MASSACHUSETTS NURSE CARE MANAGER MODEL OF OFFICE BASED ADDICTION TREATMENT: CLINICAL GUIDELINES

A COLLABORATIVE CARE APPROACH

Updated: March 9, 2018

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ACKNOWLEDGMENTS

These clinical guidelines were prepared for Boston Medical Center by Colleen T. LaBelle, MSN, RN-BC, CARN, Alexis Bergeron, MPH, LCSW, Kristin Wason, MSN, NP-C, CARN, and Alicia Ventura, MPH. Professional editing performed by Donna Beers, MSN, RN-BC, CARN, Deva Taylor, BS, and Jenny Eriksen Leary, BA. This initiative was funded by the Massachusetts Department of Public Health, Bureau of Substance Abuse Services (BSAS) as part of the State Technical Assistance and Treatment Expansion of Office Based Addiction Treatment with buprenorphine and naltrexone formulation (STATE-OBAT).

DISCLAIMER

Boston Medical Center is pleased to share its Office Based Addiction Treatment clinical guidelines with other providers. Although Boston Medical Center has attempted to confirm the accuracy of the information contained in these documents, this information 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 health care decisions they make when caring for patients. If clinicians believe that any information included in these guidelines should be revised or clarified, please contact Boston Medical Center at 617-414-7453.
The contents of these guidelines are solely the responsibility of the authors and do not necessarily represent the official views of BSAS or any other part of the Massachusetts Department of Public Health.

LaBelle, C. T.; Bergeron, L. P.; Wason, K.W.; and Ventura, A. S. *Clinical Guidelines for the Office Based Addiction Treatment Program for the use of Buprenorphine and Naltrexone Formulations in the Treatment of Substance Use Disorders*. Unpublished treatment guidelines, Boston Medical Center, 2018.

SPONSORSHIP

This publication has been made possible by the grant support of the Massachusetts Department of Public Health Bureau of Substance Abuse Services to provide expansion of treatment with medication for addiction into community settings.

ORIGINATING OFFICE

Boston Medical Center
Office Based Addiction Treatment
801 Massachusetts Avenue, 2nd floor
Boston, MA 02118
Attn: Colleen T LaBelle MSN, RN-BC, CARN
Colleen.labelle@bmc.org

PURPOSE

The purpose of these clinical guidelines 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 use disorders 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 2016 National Survey on Drug Use and Health indicate that 3.3 million people aged 12 or older in the United States (US) reported nonmedical use of prescription pain medication in the past month, and 475,000 reported heroin use during 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] From 2000 to 2015, more than half a million people died from drug overdoses.[4] Additionally, in 2015, there were approximately 1.5 times more deaths in the US related to drug overdose than deaths related to motor vehicle accidents. In the same year, overdose death rates involving a synthetic opioid, such as fentanyl (not including methadone) increased by 72.2%; increased death rates attributed to synthetic opioids were seen across all demographics, regions and in numerous states.[5] In 2016, approximately 20.1 million people in the US met criteria for a substance use disorder; however, only one in 10 of those individuals received any specialized care for their substance use disorder.[1] 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 Psychological 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, injectable, and sub-dermal implant **buprenorphine** (nonselective partial opioid agonist) and (iii) oral formulation and 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 the use of injectable naltrexone for the treatment of opioid use disorder, particularly in specific populations, though, in general, treatment outcomes have been inferior to those attained with methadone and buprenorphine maintenance.[12] At sufficiently high doses, opioid agonist maintenance treatment relieves the 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 approved by the FDA 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 a six-month follow-up, 60% were still retained in treatment and another 15% had completed treatment.[16]

In 2016, over half of individuals aged 12 and older in the US reported drinking alcohol in the past 30 days; one in three reported heavy episodic alcohol use.[1] In 2016, 15.1 million people in the US had an alcohol use disorder, comprising over 75% of people in with a substance use disorder in the country. Alcohol use exists on a spectrum, beginning with abstinence and lower-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 fourth 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 that is taken daily, and an extended-release injectable formulation, administered intramuscularly into gluteal muscle every twenty-eight days. The 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 for addiction treatment and psychosocial therapies as part of a comprehensive 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 implementing 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] Registered nurses, by virtue of their training and role in chronic disease management, are ideally suited to serve as the lynch pin in the OBAT program. OBAT nurse care manager (NCM) responsibilities encompass the full breadth of the program components: patient screening, assessment, education, care planning, medication induction, stabilization, and maintenance. Additionally, these 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 (NCM) initiative led to state grant funding of the **S**tate **T**echnical **A**ssistance **T**reatment **E**xpansion (**STATE**) **OBAT** project, which allowed for further expansion of the NCM model to community health centers across Massachusetts.[22] Participating sites received funding for NCMs and medical assistants. Initial training included an eight-hour core curriculum, and ongoing support is provided by a 24/7 telephone and e-mail assistance, job shadowing with the OBAT NCMs 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 NCMs. Other staff, including physicians, nurses, medical assistants, and social workers, also received training and technical assistance to effectively integrate primary care with treatment for both opioid use disorders and alcohol use disorders.

OBAT PHILOSOPHY

A substance use disorder is a chronic medical condition that responds best when treated with evidence-based, patient-centered, comprehensive medical care. Patients engaged in OBAT deserve to be treated with dignity and respect. The goal of OBAT is a cessation or reduction in harmful substance use, active participation and engagement in treatment, restoration of normal physiologic functions and an improvement in one's quality of life.

OBAT CLINIC STAFFING REQUIREMENTS

PROVIDERS

BUPRENORPHINE, BUPRENORPHINE/NALOXONE

QUALIFICATIONS: Qualified providers must obtain a waiver of authority to prescribe any medication that is a schedule 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.

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 an eight hour 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/PAs will be limited to treating 30 patients at a time in the first year and can then apply to HHS for an extended waiver to treat 100. This waiver cannot increase to 275 under current regulations

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

PATIENT LIMITS: For the first year of following receipt of 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 28 days, patient is discharged, that patient continues to count under that physician number until the end of that 28 day prescription.) For a provider to become eligible to treat up to 100 patients, they need to apply to SAMHSA's Center for Substance Abuse Treatment (CSAT) at www.buprenorphine.samhsa.gov for the extended waiver.

Recent legislation has expanded limits for eligible physicians to treat up to 275 patients, but 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 (AOAAM)

–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 schedule 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.

OBAT Nurse Care Managers

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

- Complete an initial eight-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, 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 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 collaborate as needed with OBAT provider, social worker/counselors, psychiatrists, pharmacy, primary care provider, and specialty care providers 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, misuse, safety, storage, and behavioral health referrals.

PROGRAM REQUIREMENTS

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

BUPRENORPHINE ADMINISTRATIVE REQUIREMENTS

- Certification, accreditation and waiver approval.
- 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 fulfills this requirement and there is no need to keep copies of the prescriptions in your office.
    - For DATA 2000 compliance, the 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.

CANDIDATES FOR OBAT

- Patient must have a *DSM-5* diagnosis of Opioid Use Disorder or Alcohol Use Disorder.
- Patient must agree with the 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.
- Patient is able to come to visits during office hours of operation.
- For patients seeking treatment with agonist medications: they must not have chronic pain requiring ongoing opioid management beyond buprenorphine/naloxone.
- For patients seeking treatment with antagonist medications: they must not have acute/chronic pain issues requiring opioid management.
- Patient must be able to be treated in an office based setting safely without harm to self or others.
- Patient should be willing to address use of other harmful and/or illicit substances.
- Treatment team should carefully assess patient for appropriateness of medication treatment in an office based setting.

PATIENT INITIATION ROADMAP

- ✓ Initial screening by OBAT staff
- ✓ Intake performed by OBAT NCM
- ✓ OBAT provider visit
- ✓ Induction
- ✓ Stabilization
- ✓ Maintenance

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.
- OBAT team reviews initial screening information and makes decision about potential appropriateness of patient receiving medication for substance use disorder in an office based setting. Appropriate candidates proceed to OBAT intake.

OBAT INTAKE

INTAKE PERFORMED BY NURSE CARE MANAGER

See Appendix 4: Nursing Intake for Intake Forms

THE OBAT NCM INTAKE INCLUDES:

- Information to lay the groundwork for a therapeutic relationship with the patient. Assess patient goals for treatment, strengths for obtaining recovery and risks to treatment success.
    - The OBAT NCM values the uniqueness of each individual and helps each person define their own goals.
- Assessment of substance use including substance use history, current status, prior treatment and recovery time.
- Review of medical, mental health and social history. Obtain appropriate signed consent forms to assist with collaboration of care with outside providers and supports.
- Education on medication for addiction treatment: what it is, how it works, medication administration, interactions, side-effects, potential adverse reactions, induction and maintenance processes.
    - The OBAT NCM reinforces that a substance use disorder is a chronic medical condition that affects numerous aspects of a person's wellbeing. The OBAT team will support the patient throughout the recovery process, even in the event of a relapse. The patient's treatment plan will be augmented as necessary to assist the patient in achieving recovery and meeting their identified treatment goals.
- Harm reduction education: overdose prevention education, overdose reversal with naloxone, rescue breathing, ensuring patient has access to naloxone.
- Mandatory screening at time of intake includes:
    - Toxicology screening and pregnancy testing
    - HIV testing strongly recommended
    - Ensure PPD screen is up to date per your institution's protocol
- Obtain laboratory tests as clinically needed.
    - Consider: complete blood count, comprehensive metabolic panel, hepatic function, pregnancy test, RPR, hepatitis A, B and C serologies.

- Review of treatment agreement and program expectations. Patient signs treatment agreement and consents for treatment.
    - Program expectations include:
        - Appointment frequency with OBAT NCM and provider. (See Appendix 10B)
        - Counseling and psychiatric assessment and follow-up if warranted. (See Appendix 10C).
        - Medication refills. (See Appendix 10F)
        - Patient-centered treatment planning and review.
        - Introduction to members of treatment team.
        - Review the medication safety brochure and discuss responsibilities for safe medication storage. (See Appendix 11A)
        - Review clinic hours and times available for scheduling visits, including afterhours emergency contact information.
        - 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.

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, this may include any communications with other providers, 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 the case of medical emergencies or specific legal circumstances. Other than in the case of a medical emergency, check with your organization's legal counsel prior to making disclosures without consent.

VISIT WITH OBAT PROVIDER

- Provider assessment visit, with physical examination 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 NCM 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, in person and in 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.
- ✓ The patient should have counseling in place or be working towards establishing treatment with a counselor who has a working knowledge of substance use disorders. Counseling may be group-based or individual.
- ✓ Toxicology screen completed and reviewed by OBAT team.
- ✓ Pregnancy test for women of childbearing age.
    - If positive HCG, OBAT team will immediately assist patient engagement with appropriate OB providers and will manage the patient in OBAT until a warm handoff occurs.
- ✓ If patient presents from detoxification, OBAT team should attempt to obtain discharge paperwork that includes medications administered (i.e. methadone administered in detox will delay induction with partial-agonist or antagonist due to risk of precipitated withdrawal). This paperwork must be reviewed by the treatment team.
- ✓ NCM consults with waivered provider after initial visit and obtains the prescription from the waivered provider.
- ✓ After OBAT team review, schedule induction per protocol in collaboration with patient and team: date, time, prescription, and clinic schedule.
- ✓ NCM telephones patient to review induction plan, and faxes hard copy signed prescription to pharmacy for patient to pick up on day of induction.
- ✓ Patient presents to clinic for induction.

BUPRENORPHINE/NALOXONE INDUCTION

PRIOR TO INDUCTION

- Patient discontinues use of illicit opioids prior to buprenorphine/naloxone induction to avoid risk of precipitated withdrawal.

- Time-line for opioid discontinuation to be determined as part of induction treatment plan and to be based upon patient's medical status, current opioid use and opioid dependency.

    - Short-acting opioids: typically discontinue 8-12hrs prior to scheduled induction.

    - Long-acting opioids: typically discontinue 12-24hrs prior to scheduled induction.

    - Methadone: typically discontinue 36-96hrs prior to scheduled induction.

        - Methadone to buprenorphine transfers are especially complex due to the long half-life of methadone and unpredictable metabolic clearance.

        - Please refer to the section on methadone to buprenorphine transfers in this manual, pp. 63-64.

DAY 1: INDUCTION

- The patient arrives at clinic in early withdrawal, with prescription medication in hand.

- For patients who are actively using opioids other than buprenorphine, the NCM assesses symptoms with Clinical Opioid Withdrawal Scale (COWS), if the COWS score is >6-12, the OBAT NCM instructs the patient to take the buprenorphine/naloxone as prescribed per their prescription order and per clinic protocol sublingually or in the buccal mucosa.

- 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.

- OBAT NCM supervises medication administration, and educates the patient as to appropriate technique as this is a sublingual/buccal administration that requires 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 transmucosally, 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 as directed 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.

- Dose will continue to be titrated per prescription instructions and/or until signs and symptoms of withdrawal subside. Typically patients will titrate to 8-12mg by the end of the first day; however, this dose may be less or could be higher, and will vary according to a patient's level of physical opioid dependence at the onset of treatment.

- Update Nurse Manager by end of the day in case of off-hours calls or concerns.

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 OBAT NCM by phone a few hours later. If increased symptoms occur throughout the day, the patient may increase their dosage 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 NCM 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 typically 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.

- This 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 treatment for substance use disorder or in a medical settings.

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

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

- Refills are permitted, but the 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 NCM weekly for four to six weeks until stable. If toxicology screens are negative and the patient is adherent to the treatment plan, they may then progress to the maintenance phase.

BUPRENORPHINE/NALOXONE MAINTENANCE

Once stable, clinic visits every two to four weeks, with refills that coincide with visits.

Goal: monthly visits for a few months; ultimately, random visits if appropriate for patient; random is more effective in assisting patients (ASAM, White Paper, 2013).

- 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: NURSE FOLLOW-UP FORM):

- Sample collection for toxicology.
- Assessment of status: medication dose, adherence, tolerance, side effects, cravings and withdrawal; safe storage, recovery, relapse, as well as medical, social and psychiatric issues should all be addressed as indicated.
- Review of treatment plan: visit frequency, counseling, and assess need for additional support.
- OBAT NCM's notes should be documented in the clinical record and available to the entire clinical team, including waivered providers.
- Lab testing: if LFTs were elevated at induction, consider rechecking within one to two months or sooner depending on degree of elevation, and regularly monitor thereafter. Elevations are more common in patients with hepatitis C and HIV infection.
- If there is a history of risky alcohol use, address concerns with patient, consider use of breathalyzer at each visit.
    - Acamprosate (Campral) and disulfiram (Antabuse) 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.
- Contact other OBAT team members as needed, including waivered OBAT provider and PCP if different and warranted.
    - Waivered OBAT provider visits to occur at least every three to four months.
- Review and confirm contact information, including pharmacy of choice, at each visit.

- Refills for up to six months may be provided once the patient is stable and these prescriptions are faxed to a pharmacy with information kept on file.

- In addition to office visits, OBAT NCM performs telephone contact for support as needed.

NALTREXONE INITIATION: PATIENT SELECTION

CANDIDATES FOR TREATMENT WITH NALTREXONE INCLUDE PATIENTS WHO:

- Are not currently using opioids, but have a history of opioid use disorder and are at risk for relapse.
- Have a high degree of motivation for abstinence from opioids.
- Have been successful on opioid agonists and wish to discontinue agonist therapy.
- Are not interested in agonist/partial agonist therapy to treat their opioid use disorder.
- Have not experienced successful treatment with agonist therapy.
- Have a history of alcohol use disorder.

CONTRAINDICATIONS:

- × Patients with advanced liver disease or acute hepatitis.
- × Patients with 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 an anesthesia consult. If a patient has a surgical procedure pending, they 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 five times 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. At this time, labeling from the manufacturer advises against breastfeeding while on naltrexone, both with oral and injectable formulations.

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

- ✓ The patient should have counseling in place or be working towards establishing treatment with a counselor who has a working knowledge of substance use disorders. Counseling may be group-based or individual.

- ✓ The patient must be cleared by psychiatry if concerning mental health history.

- ✓ Labs appropriate: HCG neg. LFTs < 5x normal.

    - If positive HCG, OBAT team will immediately assist patient engagement with appropriate OB providers.

- ✓ UTS that is negative for opioids.

    - Detoxification from opioids should be completed prior to the administration of naltrexone to prevent precipitated or spontaneous withdrawal. The patient must not be experiencing withdrawal symptoms. Patients should discontinue short-acting opioids at least three to seven days prior to starting naltrexone. If taking long-acting opioids such as methadone or buprenorphine, the patient must be off for at least seven to 10 days.

    - Detoxification from alcohol is not always necessary. However, detoxification from alcohol is recommended prior to naltrexone initiation if a patient has a history of alcohol-related seizures, delirium tremens (DTs), longstanding daily use, presence of withdrawal signs or symptoms, or as otherwise clinically indicated.

    - If patient presents from detoxification or other inpatient treatment, the OBAT team should attempt to obtain discharge paperwork that includes medications administered (i.e. methadone or buprenorphine administered in detox will delay induction with antagonist due to risk of precipitated withdrawal). This paperwork must be reviewed by the treatment team.

- ✓ The NCM 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.

- ✓ The NCM telephones patient to review medication initiation plan and prescribes 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 the oral formulation for a few days before receiving their first extended-release naltrexone injection to assess for side effects and any contraindications.
- Patient to be given an emergency card, bracelet and/or dog tag.
- The first naltrexone dose should be observed in the 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 opioids.
- The patient must be off short acting opioids for at least three to seven days. If they are taking long-acting opioids such as methadone or buprenorphine, the patient must be off for seven to10 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 toxicology 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 there are 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:* **Stop** the naloxone challenge immediately if the patient experiences any symptoms of withdrawal. Do not give any more naloxone. In dependent individuals, naloxone will precipitate withdrawal that usually emerges within five to 10min and dissipates within 30min. 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 one to two days and repeat naloxone challenge.

NALTREXONE CHALLENGE WITH ORAL FORMULATION

- UTS negative for all opioids.
- The patient must be off short-acting opioids at least three to seven days, long-acting requires at least seven to 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 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:* **Stop** the naltrexone challenge immediately if the patient experiences any symptoms of withdrawal. Do not give any more naltrexone. Reassure the patient that the symptoms will begin to dissipate in four to six hours. 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 one to two days for a repeat naltrexone challenge.

EXTENDED-RELEASE INJECTABLE NALTREXONE 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 seven 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 specifically 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 break through the opioid blockade can also result in fatal overdose. The OBAT NCM should outreach to and attempt to reengage with patients who miss an injection.

- **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. Patients should be evaluated, monitored and treated appropriately, and families and caregivers should be alerted to the need to monitor patients for depression or suicidality.

* Taken from: Substance Abuse and Mental Health Services Administration. Clinical Use of Extended-Release Injectable Naltrexone in the Treatment of Opioid Use Disorder: A Brief Guide. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2015.
**Adapted from: Alkermes. Opioid Dependence Efficacy and Safety. Vivitrol Prescribing Information. 2017. https://www.vivitrol.com/content/pdfs/prescribing-information.pdf

NALTREXONE (ORAL OR INJECTABLE) STABILIZATION

- Patient returns to clinic after one week for assessment, urine/swab toxicology 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 the patient status prior to administering medication. Consider naloxone/naltrexone challenge if opioid use is suspected or if injection has lapsed for an extended period of time. Augment treatment plan as needed.

- Patient sees NCM weekly for four to six weeks until stable. If the toxicology screens and breathalyzer screens are negative and the patient is adherent to the treatment plan, they then may progress to the maintenance phase.

NALTREXONE MAINTENANCE

- Once stable, clinic visits every two to four 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 sample for toxicology screening.
- Assessment of status: recovery, relapse, and medical, social and psychiatric issues should be addressed as indicated.
    - For management of pain in patients who are engaged in naltrexone treatment, refer to section titled "Pain Management: Naltrexone" or to Appendix 13.
- Monitor and assess for potential medication side-effects or adverse reactions: injection site reaction, hepatic complications, gastrointestinal distress, depression, eosinophilic pneumonia, etc.
- Review of treatment plan: visit frequency, counseling, assess need for additional support.
- If there is a history of risky alcohol use, address concerns with patient, consider use of breathalyzer at each visit.
    - Acamprosate (Campral) and disulfiram (Antabuse) may also be offered to patients with problematic alcohol use with provider input and agreement.
- Lab testing: if liver function tests were elevated at induction, consider rechecking within one to two months or sooner depending on degree of elevation. Continue to regularly monitor LFTs thereafter.
- Contact other OBAT team members as needed, including OBAT provider and PCP if different and warranted.
- Review contact information, including specialty pharmacy, at each visit.
- OBAT provider visits at least every three to four months
- In addition to office visits, OBAT NCM performs telephone contact for support as needed.

Ongoing Patient Management: OBAT Agreement & Clinic Policies

Treatment Agreement

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

- See Appendix 9A and 9B for Treatment Agreement Forms
- Set clear expectations/guidelines.
- Explain treatment agreement verbally and provide in written form, which patients will sign and date. This form will be kept in the patient record. Review each line of the contract, and give a 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 (provide education around options and support), or the risks of transferring care from one form of medication treatment to another, or patients' ambivalence about such changes.
- The agreement reinforces that a substance use disorder is a chronic medical condition that affects numerous aspects of a person's wellbeing. The OBAT team will support the patient throughout the recovery process, even in the event of a relapse. The patient's treatment plan will be augmented as necessary to assist the patient in obtaining recovery and achieving identified treatment goals.
- The patient can expect:
    - To be treated with dignity and respect.
    - To be notified if the office is closed and how to seek assistance if needed.
    - 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.

ADHERENCE TO PROGRAM POLICIES AND TREATMENT PROTOCOLS:

- Clinical Appointment Policy *(*See Appendix 10B*):* All patients who participate in the Office Based Addiction Treatment program are required to keep all appointments with their primary care providers, OBAT providers, and OBAT NCMs. 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. If 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 make an effort to arrive on time for scheduled appointments.

- Patients are required to see their OBAT provider at least once every three to four months and more frequently if needed, per recommendation of the 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.

    - Consider increasing visit and prescription frequency until the patient is seen by their provider. In some cases, the treatment team may choose to hold prescriptions until the patient is seen for an office visit by an OBAT provider.

- Patients struggling to meet program requirements may need to be referred to another program or level of care.

- Procedures for contacting the OBAT team when the office is closed:

    - All patients have an emergency card that displays a phone number that is monitored by OBAT clinical staff during off hours. This number is also recorded on the clinic phone line. This number should be called off hours if the patient has a medical emergency that may require pain management, or if they have an issue with their prescription.

BEHAVIOR EXPECTATIONS

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 of hands until the labeled urine sample is handed to the medical assistant in a bio-hazardous bag.
- No flushing of 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.
- Observed urine screens are discouraged. Oral swabs may be utilized in place of observed urine screens. If it becomes necessary to do observed urine screening, the patient may be referred to a chain of custody location for urine screening or to a higher level of care.

TAMPERING:

If the urine sample is questionable:

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

- The patient will be 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.

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

- When an acceptable urine sample is obtained, the patient will receive a buprenorphine/naloxone prescription refill, naltrexone prescription or extended-release naltrexone injection.

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 (NCM), who will review the medication record, consult with provider, pharmacy and the prescription drug monitoring program (PDMP) if needed, to confirm dosage, refill amounts, and timing of refill.

- OBAT (NCM) will check insurance coverage, preferred covered medication formulary, and need for prior authorization.

- Following confirmation, OBAT (NCM) will generate an 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 (NCM) will generate a confidential fax cover sheet, confirm the pharmacy information from the electronic medical record and fax the prescription to the pharmacy on the patient's record.

- After the prescription has been faxed, the OBAT NCM will stamp the prescription "faxed," place the prescription in a confidential locked file for 30 days in case of fax error or if there is a need to review the prescription at a later date.

- All prescriptions will be destroyed after thirty days; they are placed into a locked/confidential recycle bin by two OBAT NCMs.

- 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 one week with no refills.

- Following four to six weeks of treatment, if the patient is moving into the stabilization phase, prescription refills will increase to two week intervals with up to four refills.

- Following eight weeks on maintenance with two week refills, if the patient continues to progress, prescriptions will increase to three to four week prescriptions and then to monthly if the OBAT team feels the patient is stable and has adequate support 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 longer-interval prescriptions, the OBAT team will make the decision to continue with shorter-interval prescriptions for as long as necessary.

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

    - Weekly prescriptions with refills, work with shelter staff in an effort to find feasible methods to support the patient and secure their medication if possible.

LOST, STOLEN OR DESTROYED BUPRENORPHINE/NALOXONE:

- *Lost or Stolen Medication:* Buprenorphine/naloxone 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 agreement. However, cases will be reviewed on an individual basis by the OBAT team if requested by the patient. 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 more than a one week supply of replacement prescription is needed, the prescription amount will go back to weekly prescriptions until the team feels it is safe for the patient to be given a larger quantity of medication.

- *Destroyed/damaged:* If able, the patient should be instructed to bring the reported medication in for the OBAT team to review. A decision will be rendered by the team on how best to proceed. If a patient reports destroyed/damaged medication, the prescription amount will go back to weekly prescriptions until 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 toxicology screen. At this time, patients will receive additional education about safe handling and storage of buprenorphine/naloxone by the OBAT NCMs and/ or providers to prevent these events from reoccurring. The treatment plan should be reviewed along with length of prescription and frequency of visits to further assess and ensure that there are not additional concerns or needs.

- 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/films down on counters, sinks, dresser, and nightstands or in any public unsecure space.
- ✓ 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 a labeled prescription bottle with child-proof cap.
- ✓ Patient's prescribed buprenorphine/naloxone film should store with an official pharmacy label at all times. Patients may request a second label from the pharmacy if they plan to carry medication on their person.
- ✓ Avoid carrying medication 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. (See Appendix 11C).
- ✓ Suggest to patients that they obtain a locked bag or a lock box to store buprenorphine/naloxone and any other controlled substances safely and out of reach. Reinforce safe storage out of common areas and away from children and others.

[†] Adapted from: "Protecting Others and Protecting Treatment" STATE OBOT (State Technical Assistance Treatment Expansion Office Based Opioid Treatment of Buprenorphine), and Massachusetts Department of Public Health Bureau of Substance Abuse Services (BSAS). 2016.

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 maybe referred to a higher level of care.
    - Clinicians should always carefully weigh the risk versus benefit of continuing treatment in an office based setting prior to referring to another level of care.
- Situations when the OBAT team may recommend more intensive levels of care:
    - Ongoing use despite adequate buprenorphine/naloxone dosing: no cravings, withdrawal symptoms and adequate narcotic blockage.
    - Opioid use during the end of an extended-release naltrexone injection dosing interval.
    - Multiple negative buprenorphine UTS results for patients taking prescription buprenorphine.
    - 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.
- If the patient complies with the intensive treatment plan and has had some improvement in substance use, team will restructure treatment as needed and continue treatment with buprenorphine/naloxone.
- Patients who are referred to a higher level of care or are discharged will be reconsidered for future treatment in OBAT.

REVISION OF TREATMENT PLAN MAY INCLUDE:

- More frequent visits
- Shortened prescription intervals
- 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 and treatment per psychiatric assessment
- Residential treatment
- DCF involvement
- Increased collaboration with community providers
- Increased engagement with law enforcement
- Family/support involvement

REFERRAL TO HIGHER LEVEL OF CARE MAY INCLUDE:

- Detoxification/CSS/TSS
- Residential treatment
- Methadone maintenance
- Directly observed buprenorphine/naloxone daily dosing in OTP
- 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), the 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 the patient provides adequate explanation regarding negative buprenorphine/naloxone to OBAT NCM on the phone, the OBAT NCM will establish a follow-up plan for the patient 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 should be obtained and sent for confirmatory testing (i.e. GC/MS) that includes checking for the presence of buprenorphine's metabolite, norbuprenorphine.

- At return visit, the negative urine screen result is addressed.

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

    - Assess and modify treatment plan as needed. If the 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 their prescribed dose). The entire OBAT team should be consulted prior to adjusting a patient's medication dose.

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

- Assess dose. If the dose is less than 4-6mg, urine may need to be sent for confirmatory testing due to the cut-off limits of the test and therefore its inability to react positive to buprenorphine.

POSITIVE OPIOIDS

- Report of opioid use or positive opioid toxicology screen result is addressed by OBAT NCM during visit or through subsequent phone conversation(s) and the treatment plan is intensified accordingly to meet the needs of the patient.
    - If the patient has a positive UTS and does not admit to use at the visit and denies use when addressed on the phone with OBAT NCM, the patient must return to clinic for repeat as soon as possible, within 24-48 hours.
    - A report of opioid use or a positive opioid UTS will result in intensification of the treatment plan potentially including: increased frequency of clinic visits, confirm attendance and increase frequency of counseling, encourage meetings, provide education on relapse prevention and overdose and send naloxone prescription to pharmacy. This includes the patient returning to weekly clinic visits until they are stable.
    - If the patient has three to four consecutive weeks of positive opioid urines, the patient will be assisted with a transfer to a higher level of care. The 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.
        - Again, clinicians should always carefully weigh the risk versus benefit of continuing treatment in an office based setting prior to referring to another level of care.

POLYSUBSTANCE USE:

COCAINE

- Report of cocaine use or a positive cocaine UTS result is addressed by the OBAT NCM during the visit or through a subsequent phone conversation and the treatment plan is intensified accordingly to meet the needs of the patient.
    - If the patient has a positive UTS and does not admit to use at the visit and denies use when addressed on the phone with OBAT NCM, the patient must return to clinic for repeat as soon as possible, within 24-48 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.
    - 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 NCM during visit or through a subsequent phone conversation and the treatment plan is intensified accordingly to meet the needs of the patient.
    - If the patient has a positive UTS and does not admit to use at the visit and denies use when addressed on the phone with OBAT NCM, the patient must return to clinic for repeat as soon as possible, within 24-48 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 they are stable.
    - If the patient reports that they are struggling with attention deficit and/or hyperactivity, offer the patient a referral to psychiatry for evaluation.
    - If the patient reports diagnosis of ADHD and requests amphetamine medications, the patient should undergo a neuro-psych evaluation for a proper diagnosis.
    - Run prescription drug monitoring program (PDMP) to check for unreported prescribed medications.
    - Two to three UTS positive for illicit amphetamine in a row may result in further intensification of the treatment plan, such as referral to IOP and/or a relapse

prevention group, or other self-help, increased counseling, and/or increased OBAT visits.

- 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 a positive benzodiazepine UTS result is addressed by the OBAT NCM during the visit or through a subsequent phone conversation and the treatment plan is intensified accordingly to meet the needs of the patient.
    - If the patient has a positive UTS and does not admit to use at the visit and denies use when addressed on the phone with OBAT NCM, the patient must return to clinic for repeat as soon as possible, within 24-48 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 they are stable.
    - If the patient reports they are struggling with anxiety, offer a referral to psychiatry for evaluation. Providers should make every effort to stay clear of benzodiazepines and other medications with potential for misuse.
- Run prescription drug monitoring program (PDMP) to check for unreported prescribed medications.
- Urine samples will be sent for confirmatory testing and identification of the medication if positive for benzodiazepines twice in a row.
- Ongoing benzodiazepine misuse despite intensified treatment plan may 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 breathalyzer, and additional clinical supports and monitoring as needed.
- Patients presenting to clinic smelling of alcohol, have a positive breathalyzer result, or report risky alcohol use will require treatment plan revision. Additionally, a safety assessment should be completed, which may include their ability to care for any accompanying children or alternate transportation home.

- Patients struggling with alcohol use and/or cravings may be offered acamprosate (Campral) or disulfiram (Antabuse) with provider input and agreement. Patients managed on buprenorphine/naloxone cannot be treated with any naltrexone formulation, as these medications are contraindicated. See Appendix 8A for Consent to Treat with Disulfiram form.

- 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.

Clinicians should always carefully weigh the risk versus benefit of continuing treatment in an office based setting prior to referring to another level of care.

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), the patient is called by the OBAT NCM within 24 hours of the result in an effort to address a potential relapse or medication issue.

- As with patients who are prescribed buprenorphine, clinicians should always carefully weigh the risk versus benefit of continuing treatment with naltrexone in the current treatment setting prior to referring to another level of care.

OPIOIDS

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

    - If the patient has a positive UTS and does not admit to use at the visit and denies use when addressed on the phone with OBAT NCM, the patient must return to clinic for repeat as soon as possible, within 24-48 hours.

- Intensify OBAT plan, including: increased frequency of clinic visits, confirm attendance and increase frequency of counseling, encourage meetings, provide relapse prevention education and overdose prevention education and a prescription for naloxone. This also includes the patient returning to weekly clinic visits until they are 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 the naltrexone interval (within a week of the 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. The 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, urine EtG or breathalyzer screening is advised as needed.

- 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 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) or disulfiram (Antabuse) with provider input and agreement. See Appendix 8A for Consent to Treat with Disulfiram form.

- Patients presenting to clinic appearing impaired, smelling of alcohol, have a positive breathalyzer result, provides reports of ongoing alcohol use, or noted ED admissions for alcohol use disorder will require urgent team assessment and revision of treatment plan, safety assessment, and 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 NCM during the visit or through a subsequent phone conversation and the treatment plan is intensified accordingly to meet the needs of the patient.

    - If the patient has a positive UTS and does not admit to use at the visit and denies use when addressed on the phone with OBAT NCM, the patient must return to clinic for repeat as soon as possible, within 24-48 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 they are stable.

    - Ongoing positive urine screens for cocaine will result in further intensification of the treatment plan such as referral to IOP and/or a relapse prevention group, increased counseling.

    - 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 the OBAT NCM during the visit or through a subsequent phone conversation and the treatment plan is intensified accordingly to meet the needs of the patient.
    - If the patient has a positive UTS and does not admit to use at the visit and denies use when addressed on the phone with OBAT NCM, the patient must return to clinic for repeat as soon as possible, within 24-48 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 they are stable.
    - If the patient reports they are struggling with attention deficit and/or hyperactivity, offer the patient a referral to psychiatry for evaluation.
    - If the patient reports a diagnosis of ADHD and is requesting amphetamine medications, the patient will be required to undergo neuro-psych evaluation for a proper diagnosis.
    - Run prescription drug monitoring program (PDMP) to check for unreported prescriptions.
    - Ongoing 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.
    - 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 the OBAT NCM during a visit or through a subsequent phone conversation and the treatment plan is intensified accordingly to meet the needs of the patient.
    - If the patient has a positive UTS and does not admit to use at the visit and denies use when addressed on the phone with the OBAT NCM, patient must return to clinic for repeat as soon as possible, within 24-48 hours.
- A positive result is addressed by the OBAT NCM, relapse prevention education will be provided and the treatment plan will be 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 they are stable.

- If the patient reports they are struggling with anxiety, offer the patient a referral to psychiatry for evaluation. Every effort should be made to avoid medications with potential for misuse.
- Run prescription drug monitoring program (PDMP) to check for unreported prescriptions.
- Urine samples will be sent for confirmatory testing and identification of the benzodiazepine if positive for benzodiazepines twice in a row.
- Two to 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.
- Ongoing 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 IMPAIRED

Any patient who presents to the clinic intoxicated (i.e. under the influence of alcohol or any other substance) will require urgent team assessment, safety assessment, and revision of their treatment plan. Additionally, if a patient who presents intoxicated is accompanied by a child or other dependent, please refer to your institution's policies regarding safety concerns and mandated reporting.

BUPRENORPHINE/NALOXONE TAPERING

- A substance use disorder is a chronic and complex condition, therefore enforcing a predefined treatment duration is not recommended nor is it advised.

- 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.

    - Buprenorphine/naloxone should be tapered over days, weeks, or months, depending on patient's tolerance of symptoms.

- Upon abrupt buprenorphine discontinuation, withdrawal syndrome may occur.

    - Subjective withdrawal symptoms typically begin within the first three days.

    - 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 or years following discontinuation of the medication. It is important to respond to patient's protracted withdrawal symptoms to support their recovery process and avoid relapse.

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

    - Negative buprenorphine screens.

    - Ongoing opioid use or use of other illicit drugs and **the risk of continuing treatment outweighs the benefit.**

    - Patient presents to OBAT clinic impaired, incidence of overdose, or hospitalization related to substance use and **the risk of continuing treatment outweighs the benefit.**

    - Multiple missed appointments or inability to contact patient:

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

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

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 the 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, who have a positive breathalyzer result provides reports of ongoing ETOH use, or has noted ED admissions for ETOH use and **the risk of continuing treatment outweighs the benefit.**

    - Ongoing use of other illicit drugs 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 and **the risk of continuing treatment outweighs the benefit.**

- Multiple missed appointments or the inability to contact patient:

    - If a patient misses an initial appointment for an extended-release naltrexone injection, he/she should be instructed to receive the next injection as soon as possible. Reassess the patient status prior to administering the medication. Conduct a naloxone/naltrexone challenge if there is risk of precipitating withdrawal. Augment the treatment plan as needed.

    - 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.

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

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 urgent assessment. This assessment should include toxicology testing and a medication count. When possible, confirmatory testing (i.e. via GC/MS) is recommended to confirm presence 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).

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, and/or threatening safety of staff or other patients.

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 use disorder 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 return to use or 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. Please support patients during this process.
- Target methadone dose: 20-30mg daily for one to two weeks prior to transition is optimal but 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 between one to two weeks.

- It is not necessary to begin with buprenorphine mono-tablet (Subutex) before initiating buprenorphine/naloxone, provided that the 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 the 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 a COWS score of 13-15, rather than by time since last methadone dose.

- Close monitoring and small amounts of clonidine, anxiolytics (including benzodiazepines), sedative/hypnotics, bentyl, trazadone, 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 three times daily until maintenance dosing as attained). Frequent visits, adequate supports, and supportive environment to assist in the transition.

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

- **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 a COWS score 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 they are absent. Patients transitioning from methadone may require higher dosing initially and then taper down over time.

- Continue induction according to patient's 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 with making this transition and not jeopardizing relapse.

BUPRENORPHINE TO NALTREXONE TRANSFERS

TRANSITIONING FROM BUPRENORPHINE/NALOXONE MAINTENANCE TO NALTREXONE

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 five to seven 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 two weeks.[25]

- Sigmon et al. (2009) conducted a pilot study of 15 opioid dependent individuals enrolled to complete buprenorphine/naloxone stabilization, a two-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 two-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 two to four days, combined with increasing doses of naltrexone. Following buprenorphine discontinuation, patients received naltrexone 50mg and were discharged. Higher withdrawal discomfort was reported in the initial two days of treatment. All patients completed the protocol. Results: 33% of patients were still taking naltrexone after four 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 is administered every 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. the patient begins to experience withdrawal that interferes with functioning or leads to return to use, or the patient does not tolerate the medication), the patient may return to buprenorphine treatment without a gap in treatment.
- The 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 five to seven 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. Please support patients during this process.
    - 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 results that are negative for ALL opioids rather than by last buprenorphine dose; family pressure; 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 three times daily until free of withdrawal signs/symptoms and the patient is 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.

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 NCM.

- UTS negative for all opioids.

- 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 antiretroviral medications.
- Buprenorphine/naloxone use does not interfere with clinical response to antiretroviral medications.
- Side effects from drug interactions between HIV medications and buprenorphine/naloxone are less severe/significant than those experienced with methadone.
- Reassure patients that treatment for their opioid dependence will not interfere with treatment for their HIV disease management.

CONSIDERATIONS:

- 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 should determine treatment selection.
    - With opioid agonists, 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.

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 of 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 seven patients with hepatitis C using buprenorphine/naloxone who had increased ALT 39x normal.[29]
        - All continued buprenorphine/naloxone; 50% dose reduction in three patients.
        - All recovered without any clinical complications.
- When initiating buprenorphine/naloxone treatment it is important to do baseline hepatic testing and then retest transaminases as needed based of clinical assessment.

NALTREXONE

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

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

- Draw follow-up AST and ALT eight to12 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 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 six-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 six-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, you 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 their clinical team or present to an emergency department for evaluation if present.

PREGNANCY AND BREASTFEEDING

OPIOID USE DISORDER IN PREGNANCY IS CONSIDERED HIGH-RISK.

- First trimester: risk for spontaneous abortion.
- Third 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 in 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, 1.1mg vs. 10.4mg) 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 principles 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 seven previously published studies found no evidence of adverse maternal or neonatal outcomes related to the 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 complications 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 if available.
- Minimal information exists on dosing changes by trimester.
- Once-daily dosing is effective in pregnancy, however many require divided dosing.
- Frequent follow up visits should include: assessment, support, UTS, safety assessment, counseling, education and social determinants of health screening.
- Women should be encouraged to breastfeed provided their UTS are negative for opioids and the mother is not prescribed any other medications that are contraindicated for breastfeeding.
- Breastfeeding 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 breastfeeding infant is exposed to only 1/10 of buprenorphine/naloxone ingested.

- Breastfeeding during buprenorphine/naloxone use does not suppress neonatal abstinence syndrome. However the close contact afforded by breastfeeding has been shown to assist with symptoms of NAS and enhances maternal-child bonding.

- Cessation of breastfeeding is not associated with the onset of neonatal abstinence syndrome.

- **Naltrexone in Pregnancy:** Little research has been conducted to evaluate the safety or efficacy of naltrexone in pregnancy. Naltrexone, in 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, a decision should be made to either discontinue the medication or discontinue nursing. Labeling from the manufacturer advises against breastfeeding while taking naltrexone, both with oral and injectable formulations.

FOR ADDITIONAL GUIDANCE REGARDING THE CARE OF WOMEN WITH OPIOID USE DISORDER:

- Institute for Health and Recovery, Massachusetts Perinatal Quality Collaborative**.** Maternal Opioid Use During Pregnancy Toolkit. *"This toolkit provides guidance in regards to the medical, psychological and social needs of pregnant women with opioid use disorders thereby improving maternal and newborn health outcomes. It has been developed to help maternal health providers advance the clinical interventions by offering screening, treatment engagement and coordinated care throughout the pregnancy and post-delivery."* http://www.healthrecovery.org/maternal-opioid-use/

[‡] Adapted from information accessed at: https://www.vivitrol.com/important-safety-information

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 the 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 two to three weeks of stabilization, reassess patients for psychiatric symptomatology.
- Substance-induced psychiatric disorders generally resolve within one to two weeks of treatment initiation and cessation of substance use.
- 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: 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 use disorder 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 may necessitate higher opioid doses at shorter dosing intervals. All patients on buprenorphine/naloxone maintenance should be co-managed with their buprenorphine/naloxone provider during the pre- and post-procedure periods.[35]

BUPRENORPHINE: PERI-PROCEDURE MANAGEMENT

RECOMMENDATIONS:

- Daily buprenorphine/naloxone dosing remains uninterrupted. Patient takes usual buprenorphine/naloxone maintenance dose on the morning of procedure.
    - Because of its high affinity at the opioid receptor, consider fentanyl as the opioid of choice for analgesia during procedures and in the PACU for these patients.
- Continue patient's home dose of buprenorphine/naloxone post-operatively.
    - Consider splitting the patient's usual buprenorphine/naloxone dose into every eight hour dosing (e.g., 24mg per day changed to 8mg every eight hours)
- If further pain control is needed, begin by utilizing multimodal pain management with non-opioids (NSAIDs, acetaminophen, lidocaine patches etc.).
- Consider the use of local and regional anesthesia as indicated.
- If opioids are needed for breakthrough pain, standard dosing protocols should initially be utilized with careful monitoring and the understanding that patients with a history of OUD may require higher than usual doses due to cross tolerance and increased pain sensitivity.
- PCA's without a basal component may be considered in addition to a patient's buprenorphine if the pain is not adequately captured. If a PCA is utilized, discontinue oral PRN opioids.
- The buprenorphine/naloxone provider should be contacted pre-and post-procedure to assist in ongoing assessment, support, and pain management.
- Schedule patient to be seen by their buprenorphine/naloxone prescriber within one week post procedure.

BUPRENORPHINE: ACUTE AND CHRONIC PAIN MANAGEMENT

GENERAL PRINCIPLES FOR PAIN MANAGEMENT ON BUPRENORPHINE/NALOXONE:

- Patients physically dependent on opioids require maintenance on daily equivalence before any pain relief is achieved with opioid analgesics (the "opioid debt").
    - Evidence-based data now supports continuing patients on their daily maintenance dose of buprenorphine/naloxone during periods of acute pain, rather than discontinuing and later restarting buprenorphine treatment. Maintaining buprenorphine/naloxone has been shown to increase pain control while allowing the patient to remain stabilized on their medication treatment for OUD.
- Reassure patients that their addiction will not be an obstacle to aggressive pain management.
- Include patients in decision-making process to alleviate anxiety.
- Establish clear goals for pain management.
- Promote pain reduction rather than elimination.
- Reach for improved function.
- Address associated symptoms.
- Use a multimodal approach to pain management:
    - Consider splitting the patient's usual buprenorphine/naloxone dose into every eight hour dosing (e.g., 24mg per day changed to 8mg every eight hours).
    - Consider a modest increase in patient's buprenorphine/naloxone maintenance dose.
    - Try non-opioids and adjuvant therapies next.
        - Examples include: acupuncture, acupressure, massage, physical therapy, hydrotherapy, mindful meditation, NSAIDs, acetaminophen, topical lidocaine, SSRIs, TCAs, etc.
    - Use opioid analgesics as the last option.
- If opioid analgesics are necessary for treatment of chronic pain, buprenorphine/naloxone should be discontinued and methadone maintenance initiated.

SAMPLING OF THE EVIDENCE:

- Macintyre et al., (2013) performed a retrospective cohort study comparing pain relief and opioid requirements in the first 24 hours after surgery in 22 patients maintained on buprenorphine and 29 patients maintained on methadone, who were also prescribed patient-controlled analgesia. The study found no significant differences in pain scores, incidence of nausea or vomiting requiring treatment, or sedation between the buprenorphine or methadone maintained patient groups overall. Additionally it was found that buprenorphine maintained patients who were not given their usual buprenorphine dose the day after surgery used significantly more patient-controlled analgesia (P=0.02) compared with those who had received their dose.[36]

- Kornfield and Manfredi (2010) performed a literature review examining five buprenorphine-maintained patients who underwent seven planned major surgical procedures with high levels of anticipated post-operative pain (right-side colectomy, small bowel resection, L and R knee replacements, bilateral mastectomy, breast reconstruction, X-Stop procedure). In all seven cases, daily buprenorphine maintenance dosing was uninterrupted. Full agonist opioids and non-opioid analgesics were used in conjunction with daily buprenorphine dosing. In all seven surgical cases, good to excellent pain control was achieved.[37]

- Silca & Rubenstein (2016) presented a case comparing two different outcomes for the same surgical course performed at two different times on the same chronic pain patient. Results showed that pain control was easier to achieve, and functional recovery was greater when buprenorphine was maintained throughout the perioperative period when compared with using a full mu agonist opioid for chronic pain perioperatively.[38]

PAIN MANAGEMENT PROTOCOL: NALTREXONE

BACKGROUND:

- These guidelines are designed for patients maintained on naltrexone undergoing invasive procedures. There is currently a lack of evidence-based research to direct the management of patients prescribed naltrexone in the peri-procedure period. Below are guidelines using expert opinions based on pharmacological principles of naltrexone with the intent to avoid under-treatment of acute pain while also avoiding potential disruption of opioid use disorder and/or alcohol use disorder treatment.

- 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.[39]

- All OBAT patients receiving naltrexone treatment should be co-managed with their OBAT provider during the pre- and post-procedure period, as well as during periods of acute and chronic pain.

OBAT Policy for Naltrexone Patients Requiring Surgery:

- Patient to notify OBAT staff of expected procedure as soon as they are aware of it.
- 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.
- If possible, extended-release naltrexone should be discontinued four to five weeks prior to the planned surgery/procedure date.
    - May bridge patient with oral naltrexone.
    - Oral naltrexone should be discontinued 48-72 hours before the procedure.[38]
- 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 oral naltrexone should be discontinued 72 hours beforehand. 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.
- Schedule patient to be seen by their OBAT provider as soon as possible post-procedure to have their post-procedure pain managed and to be safely restarted on naltrexone when it is safe to do so.

NALTREXONE: CHRONIC PAIN MANAGEMENT

- Chronic pain requiring opioid medications is a contraindication for naltrexone and should be evaluated as part of the OBAT screening process.

- For patients seeking medication treatment for an opioid use disorder who also have severe chronic pain, agonist medications should be considered, including buprenorphine/naloxone or methadone maintenance therapy.

- 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 multimodal approach to pain management:

        - Try non-opioids initially.

        - Try adjuvant therapies next.

NALTREXONE: UNANTICIPATED ACUTE PAIN MANAGEMENT

- If a patient receiving ongoing extended-release naltrexone injections experiences unanticipated severe, acute pain or requires emergent surgery, refer to "Reversal of Extended-Release Injectable Naltrexone".
- For patients taking oral naltrexone with unanticipated acute pain:
    - Include patients in decision-making process to allay anxiety.
    - Address underlying cause of pain.
    - Establish clear goals for pain management:
        - Pain reduction rather than elimination.
        - Improved function.
        - Addressing associated symptoms.
- Use multimodal approach to pain management:
        - Try non-opioids initially.
        - Try adjuvant therapies next.
- For patients prescribed a formulation of naltrexone, if opioid analgesics are absolutely necessary for treatment of unanticipated acute pain, naltrexone should be discontinued.
    - If this occurs, higher than usual doses of opioids may be attempted to overcome naltrexone's opioid antagonist effects.
    - Prescribing opioids to a patient that has been maintained on a formulation of naltrexone must be done with close observation for respiratory depression. Refer to "Reversal of Extended-Release Injectable Naltrexone."
    - Patients should be monitored closely with increased supports throughout the acute pain period.

REVERSAL OF EXTENDED-RELEASE INJECTABLE NALTREXONE[4]

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.

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

[4] Adapted from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2010/021897s015lbl.pdf

APPENDICES

APPENDIX 1: DSM-5 CHECKLIST OF DIAGNOSTIC CRITERIA: OPIOID USE DISORDER

A problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by at least 2 of the following, occurring within a 12-month period:

Diagnostic Criterion	Meets Criterion?	Additional/ Supporting Information
1. Opioids are often taken in larger amounts or over a longer period than was 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 or urge to use opioids.		
5. Recurrent opioid use resulting in a 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 opioid use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.		
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. A 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. Opioids (or a closely related substance) are taken to relieve or avoid withdrawal symptoms.		

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

Specify if:

In early remission: After full criteria for opioid use disorder were previously met, none of the criteria for opioid use disorder have been met for at least 3 months but for less than 12 months (with the exception that Criterion 4, "Craving, or a strong desire or urge to use opioids," may be met).

In sustained remission: After full criteria for opioid use disorder were previously met, none of the criteria for opioid use disorder have been met at any time during a period of 12 months or longer (with the exception that Criterion 4, "Craving, or a strong desire or urge to use opioids," may be met).

On maintenance therapy: This additional specifier is used if the individual is taking a prescribed agonist medication such as methadone or buprenorphine and none of the criteria for opioid use disorder have been met for that class of medication (except tolerance to, or withdrawal from, the agonist). This category also applies to those individuals being maintained on a partial agonist, an agonist/antagonist, or a full antagonist such as oral naltrexone or depot naltrexone.

In a controlled environment: This additional specifier is used if the individual is in an environment where access to opioids is restricted.

Current severity:

- *Mild:* Presence of 2–3 symptoms. **Code as: F11.10 (ICD-10)**
- *Moderate:* Presence of 4–5 symptoms. **Code as: F11.20 (ICD-10)**
- *Severe:* Presence of 6 or more symptoms. **Code as: F11.20 (ICD-10)**

APPENDIX 2: DSM-5 CHECKLIST OF DIAGNOSTIC CRITERIA: ALCOHOL USE DISORDER

A problematic pattern of alcohol use leading to clinically significant impairment or distress, as manifested by at least two of the following, occurring within a 12-month period:

Diagnostic Criterion	Meets Criterion?	Additional/Supporting Information
1. Alcohol is often taken in larger amounts or over a longer period than was intended.		
2. There is a persistent desire or unsuccessful efforts to cut down or control alcohol use.		
3. A great deal of time is spent in activities necessary to obtain alcohol, use alcohol, or recover from its effects.		
4. Craving, or a strong desire or urge to use alcohol.		
5. Recurrent alcohol use resulting in a failure to fulfill major role obligations at work, school, or home.		
6. Continued alcohol use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of alcohol.		
7. Important social, occupational, or recreational activities are given up or reduced because of alcohol use.		
8. Recurrent alcohol use in situations in which it is physically hazardous.		
9. Alcohol use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by alcohol.		
10. Tolerance, as defined by either of the following:		
A. A need for markedly increased amounts of alcohol to achieve intoxication or desired effect.		
B. A markedly diminished effect with continued use of the same amount of alcohol.		
11. Withdrawal, as manifested by either of the following:		
A. The characteristic withdrawal syndrome for alcohol (refer to Criteria A and B of the criteria set for alcohol withdrawal, pp. 499–500).		
B. Alcohol (or a closely related substance, such as a benzodiazepine) is taken to relieve or avoid withdrawal symptoms.		

Specify if:

- **In early remission:** After full criteria for alcohol use disorder were previously met, none of the criteria for alcohol use disorder have been met for at least 3 months but for less than 12 months (with the exception that Criterion 4, "Craving, or a strong desire or urge to use alcohol," may be met).
- **In sustained remission:** After full criteria for alcohol use disorder were previously met, none of the criteria for alcohol use disorder have been met at any time during a period of 12 months or longer (with the exception that Criterion 4, "Craving, or a strong desire or urge to use alcohol," may be met).
- **In a controlled environment:** This additional specifier is used if the individual is in an environment where access to alcohol is restricted.

Current severity:

- ☐ *Mild:* Presence of 2–3 symptoms. **Code as: F10.10 (ICD-10)**
- ☐ *Moderate:* Presence of 4–5 symptoms. **Code as: F10.20 (ICD-10)**
- ☐ *Severe:* Presence of 6 or more symptoms. **Code as: F10.20 (ICD-10)**

APPENDIX 3: TELEPHONE SCREENING

Demographic Info

How did you hear about the hotline?

☐ 1 = Spouse ☐ 2 = Friend ☐ 3 = Medical Provider
☐ 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

Substance Use History

	Age of initiation	*Date of most recent use*	*Frequency?*	*Route of administration*	*Amounts used*
What is your substance 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*** ***__Oxycodone product*** ***__Buprenorphine*** ***__Methadone*** ***__Other opioid_____***					
Benzodiazepine					
Alcohol					
Cocaine					
Amphetamines Including methamphetamine					
Tobacco					
Other					

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

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

What substances have you used in the past?
Includes age of first use, date of most recent use, route, frequency, and quantity.
☐ 1 = heroin
☐ 2 = fentanyl
☐ 3 = buprenorphine/naloxone
☐ 4 = methadone
☐ 5 = oxycodone product
☐ 6 = other opioid
☐ 7 = cocaine
☐ 8 = benzodiazepines
☐ 9 = Nothing
☐ 10 = Alcohol
☐ 11= Amphetamines
☐ 12 = Other
☐ 13 = Nothing

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 ever engaged in treatment for a substance use disorder? ☐ 1= Yes ☐ 2 = No

If yes, how many times to each type?
_____ Detoxification Program
_____ Residential (Rehab or Halfway House)
_____ Buprenorphine/naloxone maintenance
_____ Naltrexone (oral or injectable)
_____ Driving Impaired Program
_____ Methadone maintenance
_____ Intensive Outpatient Program

Do you attend peer support 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 engaged in a Methadone Maintenance program? ☐ 1= Yes ☐ 2 = No

Are you currently on Methadone Maintenance? ☐ 1= Yes ☐ 2 = No

If yes to currently on engaged in Methadone treatment:

Where are you engaged in Methadone Maintenance? _____

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? _____

If not currently engaged in methadone treatment:

When were you on Methadone Maintenance? _____

Where were you on Methadone Maintenance? _____

How long were you on Methadone Maintenance? _____

What was your dose? _____

Why did you stop Methadone treatment? _____

Buprenorphine History

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

If yes:

Where were you prescribed buprenorphine/naloxone:_____

When were you prescribed 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:

Where were you prescribed naltrexone:_____

When were you prescribed naltrexone? _____

Did you ever receive an extended-release naltrexone injection? _____

Why did you stop naltrexone treatment? _____

Mental Health History

Are you currently seeing a psychiatrist, psychologist or counselor for a mental health issue?
☐ 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.

Are you willing to sign a consent for release of 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)

If yes:
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 status)

If yes:
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., per program protocol…

Health status

Have you ever been diagnosed with any medical conditions? Mark all that apply.
☐ 1=Diabetes (specify type): _____
☐ 2=Heart disease (specify type): _____
☐ 3=Cancer (specify type): _____
☐ 4=Asthma
☐ 5=Tuberculosis (TB)
☐ 6=Endocarditis
☐ 7=Skin infection
☐ 8= HIV ➔ If yes, are you currently in care? ☐ 1= Yes ☐ 2 = No
☐ 9= Hepatitis A
☐ 10= Hepatitis B ➔ If yes, have you been treated? ☐ 1= Yes ☐ 2 = No
☐ 11= Hepatitis C ➔ If yes, have you been treated? ☐ 1= Yes ☐ 2 = No
☐ 12= Seizure disorder ➔ Are you on medications? ☐ 1= Yes ☐ 2 = No
☐ 13= Head Trauma/Brain Injury
☐ 14= Pancreatic Problems
☐ 15= Other (specify type):_____
☐ 16= None

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

If yes, please briefly explain:_____

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____

Health Care Provider Information

Where do you get most of your healthcare? _____

When was the last time you saw a health care provider?
☐ 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 provider? _____

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 disorder? ☐ 1= Yes ☐ 2 = No

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

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 disorder?
☐ 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 or rent
☐ 3 = In a house or apartment owned or rented by family or friends
☐ 4 = Hotel
☐ 5 = Alcohol or substance use 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:

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 contraception are you currently utilizing? (check all that apply)
☐ Relying on male condoms
☐ Oral contraceptives
☐ Injection (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:

Substance Use History

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

☐ 14 = Nothing

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

If yes, where/who is prescribing your buprenorphine/naloxone? _____

What was your dose? _____

When did you receive your most recent prescription? _____

Naltrexone:

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

If yes, when were you on naltrexone? _____

Have you ever received an extended-release naltrexone injection? _____

If yes, when was your most recent injection? _____

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? _____

Health status

Have you ever been diagnosed with any medical conditions? Mark all that apply.
☐ 1=Diabetes (specify type): _____
☐ 2=Heart disease (specify type): _____
☐ 3=Cancer (specify type): _____
☐ 4=Asthma
☐ 5=Tuberculosis (TB)
☐ 6=Endocarditis
☐ 7=Skin infection
☐ 8= HIV ➔ If yes, are you currently in care? ☐ 1= Yes ☐ 2 = No
☐ 9= Hepatitis A
☐ 10= Hepatitis B ➔ If yes, have you been treated? ☐ 1= Yes ☐ 2 = No
☐ 11= Hepatitis C ➔ If yes, have you been treated? ☐ 1= Yes ☐ 2 = No
☐ 12= Seizure disorder ➔ Are you on medications? ☐ 1= Yes ☐ 2 = No

☐ 13= Head Trauma/Brain Injury
☐ 14= Pancreatic Problems
☐ 15= Other (specify type):_____
☐ 16= 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?_____

Have you been tested for Hepatitis C? ☐ 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____

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 treatment agreement 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 benzodiazepine, other sedating medications 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 opioid 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 naltrexone 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 identification: bracelet and/or dog tag.

☐ Patient has been informed that both buprenorphine/naloxone and naltrexone are Category C medications. Breastfeeding is a currently contraindicated during naltrexone treatment.

☐ Labs sent if indicated may include complete blood count (CBC), Hepatitis A, B, and C serologies, and comprehensive metabolic panel. Required testing includes human chorionic gonadotropin (hCG), urine toxicology screen, and HIV testing strongly recommended.

☐ Overdose education provided. Pt has been trained and has access to use a naloxone rescue kit, if not a prescription is sent to the pharmacy

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/Re-Evaluation

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

☐ Patient Presents for Subsequent Induction/Re-Evaluation

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:

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 OBAT provider 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
☐ Injection (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 peer support 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

Urine toxic screen sent? ☐ 1 = Yes ☐ 2 = No

Urine sample sent for confirmatory testing: ☐ 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 OBAT provider 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 peer support 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

Urine toxic screen sent? ☐ 1 = Yes ☐ 2 = No

Urine sample sent for confirmatory testing: ☐ 1 = Yes ☐ 2 = No

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

Comments:_____

APPENDIX 7: INTAKE CHECK-LIST

Intake Checklist

INTAKE ITEM	**Date & Initials**
INTAKE VISIT WITH NURSE	
CONSENT FORM SIGNED	
PARENTAL CONSENT SIGNED	
HIV TESTING Y / N	
TREATMENT AGREEMENT SIGNED	
LABS DRAWN	
UTS OBTAINED	
HQN (ALL WOMEN) HCG?	
BCP REVIEW (*ALL WOMEN & DOCUMENTED IN NOTE*)	
MEDICATION LIST	
ALLERGIES LIST	
CONSENT FOR COUNSELOR/PSYCHIATRIST	
CONSENT FOR PROBATION/PAROLE OFFICER	
OTHER CONSENT IF NEEDED	
EMERGENCY CONTACT INFO AND CLINIC CONTACT INFO	
HCV REFERRAL	
PPD CURRENT	
ORIENTATION TO THE TEAM AND ITS LOCATION. PROVIDED CONTACT INFORMATION.	
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 opioid dependence. Qualified providers 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 or other sedating medications may result in overdose or death.

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 may 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

Naltrexone is a prescription medication that is used to:

- Prevent relapse to opioid use
- Treat alcoholism

You cannot start naltrexone now if you:

- Are currently using opioids
- Are currently having withdrawal from 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 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 •Swelling, redness and warmth
•Area feels hard, lumpy •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 •Trouble breathing or wheezing
•Chest pain •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 •More tired than normal,
•Dark urine •White stool or diarrhea
•Stomach pain, or loss of appetite

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 does not 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 naltrexone affects you. _____

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

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

Relapse to opioids 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 opioids. Alert your family, friends, or close contacts that you are on naltrexone 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. _____

For all women of childbearing age: a pregnancy test will be completed before treatment has begun and then before each next injection. If you learn you are pregnant at any time, please alert your medical team. _____

You will see your treatment 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

BOSTON MEDICAL CENTER
CONSENT FOR TREATMENT WITH DISULFIRAM

- Disulfiram (Antabuse) is a medication that is used to help prevent relapse to alcohol.

- The body is not able to process alcohol while taking disulfiram. This includes even very small doses that may be absorbed from perfume, hand sanitizer, food items (dressings, vinegars, marinades, sauces, extracts etc.) and alcoholic beverages. It is important to check labels of items that will go in or on your body.

- Disulfiram should NOT be taken if you have consumed alcohol within the past 12 hours.
- An alcohol-disulfiram reaction may include: trouble breathing, throbbing pain in head and neck, nausea, vomiting, sweating, thirst, palpitations, weakness, dizziness, blurred vision and confusion. Severe reactions may involve respiratory failure, heart failure, unconsciousness, seizure and death.
- The larger the dose of the alcohol, the stronger the disulfiram-alcohol effect. The reaction can last from 30 minutes to several hours, or as long as it takes for the alcohol to be metabolized.

- Disulfiram-alcohol reaction may occur for up to 2 weeks after stopping medication.

- This medication can affect your liver. Blood will be drawn before starting treatment, again soon after starting treatment and then as needed to make sure your liver is healthy. Tell your treatment team or seek emergency care if you develop any of these symptoms:

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

- Allergic reactions can happen when taking disulfiram. Alert your treatment team 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

- The most common side-effect of disulfiram is drowsiness, but severe adverse reactions have occurred in some individuals. These include: liver failure, nerve irritation/ neuropathy, psychosis, acne, skin rash, impotence, and inflammation of the optic nerve.

- There are some medications that should not be taken with disulfiram (metronidazole, dronabinol, certain cough medicines, others). It is important to let your providers know that you are prescribed disulfiram. Do not change your medications without checking with your provider.

- It is not known if disulfiram is safe during pregnancy or if it can be passed into breast milk. A pregnancy test will be done before treatment has begun. If you learn you are pregnant at any time please alert your medical team. Disulfiram is not recommend while breastfeeding.
- Store disulfiram at room temperature, in a light-resistant container. Keep all drugs out of the reach of children and pets.
- Relapse to alcohol is very dangerous after being on disulfiram. Alert your family, friends and close contacts that you are on disulfiram and about the risk of a severe reaction should you have a relapse
- Breathalyzers and toxicology screens will be done at each OBAT visit to help assure abstinence from alcohol.
- Disulfiram 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

_____ _____

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)

AUTHORIZE _____ TO
(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 Buprenorfina y tomar más opioides pueden resultar en una sobredosis de opioides.

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

Combinar Buprenorfina/naloxone con alcohol y otros medicamentos puede ser dañino. Combinar Buprenorfina/naloxone con medicinas como Klonopin, Valium, Haldol, Libium, Ativan u otros medicamentos sedantes puede resultar en sobredosis o 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 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 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

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 agreement, as follows.

I agree to keep, and be on time to, all my scheduled appointments with my doctor and nurse, and to conduct myself in a courteous manner in the clinic. 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 due to the fact it is a controlled substance. 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 provider 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 provider has instructed and not to alter the way I take my medication without first consulting my provider 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 may result in a positive opioid screen.

I understand that if I misuse other illicit substances or medications, this issue will be addressed through changes in my treatment plan to assist me. If I continue to struggle with ongoing substance 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, which may include 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 regularly access the State Prescription Monitoring Program (PDMP) 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 referral to another level of care.

I understand that the Boston Medical Center Office Based Addiction Treatment Program does not have a chain of custody over urine toxicology screens. The purpose of these toxicology 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.

Using a new medicine can cause you to react in a number of ways. It is recommended that you do not drive when you first start using a new medicine until you know how that medication affects you.

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, 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)

CONTRATO DE TRATAMIENTO CON BUPRENORFINA

Como paciente del protocolo de Buprenorfina para el tratamiento del desorden de uso de opioides, yo libre y voluntariamente acepto este acuerdo para tratamiento, como sigue.

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 debido al hecho que es una sustancia controlada. 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.

Estoy de acuerdo con no consumir semillas de amapola mientras este en esté en el programa de tratamiento. Consumir semillas de amapola puede resultar en una prueba de opioides positiva.

Entiendo que si uso otras sustancias ilegales o medicamentos, esta situación va a ser 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.

Pruebas de opioides positivas serán evaluadas por el equipo de tratamiento, lo que puede resultar en tratamiento más intensivo.

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 PDMP, 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.

Entiendo que el BMC OBAT no tiene una cadena de custodia sobre las pruebas de toxicología en orina. El propósito de estas pruebas de toxicología es para mi tratamiento en BMC solamente. Si los pacientes tienen requisitos legales or de su programa que requieren pruebas de toxicología en orina observadas, estas deben ser hechas independiente de su tratamiento en 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 las medicinas solas no son suficiente tratamiento para mi enfermedad, y estoy de acuerdo en participar en educacion, consejeria y programas de prevencion de recaidas segun provistos para asistirme en mi tratamiento.

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.
- If an emergency arises outside or normal office hours that requires immediate attention from OBAT staff, patients should call the OBAT on call number at 857-225-0136.
- Patients are required to keep the OBAT clinic updated on all phones numbers and ways to be contacted.
- An OBAT Clinic NCM 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 the treatment plan may need to be reviewed and changed to better meet your clinical needs t
- Ongoing positive urine screens for opioids will prompt a revision of the treatment plan including referral to more structured treatment options.
- Ongoing struggles with other substances will require a restructured treatment plan potentially 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.

- If an appointment cannot be kept, it is the patient's responsibility to reschedule the appointment. 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.

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 as these individuals may be at increased risk for relapse. However, patients who do not engage in counseling or outside recovery support services should continue to receive more intensive monitoring from the OBAT team.

- 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.

- 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:

- 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 on clinic property.

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 may call the patient sporadically to come in to the clinic for a random 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 does not return for a random callback 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 Office Based Addition 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 may 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.
- Observed urines are discouraged. Oral swabs may be utilized in place of observed urines. If it becomes necessary to do observed urines the patient may be referred 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: PEDIATRIC EXPOSURE TO BUPRENORPHINE/ NALOXONE

ORDER @ HTTP://MASSCLEARINGHOUSE.EHS.STATE.MA.US/PRODUCT/SA1064KIT.HTML

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

APPENDIX 11B: 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**_____

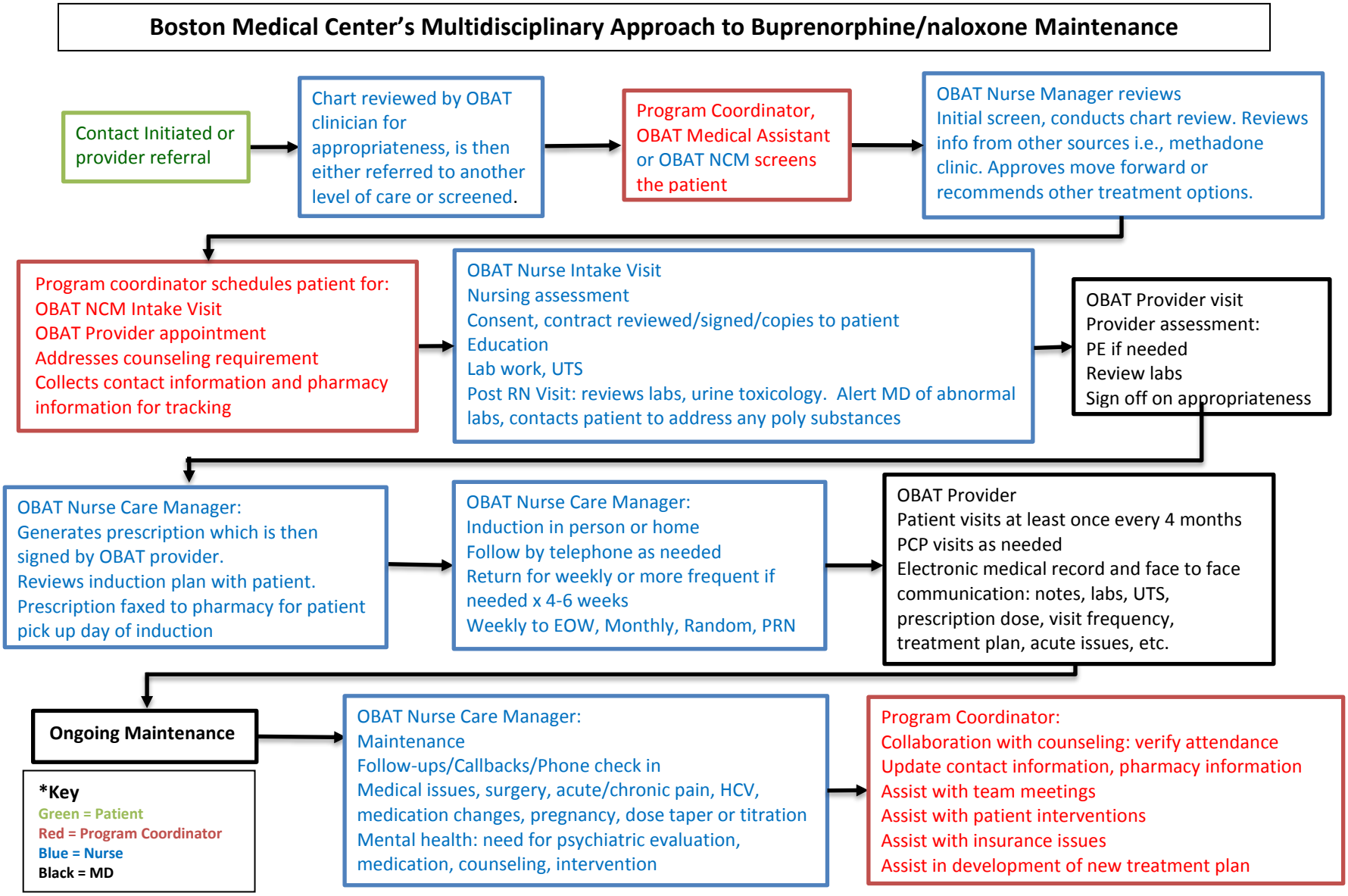
Circle the number/description which best corresponds to your patient's present symptoms

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), 253-25

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



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

Methadone	Buprenorphine/Naloxone 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
  • 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

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.

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

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.

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)

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.

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 12D: CLINICAL TOOLS: PHARMACOTHERAPY FOR ALCOHOL USE DISORDER

Source: 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

Naltrexone Oral	Naltrexone Injectable	Acamprosate	Disulfiram
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)

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.

Naltrexone Oral	Naltrexone Injectable	Acamprosate	Disulfiram
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

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.

Naltrexone Oral	Naltrexone Injectable	Acamprosate	Disulfiram
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
• 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

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.

Naltrexone Oral	Naltrexone Injectable	Acamprosate	Disulfiram
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)
• 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
• 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)	

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.

Naltrexone Oral	Naltrexone Injectable	Acamprosate	Disulfiram
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
• 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

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.

Naltrexone Oral	Naltrexone Injectable	Acamprosate	Disulfiram
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

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.

<table>
<tr><th>Naltrexone Oral</th><th>Naltrexone Injectable</th><th>Acamprosate</th><th>Disulfiram</th></tr>
<tr><td colspan="4">Patient Education</td></tr>
<tr><td>• 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</td><td>• 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</td><td rowspan="2">• Report any new or worsening depression or suicidal thinking</td><td rowspan="2">• 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</td></tr>
<tr><td colspan="2">• 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</td></tr>
</table>

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. Perioperative Management of Non-Pregnant Patients on Maintenance Therapy for Opioid Dependence

Buprenorphine, methadone, and naltrexone are pharmacologic therapies indicated for maintenance treatment of opioid use disorder. The appropriate treatment of acute pain in patients on buprenorphine and methadone 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 and methadone maintenance should be co-managed with their buprenorphine or methadone provider during the pre- and post-procedure period. Addiction medicine is available for consultation to assist with recommendations for opioid use disorder management in the postoperative period.

These guidelines are designed for patients maintained on chronic opioids, buprenorphine, methadone or naltrexone therapy undergoing invasive procedures. There is currently a lack of evidence-based studies to direct the management of patients on buprenorphine, methadone, or naltrexone maintenance in the peri-procedural period. Below are guidelines using expert opinion based on pharmacological principles with the intent to avoid sub therapeutic acute pain management while also preventing opioid withdrawal and disruption of opioid use disorder management.

See Table 1 for recommendations for perioperative management.

References:

Reginald LD et al. Overriding the blockade of antinociceptive actions of opioids in rats treated with extended-release naltrexone. Pharmacology, Biochemistry and Behavior 2008;89:515-522.

Roberts DM, Meyer-Witting M. High-dose buprenorphine: perioperative precautions and management strategies. Anaesth Intensive Care 2005;33:17-25.

Alford DP, et al. Acute Pain Management for Patients Receiving Maintenance Methadone or Buprenorphine Therapy. Ann Intern Med 2006:144(2): 127-134.

Other Related Guidelines or Policies: Methadone and Buprenorphine during Pregnancy, Epidural and Intrathecal Analgesia, Sedation and Pain Control – ICU, Pain Management (Adult), Patient-Controlled Analgesia (PCA) - Adult

Originated from: Daniel Alford, MD, Colleen LaBelle, RN, Mauricio Gonzalez, MD, Samantha Bastow, PharmD, Peter Golenia, PharmD, BCPS

Approved by: Formulary Management Committee (April 2012)

Reviewed by: William Vincent, PharmD (September 2014)

Last reviewed: Kevin Yeh, PharmD & William Vincent, PharmD (Feb 2016)

Table 1

Opioid Dependence Patient Category	Pre-operative Pain Recommendations	Post-operative Pain Recommendations
Chronic Pain on Chronic Opioid Therapy **Inclusion:** Patient on chronic opioids > 2 weeks or with other signs of physical dependence. Does not include patients taking occasional or prn opioids for breakthrough pain.	Continue standing opioid dose the day of surgery. Hold any usual PRN breakthrough opioid doses the day of surgery.	Continue equivalent chronic opioid dose (IV if patient strict NPO) with hold parameters for sedation. For acute postoperative pain, utilize multimodal pain management with non-opioid medications (NSAID, acetaminophen, epidural/spinal analgesia, nerve blocks) as indicated. If opioids are required for breakthrough pain, patients with history of chronic opioid use may require higher than usual doses due to cross tolerance. PCA's may be considered if pain is not adequately captured. This may be utilized with or without a basal component.
Methadone Maintenance Therapy	Confirm methadone dose with patient's methadone maintenance treatment program (MMTP). Continue usual dose of methadone the day of surgery. The patient may need to arrange home doses of methadone ("medical take home doses") with his or her MMTP if they are unable to go to the MMTP on the day of surgery. If this is not	Continue usual daily methadone dose. If the patient is strict NPO, they should receive 50%-75% of their usual methadone dose given IV, divided into 2-4 doses/day (e.g. if usual dose is 60 mg PO daily, appropriate IV doses would be approximately 15 mg IV BID or 10 mg IV TID). For acute postoperative pain, utilize multimodal pain management with non-opioid medications (NSAID, acetaminophen, epidural/spinal analgesia, nerve blocks) as indicated.

	possible, the patient should receive his or her usual confirmed methadone dose in the pre-operative area.	If opioids are required for breakthrough pain, patients with history of opioid use disorder may require higher than usual doses due to cross tolerance and increased pain sensitivity. PCA's without basal component may be considered in addition to patient's methadone if pain is not adequately captured. Remember to discontinue other oral PRN opioids. On discharge, the patient should be given a "last dose letter" addressed to the MMTP and whether any modifications have been made. The discharge case manager and patient may need to arrange for home doses of methadone ("medical take home doses") with his or her MMTP if he or she is unable to go to the MMTP on the days of after discharge.
Buprenorphine Maintenance Therapy	Take AM dose of buprenorphine on the day of the procedure.	Continue patient's home dose of buprenorphine post-operatively. Consider splitting patient's totally daily buprenorphine dose into q8h schedule for better pain coverage. For acute postoperative pain, utilize multimodal pain management with non-opioid medications (NSAID, acetaminophen, epidural/spinal analgesia, nerve blocks) as indicated. If opioids are required for breakthrough pain, patients with history of opioid use disorder may require higher than usual doses due to cross tolerance and increased pain sensitivity. PCA's without basal component may be considered in addition to patient's buprenorphine if pain is not adequately captured. Remember to discontinue other oral PRN opioids.
Naltrexone (oral or depot) Maintenance Therapy	Discontinue oral naltrexone 72 hours before surgery. Discontinue depot naltrexone 1 month prior to elective surgery, if possible.	Utilize multimodal pain management with non-opioid medications (NSAIDs, acetaminophen, epidural/spinal analgesia, nerve blocks) as indicated. If surgery performed emergently or naltrexone was not discontinued prior to surgery, naltrexone should be discontinued postoperatively. If this occurs, higher than usual doses of opioids may be attempted to

		overcome naltrexone's opioid antagonist effects. This must be done with close observation for respiratory depression.

APPENDIX 14: GUIDELINE FOR BREASTFEEDING IN THE SETTING OF PRENATAL SUBSTANCE USE

Boston Medical Center – Maternal Child Health Policy and Procedure Manual

Guideline for Breastfeeding in the Setting of Prenatal Substance Use

Guideline:	16.02.090
Issued:	July 2008
Last Revised/reviewed:	June 2015
Section:	Maternal Child Health

Purpose:

- These breastfeeding guidelines apply to women with a history of SUBSTANCE USE DISORDER during the current pregnancy. This includes women on maintenance Methadone and Buprenorphine (Subutex). These guidelines do not include breastfeeding in the setting of isolated Marijuana use.

Guideline/Policy Statement:

TREAMENT PROGRAM CRITERIA:

1. Mothers with a history of SUBSTANCE USE DISORDER **must be enrolled in an Addiction Recovery Program during the pregnancy to be considered eligible to breastfeed** which includes the following:
   - Project RESPECT at BMC is a comprehensive Addiction Treatment and Prenatal Care Program; compliance with this program equals compliance with prenatal care **AND** addiction recovery treatment.
   - For women **not** in Project RESPECT, Addiction Recovery Program may include: Intensive Outpatient Program (IOP), Residential Program, other Methadone/ Buprenorphine Maintenance Programs.
2. For **all** Project RESPECT patients: a provider assessment of breastfeeding eligibility will be made in the patient's Electronic Medical Record.

PRENATAL CARE CRITERIA:

1. Mothers with a history of SUBSTANCE USE DISORDER **must have received adequate prenatal care** defined as attendance of 50% or more of prenatal / RESPECT visits OR attended 5 or more prenatal / RESPECT visits in order to be considered eligible to breastfeed. At least 2 of these visits should be within the last 2 months prior to delivery. Note that visits with other RESPECT providers such as ATU and nursing visits are part of routine care (visits do not need to be with an OB provider).
2. Please consult with the RESPECT / Substance Use Breastfeeding Team (see below) if the mother delivers preterm and unclear if she meets the prenatal care criteria.

ADMISSION URINE TOXICOLOGY SCREENING:

1. A urine toxicology screen will be obtained for all mothers with SUBSTANCE USE DISORDER on admission to Labor & Delivery (L&D). This includes:
    - "Basic Screen" (Amphetamines, barbiturates, benzodiazepines, cocaine metabolites, opiates) AND
    - "Expanded opioid panel" (buprenorphine, methadone, and oxycodone).
2. A positive screen is a urine toxicology screen positive for any unprescribed medications.
3. Testing for marijuana (THC) is not routine or recommended. THC use is determined by maternal verbal report; routine testing is unreliable as it does not reflect true usage.

URINE TOXICOLOGY SCREEN RESULTS PRIOR TO DELIVERY: Please refer to Appendix A: Breastfeeding Prenatal Substance Use Algorithm.

Provided the mother meets the Treatment Program AND Prenatal Care criteria for eligibility, mothers will be further divided into two groups:

- **Positive** urine toxicology screen on L&D, or less than 4 weeks prior to delivery.
- **Negative** urine toxicology screen on L&D and for 4 weeks or more prior to delivery.

For those with a **positive urine toxicology** screen on L&D, or less than 4 weeks prior to delivery:

1. Mothers are ineligible to provide breastmilk to the infant at the time of delivery.
2. Mothers who wish to establish a milk supply will be encouraged to pump and save their milk with Lactation Services/Breast pump provided.
3. Pumped milk in the setting of a positive screen will be labeled in accordance with the MCH Policy Breastmilk Administration and Storage for the Hospitalized Infant AND be identified with a red dot until a documented negative urine screen.
4. All pumped milk will be stored in the NICU and frozen immediately.
5. The infant's Attending Physician will review any positive urine screens as notified by the mother's Providers and Lactation Services. The Attending will determine if milk pumped during the period of the positive screen will be discarded.
6. Mothers may be re-considered for eligibility weekly (See below re-eligibility criteria).
7. The mother's Providers or Lactation Consultant will be responsible for notifying the Pediatric Inpatient Social Worker when the mother meets criteria (3 consecutive negative urine toxicology screens at least 1 week apart) to begin providing milk to the infant. The infant's medical team will then be notified.

For those with a **negative urine toxicology** screen on L&D and for 4 or more weeks prior to delivery:

1. Those mothers with a negative urine toxicology screen on admission to L&D AND no positive urine toxicology screens within the past 4 weeks are eligible to provide breastmilk to the infant.
2. Please consult with the RESPECT/Substance Use Disorder Breastfeeding Team (see below) if questions regarding timing of negative urine screens.

UNAVAILABLE PRENATAL RECORDS:

1. For those women for whom the L&D admission urine toxicology screen is negative, and records are unavailable at the time of delivery to confirm other criteria for breastfeeding eligibility, breastfeeding may be initiated while awaiting records.
2. The mother should be informed of our breastfeeding guidelines prior to initiation and should sign a release for her medical/ treatment records.

BREASTFEEDING INELIGIBLE MOTHERS:

1. Mothers who do not meet the criteria listed above will be encouraged to formula feed.
2. Instructions on how to safely formula feed her infant will be provided to the mother; Refer to link unde Section for "Bottlefeeding Basics Pamphlet by WIC Nutrition Program".
3. If mother insists on breastfeeding, mother will be informed that this is not recommended according to guidelines. This discussion will be **documented** in the medical record.
4. If at any time there is concern for the **safety** of infant, mother and infant may be separated by an Atten Order. The decision to separate mother and infant should be an interdisciplinary decision supported by 2 level individuals: the baby's Attending Physician AND another Attending Provider (including maternal p midwife, nurse practitioner, nurse manager or social worker. If there is agreement that mother and infant separated, strongly consider contacting DCF.

RE-CONSIDERATION OF BREASTFEEDING ELIGIBILITY:

1. For those mothers who wish to breastfeed, but do not meet criteria at the time of delivery, weekly postı toxicology screening is recommended until the mother has a total of **3 consecutive negative screens**, sep least 1 week.
2. Mothers may have toxicology screens performed by Project RESPECT or may be seen by the BMC Ge clinic.
3. Results of toxicology screens will be available in the Electronic Medical Record.
4. The mother's Providers or Lactation Consultant will be responsible for notifying the Pediatric Inpatien Worker when the mother meets criteria to begin providing milk to the infant. The medical team will then
5. Prior to that, the mother may pump and save her milk with Lactation Services provided.

Application:

- Women with a history of SUBSTANCE USE DISORDER during the current pregnancy includin maintenance Methadone and Buprenorphine (Subutex).

Exceptions:

- Does not include breastfeeding in the setting of isolated Marijuana use.

Equipment:

- Breast Pump when applicable

Procedure:

- Please refer to **Appendix A: Breastfeeding Prenatal Substance Use Algorithm.**

Responsibility:

- RN, MD, CNM

Clinical Information:

PROJECT RESPECT CONTACTS:

- For questions concerning individual patient eligibility not addressed by the above guidelines, please Project RESPECT at 617-414-2000
- Kelley Saia (#5530), Michelle Sia (#5559), Jordana Price (#3212)

Also available to discuss patients:

- Sarah Katherman, LICSW (#2593), Project RESPECT Social Worker
- Andrea Hutcheson (Hutch) Warden, MSN, NP (#8011), Project RESPECT Nurse Practitioner
- Nurse on Project RESPECT RN line: 617-414-4165

Available to discuss these guidelines:

- Elisha Wachman (#3693), Robin Humphreys (#6576)

Forms:

- Electronic Medical Record

Other Related Policies:

- MCH Policy 16.01.300 Urine Toxicology Screen of Maternity Patients

Initiated by:

- BMC Taskforce for Breastfeeding in the Setting of Prenatal Substance Use

Reviewed by:

- Well Baby Unit, NICU, Pediatric Inpatient Unit, Project RESPECT, Social Work, Lactation Services, Obstetrics, Child Protection Team, Outpatient Pediatrics, Family Medicine, Perinatal Committee

References:

AAP Policy Statement: Breastfeeding and the use of Human Milk (2012). Pediatrics, 2012; 129(3).

ABM Clinical Protocol #21: Guidelines for Breastfeeding and Substance Use or Substance Use Disorder. Breastfeeding Medicine, 2015; 10(3).

ACOG Committee Opinion: Opioid Abuse, Dependence, and Addiction in Pregnancy, 2012, Number 524.

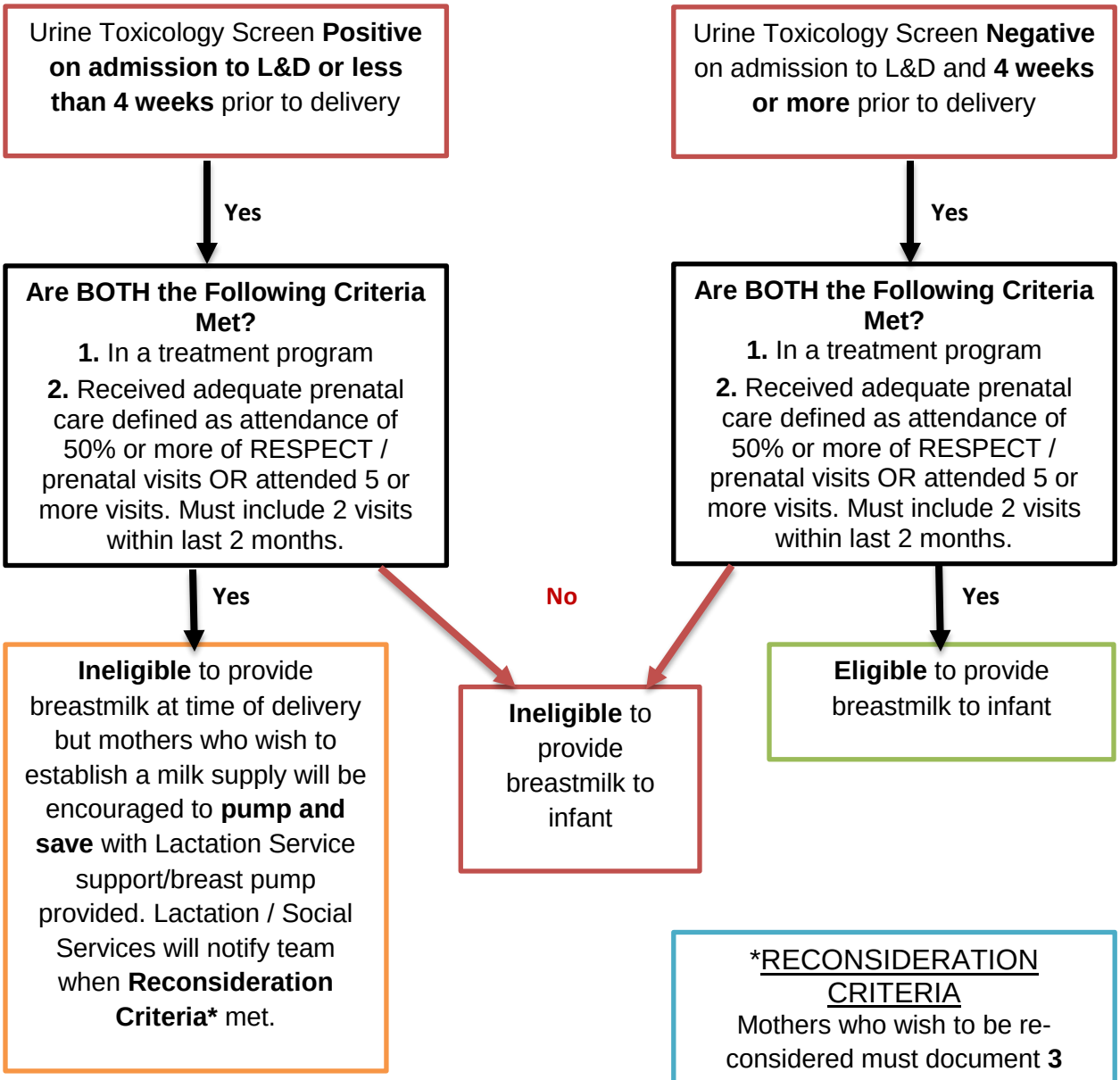
Pritham UA, Breastfeeding Promotion for Management of Neonatal Abstinence Syndrome. *JOGNN*, 2013; 42:517-26.

Bagley SM, Wachman EM, Holland E, Brogly S. Review of the assessment and management of neonatal abstinence syndrome. *Addict Sci Clin Pract*, 2014; 9(1): 19.

Kotelchuck M. ACOG Adequacy of Prenatal Care Utilization Index, 1994.

Bottlefeeding Basics, WIC Pamphlet,
http://www.nal.usda.gov/wicworks/Sharing_Center/MA/NewMAMaterials/Bottlefeed_Eng.pdf
http://www.nal.usda.gov/wicworks/Sharing_Center/MA/NewMAMaterials/Bottlefeed_Sp.pdf

Appendix A: Breastfeeding Prenatal Substance Use Algorithm



If Prenatal Records Not Available:

1. Mother will be informed of our Breastfeeding Guidelines
2. Mother will sign a release allowing us to obtain her records
3. Provided negative Urine Toxicology on admission to L&D, may initiate breastfeeding while awaiting records

APPENDIX 15: 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

American Society of Addiction Medicine (ASAM)
National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use. June 2015. https://asam.org/resources/guidelines-and-consensus-documents/npg

Drug Testing: A White Paper of the American Society of Addiction Medicine. Oct, 2013
https://www.asam.org/docs/default-source/public-policy-statements/drug-testing-a-white-paper-by-asam.pdf

Institute for Health and Recovery, Massachusetts Perinatal Quality Collaborative
Maternal Opioid Use During Pregnancy toolkit
"This toolkit provides guidance in regards to the medical, psychological and social needs of pregnant women with opioid use disorders thereby improving maternal and newborn health outcomes. It has been developed to help maternal health providers advance the clinical interventions by offering screening, treatment engagement and coordinated care throughout the pregnancy and post-delivery."
http://www.healthrecovery.org/maternal-opioid-use/

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

Massachusetts Health Promotion Clearinghouse
Provides free health promotion materials for Massachusetts residents, health care providers, and social service providers
https://massclearinghouse.ehs.state.ma.us/

National Institute for Drug Abuse
https://www.drugabuse.gov/publications/orderable

National Institute on Alcohol Abuse and Alcoholism
https://niaaa.nih.gov/publications/brochures-and-fact-sheets

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

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 or naltrexone.
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/

In-Person 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 every day, 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

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
PCSS – Providers Clinical Support System for MAT

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 16: LIST OF ACRONYMS

BMC: Boston Medical Center

BSAS: Bureau of Substance Abuse Services

CFR-42: Code of Federal Regulations, Title 42

CNS: Central Nervous System

COWS: Clinical Opioid Withdrawal Scale

CSAT: SAMHSA's Center for Substance Abuse Treatment

CSS: Clinical Stabilization Services (short-term inpatient stabilization)

DATA 2000: Drug Addiction Treatment Act of 2000

DEA: US Drug Enforcement Agency

DCF: Department of Children and Families

DSM: Diagnostic and Statistical Manual of Mental Disorders

ETOH: Alcohol

FDA: Food and Drug Administration

GC/MS: Gas Chromatography/Mass Spectrometry

HCG: Human Chorionic Gonadotropin

HIPAA: Health Insurance Portability and Accountability Act

IOP: Intensive Outpatient Program (counseling)

LFT: Liver Function Test

NAS: Neonatal Abstinence Syndrome

NCM: Nurse Care Manager

NSAID: Non-steroidal Anti-inflammatory Drug

NSDUH: National Survey on Drug Use and Health

OBAT: Office Based Addiction Treatment

OUD: Opioid Use Disorder

OTP: Outpatient Treatment Program (daily medication administration treatment)

PCA: Patient Controlled Analgesia

PDMP: Prescription Drug Monitoring Program

STATE-OBAT: State Technical Assistance and Treatment Expansion of Office Based Addiction Treatment with buprenorphine and naltrexone formulation

TSS: Transitional Stabilization Services (inpatient "holding" facility)

UTS: Urine Toxicology Screening

APPENDIX 17: REFERENCES

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