolerance to opioid analgesics; therefore, adequate pain control will often necessitate higher opioid doses at shorter dosing intervals.
- All patients on buprenorphine/naloxone maintenance should be co-managed with their buprenorphine/naloxone provider during the pre- and post-procedure periods.

Acute Pain Management in Patients on Buprenorphine/Naloxone

Little empirical or experimental evidence is available to guide management of acute pain in patients taking buprenorphine/naloxone. Whenever possible, OBOT staff should discuss acute pain management options before invasive procedures to reduce anxiety about uncontrolled pain

or relapse to illicit opioid use. Local or regional anesthesia should be considered, if possible. Communication between the buprenorphine provider and clinicians managing acute pain is imperative.

Several acute pain management options are possible:

1. Maintain current buprenorphine dosing and add non-opioid medications for acute pain. For instance, a routine dental procedure could be treated with NSAIDs, acetaminophen, or the combination of the two.
2. Split the current buprenorphine dose into three daily doses, in addition to non-opioid medication.
3. Increase and split the buprenorphine dose temporarily for a few days after the procedure, in addition to non-opioid medications. This may be necessary for a complicated dental or surgical procedure.
4. Split and increase or maintain buprenorphine and add short-acting full agonist opioid medication, in addition to non-opioid medications. This option may be necessary for more painful surgical procedures. Fentanyl and hydromorphone are preferred in this situation, because their affinity for the opioid receptor is higher than other full agonists. Patients on buprenorphine/naloxone, like patients in methadone maintenance treatment, can be expected to require higher full agonist opioid doses provided at shorter intervals.
5. Discontinue buprenorphine in the pre-procedure period, treat pre-operative and peri-operative pain with full opioid agonists, and return to buprenorphine once post-operative pain has lessened. If this option is chosen, buprenorphine should not be discontinued more than 24 hours in advance of elective surgery.

When acute pain management cannot be planned in advance, option 4 or 5 can be used. Patient-controlled analgesia (PCA) without a basal rate may be appropriate. Recent clinical practice has increasingly favored maintaining or increasing buprenorphine dose and adding full agonist opioids. This has the advantage of avoiding the anxiety and relapse risk that a patient may experience when successful buprenorphine treatment is interrupted.

Patients Requiring Chronic Pain Management

Buprenorphine/naloxone maintenance may not reliably alleviate all pain; however, patients transferring to buprenorphine from full opioid agonists prescribed for chronic pain often report significant analgesia and improved functional status. General principles for chronic pain management include:

- Reassure patients that their addiction will not be an obstacle to aggressive pain management.
- Become familiar with non-opioid management of chronic pain.
- Include patients in the decision-making process to allay anxiety.
- Establish clear goals for pain management:
    - Pain reduction rather than elimination

  - Improved function
  - Addressing associated symptoms
- Use a multidimensional approach to pain management, including non-opioid medications and non-medication modalities:
  - Try non-opioids initially.
  - Try adjuvant therapies next.
- If opioid analgesics are necessary for treatment of chronic pain, discontinue buprenorphine/naloxone and initiate methadone maintenance.

APPENDIX 1: TELEPHONE OR IN-PERSON SCREENING FOR BUPRENORPHINE/NALOXONE

DEMOGRAPHIC INFORMATION

How did you hear about our program?

❑ 1 = Spouse
❑ 2 = Friend
❑ 3 = Physician
❑ 4 = Flier
❑ 5 = Parent
❑ 6 = State hotline
❑ 7 = Physician locator
❑ 8 = Other (specify) _____

Are you pregnant?

❑ 1 = Yes
❑ 2 = No
❑ 3 = Don't know
❑ 4 = Tubal ligation
❑ 5 = Menopause
❑ 6 = History of hysterectomy

If no, do you use contraception? ❑ 1 = Yes ❑ 2 = No

Current address _____

Phone _____ **Is it OK to leave a message?** ❑ 1 = Yes ❑ 2 = No

Emergency contact _____ **Phone**_____

Is the emergency contact aware of your addiction? ❑ 1 = Yes ❑ 2 = No

DRUG USE HISTORY

What is your drug of choice?	Age at First Use 0 if never used	Last Use 1 = 12 or more months ago (specify date) 2 = 3–11 months ago 3 = 1–2 months ago 4 = 1–3 weeks ago 5 = Used this week	How Often Used? 1 = Less than 1/month 2 = 1–3 times/month 3 = 1–2 times/week 4 = 3–6 times/week 5 = Daily	Route of Admin. 1 = Oral 2 = Smoking 3 = Intranasal 4 = Intravenous injection 5 = Skin popping 6 = Other	Amount Used
Opioid ❑ Heroin ❑ OxyContin ❑ Other oxycodone-containing product ❑ Methadone ❑ Other _____					
Benzodiazepine					
Alcohol					
Cocaine					
Amphetamines Including Methamphetamine					
Tobacco					
Other					

Have you ever shared needles? ❑ 1 = Yes ❑ 2 = No

Have you ever participated in a needle exchange program? ❑ 1 = Yes ❑ 2 = No

Have you ever overdosed? ❑ 1 = Yes ❑ 2 = No

Number of lifetime overdoses _____

Have you ever been hospitalized due to an overdose? ❑ 1 = Yes ❑ 2 = No

SUBSTANCE USE TREATMENT HISTORY

Have you had any substance abuse treatment? ❑ 1 = Yes ❑ 2 = No

If yes, how many times for each type?

_____ Detox

_____ Drunk driving program

_____ Residential rehabilitation or halfway house

_____ Methadone maintenance

_____ Buprenorphine/naloxone maintenance

Are you currently participating in any form of substance abuse treatment?

❑ 1 = 12-Step program (for example, Narcotics Anonymous, Alcoholics Anonymous)

❑ 2 = Outpatient counseling

❑ 3 = Acupuncture

❑ 4 = Intensive outpatient program

❑ 5 = Other (specify) _____

How many attempts have you made to stop using? _____

Do you attend meetings? Check all that apply.

❑ 1 = AA

❑ 2 = NA

❑ 3 = Smart Recovery

❑ 4 = Other (specify) _____

How many meetings do you attend each week?

❑ 1 = 1–2 per week

❑ 2 = 3–4 per week

❑ 3 = 5–6 per week

❑ 4 = Daily

❑ 5 = None

❑ 6 = Other (specify) _____

Do you have a sponsor? ❑ 1 = Yes ❑ 2 = No

Do you have a history of any other addictive behaviors such as?

❑ 1 = Gambling

❑ 2 = Sex

❑ 3 = Shopping

❑ 4 = Eating disorder (for example, overeating, bulimia, anorexia)

❑ 5 = Other (specify) _____

❑ 6 = No

CRIMINAL HISTORY

Have you ever been incarcerated? ❑ 1 = Yes ❑ 2 = No

What is the longest period of time you spent in jail/prison? _____

Are you on probation? ❑ 1 = Yes ❑ 2 = No

Are you on parole? ❑ 1 = Yes ❑ 2 = No

Are you facing potential jail time? ❑ 1 = Yes ❑ 2 = No

Do you have outstanding legal issues? ❑ 1 = Yes ❑ 2 = No

If yes, can you tell us about them? _____

METHADONE HISTORY

Have you ever been on methadone maintenance? ❑ 1 = Yes ❑ 2 = No

When were you on methadone maintenance? _____

Where were you on methadone maintenance? _____

How long were you on methadone maintenance? _____

What was your dose? _____

What was your maximum dose? _____

Why did you stop methadone treatment? _____

Are you currently on methadone maintenance? ❑ 1 = Yes ❑ 2 = No

What is your dose? _____

Where are you receiving services for your methadone treatment? _____

What is the name of your counselor at the methadone clinic? _____

How long have you been in your current methadone maintenance program? _____

Are you receiving take-homes doses? ❑ 1 = Yes ❑ 2 = No

If yes, how many? _____

BUPRENORPHINE HISTORY

Have you ever been prescribed buprenorphine/naloxone before? ❑ 1 = Yes ❑ 2 = No

If yes, when were you on buprenorphine/naloxone? _____

What was your dose? _____

Why did you stop taking the buprenorphine/naloxone? _____

MENTAL HEALTH HISTORY

Have you ever been diagnosed with any of the following mental health conditions?

❑ 1 = Depression
❑ 2 = Anxiety
❑ 3 = Bipolar
❑ 4 = Schizophrenia
❑ 5 = Obsessive compulsive disorder (OCD)
❑ 6 = Post-traumatic stress disorder (PTSD)
❑ 7 = Attention deficit disorder
❑ 8 = Panic attacks
❑ 9 = Other (specify) _____

Are you taking medications for this/these problem(s)? ❑ 1 = Yes ❑ 2 = No

If yes, what medications are you taking? _____

Have you ever taken medications for a mental health condition? ❑ 1 = Yes ❑ 2 = No

If yes, what medications did you take? _____

Are you seeing a psychiatrist, psychologist, or counselor for this/these problem(s)?
❑ 1 = Yes ❑ 2 = No

Where do you see your psychiatrist, psychologist, or counselor? _____

What is this individual's name? _____

How often do you see this person? _____

How many times have you seen this person in the last 6 months? _____

Will you sign a consent form to release information so that we can communicate with your psychiatrist, psychologist, or counselor about your treatment plan?
❑ 1 = Yes ❑ 2 = No

Have you ever been hospitalized for mental health issues? ❑ 1 = Yes ❑ 2 = No

Have you ever attempted to end your life or to hurt yourself? ❑ 1 = Yes ❑ 2 = No

How many times did you try to end your life or to hurt yourself? _____

Do you currently have thoughts about hurting yourself or ending your life?
❑ 1 = Yes ❑ 2 = No (If no, skip the next two questions.)

Do you currently have a plan for how you would hurt yourself or end your life?
❑ 1 = Yes ❑ 2 = No

Do you have the means to carry out your plan? ❑ 1 = Yes ❑ 2 = No

Have you ever attempted or thought about homicide (killing someone else)?
❑ 1 = Yes ❑ 2 = No (If no, skip the next two questions.)

Are you thinking about killing someone? ❑ 1 = Yes ❑ 2 = No

Do you have the means to carry this out? ❑ 1 = Yes ❑ 2 = No

HEALTH STATUS

Have you ever been diagnosed with other medical conditions? Check all that apply.

❑ 1 = Diabetes (specify type) _____

❑ 2 = Heart disease (specify type) _____

❑ 3 = Cancer (specify type) _____

❑ 4 = Asthma

❑ 5 = Hepatitis C ➔ If yes, have you been treated? ❑ 1 = Yes ❑ 2 = No

❑ 6 = Tuberculosis (TB)

❑ 7 = Endocarditis

❑ 8 = Abscesses

❑ 9 = Skin infection

❑ 10 = HIV ➔ If yes, are you currently in care? ❑ 1 = Yes ❑ 2 = No

❑ 11 = Hepatitis B

❑ 12 = Hepatitis A

❑ 13 = Seizure disorder ➔ Are you on medications? ❑ 1 = Yes ❑ 2 = No

❑ 14 = High blood pressure

❑ 15 = Head trauma/injuries

❑ 16 = Pancreatic problems

❑ 17 = Other (specify) _____

❑ 18 = None

Are you taking any other medications? ❑ 1 = Yes ❑ 2 = No

If yes, what medications are you taking? _____

Have you been tested for HIV? ❑ 1 = Yes ❑ 2 = No

If yes, did you go back for the results? ❑ 1 = Yes ❑ 2 = No

If yes, when was the last time you were tested? _____

Have you ever had surgery? ❑ 1 = Yes ❑ 2 = No

If yes, why did you have surgery? _____

Do you have any pending surgeries? ❑ 1 = Yes ❑ 2 = No

What kind of medical insurance do you have? Check all that apply.

❑ 1 = Medicare ➔ Does the patient have Medicare Part D? ❑ 1 = Yes ❑ 2 = No
If yes, which plan? _____

❑ 2 = Medicaid (specify) _____

❑ 3 = Hospital/Clinic Free Care

❑ 4 = Private insurance (specify) _____

❑ 5 = No insurance (self-pay)

❑ 6 = Don't know

❑ 7 = Other (specify) _____

PAIN ASSESSMENT

Do you have chronic pain? ❑ 1 = Yes ❑ 2 = No

Please rate your pain, on a scale from 0 to 10, without any pain medications (prescribed or bought on the street).

____0____1____2____3____4____5____6____7____8____9____10____

PHYSICIAN INFORMATION

Where do you get most of your healthcare services? _____

When was the last time you saw a doctor?

❑ 1 = Last week ❑ 4 = Within the past 6 months

❑ 2 = Last month ❑ 5 = Within the past year

❑ 3 = Within the past 3 months ❑ 6 = More than 1 year ago

What is the name of your doctor? _____

Are you willing to change your primary care to a Harborview Medical Center primary care clinic? ❑ 1 = Yes ❑ 2 = No

EMPLOYMENT

Are you currently employed? ❑ 1 = Yes ❑ 2 = No

If yes, what do you do for work? _____

Are you working full or part time? _____

What days of the week do you work and how many hours per day do you work?

_____

SOCIAL SUPPORT

What is your relationship status?

❑ 1 = Single (skip the remaining questions in this section)

❑ 2 = Married

❑ 3 = Long-term relationship

❑ 4 = Divorced

❑ 5 = Other (specify) _____

Do you live with your partner/significant other? ❑ 1 = Yes ❑ 2 = No

Does your partner have a history of substance use/abuse? ❑ 1 = Yes ❑ 2 = No

Is your partner/significant other currently in treatment? ❑ 1 = Yes ❑ 2 = No

If yes, what kind of treatment are they in?

❑ 1 = Buprenorphine/naloxone

❑ 2 = Methadone maintenance

❑ 3 = Abstinence

❑ 4 = Residential

❑ 5 = Other (specify) _____

How satisfied are you with the support you get from your partner/significant other?

❑ 1 = Very satisfied

❑ 2 = Satisfied

❑ 3 = Fairly satisfied

❑ 4 = Not satisfied

❑ 9 = N/A

FAMILY HISTORY

Do any other family members have a history of substance use/abuse? ❑ 1 = Yes ❑ 2 = No

TRANSPORTATION

How do you get around?

❑ 1 = I drive ➔ Do you have your own car? ❑ 1 = Yes ❑ 2 = No

❑ 2 = Public transportation

❑ 3 = Walk or bike

❑ 4 = I get a ride from a family member/friend

❑ 5 = Other (specify) _____

Do you have a driver's license? ❑ 1 = Yes ❑ 2 = No

How would you get to HMC if you needed to get here?

❑ 1 = I would drive

❑ 2 = Public transportation

❑ 3 = I would walk or bike

❑ 4 = I would get a ride from a family member/friend

❑ 5 = Other (specify) _____

Would you be able to come to HMC within 48 hours' notice? ❑ 1 = Yes ❑ 2 = No

HOUSING

Have you spent 1 or more weeks on the street or in a shelter in the last 3 months?
❑ 1 = Yes ❑ 2 = No

What type of place are you living in now?

❑ 1 = House or apartment you own

❑ 2 = House or apartment you rent

❑ 3 = House or apartment owned or rented by family or friends

❑ 4 = Hotel

❑ 5 = Alcohol or drug treatment program

❑ 6 = Shelter

❑ 7 = Street or car

❑ 8 = Other (specify) _____

❑ 9 = Don't know

Who do you live with at this time?

❑ 1 = I live alone

❑ 2 = I live with my partner/significant other

❑ 3 = I live with family members

❑ 4 = I live with friends

❑ 5 = Other (specify) _____

Can you tell me what your goals are for treatment?

_____

_____

_____

_____

APPENDIX 2: NURSE CARE MANAGER INTAKE TOOL

Before intake, the nurse case manager reviews the phone screening completed by the program manager.

Nursing Summary

Name _____

Are you pregnant?

❑ 1 = Yes

❑ 2 = No

❑ 3 = Don't know

❑ 4 = Tubal ligation

❑ 5 = Menopause

❑ 6 = History of hysterectomy

If no, do you use contraception? ❑ 1 = Yes ❑ 2 = No

DRUG USE HISTORY

What are you currently using?

❑ 1 = Heroin (amount) _____

❑ 2 = OxyContin (amount) _____

❑ 3 = Methadone (amount) _____

❑ 4 = Other pain relievers (for example, Percocet, Vicodin) (amount) _____

❑ 5 = Cocaine

❑ 6 = Benzodiazepines (for example, Klonopin, Xanax, Ativan) (amount) _____

❑ 7 = Nothing

❑ 8 = Alcohol

❑ 9 = Amphetamines

❑ 10 = Buprenorphine/naloxone ➔ How much are you using per day? _____

❑ 11 = Other (specify) _____

METHADONE AND BUPRENORPHINE HISTORY

Are you currently on methadone maintenance? ❑ 1 = Yes ❑ 2 = No

What is your dose? _____

Have you ever been prescribed buprenorphine/naloxone before? ❑ 1 = Yes ❑ 2 = No

If yes, when were you on buprenorphine/naloxone? _____

What was your dose? _____

If you stopped taking buprenorphine/naloxone, why did you stop taking it?
_____

Are you still on buprenorphine/naloxone? ❑ 1 = Yes ❑ 2 = No

Have you ever taken illicit buprenorphine/naloxone? ❑ 1 = Yes ❑ 2 = No

Have you ever experienced precipitated withdrawal when taking buprenorphine/naloxone?
❑ 1 = Yes ❑ 2 = No

MENTAL HEALTH HISTORY

Have you ever been diagnosed with any of the following mental health conditions?

❑ 1 = Depression ☐ 5 = Obsessive compulsive disorder (OCD)

❑ 2 = Anxiety ☐ 6 = Post-traumatic stress disorder (PTSD)

❑ 3 = Bipolar ☐ 7 = Attention deficit disorder

❑ 4 = Schizophrenia ☐ 8 = Panic attacks

☐ 9 = Other (specify) _____

Are you taking medications for this/these problem(s)? ❑ 1 = Yes ❑ 2 = No

If yes, what medications are you taking? _____

Have you ever taken medications for a mental health condition? ❑ 1 = Yes ❑ 2 = No

If yes, what medications did you take? _____

HEALTH STATUS

Have you ever been diagnosed with any other medical conditions? Check all that apply.

❑ 1=Diabetes (specify type) _____

❑ 2=Heart disease (specify type) _____

❑ 3=Cancer (specify type) _____

❑ 4=Asthma

❑ 5= Hepatitis C ➔ If yes, have you been treated? ❑ 1 = Yes ❑ 2 = No

❑ 6=Tuberculosis (TB)

❑ 7=Endocarditis

❑ 8=Abscesses

❑ 9=Skin infection

❑ 10= HIV ➔ If yes, are you currently in care? ❑ 1 = Yes ❑ 2 = No

❑ 11= Hepatitis B

❑ 12= Hepatitis A

❑ 13= Seizure disorder➔ Are you on medications? ❑ 1 = Yes ❑ 2 = No

❑ 14= High blood pressure

❑ 15= Head trauma/injuries

❑ 16= Pancreatic problems

❑ 17= Other (specify) _____

❑ 18= None

This information may already be documented in the patient's electronic health record.

Past Medical History

Current Medications

Allergies

Have you been tested for HIV? ❑ 1 = Yes ❑ 2 = No

If yes, did you go back for the results? ❑ 1 = Yes ❑ 2 = No

If yes, when was the last time you were tested? _____

Do you have any pending surgeries? ❑ 1 = Yes ❑ 2 = No

PAIN ASSESSMENT

Do you have chronic pain? ❑ 1 = Yes ❑ 2 = No

If yes, please explain:

Please rate your pain, on a scale from 0 to 10, without any pain medications (prescribed or bought on the street).

___0____1____2____3____4____5____6____7____8____9____10____

Has your pain lasted 3 months or longer? ❑ 1 = Yes ❑ 2 = No

Comments

_____

_____

_____

_____

Can you tell me what your goals are for treatment?

_____

_____

_____

_____

- ❑ The OBOT program reviewed requirements with the patient including medical and OBOT appointments, UDSs (observed and unobserved), and possible random call-backs with pill counts. The patient is aware of their responsibility for their buprenorphine/naloxone medication. The patient has been informed to keep medication in a safe undisclosed place and out of reach of children and visitors. If living in a shelter, the patient has been informed to keep medication in a locked storage unit.
- ❑ The OBOT consent form and contract have been read to and reviewed with the patient. The patient voluntarily signed and dated the consent form. A copy was given to the patient and the original was placed in the patient's records. The patient had the opportunity to ask questions.
- ❑ The OBOT program reviewed the following aspects of buprenorphine/naloxone treatment with the patient: medication doses, potential side effects including elevations in transaminases, potential lethal interaction with benzodiazepines and alcohol, safe administration, and secure storage. Written information was provided to the patient. The patient expressed that they understood the information provided and wished to schedule the induction phase time and date.
- ❑ UDS specimen was submitted to the lab.

APPENDIX 3: SAMPLE CONSENT FORMS

Consent for Treatment with Buprenorphine / Naloxone

Buprenorphine/naloxone is a Food and Drug Administration-approved medication for treatment of people with opioid use disorder (OUD). Buprenorphine/naloxone can be used for detoxification or for maintenance therapy. Maintenance therapy can continue as long as medically necessary. It is estimated that a patient will take buprenorphine/naloxone for at least 6 months.

Buprenorphine/naloxone treatment can result in physical dependence of an opioid. Withdrawal from buprenorphine/naloxone is generally less intense than withdrawal from heroin or methadone. If buprenorphine/naloxone is suddenly discontinued, some patients have no withdrawal symptoms; others may have symptoms such as muscle aches, stomach cramps, or diarrhea lasting several days. To minimize the possibility of opioid withdrawal, buprenorphine/naloxone should be discontinued gradually over several weeks or more.

If you are dependent on opioid, you should be in as much withdrawal as possible when you take the first dose of buprenorphine/naloxone. If you are not in withdrawal, buprenorphine/naloxone can cause severe opioid withdrawal.

It may take several days to transition from the opioid that you had been taken to buprenorphine/naloxone. During this time, use of any other opioids may cause an increase in symptoms. After stabilizing on buprenorphine/naloxone, the use of other opioid will have less effect. Attempts to override the buprenorphine/naloxone by taking more opioids could result in an opioid overdose.

Do not take any other medications without first talking to your healthcare provider.

Combining buprenorphine/naloxone with alcohol or other medications may be hazardous. Combining buprenorphine/naloxone with medications such as Klonopin, Valium, Haldol, Librium, and Ativan has resulted in deaths.

The form of buprenorphine that you will be taking (buprenorphine/naloxone) is a combination of buprenorphine with a short-acting opioid blocker (naloxone). If the buprenorphine/naloxone tablet were dissolved and injected by someone taking heroin or another strong opioid (e.g., morphine), it would cause severe opioid withdrawal.

Buprenorphine/naloxone tablets and films **must** be held under the tongue until they completely dissolve. Buprenorphine/naloxone will not be absorbed from the stomach if it is swallowed.

Print Name	Signature	Date
Witness Name	Signature	Date

Consent for Release of Information

Many standard release of information forms include an option to include drug and alcohol treatment records. This option should be routinely included when requesting or releasing OBOT or specialty addiction treatment records.

I, _____, born on _____,
(patient name) (patient birth date)

SSN _____, authorize _____ to
(patient Social Security #) (clinic or doctor's name)

disclose to _____
(name and location of person/organization to receive information)

the following information: _____

_____.

The purpose of this disclosure is_____.

This authorization expires on _____, or whenever _____ is no longer providing me with services.

I understand that my records are protected under federal regulations and cannot be disclosed without my written consent unless otherwise provided for in the regulations. I also understand that I may revoke this consent at any time except to the extent that action has been taken in reliance on it.

Signature of patient _____ Date _____

Signature of witness _____ Date _____

ATTENTION RECIPIENT

Notice Prohibiting Redisclosure

This information has been disclosed to you from the records protected by federal confidentiality rules (42 CFR, Part 2). The federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR, Part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The federal rules restrict any use of this information to criminally investigate or prosecute any alcohol or drug abuse patient.

Special Consents

In addition to standard Health Insurance Portability and Accountability Act laws, federal regulations mandate strict confidentiality for information about patients being treated for substance use disorders (42 CFR, Part 2). The law requires written patient consent before information about substance abuse treatment can be disclosed to any other source. For buprenorphine/naloxone treatment, this may include any communications with other physicians, treatment centers, significant others, or pharmacies.

Specific actions that are prohibited without consent include the following:

- Providing information regarding a patient's past, present, or future participation in substance abuse treatment.
- Disclosing or transmitting a patient's substance use-related medical records.
- Use of a letterhead that identifies the office as a substance use treatment provider.
- Providing information about those who have applied for treatment or have been interviewed, regardless of whether they actually commenced treatment.
- Providing information about deceased patients.
- Verifying information that inquirers already possess—in other words, a program can neither confirm nor deny that a patient was being treated there.

Some exceptions to the disclosure laws include medical emergencies or legal situations.

Patient Consent and Release Form for Buprenorphine/Naloxone Treatment During Pregnancy

I, _____, am currently receiving prenatal care from Harborview Medical Center. Because I am currently prescribed buprenorphine/naloxone for treatment of my opioid addiction and do not wish to take methadone, my doctor has referred me to the Adult Medicine Clinic Office-Based Opioid Treatment (OBOT) program for treatment with buprenorphine/naloxone for my opioid addiction during my pregnancy. During my pregnancy, I agree to be switched from the combination buprenorphine/naloxone tablet to the non-combination buprenorphine tablet (Subutex®) as recommended by national addiction treatment guidelines. The Harborview Medical Center OBOT team will coordinate with my obstetrician.

I have met with _____ at the Adult Medicine Clinic OBOT program and s/he has discussed with me and I understand the risks and benefits of taking buprenorphine/naloxone and those associated with taking methadone during my pregnancy.

I have been informed that the federal Food and Drug Administration (FDA) has not approved the use of buprenorphine/naloxone for the treatment of opioid addiction in pregnant women. Methadone has been FDA approved for the treatment of opioid addiction during pregnancy, and for more than 40 years methadone has shown to be safe and effective during pregnancy. Therefore, it is currently believed that methadone is safer than buprenorphine/naloxone for the treatment of opioid addiction during pregnancy.

Although few research studies have been completed in Europe and research is now being conducted in the United States on the effects of buprenorphine/naloxone on pregnant women and their fetuses, currently not enough information is available to say that buprenorphine/naloxone is safe during pregnancy.

There have been studies of the effects of buprenorphine/naloxone on laboratory animals. Buprenorphine/naloxone has caused some bone problems in laboratory animal embryos and fetuses after injections of buprenorphine/naloxone but not when the same amount of buprenorphine/naloxone was given by mouth.

A possible problem of taking any opioid (e.g., heroin, methadone, buprenorphine/naloxone) during pregnancy is that after birth the child may experience neonatal abstinence syndrome (NAS). Babies with NAS may suffer from sleep disturbances, feeding difficulties, tremor, sneezing, irritability, vomiting, weight loss, and seizures. Many of these infants require hospitalization, often for long periods.

I understand these risks and benefits and have decided to take buprenorphine (Subutex®) rather than methadone. I understand that medical knowledge on the actual or potential risks of buprenorphine/naloxone on pregnant women and the fetus is not certain. I accept responsibility for this decision.

I hereby release and agree to hold harmless Harborview Medical Center, its Adult Medicine Clinic OBOT program, the prescribing doctor, and the hospital's officers, directors, agents, and employees from any liability that may arise in connection with my taking buprenorphine (Subutex®) during my pregnancy.

Patient	Date/time
Physician prescriber	Date/time
Witness	Date/time

Consent for Parental Notification

The Harborview Medical Center's (HMC) Adult Medicine Clinic (AMC) Office-Based Opioid Treatment (OBOT) program has a policy for patients under age 18 that requires that program staff be permitted to contact parents/guardians of the patient.

It is important for AMC staff to be able to contact your parents or guardians if changes to your treatment are needed. Contact with parents/guardians might be warranted to report results of urine drug screens (positive or negative), if HMC OBOT staff feel that more intensive treatment needs to be considered, or if staff are concerned about your safety. We will do everything we can to respect your confidentiality, but if we feel you need intensified treatment, you have a positive urine drug screen, or you are at risk of harming yourself or someone else, we are required to contact your parents or guardians.

HMC OBOT staff feel that communicating with parents/guardians as needed is critical to providing you with safe and effective treatment. We feel that your parents' support and involvement will be beneficial to you and to your success in your recovery.

The signature below certifies that I have given HMC OBOT staff permission to contact my parents/guardians regarding my treatment provided by HMC.

Print Name	Signature	Date
Witness Name	Signature	Date

APPENDIX 4: BUPRENORPHINE TREATMENT AGREEMENT

As a patient in the buprenorphine protocol for treatment of an opioid use disorder, I freely and voluntarily agree to accept this treatment agreement, as follows.

I agree to keep, and be on time to, all my scheduled appointments with my doctor and nurse and to conduct myself in a courteous manner in the clinic.

I agree not to arrive at the clinic intoxicated or under the influence of drugs. If I do, the doctor or nurse may not see me, and I will not be given any medication until my next scheduled appointment.

I agree not to sell, share, or give any of my medication to another person. I understand that such mishandling of my medication is a serious violation of this agreement and would result in my treatment being terminated without recourse for appeal.

I agree not to deal, steal, or conduct any other illegal or disruptive activities in the clinic or on hospital grounds; this is grounds for immediate discharge.

I agree not to tamper with specimens for urine drug screens. If I do so, this may be grounds for immediate discharge and referral to a more intensive treatment program or I will be asked to submit to a supervised urine specimen in a setting with chain of custody.

I agree that my prescriptions can be given to me only at my regularly scheduled times. Missed appointments may result in my not being able to get medication until the next scheduled visit.

I agree that the medication I receive is my responsibility and that I will keep it in a safe and secure place. I agree that lost medication may not be replaced regardless of the reasons for such a loss.

I agree that if I obtain medication from any doctors, pharmacies, or other sources that I will inform my physician and/or Harborview Medical Center's (HMC) Adult Medicine Clinic (AMC) Office-Based Opioid Treatment (OBOT) nurse immediately.

I understand that mixing buprenorphine with other medications, especially benzodiazepines (such as Klonopin, Ativan, Valium, and Xanax), and other drugs can be dangerous. I understand that a number of deaths have been reported among people mixing buprenorphine with benzodiazepines.

I agree to take my medication as the doctor has instructed and not to alter the way I take my medication without first consulting my doctor or nurse.

I agree to random urine drug screens and to bring in my remaining buprenorphine tablets when requested by my doctor or nurse.

I agree not to consume poppy seeds while in this treatment program. Poppy seed consumption will not be accepted as an excuse for a positive opioid screen.

I understand that my treatment plan may change to random call-back visits only and that I need to have working telephone contacts that are updated as changed. When called for random call-backs, I need to respond within 24 hours by telephone. Non-response to call-backs will be considered the same as positive urine specimens.

I understand that should I choose to abuse other illicit substances, this issue will be addressed through changes in my treatment plan to help me address this use. If I continue to struggle with ongoing drug use, this could be grounds for transfer to more intensive treatment options.

Positive urine screens for opioids will be evaluated by the treatment team. Ongoing positive results (specifically, 2 positive results in 1 month) or missed urine tests may be grounds for transfer to more intensive treatment options.

Urine screen results that are negative for buprenorphine will be evaluated by the team and toxicologist and are grounds for transfer to another level of care or discharge.

HMC OBOT will periodically access the state prescription drug monitoring program to review medication profiles on all patients to ensure patients are not receiving other controlled substances from other providers. If patients are found to be accessing prescriptions from other providers, this finding will be reviewed by the HMC OBOT team. If it is determined that the medications obtained by other non-OBOT providers are in violation of the treatment agreement, the HMC OBOT team will evaluate the situation and may discharge me from the HMC OBOT program.

I understand that the HMC OBOT program will not release the results of my urine toxicology screens to any other agency, program, or institution. The reason for this policy is that AMC does not have a chain of custody over the urine specimens; these tests are for my treatment at AMC only. If patients have legal or program requirements that require observed urine toxicology testing, this should be done independent of my treatment at AMC.

If I am woman of childbearing age, it is strongly recommended that I use contraceptives while on treatment. If I become pregnant while on buprenorphine/naloxone, I will alert my healthcare providers immediately so they can assist me in taking steps to keep me and the fetus safe.

If at any time I am discharged from this program, I may be reconsidered at a future time to determine whether office-based treatment may be an option for me.

I understand that medication alone is not sufficient treatment for my disease, and I agree to participate in the patient education, substance abuse counseling, and relapse prevention programs, as provided, to assist me in my treatment.

I understand that my records, course of treatment, and medical care will be kept in an electronic health record under a confidential locked filing system. These notes will be visible to any healthcare professional involved in my care.

Print Name	Signature	Date
Witness Name	Signature	Date

APPENDIX 5: INDUCTION PROTOCOLS

❑ Patient presents for first induction.

❑ Patient evaluated using COWS.

Patient scored _____on COWS first assessment.

Patient self-administered _____ mg sublingually as prescribed.

❑ Patient was assessed and instructed in proper administration.

❑ Patient observed to tolerate medication.

Summary 1
COWS First Assessment

Resting Pulse Rate
- ❑ 0 = Pulse rate 80 or below
- ❑ 1 = Pulse rate 81–100
- ❑ 2 = Pulse rate 101–120
- ❑ 3 = Pulse rate greater than 120

Sweating
- ❑ 0 = No report of chills or flushing
- ❑ 1 = Subjective report of chills or flushing
- ❑ 2 = Flushed or observable moistness on face
- ❑ 3 = Beads of sweat on brow or face
- ❑ 4 = Sweat streaming off face

Restlessness During Assessment
- ❑ 0 = Able to sit still
- ❑ 1 = Reports difficulty sitting still, but is able to do so
- ❑ 3 = Frequent shifting or extraneous movements of legs/arms
- ❑ 5 = Unable to sit still for more than a few seconds

Pupil Size
- ❑ 0 = Pupils pinned or normal size for room light
- ❑ 1 = Pupils possibly larger than normal for room light
- ❑ 2 = Pupils moderately dilated
- ❑ 5 = Pupils so dilated that only the rim of the iris is visible

Bone or Joint Aches
- ❑ 0 = Not present
- ❑ 1 = Patient reports mild diffuse discomfort
- ❑ 2 = Patient reports severe diffuse aching of joints/muscle
- ❑ 4 = Patient is rubbing joints/muscles and is unable to sit still because of discomfort

Runny Nose or Tearing

- ❑ 0 = Not present
- ❑ 1 = Nasal stuffiness or unusually moist eyes
- ❑ 2 = Nose running or eyes tearing
- ❑ 4 = Nose constantly running or tears streaming down cheeks

GI Upset

- ❑ 0 = No GI symptoms
- ❑ 1 = Stomach cramps
- ❑ 2 = Nausea or loose stool
- ❑ 3 = Vomiting or diarrhea
- ❑ 5 = Multiple episodes of diarrhea or vomiting

Tremor

- ❑ 0 = No tremor
- ❑ 1 = Tremor can be felt, but not observed
- ❑ 2 = Slight tremor observable
- ❑ 4 = Gross tremor or muscle twitching

Yawning

- ❑ 0 = No yawning
- ❑ 1 = Yawning once or twice during assessment
- ❑ 2 = Yawning three or more times during assessment
- ❑ 4 = Yawning several times per minute

Anxiety or Irritability

- ❑ 0 = None
- ❑ 1 = Patient reports increasing irritability or anxiousness
- ❑ 2 = Patient obviously irritable/anxious
- ❑ 4 = Patient so irritable or anxious that participation in the assessment is difficult

Gooseflesh Skin

- ❑ 0 = Skin is smooth
- ❑ 3 = Piloerection of skin can be felt or hairs standing up on arms
- ❑ 5 = Prominent piloerection

Total COWS Score _____

Score: 5–12 = Mild
13–24 = Moderate
25–36 = Moderately severe
More than 36 = Severe withdrawal

APPENDIX 6: NURSE CARE MANAGER FOLLOW-UP FORM

OBOT Follow-Up

Date _____ Patient Name _____

Patient reports (check all that apply)

- ❑ No illicit substance use
- ❑ Marijuana
- ❑ Opioid use
- ❑ Amphetamine use
- ❑ Alcohol use
- ❑ Benzodiazepine use
- ❑ Other use (specify) _____

Patient is taking buprenorphine

❑ As directed ❑ Other than prescribed (specify) _____

Patient has _____ doses remaining. Patient's most recent dose was

❑ Yesterday ❑ Today

Patient reports

- ❑ No symptoms of withdrawal or craving
- ❑ No adverse effects
- ❑ Craving
- ❑ Symptoms of withdrawal
- ❑ Other (specify) _____

Subjective Data

Assessment and Plan

Prescription for (specify amount) _____ films/tablets sent to (specify)

_____ pharmacy. Prescription should last until (specify)

_____.

Most Recent UDS Results and Dates

_____

_____

Patient Data

Primary care physician _____

Buprenorphine prescriber _____

Appointment Interval

❑ Weekly ❑ Every 2 weeks ❑ Monthly

Buprenorphine History

Medication start date _____

Nurse order date _____

Buprenorphine Dose

❑ 2 mg	❑ 8 mg	❑ 16 mg
❑ 4 mg	❑ 10 mg	❑ 20 mg
❑ 6 mg	❑ 12 mg	❑ 24 mg

Dose Adjustments (date and reason)

_____

_____

Date of Last PDMP Check _____

APPENDIX 7: PATIENT HANDOUTS

Pediatric Exposure to Buprenorphine/Naloxone

Guidelines From the Centers for Disease Control and Prevention:

Recommendations to prevent harmful exposures to buprenorphine
Buprenorphine-containing products can be harmful to children not only when a whole table or film is swallowed, but also when they are licked or placed in the mouth. • Keep medication out of sight and reach of children. • Use a locked box, bag, or cabinet for safe storage of medication. • Always keep medication in its original, labeled prescription container, with child-resistant closure when appropriate. • Do not place tablets or films on counters, sinks, dressers, or nightstands for later use. • Discard used buprenorphine film wrapping immediately by folding the package together, placing it in the trash, and securing the trash. Buprenorphine bottles and film wrapping can contain enough leftover medicine to cause problems for young children. • Do not store medication in your pocket, back, purse, backpack, or other carrying case. • Avoid leaving medication in the bathroom, car, or any publicly accessible space.

Washington State Poison Control Hotline: (800) 222-1222

COWS Scale

Opioid Withdrawal Record (Induction Form)*

(Adapted from the Clinical Opiate Withdrawal Scale)

Patient Name _____ **Treatment Start Date** _____

Circle the number/description that best corresponds to your patient's present symptoms.

Parameter	**Baseline Observation** **1st Dose** _____mg Time given _____ am / pm	**1st Dose Observation** _____minutes after 1st dose	**1st Dose, 2nd Observation** (if needed) _____minutes after 1st dose	**2nd Dose** (if needed) Time given _____am / pm	**2nd Dose Observation** _____minutes after 2nd dose
Resting Pulse Rate _____beats/minute *Measure after patient is sitting/lying for 1 minute*					
0 Pulse rate 80 or below 120	0	0	0	0	0
1 Pulse rate 81–100	1	1	1	1	1
2 Pulse rate 101–120	2	2	2	2	2
4 Pulse rate greater than 120	4	4	4	4	4
Sweating *Over past 30 minutes; not accounted for by room temperature or patient activity*					
0 No report of chills or flushing	0	0	0	0	0
1 Subjective report of chills or flushing	1	1	1	1	1
2 Flushed or observable moistness on face	2	2	2	2	2
3 Beads of sweat on brow or face	3	3	3	3	3
4 Sweat streaming off face	4	4	4	4	4
Restlessness *Observation during assessment*					
0 Able to sit still	0	0	0	0	0
1 Reports difficulty sitting still, but is able to do so	1	1	1	1	1
3 Frequent shifting or extraneous movements of legs/arms	3	3	3	3	3
5 Unable to sit still for more than a few seconds	5	5	5	5	5
Tremors *Observation of outstretched hands*					
0 No tremor	0	0	0	0	0
1 Tremor can be felt, but not observed	1	1	1	1	1
2 Slight tremor observable	2	2	2	2	2
4 Gross tremor or muscle twitching	4	4	4	4	4
Pupil Size					
0 Pupils pinned or normal size for room light	0	0	0	0	0
1 Pupils possibly larger than normal for room light	1	1	1	1	1
2 Pupils moderately dilated	2	2	2	2	2
5 Pupils so dilated that only the rim of the iris is visible	5	5	5	5	5

Parameter	**Baseline Observation** **1st Dose** _____mg Time given _____ am / pm	**1st Dose Observation** _____minutes after 1st dose	**1st Dose, 2nd Observation** (if needed) _____minutes after 1st dose	**2nd Dose** (if needed) Time given _____am / pm	**2nd Dose Observation** _____minutes after 2nd dose
GI Upset *Over last 30 minutes* 0 No GI symptoms 1 Stomach cramps 2 Nausea or loose stool 3 Vomiting or diarrhea 5 Multiple episodes of diarrhea or vomiting	0 1 2 3 5	0 1 2 3 5	0 1 2 3 5	0 1 2 3 5	0 1 2 3 5
Anxiety or Irritability 0 None 1 Patient reports increasing irritability or anxiousness 2 Patient obviously irritable/anxious 4 Patient so irritable/anxious that participation in assessment is difficult	0 1 2 4	0 1 2 4	0 1 2 4	0 1 2 4	0 1 2 4
Bone or Joint Aches *If patient was having pain previously, gauge the additional component attributed to opioid withdrawal only* 0 Not present 1 Mild diffuse discomfort 2 Patient reports severe diffuse aching of joints/muscles 4 Patient is rubbing joints or muscles and is unable to sit still because of discomfort	0 1 2 4	0 1 2 4	0 1 2 4	0 1 2 4	0 1 2 4
Yawning *Observation during assessment* 0 No yawning 1 Yawning once or twice during assessment 2 Yawning three or more times during assessment 4 Yawning several times/minute	0 1 2 4	0 1 2 4	0 1 2 4	0 1 2 4	0 1 2 4
Runny Nose or Tearing *Not accounted for by cold symptoms or allergies* 0 Not present 1 Nasal stuffiness or unusually moist eyes 2 Nose running or tearing 4 Nose constantly running or tears streaming down cheeks	0 1 2 4	0 1 2 4	0 1 2 4	0 1 2 4	0 1 2 4
Gooseflesh Skin 0 Skin is smooth 3 Skin piloerection can be felt or hairs standing up on arms 5 Prominent piloerection	0 3 5	0 3 5	0 3 5	0 3 5	0 3 5

* Source: Wesson, D. R., & Ling, W. (2003). The Clinical Opiate Withdrawal Scale (COWS). *Journal of Psychoactive Drugs, 35*(2), 253–259.

Overdose Education*

Opioids Include:

Heroin and **prescription pain medications**:

Vicodin *(hydrocodone)*	Fentanyl
OxyContin *(oxycodone)*	Percocet
Dilaudid *(hydromorphone)*	Methadone
MS Contin *(morphine)*	...and others

- If someone takes more opioids than their body can handle, they can pass out, stop breathing, and die.
- Overdose can take minutes or even hours to occur.
- Anyone who uses opioids can overdose.

Opioid Overdose Risks

- **Restarting opioids after a break.** Tolerance drops within a few days.
- **Using opioids at the same with alcohol or sedating drugs** like sleep aids and benzodiazepines ("benzos" like Valium and Xanax). Mixed together, they can slow breathing even more.
- Taking **prescription pain medicine more often** or in **higher doses** than prescribed.
- **Any heroin use** due to its wide range of purity.
- **Taking someone else's** pain medication.
- **Using long-acting opioids** (like methadone) or powerful opioids (like fentanyl).
- **Heart or lung disease**.

If someone has overdosed before, they are more likely to overdose again.

How can I get naloxone?

Naloxone (Narcan®) is a prescription medicine that can temporarily stop the effect of opioids and help a person start breathing again. It can be given as an injection into a muscle or as an intranasal spray. It is easy and very safe to use.

In WA State, you can get a prescription for naloxone if you think you could:

- overdose on opioids yourself.
- help someone else who has overdosed.

Go to stopoverdose.org to see if naloxone is available from a pharmacy, doctor or health department near you.

Resources

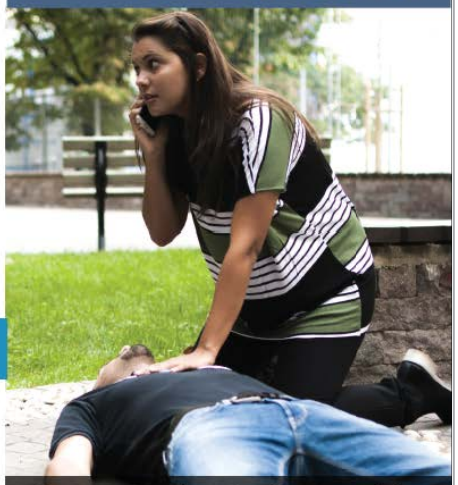
Safer use of pain medication:
Washington Department of Health
tinyurl.com/wa-doh-tad

Addiction treatment:
Washinton Recovery Help Line
24 hour crisis help and referral
warecoveryhelpline.org
1-866-789-1511
Suboxone/burprenorphine providers
tinyurl.com/bup-locator
Treatment services in the US
findtreatment.samhsa.gov

This brochure is not a substitute for more complete overdose response training from a medical provider or health educator. For more info go to: stopoverdose.org

Revised August 2017

Opioid Overdose



If someone you know is taking prescription pain medication or using heroin...

...would you know what to do if they accidentally overdosed?

This information could help you save a life.

Center for Opioid Safety Education

*Source: stopoverdose.org. Included with permission.

Taking Action in an Opioid Overdose

1 Check: Could this be an opioid overdose?

Look and listen for:

- Slow or no breathing
- Gurgling, gasping, or snoring
- Clammy, cool skin
- Blue lips or nails
- Pill bottles, needles, or alcohol

Try to wake them up:

- Shake them and call their name.
- Rub your knuckles hard over their chest bone.

If they don't wake up, you need to act fast!

2 Call 911.

- Say where you are and that the person isn't breathing.
- You don't need to say anything about drugs or medications.

3 Give naloxone and start rescue breathing.

- **Give the naloxone.** Follow the instructions on the package or in the overdose rescue kit.
- **Start rescue breathing.**
- If they don't respond in 3-5 minutes, give a **second dose of naloxone. Keep rescue breathing.**

Do rescue breathing even if you don't have naloxone. Oxygen is critical!

4 Stay with them.

- If they start to wake up and breathe, stay with them.
- **Watch them until medical help arrives.** Naloxone wears off in 30-90 minutes. When it does, the person can stop breathing again.
- If you must leave, put them into the recovery position and in a place they can be found.

Good Samaritan Law

If you get medical help for an overdose or alcohol poisoning, you and the victim cannot be charged for drug use, possession, or underage drinking.

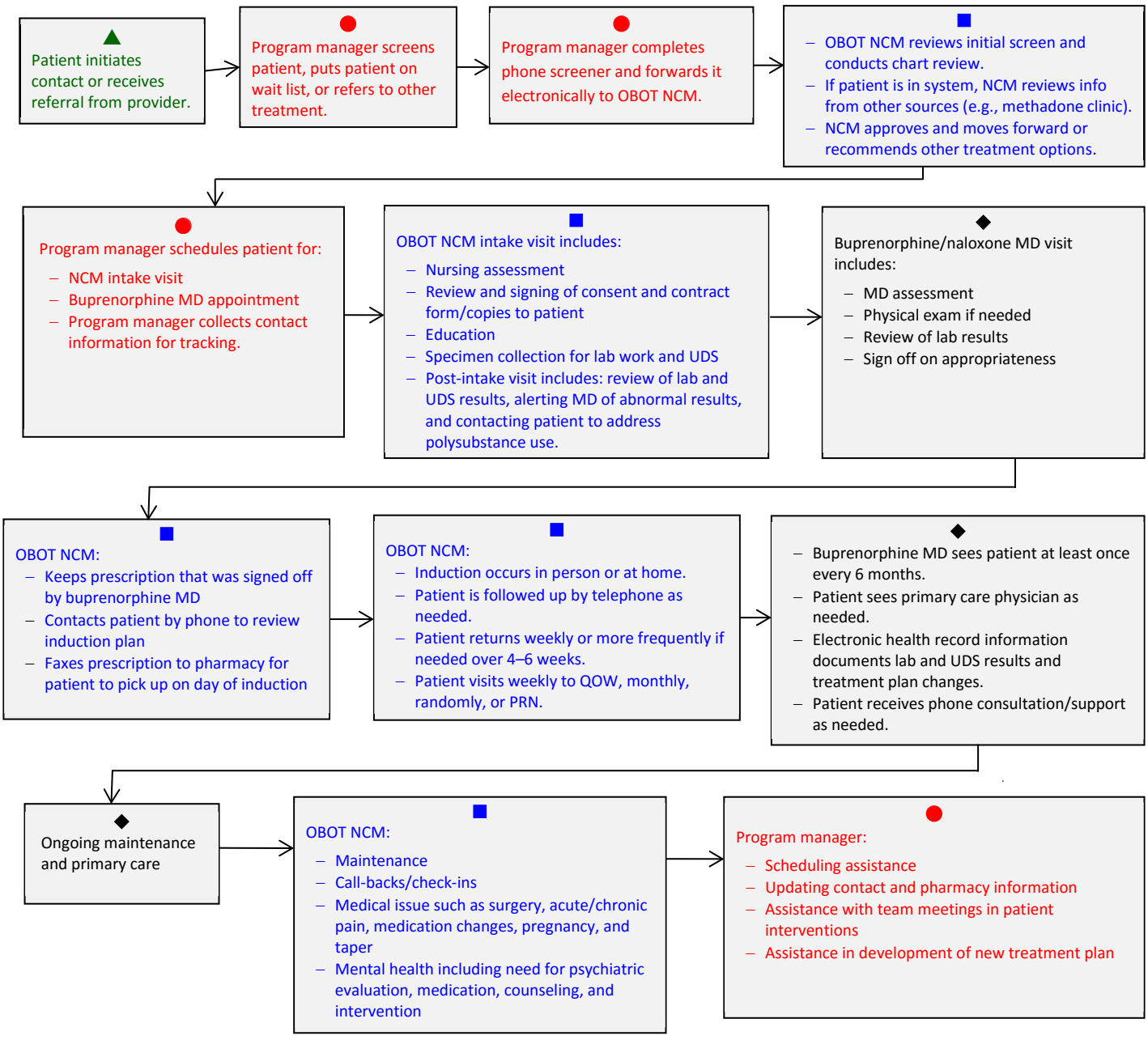
WA RCW 69.50.315

Rescue Breathing

- Tilt head back. Lift chin. Pinch nose.
- Give **2 quick breaths**. Chest should rise.
- Then give **1 slow breath every 5 seconds**.
- **Keep going** until they start breathing or until help arrives.

Recovery Position

Adult Medicine Clinic's Multidisciplinary Approach to Buprenorphine/ Naloxone Maintenance



▲ **Green = Patient**

● **Red = Program manager**

■ **Blue = Nurse care manager (NCM)**

◆ **Black = Physician (MD)**

UW Medicine

HARBORVIEW
MEDICAL CENTER