OBAT

POLICY AND PROCEDURE MANUAL

POLICIES AND PROCEDURE MANUAL OF THE OFFICE BASED ADDICTION TREATMENT PROGRAM FOR THE USE OF BUPRENORPHINE AND NALTREXONE FORMULATIONS IN THE TREATMENT OF SUBSTANCE USE DISORDERS

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DISCLAIMER

Boston Medical Center is pleased to share its Office Based Addiction Treatment Manual with other providers. Although Boston Medical Center has attempted to confirm the accuracy of the information contained in this manual, this manual is not a substitute for informed medical decision making by an appropriate, licensed provider. Clinicians must confirm the appropriateness of all treatment that they provide to a patient and are responsible for the decisions they make when caring for patients. If clinicians discover something in this manual should be revised or clarified, please contact Boston Medical Center at 617-414-7453.
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PURPOSE

The purpose of this manual is to provide detailed policies and protocols of the Office Based Addiction Treatment program for the use of buprenorphine (alone and in combination with naloxone) and naltrexone (oral and extended-release injectable formulations) in the treatment of substance use disorders at Boston Medical Center.

These policies and protocols are meant to provide best practice guidelines to clinicians utilizing buprenorphine and/or naltrexone for the management of opioid and alcohol use disorders in mainstream medical practices, and to expand access to treatment.

INTRODUCTION TO OFFICE-BASED ADDICTION TREATMENT (OBAT) PROGRAM

Federal data from the 2014 National Survey on Drug Use and Health (NSDUH) indicate that 4.3 million people aged 12 or older in the United States reported nonmedical use of prescription pain medication in the past month and 435,000 reported use of heroin in the past month.[1] Largely driven by opioids, drug overdose is the leading cause of personal injury-related death in the US.[2] Since 1999 the rate of overdose death involving any opioid has quadrupled.[3] In 2014, there were approximately 1.5 times more US deaths related to drug overdose than deaths related to motor vehicle accidents.[4] In the same year, heroin overdose death rates increased sharply by 26% and the rate of overdose death involving a synthetic opioid, such as fentanyl (not including methadone) nearly doubled.[1] In 2015, 27 million people in the US (or 8% of the total population age 12 and older) met criteria for a substance use disorder in the last year; less than 10% of these individuals received any specialized care for their substance use disorder.[5] This treatment gap has been attributed to numerous barriers such as lack of patient and provider knowledge of evidence-based treatments, limited treatment capacity, stigma, and financial, legislative, and geographic obstacles.[6–9]

Substance use disorders are a group of chronic medical conditions defined in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) of the American Psychiatric Association that require long-term treatment and support.[10] The US Food and Drug Administration (FDA) has approved three medications for the treatment of opioid use disorder: (i) oral **methadone** (full opioid agonist); (ii) oral transmucosal and sub-dermal implant **buprenorphine** (nonselective partial opioid agonist) and (iii) long-acting injectable **naltrexone** (opioid antagonist). The most effective treatment for opioid use disorder involves medication maintenance for an adequate duration of time; the effectiveness of opioid agonist maintenance for treatment of opioid use disorder has been extensively documented through randomized clinical trials, quasi-experimental designs and program evaluations.[11] There is evidence to support use of injectable naltrexone for treatment of opioid use disorder, particularly in special populations, though treatment outcomes have been inferior to those attained with methadone and buprenorphine maintenance.[12] At sufficiently high doses, opioid agonist maintenance treatment relieves craving for opioids.[13] Continuous, steady-state medication maintenance treatment decreases the interaction between the opioid agonist medication (i.e., methadone or buprenorphine) and the μ-opioid receptors in the brain, blocking or attenuating the euphoric effects of illicit opioids (e.g., heroin).[14]

Buprenorphine/naloxone was the first medication available to treat opioid dependence by prescription in a physician's office or clinic outside of a traditional Outpatient Treatment

Program (OTP). Prior to the advent of buprenorphine/naloxone, methadone was the only medication FDA approved to treat opioid use disorder in the US and it can only be dispensed at licensed methadone maintenance clinics. Unlike methadone, which is a full opioid agonist, buprenorphine is a μ-opioid receptor partial agonist. Due to a slow disassociation from the opioid receptor, the withdrawal syndrome from buprenorphine is milder when compared to that resulting from full opioid agonists (i.e., methadone). Naloxone, an opioid receptor antagonist, was added to buprenorphine to deter misuse (i.e., injection) and diversion. When administered sublingually, naloxone is poorly absorbed and has little to no pharmacological effects.[15] Buprenorphine without naloxone (mono tablet) is typically only prescribed to women during pregnancy. Nationally, the number of patients receiving treatment with buprenorphine/naloxone has been increasing steadily, with good treatment retention. A recent evaluation of the federal buprenorphine waiver program (DATA 2000), found that of the 433 patients on buprenorphine maintenance interviewed, at six-month follow-up 60% were still retained in treatment and another 15% had completed treatment.[16]

In 2014, over half of individuals age 12 and older in the US reported drinking alcohol in the past 30 days; 2 in 5 reported binge alcohol use.[1] In 2014, 17 million people in the US had an alcohol use disorder, comprising 79.1% of people in the US with a substance use disorder. Alcohol use exists on a spectrum, beginning with abstinence and low risk drinking ranging all the way to severe alcohol use disorder or addiction. Typically the severity of consequences positively correlates with consumption. Unhealthy alcohol use is associated with risk of serious chronic health conditions (e.g., liver cirrhosis) as well as risks related to acute intoxication and alcohol withdrawal such as accidental injury and death.[17] Excessive alcohol use is the 4th leading cause of preventable death in the US;[18] between 2006 and 2010 there were 88,000 alcohol-related deaths in the US.[19]

Naltrexone is a competitive mu, kappa, and delta opioid receptor antagonist that blocks the effects of opioids by competitive binding. Naltrexone is available as an oral tablet which is taken daily, and an extended-release injectable formulation (i.e., Vivitrol) administered intramuscularly into gluteal muscle every twenty-eight days. The US FDA approved the oral formulation of naltrexone for treatment of alcohol use disorder in 2006, and the extended-release version was approved in 2010 for treatment of both alcohol use disorder and opioid dependency following detoxification. The mechanism of action of naltrexone in alcohol use disorder is less clear but is related to blockage of opiate receptors related to the rewarding effects of alcohol use and craving.[20]

Patients with substance use disorders should be offered medication treatment for addiction and psychosocial therapies as part of a comprehensive treatment plan to treat their disease. Like other chronic disease models, substance use disorders can be effectively managed in a primary care office or community clinic by employing models of care such as Boston Medical Center's

Office-Based Addiction Treatment (OBAT) Program's Nurse Care Manager Model. Integration of addiction treatment into office-based primary care settings is imperative to expanding access to effective addiction treatment and implementation of evidence-based models of care.

INTRODUCTION TO THE NURSE CARE MANAGEMENT MODEL OF OBAT

Boston Medical Center (BMC), which has one of the largest office based addiction treatment (OBAT) programs in New England, has successfully expanded patient access to buprenorphine/naloxone treatment by implementing a nurse care manager model within its OBAT program.[21] Nurse care managers, by virtue of their training and role in chronic disease management, are ideally suited to serve as the lynch pin in the OBAT program. Nurse care manager responsibilities encompass the full breadth of the program components: patient screening, assessment, education, care planning, medication induction, stabilization, and maintenance. Additionally, nurses are responsible for on-going medical management, coordination of follow-up care, treatment intervention, telephone monitoring, relapse prevention, overdose education and support for patient self-management.

The initial success of the BMC nurse care manager initiative led to state grant funding of the **S**tate **T**echnical **A**ssistance **T**reatment **E**xpansion (**STATE**) **OBAT** project, which allowed for the further expansion of the nurse care manager model to Community Health Centers across Massachusetts.[22] Participating sites received funding for nurse care managers and medical assistants. Initial training included an 8-hour core curriculum, and ongoing support including 24/7 telephone and e-mail assistance, job shadowing with the OBAT nurse care managers at BMC, telephone conference calls, site visits by the Director, training and case reviews at rotating sites, and mandatory quarterly training on relevant issues to all State OBAT Nurses. Other staff, including physicians, nurses, medical assistants, and social workers, also received training and technical assistance to integrate primary care with treatment for opioid use disorders and alcohol use disorders.

OBAT CLINIC STAFFING REQUIREMENTS

PROVIDERS

BUPRENORPHINE, BUPRENORPHINE/NALOXONE

QUALIFICATIONS: Qualified providers must obtain a waiver of authority to prescribe any medication that is a scheduled III, IV, or V and FDA approved for the treatment of opioid dependence for the purpose of detoxification or maintenance treatment of patients with opioid dependence. With DATA 2000, physicians became legally qualified to receive waiver training. In July 2016 the Comprehensive Addiction and Recovery Act was signed into law increasing buprenorphine prescription authority to also include physician assistants and nurse practitioners for 5 years (until Oct, 2021).

PHYSICIAN WAIVER ELIGIBILITY: To be eligible for a waiver, providers must have a current state medical license, a valid registration number from the US Drug Enforcement Agency (DEA), completion of 8hrs of an approved waiver training course, and one or more of the following:

- Board subspecialty certification for addiction psychiatry (*American Board of Medical Specialties),* addiction (*American Society of Addiction Medicine*), or addiction medicine (*American Osteopathic Academy of Addiction Medicine)*

  –OR–

- Participation as an investigator in one or more trials that led to the FDA approval of buprenorphine/naloxone or another Schedule III-V narcotic medication used for the maintenance or detoxification treatment of opioid addiction

  –OR–

- Other training or experience deemed equivalent by either the state Medical Board or by the Secretary of Health and Human Services (HHS).

NP/PA WAIVER ELIGIBILITY: To be eligible for a waiver, NPs and PAs must complete 24 hours of approved training that covers the following topics: opioid maintenance and detoxification; clinical use of all FDA-approved drugs for medication-assisted treatment; patient assessment; treatment planning; psychosocial services; staff roles; and diversion control. NPs and PAs who are approved to prescribe buprenorphine must be supervised by or work in collaboration with a qualifying physician if required by law in their state. NP/PA will be limited to 30 patients at a time in the first year and then can apply to HHS for an extended waiver to 100.

REFERRALS: Providers must be able to refer patients to counseling or psychiatric services.

PATIENT LIMITS: For the first year of receiving a waiver, providers are limited to treating 30 active patients at any given time; after the first year, they are limited to treating 100 patients at

any given time. (e.g., prescription written for 30 days, patient is discharged, that patient continues to count under that physician number until the end of that 30 day prescription.) To become eligible to treat up to 100 patients per provider the provider needs to apply to CSAT for the extended waiver prior to increasing to 100 patients.

Recent legislation has expanded limits for eligible physicians to treat up to 275 patients, the rule does not extend prescribing authority to other clinicians. Eligible physicians must complete a 'Request for Patient Increase Form' and receive approval prior to increase. To be eligible for a patient limit of 275 a physician must have a current waiver to treat up to 100 patients, and must have maintained that waiver for at least one year without interruption.

Physicians wishing to increase to a patient limit of 275 must also meet one of the following requirements:

- Hold a board certification in addiction psychiatry or addiction medicine
    - Certifying agencies: American Board of Medical Specialties (ABMS), American Society of Addiction Medicine (ASAM), American Board of Addiction Medicine (ABAM), American Osteopathic Academy of Addiction Medicine

–OR–

- Practice in a "qualified practice setting".
    - A "qualified practice setting" must: provide professional coverage for patient emergencies during hours when the practice is closed, provide access to case-management services, accept third-party payment for health service costs, utilize health information technology, and be registered by their State prescription drug monitoring program where operational.

NALTREXONE

Naltrexone is not a scheduled medication and therefore does not require a special licensure, certification, or waiver to prescribe. Any individual who is licensed to prescribe medication (physician, nurse practitioner or physician assistant) may prescribe and/or administer naltrexone. There is no limit to the number of patients that a provider could legally treat with naltrexone. However, when treating patients with substance use disorders, it is important that providers understand the nature of the underlying disorder, the pharmacological properties of available medications, and the importance of patient selection and monitoring.

NURSE CARE MANAGERS

- Licensed to practice nursing in the state for which they are practicing.

- Complete an initial 8-hour nurse care management training curriculum: Office-based treatment with buprenorphine/naloxone, including the use of buprenorphine/naloxone for the treatment of opioid use disorder in the office setting, based on the TAP 30. Training regarding the use of naltrexone for the treatment of alcohol use disorder and prevention of relapse to opioid dependence.

CURRICULUM INCLUDES:

- Legislative regulations, DEA requirements, pharmacology of buprenorphine/naloxone and naltrexone, considerations in determining patient appropriateness, induction and management procedures, guidelines for pain management, safety, storage, diversion, and psychological counseling during OBAT treatment including self-help and holistic supports, relapse, special circumstances such as pregnancy, adolescence, elderly, chronic disease, surgery, pain management, HIV, and hepatitis C.

- Attend "booster trainings" on topics relevant to OBAT program (e.g., hepatitis C treatment and management, urine toxicology screening [UTS], relapse prevention, overdose prevention education, motivational interviewing, retention, harm reduction, compassion fatigue, case discussions, materials development, and networking)

RESPONSIBILITIES:

- Oversight of buprenorphine/naloxone and naltrexone intake assessment, induction, stabilization, maintenance and relapse management.

- Ensuring that state and federal guidelines are followed, and collaborating as needed with OBAT provider, social worker/counselors, psychiatrists, pharmacy, primary care physician, and specialty care physicians to whom the patient has been referred.

- Coordinating between OBAT provider and pharmacy: obtain medication history, assist with prescription processing and refills, prior authorizations, insurance issues, concerns of diversion, use, safety, storage, and behavioral health referrals.

PROGRAM MANAGER

- Provides administrative support to the team: completes state reporting requirements, assists with resolving insurance issues, prior authorizations, patient scheduling, team meetings, staffing, program issues, meetings and supervision of data coordinator and hotline coordinator.
- Manages provider files (e.g., DEA numbers, curriculum vitae, state licensure).
- Supports DEA site visits.
- Manage insurance issues, keep current with changes and pass this information along as warranted.
- Manages lists of patients per provider to assure compliance with DEA requirements.
- Assists with program and State requests for data.
- Manages OBAT provider meetings with nurses, medical assistants, providers, medical director, project coordinator, and program director.
- Collaborates with outside agencies as needed to foster relationships with OBAT and better serve our patients (e.g., counseling services, psychiatry, Department of Children and Families, and Corrections).
- Supports specialty programs (e.g., criminally involved, pregnant women, and adolescents)

PROGRAM REQUIREMENTS

SAMHSA'S CENTER FOR SUBSTANCE ABUSE TREATMENT (CSAT) DIVISION OF PHARMACOLOGIC THERAPIES

BUPRENORPHINE ADMINISTRATIVE REQUIREMENTS

- Certification, accreditation and waiver approval.
- Provide training for prescribers and addiction professionals on the use of medications in the treatment of opioid dependence.
- Maintain accurate provider records.
- Records on dispensation of buprenorphine and buprenorphine/naloxone must be kept in accordance with DEA regulations for controlled substances as described in 21 CFR 1304.03(b).
- Records on prescription and dispensation of medications for the detoxification and maintenance treatment of opioid dependence must be kept in accordance with DEA regulations 21 CFR 1304.03(c)
    - Maintain log to include patient identifier, name, dose, and quantity of drug prescribed/dispensed, and date.
    - Requirement may be fulfilled by keeping copies of prescriptions in the patient record. Electronic medical records where the prescription records can be accessed fills this requirement and there is no need to keep copies of the prescriptions in your office.
    - For DATA 2000 compliance, DEA only needs to review records for medications used in the treatment of opioid dependence; therefore, an option is to keep separate records for these medications to facilitate the review.

CONSIDERATIONS TO REFER A PATIENT FOR MEDICATION TREATMENT FOR ADDICTION IN OBAT

- Patient must have a DSM-5 diagnosis of Opioid Use Disorder or Alcohol Use Disorder. See Appendix 2
- 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 goals of OBAT program:
  - Prevention/reduction of withdrawal symptoms and cravings for opioids and/or alcohol
  - Addressing any psychiatric problems through consultation with the multi-disciplinary treatment team and follow through with necessary referrals and treatment.
- Restoration of normal physiological functions that may have been disrupted by substance use and improvement in quality of life.
- Logistics: patient is able to come to required visits during hours of office operation, patient has access to transportation options, patient is able to comply with visit and counseling requirements.
- For patients seeking treatment with agonist medications: they must not have chronic pain requiring opioid management beyond buprenorphine/naloxone.
- For patients seeking treatment with antagonist medication: they must not have acute/chronic pain issues requiring opioid management.
- Patient must not be in need of higher levels of care with more intense management (i.e., daily monitoring and assessment, medication administration due to advanced psychiatric illness, acute or chronic pain requiring ongoing opioid management).
- Patient must be able to be treated in an office based setting safely without harm to self or others.
- Patient must not be actively poly-substance using and if so is willing to engage in detoxification from other illicit substances not including opioids prior to induction.

PATIENT INITIATION ROADMAP

INITIAL SCREENING: PHONE OR IN PERSON SCREENING BY OBAT STAFF

- See Appendix 3: Telephone Screening.

- *Phone screener includes*: Review of medical, social, and substance use history as well as current use. Demographics, living situation, insurance, safety and treatment goals are also reviewed.

INTAKE PERFORMED BY NURSE CARE MANAGER

See Appendix 4: Nursing Intake

RN Intake Includes:

- Education on buprenorphine/naloxone and/or naltrexone: what it is, how it works, medication administration, interactions, side-effects, potential adverse reactions, safety, storage, self-care, induction, maintenance, detoxification, tapering, withdrawal. Patient signs and reviews treatment agreement and consents for treatment.

- Obtain laboratory tests to include the following if clinically needed: complete blood count, comprehensive metabolic panel, hepatic function, pregnancy test (required on all females of child-bearing age, unless not clinically indicated), RPR, hepatitis A, B and C serologies, HIV testing recommended, and urine toxicology screening (UTS) (all patients are to have UTS at this visit). Labs will be ordered based upon current clinical information.

CONSENTS (*SEE* APPENDIX *8A – 8E*)

In addition to standard HIPAA laws, federal regulations mandate strict confidentiality for information about patients being treated for substance use disorders (42 CFR Part 2). Additionally, the law requires written patient consent before information about addiction treatment can be disclosed to any other source. For OBAT 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 addiction treatment.
- × Disclosing or transmitting a patient's addiction-related medical records.
- × Use of a letterhead that identifies the office as an addiction 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 (SAMHSA, 1994b).

There are some exceptions to the disclosure laws, such as in case of medical emergencies or legal situations.

REVIEW OF PROGRAM EXPECTATIONS:

- Appointment frequency with nursing and provider. (See Appendix 10B)
- Counseling requirement (See Appendix 10C) and psych assessment and follow up if warranted.
- Medication refills. (See Appendix 10F)
- Relapse prevention and support.
- Treatment planning and review.
- Enhanced treatment as required.
- Team meetings and assessment if needed.
- Medical supports, involvement with medical team.
- Team involvement in treatment to include: nurses, program directors and administrators, providers, counselors, family or other supports if available, and psych supports.
- Review and educate patient on: expected adverse events including potential for withdrawal, precipitated withdrawal, opioid antagonism and other side effects. See package inserts (See Appendix 11A)
- Review and educate patient on: safe storage, responsibilities for medication storage and lost/stolen policies (See Appendix 10D) handling, and use of medication, including pediatric exposure concerns. Pediatric Exposure Brochure (See Appendix 11D).
- Inform the patient that the initial interview is not a guarantee of treatment. Following the interview, the team must review each case, including lab results, before determining whether buprenorphine/naloxone or naltrexone treatment is an appropriate option for the patient in this outpatient treatment setting.
- Review clinic hours and times available for scheduling visits.
- If unable to meet the patient's needs and the program requirements, site will assist in referring the patient to another treatment setting that may be better able to meet the needs of the patient.

VISIT WITH OBAT PROVIDER

- Provider assessment visit, with PE if needed, and review of laboratory test results. Provider confirmation of DSM-5 diagnosis of Opioid Use Disorder or Alcohol Use Disorder and assessment of appropriateness for medication treatment for addiction with either buprenorphine/naloxone or naltrexone.

- OBAT Nurse will manage the patient under the guidance of the provider with close clinical follow-up and ongoing communication with the waivered provider by telephone, electronic medical record, and team meetings.

- Follow-up visits with waivered provider occur at a minimum of once every four months.

    - Communication with OBAT provider is ongoing through EMR, phone contact and in person communication.

- Follow up with primary care provider as warranted based on medical needs. Often the PCP and the OBAT provider are the same, and this will not apply.

TREATMENT INITIATION, STABILIZATION & MAINTENANCE

CHECKLIST: PRIOR TO BUPRENORPHINE/NALOXONE INDUCTION

- ✓ Treatment agreement and consents are reviewed and signed.
- ✓ Reinforce to patient the need for frequent appointment adherence, and establish whether this is realistic, if patient states it is not manageable, this needs to be addressed with the team prior to initiating treatment.
- ✓ Counseling services must be in place prior to the patient starting treatment.
- ✓ UTS that is negative for all illicit substances other than opioids.
- ✓ Negative pregnancy test for women of childbearing age.
    - If positive HCG, OBAT team will immediately assist patient engagement with appropriate OB providers
- ✓ Clinical team may refer a patient to detox or a patient may present from detox prior to start of buprenorphine/naloxone treatment. Patient should bring discharge paperwork with medication protocol to confirm what was prescribed (benzodiazepines or methadone) while in detox. These substances may be present in UTS if induction occurs shortly after discharge from detox.
- ✓ Nurse Care Manager consults with waivered provider after initial visit and obtains the prescription from the prescriber
- ✓ After OBAT team review, schedule induction per protocol in collaboration with patient and team: date, time, prescription, and clinic schedule.
- ✓ Nurse Case Manager telephones patient to review induction plan, and faxes prescription to pharmacy for patient to pick up on day of induction.
- ✓ Patient presents to clinic for induction.

BUPRENORPHINE/NALOXONE INDUCTION

Day 0: Induction

- Patient arrives at clinic in early withdrawal, with prescription medication in hand.
- For patients who are actively using opioids other than buprenorphine, the Nurse Care Manager assesses symptoms with Clinical Opioid Withdrawal Scale (COWS), if the COWS score is >6-12 the NCM instructs the patient to take the buprenorphine/naloxone as prescribed and per clinic protocol. (See Appendix 11E)
- For patients who are self-maintaining with buprenorphine/naloxone, assessment utilizing the COW scale may not be necessary. Use clinical judgment and refer to recent urine toxicology.
- NCM supervises medication administration, and educates the patient as to appropriate technique as this is a sublingual/buccal administration that necessitates being kept in the mouth for a long period of time for appropriate absorption.
- Buprenorphine/naloxone 2-4mg initial dose is removed by the patient from their medication bottle, taken sublingually, observed and under instruction by the OBAT NCM for proper administration.
- Reassess after 30-60 minutes, and instruct patient to then take their second dose of 2-4mg sublingually if needed, again observed and supervised by the OBAT NCM for proper administration.
- Provide written instructions, establish follow-up plan including same-day telephone check-in and clinic visits.
- For telephone induction, contact patient during first hour, then every 2 hours for the next 4 hours, and then as needed. Dose will continue to be titrated per prescription instructions and/or until signs and symptoms of withdrawal subside.
- Update Nurse Manager by end of the day in case of calls or concerns off hours.

Day 1:

- Patient checks in by telephone, and as needed during that day. Dosage is titrated per prescription instructions and until patient symptoms stabilize. Provide support and ongoing education; update Nurse Manager and OBAT Provider as needed. Typically patients will titrate to 8mg by the end of day 1, however, this dose may be less or could be higher when transitioning patients from long-acting opioids.

Day 2 through Day 7:

- Patient is instructed to take total dose equivalent from day one upon awakening. Patient is then required to check in with the NCM by phone a few hours later. If increased symptoms throughout the day, the patient may increase up to 16mg. Daily check-in with a phone note as needed; patient to return to clinic within one week or sooner if needed.

- Patient sees Nurse Care Manager weekly until stable, then every other week, and progresses to monthly as clinically indicated. If a patient requires more support (i.e., homeless) they may present in person for more frequent visits.

BUPRENORPHINE/NALOXONE STABILIZATION

Goal: stabilization of dosing. Target buprenorphine/naloxone dose = 8-16 mg/day (maximum of 24mg/day) or less. May be taken in divided doses.

- Narcotic blockade is reached at 16mg and is recommended in the early stages of recovery http://www.naabt.org/education/pharmacoloy_of_buprenorphine.cfm

- Divided dosing is especially helpful for patients with chronic pain for dual effectiveness and avoidance of narcotic medications.

- Medication has a long half-life. The majority of patients take buprenorphine/naloxone twice daily, the prescription may need to be specifically written as twice daily dosing to allow some patients to receive it twice daily while engaged in residential programs.

- Patient returns to clinic after one week for assessment, prescription renewal, urine toxic screening/swab, counseling, education, support, and evaluation of mental health and other needs.

- No prescriptions lasting longer than 1 week are to be given during this phase.

- Refills are permitted, but patient must provide pharmacy information as all prescriptions are faxed to the pharmacies. Patients are never given a hard copy of the prescription.

- Patient sees Nurse Care Manager weekly for 4-6 weeks until stable. If urine screens are negative, patient is attending counseling and weekly clinic visits as scheduled, they then may progress to the maintenance phase.

BUPRENORPHINE/NALOXONE MAINTENANCE

Once stable, clinic visits every 2 to 4 weeks, with refills that coincide with visits.

Goal: monthly visits for a few months; ultimately, random visits as needed if appropriate for patient; random is more effective in assisting patients in their recovery and should be the goal instead of monthly.

- Many patients will remain on visits more frequently than monthly as patients find these visits important to their recovery process.
- Each decrease in visit frequency requires treatment team review.

Clinic visits to include (See Appendix 6: Nursing Follow-up Form):

- Collection of urine sample/swab for toxicology.
- Lab testing: if LFTs were elevated at induction, they must be re-checked within 1-2 months or sooner depending on degree of elevation, and must continue to be regularly monitored thereafter. Elevations are more common in patients with hepatitis C and HIV infection.
- If history of risky alcohol use, breathalyzer at each visit; if patient is struggling with alcohol use, this must be addressed by the team.
    - Acamprosate (Campral), disulfiram (Antabuse), topiramate (Topamax) may be offered to patients with alcohol dependence with provider input and agreement.
    - Patients managed on buprenorphine/naloxone cannot be treated with any naltrexone formulation, as these medications are contraindicated.
- Assessment of status: recovery, relapse, medical issues, should be addressed as indicated. Contact other OBAT team members as needed, including OBAT provider and PCP if different and warranted.
- Review of current buprenorphine/naloxone dose, adherence, and correct administration techniques
- Review of treatment plan: (counseling, meetings), need for further psychiatric treatment, difficulties with obtaining or using buprenorphine/naloxone, incidence of side effects, presence of cravings or withdrawal, instances of drug use.
- Medical case management with brief counseling support.
- Review contact information, including pharmacy at each visit.

- Refills for up to 6 months may be provided once stable and these are faxed to a pharmacy with pharmacy information kept on file.

- Visits with waivered OBAT provider at least every 3-4 months, with review of medical record, lab test results, recovery status and UTS results.

- RN performs telephone contact for support, monitors medical issues, pregnancy status, medication changes, any pending needs for surgery, acute/chronic pain management, and need for psychiatric assessment.

NALTREXONE INITIATION: PATIENT SELECTION

Candidates for treatment with naltrexone include patients who:

- Are not currently using opioids, but have a history of opioid misuse disorder/dependence and are at risk for relapse
- Struggle with alcohol use and are deemed capable of abstaining from alcohol in an office-based treatment setting
- Have a high degree of motivation for abstinence
- Have been successful on opioid agonists and wish to discontinue agonist therapy
- Are not interest in agonist/partial agonist therapy to treat their opioid use disorder
- Certain patients who have not experienced successful treatment with agonist therapy

Contraindications:

× Advanced liver disease or acute hepatitis

× Moderate to severe renal impairment

× Patients with chronic or acute pain that requires opioid analgesics

× Patients who are unable to remain opioid free for extended periods of time

× Patients with advanced psychiatric disease, active suicidal/homicidal ideation, especially if symptoms worsen during withdrawal

× Patients who are currently opioid dependent, or taking opioids, or have an opioid positive urine screen

× A patient who fails the naloxone/naltrexone challenge test

× Patients who have displayed a hypersensitivity to naltrexone, PLG, carboxymethyl cellulose, or any other components of the diluent

Special considerations:

Pain: chronic pain must be managed with non-opioids. Acute pain requires anesthesia consult. If a patient has a surgical procedure pending, may want to consider delaying naltrexone treatment until after the procedure.

Cirrhosis: Naltrexone is extensively metabolized through the liver and should not be administered if AST/ALT are more than 5x normal limits.

Pregnancy: There has not been sufficient research to assess the safety or efficacy of naltrexone in pregnancy. Naltrexone, both oral and injectable formulations, are Category C medications. The provider would need to evaluate the risk/benefit and appropriate consent of unknown risk should be utilized.

Breastfeeding: It is known that naltrexone from the oral formulation passes into breast milk. It is not known if extended-release injectable naltrexone passes into breast milk. In vivo studies indicate potential tumorigenicity. Labeling from the manufacturer advises against breast feeding while on naltrexone, both with oral and injectable formulations.

Anemia/Thrombocytopenia: Administer extended-release injectable naltrexone with caution and observe site for bleeding. Consider oral formulation

Obese/large body habitus: Extended-release injectable naltrexone must be administered IM into gluteal muscle using the contents of the medication package. Alternate treatment may be considered for patients whose body habitus precludes an intramuscular gluteal injection with one of the provided needles. Consider oral formulation.

CHECKLIST: PRIOR TO NALTREXONE INITIATION

- ✓ Treatment agreement and consents are reviewed and signed.
- ✓ Reinforce with patient the need for frequent appointment adherence, and establish whether this is realistic, if patient states it is not manageable, this needs to be addressed with the team prior to initiating treatment.
- ✓ Counseling services must be in place prior to the patient starting treatment.
- ✓ Patient cleared by psychiatry if concerning mental health history
- ✓ Labs appropriate: HCG neg. LFTs < 5x normal
- ✓ UTS that is negative for all illicit substances
    - Detoxification from opioids should be completed prior to the administration of naltrexone to prevent precipitated or spontaneous withdrawal. The patient must be off short-acting opioids 5-7 days. If taking long-acting opioids such as methadone or buprenorphine, the patient must be off for at least 7-10 days.
    - Detoxification from alcohol should occur prior to naltrexone initiation if a patient has a history of alcohol-related seizures, DTs, longstanding daily use, presence of withdrawal signs or symptoms, or as otherwise clinically indicated.
    - Clinical team may refer a patient to detox or a patient may present from detox prior to start of naltrexone treatment. Patient should bring discharge paperwork with medication protocol to confirm what was prescribed (benzodiazepines, opioid agonists) while in detox. Benzodiazepines prescribed in detox may be present in UTS if naltrexone initiation occurs shortly after discharge from detox. Opioids however, will need to be cleared and 5-10 days should pass between last opioid dose and naltrexone initiation to prevent precipitated withdrawal.
- ✓ Nurse Care Manager consults with OBAT provider and clinical team after initial visit. After OBAT team review, schedule induction per protocol in collaboration with patient and team: date, time, prescription, and clinic schedule.
- ✓ Nurse Case Manager telephones patient to review medication initiation plan and orders medication. Oral naltrexone tablet prescription may be e-faxed to pharmacy for patient to pick up. Extended-release injectable naltrexone often requires insurance prior authorization and ordering through a specialty pharmacy, this process may take several days and requires thoughtful planning.
- ✓ Patient presents to clinic for induction/medication initiation.

NALTREXONE INITIATION

- Patients should be started on the oral form of the medication, prior to receiving the extended-release IM injection

    - This is to mitigate allergic reactions, side effects, adverse reactions or any other intolerance of the medication

    - Typically, patients will remain on oral formulation for about one week before receiving their first extended-release naltrexone injection to assess for side effects and any contraindications.

- Patient to be given emergency card, bracelet and/or dog tag

- The first naltrexone dose should be observed in clinic.

- A "naloxone challenge" or "naltrexone challenge" should be performed for all patients who are naltrexone or naloxone naïve, and/or prior to receiving extended-release injectable naltrexone

NALOXONE CHALLENGE

- UTS negative for all illicit substances including all opioids.
- The patient must be off short acting opioids 5-7 days. If taking long acting opioids such as methadone or buprenorphine, the patient must be off for 7-10 days or longer.
- Obtain baseline BP and pulse.
- Obtain baseline Clinical Opiate Withdrawal Score (COWS).
    - If the patient is still having signs of opioid withdrawal even if the drug screen is negative, do not perform a Naloxone Challenge. It will be positive.
- A total of 0.8-1.2mg naloxone hydrochloride should be administered IM. This may be divided into two doses to minimize risk of severe withdrawal.
    - Administer 0.4mg naloxone hydrochloride IM
        - Complete COWS at 15min and again at 30min following injection
    - If no signs or symptoms of withdrawal, administer a second dose of 0.4 - 0.8mg naloxone hydrochloride IM
        - Observe and complete COWS at 15min and again at 30min following this second injection
- *Negative Naloxone Challenge*- No change in subjective or objective signs of withdrawal. Proceed with administering full dose naltrexone or extended-release injectable naltrexone
- *Positive Naloxone Challenge*- If the patient experiences any symptoms of withdrawal stop the naloxone challenge immediately. Do not give any more naloxone. In dependent individuals, naloxone will precipitate withdrawal that usually emerges within 5-10 min and dissipates within 30 min. These symptoms should be mild. The most common early signs of a positive challenge will be the patient reporting an increase in anxiety and an increase in heart rate. Have the patient come back in 1-2 days and repeat naloxone challenge.

NALTREXONE CHALLENGE WITH ORAL FORMULATION

- UTS negative for all illicit substances including all opioids.
- The patient must be off short acting opioids 5-7 days, long-acting requires 7-10 days.
- Obtain baseline BP and pulse.
- Obtain baseline Clinical Opiate Withdrawal Score (COWS).
    - If the patient is still having signs of opioid withdrawal, even if the drug screen is negative, do not perform a Naltrexone Challenge. It will be positive.
- Observe patient self-administer 25mg naltrexone by mouth. Advise patient to remain in the clinic for 45-60 minutes to monitor the presence/absence of withdrawal symptoms.
- *Negative Naltrexone Challenge*- No change in subjective or objective signs of withdrawal. Proceed with extended-release naltrexone injection per protocol.
- *Positive Naltrexone Challenge*- If the patient experiences any symptoms of withdrawal stop the naltrexone challenge. Do not give any more naltrexone. Reassure the patient that the symptoms will begin to dissipate in 4-6hrs. The most common early signs of a positive challenge will be patient report of increased anxiety and an increase in heart rate. Symptom management with adjunctive medications to occur as appropriate with provider input. Have the patient come back in 1-2 days for a repeat naltrexone challenge.

EXTENDED-RELEASE INJECTABLE NALTREXONE (VIVITROL) ADMINISTRATION

- Obtain extended-release injectable naltrexone from pharmacy per written prescriber order. Standard dose is 380mg IM. Do not prepare suspension prior to patient arrival.

- Extended-release injectable naltrexone should be stored in the refrigerator. Prior to preparation, allow the drug to reach room temperature. This takes about one hour.

- After meeting with the patient and ensuring continued opioid abstinence, reconstitute and immediately administer medication following the specific detailed directions contained in the extended-release injectable naltrexone medication package insert.

    - UTS negative for all opioids, and/or negative Naloxone/Naltrexone Challenge

- Extended-release injectable naltrexone should be administered as an intramuscular gluteal injection every 28 days.

Special Notes:

- Unrefrigerated, extended-release injectable naltrexone can be stored at temperatures not exceeding 25 °C (77 °F) for no more than 7 days prior to administration. Do not expose unrefrigerated product to temperatures above 25 °C (77 °F). This medication should never be frozen.

    - Mark the medication each time it is removed and returned to the refrigerator.

- A properly mixed suspension will be milky white, will not contain clumps, and will move freely down the walls of the vial.

- Use only the needles specially designed for administration of extended-release injectable naltrexone. Select the appropriate needle based on patient's body habitus. Do not make any substitutions for components in the medication carton.

- Extended-release injectable naltrexone is administered as an intramuscular gluteal injection and must not be given subcutaneously or intravenously. A subcutaneous injection may increase the likelihood of severe injection site reactions.

- Administer the suspension by deep intramuscular injection into a gluteal muscle, alternating buttocks per monthly injection. Aspirate for blood before injecting.

- If the needle clogs during administration, the needle must be withdrawn from the patient, capped with the attached needle protection device, and replaced with the provided spare administration needle. Gently push on the plunger until a bead of the suspension appears at the tip of the needle. The remainder of the suspension should then be administered into an adjacent site in the same gluteal region.

- Document administration of extended-release injectable naltrexone and note right or left gluteal injection site.

- Advise patient to contact the OBAT clinic, or go to the Emergency Department in the event of suspected injection site or other adverse reaction

Adverse effects and patient education:[23]

- **Injection Site Reactions:** Providers should be trained in proper techniques for IM injections to prevent problems. Extended-release injectable naltrexone injections may cause pain or tenderness at the injection site, which usually resolves in a few days. More serious reactions such as swelling, erythema, bruising, and pruritus have been reported, generally as the result of an inadvertent subcutaneous injection.

- **Vulnerability to Opioid Overdose:** Following injection with extended-release naltrexone, a patient's opioid tolerance is reduced markedly from baseline prior to treatment. Accordingly, patients are vulnerable to potentially fatal overdose approaching the end of the dosing interval, if a dose is missed or if treatment is discontinued. Attempting to breakthrough the opioid blockade can also result in fatal overdose.

- **Hepatic Injury:** There have been cases of hepatitis and clinically significant liver injury associated with extended-release injectable naltrexone. Patients should be made aware of this risk.

- **Depression and Suicide**: In pre-market clinical trials of extended-release injectable naltrexone, reports of depression were overall infrequent but more common in the group that received injectable naltrexone than the group that received the placebo. There were also 2 completed suicides both in the group that received injectable naltrexone. Patients should be monitored and treated appropriately, and families and caregivers should be alerted to the need to monitor patients for depression or suicidality.

NALTREXONE (ORAL OR INJECTABLE) STABILIZATION

- Patient returns to clinic after one week for assessment, urine/swab toxic screening, breathalyzer, counseling, education, support, and evaluation of mental health, medical, and other needs.

- If a patient misses an extended-release naltrexone injection, he/she should be instructed to receive the next injection as soon as possible. Reassess patient status prior to administering medication. Consider naloxone/naltrexone challenge if suspected opioid use or if injection has lapsed for an extended period of time. Augment treatment plan as needed.

- Patient sees Nurse Care Manager weekly for 4-6 weeks until stable. If urine screens and breathalyzer screens are negative, patient is attending counseling and weekly clinic visits as scheduled, they then may progress to the maintenance phase.

NALTREXONE MAINTENANCE

- Once stable, clinic visits every 2 to 4 weeks.
- ***Goal:*** Clinic visits every 28 days, occurring on the date of the patient's extended-release naltrexone injection
    - Each decrease in visit frequency requires treatment team review.

Clinic visits to include (See Appendix 6: Nursing Follow-up Form):

- Collection of urine sample for toxicology.
- If alcohol use disorder, breathalyzer at each visit.
- Lab testing: if liver function tests were elevated at induction, they must be re-checked within 1-2 months or sooner depending on degree of elevation, and must continue to be regularly monitored thereafter.
- Assessment of status: recovery, relapse, and medical issues should be addressed as indicated. Contact other OBAT team members as needed, including OBAT provider and PCP if different and warranted.
- Monitor and assess for potential medication side-effects or adverse reactions: injection site reaction, hepatic complications, gastrointestinal distress, depression, eosinophilic pneumonia, etc.
- Review treatment plan: OBAT visit frequency, counseling, meetings, the need for further psychiatric treatment, incidence of medication side effects or adverse reactions, presence of drug or alcohol cravings, instances of drug or alcohol use.
- Medical case management with brief counseling support.
- Review contact information, including pharmacy at each visit.
- OBAT provider visits at least every 3-4 months, with review of medical record, lab test results, recovery status and UTS results.
- NCM performs telephone contact for support, monitors medical issues, pregnancy status, medication changes, any pending needs for surgery, acute/chronic pain management, and need for psychiatric assessment.

Ongoing Patient Management:

OBAT Treatment Agreement & Clinic Policies

TREATMENT AGREEMENT

Engage patients into the treatment plan, along with the OBAT Team. Individualize treatment to meet the needs of the patient. Encourage patient involvement into their treatment.

- Set clear expectations/guidelines.

- Explain treatment agreement verbally and provide in written form, which patients will sign and date and which will be kept in the record. Review each line of the contract, give a second copy to the patient to take home for their review.

    - Encourage patients to ask questions.

    - Review this agreement again with the patient intermittently during the course of treatment and as needed.

    - Provide reassurance about common issues, such as patients' concerns about entering treatment (if they are using illicit opioids, presently "not using," education around options and support), or the risks of changing from other medication treatment for addiction settings (such as methadone), successful involvement in other program treatment, (such as methadone); patients' ambivalence about such changes should be addressed. Ability to meet program requirements, such as making appointments. If patient is unable to meet program requirements, an appropriate referral will be made to a treatment program that better suits the patient's needs.

- Make it clear that these expectations are reviewed with all new patients treated in the OBAT program. The OBAT team should also convey that these rules and expectations are applicable to all patients equally, and if unable to comply with treatment agreement, changes in treatment modality to better meet the needs of the individual may be explored.

    - Rules/expectations should be periodically reviewed and/or revised as needed; treatment agreement is signed — (See Appendix 9A and 9B).

TREATMENT PHILOSOPHY

- Review the OBAT team's approach to treatment for addiction (e.g., a chronic medical disorder that responds best when treated with medications combined with non-pharmacological recovery supports), the goal of treatment (e.g., cessation of illicit drug use), and the proper approach to treating patients (e.g., with dignity and respect).

- The patient can expect:
    - To be treated with dignity and respect.
    - To be notified if the office is closed.
    - That confidentiality will be maintained in compliance with CFR 42.
    - To have a means for contacting a member of the OBAT Team or a colleague for emergencies at night, weekends and when the office is closed.
    - BMC Mission: "We will provide consistently excellent accessible health services to all in need of care regardless of status or ability to pay- exceptional care, without exception."

ADHERENCE TO PROGRAM POLICIES AND TREATMENT PROTOCOLS:

- *Clinical Appointment Policy (*See Appendix 10B*):* All patients who participate in the Boston Medical Center Office Based Addiction Treatment program (OBAT) are required to keep all appointments with their primary care providers, OBAT providers, and OBAT nurses. These appointments are critical to the continuation of care.
- If an appointment cannot be kept, it is the patient's responsibility to reschedule the appointment.
- Appointments with the OBAT team are part of the treatment and should these appointments need to be rescheduled it is the patient's responsibility to do so. This does not include random callbacks, please see policy under random call backs.
- Patients are expected to arrive on time for all scheduled appointments. Appointments with providers may need to be rescheduled if patients arrive late.
- Patients are required to see their OBAT provider at least once every 3-4 months and more frequent if needed per provider, or other medical staff. If patients do not show up for medical appointments with their OBAT provider and do not call to inform OBAT staff that they are unable to make the appointment, or arrange for rescheduling, the treatment plan will be revised accordingly.
    - *Buprenorphine/Naloxone:* Initially prescriptions will return for weekly visits until seen by the provider. If patients continually miss OBAT prescriber appointments and they exceed the 4-month visit timeframe, then buprenorphine-naloxone prescriptions may be held until the patient is seen for an office visit by an OBAT provider.
    - *Naltrexone:* Consider naltrexone oral tablets vs. extended-release injection until adherence to treatment plan occurs including attendance at clinic appointments.

- Patients struggling with program requirements may be referred to another level of care.
- Procedures for contacting the OBAT Team when the office is closed:
    - All patients have an emergency card with the OBAT Program Director's emergency cell phone number on the back. This number should be called off hours only if the patient has a medical emergency that may require pain management, or if they have an issue with their prescription.

BEHAVIOR EXPECTATIONS

Providing treatment for substance use disorders in an office based/primary care setting requires that addiction treatment is provided in the same space that many other patients receive care for a variety of health issues. To avoid disrupting clinic workflow patients are expected to conduct themselves in an appropriate manner. Examples of disruptive/inappropriate behaviors include: insulting or inappropriate language, outbursts, threats, yelling, and aggression toward staff, patients or visitors. To provide an optimum treatment environment for all, patients, visitors and staff are expected to maintain appropriate behaviors in the clinic and on the grounds of Boston Medical Center.

URINE TOXICOLOGY SCREENING POLICY (SEE APPENDIX 10G):

- All belongings (coats, bags, etc.) are left in the office of the medical assistant or outside the bathroom door.

- No washing hands until the urine sample is handed to the Medical Assistant in a bio-hazardous bag.

- No flushing toilet until urine sample is handed to the gloved Medical Assistant.

- Urine samples will be required at each visit.

- Clinic policy: any questionable urine is an automatic repeat the same day.

- Random observed urines can be conducted by same sex personnel in extreme situations, however this is not routine. Oral swabs may be utilized in place of observed urines. If it becomes necessary to do observed urines the patient will be referred out to a chain of custody location for urine screening or to a higher level of care.

TAMPERING:

Any urine sample that is questionable:

- Patient will be asked to repeat urine immediately, a discussion with take place to address what may be going on to in an effort to assist the patient.

- Counseled by the OBAT NCM about the importance of UTS monitoring and honesty in treatment to ensure that the team has the ability to provide appropriate treatment Reinforce that the OBAT team is here to help if the patient is struggling.

- Patient is told that tampering may be grounds for referral to a higher level of care.

- Patients will receive a buprenorphine/naloxone prescription refill, naltrexone prescription or extended-release naltrexone injection when an acceptable urine is obtained.

BUPRENORPHINE/NALOXONE PRESCRIPTION POLICIES

The role of the provider/nurse care manager, the office staff, and the patient in the handling of prescriptions/medications:

- Prescriptions will be processed by an OBAT nurse, who will review the medication record, consult with pharmacy and the provider if needed, to confirm dosage, refill amounts, and timing of refill.

- OBAT nurse will check insurance coverage, preferred medication formulary, and need for prior authorization.

- OBAT nurse following confirmation will generate electronic prescription under the waivered provider's name, print this electronic prescription and then hand deliver to the waivered provider for signature.

- Once signed the OBAT nurse will generate a confidential fax cover sheet, look up and confirm the pharmacy information from the EMR and fax the prescription to the pharmacy on record.

- After the prescription has been faxed the NCM will stamp the prescription "faxed," place the prescriptions in a confidential locked file for 30days in case of fax error or the need to review the prescription.

- All prescriptions held for 30days will then be destroyed in a locked/confidential recycle bin by 2 OBAT nurses.

- Prescription records are maintained in the electronic medical record for review by clinicians as needed and for DEA regulatory purposes.

Maximum number of days medication will be provided with a prescription:

- At the time of treatment initiation, all prescriptions will be written for a maximum of 1 week with no refills and faxed to the Boston Medical Center outpatient pharmacy.

- Following 4-6 weeks on treatment if patient is moving in to the stabilization phase of treatment, prescription refills will increase to 2 week prescriptions with up to 4 refills.

- Following 8 weeks on maintenance with 2 week refills, if patient continues to progress prescriptions will increase to 3-4 week prescriptions and then to monthly if the OBAT Team feels this patient is stable enough and with adequate supports to progress to this level.

- Prescriptions are faxed to the designated pharmacy within 24 hours of a scheduled visit.

- Patients must keep scheduled appointments to obtain prescription refills.

- If a patient begins to struggle in their recovery process or the staff are concerned about giving the patient larger prescriptions, the OBAT Team will make the decision to continue with smaller prescriptions for as long as needed.

- If a patient is homeless, living in an unsafe or unstable setting, the OBAT Team, along with the patient, will develop a plan that promotes security of their treatment.

    - Weekly prescriptions with refills, shelter setting that has nursing staff to manage the medication, secure locker in the shelter, locked medication bag held by shelter staff, housing staff and the patient holds the key.

Lost, stolen or destroyed buprenorphine/naloxone:

- *Lost:* Prescriptions are generally not replaced; patients are informed of this at the time of intake. This notification is done both verbally as well as in writing in the OBAT treatment agreement. Cases will be reviewed on an individual basis by the OBAT Team, if requested by the patient, and a decision will be rendered. If a decision is made to replace the medication, it will be a one-time event and a lost/stolen prescription will not be replaced in the future should this occur. If a patient loses their medication and the prescription is for more than 1 week, the prescription amount will go back to weekly prescriptions until such time that the team feels it is safe for the patient to be given a larger quantity of medication.

- *Stolen:* Prescriptions are generally not replaced; this is documented in the treatment agreement at time of intake. Cases will be reviewed if the patient requests a review by the OBAT team and a decision will be rendered. The patient will be asked to obtain a police report and bring it in to the clinic or pharmacy. If a decision is made to replace the medication it will be a onetime event and will not be replaced in the future should this occur. If a patient has their medication stolen, the prescription amount will go back to weekly prescriptions until such time that the team feels it is safe for the patient to be given a larger quantity of medication.

- *Destroyed/damaged:* Medication reported as being destroyed or damaged. If able, the patient should be instructed to bring the reported medication in to the OBAT Team for review. A decision will be rendered by the team as to how to best proceed. If a patient reports destroyed/damaged medication, the prescription amount will go back to weekly prescriptions until such time that the team feels it is safe for the patient to be given a larger quantity of medication

- In all of these events: lost, stolen, destroyed, or damaged medications, prior to receiving a replacement prescription the patient will be asked to return to the OBAT clinic within 24 hours for assessment and UTS. At this time, patients will receive education by the OBAT Team nurse care managers and/ or providers to prevent these events from reoccurring.

- If the patient continues to experience events of: lost, stolen, damaged or destroyed medications, the team will meet to address this and the potential need to refer the patient to a more structured treatment setting to better safeguard their treatment and their recovery.

SAFE AND PROPER STORAGE OF MEDICATION:

- ✓ Keep medication out of sight/reach of children.
- ✓ Use a locked box, bag, or cabinet for safe storage.
- ✓ Do not put tablets down on counters, sinks, dresser, or nightstands.
- ✓ It is easier for children to put small pieces and crumbs in their mouth.
- ✓ To prevent breakage, keep cotton or tissue in the bottle.
- ✓ Always keep in labeled prescription bottle with child proof cap.
- ✓ Patient's prescribed Buprenorphine/Naloxone film should keep medication with an official pharmacy label at all times. Patients may request a second label from pharmacy if they plan to carry medication on their person.
- ✓ Avoid carrying in your pocket, bag, purse, or backpack.
- ✓ Avoid leaving in the bathroom, car, or any public space**.**
- ✓ Call 911 if an accidental exposure occurs and or go to the nearest emergency department.
- ✓ Give all patients a copy of the safety and storage brochure and review the bullet points with them.
- ✓ Suggest to patients obtain a locked bag or lock box to store buprenorphine/naloxone and any other controlled substances. Reinforce safe storage out of common areas and away from children and others.

Addressing Patient Struggles, Relapse & Discontinuation of Treatment

- OBAT is a harm reduction model and therefore does not recommend automatic discharge for patients who struggle with substance use while engaged in medication treatment for addiction.

    - If a relapse occurs, the treatment plan should first be revised to increase monitoring and supports. In a case of continued use despite an intensified treatment plan, a patient will be referred to a higher level of care.

- Situations in which the OBAT Team may recommend more intensive levels of non-pharmacological treatments:

- Ongoing use despite adequate buprenorphine/naloxone dosing: no cravings, withdrawal and adequate narcotic blockage.

- Opioid use during the end of an extended-release naltrexone injection dosing interval.

- Multiple negative buprenorphine UTS results for buprenorphine prescribed patients.

- Ongoing use of benzodiazepines, barbiturates, cocaine/stimulants, alcohol or other central nervous system depressants (gabapentin, quetiapine, clonidine, promethazine etc.) causing impairment, sedation, overdose, medical events, and/or hazardous unsafe behaviors despite interventions by the OBAT Team.

- Presenting intoxicated (i.e., under the influence of alcohol or other substances), incidence of overdose, or hospitalization related to substance use.

- The risk of continuing treatment outweighs the benefit.

REVISION OF TREATMENT PLAN MAY INCLUDE:

- MORE FREQUENT VISITS
- SHORTENED PRESCRIPTIONS
- LOSS OF REFILLS
- CONFIRMATION OF COUNSELING AND TEAM ENGAGEMENT WITH COUNSELOR
- CLINICAL TEAM MEETING WITH PATIENT
- REFERRAL TO RELAPSE PREVENTION GROUPS OR INDIVIDUAL THERAPY
- REFERRAL TO IOP
- PSYCHIATRIC EVALUATION
- RESIDENTIAL TREATMENT
- DCF INVOLVEMENT
- INCREASED COLLABORATION WITH COMMUNITY PROVIDERS
- INCREASED ENGAGEMENT WITH LAW ENFORCEMENT

REFERRAL TO HIGHER LEVEL OF CARE MAY INCLUDE:

- DETOXIFICATION/CSS/TSS
- RESIDENTIAL TREATMENT
- METHADONE MAINTENANCE
- DIRECTLY OBSERVED BUPRENORPHINE/NALOXONE DAILY DOSING IN OTP
- SECTION 35
- DUAL DIAGNOSIS

BUPRENORPHINE/NALOXONE: RELAPSE & ABERRANT URINE TOXIC SCREEN RESULTS

- In all cases of an unexplained UTS (i.e., patient did not report substance use at visit or report inappropriate medication management at visit) patient is called by the OBAT NCM within 24 hours of UTS result in an effort to address a potential relapse or medication issue.

NEGATIVE BUPRENORPHINE

- If patient provides adequate explanation regarding negative buprenorphine/naloxone to OBAT NCM on the phone, the NCM will establish a follow-up plan to return to clinic within one week.

- If the patient is unable to provide an explanation regarding negative buprenorphine/naloxone, they should return to the clinic within 24 hours.

- Repeat UTS will be sent for confirmation via GC/MS testing.

- At return visit, negative urine result is addressed.

    - Review medication administration and dosing schedule. Consider diversion and possible relapse.

    - Assess and modify treatment plan as needed. If patient is struggling, return to weekly clinic visits and prescriptions.

    - The patient's buprenorphine/naloxone dose may need to be adjusted (i.e., increased if struggling, decreased if taking less than prescribed dose). The entire OBAT team should be consulted prior to adjusting a patient's medication dose.

    - If patient denies any reason for negative buprenorphine/naloxone, and repeat is again negative, patient may be referred to a higher level of care.

- Assess dose, if dose is less than 4-6mg, urine may need to be sent for confirmation due to the cut off limits of the test and therefore inability to react positive to buprenorphine/naloxone.

POSITIVE OPIOIDS

- Report of opioid use or positive opioid UTS result is addressed by OBAT nurse during visit or through subsequent phone conversation and the treatment plan is intensified accordingly to meet the needs of the patient.

    - If patient has a positive UTS and does not admit to use at visit and denies use when addressed on the phone with NCM, patient must return to clinic for repeat as soon as possible, within 48 hours.

    - A report of opioid use or a positive opioid UTS will result in intensification of the treatment plan including: increased frequency of clinic visits, confirm attendance and increase frequency of counseling, encourage meetings, provide Relapse Prevention Education and Overdose Prevention Education. This includes the patient returning to weekly clinic visits until stable.

    - If the patient has 3-4 consecutive weeks of positive opioid urines, patient will be assisted with transfer to higher level of care. Patient may return to OBAT at a later date after the OBAT team and patient meet to assess how to assist them differently in their treatment moving forward.

POLYSUBSTANCE USE:

COCAINE

- Report of cocaine use or positive cocaine UTS result is addressed by OBAT nurse during visit or through subsequent phone conversation and the treatment plan is intensified accordingly to meet the needs of the patient.
    - If patient has a positive UTS and does not admit to use at visit and denies use when addressed on the phone with NCM, patient must return to clinic for repeat as soon as possible, within 48 hours.
- A report of cocaine use or a positive cocaine UTS will result in intensification of the treatment plan, relapse prevention education and support. This includes the patient returning to weekly clinic visits until stable.
    - Two to three cocaine positive urine screens in a row will result in further intensification of the treatment plan such as referral to IOP and/or a Relapse Prevention Group, increased counseling.
    - Four positive urine screens in a row will result in decreasing of buprenorphine/naloxone dose by 2- 4mg. If urine screens continue to be positive for cocaine, buprenorphine/naloxone dose will continue to be decreased by 2- 4mg every one to two weeks
    - Buprenorphine/naloxone dose will return to maintenance dose when the patient has successfully provided urine screens that are negative for cocaine.
    - Contingency management combined with psychosocial support (CBT, counseling) has been shown to be an effective strategy for decreasing stimulant misuse and should be considered when possible.

AMPHETAMINES

- Report of illicit amphetamine use or positive amphetamine UTS result is addressed by OBAT nurse during visit or through subsequent phone conversation and the treatment plan is intensified accordingly to meet the needs of the patient.
    - If patient has a positive UTS and does not admit to use at visit and denies use when addressed on the phone with NCM, patient must return to clinic for repeat as soon as possible, within 48 hours.
- A report of illicit amphetamine use or a positive amphetamine UTS will result in intensification of the treatment plan, relapse prevention education and support. This includes the patient returning to weekly clinic visits until stable.
    - If patient reports struggling with attention deficit and/or hyperactivity, offer patient referral to psychiatry for evaluation.

- If patient reports diagnosis of ADHD and is requesting amphetamine medications, patient will be required to undergo neuro-psych evaluation for a proper diagnosis.

- Run Prescription Monitoring Program (PMP) to check for prescription not reported

- Two-three UTS positive for illicit amphetamine in a row will result in further intensification of the treatment plan such as referral to IOP and/or a Relapse Prevention Group, increased counseling.

- Four consecutive positive UTS will result in decreasing buprenorphine/naloxone dose by 2- 4mg. If urine screens continue to be positive for illicit amphetamines, buprenorphine/naloxone dose will continue to be decreased by 2- 4mg every one to two weeks

- Buprenorphine/naloxone dose will return to maintenance dose when the patient has successfully provided urine screens that are negative for amphetamines.

- Contingency management combined with psychosocial support has been shown to be an effective strategy for decreasing stimulant misuse and should be considered.

BENZODIAZEPINES

- Report of illicit benzodiazepine use or positive benzodiazepine UTS result is addressed by OBAT nurse during visit or through subsequent phone conversation and the treatment plan is intensified accordingly to meet the needs of the patient.
    - If patient has a positive UTS and does not admit to use at visit and denies use when addressed on the phone with NCM, patient must return to clinic for repeat as soon as possible, within 48 hours.
- A report of illicit benzodiazepine use or a positive benzodiazepine UTS will result in intensification of the treatment plan, relapse prevention education, and overdose prevention education. This includes the patient returning to weekly clinic visits until stable.
    - If patient reports struggling with anxiety, offer referral to psychiatry for evaluation. Providers should make every effort to stay clear of benzodiazepines and other sedating medications with potential for misuse.
- Run Prescription Monitoring Program (PMP) to check for unreported prescribed medications.
- Urines will be sent for confirmatory levels and identification of the medication if positive for benzodiazepines twice in a row.

- Ongoing benzodiazepine misuse will result in referral to a higher level of care. Patient may return to OBAT at a later date after the OBAT team and patient meet to assess how to assist them differently in their treatment moving forward.

ALCOHOL

- Patients with concerning alcohol use or co-morbid alcohol use disorder will be required to submit to intermittent breathalyzers, and additional clinical supports and monitoring as needed.

- Patients presenting to clinic smelling of alcohol, positive breathalyzer, or reporting risky alcohol use will require immediate revision of treatment plan.

- Patients struggling with alcohol use and/or cravings may be offered acamprosate (Campral), disulfiram (Antabuse), topiramate (Topamax) with provider input and agreement. Patients managed on buprenorphine/naloxone cannot be treated with any naltrexone formulation, as these medications are contraindicated.

- Ongoing alcohol misuse, presenting to clinic impaired or noted ED visits or hospital events for ETOH intoxication/use will result in referral to a higher level of care. Patient may return to OBAT at a later date after the OBAT team and patient meet to assess how to assist them differently in their treatment moving forward.

NALTREXONE RELAPSE & ABERRANT URINE TOXICOLOGY SCREEN RESULTS

- In all cases of an unexplained toxicology results (i.e., patient did not report substance use at visit) patient is called by the OBAT NCM within 24 hours of result in an effort to address a potential relapse or medication issue.

OPIOIDS

- Report of opioid use or positive opioid UTS result is addressed by OBAT nurse during visit or through subsequent phone conversation and the treatment plan is intensified accordingly to meet the needs of the patient.
    - If patient has a positive UTS and does not admit to use at visit and denies use when addressed on the phone with NCM, patient must return to clinic for repeat as soon as possible, within 48 hours.
- Intensify OBAT treatment plan including: increased frequency of clinic visits, confirm attendance and increase frequency of counseling, encourage meetings, provide Relapse Prevention Education and Overdose Prevention Education. This includes the patient returning to weekly clinic visits until stable.
- Educate the patient about the increased sensitivity to opioids and the consequential increased risk of a fatal overdose in the event of a relapse. Reduced tolerance is especially concerning at the end of a dosing interval. However, an attempt to overcome the opioid blockade effect of extended-release injectable naltrexone is possible at any point and is extremely dangerous with the potential to cause respiratory arrest and circulatory collapse.
- If relapse occurs towards the end of naltrexone interval (within a week of injection due date), restart the patient on naltrexone only after obtaining a UTS negative for opioids and a successful naloxone/naltrexone challenge has been performed. Do not administer naltrexone if there is any chance opioids are on board.
- With an opioid relapse, a clinical assessment should always occur to evaluate if continuing with naltrexone treatment is in the best interest of the patient or if a different level of care should be considered.
- If the patient is unable to abstain from using opioids for a long enough period of time to safely be restarted on naltrexone, referral to a higher level of care (detox, residential, buprenorphine-naloxone treatment, methadone maintenance) should occur. Patient may return to OBAT for naltrexone treatment at a later date after the team and patient meet to assess how to assist them differently in their treatment moving forward.

ALCOHOL

- For patients with known alcohol use disorder or concerning alcohol use, in addition to urine toxic screening, breathalyzers to be utilized at every patient encounter.

- Patients with positive alcohol screens or reporting alcohol use should receive education about the cumulative toxic liver effects of naltrexone as this medication is extensively metabolized through the hepatic system.

- Intensify OBAT treatment plan, including increased frequency of clinic visits, urine screening, and counseling. Encourage meetings and recovery supports.

- Patients struggling with alcohol use and/or cravings may be offered acamprosate (Campral), disulfiram (Antabuse), topiramate (Topamax) with provider input and agreement.

- Patients presenting to clinic appearing impaired, smelling of alcohol, positive breathalyzer, provides reports of ongoing alcohol use, or noted ED admissions for alcohol use disorder will require immediate team assessment and revision of treatment plan, referral to higher level of care may be necessary.

POLYSUBSTANCE USE:

COCAINE

- Report of cocaine use or positive cocaine UTS result is addressed by OBAT nurse during visit or through subsequent phone conversation and the treatment plan is intensified accordingly to meet the needs of the patient.

    - If patient has a positive UTS and does not admit to use at visit and denies use when addressed on the phone with NCM, patient must return to clinic for repeat as soon as possible, within 48 hours.

- A report of cocaine use or a positive cocaine UTS will result in intensification of the treatment plan, relapse prevention education and support. This includes the patient returning to weekly OBAT visits until stable.

    - Two to three positive urine screens in a row will result in further intensification of the treatment plan such as referral to IOP and/or a Relapse Prevention Group, increased counseling.

    - Four positive urine screens in a row will result in change to naltrexone tablets rather than continue with extended-release injectable naltrexone.

    - Extended-release injectable naltrexone may resume once the patient has successfully provided urine screens that are negative for cocaine.

- Contingency management combined with psychosocial support has been shown to be an effective strategy for decreasing stimulant misuse and should be considered.

AMPHETAMINES

- Report of illicit amphetamine use or positive amphetamine UTS result is addressed by OBAT nurse during visit or through subsequent phone conversation and the treatment plan is intensified accordingly to meet the needs of the patient.
    - If patient has a positive UTS and does not admit to use at visit and denies use when addressed on the phone with NCM, patient must return to clinic for repeat as soon as possible, within 48 hours.
- A report of illicit amphetamine use or a positive amphetamine UTS will result in intensification of the treatment plan, relapse prevention education and support. This includes the patient returning to weekly clinic visits until stable.
    - If patient reports struggling with attention deficit and/or hyperactivity, offer patient referral to psychiatry for evaluation.
    - If patient reports diagnosis of ADHD and is requesting amphetamine medications, patient will be required to undergo neuro-psych evaluation for a proper diagnosis.
    - Run Prescription Monitoring Program (PMP) to check for unreported prescriptions
    - Two-three consecutive UTS positive for illicit amphetamine will result in further intensification of the treatment plan such as referral to IOP and/or a Relapse Prevention Group, increased counseling.
    - Four consecutive positive UTS will result in a temporary change to weekly naltrexone tablet prescriptions rather than continue with extended-release injectable naltrexone.
    - Extended-release naltrexone injections may resume once the patient has successfully provided urine screens that are negative for amphetamines.
    - Contingency management combined with psychosocial support has been shown to be an effective strategy for decreasing stimulant misuse and should be considered.

BENZODIAZEPINES

- Report of illicit benzodiazepine use or positive benzodiazepine UTS result is addressed by OBAT nurse during visit or through subsequent phone conversation and the treatment plan is intensified accordingly to meet the needs of the patient.
    - If patient has a positive UTS and does not admit to use at visit and denies use when addressed on the phone with NCM, patient must return to clinic for repeat as soon as possible, within 48 hours.

- Positive result is addressed by OBAT nurse, relapse prevention education will be provided and the treatment plan intensified. A report of illicit benzodiazepine use or a positive benzodiazepine UTS will result in intensification of the treatment plan, relapse prevention education, and overdose prevention education. This includes the patient returning to weekly clinic visits until stable.

    - If patient reports struggling with anxiety, offer patient referral to psychiatry for evaluation. Every effort should be made to avoid sedating medications and those with potential for misuse.
    - Run Prescription Monitoring Program (PMP) to check for unreported prescriptions
    - Urines will be sent out confirmatory testing of levels and identification of the benzodiazepine if positive for benzodiazepines twice in a row.
    - Two-three consecutive UTS positive for illicit benzodiazepines will result in further intensification of the treatment plan such as referral to IOP and/or a Relapse Prevention group, increased counseling.
    - Consider a temporary change to weekly prescriptions of naltrexone tablets rather than continue extended-release naltrexone injections until patient stabilizes.
    - Four or more consecutive positive illicit benzodiazepine UTS will result in referral to a higher level of care. Patient may return to OBAT for naltrexone treatment at a later date after the team and patient meet to assess how to assist them differently in their treatment moving forward.

PRESENTING INTOXICATED

Any patient who presents to the clinic intoxicated (i.e. under the influence of alcohol or any other substance) will require immediate team assessment and revision of treatment plan.

BUPRENORPHINE/NALOXONE TAPERING

- Upon abrupt discontinuation, withdrawal syndrome may 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, may be longer.
- Autonomic withdrawal signs (lacrimation, rhinorrhea, tremors, chills, gooseflesh).
- General complaints include: restless leg, insomnia, anxiety, abdominal distress.
- Protracted abstinence syndrome can occur and persist for months-years following discontinuation of the medication. It is important to respond to patient's protracted withdrawal symptoms (anxiety, insomnia, depression) to support their recovery process and avoid relapse.
- Buprenorphine/naloxone should be tapered over days, weeks, or months, depending on patient tolerance of symptoms.
- Some patients may choose to taper off of buprenorphine/naloxone. These patients will continue to be supported by the OBAT team and receive assistance with dose decreases, and management of withdrawal symptoms. The taper duration is individualized to the patient and should be continually adjusted to meet the patient's needs.
- Tapering/discharge from program or initiation of intensive treatment plan should be considered for the following cases:
- Ongoing opioid use or use of other illicit drugs: three or more positive urine toxicology results in a row for opioids or other illicit drugs and the risk of continuing treatment outweighs the benefit.
- Negative buprenorphine screens.
- Patient presents to OBAT clinic impaired, incidence of overdose, or hospitalization related to substance use.
- If treatment is intensified to include increased visit frequency, counseling, IOP, meeting attendance, and patient continues "regular" use of opioids or other illicit drugs, then the treatment team may discontinue buprenorphine/naloxone treatment and refer the patient to a higher level of care
- If patient complies with the intensive treatment plan and has had some improvement in drug use, team will restructure treatment as needed and continue treatment with buprenorphine/naloxone.

- Patients who are referred to a higher level of care or discharged, will be reconsidered for future treatment in OBAT

- Multiple missed appointments or inability to contact patient:

  - Address with treatment team and document in electronic medical record. If unable to reach patient prescription refills should be canceled in hopes this will bring the patient back in to care

NALTREXONE DISCONTINUATION

- There is no withdrawal syndrome associated with naltrexone discontinuation.

- Some patients may choose to discontinue naltrexone. These patients may continue to be supported by the OBAT team and receive assistance with their recovery in terms of monitoring and clinical management. Patients choosing to discontinue naltrexone should be encouraged to continue psychosocial therapies and mutual-help groups.

- Some patients may stop naltrexone due to side-effects or adverse reactions. In this case, alternative treatment strategies should be discussed.

- Naltrexone discontinuation/discharge from program or initiation of intensive treatment plan should be considered for the following cases:

- *Opioid use:* Two to three recent positive urine toxicology results for opioids and the risk of continuing treatment outweighs the benefit. Consider discontinuing naltrexone treatment sooner if opioid use is occurring towards the end of the extended-release naltrexone dosing interval as this places the patient at increased risk for fatal overdose.

- *Alcohol use:* Patients presenting to clinic smelling of alcohol, positive breathalyzer, provides reports of ongoing ETOH use, or noted ED admissions for ETOH use

- Ongoing use of other illicit drugs: three or more positive urine toxicology results in a row for illicit drugs (cocaine, amphetamines, benzodiazepines, gabapentin, or other central nervous system depressant) and the risk of continuing treatment outweighs the benefit.

- Patient presents to OBAT clinic impaired or reports of impairment, incidence of overdose, or hospitalization related to substance use.

- If treatment is intensified to include increased visit frequency, counseling, IOP, meeting attendance, and patient continues use of opioids or other illicit substances, then the treatment team may discontinue naltrexone treatment and refer the patient to a higher level of care.

- Patients who are referred to a higher level of care or discharged, will be reconsidered for future treatment in OBAT

- If patient complies with the intensive treatment plan and has had some improvement in substance use, team will restructure treatment as needed and continue treatment naltrexone and resume extended-release naltrexone injections.

- Multiple missed appointments or inability to contact patient:

- Initially if a patient misses an extended-release naltrexone injection, he/she should be instructed to receive the next injection as soon as possible. Reassess patient status prior to

administering medication. Naloxone/naltrexone challenge if suspected opioid use or if injection has lapsed for an extended period of time. Augment treatment plan as needed.

- Consider a temporary change to weekly naltrexone tablet prescriptions rather than continue with extended-release injectable naltrexone until patient is able to adhere to treatment plan

- Multiple missed appointments should be addressed with the patient and the treatment team. Risk may outweigh benefits of continuing naltrexone treatment, document in electronic medical record.

OBAT DISCHARGE

- If a patient is discharged from OBAT they are welcome to re-engage except if there are administrative or safety concerns connected with the discharge.
    - Examples of administrative and safety issues: violence or criminal activity on hospital grounds, police report or other documentation of patient selling prescribed medication, inappropriate behavior in a clinic setting, threatening safety of staff or other patients.

DIVERSION

In cases of suspected diversion (i.e., suspicious buprenorphine negative urines, requests for early refills, reports of lost/stolen/destroyed medication, requests for dose increase) the patient should be asked to come into the clinic for an immediate assessment. This assessment should include toxicology testing and a medication count. When possible, GC/MS testing is recommended to confirm levels of buprenorphine and its metabolite norbuprenorphine.

Any patient known to be diverting buprenorphine will be evaluated by the treatment team to discuss appropriate next steps and possibly discharged from the OBAT program (e.g., patient will be seamlessly transitioned to methadone or another level of care).

SPECIFIC POPULATIONS

METHADONE TO BUPRENORPHINE TRANSFERS

TRANSITIONING FROM METHADONE MAINTENANCE TO BUPRENORPHINE NALOXONE

Potential benefits of transitioning to buprenorphine/naloxone:

- Decreased risk of overdose as medication is a partial agonist.
- Integrated addiction treatment in an office based setting with medical care and the ability to obtain FDA approved medications for opioid dependence at a local pharmacy.

- Work with methadone clinic staff to coordinate the methadone taper with the transition to buprenorphine/naloxone:
  - Establish with both patient and methadone clinic that, if the transition to buprenorphine/naloxone is unsuccessful (e.g.,, patient begins to experience withdrawal that interferes with functioning or leads to relapse, patient does not tolerate the medication), the patient may return to methadone treatment without a gap in treatment.
  - Educate patients regarding appropriate methadone dose levels for transferring to buprenorphine/naloxone. To decrease the level of physical opioid dependence and minimize the chance for precipitated withdrawal, most patients will need to have their dose tapered to 30mg before beginning buprenorphine/naloxone treatment.
- The tapering and transitioning period may include discomfort and increased risk for relapse.
- Target methadone dose: 20-30 mg daily for one to two weeks prior to transition is optimal but is not always necessary.
- Alternate approach: taper methadone dose to the point of patient discomfort; with objective withdrawal symptom documentation via COWS, buprenorphine/ naloxone can then be initiated.
- Inpatient detoxification is another option to assist a patient in the transition from methadone to buprenorphine/naloxone
- Advise patient to arrange for time off of work during the transition, family support with childcare and other responsibilities as discomfort may last 1-2 weeks.

- It is not necessary to begin with buprenorphine mono-tablet (Subutex) before initiating buprenorphine/naloxone, provided that patient is in an adequate state of withdrawal.

- Timing for last methadone dose/first buprenorphine/naloxone dose is difficult to predict

    - Generally, at least 36-96 hours after last methadone dose, but utilizing clinical assessment and judgment is essential.

    - Long half-life of methadone (storage in body tissues, especially liver) causes unpredictable clearance.

    - Initiation of buprenorphine/naloxone should be guided by withdrawal symptoms objectively documented with COWS score 13-15, rather than by time since last methadone dose.

- Clonidine, anxiolytics (including benzodiazepines), and NSAIDs may be used to manage distressing withdrawal symptoms and continued during induction if prescribed by provider.

- More intensive stabilization support may be needed (e.g.,, telephone contact up to 3 times daily until maintenance dosing as attained). Frequent visits, adequate supports, supportive environment to assist in the transition.

- Providers should be experienced in induction prior to transitioning a patient from methadone maintenance to buprenorphine.

- **Having the patient go to an inpatient detoxification to make this transition can be a safer, more effective way to get the patient from methadone maintenance to buprenorphine/naloxone.**

Induction recommendations:

- Once COWS of 13-15 is documented, start buprenorphine/naloxone at 2mg/0.5mg sublingually as prescribed.

- Continue to dose patient as prescribed until physical withdrawal symptoms have been reduced to manageable levels or absent. . Patients transitioning from methadone may require higher dosing initially and then taper down over time.

- Continue induction according to patients' prescription order, assessing symptoms of withdrawal and cravings.

- Symptom management with adjunctive medications as appropriate with provider input.

- Support and access to providers is critical in assisting patients in making this transition and not jeopardizing relapse.

BUPRENORPHINE TO NALOXONE TRANSFERS

TRANSITIONING FROM BUPRENORPHINE/NALOXONE MAINTENANCE TO NALOXONE

There have been several observation pilot studies conducted to explore the transition from buprenorphine to naltrexone. The vast majority were not randomized controlled trials.

- Per Mannelli et al. (2012), *"Taken together, published clinical practice recommends induction to full dose naltrexone 5–7 days after buprenorphine discontinuation… The studies we have reviewed here show the feasibility of transferring opioid dependent patients from buprenorphine to naltrexone in a shorter time, if an inpatient treatment option is available."*[24]

- A study by Kosten et al. (1993) found that administration of very low-dose oral naltrexone (1mg) did not induce significant withdrawal in buprenorphine-treated opioid dependent individuals. In participants who discontinued buprenorphine-naloxone and were given naltrexone 1mg titrated to full dose, naltrexone maintenance could be initiated in about half with only a small proportion remaining in treatment after 2 weeks.[25]

- Sigmon et al. (2009) conducted a pilot study of 15 opioid dependent individuals enrolled to complete buprenorphine-naloxone stabilization, a 2-week buprenorphine-naloxone taper, and naltrexone induction once urine levels of buprenorphine-naloxone were undetectable. Overall, rates of abstinence were high during the stabilization and taper periods and decreased markedly following taper off of buprenorphine-naloxone. The authors concluded that while a 2-week taper may be appropriate for a subset of individuals it is unlikely to be sufficient for the majority of individuals with opioid use disorders.[26]

- Inpatient study by Clark et al., a small group of heroin users and buprenorphine-treated patients tapered buprenorphine in 2 to 4-days, combined with increasing doses of naltrexone. Following bupe discontinuation, patients received naltrexone 50 mg and were discharged. Higher withdrawal discomfort was reported in the initial 2 days of treatment. All patients completed the protocol. Results: 33% of patients were still taking naltrexone after 4 weeks, but overall opioid use was reduced by 50% or more compared with treatment admission.

Potential benefits of transitioning from buprenorphine/naloxone to naltrexone:

- Naltrexone is a long-acting medication

- Naltrexone tablets have a half-life of 14hrs and can/should be dosed on a once daily regimen

- Extended-release injectable formulation lasts 28 days. Patients receive one injection in the clinic every four weeks thus reducing the need for self-discipline and the burden of daily medication dosing.

- Naltrexone indication for use includes BOTH prevention of relapse to opioids and assistance with treating alcohol use disorder
    - Naltrexone mutes the reinforcing effects of alcohol.
- No opioid dependency
    - Patients may choose to stop naltrexone treatment at any time without having to undergo opioid withdrawal
- No psychoactive effects
- Treatment is also provided within an established medical system with integration of addiction treatment alongside medical care with the ability to obtain FDA approved medications for opioid use disorder and alcohol use disorder.
    - Insurance may require use of a specialty pharmacy and prior authorization
- Antagonist medications such as naltrexone accelerate the opioid agonist detoxification process and are often prescribed post-detoxification to help prevent relapse.

Considerations:

When transitioning from buprenorphine to naltrexone, work with current buprenorphine clinic staff to coordinate the buprenorphine taper with the transition to naltrexone:

- Establish with both patient and buprenorphine clinic that, if the transition to naltrexone fails (e.g., patient begins to experience withdrawal that interferes with functioning or leads to relapse, patient does not tolerate the medication), the patient may return to buprenorphine treatment without a gap in treatment.
- Long half-life of buprenorphine and slow dissociation for mu opioid receptor causes unpredictable clearance.
    - Timing for last buprenorphine dose/first naltrexone dose is difficult to predict.
    - The limited amount of available data suggests that patients may do best when tapered to 2-4mg of buprenorphine/naloxone daily for one week, waiting 5-7 days between last dose of buprenorphine/naloxone and the first dose of naltrexone, and then starting with low dose naltrexone by mouth.
    - The tapering and transitioning period will include discomfort and increased risk for relapse.
    - Educate patients regarding appropriate buprenorphine dose levels for transferring to naltrexone. To decrease the level of physical opioid dependence and minimize

the chance for severe precipitated withdrawal, most patients will need to have their dose tapered to 2mg before beginning naltrexone treatment.

- Advise patient to arrange for time off work during the transition, family support with childcare and other responsibilities as discomfort may last several days.

- Initiation of naltrexone should be guided by patient motivation, clinical judgment, and UTS result negative for ALL opioids rather than by last buprenorphine dose, family pressure, or law enforcement desire for patient to be on antagonist treatment.

- Withdrawal signs and symptoms will occur causing patient discomfort.

  - Intensive stabilization and support may be needed (e.g.,, telephone contact up to 3 times daily until free of withdrawal signs/symptoms and patient stable). Frequent visits, adequate supports, supportive environment to assist in the transition.

  - Clonidine, anxiolytics (including benzodiazepines), and NSAIDs may be used to manage distressing withdrawal symptoms and continued during induction if prescribed by provider and closely monitored.

- Begin with naltrexone tablets before administering extended-release injectable naltrexone.

- Having the patient go to an inpatient detox to make this transition can be a safer, more effective way to get the patient from buprenorphine maintenance to naltrexone.

Suggested Buprenorphine to Naltrexone Protocol:

- Patient to reduce daily buprenorphine dose to 2mg for one week

- Establish last dose date with patient. Five to seven days after final buprenorphine dose, patient to come to clinic with naltrexone tablet prescription bottle for naltrexone induction appointment with OBAT nurse.

- UTS negative for all opioids and illicit substances.

- Negative Naloxone/Naltrexone Challenge.

- Always initiate naltrexone treatment with oral naltrexone formulation versus extended-release injectable formulation to mitigate allergic reactions, side-effects and adverse reactions.

- Symptom management with adjunctive medications to occur as appropriate with provider input.

- Support and access to providers is critical in assisting patients in making this transition and not jeopardizing relapse.

PATIENTS WITH HIV

- Naltrexone: almost no interaction with antiretrovirals
- Buprenorphine/naloxone use does not interfere with clinical response to antiretrovirals.
- Reassure patients that treatment for their opioid dependence will not interfere with treatment for their HIV disease management.
- Protease inhibitors may increase buprenorphine/naloxone levels; however, no clinically significant increases or toxicities have been observed, with a few exceptions:
- Atazanavir and atazanavir/ritonavir have been found to cause significant increases in buprenorphine/naloxone levels, with subsequent sedation and cognitive impairment.
- Decrease the buprenorphine/naloxone dosage until the symptoms disappear.
- Non-nucleoside reverse transcriptase inhibitors (NNRTIs) may decrease buprenorphine/naloxone levels and cause withdrawal symptoms.
- May need to increase the buprenorphine/naloxone dose.
- Buprenorphine/naloxone may slightly increase protease inhibitor levels.
- Initiation of medication-assisted opioid treatment during HAART maintenance:
- Clinical needs for opioids should determine treatment selection.
- Patients may benefit from a trial of buprenorphine/naloxone because of the more benign drug interaction profile of buprenorphine/naloxone compared with methadone.

Initiation of HAART during buprenorphine/naloxone maintenance:

- Continue usual buprenorphine/naloxone dose.
- Advise patient of possible side effects.
- Atazanavir/ritonavir: sedation, impaired thinking. Decrease buprenorphine/naloxone dose accordingly.
- Efavirenz (Sustiva): withdrawal symptoms: Increase buprenorphine/naloxone dose accordingly.

- Side effects from drug interactions between HIV medications and buprenorphine/naloxone are less severe/ significant than those experienced with methadone.

PATIENTS WITH HEPATITIS C

Buprenorphine

- Both buprenorphine and naloxone are extensively metabolized by the liver.

- Most recent guidelines indicate that there are minimal concerns co-managing HCV and opioid use disorders utilizing buprenorphine/naloxone.[27]

    - Current data suggests that liver injury from buprenorphine occurs rarely, however patients with hepatitis C are at higher risk to elevations in transaminases and reversible hepatic injury. Most of the evidence suggests that these elevations are related to underlying liver disease and not buprenorphine exposure. Serious hepatic injury is rare.

    - Buprenorphine maintenance may have indirect beneficial effect on liver health via reduction of illicit opioid use.

- A single-dose study of 43 patients compared buprenorphine/naloxone exposure in healthy individuals to persons with mild, moderate, or severe hepatic impairment. Study results indicate that individuals with more advanced hepatic impairment experience higher peak exposure levels of naloxone vs buprenorphine when compared to healthy subjects.[15]

    - Dose adjustment may be required for some patients with severe liver disease.

    - May consider mono-tablet in some cases of severe liver disease.

- There are a small number of case reports of intravenous use of buprenorphine/naloxone by patients with hepatitis C resulting in increased alanine aminotransferase levels to 30-50 times normal.[28]

- Case reports of 7 patients with hepatitis C using buprenorphine/naloxone who had increased ALT 39x normal.[29]

    - All continued buprenorphine/naloxone; 50% dose reduction in 3 patients.

    - All recovered without any clinical complications.

- Important to do baseline testing and then to retest transaminases as needed based of clinical assessment.

Naltrexone

- Naltrexone is extensively metabolized through the liver and clinical judgement should be used prior to administeration in cases of advanced liver disease or acute hepatitis.

- AST and ALT should both be less than 5x the upper limit of normal at treatment initiation.

- Draw follow-up AST and ALT 8-12 weeks after initiation of naltrexone. At present there is no empirical evidence to support frequency of monitoring; clinical discretion should be used to guide frequency.[27]

    - Cases of hepatitis and clinically significant liver dysfunction were observed in association with extended-release injectable naltrexone (Vivitrol) treatment during the clinical development program and in the post-marketing period.

    - A randomized, double-blind, placebo-controlled trial of 624 individuals with alcohol dependence (DSM-IV) and recent heavy drinking, designed to assess the hepatic safety of injectable naltrexone found no difference in hepatic function at 6-months between participants on injectable naltrexone at the US FDA approved dose (380mg) compared to those receiving a placebo.[30]

    - In a study of 250 participants (89% had history of HCV) at 6-month follow-up, elevations in AST, ALT, and GGT greater than three times the upper limit of normal were not statistically different in patients treated with injectable naltrexone in compared with placebo.[31] The majority of participants who contributed liver enzyme level elevations greater than three times the upper limit of normal had chronic HCV infection

- Discontinue use of extended-release injectable naltrexone in the event of symptoms or signs of acute hepatitis (e.g., abdominal pain, nausea, vomiting, fever, dark urine, clay-colored stools, jaundice, or icterus; or ALT or AST levels greater than 10x the upper limit of normal).[27]

    - If no evidence that liver enzyme elevation is related to medication can restart once ALT and AST fall below 10X the upper limit of normal

- For all patients prescribed either buprenorphine/naloxone or naltrexone, hepatic enzymes should be monitored at regular intervals throughout the course of treatment.

- Patients should receive education about the signs/symptoms of liver inflammation and be advised to report these signs/symptoms to clinical team or present to emergency department for evaluation if present.

PREGNANCY AND BREASTFEEDING

Opioid use disorder in pregnancy is considered high-risk.

- 1st trimester, risk for spontaneous abortion.
- 3rd trimester, risk for withdrawal-induced fetal distress, premature labor, and intrauterine death.
- Educate pregnant patients on the benefits of maintaining opioid replacement during pregnancy.
- Decreased risk for relapse and therefore reduced complications from illicit opioid use.
- Constant levels of fetal opioid exposure result in reduced risk for adverse fetal outcomes related to multiple withdrawals.
- Decreased rate of adverse fetal outcomes such as low birth weight.
- Incidence of neonatal abstinence syndrome is 47%

Both methadone and buprenorphine (both combo and mono-tablet formulations) are Category C in pregnancy.

- There is more substantial data and clinical experience utilizing methadone versus buprenorphine during pregnancy.
- In 2012, the American College of Obstetricians and Gynecologists (ACOG) concluded that there is evidence to support the use of buprenorphine as a potential first-line medication for opioid dependent women.
- A longitudinal study of 73 children evaluated at 24 months (n = 24 exposed to buprenorphine in utero, and n = 19 exposed to methadone in utero, n = 30 non-exposed controls) found no differences between groups in temperament or neurological development during the first two years of life.[32]
- A double blind randomized controlled trial of 175 pregnant women with opioid use disorder treated with buprenorphine or methadone maintenance compared maternal and neonatal outcomes between the two groups. A total of 131 neonates were born to mothers followed through the end of their pregnancy (58 exposed to buprenorphine and 73 exposed to methadone). [33]

- Neonates in the buprenorphine group required significantly less morphine (mean dose, 1.1 mg vs. 10.4 mg) than neonates in the methadone group. They also had significantly shorter hospital stays (10.0 days vs. 17.5 days) and significantly shorter duration of treatment for neonatal abstinence syndrome (4.1 days vs. 9.9 days). The two groups did not vary with regard to maternal or neonatal adverse events.

Buprenorphine in Pregnancy: Due to a lack of safety data on buprenorphine/naloxone maintenance in pregnancy it is typical that pregnant women with opioid use disorder are either started on methadone or the buprenorphine mono product or switched from buprenorphine/naloxone to the mono product (buprenorphine) or methadone.

- For several decades in the absence of additional safety data two principals have guided the recommendation to use the mono product over buprenorphine naloxone: (i) pregnant women should limit exposure to exogenous compounds, and (ii) animal studies have suggested the possibility that naloxone could cause maternal and fetal hormonal changes.

- Additional research is still needed; a recent review comprised of preliminary findings from 7 previously published studies found no evidence of adverse maternal or neonatal outcomes related to use of buprenorphine/naloxone as compared to buprenorphine alone (mono product) or methadone.[34] Currently many providers use buprenorphine/naloxone for treatment of opioid use disorder during pregnancy without complication or notable adverse events.

BUPRENORPHINE PROTOCOL FOR PREGNANT WOMEN

- Provide smaller prescriptions to limit diversion potential and promote safety.
- Schedule more frequent follow-up visits during pregnancy.
- Refer for high-risk obstetric service.
- Minimal information exists on dosing changes by trimester.
- Once-daily dosing is effective in pregnancy, however some may require divided dosing.
- Frequent follow up visits should include: assessment, support, UTS, safety assessment, counseling, education and social determinants of health.
- Women should be encouraged to breast feed provided their UTS are negative for opioids and the mother is not prescribed any other medications that are contraindicated for breast feeding.
- Breast-feeding women should be maintained on buprenorphine/naloxone.
- Buprenorphine/naloxone is passed into breast milk at 1:1 plasma: milk ratio.

- Because of poor oral bioavailability of buprenorphine/naloxone, the breast-feeding infant is exposed to only 1/10 of buprenorphine/naloxone ingested.

- Breast-feeding during buprenorphine/naloxone use does not suppress neonatal abstinence syndrome. However it has been shown to assist with symptoms of NAS and enhances maternal-child bonding.

- Cessation of breast-feeding is not associated with onset of neonatal abstinence syndrome.

- *Naltrexone in Pregnancy:* Little research has been conducted to evaluate the safety or efficacy of naltrexone in pregnancy. Naltrexone, both oral and injectable formulations, are considered Category C medications.

- *Naltrexone with Breastfeeding:* It is not known if extended-release injectable naltrexone passes into breast milk. It is known that naltrexone from the oral formulation does pass into breast milk. Due to the potential tumorigenicity shown for naltrexone in animal studies, and because of the serious adverse reactions in nursing infants from injectable naltrexone (Vivitrol), a decision should be made to either discontinue the medication or discontinue nursing. Labeling from the manufacturer advises against breast feeding while taking naltrexone, both with oral and injectable formulations.

DUAL DIAGNOSIS

BUPRENORPHINE/NALOXONE

- Buprenorphine/naloxone is metabolized in the liver by the cytochrome P450 3A4 system.
- Clinical experience has not uncovered significant drug-drug interactions with buprenorphine/naloxone.
- Dosing changes are generally not necessary, as opposed to methadone dosing, which is highly influenced by concomitant medication use.
- Reassure patients with comorbid psychiatric conditions that use of buprenorphine/naloxone is not a barrier to treatment of their psychiatric condition.

NALTREXONE

- The cytochrome P450 system is not involved in naltrexone metabolism. In vitro CYP studies have demonstrated that naltrexone is not an inhibitor or inducer of major CYP enzymes.

Dual Diagnosis Treatment in OBAT

- All patients are assessed for psychiatric disorders as a component of OBAT screening procedures.
- After 2-3 weeks of stabilization, reassess patients for psychiatric symptomatology.
- Substance-induced psychiatric disorders generally resolve within 1-2 weeks of treatment initiation and cessation of substance misuse.
- Psychiatric symptoms that persist beyond 30 days after cessation of substance use are suggestive of an independent psychiatric condition. These patients should be offered a referral to Behavioral Health services for a mental health evaluation.
    - For patients engaged in psychiatry services, obtain patient-signed CFR42 consent for release of information to facilitate coordination of care with mental health providers
- **Benzodiazepines should be used cautiously with patients receiving buprenorphine/naloxone because of the potential for increased CNS depression, including sedation, respiratory depression and the potential for misuse in the patient with the disease of addiction. Patient history of benzodiazepine misuse should also be explored prior to prescribing.**

PAIN MANAGEMENT PROTOCOL ON BUPRENORPHINE/NALOXONE

BUPRENORPHINE/NALOXONE PATIENTS REQUIRING SURGERY

Background: These guidelines are designed for patients maintained on buprenorphine or buprenorphine/naloxone undergoing invasive procedures. There is currently a lack of evidence-based studies to direct the management of patients on buprenorphine/naloxone maintenance in the peri-procedure period. Below are guidelines using expert opinions based on pharmacological principles with the intent to avoid under-treatment of acute pain while also avoiding potential 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. These patients have also 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 period.

PROTOCOLS: PERI-PROCEDURE MANAGEMENT

1) WITHOUT EXPECTED NEED FOR OPIOID ANALGESICS

RECOMMENDATIONS:

- Patient takes usual buprenorphine/naloxone dose on the morning of procedure.
- If patient unexpectedly requires post-procedure opioid analgesics follow protocol B (*Post-procedure management*).
- If pain control is needed, split usual buprenorphine/naloxone dose into every 8 hour dosing (e.g.,, 24 mg per day changed to 8 mg every 8 hours) and add NSAIDS and/or acetaminophen and/or tramadol).
- Consider the use of local and regional anesthesia when indicated.
- The buprenorphine/naloxone provider should be contacted to assist in ongoing assessment, support, and post-procedure pain management.

2) WITH EXPECTED NEED FOR OPIOID ANALGESICS

RECOMMENDATIONS:

- Take last buprenorphine/naloxone dose on the morning of the day prior to the procedure.
- Hold buprenorphine/naloxone dose on day of procedure.
- **Pre-procedure**: give single dose of sustained-release morphine (e.g., MS Contin) 15 mg on the day of procedure (the prescription for the single dose of pre-procedure morphine can be given by the patient's buprenorphine/naloxone prescriber, primary care physician or the Internal Medicine Preoperative Assessment Clinic (IMPAC) provider).
- **Post-procedure**: Opioids analgesics should be started using standard dosing protocols with careful monitoring since patients with opioid addiction often have decreased pain tolerance and cross-tolerance to opioid analgesics resulting in a need for higher opioid doses and shorter dosing intervals. Because of its high affinity at the opioid receptor, consider fentanyl as the opioid of choice for analgesia during procedures and in PACU for these patients.

POST-PROCEDURE MANAGEMENT

1) INPATIENT ANALGESIA WITH OPIOIDS

RECOMMENDATIONS:

- Continue to hold buprenorphine/naloxone.
- All patients should be placed on sustained-release morphine (e.g., MS Contin 15mg bid) to address the patients' baseline opioid requirements and for pain control.
- If patient also requires parenteral analgesia for breakthrough pain, use PCA with NO basal dose. Continue sustained-release morphine.
- If the patient is NPO, use a basal dose of opioid to address the patient's baseline opioid requirements along with PCA or parenteral dosing for pain control.
    - If patient does not require parenteral analgesia for breakthrough pain, use short acting oral opioids (e.g., oxycodone, morphine. Continue sustained-release morphine).
    - Consider local or regional anesthesia when indicated.
    - Consider adjuvant therapy with NSAIDs and acetaminophen if appropriate.

2) OUTPATIENT ANALGESIA WITH OPIOIDS

RECOMMENDATIONS:

- ✓ Continue to hold buprenorphine/naloxone.
- ✓ All patients should be continued on sustained-release morphine 15 mg bid.
- ✓ Discharge patient with enough sustained-release morphine to last until the patient's follow-up appointment with their buprenorphine/naloxone prescriber.
- ✓ Treat patient's breakthrough pain with short acting opioids e.g.,, oxycodone, morphine, hydrocodone.
- ✓ Schedule patient to be seen by their buprenorphine/naloxone prescriber within 1 week post procedure to have their post-procedure pain managed and to be restarted on buprenorphine/naloxone maintenance when it is safe to do so.

CHRONIC PAIN MANAGEMENT

- General principles for chronic pain management on buprenorphine/naloxone:
- Reassure patients that their addiction will not be an obstacle to aggressive pain management.
- Include patients in decision-making process to allay anxiety.
- Establish clear goals for pain management
- Pain reduction rather than elimination.
- Improved function.
- Addressing associated symptoms.
- Use multidimensional approach to pain management:
- Try non-opioids initially.
- Try adjuvant therapies next.
- Use opioid analgesics as last option.
- If opioid analgesics are necessary for treatment of chronic pain, buprenorphine/naloxone should be discontinued and methadone maintenance initiated.

ACUTE PAIN MANAGEMENT

- Patients physically dependent on opioids require maintenance on daily equivalence before any pain relief is achieved with opioid analgesics (the "opioid debt").
- Evidence suggests that patients receiving buprenorphine/naloxone have reduced pain tolerance.

General principles for acute pain management:

- Reassure patient that their addiction will not be an obstacle to aggressive pain management.
- Include patient in decision-making process to allay anxiety.
- Try non-opioids initially.
- Try adjuvant therapies next.
- Use opioid analgesics as last option.
- Buprenorphine/naloxone may antagonize the effects of previously administered full opioid agonist analgesics.
- Degree of this effect depends on proportion of receptors occupied.
- Time since last opioid dose.

Mild to moderate pain (e.g.,dental extraction):

- ✓ Continue buprenorphine/naloxone maintenance.
- ✓ Use short-acting opioid analgesics.

Moderate to severe pain (e.g., renal stone):

- ✓ Discontinue buprenorphine/naloxone.
- ✓ Treat with opioid analgesics until pain resolves.
- ✓ Re-induction with buprenorphine/naloxone per protocol.

Inpatient management of moderate to severe pain (e.g., elective surgery):

- ✓ Discontinue buprenorphine/naloxone.

- ✓ Patients may require doses of methadone up to 30-40 mg daily for opioid maintenance.
- ✓ Treat pain with opioid analgesics until pain resolves.
- ✓ Discontinue methadone and re-induction with buprenorphine/naloxone per protocol.

NALTREXONE: PAIN MANAGEMENT

Background:

- There is currently a lack of evidence-based research to direct the management of patients prescribed naltrexone in the peri-procedure period.

- The pain-relieving effects of opioid agonists are blocked while on naltrexone. This includes pure mu agonists such as methadone or morphine derivatives, partial agonists, as well as mixed agonist/antagonists. In order to overcome the pharmacologic blockade of extended-release injectable naltrexone, extremely high doses of opioids are required to achieve adequate analgesia. This could lead to accidental overdose. It is therefore recommended that non-opioid analgesics be prescribed for pain management in these patients when possible. Non-steroidal anti-inflammatory agents are first-line. Regional nerve blocks and dissociative analgesics such as ketamine have also been recommended. However, expert consultation by an informed experienced pain specialist should occur (AATOD).

- All OBAT patients receiving naltrexone treatment should be co-managed with their OBAT provider during the pre- and post-procedure period.

OBAT Policy for Naltrexone Patients Requiring Surgery:

- Patient to notify OBAT staff of expected procedure ASAP.
- Obtain signed consent for release of information with CFR42 for the surgical/medical team.
    - OBAT clinical team to work with surgical team to manage pre and post procedure pain
- 6 weeks should occur between most recent extended-release naltrexone injection and planned surgery/procedure date.
    - May bridge patient with oral naltrexone.
    - Oral naltrexone should be discontinued 48-72 hours before the procedure.
- Before minor or intermediate elective surgery the possibility of managing the pain with non-opioids needs to be balanced against the risk of the patient relapsing.
- If a patient is to undergo major surgery where severe post-operative pain is expected then again oral naltrexone should be discontinued 72 hours before-hand. A degree of resistance to opioid analgesics should be expected, although increased sensitivity is also a possibility.
- Patients should be monitored closely with increased supports throughout the peri-procedure period.

NALTREXONE: CHRONIC/ACUTE PAIN MANAGEMENT

- Chronic pain requiring opioid medications is a contraindication for naltrexone and should be evaluated as part of OBAT screening process.
- General principles for chronic pain management for patients engaged in naltrexone treatment:
- Include patients in decision-making process to allay anxiety.
- Establish clear goals for pain management
- Pain reduction rather than elimination.
- Improved function.
- Addressing associated symptoms.
- Use multidimensional approach to pain management:
- Try non-opioids initially.
- Try adjuvant therapies next.
- If opioid analgesics are necessary for treatment of pain, naltrexone should be discontinued.
- For patients with chronic pain who are prescribed naltrexone to treat an opioid use disorder, buprenorphine/naloxone or methadone maintenance therapy may be considered in place of naltrexone treatment.

Reversal of Extended-Release Injectable Naltrexone

In an emergency situation in patients receiving extended-release injectable naltrexone, suggestions for pain management include regional analgesia or use of non-opioid analgesics.

- If opioid therapy is required as part of anesthesia or analgesia, patients should be continuously monitored in an anesthesia care setting by persons not involved in the conduct of the surgical or diagnostic procedure.

- The opioid therapy must be provided by individuals specifically trained in the use of anesthetic drugs and the management of the respiratory effects of potent opioids, specifically the establishment and maintenance of a patent airway and assisted ventilation.

- Irrespective of the drug chosen to reverse extended-release injectable naltrexone blockade, the patient should be monitored closely by appropriately trained personnel in a setting equipped and staffed for cardiopulmonary resuscitation.

APPENDICES

APPENDIX 1: DSM-5 CRITERIA: OPIOID USE DISORDER

Worksheet for DSM-5 criteria for diagnosis of Opioid Use Disorder

Diagnostic Criteria (Opioid Use Disorder requires at least 2 criteria be met within a 12 month period)	**Meets criteria?** Yes OR No	**Notes/Supporting information**
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.

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

APPENDIX 2: DSM-5 CRITERIA: ALCOHOL USE DISORDER

Alcohol Use Disorder DSM–5

In the past year, have you:

1. Had times when you ended up drinking more, or longer, than you intended?
2. More than once wanted to cut down or stop drinking, or tried to, but couldn't?
3. Spent a lot of time drinking? Or being sick or getting over other aftereffects?
4. Wanted a drink so badly you couldn't think of anything else?
5. Found that drinking—or being sick from drinking—often interfered with taking care of your home or family? Or caused job troubles? Or school problems?
6. Continued to drink even though it was causing trouble with your family or friends?
7. Given up or cut back on activities that were important or interesting to you, or gave you pleasure, in order to drink?
8. More than once gotten into situations while or after drinking that increased your chances of getting hurt (such as driving, swimming, using machinery, walking in a dangerous area, or having unsafe sex)?
9. Continued to drink even though it was making you feel depressed or anxious or adding to another health problem? Or after having had a memory blackout?
10. Had to drink much more than you once did to get the effect you want? Or found that your usual number of drinks had much less effect than before?
11. Found that when the effects of alcohol were wearing off, you had withdrawal symptoms, such as trouble sleeping, shakiness, restlessness, nausea, sweating, a racing heart, or a seizure? Or sensed things that were not there?

The presence of at least 2 of these symptoms indicates an Alcohol Use Disorder (AUD).

Mild: 2 to 3 symptoms
Moderate: 4 to 5 symptoms
Severe: 6 or more symptoms

*National Institute on Alcohol Abuse and Alcoholism. 301.443.3860. NIH Publication No. 13-7999 July 2015

APPENDIX 3: TELEPHONE SCREENING

Demographic Info

How did you hear about the hotline?

☐ 1 = Spouse ☐ 2 = Friend ☐ 3 = Physician
☐ 4 = Flyer ☐ 5 = Parent ☐ 6 = State Hotline
☐ 7 = Physician Locator ☐ 8 = Other: _____

Are you pregnant at this time?

☐ 1 = Yes
☐ 2 = No
☐ 3 = Don't Know
☐ 4 = Tubal ligation
☐ 5 = Menopause
☐ 6 = History of hysterectomy
☐ 7 =Other

If no, are you on birth control? ☐ 1= Yes ☐ 2 = No

Current Address_____

Phone _____ Is it ok to leave a message? ☐ 1= Yes ☐ 2 =No

Phone _____

Emergency Contact _____ Phone _____

Is the Emergency Contact aware of your addiction? ☐ 1= Yes ☐ 2 = No

Drug Use History

	Age of first use	*Last use*	*How often used?*	*Route of admin.*	*Amounts used*
What is your drug of choice?*	0 IF NEVER USED	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	1=LESS THAN 1/MONTH 2=1-3 TIMES/MONTH 3=1-2 TIMES/WEEK 4=3-6 TIMES/WK 5=DAILY	1=ORAL 2=SMOKING 3=INTRANASAL 4=INTRAVENOUS INJECTION 5=SKIN POPPING 6=OTHER	
Opioid ***__Heroin*** ***__Fentanyl*** ***__Oxycontin*** ***__Other oxycodone containing product*** ***__Methadone*** ***__Other_____***					
Benzodiazepine					
Alcohol					
Cocaine					
Amphetamines Including methamphetamine					
Tobacco					
Other					

What are you currently using at this time?
Includes age of first use, last use, route, frequency, and quantity.

☐ 1 = heroin
☐ 2 = fentanyl
☐ 3 = oxycontin
☐ 4 = methadone
☐ 5 = oxycodone product
☐ 6 = cocaine
☐ 7 = benzodiazepines
☐ 8 = Nothing
☐ 9 = Alcohol
☐ 10= Amphetamines
☐ 11 = Buprenorphine/naloxone
☐ 12 = Other

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

Have you ever belonged to the 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

Was naloxone administered? ☐ 1= Yes ☐ 2 = No

Recovery History

What was the longest period of time that you have been in recovery?

_____

When was this? _____

Addiction Treatment History

Have you had any addiction treatment? ☐ 1= Yes ☐ 2 = No

If yes, how many times to each type?

_____ Detox Program
_____ Residential (Rehab or Halfway House)
_____ Buprenorphine/naloxone maintenance
_____ Driving Impaired Program
_____ Methadone maintenance
_____Naltrexone (oral or injectable)

Are you currently participating in any form of addiction treatment?

☐ 1= 12 step programs (NA, AA)
☐ 2= Outpatient Counseling
☐ 3= Acupuncture
☐ 4= Intensive Outpatient Program (IOP)
☐ 5= OCC
☐ 6= Other: _____

Do you attend meetings (check all that apply):

☐ 1= AA
☐ 2= NA
☐ 3= Smart Recovery
☐ 4= Other _____

How many meetings do you attend each week?

☐ 1 = 1-2 week
☐ 2 = 3-4 week
☐ 3 = 5-6 week
☐ 4 = Daily
☐ 5 = None

☐ 6 = Other:

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

Do you have any history of any other addictive behaviors such as?
☐ 1 = Gambling
☐ 2 = Sex
☐ 3 = Shopping
☐ 4 = Eating disorder (over eating, bulimia, anorexia)
☐ 5 = Other:
☐ 6 = No

Comments: _____

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 any potential jail time? ☐ 1= Yes ☐ 2 = No

Do you have any 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 your Methadone clinic? _____

How long have you been in your current Methadone Maintenance Program? _____

Are you receiving take-homes? ☐ 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 buprenorphine/naloxone? _____

Naltrexone History

Have you ever been prescribed naltrexone before?
☐ 1= Yes ☐ 2 = No

If yes, when were you on naltrexone? _____

Why did you stop naltrexone treatment? _____

Mental Health History

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

☐ 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:

Are you currently 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 them? _____

How many times have you seen this person in the last six months? _____ Times.

Will you sign consent 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 to homicide question)

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 to health care)

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

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

Are you willing to Contract for Safety, call 911 etc.

Health status

Have you ever been diagnosed with any other medical conditions? Mark 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 type):
☐ 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

Pain

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

Please rate your pain, on a scale from 0 – 10, without any pain medications (prescribed or bought on the street)
____0____1____2____3____4____5____6____7____8____9____10____

Please rate your pain, on a scale from 0 – 10, WITH 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? _____

When was the last time you saw a doctor?
☐ 1= Last week
☐ 2= Last month
☐ 3= Within the past 3 months
☐ 4 = Within the past 6 months
☐ 5 = Within the past year
☐ 6 = More than 1 year ago

What is the name of your doctor? _____

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 next question)
☐ 2 = Married
☐ 3 = Long term relationship
☐ 4 = Divorced
☐ 5 = Other_____

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

Does your partner have a history of substance use? ☐ 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

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?
☐ 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
☐ 4 = I get a ride from a family/friend
☐ 5 = Other _____

Do you have a valid form of government issued identification? ☐ 1 = Yes ☐ 2 = No

How would you get to BMC if you needed to get here?
☐ 1 = I would drive
☐ 2 = Public Transportation
☐ 3 = I would walk
☐ 4 = I get a ride from a family/friend
☐ 5 = Other _____

Housing

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

What type of place are you living in now?
☐ 1 = In a house or apartment you own.
☐ 2 = In a house or apartment you rent
☐ 3 = In a 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 other):_____
☐ 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: _____

Can you tell me what your goals are for treatment?

APPENDIX 4: NURSING INTAKE

Nursing Summary:
Name _____

Are you pregnant at this time?
☐ 1 = Yes
☐ 2 = No
☐ 3 = Don't Know
☐ 4 = Tubal ligation
☐ 5 = Menopause
☐ 6 = History of hysterectomy
☐ 7 =Other

If no, are you on birth control? ☐ 1= Yes ☐ 2 = No

If yes, which method of birth control are you currently on? (check all that apply)
☐ Relying on male condoms
☐ Oral contraceptives
☐ Shot (e.g. Depo-Provera)
☐ Hormonal implant
☐ Intrauterine device/contraception (IUD or IUC)
☐ Vaginal ring
☐ Patch
☐ Female barrier method (e.g. diaphragm, female condom)
☐ Rhythm/Fertility Awareness Methods/Withdrawal
☐ Other:

Drug Use History

What are you currently using at this time?
Includes age of first use, last use, route, frequency, and quantity.
☐ 1 = heroin
☐ 2 = fentanyl
☐ 3 = oxycontin
☐ 4 = methadone
☐ 5 = oxycodone product
☐ 6 = cocaine
☐ 7 = benzodiazepines
☐ 8 = Nothing
☐ 9 = Alcohol
☐ 10= Amphetamines
☐ 11 = Buprenorphine/naloxone
☐ 12 = Other

Do you have any history of any other addictive behaviors such as?
☐ 1 = Gambling
☐ 2 = Sex
☐ 3 = Shopping
☐ 4 = Eating disorder (over eating, bulimia, anorexia)
☐ 5 = Other:
☐ 6 = No

Comments:_____

Prior Substance Use Disorder Treatment History

Methadone:

Have you ever been on Methadone Maintenance? ☐ 1= Yes ☐ 2 = No

When and where were you on Methadone Maintenance?
_____

What was your 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 your Methadone clinic?_____

Buprenorphine/Naloxone:

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 buprenorphine/naloxone? _____

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

Naltrexone:

Have you ever been prescribed naltrexone before?
☐ 1= Yes ☐ 2 = No

If yes, when were you on naltrexone? _____

Why did you stop naltrexone treatment?_____

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: _____

Are you currently taking any medication for this/these problem(s)?
☐ 1= Yes ☐ 2 = No

If yes, what medications are you taking? _____

Have you ever taken any medication 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? Mark 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 type):
☐ 18= None

PMH 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

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

If yes, please explain:

_____

_____

Please rate your pain, on a scale from 0 – 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?

_____

_____

Check all appropriate boxes:

☐ OBAT program reviewed with patient including requirements to keep medical and OBAT appointments, urine toxic screens and possible random call backs with medication counts. He / She is aware of his/her responsibility for their buprenorphine/naloxone medication. Informed to keep medication in a safe undisclosed place, out of reach of children and visitors. Informed to keep medication in a locked storage unit.

☐ OBAT consent and contract read to and reviewed with the patient. Patient voluntarily signed and dated consent. A copy was given to the patient and the original was placed in the chart. Opportunity for questions provided.

☐ Discussed buprenorphine/naloxone - reviewed medication, potential side effects including elevations in transaminases, potential lethal interaction with benzodiazepines and ETOH, safe administration and storage. Written information also provided to pt. Patient verbalizes understanding of information provided and wishes to schedule induction phase time and date.

☐ Discussed naltrexone - reviewed potential side effects and adverse reactions including injection site reactions, allergy, pneumonia, increase transaminases, depression, dizziness, opioid blocking effects, and decreased opioid tolerance. Patients need to be opiate free for an extended period of time prior to administration to prevent precipitated or spontaneous withdrawal. Patients who are naltrexone naive will begin with the tablet form of the medication to assess for side effects or adverse reactions. Written info provided to patient. Patient verbalized understanding and wishes to initiate naltrexone treatment.

☐ Contact numbers of medical providers and wallet size buprenorphine/naloxone information given to pt. Patient instructed to give these cards to family members or friends in case patient is ever hospitalized.

☐ Contact numbers of medical providers and wallet size extended-release naltrexone (Vivitrol) information given to pt. Patient instructed to give these cards to family members or friends in case patient is ever hospitalized. Patient also provided with naltrexone medical alert bracelet and/or dog tag.

☐ Patient has been informed that buprenorphine/naloxone and naltrexone are Category C medications. Breastfeeding is a contraindication for naltrexone treatment.

☐ Labs sent: complete blood count (CBC), Hepatitis A, B, and C serologies, comprehensive metabolic panel, HIV, human chorionic gonadotropin (hCG), urine toxicology screen.

☐ Overdose education provided. Pt has been trained and has access to use a naloxone rescue kit.

APPENDIX 5: INDUCTION NOTE

☐ Patient Presents for First Induction

Evaluated using COW scale? ☐ Yes ☐ No

Scored _____on COW Scale First Assessment

Patient self-administered _____ mg sl as prescribed

☐ Assessed and instructed patient in proper administration
☐ Patient observed to tolerate medication

Summary 1:
COW Scale First Assessment

Resting Pulse Rate
☐ 0 = pulse rate 80 or below
☐ 1 = pulse rate 80-100
☐ 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 possible 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 = mild diffuse discomfort
☐ 2 = patient reports severe diffuse aching of joints/muscle

☐ 4 = patient is rubbing joints or 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 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/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 Score _____

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

☐ Patient Presents for Second Induction

Evaluated using COWS scale? ☐ Yes ☐ No

Scored _____on COWS Scale Second Assessment

Patient self-administered _____ mg sl as prescribed

☐ Assessed and instructed patient in proper administration
☐ Patient observed to tolerate medication

APPENDIX 6: NURSING FOLLOW-UP

Buprenorphine/Naloxone Nursing Follow-up Visit:

Visit type:
☐ Scheduled
☐ Call back
☐ Walk-in
☐ Random call back

Reason for visit:

Current dose of buprenorphine/naloxone:
☐ 1 = 2mg ☐ 4 = 8mg ☐ 7 = 16mg ☐ 10 = 28mg
☐ 2 = 4mg ☐ 5 = 10mg ☐ 8 = 20mg ☐ 11 = 32mg
☐ 3 = 6mg ☐ 6 = 12mg ☐ 9 = 24mg ☐ 12 = Other _____

Is patient taking buprenorphine/naloxone as directed?
☐ 1 = Yes ☐ 2 = No

The patient's dose is:
☐ stable
☐ titrating up
☐ tapering down

How often is patient taking buprenorphine/naloxone?
☐ 1 = single dose ☐ 2 = divided dose ☐ 3 = other:

If taking more than once a day, what is the reason?
☐ 1 = Sleep
☐ 2 = Habit
☐ 3 = Mentally feels better
☐ 4 = Energy

Is patient experiencing?
☐ Cravings
☐ Withdrawal symptoms
☐ Side effects
☐ Other:
☐ Patient denies cravings/withdrawal symptoms

Comments:

Have there been any changes to your medications since your last visit?
☐ 1 = Yes ☐ 2 = No

If yes, please list: _____

Do you have any active medical issues? ☐ 1 = Yes ☐ 2 = No

If yes, please list: _____

PCP Name: _____

OBAT Provider Name:_____

Was the last visit within 4 months? : _____

When were the patient's last labs drawn: _____

Female Patients: Any chance that you are pregnant at this time?
☐ 1 = Yes
☐ 2 = No
☐ 3 = Don't Know
☐ 4 = Tubal ligation
☐ 5 = Menopause
☐ 6 = History of hysterectomy
☐ 7 =Other

If no, are you on birth control? ☐ 1= Yes ☐ 2 = No

If yes, which method of birth control are you currently on? (check all that apply)
☐ Relying on male condoms
☐ Oral contraceptives
☐ Shot (e.g. Depo-Provera)
☐ Hormonal implant
☐ Intrauterine device/contraception (IUD or IUC)
☐ Vaginal ring
☐ Patch
☐ Female barrier method (e.g. diaphragm, female condom)
☐ Rhythm/Fertility Awareness Methods/Withdrawal
☐ Other:

Has patient used any substances?
☐ Opioids
☐ Cocaine
☐ THC
☐ ETOH
☐ Benzodiazepines
☐ Amphetamines
☐ Prescribed controlled substance - reason for prescription:
☐ Patient denies all drug use

☐ None
☐ Other:

Comments:_____

Is patient engaged in counseling? ☐ 1 = Yes ☐ 2 = No

Location of counseling: _____

What is the name of your counselor:_____

How often is the patient going to counseling?
☐ 1 = Once a week
☐ 2 = Every other week
☐ 3 = Once a month
☐ 4 = Every 2-3 months
☐ 5 = Other:

Has the patient missed any counseling appointments? ☐ 1 = Yes ☐ 2 = No

What is the reason for the missed appointments?

Is the patient seeing a psychiatrist? ☐ 1 = Yes ☐ 2 = No

Name of psychiatrist: _____

How often is the patient seeing a psychiatrist?
☐ 1 = Once a week
☐ 2 = Every other week
☐ 3 = Once a month
☐ 4 = Every 2-3 months
☐ 5 = Other:

Are you attending meetings? ☐ 1 = Yes ☐ 2 = No

If yes, which meetings do you attend (check all that apply)
☐ 1 = AA
☐ 2 = NA
☐ 3 = Smart Recovery
☐ 4 = Other: _____

If yes, how many meetings do you attend each week?
☐ 1 = 1-2 week
☐ 2 = 3-4 week
☐ 3 = 5-6 week

☐ 4 = Daily
☐ 5 = Other
Are there any changes in your housing status? ☐ 1 = Yes ☐ 2 = No

The following portions of the patient's history were reviewed and updated as appropriate:
☐ Medication List
☐ Recent Lab Results
☐ Allergies
☐ Problem List
☐ Other

Recovery education/support conducted during this session? ☐ 1 = Yes ☐ 2 = No

Educated/supported the patient in:
☐ 1 = Attending meetings
☐ 2 = Attending counseling
☐ 3 = Addiction behavior
☐ 4 = Recovery issues
☐ 5 = Relapse prevention
☐ 6 = Relationship/family issues
☐ 7 = Obtaining a sponsor
☐ 8 = Job training
☐ 9 = School/vocational training
☐ 10 = Other:

Treatment plan reviewed ☐ 1 = Yes ☐ 2 = No

UTS/buprenorphine/naloxone Level Sent ☐ 1 = Yes ☐ 2 = No

UTS was: ☐ 1 = Observed ☐ 2 = Unobserved

Urine sample sent to outside lab: ☐ 1 = Yes ☐ 2 = No

RTC: ☐ 1 = Scheduled ☐ 2 = Random call back

Comments:_____

Naltrexone Nursing Follow-up Visit:

Visit type:
☐ Scheduled
☐ Call back
☐ Walk-in
☐ Random call back

Patient Receives:
☐ oral naltrexone
☐ extended-release injectable naltrexone

Last injection Date: _____

Last injection location:
☐ Right side
☐ Left side

Is patient experiencing?
☐ Cravings
☐ Medication side effects
☐ Medication adverse reactions
☐ Other:
☐ Patient denies cravings/withdrawal symptoms/adverse effects

OBAT Provider Name:_____

Was the last visit within 4 months? : _____

Female Patients: Any chance that you are pregnant at this time?
☐ 1 = Yes
☐ 2 = No
☐ 3 = Don't Know
☐ 4 = Tubal ligation
☐ 5 = Menopause
☐ 6 = History of hysterectomy
☐ 7 =Other

If no, are you on birth control? ☐ 1= Yes ☐ 2 = No

If yes, which method of birth control are you currently on? (check all that apply)
☐ Relying on male condoms
☐ Oral contraceptives
☐ Shot (e.g. Depo-Provera)
☐ Hormonal implant
☐ Intrauterine device/contraception (IUD or IUC)

☐ Vaginal ring
☐ Patch
☐ Female barrier method (e.g. diaphragm, female condom)
☐ Rhythm/Fertility Awareness Methods/Withdrawal
☐ Other:

Has patient used any substances:
☐ Opioids
☐ Cocaine
☐ THC
☐ ETOH
☐ Benzodiazepines
☐ Amphetamines
☐ Prescribed controlled substance - reason for prescription:
☐ Patient denies all drug use
☐ None
☐ Other:

Patient reports the following medical issues: _____

Is patient engaged in counseling? ☐ 1 = Yes ☐ 2 = No

Location of counseling: _____

What is the name of your counselor:_____

How often is the patient going to counseling?
☐ 1 = Once a week
☐ 2 = Every other week
☐ 3 = Once a month
☐ 4 = Every 2-3 months
☐ 5 = Other:

Has the patient missed any counseling appointments? ☐ 1 = Yes ☐ 2 = No

What is the reason for the missed appointments? _____

Is the patient seeing a psychiatrist? ☐ 1 = Yes ☐ 2 = No

Name of psychiatrist: _____

How often is the patient seeing a psychiatrist?
☐ 1 = Once a week
☐ 2 = Every other week
☐ 3 = Once a month
☐ 4 = Every 2-3 months

☐ 5 = Other:

Are you attending meetings? ☐ 1 = Yes ☐ 2 = No

If yes, which meetings do you attend (check all that apply)
☐ 1 = AA
☐ 2 = NA
☐ 3 = Smart Recovery
☐ 4 = Other: _____

If yes, how many meetings do you attend each week?
☐ 1 = 1-2 week
☐ 2 = 3-4 week
☐ 3 = 5-6 week
☐ 4 = Daily
☐ 5 = Other

The following portions of the patient's history were reviewed and updated as appropriate:
☐ Medication List
☐ Recent Lab Results
☐ Allergies
☐ Problem List
☐ Other

Today's injection was given on the _____:
☐ Right side
☐ Left side

Are there any changes in your housing status? ☐ 1 = Yes ☐ 2 = No

Recovery education/support conducted during this session? ☐ 1 = Yes ☐ 2 = No

Educated/supported the patient in:
☐ 1 = Attending meetings
☐ 2 = Attending counseling
☐ 3 = Addiction behavior
☐ 4 = Recovery issues
☐ 5 = Relapse prevention
☐ 6 = Relationship/family issues
☐ 7 = Obtaining a sponsor
☐ 8 = Job training
☐ 9 = School/vocational training
☐ 10 = Other:

Treatment plan reviewed ☐ 1 = Yes ☐ 2 = No

UTS Sent: ☐ 1 = Yes ☐ 2 = No

UTS was: ☐ 1 = Observed ☐ 2 = Unobserved

Urine sample sent to outside lab: ☐ 1 = Yes ☐ 2 = No

Comments:

APPENDIX 7: INTAKE CHECK-LIST

Intake Checklist

INTAKE ITEM	**Date & Initials**
INTAKE VISIT WITH NURSE	
CONSENT FORM SIGNED	
PARENTAL CONSENT SIGNED	
PHARMACY FORM SIGNED	
TREATMENT AGREEMENT SIGNED	
LABS DRAWN	
UTS OBTAINED	
HQN (ALL WOMEN) HCG?	
BCP REVIEW (*ALL WOMEN & DOCUMENTED IN NOTE, EXCEL SHEET*)	
MEDICATION LIST	
ALLERGIES LIST	
CONSENT FOR COUNSELOR/PSYCHIATRIST	
CONSENT FOR PAROLE OFFICER	
OTHER CONSENT IF NEEDED	
EMERGENCY CONTACT INFO AND CLINIC CONTACT INFO	
HCV REFERRAL	
LAST PPD *(>6MONTHS NEEDS TO BE DONE)*	
ORIENTATION TO THE TEAM AND ITS LOCATION	
COMPLETE DPH PAPERWORK	

APPENDIX 8A: TREATMENT CONSENT

Consent for Treatment with Buprenorphine/Naloxone:

Buprenorphine/naloxone is a FDA approved medication for treatment of people with opiate dependence. Qualified physicians can treat up to 30 patients for opioid dependence with buprenorphine/naloxone for the first year of practice and then can apply for another waiver to increase to 100 patients, some qualified providers may treat up to 275 patients. Buprenorphine/naloxone can be used for detoxification or for maintenance therapy. Maintenance therapy can continue as long as medically necessary, it is estimated that one will be on buprenorphine/naloxone for at least 6months.

Buprenorphine/naloxone treatment can result in physical dependence of an opioid. Withdrawal from buprenorphine/naloxone is generally less intense than with 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 get used the transition from the opioid that had been taken and using buprenorphine/naloxone. During this time any use of other opioids may cause an increase in symptoms. After becoming stabilized 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.

You should not take any other medications without first discussing with your health care provider.

Combining buprenorphine/naloxone with alcohol or other medications may be hazardous. Combining buprenorphine/naloxone with medications such as Klonopin, Valium, Haldol, Librium, 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 (i.e., Morphine), it would cause severe opioid withdrawal.

Buprenorphine/naloxone tablets/Film **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 Sign Name Date

_____

Witness Date

BOSTON MEDICAL CENTER
CONSENT FOR TREATMENT WITH NALTREXONE

Oral Naltrexone (Revia) and Extended-Release Injectable Naltrexone (Vivitrol)

Naltrexone is a prescription medication that is used to:

- Prevent relapse to opiate/opioid use
- Treat alcoholism

You cannot start naltrexone now if you:

- Are currently using opiates/opioids
- Are currently having withdrawal from opiate/opioid use

It is necessary to stop all drugs/medications that have any opiates/opioids in them 7-10 days before starting naltrexone to avoid getting sick. It is also important that you **NOT** have any opioids (such as: methadone, buprenorphine, heroin, oxycodone, ultram, etc) in your body and **NOT** be currently withdrawing when you begin treatment.

Urine drug screens will be done before each injection to assure abstinence from opioids

Because extended-release naltrexone (Vivitrol) is an injection, it cannot be taken out of the body. To make sure there are no allergies, all patients who have never taken this medication must begin with a dose by mouth (tablet form). If you are not allergic to the tablet, you can move on to the injection.

A reaction at the site of injection may occur that may be serious. It is important to get medical attention for reactions that get worse or that you are unsure of, including the following:

- •Intense pain
- •Area feels hard, lumpy
- •Swelling, redness and warmth
- •Blisters, and/or skin is open

Allergic reactions can happen soon after an injection of naltrexone. Tell your doctor or get immediate medical help if you have any of these symptoms:

- •Skin rash
- •Chest pain
- •Trouble breathing or wheezing
- •Dizziness or fainting
- •Swelling of eyes, mouth, tongue, or face

Because naltrexone can affect your liver, and blood will be drawn before starting treatment to check the levels and then as needed during treatment to make sure your liver is healthy. If you develop any symptoms during treatment such as:

- •Yellowing of the skin or eyes
- •Dark urine
- •Stomach pain, or loss of appetite
- •More tired than normal,
- •White stool or diarrhea

You should contact your doctor or be seen by a medical provider and tell them about the medication you are taking.

You may experience depression while on naltrexone. If you develop depression it is important to tell someone and/or alert your medical providers. If you feel like harming yourself or someone else, you should go to your local emergency room or call 911 if you cannot reach your medical providers.

You may develop signs/symptoms of pneumonia on this medication:

- •Shortness of breath
- •Wheezing
- •Cough that doesn't go away
- •Difficulty breathing
- •Fevers

If so, please go to your local emergency room or call 911 if you are not physically able to do so. _____

Dizziness may occur on naltrexone treatment. You should avoid driving, operating heavy or dangerous machinery until you are sure how Vivitrol affects you. _____

Use of large doses of heroin or other opiates/opioids (morphine, oxycodone, Percocet, Oxycontin, methadone, codeine, etc) while on Vivitrol could cause serious injury, coma or death. _____

If you were addicted to opioids/opiates before naltrexone, you **Will** be more sensitive to lower doses of opioids/opiates and at **Risk** for an **Overdose** should you have a relapse.

Relapse to opiates is very dangerous after being on naltrexone. Do not pick up using what you used before starting naltrexone; your body will be more sensitive to opiates. Alert your family, friends, or close contacts that you are on Vivitrol and about the risk of an overdose should you have a relapse.

You should carry alert information so others know you are on naltrexone in a medical emergency: medical alert necklace, bracelet and/or emergency card. _____

You cannot be on naltrexone and be pregnant. A pregnancy test will be done before treatment is begun and then each month before your next injection. If you learn you are pregnant at any time please alert your medical team. _____

You will see your medical team frequently in the beginning and then less frequently as you become more stable. However it is important to be followed closely for support and assessment. During your treatment you should expect the following:

- •Urine drug screens at visits
- •Clinical check-ins
- •Check in: social supports/ recovery network
- •Physician visits
- •Blood work as indicated
- •Monthly injections

_____

Naltrexone treatment is only one part of your treatment. It is important that you seek counseling support services along with the medical part of your treatment to assist you in your recovery process. _____

In an emergency situation if you require pain management with opioid/opiate medications it is important that your medical team know that you are on naltrexone. You would require medical management by providers trained in the use of anesthetic drugs and management of potential respiratory effects. Carry emergency contact information with you at all times and have your team contacted if needed to assist in your care. _____

_____ _____

Patient Name Date

_____ _____

Provider Name Date

APPENDIX 8B: CONSENT FOR RELEASE OF INFORMATION

CONSENT FOR RELEASE OF INFORMATION

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 the 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 _____ Dated _____

Signature of witness _____ Dated _____

ATTENTION RECIPIENT:
Notice Prohibiting Re-disclosure

This information has been disclosed to you from the records protected by Federal confidentiality rules (42 C.F.R. 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 C.F.R. 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.

APPENDIX 8C: APPOINTED PHARMACY CONSENT

APPOINTED PHARMACY CONSENT

(buprenorphine HCl/naloxone HCl dihydrate) sublingual tablet or film
(buprenorphine HCl) sublingual tablet, naltrexone (oral or extended-release injectable)

I _____ do hereby: (**check all that apply**)
Patient Name (Print)

□ Authorize _____ at the above address to disclose my treatment for opioid dependence to employees of the pharmacy specified below. Treatment disclosure most often includes, but may not be limited to, discussing my medications with the pharmacist, and faxing/calling in my buprenorphine/naloxone prescriptions directly to the pharmacy.

□ Agree to purchase all buprenorphine/naloxone, and any other medications related to my treatment from the pharmacy specified below.

□ Agree not to use any pharmacy other than the one specified below for the duration of my treatment with the physician specified above, unless specific arrangements have been made with the physician.

□ Agree to make payment arrangements with the pharmacy specified below in advance of treatment, so that my buprenorphine/naloxone prescriptions can be filled and either delivered to the office addressed given above or picked-up by employees of the same.

I understand that I may withdraw this consent at any time, either verbally or in writing except to the extent that action has been taken in reliance on it. This consent will last while I am being treated for opioid dependence by the physician specified above unless I withdraw my consent during treatment. This consent will expire 365 days after I complete my treatment, unless the physician specified above is otherwise notified by me.

I understand that the records to be released may contain information pertaining to psychiatric treatment and/or treatment for alcohol and/or drug dependence. These records may also contain confidential information about communicable diseases including HIV (AIDS) or related illness. I understand that these records are protected by the Code of Federal Regulations Title 42 Part 2 (42 CFR Part 2) which prohibits the recipient of these records from making any further disclosures to third parties without the express written consent of the patient.

I acknowledge that I have been notified of my rights pertaining to the confidentiality of my treatment information/records under 42 CFR Part 2, and I further acknowledge that I understand those rights.

_____

Patient Signature Date

_____

Parent/Guardian Signature Parent/Guardian Name (Print) Date

_____

Witness Signature Witness Name (Print) Date

APPOINTED PHARMACY:

NAME_____ PHONE_____

ADDRESS_____

CONFIDENTIALITY OF ALCOHOL AND DRUG DEPENDENCE PATIENT RECORDS

THE CONFIDENTIALITY OF ALCOHOL AND DRUG DEPENDENCE PATIENT RECORDS MAINTAINED BY THIS PRACTICE/PROGRAM IS PROTECTED BY FEDERAL LAW AND REGULATIONS. GENERALLY, THE PRACTICE/PROGRAM MAY NOT SAY TO A PERSON OUTSIDE THE PRACTICE/PROGRAM THAT A PATIENT ATTENDS THE PRACTICE/PROGRAM, OR DISCLOSE ANY INFORMATION IDENTIFYING A PATIENT AS BEING ALCOHOL OR DRUG DEPENDENT UNLESS:

1. THE PATIENT CONSENTS IN WRITING;
2. THE DISCLOSURE IS ALLOWED BY A COURT ORDER, OR
3. THE DISCLOSURE IS MADE TO MEDICAL PERSONNEL IN A MEDICAL EMERGENCY OR TO QUALIFIED PERSONNEL FOR RESEARCH, AUDIT, OR PRACTICE/PROGRAM EVALUATION.

VIOLATION OF THE FEDERAL LAW AND REGULATIONS BY A PRACTICE/PROGRAM IS A CRIME. SUSPECTED VIOLATIONS MAY BE REPORTED TO APPROPRIATE AUTHORITIES IN ACCORDANCE WITH FEDERAL REGULATIONS.

FEDERAL LAW AND REGULATIONS DO NOT PROTECT ANY INFORMATION ABOUT A CRIME COMMITTED BY A PATIENT EITHER AT THE PRACTICE/PROGRAM OR AGAINST ANY PERSON WHO WORKS FOR THE PRACTICE/PROGRAM OR ABOUT ANY THREAT TO COMMIT SUCH A CRIME.

FEDERAL LAWS AND REGULATIONS DO NOT PROTECT ANY INFORMATION ABOUT SUSPECTED CHILD ABUSE OR NEGLECT FROM BEING REPORTED UNDER STATE LAW TO APPROPRIATE STATE OR LOCAL AUTHORITIES.

APPENDIX 8D: SPANISH CONSENT FOR TREATMENT WITH BUPRENORPHINE/ NALOXONE:

PROGRAMA PARA EL TRATAMIENTO CONTRA ADICCION EN EL CONSULTORIO MEDICO (OBAT)

Consentimiento para el tratamiento con Buprenorfina en el Boston Medical Center.

Buprenorfina es un medicamento aprobado por la Administración de Drogas y Alimentos (FDA, por sus siglas en inglés) para el tratamiento de personas con adicción a los opioides. Médicos calificados pueden tratar con Buprenorfina hasta 30 pacientes con dependencia a los opioides. La Buprenorfina puede ser utilizada para la desintoxicación o para una terapia de mantenimiento. Esta terapia puede continuar mientras sea clínicamente necesaria, se estima que se estará tomando Buprenorfina, al menos, durante seis (6) meses.

El tratamiento con Buprenorfina puede resultar en una dependencia física a un opioide. La supresión del Buprenorfina, generalmente, es menos intensa que con heroína o metadone. Si el Buprenorfina se descontinúa de repente, es posible que algunos pacientes no presenten síntomas de retirada ("withdrawal"); otros pueden manifestar síntomas como dolores musculares, dolores estomacales, o diarrea durante varios días. Para minimizar la posibilidad de síntomas de retirada de opioides, la Buprenorfina deberá descontinuarse gradualmente durante varias semanas o más.

Si usted es adicto a los opioides, cuando tome la primera dosis de Buprenorfina, deberá estar desintoxicado lo más posible; si no lo está, el Buprenorfina puede causarle consecuencias graves al suprimir el opioide.

Le tomará varios días para acostumbrarse a la transición del opioide tomado y al uso del Buprenorfina. El uso de cualquier otro opioide durante este tiempo, podrá aumentar los síntomas. Una vez estabilizado con la Buprenorfina, el uso de otro opioide tendrá menos efecto. Intentos de hacer caso omiso al Buprenofina y tomar más opioides pueden resultar en una sobredosis de opioides.

No debe tomar ningún otro medicamento sin antes consultarlo con su médico.

La combinación del Buprenorfina con bebidas alcohólicas u otros medicamentos puede ser peligrosa. La combinación del Buprenorfina con medicamentos como el Klonopin, Valium, Haldol, Librium y Ativan han causado la muerte.

La composición del Buprenorfina (Suboxone) que tomará es una combinación de Buprenorfina con un bloqueador del opioide de rápida acción (Naloxone). Si la tableta de Suboxone estuviere disuelta e inyectada por alguna persona que estuviere inyectándose heroína o cualquier otro opioide fuerte (i.e., Morfina), causaría grave retirada de opioide (grave "withdrawal").

Las tabletas de Buprenorfina **tienen** que colocarse bajo la lengua hasta que estén completamente disueltas, el estómago no absorberá las tabletas si se traga la Buprenorfina.

_____	_____	_____
Nombre en letra de molde	Firma	Fecha

_____	_____
Testigo	Fecha

APPENDIX 8E: CONSENT FOR PARENTAL NOTIFICATION

Consent for Parental Notification

The Boston Medical Center Office Based Addiction Treatment Program (OBAT) has a policy for patients under 25 years of age that requires that OBAT staff be permitted to contact parents/guardians of the patient. We feel that it is important that we be able to contact your parents or guardian in the event that changes to your treatment are needed. Contact with parents/guardians might be warranted to report results of urine screens (positive or negative), if OBAT staff feel that more intensive treatment needs to be considered, or if we are concerned about a patient's safety. We will do everything we can to respect your confidentiality, but in the event that we feel you need intensified treatment, or you have a positive urine screen, or you are at risk of harming yourself or someone else, we are required to contact your parents or guardians.

OBAT staff feel that communicating with parents/guardians as needed is critical to our ability to provide you with safe and effective treatment. We feel that their support and involvement will be beneficial to you and to your success in your recovery.

The signature below certifies that I have given OBAT staff permission to contact my parents/guardians regarding my treatment here at Boston Medical Center.

_____

Print Name Sign name Date

_____

Witness Name Sign name Date

APPENDIX 9A: BUPRENORPHINE/NALOXONE TREATMENT AGREEMENT

Office Based Addiction Treatment Program
BUPRENORPHINE TREATMENT AGREEMENT

As a patient in the buprenorphine protocol for treatment of opioid use disorder, I freely and voluntarily agree to accept this treatment contract, 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. It is my responsibility to call the clinic if I will be late/early or need to reschedule my appointment.

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 my treatment plan will be adjusted accordingly.

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 may result in referral to a higher level of care or discharge.

I agree not to conduct any illegal, threatening, or disruptive activities in the clinic or on the hospital campus, this is grounds for immediate discharge.

I agree not to tamper with urine screens and if I do so, this may be grounds for discharge or result in a referral to a more intensive treatment program. I understand that it is best to be honest with my treatment team if I am struggling and understand the team is here to assist me in my treatment.

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. My medication should never be kept in public places, and should be out of the reach and site of children at all times. My medication should be kept in a labeled container that displays a prescription label.

I agree that if I obtain medication from any doctors, pharmacies, or other sources that I will inform my physician and/or OBAT nurse immediately.

I understand that mixing buprenorphine with other substances, especially those which can cause sedation such as benzodiazepines or alcohol can be dangerous. I understand that a number of deaths have been reported among persons mixing buprenorphine with sedating substances.

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 call back visits that include urine drug screens and medication counts. I understand that I need to have a working telephone contact. When called for random call backs, I need to respond within 24 hours by telephone, non-response to a call back is grounds for discharge from the OBAT clinic and referral to a higher level of care.

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 if I use other illicit substances or misuse medications, this issue will be addressed through changes in my treatment plan to assist me. If I continue to struggle with ongoing drug use this could be grounds for transfer to other more intense treatment options.

Positive urine screens for opioids will be evaluated by the treatment team, ongoing positives i.e., 2 positives in one month, or missed urines will prompt a team meeting to discuss a potential treatment change to more intense treatment.

Urine screens that are negative for buprenorphine will be evaluated by the team and toxicology, and are grounds for intensification of my treatment plan, transfer to another level of care, or discharge.

BMC OBAT will periodically access the State Prescription Monitoring Program (PMP) to review medication profiles on all patients to assure patients are not receiving controlled substances from other providers. If patients are found to be accessing prescriptions from other providers, this finding will be reviewed by the OBAT team. If it is determined that the medications obtained by any other providers are in violation of the treatment agreement, the OBAT Team will evaluate the situation, address it with me, and it may result in discharge.

I understand that the Boston Medical Center Office Based Addiction Treatment 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 BMC does not have a chain of custody over the urines, the purpose of these tests are for my treatment at BMC only. If patients have legal or program requirements that require observed urine toxicology testing, this should be done independent of your treatment at BMC.

If I am female and of child bearing age it is strongly recommended that I utilize contraceptives while on treatment. If I become pregnant while on buprenorphine/naloxone I will alert my health provider immediately so they can assist me in the proper steps and treatment to keep me and my unborn baby safe. This does not mean I will be discharged from treatment, however it may require a change to the "Subutex" tablet which only has buprenorphine.

If at any time I am discharged from this program I may be reconsidered at a future time.

I understand that medication alone is not sufficient treatment for my disease, and I agree to participate in the patient education, addiction 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 medical record. These notes will be visible to any healthcare professional involved in my care at Boston Medical Center. The healthcare providers will only access your medical record if they are involved in your care.

_____	_____	_____
Printed Name	Signature	Date
_____	_____	_____
Witness	Signature	Date

APPENDIX 9B: SPANISH BUPRENORPHINE/NALOXONE TREATMENT AGREEMENT (CONTRATO DE TRATAMIENTO CON BUPRENORFINA)

PROGRAMA PARA TRATAMIENTO CONTRA ADICCIONES EN EL CONSULTORIO MÉDICO (OBAT)

Office Based Addiction Treatment (OBAT) Program

CONTRATO DE TRATAMIENTO CON BUPRENORFINA

Yo, como paciente en el protocolo buprenorfina para el tratamiento de adicción y abuso de los opioides, he acordado libre y voluntariamente aceptar el Contrato de tratamiento con las siguientes cláusulas:

Acepto: asistir, y ser puntual, a todas mis consultas fijadas con mi médico y la enfermera, y ser cortés en la clínica. Es mi responsabilidad llamar a la clínica si llegaré tarde/temprano o si necesito cambiar mi cita.

Acepto: no llegar intoxicado a la clínica o bajo la influencia de narcóticos. En caso contrario, no seré recibido por el médico, ni me será recetado ningún medicamento hasta la próxima cita fijada.

Acepto: no vender, compartir ni dar cualquiera de mis medicamentos a otra persona. Comprendo que la mala administración de mis medicamentos presenta una seria violación al presente contrato, lo cual resultará en referirme a programa de tratamiento más controlado o la terminación del tratamiento sin derecho a apelación.

Acepto: no distribuir, robar, ni realizar ninguna otra actividad ilegal o prejudicial en la clínica y en el hospital o seré dado de alta de inmediato.

Acuerdo: no falsificar los exámenes de orina; en caso contrario, esto será motivo para descontinuar inmediatamente este tratamiento y referirme a un programa de tratamiento más exhaustivo/controlado. Entiendo que es mejor ser honesto con mi equipo de tratamiento y si estoy luchando, entiendo que el equipo está disponible para ayudarme en mi tratamiento.

Acepto: que mis recetas médicos podrán ser entregados, únicamente, en mis horarios regularmente fijados. La falta a las consultas puede resultar en la imposibilidad de obtener medicamentos hasta la próxima consulta fijada.

Acepto: que soy responsable por el medicamento que recibo y que deberé guardarlo en un lugar seguro. Acepto, igualmente, que los medicamentos extraviados no podrán ser reemplazados, sea cual sea la causa de dicho extravío. Mis medicamentos nunca deben ser guardados en lugares públicos y deben ser guardados lejos del alcance de los niños en todo momento. Mi medicamento debe ser guardado en su botella que muestre el sello con la información de la receta.

Acuerdo: que si obtuviere algún medicamento de otros médicos, farmacias u otras fuentes, deberé informar a mi médico o a la enfermera.

Comprendo que mezclar buprenorfina con otros medicamentos, especialmente con benzodiazepinas como Klonopin y otras drogas puede ser peligroso. Entiendo que ha sido reportado un gran número de muertes de personas que mezclaron buprenorfina con benzodiazepinas.

Acuerdo: tomar los medicamentos como me lo ha indicado el médico, y a no alterar la forma como tomo mis medicinas sin primero consultar con mi médico o la enfermera.

Acepto: visitas para realizar exámenes de orina y a conteos de tabletas al azar. Entiendo que necesito tener un contacto telefónico que funcione. Cuando me llamen al azar, necesito responder en o antes de 24 horas ya que no responder es motivo para darme de alta de la clínica OBAT y para un referido a un nivel de tratamiento más intensivo. Las llamadas no respondidas serán consideradas igual que haber obtenido un examen de orina positivo.

Acuerdo: **no** consumir semillas de amapola mientras dure dicho tratamiento. No se aceptará el consumo de semillas de amapola como una disculpa por el examen de opioides que arroje resultado positivo.

Entiendo que, si decido abusar de otras sustancias ilícitas, dicho asunto será tratado con cambios en el plan de mi tratamiento a fin de ayudarme a enfrentar esta situación. Si continúo luchando por el uso de las drogas, esto será motivo para pasarme a otras opciones de tratamientos más exhaustivos.

Los exámenes de orina que salgan con resultado positivos como consecuencia de los opioides, serán evaluados por el equipo del tratamiento, los exámenes positivos en proceso, i.e., 2 positivos, o los exámenes de orina que no se realicen en un mes serán motivo para darme de alta y pasarme a otras opciones de otros tratamientos más exhaustivos.

Los análisis de orina que son negativas para la buprenorfina serán evaluados y positivos para toxicología son motivos para el traslado a otro nivel de atención o para ser dado de alta.

BMC OBAT periodicamente va a acceder a la sistema estatal de monitoreo de recetas (State Prescription Monitoring Program, o PMP, por sus siglas en inglés) para asegurarse que los pacientes no estén recibiendo otra sustancias controladas de otros proveedores. Si se encuentra que los pacientes accesan recetas de otros proveedores, este resultado será revisado por el equipo de OBAT. Se determina que los medicamentos obtenidos por proveedores fuera del equipo de OBAT constituyen una violación al acuerdo de tratamiento, e equipo de OBAT evaluará la situación y podría resultar en ser dado de alta del Programa BMC OBAT.

Yo entiendo que el Programa de Tratamiento contra Adicciones en el Consultorio Médico, OBAT, por sus siglas en inglés) de Boston Medical Center no dará a conocer los resultados de mis análisis de toxicología en orina a ninguna otra agencia, programa o institución. La razón de esta política es que BMC no tiene una cadena de custodia de las muestras de orina y el propósito de estas pruebas es para mi tratamiento en BMC solamente. Si los pacientes tienen obligación legal o están en un programa que requiere toxicologías de orina monitoreadas, esto debe hacerse independiente de su tratamiento en el BMC.

Si soy del sexo femenino y en edad para tener hijos (edad reproductiva) es muy recomendable que utilice anticonceptivos durante la administración de buprenorfina/ naloxone. Tengo que avisar a mi profesional de salud inmediatamente para que así me pueda ayudar en los pasos adecuados y el tratamiento para mantenerme a mí y a mi bebé sanos.

Si, en cualquier momento, me dan de alta de este tratamiento, se reconsiderará si el procedimiento en el consultorio médico es la mejor opción para mí en el futuro.

Entiendo que el tratamiento, sólo con la administración de medicamentos, no es suficiente para mi enfermedad, y acepto participar en los programas de educación para el paciente, terapias para prevenir el abuso de sustancias y prevención a una recaída para que me ayuden en mi tratamiento según me sean ofrecidos.

Entiendo que mi historial, tratamiento e informes médicos serán guardados en los bajo un sistema cerrado de archivos electrónicos confidenciales. Cualquier profesional de la salud que esté participando en mi asistencia médica podrá accesar a estas anotaciones.

_____	_____	_____
Nombre en letra de molde	Firma	Fecha
_____	_____	_____
Testigo	Firma	Fecha

APPENDIX 10A: TREATMENT PROGRAM REQUIREMENTS

Treatment Program Requirements:

- Patients must keep their scheduled appointments with their OBAT provider.
- Refills will occur at the time of your follow up appointment with the OBAT nurse or provider.
- If an emergency or a schedule change creates a conflict with these appointments patients need to contact the OBAT Clinic at 617-414-4107 as soon as possible to address the situation and reschedule the appointment.
- Patients are required to keep the OBAT clinic updated on all phones numbers and ways to be contacted.
- An OBAT Clinic RN may call patients for random callbacks and patients must respond by phone within 24 hours of a call and be prepared to come in within 48 hours of a call. If a patient does not respond to a call back this will be considered as positive urine and a violation of the treatment contract.
- Two to three positive urine screens for opioids in a one month period is grounds for revision of the treatment plan including referral to more structured treatment options.
- Ongoing struggles with other substances will require a restructured treatment plan including referral to a higher level of care.
- The OBAT clinic must have the name and number of the pharmacy that the patient is using. This information will be kept on file.
- If there are any changes in medications or medical issues including: surgery, medications, hospitalizations, or problems with your OBAT prescription please contact the OBAT nurse at 617-414-4107

APPENDIX 10B: CLINICAL APPOINTMENT POLICY

Clinical Appointment Policy:

- All patients who participate in the Boston Medical Center Office Based Addiction Treatment (OBAT) program are required to keep all appointments with their primary care providers, OBAT providers, and OBAT nurses. These appointments are critical to the continuation of care.

- Patients are expected to keep all scheduled appointments. If an appointment cannot be kept, it is the patient's responsibility to reschedule the appointment.

- Appointments with the OBAT team are part of the treatment plan. Should these appointments need to be rescheduled it is the patient's responsibility to do so. These include appointments with nursing, project coordinator, counseling and or groups. This does not include random callbacks, please see policy under random call backs.

- Patients are expected to arrive on time for all scheduled appointments. Appointments with providers may need to be rescheduled if patients arrive late.

- Patients are required to see their OBAT provider at least once every 3-4 months and more frequent if needed per provider, or other medical staff.

- If patients do not show up for medical appointments with their OBAT provider and do not call to inform OBAT staff that they are unable to make the appointment, or arrange for rescheduling, the treatment plan will be revised accordingly.

    - Buprenorphine/Naloxone: Initially prescriptions will return to weekly with weekly visits until seen by the provider. If patients continually miss OBAT prescriber appointments and they exceed the four-month visit timeframe, then buprenorphine-naloxone prescriptions may be held until the patient is seen for an office visit by an OBAT provider.

    - Naltrexone: Consider naltrexone oral tablets vs. extended-release injection until adherence to treatment plan occurs including attendance at clinic appointments

APPENDIX 10C: COUNSELING POLICY

Counseling Policy:

Patients of the Boston Medical Center Office Based Addiction Treatment (OBAT) program are strongly encouraged to engage in counseling and/or similar intensive recovery support through outside programs. If needed patients should receive assistance with referrals and linkages for counseling and recovery support services from OBAT staff. Patients are encouraged to attend a minimum of twice monthly counseling visits for the first 12 weeks of treatment. *Patients should not be discharged from the OBAT Program if they do not comply with this recommendation.* However, patients who do not engage in counseling or outside recovery support services should continue to receive more intensive monitoring from the OBAT team. It is not recommended to discharge patients from care who are not engaged in outside counseling/recovery support services as these individuals may be at increased risk of relapse.

- Patients will agree to sign consent to release information so that OBAT program staff can communicate with the patient's entire care management team, including those providing outside counseling and recovery support.
- Patients are strongly encouraged to go to weekly or twice monthly counseling (or per the recommendations of the counselor).
- Patients will be expected to discuss their engagement in counseling and other outside recovery services with the OBAT team.
- Groups, IOP's (Intense Outpatient Programs), Residential, and Halfway houses are methods of treatment that are accepted as counseling.
- If an individual's counselor or other medical provider recommends that the patient seeks psychiatric evaluation then the patient is required to follow through with this and the decided upon plan of treatment.
- Role of counseling:
  - Educate patient at the onset and ongoing about the importance of adjunct counseling and recovery support and its role. Reinforce that medication alone rarely addresses all aspects of recovery and building recovery capital will improve their chances of success.
  - Educate patients that at the start of treatment, weekly counseling, in the form of either one-on-one or in a group format is strongly encouraged. Patients are welcome to participate in counseling specific to buprenorphine/naloxone or naltrexone, as they may find it helpful to discuss their treatment openly with others who are engaged in the same treatment.

- The role of self-help peer-support groups

  - Remind patients that recovery is a process that will take a lot of time and commitment. Attending peer-support groups may not be the right treatment modality for them at the start of treatment but something that they may choose later on. They may also decide that peer-support groups are not helpful and prefer other recovery support options. It is important that the patient is empowered and given options.

  - AA, NA and SMART Recovery are examples of self-help treatment options

  - Encourage patients to attend meetings and to keep going, to try different meetings if one does not feel like it "fits." Encourage patients not to have high expectations, not to focus on what everyone else is or is not doing, to "take what they need and leave the rest." Remind patients that it often takes some time to build a connection and establish a sense of belonging.

  - Encourage patients to join a home group, to get involved in the meetings (set up, clean up, make the coffee, etc.).

  - For some patients, getting a sponsor, or forming a healthy relationship with another person in recovery, may be a goal they work toward. Patients often report feeling that making this connection is an important piece in one's recovery process.

- Hand out AA, NA, SMART Recovery and other meeting books to patients. Assist patients by highlighting some meetings near their work or home at hours that are convenient for them. Contract with them to try a certain number between now and your next visit.

- Provide patients with websites for NA, AA, Smart Recovery, Emotional Recovery, Online meetings.

APPENDIX 10D: BEHAVIOR POLICY

Behavior Policy:

As a patient at the Boston Medical Center Office Based Addiction Treatment (OBAT) program, you have made a voluntary decision to participate in this program. We seek to provide an optimum treatment environment for all patients, therefore, patients are expected to maintain appropriate behaviors such as:

- Not coming to clinic intoxicated or under the influence of drugs.
- No dealing of drugs, stealing, or any other illegal or disruptive activities in the clinic environment, or on hospital grounds.
- No tampering with or falsifying urine toxicology tests.
- No disruptive behavior i.e., loud, aggressive behavior, etc. will be tolerated in the clinic.
- No verbal or physical threats towards anyone including: OBAT staff, clerical, pharmacy, other patients, etc of any kind will be tolerated. Should this behavior occur it is grounds for immediate discharge from the program.
- No possession or use of guns, knives, mace or harmful objects.

APPENDIX 10E. RANDOM CALLBACK POLICY

Random Callback Policy

- To monitor and verify the proper use of the buprenorphine/naloxone we are prescribing, the OBAT nurse will call the patient sporadically to come in to the clinic for a random urine toxicology test and a medication count.

- The patient must return this call promptly, and must come to the clinic within 24 hours of the initial call with the medicine bottle and all of the remaining buprenorphine/naloxone pills or films.

- The patient may be asked to do an observed dose in the clinic observed by the OBAT nurse or provider to further assess adherence.

- For this policy to function, the patient must ensure that we have current and accurate contact information.

- It is the patient's responsibility to tell the OBAT nurse immediately if there are any changes to this information.

- If the patient fails to return for a monitoring visit the OBAT Team will meet and reassess the treatment plan with adjustments such as: shorter times between office visits, shorter prescriptions, no refills, etc.

APPENDIX 10F: MEDICATION ADMINISTRATION POLICY

Medication Administration Policy: Buprenorphine/Naloxone

All patients who participate in the Boston Medical Center Addiction Based Opioid Treatment program (OBAT) are required to follow the instructions of the OBAT Staff and your provider regarding your buprenorphine/naloxone prescription.

- Patients must take their buprenorphine/naloxone prescription as directed by the prescribing provider.
- Patients cannot take more of their prescription without first discussing this with an OBAT nurse.
- Once stabilized, you will receive a prescription with refills.
- Buprenorphine/naloxone is a controlled substance, therefore prescriptions should be filled on the scheduled fill date. Buprenorphine/naloxone cannot be refilled more than 2 days early.
- Patients are required to have an identified pharmacy that is kept on file by the OBAT team, should you change the pharmacy, the OBAT team must be notified. Appropriate release should be signed by the patient and kept on file.
- Refills will be canceled if patients do not return for scheduled visits or when randomly requested.
- Patients are required to find a safe place to store the medication where it will not be lost, stolen or destroyed.
- It is strongly advised that patients do not carry the buprenorphine/naloxone on their person, keep it in a vehicle, or bring to work, etc. as it is a controlled medication and cannot be refilled more than two days prior to scheduled date. Reports of lost/stolen/destroyed medication require a team consult.
- The OBAT team expects that patients will inform their other providers (therapists, counselors, physicians, etc.) that they are taking buprenorphine/naloxone and that they are in treatment here at Boston Medical Center.
- Any time a patient is prescribed any other medication they need to contact the OBAT team and inform them of the new medication.
- It is strongly advised that patients carry the emergency identification card on buprenorphine/naloxone on their person, and give this card to a provider should they have the need for medical treatment.

- Patients are also expected to disclose to OBAT staff if they are being seen by other providers (pain management specialists, psychiatrists, counselors, physicians, etc.) and whether they have been prescribed medications by these providers.

APPENDIX 10G: URINE TOXICOLOGY POLICY

Urine Toxicology Policy

- All belongings (coats, bags, etc.) are left in the office of the medical assistant or outside the bathroom door.
- No washing hands until the urine sample is handed to the Medical Assistant in a bio-hazardous bag.
- No flushing toilet until urine sample is handed to the gloved Medical Assistant.
- Urine samples will be required at each visit.
- Clinic policy: any questionable urine is an automatic repeat the same day.
- Random observed urines can be conducted by same sex personnel in extreme situations, however this is not routine. Oral swabs may be utilized in place of observed urines. If it becomes necessary to do observed urines the patient may be referred out to a chain of custody location for urine screening or to a higher level of care.

Any urine sample that is questionable

- Patient will be asked to repeat urine immediately.
- Counseled by the OBAT NCM about the importance of UTS monitoring and honesty in treatment to ensure that the team has the ability to provide appropriate treatment. Reinforce that the OBAT team is here to help if the patient is struggling.
- Patient is told that tampering may be grounds for referral to a higher level of care.
- Patients will receive a buprenorphine/naloxone prescription refill, naltrexone prescription or extended-release naltrexone injection when an acceptable urine is obtained.

APPENDIX 11A: PATIENT HANDOUT: BUPRENORPHINE HIGH RISK PREGNANCY PROGRAM

Buprenorphine is emerging as a safe alternative to Methadone in pregnancy

Preliminary data on Buprenorphine's use during pregnancy (22 published studies) suggest a trend toward maternal and neonatal benefit

The Physician's Clinical Support System (PCSS) **Guidance for Buprenorphine prescribers recommends Buprenorphine mono-therapy, *Subutex*, only during pregnancy**

Due to the potential ***street value of Subutex***, treatment during pregnancy requires frequent visits, short prescription intervals and close urine toxicology monitoring

PCSS recommends pregnant women on Buprenorphine be followed by high-risk obstetricians knowledgeable in opioid addiction and neonatal withdrawal

Do you have patients who meet these criteria?

- 18 years or older
- History of opioid addiction
- Positive urine pregnancy test
- Interested in Subutex treatment
- On Suboxone Maintenance

Boston Medical Center's Subutex in Pregnancy Program provides

- High Risk Obstetrical Care with three full-time obstetricians trained in addiction in pregnancy
- Full-time Nurse Care Manager specializing in Subutex in pregnancy
- Weekly On-Site Group Counseling Services conducted by LCSW experienced in addiction medicine
- On-Site Psychiatric Services coordinated with prenatal visits for patients with psychiatric co-morbidities
- Believe Project Birth Sister Program Peer support for recovery, pregnancy, labor and parenting

Please contact:

Maureen Sullivan, RN
OB/GYN Associates
Boston Medical Center
617-414-5076

STATE OBOT Hot-Line
617-414-6926

Colleen LaBelle, RN. CARN
State Program Director
1-617-414-7453

References

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Johnson, et al. Use of buprenorphine in pregnancy: patient management and effects on the neonate. Drug and Alcohol Dependence (70), 2003

Jones, et al. Buprenorphine verses methadone in the treatment of pregnant opioid-dependent patients: effects on the neonatal abstinence syndrome. Drug and Alcohol Dependence. 2005

Lacroix, et al. Buprenorphine in pregnant opioid-dependent women: first results of a prospective study. Addiction (99), 2004

Schindler, et al. Neonatal outcome following buprenorphine maintenance during conception and throughout pregnancy. Addiction (98). 2003

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www.bmc.org

Kelley Saia, RN, M.D. and Maureen Sullivan, RN
Boston Medical Center
OB/GYN Associates
2008
617-414-5076

APPENDIX 11B: PATIENT HANDOUT: BREASTFEEDING AND METHADONE MAINTENANCE

Boston Medical Center's Breastfeeding Program

The BMC team will support and encourage women who are interested in breastfeeding and have had negative urine toxicology screens for at least 4 weeks prior to delivery.

While your infant is in the hospital, you will be asked to give a urine specimen *every* **Monday** and **Thursday** from: **1-3pm in the Women's Center**

For details of this program protocol, ask your doctor or nurse

BREASTFEEDING AND METHADONE MAINTENANCE

BENEFITS OF BREASTFEEDING

Breast milk is an ideal source of nutrition for your infant because of its many health benefits.

It contains healthy cells, antibodies, and a high concentration of good bacteria to ***protect infants*** from harmful bacteria.

Breastfeeding has been shown to decrease the risk of ***ear infections, respiratory infections, gastro-intestinal illness*** and possibly decrease SIDS and diabetes.

The act of breastfeeding has also been shown to help mothers and their infants bond together in the first few months of life.

SAFETY OF BREASTFEEDING WITH METHADONE

According to the American Academy of Pediatrics, it is ***safe to breastfeed*** while taking methadone.

Many studies have been done to examine the safety of methadone in breastfeeding.

Less than **1%** *of your daily dose of methadone is transferred to your infant through breast milk*

The amount of methadone in your baby's bloodstream after breastfeeding is almost undetectable

Levels of methadone in your milk are highest in the first 6 hours after your dose of methadone

HEPATITIS C

If you have Hepatitis C (HCV), it is safe to breastfeed.

The Center for Disease Control and the American Academy of Pediatrics support the safety of breastfeeding with HCV

However, if you have HCV and your nipples are cracked or bleeding you should* NOT *breastfeed.

REASONS NOT TO BREASTFEED

You should NOT breastfeed if you have:
- HIV
- Tuberculosis
- Relapsed on drugs

If you relapse, you should give your baby formula or breast milk that you have previously pumped and refrigerated.

RESOURCES

La Leche League International
http://www.lalecheleague.org/nb.html

American Academy of Pediatrics
www.aap.org/healthtopics/breastfeeding.cfm

American Academy of Family Physicians
http://www.aafp.org/afp/20010915/991ph.html

Department of Health and Human Services
Centers for Disease Control and Prevention
http://www.cdc.gov/breastfeeding/

National Women's Health
Information Center
http://www.4women.gov/Breastfeeding
http://www.womenshealth.gov

National Breastfeeding Helpline
Phone: 1-800-994-9662
Hours: Mon-Fri 9am-6pm

Substance Abuse &
Mental Health Services Administration
http://www.samhsa.gov

National Drug and Alcohol Treatment
Referral Routing Service and Center
for Substance Abuse Treatment
Phone: 1-800-662-HELP (4357)

BMC Women's Center
1-617-414-4165

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Geraghty et al. Methadone Levels in Breast Milk. Journal of Human Lactation, 1997; 13: 227-230.

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Begg et al. Distribution of R- and S-methadone into human milk during multiple, medium to high oral dosing. British Journal of Clinical Pharmacology, 2001; 52: 681-685.

Philipp et al. Methadone and Breastfeeding: New Horizons. Pediatrics. 200

BOSTON MEDICAL CENTER
www.bmc.org

This resource is for informational purposes only and is not a substitute for professional medical or health advice, examination, diagnosis, or treatment. Please see your doctor if you have any additional questions.

Kathleen Hong and Kelley Saia,
Department of OB/GYN, 2007

APPENDIX 11C: PATIENT HANDOUT: PEDIATRIC EXPOSURE TO BUPRENORPHINE/ NALOXONE

Protecting Others and Protecting Treatment

KEEPING BUPRENORPHINE* SAFE AND AWAY FROM CHILDREN

REGIONAL CENTER FOR POISON CONTROL AND PREVENTION

Serving Massachusetts and Rhode Island

1-800-222-1222

*Some of the brand names are Suboxone, Subutex, Bunavail, Zubsolv

APPENDIX 11D: PATIENT HANDOUT: OVERDOSE EDUCATION

1 Know the Signs of Overdose. Save a Life.

Signs of opioid overdose may include:

- Breathing that is slow or shallow — or no breathing at all
- Very sleepy and not responding to your voice or touch
- Blue or grayish skin color, with dark lips and fingernails
- Snoring or gurgling sounds

If there are symptoms of an overdose:

- Tap, shake, and shout at the person to get a response
- If there is still no response, rub knuckles on the breast bone
- If no or little response, call 911

Opioids include: heroin, codeine, fentanyl, hydrocodone (i.e. Vicodin), hydromorphone, morphine, oxycodone (i.e. OxyContin, Percocet), etc.

2 Call 9-1-1. An Overdose Is a Medical Emergency.

An opioid overdose can cause a coma or death within minutes. A medication called naloxone (Narcan) can reverse an overdose and save a life.

When you call 9-1-1:

- Give the address
- Tell them it's an overdose so they can bring naloxone (Narcan). Or say, "My friend is not breathing."
- Stay with the person. The 9-1-1 Good Samaritan law provides protection from arrest and prosecution for drug possession.

While you wait for the ambulance:

- Do rescue breathing.
- Give naloxone (Narcan) if you have it.
- If you have to leave the person for any amount of time, place the person on their side.

Tell the ambulance staff anything you can about any alcohol or drugs the person has taken. If you cannot stay, leave a note with the information.

3 Do Rescue Breathing if Breathing Is Slowed or Stopped.

1 Make sure nothing is in the mouth.

2 Tilt head back, lift chin, pinch nose.

3 Breathe in mouth once every 5 seconds.

Get Treatment. There is Hope.

You are not alone. The following resources can help you find substance abuse treatment, prevention services, and information.

MA Department of Public Health
Bureau of Substance Abuse Services

Massachusetts Substance Abuse Information and Education Helpline

- Free and confidential information and referrals to public and private treatment programs
- Health insurance may not be required
- Translation available in 140 languages

Toll free 1-800-327-5050
Staffed 7 days a week
TTY: Use MassRelay at 711 or 1-800-720-3480
www.helpline-online.com

Massachusetts Health Promotion Clearinghouse

- Resources on prevention and treatment.

(Toll free) 1-800-952-6637
TTY: Use MassRelay at 711 or 1-800-720-3480
www.mass.gov/maclearinghouse

Massachusetts Overdose Prevention Resources

- Free and confidential training on preventing, recognizing, and responding to overdose is available. Training includes rescue breathing and how to use naloxone (Narcan).
- Naloxone (Narcan) is available at specific locations statewide. It is also available at many pharmacies. Ask your pharmacist.
- To find a naloxone (Narcan) site near you call:

Toll free 1-800-327-5050
TTY: Use MassRelay at 711 or 1-800-720-3480
Help is available in over 140 languages.
www.helpline-online.com

For information about available overdose resources visit
www.mass.gov/dph/overdose

More information on other side

APPENDIX 12A: CLINICAL TOOLS: COWS SCALE

Opioid Withdrawal Record (Induction Form)

(Adapted from Clinical Opioid Withdrawal Scale)

Patient Name_____ **Treatment Start Date**_____

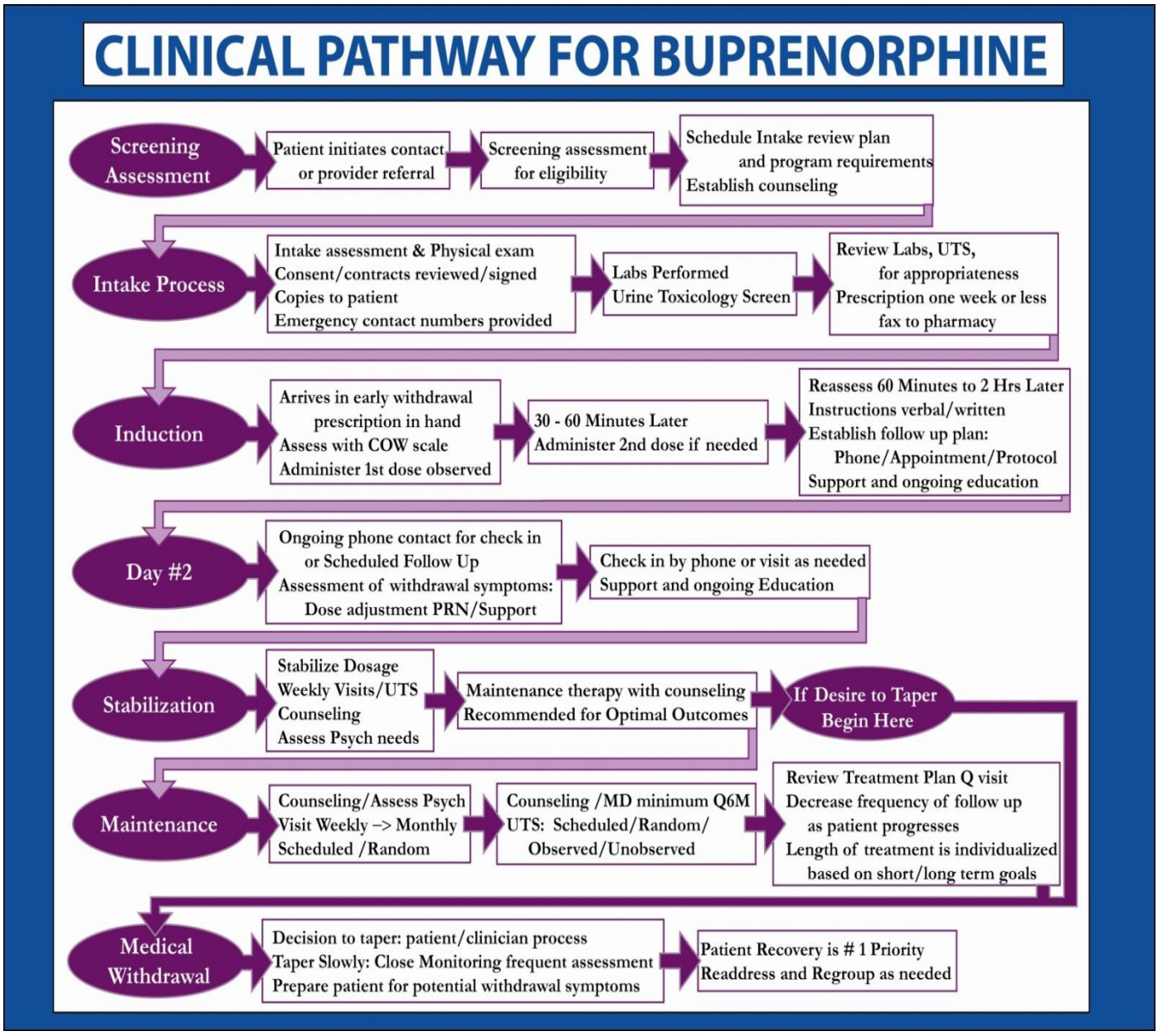
Circle the number/description which best corresponds to your patient's present symptoms

Parameter	**Baseline Observation** **Administer** 1st Dose _____mg Time given _____am/pm	**1st Dose Observation** _____min. after 1st dose	**1st Dose, 2nd Observation** (if needed) _____min. After 1st dose	**2nd dose** (if needed) _____mg Time given _____am/pm	**2nd Dose Observation** _____min. After 2nd dose
Resting pulse rate _____beats/min *Measure after patient is sitting lying for 1 minute* **0** pulse rate 80 or below **1** pulse rate 81-100 **2** pulse rate 101-120 **4** pulse rate greater than 120	**0 1 2 4**	**0 1 2 4**	**0 1 2 4**	**0 1 2 4**	**0 1 2 4**
Sweating *Over past 30 minutes; not accounted for by room temperature or patient activity* **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	**0 1 2 3 4**	**0 1 2 3 4**	**0 1 2 3 4**	**0 1 2 3 4**	**0 1 2 3 4**
Restlessness *Observation 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	**0 1 3 5**	**0 1 3 5**	**0 1 3 5**	**0 1 3 5**	**0 1 3 5**
Tremors *Observation of outstretched hands* **0** no tremor **1** tremor can be felt, but not observed **2** slight tremor observable **4** gross tremor or muscle twitching	**0 1 2 4**	**0 1 2 4**	**0 1 2 4**	**0 1 2 4**	**0 1 2 4**
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	**0 1 2 5**	**0 1 2 5**	**0 1 2 5**	**0 1 2 5**	**0 1 2 5**

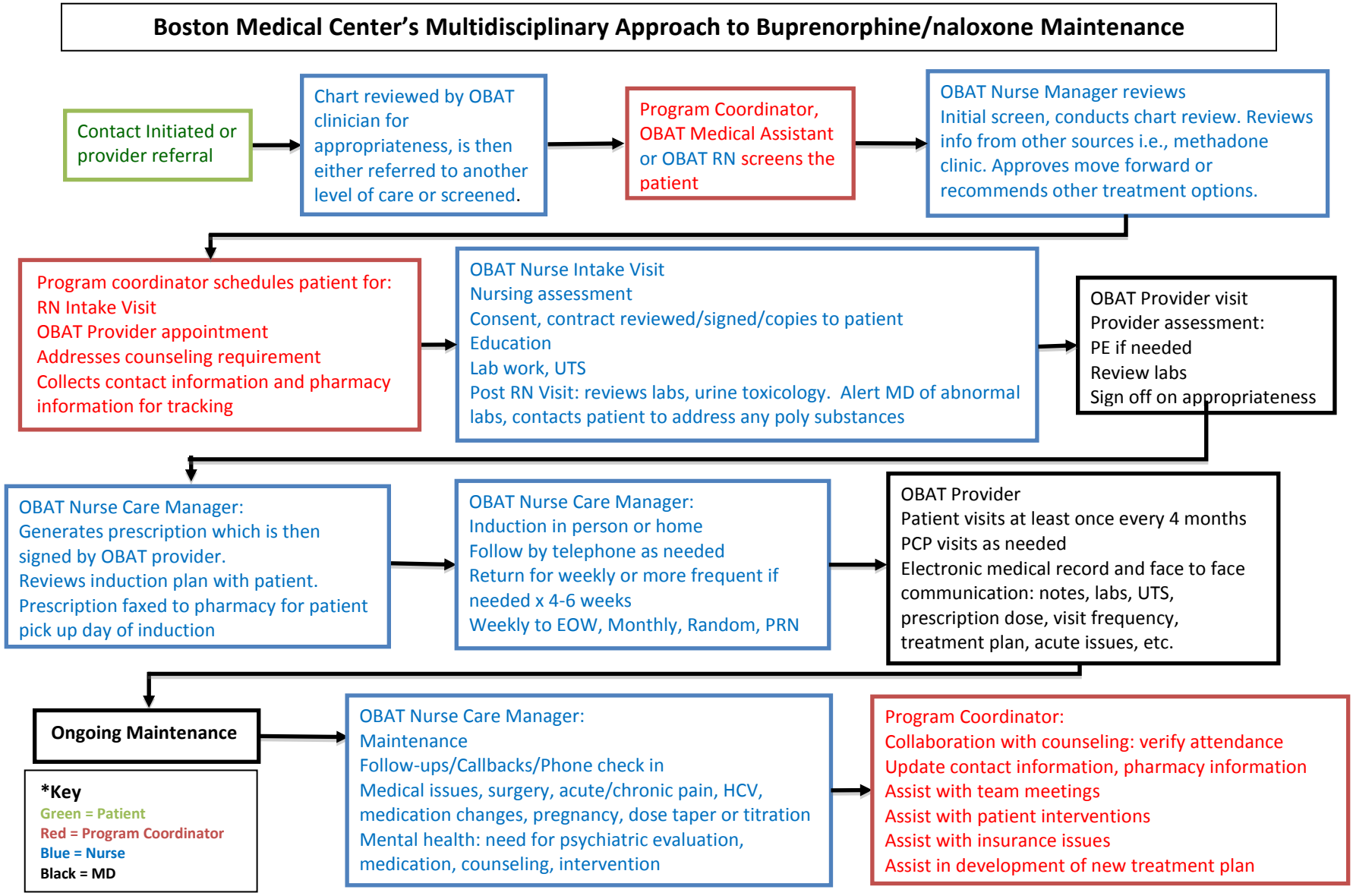
	Baseline Observation	1st Dose Observation	1st Dose, 2nd Observation	2nd Dose	2nd Dose Observation
GI upset *Over last 30 minutes* **0** no GI symptoms **1** stomach cramps **2** nausea or loose stool **3** vomiting or diarrhea **5** multiple episodes of diarrhea or vomiting	**0 1 2 3 5**	**0 1 2 3 5**	**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**
Total Score _____ Total score is the sum of all 11 items • 5-12 = mild • 13-24 = moderate • 25-36 = moderately severe • >36 = severe withdrawal	_____	_____	_____	_____	_____

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

APPENDIX 12B: CLINICAL TOOLS: CLINICAL PATHWAY



APPENDIX 12C: CLINICAL TOOLS: MULTIDISCIPLINARY APPROACH TO BUPRENORPHINE/ NALOXONE MAINTENANCE



APPENDIX 12 D: CLINICAL TOOLS: PHARMACOTHERAPY FOR OPIOID USE DISORDERS

Methadone	Buprenorphine/Naloxone or Buprenorphine	Naltrexone
Indications		
• OUD (DSM diagnosis) and patient meets Federal OTP Standards (42 C.F.R. §8.12)	• OUD (DSM diagnosis) • Willingness and stability to receive, store, and administer weekly supply of buprenorphine/naloxone	• OUD (DSM diagnosis) with: ➢ Prevention of relapse to opioid dependence/use, following opioid detoxification ➢ Treatment for alcohol use disorders ➢ Willingness and stability to receive monthly injections
Contraindications		
• Hypersensitivity	• Hypersensitivity • Chronic pain requiring opioid management beyond buprenorphine.	• Receiving opioid agonists • Physiologic opioid dependence • Failed naloxone challenge or naltrexone challenge test • Positive urine opioid screen • Acute Hepatitis or liver failure • Hypersensitivity • Advanced psychiatric disease, active suicide ideation • Breastfeeding - oral naltrexone has shown tumorigenicity in animal studies
Warnings/Precautions		

• Concurrent enrollment in another OTP
• Prolonged QTc interval
  • Use caution in patients with respiratory, liver, or renal insufficiency
  • Concurrent benzodiazepines or other CNS depressants including opioids and active AUD (potential respiratory depression
  • Use of opioid antagonists (e.g.,, parenteral naloxone, oral or parenteral nalmefene, naltrexone)
  • Pregnancy Category C
	• Buprenorphine/naloxone may precipitate withdrawal in patients on full agonist opioids
	• Use caution in patients with respiratory, liver, or renal insufficiency
	• Concurrent benzodiazepines or other CNS depressants, including opioids and active AUD (potential respiratory depression, overdose)
	• Use of opioid antagonists (e.g.,, parenteral naloxone, oral or parenteral nalmefene, naltrexone)
	• Pregnancy Category C
		• Active liver disease, cirrhosis
		• Moderate to severe renal insufficiency: unknown effects
		• Thrombocytopenia or coagulation disorders
		• Chronic and/or acute pain must be managed with non-opioids
		• Large body habitus
		• Vulnerability for fatal opioid overdose in case of relapse to opioids
		• Pregnancy Category C

Baseline Evaluation		
• Consider baseline electrocardiogram and physical examination for patients at risk for QT prolongation or arrhythmias • Toxicology screen	• Liver transaminases • Urine beta-HCG for females • Toxicology screen	• Liver transaminase levels <5x upper normal limits • CrCl (estimated or measured) 50 mL/min or greater • Ensure patient has adequate muscle mass for injection • Urine beta-HCG for females • Toxicology Screen
Dosage and Administration		
• Initial dose: 15-20 mg single dose, maximum 30 mg • Daily dose: Maximum 40 mg/day on first day • Usual dosage range for optimal effects: 60-120 mg/day • Titrate carefully, consider methadone's delayed cumulative effects • Administer orally in single dose • Individualize dosing regimens • Daily visits at OTP clinic, may receive take-home doses per clinic protocol.	Sublingual dosing: • Induction: Pt to present in mild-moderate withdrawal • Induction dose: 2-4mg initial dose, titrate per prescription instructions and/or or until withdrawal symptoms subside. • Typical Day 1 dose = 8mg • Day 2 -7: Take total dose equivalent from day 1 upon awakening. Check in with clinical team. May titrate up to 16mg. • Stabilization/maintenance: Target dose = 8-16mg (max 24mg daily) may be taken in single or bid dosing regimen. • weekly visits/prescriptions until stable, then biweekly, and eventually monthly or random callback basis	• To be administered after negative UTS and/or successful naltrexone/naloxone challenge. • Oral: 25-50mg by mouth daily • ER Injectable: 380 mg every 28 days by deep intramuscular gluteal injection • Alternate injection sites • Weekly visits until stable, then biweekly, may progress to clinic visits every 28 days occurring on the date of patient's extended-release naltrexone injection.

Alternative Dosing Schedules		
• Give in divided daily doses based on peak and trough levels that document rapid metabolism that justifies divided doses	• Divided dosing helpful for patients with chronic pain for dual effectiveness and avoidance of narcotic medications • Residential programs may require specific Sig	• Consider remaining on oral formulation for patients with coagulation disorders, thrombocytopenia or large body habitus
Dosing in Special Populations		
• Renal or hepatic impairment: Reduce dose • Elderly or debilitated: Reduce dose	• Hepatic impairment: Reduce dose • For concurrent chronic pain, consider dividing total daily dose into bid, tid, or qid daily administration	• Mild renal insufficiency (CrCl 50- 80 mL/min): No dosage adjustment necessary • Uncertain effects (no data) in moderate to severe renal insufficiency
Adverse Effects		
• Major: Respiratory depression, shock, cardiac arrest, prolongation of QTc interval on electrocardiogram and torsades de pointes ventricular tachycardia • Common: Lightheadedness, dizziness, sedation, nausea, vomiting, sweating, constipation, edema • Less common: Sexual dysfunction	• Major: Hepatitis, hepatic failure, respiratory depression (usually when misused intravenously or if combined with other CNS depressants) • Common: Headache, pain, abdominal pain, insomnia, nausea, vomiting, sweating, constipation • Sublingual buprenorphine/ naloxone film: Oral hypoesthesia, glossodynia, oral mucosal erythema	• Major: Eosinophilic pneumonia, depression, suicidality • Common: Injection-site reaction, injection site tenderness, injection site induration, nausea, abdominal pain, anorexia, headache, asthenia
Drug Interactions		

• Drugs that reduce serum methadone levels: Ascorbic acid, barbiturates, carbamazepine, ethanol (chronic use), interferon, phenytoin, rifampin, efavirenz, nevirapine, other antiretrovirals with CYP3A4 activity • Drugs that increase serum methadone level: Amitriptyline, atazanavir, atazanavir/ritonavir, cimetidine, delavirdine, diazepam, fluconazole, fluvoxamine, ketoconazole, voriconazole • Opioid antagonists may precipitate withdrawal	• Metabolized in the liver by Cytochrome P450 3A4 system • Drugs that reduce serum buprenorphine level: Ascorbic acid, barbiturates, interferon, carbamazepine, ethanol (chronic use), phenytoin, rifampin, efavirenz, nevirapine, other antiretrovirals with CYP3A4 activity • Drugs that increase serum buprenorphine level: Amitriptyline, atazanavir, atazanavir/ritonavir, cimetidine, delavirdine, diazepam, fluconazole, fluvoxamine, ketoconazole, voriconazole • Opioid partial agonist: Buprenorphine/naloxone or buprenorphine may precipitate opioid withdrawal • Opioid antagonists may precipitate withdrawal	• Opioid-containing medications, including over the counter preparations • Thioridazine (increased lethargy and somnolence)
Monitoring		
• Signs of respiratory and CNS depression • Frequent toxicology Screening	• Liver function tests prior to initiation and during therapy as needed • Frequent toxicology screening	• Repeat liver transaminase levels at 6 and 12 months and then every 12 months thereafter • Increase hepatic monitoring in cases of mild to moderate elevation (1 -5x normal limits). • Frequent toxicology Screening

Abbreviations: OUD: opioid use disorder; UTS: urine toxicology screening; Cmax: maximum concentration; CNS: central nervous system; CrCl: creatinine clearance; DSM: Diagnostic and Statistical Manual of Mental Disorders; HCG: human chorionic gonadotropin; m: meter(s); mg: milligram(s); min: minute(s); mL: milliliter(s)

Source: This chart was adapted from: Department of Veteran Affairs. The Management of Substance Use Disorders Work Group. (December 2015*). VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders.* Version 3.0-2015.

APPENDIX 12E: CLINICAL TOOLS: PHARMACOTHERAPY FOR ALCOHOL USE DISORDER

Naltrexone Oral	Naltrexone Injectable	Acamprosate	Disulfiram	Topiramate[1]	Gabapentin[1]
Indications					
AUD (DSM diagnosis) with: • Pretreatment abstinence not required but may improve response • Initial engagement in addiction-focused Medial Management and/or other recommended psychosocial intervention	AUD (DSM diagnosis) with: • Pretreatment abstinence not required but may improve response • Willingness to receive monthly injections • Difficulty adhering to an oral regimen • Initial engagement in addiction-focused Medial Management and/or other recommended psychosocial intervention	AUD (DSM diagnosis) with: • Abstinence at treatment initiation • Initial engagement in addiction-focused Medial Management and/or other recommended psychosocial intervention	AUD (DSM diagnosis) with: • Abstinence >12 hours and BAL=0 • Combined cocaine dependence • Previous response to disulfiram • Capacity to appreciate risks and benefits and to consent to treatment • Initial engagement in addiction-focused Medial Management and/or other recommended psychosocial intervention • Note: More effective with monitored administration (e.g., in clinic, with spouse, with probation officer)	AUD (DSM diagnosis) (off label) with: • Pretreatment abstinence not required but may improve response • Initial engagement in addiction-focused Medial Management and/or other recommended psychosocial intervention	AUD (DSM diagnosis) (off label) with: • Pretreatment abstinence not required but may improve response • Initial engagement in addiction-focused Medial Management and/or other recommended psychosocial intervention

Naltrexone Oral	Naltrexone Injectable	Acamprosate	Disulfiram	Topiramate[1]	Gabapentin[1]
Contraindications					
• Receiving opioid agonists • Physiologic opioid dependence with use within past 7 days • Acute opioid withdrawal • Failed naloxone/ naltrexone challenge test • Positive urine opioid screen • Acute Hepatitis or liver failure • Hypersensitivity	• Receiving opioid agonists • Physiologic opioid dependence with use within past 7 days • Acute opioid withdrawal • Failed naloxone/ naltrexone challenge test • Positive urine opioid screen • Acute Hepatitis or liver failure • Hypersensitivity • Inadequate muscle mass or body habitus too large for supplied injection needles	• Hypersensitivity • Severe renal insufficiency (CrCl ≤30 mL/min)	• Severe cardiovascular, respiratory, or renal disease • Severe hepatic dysfunction (i.e.,, transaminase levels >3 times upper limit of normal or abnormal bilirubin) • Severe psychiatric disorders, especially psychotic and cognitive disorders and suicidal ideation • Poor impulse control • Metronidazole or ketoconazole therapy which already induce a similar reaction to alcohol • Hypersensitivity	• No contraindications in manufacturer's labeling	• Hypersensitivity • History of misuse

Naltrexone Oral	Naltrexone Injectable	Acamprosate	Disulfiram	Topiramate[1]	Gabapentin[1]
Warnings/Precautions					
• Active liver disease • Severe renal failure • Breastfeeding – not advised, proven teratogenicity in animal studies • Acute/Chronic pain • Hx severe depression, acute psychiatric illness • Pregnancy Category C	• Active liver disease • Uncertain effects (no data) in moderate to severe renal insufficiency • Injection site reactions • Use intramuscular injections with caution in patients with thrombocyto-penia or coagulation disorders • Acute/Chronic pain • Breastfeeding – not advised • Hx severe depression, acute psychiatric illness • Pregnancy Category C	• Monitor for emergence of depression or suicidality • Reduce dose in patients with renal insufficiency, including elderly • Pregnancy Category C	• Alcohol-disulfiram reaction; patients must be vigilant to avoid alcohol in all forms including mouthwash, over the counter medications, etc. • Pregnancy Category C	• Do not abruptly discontinue therapy; taper dosage gradually • Cognitive dysfunction, psychiatric disturbances, and sedation may occur with use • Increased risk of suicidal ideation with antiepileptic agents, including topiramate • Pregnancy Category C	• Do not abruptly discontinue therapy; taper dosage gradually • May cause CNS depression including somnolence/ dizziness • Increased risk of suicidal ideation with antiepileptic agents, including gabapentin • Pregnancy Category C
Baseline Evaluation					
• Liver transaminase levels • Bilirubin within normal limits • Urine beta-HCG for females • Toxicology screen	• Liver transaminase levels • Bilirubin within normal limits • CrCl (estimated or measured) 50 mL/min or greater • Ensure patient has adequate muscle mass for injection • Urine beta-HCG for females • Toxicology screen	• CrCl (estimated or measured) • Urine beta-HCG for females	• Liver transaminase levels • Physical assessment • Psychiatric assessment • Electrocardiogram if indicated by history of cardiac disease • Verify abstinence with breath or BAL • Urine beta-HCG for females	• Assess renal function • Urine beta-HCG for females	• Assess renal function • Urine beta-HCG for females

Naltrexone Oral	Naltrexone Injectable	Acamprosate	Disulfiram	Topiramate[1]	Gabapentin[1]
Dosage and Administration					
• 50-100 mg orally 1 time daily	• 380 mg 1 time monthly by deep intramuscular injection	• 666 mg orally 3 times daily, preferably with meals	• 250 mg orally 1 time daily (range, 125-500 mg daily)	• Titrate up gradually over several weeks to minimize side effects • Initiate at 50 mg/day; increase to a maximum dose of 100 mg 2 times daily	• Titrate up gradually to minimize side effects • Initiate at 300 mg on day 1 and increase by 300 mg daily as tolerated to target of 1800 mg daily, administered in 3 divided doses
Alternative Dosing Schedules					
• 25 mg 1- or 2-time(s) daily with meals to reduce nausea, especially during the first week • 100 mg on Monday and Wednesday and 150 mg on Friday			• Reduce dose to 125 mg to reduce side effects • For monitored administration, consider giving 500 mg on Monday, Wednesday, and Friday	• Geriatric patients with CrCl <70 mL/min/1.73m^2 give initial dose of 25 mg/day followed by incremental increases of 25 mg at weekly intervals until an effective dose is reached	
Dosing in Special Populations					
• Hepatic or renal insufficiency: Use caution	• Mild renal insufficiency (CrCl 50-80 mL/min): No dosage adjustment necessary • Uncertain effects (no data) in moderate to severe renal insufficiency	• Moderate renal insufficiency (CrCl 30-50 mL/min): 333 mg 3 times daily • Do not administer to patients with severe renal insufficiency (CrCl ≤30 mL/min)		• CrCl <70 mL/minute/1.73m^2: Administer 50% dose and titrate more slowly • Dosage adjustment may be required in hepatic impairment	• Dosage must be adjusted for renal function, consider target dose <1800 mg daily when CrCl <60 mL/min

Naltrexone Oral	Naltrexone Injectable	Acamprosate	Disulfiram	Topiramate[1]	Gabapentin[1]
Adverse Effects					
• Common: Nausea • Other: Headache, dizziness, nervousness, fatigue, insomnia, vomiting, anxiety, somnolence	• Major: Eosinophilic pneumonia, depression, suicidality • Common: Injection-site reactions, injection site tenderness, injection site induration, nausea, headache, asthenia	• Major: Suicidality 2.4% (vs. 0.8% on placebo during the first year in clinical trials) • Common: Diarrhea (16%) • Other: Anxiety, asthenia, depression, insomnia	• Major: Hepatotoxicity, peripheral neuropathy, psychosis, delirium, severe disulfiram-ethanol reaction • Common: Somnolence, metallic taste, headache	• CNS: Paresthesia, nervousness, fatigue, ataxia, drowsiness, lack of concentration, memory impairment, confusion • Gastrointestinal: Abdominal pain, anorexia	• CNS: Dizziness, drowsiness, ataxia, fatigue • Gastrointestinal: Diarrhea, nausea/vomiting, abdominal pain
Drug Interactions					
• Opioid-containing medications, including over the counter preparations • Thioridazine (increased lethargy and somnolence)	• Opioid-containing medications, including over the counter preparations • Thioridazine (increased lethargy and somnolence)	• Naltrexone: 33% increase in Cmax of acamprosate (no dosage adjustment is recommended) • Antidepressants: Weight gain and weight loss more common than with either medication alone	• Alcohol containing medications, including over the counter preparations • Drug-drug interactions may occur with phenytoin, warfarin, isoniazid, rifampin, diazepam, chlordiazepoxide, imipramine, desipramine, and oral hypoglycemic agents	• Use extreme caution if used concurrently with alcohol or other CNS depressants • Topiramate may decrease the serum concentrations of contraceptives and decrease their effectiveness	• Use extreme caution if used concurrently with alcohol or other CNS depressants • Antacids may decrease levels of gabapentin

Naltrexone Oral	Naltrexone Injectable	Acamprosate	Disulfiram	Topiramate[1]	Gabapentin[1]
Monitoring					
• Repeat liver transaminase levels at 6 and 12 months and then every 12 months thereafter • Discontinue medication and consider alternatives if no detectable benefit after an adequate trial (50 mg daily for 3 months)	• Repeat liver transaminase levels at 6 and 12 months and then every 12 months thereafter • Discontinue if there is no detectable benefit within 3 months	• Monitor serum creatinine/CrCl, particularly in the elderly and in patients with renal insufficiency • Maintain therapy if relapse occurs	• Repeat liver transaminase levels within the first month, then monthly for first 3 months, and periodically thereafter as indicated • Consider discontinuation in event of relapse or when patient is not available for supervision and counseling	• Monitor serum creatinine/CrCl periodically, particularly in patients with renal insufficiency and in geriatric patients • Monitor for change in behavior which might indicate suicidal thoughts or depression • Discontinue medication and consider alternatives if no detectable benefit after an adequate trial (300 mg daily for 3 months)	• Monitor serum creatinine/CrCl periodically, particularly in patients with renal insufficiency and in geriatric patients • Monitor for change in behavior which might indicate suicidal thoughts or depression • Gabapentin has potential for misuse when taken in supratherapeutic doses; monitor quantities prescribed and usage patterns • Discontinue medication and consider alternatives if no detectable benefit from at least 900 mg daily for 2-3 months

Naltrexone Oral	Naltrexone Injectable	Acamprosate	Disulfiram	Topiramate[1]	Gabapentin[1]
Patient Education					
• Discuss compliance enhancing methods • Negotiate commitment from the patient regarding monitored ingestion • Side effects, if any, tend to occur early in treatment and can typically resolve within 1-2 weeks after dosage adjustment	• Report any concerning injection site reactions • Report any new or worsening depression or suicidal thinking • May cause allergic pneumonia; contact provider if patient develops signs and symptoms of pneumonia	• Report any new or worsening depression or suicidal thinking	• Avoid alcohol in food and beverages, including medications • Avoid disulfiram if alcohol intoxicated • May cause sedation; caution operating vehicles and hazardous machinery • Discuss compliance enhancing methods • Family members should not administer disulfiram without informing patient • Provide patients with wallet cards that indicate the use of disulfiram	• Administer without regard to meals • It is not recommended to crush, break, or chew immediate release tablets due to bitter taste • Caution patients about performing tasks requiring mental alertness	• Take first dose on first day at bedtime to minimize somnolence and dizziness • Caution patients about performing tasks requiring mental alertness
• If signs and symptoms of acute Hepatitis occur, discontinue naltrexone and contact provider immediately • Very large doses of opioids may overcome the effects of naltrexone and lead to serious injury, coma, or death • Small doses of opioids, such as in analgesic, antidiarrheal, or antitussive drugs, may be blocked by naltrexone and fail to produce a therapeutic effect • Patients who have previously used opioids may be more sensitive to toxic effects of opioids after discontinuation of naltrexone					

[1] Not FDA labeled for treatment of AUD

Abbreviations: AUD: alcohol use disorder; BAL: blood alcohol level; Cmax: maximum concentration; CNS: central nervous system; CrCl: creatinine clearance; DSM: Diagnostic and Statistical Manual of Mental Disorders; HCG: human chorionic gonadotropin; m: meter(s); mg: milligram(s); min: minute(s); mL: milliliter(s)

Source: Department of Veteran Affairs. The Management of Substance Use Disorders Work Group. (December 2015*). VA/DoD Clinical Practice Guideline for the Management of Substance Use Disorders.* Version 3.0-2015.

APPENDIX 13: RESOURCE LIST

Practice Guidelines:

Bureau of Substance Abuse Services (BSAS). Principles of Care and Practice Guidance
"The Bureau of Substance Abuse Services actively promotes practice improvement in prevention, treatment and recovery systems of care…BSAS publishes Practice Guidance papers, which describe best practices as well as why and how practice in specific areas can be improved."
http://www.mass.gov/eohhs/gov/departments/dph/programs/substance-abuse/providers/program-licensing/principles-of-care-and-practice-guidance.html

BSAS Practice Guidance: Integrating Medication into Behavioral Treatment
http://www.mass.gov/eohhs/docs/dph/substance-abuse/care-principles/care-principles-guidance-mat.pdf

The Center for Social Innovation: Training for Massachusetts Addiction Professionals
"…Promotes best practices that improve the lives of marginalized and vulnerable people. We focus on complex public health problems such as homelessness, trauma, mental illness, and addiction."
200 Reservoir Street, Suite 202, Needham, MA 02494
Tel: 617-467-6014/info@center4si.com
http://center4si.com/praxis/resources/

Substance Abuse and Mental Health Services Administration (SAMHSA). *Frequently Asked Questions About Buprenorphine and the Drug Addiction Treatment Act of 2000 (DATA 2000).*
http://buprenorphine.samhsa.gov/faq.html#A8

American Society of Addiction Medicine (ASAM)
Summary of the Comprehensive Addiction and Recovery Act (CARA)
http://www.asam.org/advocacy/issues/opioids/summary-of-the-comprehensive-addiction-and-recovery-act

Educational Materials:

SAMHSA. *Know Your Rights: Rights for Individuals on Medication-Assisted Treatment.*
DHHS Publication No. (SMA) 09-449 Printed 2009
http://www.**samhsa.gov**/sites/default/files/partnersforrecovery/docs/**Know_Your_Rights_Brochure**_0110.pdf

SAMHSA. Free Poster: *Medication-Assisted Treatment (MAT), Works Great for Me.* 2005.
http://store.samhsa.gov/product/Medication-Assisted-Treatment-MAT-Works-Great-for-Me/AVD234

Harm Reduction Coalition. SKOOP brochure: *Skills and Knowledge on Overdose Prevention.*
This brochure from the SKOOP Project explains the basics of overdose risk, recognition and response in both English and Spanish.
http://harmreduction.org/wp-content/uploads/2011/12/SKOOPPamphlet.pdf

Confidentiality:

Legal Action Center. *Substance Use: Confidentiality Resources:*
http://lac.org/resources/substance-use-resources/confidentiality-resources/

US Government Publishing Office. Electronic Code of Federal Regulations. *Federal Regulations 42 CFR Part 2: Confidentiality of Alcohol and Drug Abuse Patient Records.*
www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title42/42cfr2_main_02.tpl

Safe Prescribing Practices:

Providers Clinical Support System – Medication Assisted Treatment
In response to the opioid misuse epidemic, the goal of PCSS-MAT is to make available the most effective medication treatment for addictions to serve patients in a variety of outpatient settings.
T (888) 572-7724 | **F** (401) 272-0922 pcssmat@aaap.org

Scope of Pain – Safe and Competent Opioid Prescribing Education
A series of continuing medical and nursing education activities designed to help providers effectively manage patients with chronic pain, when appropriate, with opioid analgesics. Ongoing live conferences and online trainings, also an "Ask an Expert" online forum.
www.scopeofpain.com/

My TopCare - Transforming Opioid Prescribing in Primary Care
Research and services available for prescribers, pharmacists and patients.
BMC - General Internal Medicine **T** (617) 414-6938 **F** (617)414-4676 mytopcare.org

Overdose Education and Naloxone:

Boston Public Health Commission (BPHC). Overdose Training & Narcan Education
www.bphc.org/whatwedo/Addiction-Services/prevention/Pages/Narcan-Program.aspx

Connection to Services

Assistance with locating harm reduction therapies, detoxification beds, and connection to a variety of health and social services. Walk-ins welcome. All levels of insurance.

Boston Medical Center, Project Assert 850 Harrison Ave, Boston, MA (Open everyday, 8am-12:30am)	Boston	617-414-4388
Boston Public Health Commission, PAATHS 774 Albany St, Boston, MA (M-F 7am-3pm)	Boston	855-494-4057

Treatment Locator - Hotline/Resources

Massachusetts Substance Abuse Information and Education, Treatment resource linkage
Find information for a variety of addiction treatment programs including: detoxification programs, residential treatment, sober housing, dual diagnosis programs, outpatient counseling, and medication treatment for addiction with methadone, buprenorphine (Suboxone) or naltrexone (Vivitrol).
Website: http://hria.force.com/ Phone: 800-327-5050

Massachusetts Treatment and Referral Hotline:
The Hotline can make referrals and offer information about medication treatment for addiction options (methadone, buprenorphine and naltrexone) available in Doctors' offices statewide. Information is available for both adolescents and adults
Phone: 1-866-414-6926 or 1-617-414-6926

Opioid Treatment Locator - http://dpt2.samhsa.gov/treatment/directory.aspx
SAMHSA Behavioral Health Treatment Locator - https://findtreatment.samhsa.gov/
Methadone Treatment Locator – 800-755-9603
http://www.opiateaddictionresource.com/treatment/methadone_clinic_directory

State Without StigMA
Helpline: 1-800-327-5050 (tty: 1-800-439-2370)
www.mass.gov/eohhs/gov/departments/dph/stop-addiction/state-without-stigma/

Emergency Services

Boston Emergency Services Team (BEST).
Provides 24hr emergency mental health services to individuals, families and organizations in Chelsea, East Boston, Revere, Winthrop, Boston, and Roslindale.
(800) 981-4357

Veteran's Crisis Line: 1-800-273-8255 TTY: 1-800-799-488

Services for Active Users

AHOPE – A harm reduction and needle exchange site for active drug users. Provides a range of services including: free HIV and STI testing, referral for treatments, Overdose Education and Narcan training, risk reduction counseling. Open M-F: 7:30am-4pm. 617-534-3967

Family Resources:

Learn to Cope: "*A support organization that offers education, resources, peer support and hope for parents and family members coping with a loved one addicted to opioids or other drugs."*

Meeting locations throughout the state of Massachusetts.
Office hours: Monday through Friday, 8:30 - 4:30 Office phone: 508-738-5148
Peer Recovery Specialist: 508-801-3247 www.Learn2cope.org

COASA: Children of Alcoholism and Substance Abuse
Contact: COASA, c/o Maureen McGlame Robert F. Kennedy Children's Action Corps 11 Beacon Street Boston, MA 02108 Tel: 617.227.4183 Fax: 617.227.2069

Institute for Health and Recovery - *Outpatient services for adults, youth, and families struggling with substance use or mental health issues. Provides treatment in your home, community, or in IHR offices of Boston, Cambridge or Lowell. IHR serves most towns in greater Boston and all of northeast Massachusetts*.
617-661-3991 www.healthrecovery.org/

Alanon/Alateen – *Anonymous support group. Members share personal experiences and stories, and invite other members to determine for themselves what lesson they could apply to their own lives.*
(508) 366-0556 www.al-anon.alateen.org/

Adolescent Services

Youth and Young Adult Services Directory
Directory of programs licensed and/or funded by the Massachusetts Department of Public Health including: outpatient services, detox, extended treatment, residential treatment, recovery high schools, family intervention and more.
Toll free: 866-705-2807 Or 617-661-3991
TTY: 617-661-9051
www.mass.gov/dph/youthtreatment

Boston Medical Center CATALYST Clinic
(Center for Addiction Treatment for AdoLescents/Young adults who use SubsTances)
Multidisciplinary team that provides comprehensive care for patients ages 25 and younger who are affected by substance use in an integrated, outpatient general health setting. Offers assessment, diagnosis and treatment of substance use disorders and comorbidities. Patients must receive or be willing to receive primary care at Boston Medical Center.
For more information contact: (617) 414-6655

Children's Hospital, Adolescent Substance Abuse Program (ASAP)
Phone: 1-617-355-2727 TTY: 1-800-439-2370

Recovery High Schools:
"…provide a safe, sober and supportive school environment in which youth in recovery can develop the skills and strengths needed for personal, academic, vocational and community success".
www.massrecoveryhs.org/

Youth Intervention Programs

Bridge Over Troubled Waters	Boston	617-423-9575

ROCA Youth Development Center	Chelsea	617-889-5210
Eastern District - Juvenile Diversion Program	Salem	978-745-6610

Organizations for Medical Professionals Struggling with Addiction or Personal Issues

MNA Peer Assistance Program - Network of volunteer nurses reaching out to other nurses whose life and/or profession are affected by alcohol or other drugs. Non-disciplinary. Free & confidential support.
Please call us at: 781-821-4625 x755 or 800-882-2056 x755

Nursing Substance Abuse Rehab Program (SARP) – A program that assists nurses who have problems with alcohol and/or drugs return to practice while protecting the public's health, safety and welfare. SARP is a voluntary alternative to disciplinary action for nurses who have substance use problems.
For more info on SARP please call: 617-973-0800

USA Pharmacist Recovery Network – "…provides help and hope to pharmacists and student pharmacists dealing with substance use issues".
http://www.usaprn.org/

National Organizations – Research, Education, Clinical Guidance

ASAM – American Society of Addiction Medicine
NIDA – National Institute on Drug Abuse
SAMHSA - Substance Abuse and Mental Health Services Administration

Organizations for Medical Professionals – Advocacy, Education, Research

MA Chapter of the International Nurses Society on Addictions - *"An organization that was founded by and for nurses committed to the prevention, treatment and management of addictive disorders".*
Open to ALL Massachusetts nurses. Meetings occur on the second Tuesday of every month from 5-7pm at 801 Mass Ave in Boston.
Contact: Colleen LaBelle 617-414-7453 or visit http://addictionnurses.org/

Massachusetts Medical Society – Professional association for physicians and medical students that is dedicated to educating and advocating for the patients and physicians of Massachusetts. Offers online CME courses and live events.
For general info about MMS Membership and Services: Email: info@massmed.org or call (781) 434-7311

Outpatient Counseling and Case Management Services

Mens Health and Recovery – 774 Albany St Boston, MA 617-534-2185
MOMs and MORE Program – 774 Albany St Boston, MA 617-534-7411
Hope House – 8 Farnum St Boston, MA 617-971-9370 or e-mail:

outpatient@hopehouseboston.org
AdCare – Locations throughout eastern MA, Toll free: 800-345-3552 or http://adcare.com/
Arbour – Locations throughout eastern MA, Refer to website for location contact info: http://www.arbourhealth.com/
Riverside – Locations throughout eastern MA Phone: 781-329-4579 Fax: 781-329-8631

Vocational/Learning Resources:

Massachusetts Rehabilitation Services: Tel. (617) 357-8137 Fax (617) 482-557
Department of Career Services at 617-626-5300,
American Job Center Helpline at 1-877-872-5627 (TTY 1-877-889-5627)
*The Transformation Center (Roxbury) – 877-769-7693, transformation-center.org
*Metro Boston Recovery Learning Community – 617-305-9976
***Funded through Dept Mental Health, peer-operated support, education, advocacy.*

Housing

Boston Housing Authority - Provides affordable housing to those who qualify.
52 Chauncy Street Boston, MA 02111 M-F: 9am-5pm 617-988-4000 or (800) 545-1833 x420
HomeStart, Inc 617-652-0339 ext43
Mass Sober Housing (Worcester area) – 508-987-3888
South Shore Housing Development – 781-542-4200
South Middlesex Opportunity Council (SMOC) – 508-879-6691
MASH –MA Association of Sober Housing – 781-838-0463

Homeless Services

Boston Health Care for the Homeless Program - BHCHP's integrated model of care includes primary care, behavioral health and dental care. Case management team assists with applying for benefits, identifying housing and training opportunities, as well as other services. BHCHP also operates a medical respite facility to care for patients too sick for life in shelter or on the street but not quite sick enough to occupy an acute care hospital room.
780 Albany Street Boston, MA 02118
Phone: 857-654-1000 · Fax: 857-654-1100 · Email: info@bhchp.org

Food Source Hotline / Project Bread 800-645-8333

Abuse/Violence

Child-at-Risk Hotline	800-792-5200
Elder Abuse Hotline & Website	800-922-2275
Disabled Person's Abuse Hotline	800-426-9009
SafeLink Domestic Violence Hotline	877-785-2020
Gay Men's Domestic Violence Project	800-832-1901

Hotline/Helplines

Gay, Lesbian, Bisexual and Transgender Helpline	888-340-4528
Massachusetts Behavioral Health Partnership	800-495-0086
Massachusetts Department of Veterans Affairs	800-827-1000
National Suicide Prevention Lifeline	800-273-8255
Regional Center for Poison Control and Prevention	800-222-1222
Social Security Administration	800-772-1213
Try-To-Stop Tobacco Resource	800-879-8678

105 CMR 164.009: Access for Individuals with Disabilities

ADA - Massachusetts Facility Assessment Tool:
http://www.mass.gov/eohhs/gov/departments/dph/programs/community-health/health-disability/ada-compliance/the-massachusetts-facility-assessment-tool.html

http://www.mass.gov/eohhs/docs/dph/com-health/health-disability/mfat-intro.pdf

105 CMR 164.062: All Hazard and Emergency Planning & Procedures

TAP 34: Disaster Planning Handbook for Behavioral Health Treatment Programs
(November 2013)
http://store.samhsa.gov/product/TAP-34-Disaster-Planning-Handbook-for-Behavioral-Health-Treatment-Programs/BackInStock/SMA13-4779?WT.mc_id=EB_20140318_SMA13-4779

Barriers to Treatment:

Legal Action Center. *Confronting an Epidemic: The Case for Eliminating Barriers to Medication-Assisted Treatment of Heroin and Opioid Addiction.* March 2015.
http://lac.org/wp-content/uploads/2014/07/LAC-The-Case-for-Eliminating-Barriers-to-Medication-Assisted-Treatment.pdf

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APPENDIX 14: REFERENCES

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