

Integrating Buprenorphine Treatment for Opioid Use Disorder in Primary Care

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Overview

Opioid use disorder is treatable with FDA-approved pharmacotherapies. Buprenorphine is one such treatment option, which can be delivered in the primary care office setting. Office-based buprenorphine treatment delivered in primary care clinics is associated with decreased opioid use, higher quality of care, and improved quality of life.^{i,ii,iii,iv}

This model of integrating buprenorphine treatment into primary care settings aligns with the medical home model as it allows patients to readily access comprehensive medical and addiction services under one roof. The model follows principles of harm reduction, including reducing the harms of addiction. This enables providers to treat addiction along with other chronic medical conditions experienced by their patients. The approach secures additional patient buy-in by investing in the existing trust and communication they develop with their primary care providers.

The following integration manual is intended for implementation in primary care settings that do not already provide on-site buprenorphine treatment services.

Buprenorphine Treatment Overview

Buprenorphine, a partial opioid agonist, was approved by the FDA in 2002 for the treatment of opioid dependence. As per the Drug Addiction Treatment Act of 2000, buprenorphine can be prescribed outside the Narcotic Treatment Program (NTP) setting by physicians who have completed the necessary 8-hour training and received a special waiver.

Currently, buprenorphine is available in two sublingual preparations. One is composed of buprenorphine hydrochloride. The other is a combination tablet or film composed of buprenorphine hydrochloride and naloxone hydrochloride. Naloxone is not absorbed sublingually and use of the combination tablet decreases the risk of diversion and injection. The only indications to use the buprenorphine mono-product is with pregnancy and allergy to naloxone.

Because buprenorphine acts as a partial agonist at mu opioid receptors, it may precipitate opioid withdrawal in a patient who has recently used opioids. Patients should not be induced on buprenorphine if they have opioids in their system. The duration of time in which opioids may stay in patients' system depends on the specific pharmacologic properties of the opioid and patients' liver function (because opioids are metabolized through the liver). Typically, if patients have used a short-acting opioid such as heroin, it will remain in their system for up to 6-8 hours, or if they used a long-acting opioid such as methadone, it can remain in their system

for up to 24 hours to several days. Patients should only be initiated on buprenorphine if they are showing objective signs of opioid withdrawal (unless they have been opioid-free for at least several days).

Prior to taking a history and conducting a physical exam, one should confirm that the patient is appropriate for buprenorphine treatment, including diagnosis of an opioid use disorder. An initiation phase beginning with a low dose of buprenorphine, followed by increasing doses over several days is recommended to minimize the likelihood of precipitating opioid withdrawal. After initiation, buprenorphine may be taken once or twice daily. Once a stable dose of buprenorphine is established, a therapeutic dose can be maintained over a stable period of time.

Pre-implementation activities

The following activities should be addressed prior to the start of implementation, and will be handled by the clinic administration in partnership with the treatment team (once hired or identified) unless otherwise noted:

1. Hire key personnel (reference job descriptions and staffing plan in Appendix B).
2. Review the following clinical protocols that correspond to patient stability and experience and to provider skills and confidence at your clinic:
 - a. Initial patient selection and assessment
 - b. Preparing patients for treatment
 - c. Treatment initiation and stabilization
 - d. Maintenance treatment and monitoring
 - e. Patient-centered treatment intensification (i.e. more frequent visits, more counseling, referral to other outpatient drug treatment programs)
 - f. Treatment failure and/or transfer of care
 - g. Re-initiation of treatment after drop out
3. Create procedures to follow federal mandates for record keeping practices: Keeping and maintaining a patient log for each prescriber; ensuring confidentiality of medical records, their storage, and their maintenance for Drug Enforcement Administration (DEA) visits.
4. Create protocols for on-call and back-up systems:
 - a. For example, do all clinic patients currently have access to a provider during clinic hours and through an answering service at nights and on weekends? Does that provider know how to manage patients who are prescribed buprenorphine? If not, does that provider know how to contact the buprenorphine provider on call? The treatment team may need to carry pagers or cell phones to field specific queries and concerns from participating patients.
5. Buprenorphine prescribers will identify and have access to a clinical mentor, defined as another health professional with expert knowledge and practical experience in buprenorphine treatment.¹ Ideally, this mentor will maintain a buprenorphine practice in the same health network or geographic locale and meet for case conferences every 1-2 months. Clinic prescribers can also participate in the Physician Clinical Support System for Medication Assisted Treatment (PCSS-MAT), a national training and mentoring project.¹
 - a. To find a mentor or learn more about mentorship, visit www.pcspb.org or <http://ceitraining.org/bupren/>. To chat with other DATA-waiver approved physicians, join the free SAMHSA buprenorphine clinical discussion web board at <http://bup-webboard.samhsa.gov/login.asp?target=default.asp>.

6. Providers need to participate in necessary trainings to receive buprenorphine prescription waivers. Information about trainings is available at <http://www.samhsa.gov/medication-assisted-treatment/training-resources/buprenorphine-physician-training>.
7. Determine and document the types of insurance that will be accepted, whether or not to apply to patient assistance programs, fees, payment plans, and policies. Identify the individual at the clinic who will address prior authorization for insurance.
8. Secure sustainable patient access to buprenorphine medication. Establish a working relationship with an onsite or community pharmacy that will dispense medication and with benefits counselors to obtain coverage for opioid treatment pharmacotherapies. Buprenorphine comes in a variety of sublingual formulations. Unless patients are pregnant or allergic to naloxone, nearly all patients will receive co-formulated buprenorphine/naloxone tablets or film.
9. Establish or (strengthen existing) relationships with mental health and substance use treatment providers (on site or in the community). Create a Memorandum of Agreement (MOU) for referrals of patients who need more intensive services for addiction medicine with an agreed upon process and timeline for referral appointments.
10. The treatment team will develop a protocol for referral so that providers can refer patients who need supplemental or higher levels of care and/or the treatment of comorbid substance use and mental health disorders. Examples of types of care include counseling, mutual support groups, withdrawal/detoxification management, methadone treatment, outpatient treatment programs, and residential treatment.
11. Implement policies that address safety and boundary issues to address needs of the treatment team, clinic staff, and patients.

Assess internal and external clinic systems:

1. Treatment team members will establish (or strengthen existing) relationships with mental health and substance use treatment providers (on site or in the community).
 - a. Create a Memorandum of Agreement (MOU) for referrals of patients who need more intensive services for addiction medicine with an agreed upon process and timeline for referral appointments.
 - b. Establish community referral networks with organizations providing the following services: counseling, mutual support groups, withdrawal management, vocational training, methadone treatment, intensive outpatient treatment, and residential treatment.
2. Clinic administration will determine and document fees, payment plans, and policies, including the types of insurance that will be accepted and whether or not to apply to patient assistance programs. Clinic administration will identify the staff person at the clinic who will be the point person for addressing issues related to insurance authorization.
3. Treatment team members will secure sustainable patient access to buprenorphine medication. In order to do so, the treatment team will establish working relationship with onsite or community pharmacy that will dispense medication and working with benefits counselors to obtain coverage for opioid treatment pharmacotherapies. The treatment team will work with the pharmacy to insure that the pharmacy is able to stock the various sublingual formulations of buprenorphine (unless the patient also is pregnant, most patients will receive co-formulated buprenorphine and naloxone tablets or film).

Hire or identify intervention team members:

1. Clinic administration will hire or identify treatment team members including 2 prescribing providers and 1 clinical coordinator (utilizing the job descriptions and staffing plan in Appendix B).
2. Buprenorphine prescribers will identify and have access to a clinical mentor, defined as another health professional with expert knowledge and practical experience in buprenorphine treatment. Ideally, this mentor will maintain a buprenorphine practice in the same health network or geographic locale and meet for case conferences month. Clinic prescribers also will be encouraged to participate in the Physician Clinical Support System for Medication Assisted Treatment (PCSS-MAT), a national training and mentoring project.
 - a. To find a mentor or learn more about mentorship, visit www.pcssb.org or <http://ceitraining.org/bupren/>. To chat with other DATA-waiver approved physicians, join the free SAMHSA buprenorphine clinical discussion web board at <http://bup-webboard.samhsa.gov/login.asp?target=default.asp>.
3. Providers will participate in all necessary trainings to receive buprenorphine prescription waivers.
4. One year after obtaining waivers, providers should consider applying to the DEA to treat additional patients.

Develop, review, and implement necessary protocols and materials:

1. Treatment team members will review the following clinical guidelines provided the implementation phase of this manual that correspond to 1) patient stability and experience and 2) provider skills and confidence, and make any additions necessary:
 - a. Initial patient selection and assessment
 - b. Preparing patients for treatment
 - c. Treatment initiation and stabilization
 - d. Maintenance treatment and monitoring
 - e. Patient-centered treatment intensification (i.e. more frequent visits, more counseling, referral to other outpatient drug treatment programs)
 - f. Treatment failure and/or transfer of care
 - g. Re-initiation of treatment after drop out
2. Treatment team members will create procedures to follow federal mandates for record keeping practices. This includes keeping and maintaining a patient log for each prescriber, ensuring secure medical record storage, and maintaining records for Drug Enforcement Administration (DEA) visits.
3. Treatment team members will create protocols for provider on-call and back-up systems that answers questions related to managing care outside of normal clinic hours. For example, do all clinic patients currently have access to a provider during clinic hours and through an answering service at nights and on weekends? Does that provider know how to manage patients on buprenorphine for the treatment of opioid use disorder? If not, does that provider know how to contact the buprenorphine provider on call?
4. The treatment team will develop a protocol for referral in the local health care community, so that the treatment team can refer patients who need supplemental or higher levels of care and/or the treatment of comorbid substance use and mental health disorders. Examples of types of care include counseling, mutual support groups,

withdrawal management (e.g. detoxification), methadone treatment, intensive outpatient treatment, crisis management interventions, and residential treatment.

5. The treatment team will implement policies that address safety and boundary issues to protect both the treatment team and the clinic staff.
6. The treatment team will develop a protocol for accepting referrals (internal and external) for patients to receive buprenorphine treatment. The protocols will be based on the following criteria:

Inclusion criteria to be eligible should include:

- Eligible for care at the treatment site
- Diagnosed with an opioid use disorder as determined by DSM-5 criteria and desiring pharmacotherapy for this disorder
- Age \geq 18 years or emancipated minor able to consent for medical and substance use treatment
- It is recommended that female patients receiving buprenorphine use adequate birth control methods (pill, IUD, condom with spermicide, abstinence, etc.)
- Able to comply with buprenorphine treatment program policies.
- Optional: Currently receiving primary care (or willing to start primary care) at the treatment site

Exclusion criteria should include:

- Severe hepatic dysfunction, i.e. AST and/or ALT \geq 5x upper limit of normal
- DSM-5 criteria for benzodiazepine use disorder
- DSM-5 criteria for alcohol use disorder
- Active suicidal ideation
- Psychiatric impairment that impedes ability to provide informed consent to make decision regarding their own care (dementia, delusional, actively psychotic)
- Methadone or opioid analgesic doses exceed levels allowing for safe transition to buprenorphine (methadone >30-60 mg)
- Patients with acute or chronic pain syndrome requiring chronic use of opioid analgesics
- Patient has serious/uncontrolled/untreated medical problems (hypertension, hepatic failure, asthma, diabetes, etc.) or psychiatric disorders.
- Patient requires a higher level of care than can be offered in the treatment clinic (i.e., methadone maintenance or mental illness chemical addiction [MICA] program)
- Patient has a known allergy/hypersensitivity to buprenorphine or naloxone

Eligible patients may be identified by their primary care or other providers at the clinic and may be referred for evaluation and treatment at the clinic. Patients also may be self-referred or be referred by any provider in the community. Using the referral protocol developed by your clinic in the pre-implementation phase, a member of the treatment team (previously identified in the referral protocol) will make contact with the patient, and will make an appointment for the patient to meet with prescribing provider for a patient assessment.

7. The treatment team will review existing patient education materials referenced in this implementation manual, and will make any necessary clinic specific additions.

Treatment team communication

As part of integrating buprenorphine treatment into primary care settings, it is ideal to have the following communication strategies implemented:

1. The treatment team (prescribing providers and buprenorphine coordinator) will meet regularly (e.g. monthly) for case conferencing.
2. The buprenorphine coordinator will receive weekly supervision from the lead prescribing provider.
3. Buprenorphine prescribers will meet with their clinical mentors on a regular basis depending on need (e.g. initially monthly, later quarterly)

Assessing and selecting patients for treatment

An important first step to integrating buprenorphine treatment into primary care settings is to ensure that patients are comprehensively assessed to determine whether they are appropriate for buprenorphine treatment. Initially, when the treatment team is inexperienced with buprenorphine treatment, it is ideal to select patients who are likely to have optimal outcomes with few complications. Once the treatment team gains experience, providing buprenorphine treatment to more complex may be warranted.

Inclusion criteria

- Eligible for primary care at the participating primary care clinic.
- Patients will have an opioid use disorder as determined by DSM-5 criteria and desire pharmacotherapy for this disorder.
- Currently receiving primary care (or willing to start primary care) at the participating primary care clinic.
- Age \geq 18 years or emancipated minor able to consent for medical and substance use treatment
- If female: It is recommended that patients receiving buprenorphine use adequate birth control methods (pill, IUD, condom with spermicide, abstinence, etc.)
- Patients must be able to comply with buprenorphine treatment policies.

Exclusion criteria

- Severe hepatic dysfunction (e.g., AST and/or ALT \geq 5x upper limit of normal)
- DSM-5 criteria for benzodiazepine use disorder
- DSM-5 criteria for alcohol use disorder
- Active suicidal ideation
- Psychiatric impairment that impedes ability to provide informed consent to make decision regarding their own care (dementia, delusional, actively psychotic)
- Methadone or opioid analgesic doses exceed levels allowing for safe transition to buprenorphine (methadone >30-60 mg)
- Patients with acute or chronic pain syndrome requiring chronic use of opioid analgesics
- Patient has serious/uncontrolled/untreated medical or psychiatric problems (hypertension, hepatic failure, asthma, diabetes, etc.)
- Patient requires a higher level of care than can be offered in the primary care clinic (i.e., methadone maintenance or mental illness chemical addiction [MICA] program)

- Patient has a known allergy/hypersensitivity to buprenorphine or naloxone

Eligible patients may be identified by their primary care or other providers at the clinic and may be referred for evaluation and treatment at the clinic. Patients also may be self-referred or be referred by any provider in the community. Using the referral protocol developed by your clinic in the pre-implementation phase, a member of the clinical team (previously identified in the referral protocol) will make contact with the patient, and will make an appointment for the patient to meet with prescribing provider for a patient assessment.

The objectives of the assessment process are to determine the patient's clinical eligibility for buprenorphine treatment, provide the basis for a treatment plan, and establish a baseline measure to evaluate a patient's response to treatment. The treatment team (which includes the prescribing physicians and Buprenorphine Coordinator) will establish whether the patient meets clinical eligibility. The team will determine with the patient whether the potential benefits of buprenorphine treatment (improved health outcomes, reduced infectious disease and overdose risks) outweigh any potential risks (diversion) to the patient or to the community.

Components of the patient assessment conducted by the treatment team will include an initial clinical encounter to:

1. Establish the diagnosis of opioid use disorder, including the duration and severity of opioid use (Appendix C).
2. Discuss current opioid use and patterns, including level of tolerance, prior treatment experiences including experiences with opioid agonists, nature and severity of opioid withdrawal symptoms, time of last opioid use and current withdrawal status (APPENDIX H)
 - a. Documentation of opioid **withdrawal** symptoms, including autonomic excitation (elevated BP, increased HR, mydriasis, tremors, and agitation/restlessness). Also note the presence or absence of yawning, rhinorrhea, piloerection, diaphoresis, lacrimation, vomiting and muscle fasciculations. To assess opioid withdrawal severity, use the Clinical Opiate Withdrawal Scale (COWS), see APPENDIX G.
 - b. Observation of possible substance **intoxication**, including but not limited to alcohol odor, patient disinhibition, or other altered mental status.
 - c. Documentation of **drug or needle use sequelae**, including presence of track marks, abscesses, cellulitis.
3. Document the patient's use of other substances, including tobacco, alcohol, benzodiazepines, and other drugs.
 - a. **Current opioid use**, i.e. type of opioid, method of administration, frequency of use, amount of use, last use.
 - b. **Other substance use:** Review alcohol, sedative, and other substance use. Chaotic alcohol and sedative (e.g. benzodiazepines) use in conjunction with the injection of buprenorphine mono-product has been associated with opioid overdose. The combined buprenorphine/naloxone formulation is recommended to deter this practice.
 - c. **Previous opioid treatments:** Review past treatment experiences, including patient response to treatment, side effects, and perceived effectiveness.
 - d. Note: DSM-5 Diagnostic Codes Related to Substance Use Disorders can be found here: <http://www.buppractice.com/printpdf/2633>
4. Identify patients who need medically supervised withdrawal management from alcohol, benzodiazepines, or other sedatives prior to initiating buprenorphine treatment.

5. Identify comorbid medical conditions and psychiatric disorders and determine how, when, and where they will be addressed.
 - a. **Liver disease:** Patients with decompensated cirrhosis may require close monitoring, low and/or infrequent doses of buprenorphine. See below regarding AST/ALT.
 - b. **Pain syndromes:** Buprenorphine has analgesic properties, but it cannot be used in patients with acute or chronic pain syndromes requiring high doses of full opioid agonist therapy (e.g. morphine, methadone, oxycodone, hydromorphone).
 - c. **Medications** metabolized by cytochrome P450 3A4 system, e.g. many psychiatric medications; 3A4 inhibitors may increase drug levels of buprenorphine causing symptoms of opioid excess.
 - d. **ALT, AST**—results over 5 times the normal upper limit may increase the risk of buprenorphine-induced hepatitis
 - a. **Urine drug testing:** Expect opiate-positive urine toxicology screens prior to initiating buprenorphine treatment.
 - b. **Pregnancy test** (serum or urine HCG) for female patients of childbearing age. Assess and document an effective **birth control method** for female patients of childbearing age.
6. Screen for communicable diseases (e.g. viral hepatitis, HIV, TB, syphilis) and manage them as clinically indicated.
7. Assess patients' access to social supports, family, friends, employment, housing, finances, and legal assistance.
8. Determine patients' readiness to participate in treatment and their goals for engaging in treatment.
9. Identify how the buprenorphine treatment will be covered (on an individual basis).
10. Provide patient education on naloxone (materials available at prescribetoprevent.org).

After completing the assessment process, the buprenorphine coordinator will discuss how buprenorphine treatment is delivered in the clinic (including the role of the physician and the clinical coordinator).

Preparing patients for treatment

Every patient to whom buprenorphine is prescribed should be prepared by the treatment team in advance to succeed.

The steps to prepare a patient for treatment are performed by the prescribing physician or the buprenorphine coordinator, and include the following:

1. Educate the patient about buprenorphine treatment and how to properly administer, safeguard, and discard the medication; what they can expect to experience at each stage of treatment; and alternatives to buprenorphine treatment.
 - Resources:
 - The Facts About Buprenorphine for Treatment of Opioid Addiction (U.S. Department of Health and Human Services)
<http://store.samhsa.gov/shin/content/SMA09-4442/SMA09-4442.pdf>
 - Medication-Assisted Treatment for Opioid Addiction: Fast Facts for Family and Friends (U.S. Department of Health and Human Services)
<https://store.samhsa.gov/shin/content/SMA09-4443/SMA09-4443.pdf>

- Useful information for patients about what buprenorphine treatment is like and how to prepare for treatment initiation can be found at the website of The National Alliance of Advocates for Buprenorphine Treatment: http://www.naabt.org/education/what_bt_like.cfm
- 2. Complete a treatment agreement describing the goals of treatment, the risks and benefits of treatment, and the relationship between the patient and the treatment team. (Appendix E).
- 3. Communicate with other providers in patient's circle of care about the treatment plan, especially with other substance use treatment or mental health providers. This will require signed releases of information to exchange health information protected by federal 42 CFR Part 2 confidentiality regulations (See example provided in Appendix).
- 4. Refer patients who need or want medically supervised withdrawal management from alcohol, benzodiazepines, or other sedatives or opioids prior to initiating buprenorphine treatment.
- 5. Prepare patients to be in an opioid-free state and have mild-moderate symptoms of opioid withdrawal on the day of buprenorphine initiation. Patients should exhibit signs of at least mild withdrawal (COWS >5) prior to receiving their first dose of buprenorphine.
 - Heroin withdrawal typically begins 8 to 24 hours after last use, peaks at 2 to 3 days, and lasts 5 to 7 days. Heroin use should be stopped at least 12 hours prior to buprenorphine initiation.
 - Methadone withdrawal typically begins 1 to 3 days after last use, peaks at 5 to 7 days, and lasts 14 to 21 days. For patients on methadone, a taper down to dose of 30-60 mg/day is recommended prior to buprenorphine initiation to reduce the risk of precipitated opioid withdrawal. Methadone administration should be stopped at least 24-48 hours prior to buprenorphine initiation
- 6. In preparation for initiating treatment and to ease discomfort, the treatment team may wish to dispense small quantities of medications to provide symptomatic relief of opioid withdrawal symptoms beforehand. In addition to anticipatory guidance, the program may wish to dispense or prescribe "kick-packs" or "comfort packs" (i.e. small quantities of medications to provide symptomatic relief of opioid withdrawal symptoms).
 - Clonidine 0.1 mg PO q 6-8 hours PRN lacrimation, diaphoresis, rhinorrhea, piloerection;
 - Loperamide (Imodium) 4mg at initial experience of diarrhea, then 2mg as needed for each episode of loose stool or diarrhea thereafter, not to exceed 16 mg/24h;
 - Acetaminophen 500-1000 mg q 4-6 hrs, ibuprofen 600 mg q 8 hrs, or naproxen 500 mg q 12 hrs as needed for myalgias or arthralgias.

Initializing, stabilizing, and maintaining patients

The goal of initiation and stabilization is to find the lowest dose of buprenorphine at which the patient discontinues or markedly reduces the use of other opioids without experiencing withdrawal symptoms, significant side effects, or cravings. When a stable buprenorphine dose is achieved, patients enter into a maintenance phase of treatment.

The treatment team should determine if it will offer home and/or office-based inductions and review protocols for each (and make any clinic-specific additions).

- Factors to consider when deciding between home and office-based inductions include:
 - a. Providers' and patients' experience with initiating buprenorphine treatment - Patients who have prior experience with buprenorphine tend to have better

outcomes than those who do not have experience with buprenorphine, and may be well-suited for home-based inductions.

- b. Patients' previous experience with buprenorphine - Patients who have previously taken buprenorphine and are familiar with its pharmacodynamics know their withdrawal/craving symptoms, and have demonstrated both comfort and skill at starting the medicine without clinical observation, are good candidates for home-based inductions. It is ideal for such patients to have telephone access to providers for advice and/or coaching through the induction, if needed.
- c. Patients' ability to tolerate opioid withdrawal symptoms - Patients who are very concerned or anxious about experiencing opioid withdrawal may want to experience withdrawal and undergo induction within a clinical setting where they can be observed. Often patients with underlying anxiety may have difficulty differentiating their symptoms due to anxiety versus opioid withdrawal. In this case, home-based inductions may be challenging.
- d. Patients transferring from methadone to buprenorphine – These patients may have difficulties with induction for two reasons:
 - i. They may have not experienced opioid withdrawal symptoms in years (because of having received methadone treatment for years) and be quite fearful or anxious of experiencing opioid withdrawal.
 - ii. Because methadone is so long-acting, they are at higher risk of precipitated withdrawal than patients who use opioids other than methadone. These patients are likely best suited for office-based inductions.
- e. Patients' circumstances – Some patients may have a difficult time taking several days off of work when buprenorphine treatment is initiated. They would likely benefit from a home induction that can occur over a weekend.

Home-based induction

For patients who undergo home-based inductions, the home-based induction instruction document should be reviewed and a clear plan should be determined (APPENDIX F/PDF)

1. The medications that will typically be provided include:
 - a. Buprenorphine 8/2mg – Typically provide enough buprenorphine such that patients can achieve a dose of 16mg per day until the next scheduled visit within 3-7 days.
 - b. Ancillary medications to treat symptoms of withdrawal, including clonidine, loperamide, and acetaminophen or NSAID (see above).
2. Review symptoms that patients will experience during opioid withdrawal. Patients should experience at least 5 of the 13 symptoms listed in the Subjective Opioid Withdrawal Scale (SOWS).
3. Review things that patients should not do. These include NOT taking buprenorphine when they have opiates in their system (including opioid analgesic or methadone), are drinking alcohol, and are taking benzodiazepines. In addition, they should NOT swallow buprenorphine (they should take it sublingually) or lose their medication.
4. Review how to take buprenorphine sublingually and not orally. Refer to the pictures in the home-based induction instruction document.
5. Develop a clear plan on dosing and timing of medication. Review when patients should stop taking their current opioid and when they should start taking buprenorphine. Write out approximate times and doses. Include the length of time that patients should wait to reassess their withdrawal symptoms. Provide contact information for patients if they have questions or problems.

6. Review with patients how to track the amount of medication they take. Review with them how they should start day 2 with the total amount of medication they took during day 1. And to start day 3 with the total amount they took during day 2. Review with them that they should typically take up to a maximum of 16mg daily until they are further assessed by a provider.
 - f. Resource: "What is Buprenorphine Treatment Like?" From The National Alliance of Advocates for Buprenorphine Treatment
(https://www.naabt.org/education/what_bt_like.cfm)

Office-based induction

The following induction protocol details the office-based procedures for assessing for symptoms of opioid withdrawal and starting and maintaining patients on buprenorphine. Patients already will have been assessed for treatment appropriateness, including confirmation of diagnosis of moderate-to-severe opioid use disorder and other clinical criteria (as described above). Home-based initiation procedures are detailed elsewhere (see Appendix F/PDF).

Subjective Data: One of the most important aspects of the initial visit for office-based induction is to assess the level of opioid withdrawal that patients are experiencing. Using the COWS, first document the patient's opioid withdrawal symptoms: cravings, anxiety, discomfort, pain, nausea, hot or cold flushes. Next, based on physical exam, document the patient's signs of withdrawal, including autonomic excitation (elevated BP, increased HR), mydriasis, tremors, agitation/restlessness. Also note the presence or absence of yawning, rhinorrhea, piloerection, hot and cold flushes, diaphoresis, lacrimation, vomiting, and muscle fasciculations. Use the COWS to score the patient's opioid withdrawal as mild, moderate or severe.

Patients should exhibit signs of at least mild withdrawal (COWS > 5) prior to receiving their first dose of buprenorphine. If patients appear intoxicated or exhibits no signs of withdrawal, then they should not be started on buprenorphine at this visit. Patients should be rescheduled for a later date or time and counseled regarding the need to present when they are experiencing at least mild opioid withdrawal. An exception may be made for patients who have gone through medical detoxification (e.g. inpatient detoxification program) or non-medical detoxification (e.g. jail) and now present opioid-free and with drug craving.

In addition to assessing signs and symptoms of opioid withdrawal, also assess for possible substance **intoxication**, including but not limited to alcohol odor, nystagmus, patient disinhibition, or other altered mental status.

Lab Results: Urine will be collected on the first day of initiation and sent to the lab for routine toxicology, or tested in the clinic using a point-of-care test kit. This test can be done frequently if needed, e.g. weekly during stabilization period.

Initial buprenorphine doses

Patients who are determined to be in at least mild opioid withdrawal (COWS >5) and who do not have signs of intoxication of other substances should receive their initial doses of buprenorphine as described below.

1. For patients exhibiting **mild** withdrawal, give buprenorphine 2-4 mg SL. For patients exhibiting **moderate** to **severe** withdrawal, give buprenorphine 4 mg SL. The sublingual tablet or film must dissolve completely under a moist tongue, which may take 5-10

minutes. Most patients experience relief of withdrawal symptoms or reduction in cravings within the first 15-20 minutes after taking the tablet or film.

- a. Note: Depending on the specific formulation prescribed, the initial doses of buprenorphine may be portions of a tablet or film, or the entire tablet or film. Because of possible prior authorization issues required by many insurance companies, prescribing the 8 mg tab or film may be the most feasible. In this case, patients may need to take $\frac{1}{4}$ or $\frac{1}{2}$ of the tablet or film as the initial dose.
2. Re-evaluate patient after 30-60 minutes.
 - a. If there is no change in symptoms (no worsening), or symptoms are somewhat improved, an additional dose of buprenorphine 2-4 mg SL may be given. Reassess the patient again in 30-60 minutes for symptom relief. This process of providing an additional dose and reassessment may occur again, or the patient may be provided with two additional 4 mg take-home doses should withdrawal or marked craving recur in the evening. The total amount of buprenorphine that is typically provided on the first day of dosing is 8-12mg.
 - b. A sudden exacerbation of opioid withdrawal symptoms after administering buprenorphine usually indicates the continued presence of other (full agonist) opioids and the phenomenon known as "precipitated withdrawal." Discuss with patient and review time of last opioid use. Give other medications at the clinic for symptom management (clonidine, loperamide, acetaminophen or NSAIDs) and instruct to return the following day for re-evaluation.
 - i. **Clonidine** 0.1 mg PO q 6-8 hours PRN lacrimation, diaphoresis, rhinorrhea, piloerection;
 - ii. **Loperamide** (Imodium) 4mg at initial experience of diarrhea, then 2mg as needed for each episode of loose stool or diarrhea thereafter, not to exceed 16 mg/24h;
 - iii. **Acetaminophen** 500-1000 mg q 4-6 hrs, **ibuprofen** 600 mg q 8 hrs, or **naproxen** 500 mg q 12 hrs as needed for myalgias or arthralgias
1. Patients should return to clinic in the next 1-2 days for re-evaluation and upward dose titration. Some patients who are well-engaged in care or have prior experience with this medication can be given a week's worth of medication on the day of induction and are able to be re-evaluated over the telephone during the first week of induction.
 - a. Note: Initial doses that are too high may acutely exacerbate withdrawal symptoms, while titrating up too slowly may needlessly prolong withdrawal—either of these situations may result in patient relapse or other treatment non-compliance.

Typical doses during the induction are as follows:

- first 24 hours: typically 8-12 mg total; should not exceed 16mg.
- days 2-3: if symptoms of opioid withdrawal continue, increase daily dose by 2-4mg depending on severity of opioid withdrawal (e.g. add 2 mg for mild withdrawal or 4 mg for mod-severe withdrawal). Typical dose is between 8-16mg, not to exceed 24 mg.

Stabilization Visits

After buprenorphine initiation, the treatment team monitors patients either daily (for unstable patients) or once or twice weekly (stable patients). Stabilization occurs over 2 visits typically (around day 3-7 and again around day 10-14; see visit schedule below). The treatment team

titrates the buprenorphine dose until the patient no longer has signs and symptoms of withdrawal or craving and has not developed signs or symptoms of opioid excess.

First stabilization visit

1. Assess opioid withdrawal using COWS worksheet (see appendix) and review use of any adjunct medications for symptom management. Obtain urine for toxicology.
2. Give total daily dose administered on the previous day. Add an additional 2 to 4 mg as needed (up to 16 mg) based on severity of withdrawal symptoms (e.g., add 2 mg for mild withdrawal or 4 mg for moderate-severe withdrawal).

A typical dose at the first stabilization visit is 16 mg, with a typical range between 8-24 mg.

Second stabilization visit

1. Have patient return for continued monitoring and stabilization – either daily (for unstable patients) or weekly with phone monitoring (very stable patients). Use COWS at each visit. Review symptoms of opioid withdrawal (using COWS) and craving. Most likely at the second stabilization visit, patients are no longer experiencing signs or symptoms of opioid withdrawal. However, they may continue to experience cravings. Continue to increase buprenorphine dose daily by 2 to 4 mg until patients no longer experience opioid withdrawal or cravings.
 - a. Criteria for dose increases:
 - Significant opioid craving (especially towards end of dosing period)
 - Significant opioid withdrawal symptoms (especially towards end of dosing period)
 - Urine toxicology persistently positive for opioids
2. **Target Dose** is the dose that results in the optimal relief of objective and subjective opioid withdrawal symptoms and cravings. The median expected dose is **16 mg** daily, though lower doses such as 8 mg per day may be sufficient and higher doses such as 24 mg may be required. **Maximum daily dose is 24 mg.**
 - a. Most patients reach their target dose within the first two weeks of treatment. Review with patients that diversion or misuse of buprenorphine may result in treatment discontinuation. Make sure that patients have an adequate supply of medication until their next visit.

Maintenance Visits

Most patients reach their target dose within the first two weeks of treatment and progress to the maintenance stage of treatment.

1. **Maintenance visits:** When a stable buprenorphine dose is achieved, patients enter into a maintenance phase of treatment. Maintenance visits can be scheduled between weekly and monthly, depending on patients' clinical stability. At a minimum, stable patients should see the prescribing provider at least every 3 months. If patients relapse or destabilize, they should return to more frequent monitoring. (See schedule below)

Visit frequency for home based induction:

- Visit Pre-induction
- Visit 3-7 days post initiation of treatment
- Visit 2-3 weeks post initiation of treatment
- Visit 4-7 weeks post initiation of treatment
- Monthly visits until 6-12 months
- If doing very well, visits every 2 months starting at month 7-13.

Visit frequency for office-based induction

- Visit Pre-induction
- Visits on day 1, 2, 3 when initiate treatment
- Visit 1-2 weeks post initiation of treatment
- Visit 3-6 weeks post initiation of treatment
- Monthly visits until 6-12 months
- If doing very well, visits every 2 months starting at month 7-13.

2. **Urine drug testing (UDT):** UDT in clinical practice is a consensual diagnostic test that: (1) Provides objective documentation of compliance with the mutually agreed-upon treatment plan; (2) Aids in the treatment and management of addiction or drug misuse; (3) Advocates for the patient in family and social issues. UDT provides an opportunity for patients to discuss substance use issues with their provider. UDT provides information about whether the prescribed buprenorphine is present and whether other substances (opioids, cocaine, benzodiazepines, etc.) are present. Results demonstrating ongoing opioid use or other substance use (e.g. cocaine) should be managed in a non-punitive manner. Opioid negative urine tests receive positive reinforcement. Unexpected results of urine tests are opportunities for counseling and brief intervention. Remember that opioid agonist therapy is not an effective treatment for substance use disorders other than opioid use disorder.

UDT frequency:

Week 1-4: Once weekly during initiation and stabilization

Month 2-12: Weekly to monthly depending upon clinical stability

It is important for providers to become familiar with the urine drug tests available in their health care systems. It is ideal to include buprenorphine in the UDT, along with opiates, oxycodone, and methadone. Other substances included in the UDT (cannabinoids, methamphetamines, benzodiazepines, cocaine, etc.) often depend on particular labs and regional epidemiology of substance use.

Counseling

Legislation mandates that all providers have the ability to refer buprenorphine-treated patients to counseling, however, recommending counseling to patients should be done on a case-by-case basis. All patients should receive an assessment of whether counseling is indicated, which should then affect treatment decisions and care plans.

Clinical considerations

Tapering patients off buprenorphine: There is no ideal duration of buprenorphine treatment. Because opioid use disorder is a chronic illness, long term management is warranted. There is no cure for substance use disorders. Depending on patients' specific situations, long term management may or may not involve opioid agonist medication. However, studies consistently demonstrate that longer duration of opioid agonist treatment is associated with better outcomes.

For those situations and patients in which the decision has been made to taper buprenorphine, the ideal patient is socially stable, has developed supportive relationships with persons not using drugs, has discovered alternative ways of dealing with the precipitants to

drug use, and is confident and motivated to taper off opioid agonist therapy. Buprenorphine-maintained patients who are clinically stable and want to discontinue treatment should be tapered slowly (e.g. decrease their buprenorphine dose by 10-25% each month). Slow tapers have been shown to be more successful than rapid tapers. The pace of a voluntary taper should be determined by the patient and could be halted or reversed at the patient's request.

Diversion, theft, threatening behavior, violence: Diversion, theft, threatening behavior, or violence are viewed at many health clinics as serious breaches of policies. Procedures should be developed to manage incidents when buprenorphine diversion is suspected. Witnessed diversion activity usually results in involuntary detoxification and discharge. Other reasons for termination of buprenorphine treatment may include an act or threat of violence against a patient or clinic staff; possession of weapons; violation of the program or clinic policies and regulations; harassment of other patients or staff on the basis of gender, ethnicity, or sexual orientation; stealing or other illegal acts on the clinic grounds; duplicate treatment in opioid agonist treatment programs (e.g., receiving methadone and buprenorphine); and tampering with urine toxicology samples.

No significant improvement or worsening clinical course: When a patient shows no significant improvement or a worsening clinical course, it may be due to progression of the illness, additional physical or psychological stressors, inadequate or inappropriate treatment, or noncompliance with treatment. The treatment team should work closely with patients during these times to help identify contributing factors and strategies to overcome them. The frequency of monitoring and counseling should be increased. When the current level of care cannot meet the needs of the patient, outside providers or programs such as intensive case management, day treatment, supportive housing, or residential treatment should be considered and offered. Transfer from office-based buprenorphine to more structured methadone treatment may be another option.

Integrating buprenorphine treatment into the clinic

The following activities are recommended to solidify integration of buprenorphine treatment throughout the clinic:

1. The treatment team should create an internal communication plan that outlines the ways in which information is diffused throughout the clinic setting. This plan should address:
 - a. How is information about new programs or treatments typically disseminated at a clinic?
 - b. How is information about new programs or treatments typically shared with community partners?
 - c. What are the best ways for the treatment team to communicate with each other?
2. The treatment team and the clinic staff should continue to work together to assess which patients could benefit from the buprenorphine intervention.
 - a. In order to accomplish this goal, the treatment team and staff should consider incorporating:
 - i. Ongoing training to clinic staff on addiction treatment (e.g., overview of addiction and addiction treatment, urine toxicology, confidentiality issues, motivational interviewing), polysubstance abuse, and buprenorphine-specific

subjects (e.g., patient selection, induction, stabilization, documentation, forms, regulations, and case studies).

- ii. Initial annual meetings with all clinic staff and treatment team members to review the status of buprenorphine treatment and how staff roles intersect with buprenorphine treatment (or ways that staff roles could better intersect with the buprenorphine treatment in the future).
3. The treatment team should hold ongoing meetings that discuss the buprenorphine treatment process, eligible patients, patient outcomes, case conferences.
4. The treatment team should determine if any changes need to be made in their clinic EMR to better support documentation of patient level data in this intervention
5. The clinic administration should meet with the treatment team periodically to discuss the status of buprenorphine treatment, any ongoing programmatic needs or concerns, and potential methods for spreading information about buprenorphine treatment throughout the clinic (or clinic system if the site is part of a larger clinical network).
6. Recruit and train additional prescribing providers at the clinic site.

Appendix

Appendix A: Logic Model

| Resources | Activities | Outputs | Short Term Outcomes | Intermediate Outcomes | Long Term Outcomes |
|--|--|--|--|---|---|
| <ul style="list-style-type: none"> •Staff <ul style="list-style-type: none"> •Prescribing Physicians •Buprenorphine Coordinator •Clinical Mentors •Program evaluator/data manager •Pharmacy •Community Health Centers •Community Partners (including substance abuse and mental health resources) | <ul style="list-style-type: none"> •Staff will participate in: <ul style="list-style-type: none"> •Education and training sessions •Mentorship •Care coordination meetings •Make referrals •Staff will work with patients through: <ul style="list-style-type: none"> •Intake •Screening •Assessment of eligibility •Substance abuse diagnosis •Induction •Maintenance •HIV primary care •Pharmacy will manage: <ul style="list-style-type: none"> •Buprenorphine dispensing •Patient education •Community Health Centers and Community Partners will provide: <ul style="list-style-type: none"> •Community outreach •Additional support to patients | <ul style="list-style-type: none"> •# prescribing physicians •# staff members attending training •referral wait time •# eligible patients •# patients induced •# patients maintained •# prescriptions filled •# patients referred to community health centers and community partners •# patient acute care visits •# patient overdose events •# all staff trainings •# meetings with clinic administration •# meetings with community partners •Clinic specific internal communications plan | <ul style="list-style-type: none"> •Increase in number of buprenorphine prescribers at clinic •Increased clinic provider awareness of treatment options •Increased patient awareness of treatment outcomes •Increased community health provider awareness of treatment options •Increased provider confidence in maintaining, sustaining, and supporting a patient while on buprenorphine •Increase in patient linkage to care •Reduction in patient opioid and substance use | <ul style="list-style-type: none"> •Increase in patient retention in buprenorphine treatment •Increase in patient retention in HIV care | <ul style="list-style-type: none"> •Reduction in patient opioid and substance use •Improvement in the following patient outcomes: <ul style="list-style-type: none"> •HIV viral load •Quality of life •Engagement in behavioral health treatment as needed (substance use disorder; mental health) •Increase in patient satisfaction with care •Integration of buprenorphine treatment for opioid use disorder in HIV primary care in the clinic setting •Hosting, sponsoring, or supporting an opioid prescription waiver program •Reduction in fatal and nonfatal opioid overdose |

Appendix B: Staffing Plan and Job Descriptions

| | |
|--|--|
| <p>Physicians (at least 2 MD or DO)</p>  | <p>The lead physician is responsible for all aspects of patient treatment including:</p> <ul style="list-style-type: none"> • conducting or reviewing patient assessments • prescribing buprenorphine in accordance with Schedule III requirements • managing initiation, stabilization, and maintenance of buprenorphine treatment (with the support from the Clinical Coordinator) • record keeping that may be referenced for a DEA inspection • providing clinical guidance and direct supervision to the Clinical Coordinator. <p>A second physician or prescriber is required to provide backup coverage in the event that the lead physician is on vacation, ill, or unavailable for any other reason.</p> |
| <p>Clinical Coordinator</p>  | <p>The clinical coordinator is a key member of the buprenorphine treatment team and serves an essential role in the implementation process. This person must possess not only the clinical knowledge and skills to participate in individual patient treatment, but also the organizational and communication skills to execute systems level activities.</p> <p>The Clinical Coordinator is responsible for:</p> <ul style="list-style-type: none"> • availability to see patients in the clinic daily, participating in patient assessment and preparation, including day-to-day program concerns, education, and counseling • supporting the patient and prescriber in buprenorphine initiation, stabilization, and maintenance treatment procedures under the supervision of the prescribing physician • assisting the prescribing physician in making referrals to community providers for counseling or higher levels of care when needed • maintaining therapeutic relationships with both the patient and the medical provider • overseeing the following patient care components: <ul style="list-style-type: none"> ○ case management ○ medication management and treatment monitoring ○ insurance authorization and troubleshooting ○ relationship building and patient linkage to additional support (drug treatment services and mental health care) ○ relationship building and facilitation of ancillary services (including patient transportation) |



Prescribing Physician

Job Description

Purpose of Position

The prescribing physician is responsible for all aspects of patient treatment and the supervision of the Buprenorphine Coordinator.

Key Responsibilities

The prescribing physician has overall responsibilities for all aspects of patient treatment including:

1. Conducting patient assessments
2. Reviewing patient assessments
3. Prescribing buprenorphine in accordance with Schedule III requirements
4. Managing initiation, stabilization, and maintenance of buprenorphine treatment (with the support from the buprenorphine coordinator)
5. Oversee record keeping that may be referenced for a DEA inspection
6. Participating in professional development and meetings with a clinical mentor

The prescribing physician has overall clinical responsibilities including:

1. Providing clinical guidance and direct supervision to the Buprenorphine Coordinator;
2. Completing 8 hours of approved training; and
3. Obtaining a waiver from SAMSHA's Center for Substance Abuse Treatment (and receiving an accompanying ID number and Drug Enforcement Agency [DEA] registration number). After the first year of prescribing buprenorphine, submitting a second notification to be able to treat up to 100 patients.

Qualifications/Requirements

- Licensed MD or DO.
- Prior clinical experience working with patients with substance use disorders, and mental health diagnoses.
- Knowledge of harm reduction philosophy, patient centered, counseling, and motivation interviewing techniques.
- Demonstrated ability to work collaboratively in a team environment.
- Demonstrated computer literacy in Microsoft and web-based applications.
- Excellent verbal and written communication skills.
- Excellent interpersonal and organizational skills.
- Knowledge of community resources; demonstrated ability to network and build strong relationships with community organizations serving priority populations as identified by the agency and/ or funder.
- Demonstrated ability to working with patients of diverse backgrounds, underserved communities, and co-morbidities.

Preferred Skills

- 2 years of experience providing primary care



Buprenorphine Coordinator

Job Description

Purpose of Position

The Buprenorphine Coordinator is a key member of the buprenorphine treatment team and serves an essential role in the implementation process. This person must possess not only the clinical knowledge and skills to participate in individual patient treatment, but also the organizational and communication skills to execute systems level activities. The Buprenorphine Coordinator is the point person that will have the most contact with the patients, and will be in constant contact with the physicians in order to communicate patient's needs and shape patients' care.

Key Responsibilities

The Buprenorphine Coordinator is responsible for:

1. Seeing patients in the clinic daily, participating in patient assessment and preparation, including day-to-day program concerns, education, and counseling
2. Enrolling patients into the treatment program, including initial assessment
3. Supporting the patient and prescriber in buprenorphine initiation, stabilization, and maintenance treatment procedures under the supervision of the prescribing physician
4. Assisting members of the health care team in the formulation and implementation of the plan of care
5. Assisting the prescribing physician in making referrals to community providers for counseling or higher levels of care when needed
6. Maintaining therapeutic relationships with both the patient and the medical provider
7. Overseeing the following patient care components:
 - a. care coordination including medication management and treatment monitoring
 - b. insurance authorization and troubleshooting
 - c. relationship building and patient linkage to additional support (drug treatment services and mental health care)
 - d. relationship building and facilitation of ancillary services (including patient transportation)
8. Sharing information with other members of the health care team and evaluation team through chart documentation, interdisciplinary team meetings and email
9. Record keeping that may be referenced for a DEA inspection

Qualifications/Requirements

- Licensed nurse (RN, LPN, NP), physician assistant, social worker, or pharmacist
- Knowledge of harm reduction philosophy, patient centered, counseling, and motivation interviewing techniques.
- Prior experience conducting individual patient education and counselling sessions.
- Demonstrated ability to work collaboratively in a team environment.
- Demonstrated computer literacy in Microsoft and web-based applications.
- Excellent verbal and written communication skills.
- Excellent interpersonal and organizational skills, including problem solving with a team.
- Knowledge of community resources; demonstrated ability to network and build strong relationships with community organizations serving priority populations as identified by the agency and/ or funder.
- Demonstrated ability to working with patients of diverse backgrounds, underserved communities, and co-morbidities

Preferred Skills

- Prior clinical experience working with patients with substance use disorders and mental health diagnoses.
- Completion of Buprenorphine Training for Multidisciplinary Addiction Professionals.

Appendix C: Worksheet for DSM-V Criteria: Diagnosis of Opiate Use Disorder

| Patient's Name: | | Date of Birth: | |
|---|----------------|----------------|-------------------------------------|
| Worksheet for DSM-5 criteria for diagnosis of opiate use disorder | | | |
| Diagnostic Criteria* (Opioid Use Disorder requires at least 2 within 12-month period) | Meets criteria | | Notes/ supporting information |
| | Yes | No | |
| 1. Opioids are often taken in larger amounts or over a longer period of time than intended. | | | |
| 2. There is a persistent desire or unsuccessful efforts to cut down or control opioid use. | | | |
| 3. A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects. | | | |
| 4. Craving, or a strong desire to use opioids. | | | |
| 5. Recurrent opioid use resulting in failure to fulfill major role obligations at work, school or home. | | | |
| 6. Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids. | | | |
| 7. Important social, occupational or recreational activities are given up or reduced because of opioid use. | | | |
| 8. Recurrent opioid use in situations in which it is physically hazardous | | | |
| 9. Continued use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by opioids. | | | |
| 10. *Tolerance, as defined by either of the following: (a) a need for markedly increased amounts of opioids to achieve intoxication or desired effect (b) markedly diminished effect with continued use of the same amount of an opioid | | | |
| 11. *Withdrawal, as manifested by either of the following: (a) the characteristic opioid withdrawal syndrome (b) the same (or a closely related) substance are taken to relieve or avoid withdrawal symptoms | | | |

* This criterion is not considered to be met for those individuals taking opioids solely under appropriate medical supervision.

Severity: **Mild:** 2-3 symptoms, **Moderate:** 4-5 symptoms. **Severe:** 6 or more symptoms.

Signed _____ Date _____

Criteria from American Psychiatric Association (2013). Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. Washington, DC, American Psychiatric Association page 541.

Appendix D: DSM-V Criteria for Substance Use Disorder

In the past 12 months, has your patient had at least two of the following occur:

1. **Risk of bodily harm** (drinking and driving, operating machinery, swimming, sharing injection equipment)
 - a. **Have you more than once driven a car or other vehicle while you were drinking (using drugs)? Or after having had too much to drink (while high)?**
 - b. **Have you more than once gotten into situations while drinking/using or after drinking/using that increased your chances of getting hurt—like swimming, using machinery, walking in a dangerous area or around heavy traffic, or having unsafe sex?**
2. **Relationship trouble** (arguments with partner, friends, physical fights while intoxicated)
 - a. **Have you continued to drink (or use drugs) even though it was causing trouble with your family or friends?**
 - b. **Have you gotten into physical fights while drinking or right after drinking (or using drugs)?**
3. **Role failure** or failure to meet obligations at home, work, school (absences, suspension, neglect of family or children)
 - a. **Have you had a period when your drinking (using drugs)—or being sick from drinking —often interfered with taking care of your home or family? Caused job troubles? School problems?**
4. Shown signs of **withdrawal**:
 - a. **How do you feel when you don't drink (use drugs)?**
 - b. **When the effects of alcohol are wearing off, have you had trouble with sleep, feeling shaky, restless, nauseated, sweaty, had a racing heart or even a seizure?**
 - c. **Have you found that when the effects of heroin/painkillers wear off, you had symptoms, such as muscle and joint aches, yawning, restlessness, nausea, stomach cramps/diarrhea, sweating, a racing heart, or anxiety? Or felt like you had come down with the flu?**
5. Shown **tolerance** (needed to use a lot more to get the same effect):
 - a. **Have you had to drink more (or use more drug X) than you once did to get the effect you want?**
 - b. **Or found that what you usually drank (or used) had much less effect than before?**
6. Not been able to stick to intended drinking or drug using **limits** (repeatedly gone over them):
 - a. **Have you had trouble keeping to any drinking limits you set for yourself? How so?**
 - b. **Have you had times when you ended up drinking (using drugs) more, or longer, than you intended? Tell me about that.**
7. Not been able to **cut down or stop** (repeated failed attempts):

- a. **Have you ever stopped or cut back before? What was that like?**
 - b. **Are you able to stop using when you want to?**
 - c. **Have you more than once wanted to cut down or stop drinking/using X, or tried to, but couldn't?**
8. Spent a lot of **time** (anticipating, or procuring, or recovering from substance):
- a. **Some patients describe their drug use as a full-time job. Have you ever felt this way too?**
 - b. **Have you spent a lot of time drinking (using drugs)? Or being sick or getting over its after-effects?**
9. Kept using despite recurrent physical or psychological **problems** i.e. crack chest pain, alcoholic gastritis, speed psychoses, skin abscesses:
- a. **Tell me about any medical problems you've had, if any, from drinking (using drug X)?**
 - b. **Have you continued to drink/use even though it was making you feel depressed or anxious or adding to another health problem? Or after having had a memory blackout?**
10. Spent **less time** on other matters (that had been important or pleasurable):
- a. **What kinds of activities given up or cut back on – that were important or interesting to you, or gave you pleasure – in order to drink (use drugs)?**
11. **Craving**, or a strong desire or urge to use substance.
- a. **Have you had such a strong desire to drink (use drugs) that it was difficult to think of anything else?**

If yes to 2 or more, then your patient meets criteria for a substance use disorder. (Mild 2-3, Moderate 4-5, Severe 6+)

Appendix E: Buprenorphine Treatment Agreement

This agreement has 5 parts:

Part 1: Tells you how and when to take your medicine

Part 2: Describes the goals of treatment

Part 3: List things that you and your doctor agree to do

Part 4: List things that could happen if you do NOT do the things listed in Part 3.

Part 5: Sign the form. You and your doctor must sign the form.

Part 1: My Medicine

| Medicine | Breakfast | Lunch | Dinner | Bedtime |
|----------|-----------|-------|--------|---------|
| | | | | |
| | | | | |
| | | | | |

Part 2: Goals of Treatment

I understand that my cravings may not completely go away. I understand that buprenorphine may not work for me.

My goals for treatment include:

Part 3: Things I agree to do

I will:

- Only get buprenorphine from my doctor
- Tell all my other doctors that I am taking buprenorphine and cannot take any other opiate medications
- Tell my doctor about ALL of the medicines I am taking (over the counter, herbs, vitamins, those ordered by other doctors)
- Tell my doctor about all of my health problems
- Only get refills during my doctor appointment (refill requests may not be honored)
- Tell my doctor if I get pain medicine from another doctor or emergency room
- Keep my buprenorphine in a safe place AND away from children
- Only get my pain medicine from [insert pharmacy name, address, phone number]
- Bring all of my unused pain medicine in their original pharmacy bottles to my doctor visits *if my doctor asked me to*. He or she may count the number of pills left in my bottle(s)
- Allow my doctor to check my urine (pee) or blood to see what drugs I am taking
- Try all treatments that my doctor suggests, including social work and mental health referrals if necessary

I will NOT:

- Share, sell, or trade my buprenorphine with anyone
- Use someone else's medicine
- Alter my urine sample (e.g. add water, use someone else's urine)
- Change how I take my medicine(s) without asking my doctor
- Ask my doctor for extra/early refills if I use up my supply before my next appointment
- Ask my doctor for extra refills if my medicine or prescription is lost or stolen.

My doctor will:

- Work with me to find the best treatment for my addiction
- Refer me for additional help when needed

Part 4. I understand

- This is a controlled narcotic medication that may result in withdrawal symptoms when stopped immediately
- If I drink alcohol or use street drugs while taking my medicine:
 - I may not be able to think clearly
 - I could become sleepy
 - I may injure myself or overdose
- If I ever:
 - Steal
 - Forge prescriptions
 - Sell my medicine
 - Disrespect clinic staff

My doctor will stop my buprenorphine treatment immediately

- If my goals in part 2 are not reached, my doctor may stop my buprenorphine treatment.
- If I do not follow this agreement, or if my doctor thinks that my medicine is hurting me more than it is helping me, my doctor:
 - Will continue to be my primary care doctor but will stop my buprenorphine treatment immediately
 - Will refer me to a specialist for treatment of pain and/or drug problems

I hereby authorize and give consent to the above named physician and/or any appropriately authorized assistants he/she may select, to administer or prescribe buprenorphine for the treatment of opioid use disorder.

The procedures to treat my condition have been explained to me. I understand that it will involve my taking the prescribed buprenorphine on the schedule determined by the treatment team.

It has been explained to me that buprenorphine itself is an opioid, but for some individuals it may not be as strong an opioid as heroin or morphine. Buprenorphine treatment can result in physical dependence. Buprenorphine withdrawal is generally less intense than that with heroin or methadone. If buprenorphine is suddenly discontinued, some patients have no withdrawal symptoms; others have symptoms such as muscle aches, stomach cramps, or diarrhea lasting several days. To minimize

the possibility of opioid withdrawal, buprenorphine should be discontinued gradually, usually over several weeks or more.

For my first dose, I should be in withdrawal as much as possible. If I am not already in withdrawal, buprenorphine can bring on severe opioid withdrawal. For that reason, for the first few days I will be asked to remain at the clinic or pharmacy for a period of time after I take a first dose. After that, I will receive a prescription and return to the designated pharmacy to pick up the medication. I will comply with the correct dosing method for buprenorphine -- holding it under the tongue until it dissolves completely, without swallowing it. Swallowing the buprenorphine will lessen its effectiveness.

I understand that it may take several days to get used to the transition from the opioid I had been using to buprenorphine. I understand that using any other opioids (like heroin) will complicate the process of stabilization on buprenorphine. I also understand that other opioids will have less effect once I become stabilized on buprenorphine. Taking more opioids to try to override the effect of buprenorphine can result in an overdose. In addition, I understand that intravenous use of buprenorphine can produce serious problems including severe withdrawal, overdose, and even death.

I understand that I will not take any other medication without first discussing it with my primary physician because combining buprenorphine with other medications or alcohol may be hazardous. The combination of buprenorphine with Valium, Librium, or Ativan has resulted in death.

I understand that during the course of treatment, certain conditions may make it necessary to use additional or different procedures than those explained to me.

I realize that for some patients, treatment may continue for relatively long periods of time. I understand that I may withdraw from the program and discontinue use of buprenorphine at any time. In this event, I shall be transferred to medically supervised withdrawal treatment or to a methadone treatment program.

I will not allow any other individual to use my buprenorphine. It is dangerous for an individual not on buprenorphine to ingest the medication. Doing so may result in serious injury or even death for that individual.

For Female Patients of Child-Bearing Age:

To the best of my knowledge,

- I am pregnant at this time.
- I am not pregnant at this time.

If I do become pregnant, I will inform my medical provider or one of his/her assistants immediately.

For All Patients:

Alternative methods of treatment, the potential benefits of treatment, possible risks involved, and the possibility of complications have been explained to me. I certify that no guarantee or assurance has been made as to the results that may be obtained from addiction treatment.

Part 5: Sign the form
Sign your name and write the date.

Sign your name:

Date:

Print your name (First and Last):

Address:

Doctor Name:

Doctor signature:

Date:

Appendix F: Home induction protocol

- See PDF

Appendix G: Clinical Opiate Withdrawal Scale (COWS)

Flowsheet for measuring symptoms over a period of time during buprenorphine initiation.

For each item, write in the number that best describes the patient's signs or symptom. Rate on just the apparent relationship to opioid withdrawal. For example, if heart rate is increased because the patient was jogging just prior to assessment, the increase pulse rate would not add to the score.

| |
|---|
| Patient's Name: _____ Date: _____ Buprenorphine initiation: Enter scores at time zero, 30min after first dose, 2 h after first dose, etc. <div style="text-align: right;">Times: _____</div> |
|---|

| | | | | |
|--|--|--|--|--|
| Resting Pulse Rate: (record beats per minute) <i>Measured after patient is sitting or lying for one minute</i> 0 pulse rate 80 or below 1 pulse rate 81-100 2 pulse rate 101-120 4 pulse rate greater than 120 | | | | |
| Sweating: <i>over past ½ hour not accounted for by room temperature or patient activity.</i> 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 <i>Observation during assessment</i> 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 <i>If patient was having pain previously, only the additional component attributed to opioids withdrawal is scored</i> 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 | | | | |

| | | | | |
|---|--|--|--|--|
| Runny nose or tearing <i>Not accounted for by cold symptoms or allergies</i> 0 not present 1 nasal stuffiness or unusually moist eyes 2 nose running or tearing 4 nose constantly running or tears streaming down cheeks | | | | |
| GI Upset: <i>over last ½ hour</i> 0 no GI symptoms 1 stomach cramps 2 nausea or loose stool 3 vomiting or diarrhea 5 Multiple episodes of diarrhea or vomiting | | | | |
| Tremor <i>observation of outstretched hands</i> 0 No tremor 1 tremor can be felt, but not observed 2 slight tremor observable 4 gross tremor or muscle twitching | | | | |
| Yawning <i>Observation during assessment</i> 0 no yawning 1 yawning once or twice during assessment 2 yawning three or more times during assessment 4 yawning several times/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 scores with observer's initials | | | | |

Score:

5-12 = mild;

13-24 = moderate;

25-36 = moderately severe;

more than 36 = severe withdrawal

Appendix H: Buprenorphine Intake Form

| SUBSTANCE ABUSE HISTORY | | | | | | | | |
|--|---|----------------------|---------------------------|--|--------------------|---|--------------------------------|------------------|
| Substance Used | Age of 1 st use | Amount of most used | Period of most use (date) | Route of administration Past Current | | Use in last 30 days (# Days) | Use in last 30 days (quantity) | Date of last use |
| Heroin | | | | | | | | |
| Street Methadone | | | | | | | | |
| Other Street Opiates (i.e. oxycontin percocet) | | | | | | | | |
| Cocaine | | | | | | | | |
| Crack | | | | | | | | |
| Benzos | | | | | | | | |
| Alcohol | | | | | | | | |
| Marijuana | | | | | | | | |
| Buprenorphine | | | | | | | | |
| Other | PCP/LSD/X/Methamphetamine/Crystal Meth: | | | | | | Cig: | |
| DRUG TREATMENT HISTORY | | | | | | | | |
| Name of Program | | Period of Attendance | | Type of Treatment | | Outcome of Treatment (Completed/discharged) | | |
| Most recent treatment | | | | | | | | |
| Previous Treatment | | | | | | | | |
| Previous Treatment | | | | | | | | |
| Duration of time sober: What helped? | | | | Detox: | #Overdoses: | | | |
| | | | | Rehab: | #Suicide Attempts: | | | |
| MENTAL HEALTH | | In care: | Refer now: | | | | | |
| Diagnoses- | | | | | | | | |
| Hospitalizations – | | | | | | | | |
| Medications – | | | | | | | | |
| Counseling - | | | | | | | | |
| Visual /Auditory Hallucinations – | | | | | | | | |
| SOCIAL HISTORY | | HIV Status: | Last HIV test: | HCV Status: | | | | |
| Sexual/Birth control use – | | | | | | | | |
| Violence/Legal: | Parole - | Probation - | Mandated | | | | | |
| Housing- | | | | | | | | |
| Employment - | Last job – | | | | | | | |
| Family& Children/Social Support - | | | | | | | | |
| Education/Literacy - | | | | | | | | |
| Place of Birth (State & Country) – | | | | | | | | |
| Total Prison Time – | | | | | | | | |
| Language spoken – | | | | | | | | |

Appendix I: Additional Resources

National Alliance of Advocates for Buprenorphine Treatment
<http://www.naabt.org/education/literature.cfm>

Mutual Mistrust in the Medical Care of Drug Users: The Keys to the “Narc” Cabinet (Merrill et al.)
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1495051/>

Confronting the Stigma of Opioid Use Disorder- and Its Treatment (Olsen and Sharfstein)
<http://jama.jamanetwork.com/article.aspx?articleid=1838170>

Patients with Addiction Need Treatment – Not Stigma (AMA Task Force to Reduce Opioid Abuse)
<http://www.asam.org/magazine/read/article/2015/12/15/patients-with-a-substance-use-disorder-need-treatment---not-stigma>

Coping with the stigma of addiction (Rosenbloom)
https://www.hbo.com/addiction/stigma/52_coping_with_stigma.html

Stigma Article Series: Part I – Patients with opioid addiction continue to face stigma (Goodheart)
<http://atforum.com/2016/02/stigma-article-series-part-i-patients-opioid-addiction-continue-face-stigma/>

Stigma Article Series: Part II – Watch Your Language! Stigmatizing Patients Who Have Addiction Disorders Can Worsen Clinical Care (Goodheart)
<http://atforum.com/2016/02/stigma-article-series-part-ii-watch-your-language-stigmatizing-patients-who-have-addiction-disorders-can-worsen-clinical-care/>

The ASM National Practice Guideline: For the Use of Medications in the Treatment of Addiction Involving Opioid Use (ASM, Updated May 2015)
<http://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/national-practice-guideline.pdf>

The ASM National Practice Guideline: For the Use of Medications in the Treatment of Addiction Involving Opioid Use Pocket Guide (ASM)
<http://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-pocketguide.pdf?sfvrsn=0>

Buprenorphine: An Office-Based Treatment for Opioid Dependence (The New York City Department of Health and Mental Hygiene)
<https://www1.nyc.gov/html/doh/downloads/pdf/chi/chi27-4.pdf>

Advisory: Sublingual and Transmucosal Buprenorphine for Opioid Use Disorder (SAMHSA)
http://store.samhsa.gov/product/SMA16-4938?WT.mc_id=EB_20160301_4938

SAMHSA Resources on Opioid or Opiates

<http://store.samhsa.gov/facet/Substances/term/Opioids-or-Opiates?pageNumber=1>

Overview of Harm Reduction (Harm Reduction Coalition)

<http://harmreduction.org/our-work/training-capacity-build/online-training-institute/overview-of-harm-reduction/>

Improving Health Care with Drug Users: Tools for Non-Clinical Providers (Harm Reduction Coalition)

<http://harmreduction.org/issue-area/issue-drugs-drug-users/improving-health-care-with-drug-users/>

Injection Drug User Cultural Competency (Harm Reduction Coalition)

<http://harmreduction.org/issue-area/issue-drugs-drug-users/injection-drug-user-cultural-competency/>

ⁱ Fiellin DA, Weiss L, Botsko M, et al. Drug treatment outcomes among HIV-infected opioid-dependent patients receiving buprenorphine/naloxone. *J Acquir Immune Defic Syndr (Suppl)*. 2011;56 (S1): S33-8. Available at: www.ncbi.nlm.nih.gov/pubmed/21317592

ⁱⁱ Altice FL, Bruce RD, Lucas GM, et al. HIV treatment outcomes among HIV-infected, opioid-dependent patients receiving buprenorphine/naloxone treatment within HIV clinical care settings: results from a multisite study. *J Acquir Immune Defic Syndr(Suppl)*. 2011;56 (S1): S22-32. Available at: www.ncbi.nlm.nih.gov/pubmed/21317590

ⁱⁱⁱ Korthuis PT, Fiellin DA, Fu R, et al. Improving adherence to HIV quality of care indicators in persons with opioid dependence: the role of buprenorphine. *J Acquir Immune Defic Syndr (Suppl)*. 2011;56 (S1): S83-90. Available at: www.ncbi.nlm.nih.gov/pubmed/21317600

^{iv} Korthuis PT, Tozzi MJ, Nandi V, et al. Improved quality of life for opioid-dependent patients receiving buprenorphine treatment in HIV clinics. *J Acquir Immune Defic Syndr(Suppl)*. 2011;56 (S1): S39-45. Available at www.ncbi.nlm.nih.gov/pubmed/21317593