GUIDELINES FOR THE TREATMENT OF OPIOID USE DISORDER IN PREGNANT AND PARENTING PATIENTS

PROJECT RESPECT:

SUBSTANCE USE DISORDER IN PREGNANCY TREATMENT PROGRAM AT BOSTON MEDICAL CENTER

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DISCLAIMER

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PURPOSE

The purpose of these clinical guidelines is to provide detailed policies and protocols for the treatment of substance use disorder in pregnant and parenting patients utilizing buprenorphine and naltrexone formulations at Boston Medical Center.

These policies and protocols are meant to provide guidance to clinicians utilizing medications for opioid use disorder throughout the peripartum period to ensure best care outcomes for both mother and infant.

INTRODUCTION

EVIDENCE SUPPORTING TREATMENT OF OPIOID USE DISORDER DURING PREGNANCY

Opioid use in pregnancy has escalated dramatically in recent years, paralleling the epidemic observed in the general population. Pregnancy provides an important opportunity to identify and treat women with substance use disorders (SUD). For pregnant patients with an opioid use disorder (OUD), medication treatment—specifically agonist (methadone) or partial-agonist (buprenorphine) therapy—is recommended and preferable to medically supervised withdrawal, which is associated with high relapse rates, thus leading to worse outcomes[1].

MEDICATIONS FOR OPIOID USE DISORDER (MOUD)

Methadone, buprenorphine, and naltrexone are all Pregnancy Category C medications

Maternal Health:

- Active/untreated OUD during pregnancy is considered high-risk.
- The benefits of initiating and maintaining MOUD during pregnancy include the many positive effects of stable recovery and the reduced complications from illicit substance use such as risk of infection, trauma exposure, unintended polysubstance use, withdrawal, and overdose morbidity and mortality.
- Patients receiving MOUD treatments do not have to stop those medications before or during pregnancy[2]. For the vast majority of patients, it is recommended to continue on MOUD during pregnancy to avoid relapse, which could further endanger both the patient and the fetus.
- Withdrawal can increase the risk for a return to substance use, preterm labor and birth, and miscarriage. Remaining on OUD medications is generally the safest choice for BOTH the mother and the baby.

Fetal Health:

- The benefits of initiating and maintaining MOUD during pregnancy include the many positive effects of maternal stable recovery and reduced complications from illicit substance use such as lack of prenatal care, risk for spontaneous abortion, intrauterine growth restriction, withdrawal-induced fetal distress, premature labor, preterm delivery, and intrauterine fetal demise.
- Consistent maternal serum opioid levels result in reduced fetal risks for adverse outcomes.

- Concern about a potential and small increased risk of birth defects associated with taking MOUD during pregnancy should be weighed against the clear risks associated with the ongoing use of illicit opioids by a pregnant patient.

Current Literature on MOUD and Pregnancy

Agonist/partial-agonist medications: Methadone and Buprenorphine

- Historically, there are more substantial data and clinical experience on utilizing methadone in pregnancy[3].

- The American College of Obstetricians and Gynecologists (ACOG) has concluded that there is sufficient evidence for both methadone and buprenorphine to be considered first-line medication options for pregnant patients with an OUD[1].

    - A longitudinal study of 73 children evaluated at 24 months (n=24 exposed to buprenorphine *in utero*, n=19 exposed to methadone *in utero*, and n=30 non-exposed controls) found no differences between groups in temperament or neurological development during the first two years of life[4].

    - The MOTHER Trial: This double-blind randomized controlled trial of 175 pregnant patients with OUD and 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).[5]

        - 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 a 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[5].

Formulation: Buprenorphine OR Buprenorphine/Naloxone in Pregnancy?

- Additional research is still needed; a recent review of preliminary findings from seven previously published studies found no evidence of adverse maternal or neonatal outcomes related to the use of buprenorphine/naloxone compared to the use of buprenorphine alone (mono product) or methadone[6]. Currently, many providers use buprenorphine/naloxone to treat OUD during pregnancy without complications or notable adverse events[3].

- Both methadone and buprenorphine (both combination and mono-tablet formulations) may lead to NAS/NOWS.

- Incidence of neonatal abstinence syndrome (NAS) or neonatal opioid withdrawal syndrome (NOWS) ranges from 30-80% nationally.

- Breastfeeding and skin-to-skin contact have been shown to significantly decrease the incidence of NAS/ NOWS [7].

Antagonist: Naltrexone

- There is currently limited data regarding the safety of naltrexone use during pregnancy. However, there is emerging data to support the potential safety of naltrexone throughout the peri-partum period.

    - In the initial case reports of nine pregnant patients who received implantable long-acting naltrexone, neonatal outcomes (weeks at delivery, birth weights, head circumference, length and Apgar at 1 and 5 minutes) associated with the maternal naltrexone implant management were unremarkable[8].

    - A cohort study observing 90 pregnant patients on methadone vs. 17 pregnant patients on implanted extended release naltrexone saw no difference in mean birth weight at delivery or gestational age but did see a higher one-minute Apgar score associated with naltrexone[9].

    - A pilot study published in 2019 showed that six mother-infant dyads taking naltrexone had no diagnosis of NOWS and a shorter length of stay compared to those born to mothers on buprenorphine [10].

    - In their guidance for treatment of pregnant and parenting patients, the expert panel from the Substance Abuse and Mental Health Services Administration (SAMSHA) did not agree on whether patients taking naltrexone should continue it during pregnancy. They state that patients "stable on naltrexone can be offered treatment with buprenorphine or methadone to prevent a return to substance use if they choose to discontinue naltrexone injections. However, this transition must be carefully managed because patients on long-acting naltrexone are no longer opioid tolerant, and the falling naltrexone level will result in increasing agonist activity over time during cross-titration." [2]

- A pregnant patient who desires to begin or remain on treatment for OUD with naltrexone should be counseled on the risks and benefits of naltrexone. As with any medication treatment during pregnancy, careful consideration of best outcomes for the mother and fetus should be decided upon by shared decision making between the medical team and expecting mother.

MOUD While Breastfeeding

Breastfeeding should be encouraged in patients who are stable on opioid agonists, who are not using illicit drugs, and who have no other contraindications, such as human immunodeficiency virus (HIV) infection. Patients should be counseled about the need to suspend breastfeeding in the event of a relapse[1].

Buprenorphine

- Buprenorphine/naloxone is passed into breast milk at 1:1 plasma: milk ratio[3].
- Because of poor oral bioavailability of buprenorphine/naloxone, the breastfeeding infant is exposed to only 1/10 of the buprenorphine/naloxone ingested.
- Breastfeeding during buprenorphine/naloxone may lessen NAS/NOWS and should be supported and encouraged for all eligible patients.
- Skin-to-skin contact between infant and care-giver (including during breastfeeding) has been shown to assist with symptoms of NAS/NOWS and enhances maternal-child/care-giver-infant bonding.
- Cessation of breastfeeding is not associated with the onset of NAS/NOWS.

Naltrexone

- The oral formulation of naltrexone does pass 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, the FDA advises against breastfeeding while on naltrexone, both oral and injectable formulations. The manufacturer acknowledges that there are no data on the effects on lactation or to the breastfed child. They advise consideration of the health benefits of breastfeeding along with the mother's medical need for naltrexone and "any potential adverse effects on the breastfed infant from naltrexone or the mother's underlying maternal condition." [11]
- Due to overwhelming evidence regarding the benefits of breastfeeding for both mother and baby, the knowledge that naltrexone is minimally excreted into breast milk, and insufficient evidence of harms to a breastfeeding infant, Project RESPECT supports patients who are benefiting from naltrexone treatment to remain on that treatment and supports them breastfeeding their child.[12]

Boston Medical Center's Project RESPECT Model of Care

Project RESPECT (Recovery, Empowerment, Social Services, Prenatal care, Education, Community and Treatment), is a high-risk obstetrical and addiction recovery medical home at Boston Medical Center (BMC) and Boston University School of Medicine (BUSM) [13]. Project RESPECT provides comprehensive obstetric and SUD treatment for pregnant patients and their newborns. The majority of Project RESPECT patients are in recovery from opioid use disorder.

More than 60 percent of Project RESPECT's referrals come from acute treatment (detoxification) centers around Massachusetts [14]. These patients are admitted to BMC's high-risk obstetrics service for up to two weeks. Here, the Project RESPECT team helps connect patients to services, safely manages acute withdrawal, and initiates MOUD (methadone, buprenorphine, or naltrexone). Intensive individualized outpatient treatment plans are then outlined for each patient based upon the severity of their disease and their treatment needs.

The outpatient medical home model of Project RESPECT provides on-site collaborative and multidisciplinary care for pregnant and post-partum patients in recovery. In this model, the Obstetrician is also the MOUD provider [13]. Throughout the pregnancy and beyond, the Project RESPECT clinical team collaborates and coordinates care with the inpatient Obstetric, Pediatric, Psychiatry, Social Work, Nursing, and Lactation teams at BMC and with multiple community-based organizations including local methadone clinics, residential treatment centers, family resources, peer supports, social services, and the Department of Public Health.

Project RESPECT's work does not stop when the baby is born [14]. In the past, Project RESPECT focused on engaging pregnant patients into sustainable treatment, but it has since expanded its focus to include the first two years after delivery.

MOUD/Project RESPECT TREATMENT TEAM AND PROGRAM REQUIREMENTS

PROVIDERS OF MEDICATION FOR OPIOID USE DISORDER

Buprenorphine and Buprenorphine/Naloxone

QUALIFICATIONS: Qualified providers must obtain a waiver of authority to prescribe medication that is Schedule III, IV, or V and FDA approved for the purpose of detoxification or maintenance treatment of patients with OUD[3]. With the Drug Addiction Treatment Act (DATA) of 2000, physicians became legally qualified to receive waiver training. In July 2016, the Comprehensive Addiction and Recovery Act (CARA) was signed into law, extending buprenorphine prescription authority to also include physician assistants and nurse practitioners. Most recently, the 2018 Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT) extended prescribing privileges to include Clinical Nurse Specialists, Certified Registered Nurse Anesthetists, and Certified Nurse Midwives (CNSs, CRNSs, and CNMs)[15].

PHYSICIAN WAIVER ELIGIBILITY: To be eligible for a waiver, physicians must have a current state medical license, a valid registration number from the US Drug Enforcement Agency (DEA), and must have completed an eight-hour approved waiver training course[3].

ADVANCED PRACTICE PROVIDER WAIVER ELIGIBILITY: To be eligible for a waiver, all Advanced Practice Providers (APPs) including Nurse Practitioners, Physician Assistants, Clinical Nurse Specialists, Certified Registered Nurse Anesthetists, and Certified Nurse Midwives must have a current state medical license and a valid DEA registration number, in addition to completing a total of 24 hours of approved training (the eight hour buprenorphine waiver course plus 16 additional hours of federally approved training). Some states require APPs who are waivered to be supervised by or work in collaboration with a qualifying physician.

Resources for completing the additional 16 hours of training are available from PCSS (https://pcssnow.org/medication-assisted-treatment/waiver-training-for-nps/), ASAM (https://elearning.asam.org/buprenorphine-waiver-course), and Harvard Global Health (https://postgraduateeducation.hms.harvard.edu/opioid-use-disorder-education-program).

REFERRALS: Providers must be able to refer patients to counseling and psychiatric services[3].

PATIENT LIMITS: The number of patients that a provider is allowed to treat at any one time is dependent upon the provider's practice setting, field of discipline and waiver status. It is imperative that a provider does not prescribe to more patients than identified on their waiver (either 30, 100, or 275). To apply for a new waiver or to request for a patient limit increase, providers must apply through SAMHSA's Center for Substance Abuse Treatment (CSAT) at https://www.samhsa.gov/medication-assisted-treatment/training-materials-resources/apply-for-practitioner-waiver. The regulations concerning buprenorphine prescriptions are often updated,

and it is therefore recommended that one review the current guidelines to ensure practice within the federal regulations: www.buprenorphine.samhsa.gov.

Naltrexone

Naltrexone is an opioid antagonist blocking any activity of opioids at the mu receptor. Patients who opt to receive treatment with naltrexone should be free of any opioid use for at least 7 to 10 days to avoid precipitated withdrawal upon initiation. It is available as a once-daily tablet or a once-monthly IM injection. Naltrexone is not a scheduled medication and does not require any special licensure, certification, or waiver to prescribe[3]. Any individual who is licensed to prescribe medication (physician or advance practice provider) may prescribe and/or administer naltrexone. There is no limit to the number of patients that a provider can legally treat with naltrexone. However, when treating patients with SUDs, 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.

MEDICATION FOR OPIOID USE DISORDER: NURSE CARE MANAGER

MOUD Nurse Care Managers (NCMs) are registered nurses who must, at a minimum, have passed the National Council Licensure Examination (NCLEX) for registered nurses (NCLEX-RN), and hold an active license in the state in which they are practicing.

Though not required, ideally MOUD NCMs will have achieved or be working toward a certification in addiction nursing (Certified Addiction Registered Nurse (CARN)), offered through the Addiction Nursing Certification Board. To be eligible to participate in the certification examination, candidates must meet the following requirements:

- Provide evidence of a current, full, and unrestricted license as a registered nurse (RN) in the United States, its territories, or Canada.
- Complete documentation verifying a minimum of 2,000 hours of current nursing experience related to addictions as an RN in a staff, administrative, teaching, private practice, consultation, counseling, or research capacity.
- Acquire a total of 30 hours of continuing education related to addictions nursing within three years of application submission.

More information about the certified addiction registered nurse (CARN) process can be found on the Center for Nursing Education and Testing website: https://www.cnetnurse.com/certified-addictions-registered-nurse/

Additional recommendations include:

- Complete an initial training curriculum covering Office-Based Addiction Treatment (OBAT)/Medication for Opioid Use Disorder (MOUD) with buprenorphine and naltrexone, in-person or online.

- Attend ongoing professional education on topics relevant to treatment for SUD (e.g., hepatitis C treatment and management, urine toxicology screening [UTS], relapse prevention, overdose education, motivational interviewing, retention to care, harm reduction, compassion fatigue, case discussions, materials development, and networking).

NURSE CARE MANAGER RESPONSIBILITIES:

- Provide patient-centered care within the nursing license scope of practice including initial assessment and intake, induction, stabilization, and maintenance phases of treatment[3].

- Collaborate with MOUD providers, social workers/counselors, psychiatrists, pharmacies, primary care providers, and specialty care providers to whom the patient has been referred.

- Coordinate between the MOUD provider and the pharmacy by assisting with prescription processing and refills, prior authorizations, and insurance issues.

- Complete appropriate documentation in medical records and comply with state, federal, and departmental policies when sharing and/or documenting patient care data.

ADMINISTRATION REQUIREMENTS

Buprenorphine is a Schedule III medication. Programs utilizing buprenorphine must therefore follow federal, state, and institutional requirements for prescribing, storing, dispensing, and otherwise managing Schedule III substances.

- Records on prescription and dispensation of medications for the detoxification and maintenance treatment of OUD must be kept in accordance with DEA regulations 21 CFR 1304.03(c).

The most up-to-date information is available through SAMHSA's Center for Substance Abuse Treatment (CSAT).

https://www.samhsa.gov/about-us/who-we-are/offices-centers/csat
SAMHSAInfo@samhsa.hhs.gov
877-SAMHSA-7 (726-4727)
TTY: 800-487-4889

CONSENTS AND CONFIDENTIALITY

In addition to standard HIPAA laws, federal regulations mandate strict confidentiality or information about patients being treated for SUDs (42 CFR Part 2)[3]. Additionally, the law requires written patient consent before information about their substance use disorder can be disclosed to any other source. For MOUD, this may include any communications with other providers, treatment centers, family, or significant others.

SPECIFICACTIONS THAT ARE PROHIBITED (WITHOUT CONSENT) INCLUDE THE FOLLOWING:

- Providing information regarding a patient's past, present, or future participation in substance use treatment.
- Disclosing or transmitting a patient's substance use disorder-related medical records.
- Use of a letterhead that identifies the office as a substance use treatment provider.
- Providing information about those who have applied for treatment or have been interviewed, regardless of whether they actually commenced treatment.
- Providing information about deceased patients.

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.

The 42CFR legislation is under review. The most up-to-date information about confidentiality and consents is available from the following resources:

Legal Action Center

https://lac.org/resources/substance-use-resources/confidentiality-resources/

SAMHSA
https://www.samhsa.gov/about-us/who-we-are/laws-regulations/confidentiality-regulation_

Center of Excellence for Protected Health Information
https://caiglobal.org/index.php?option=com_content&view=article&id=1149&Itemid=1953

Treatment Initiation, Stabilization, and Maintenance

PROJECT RESPECT PATIENT ROAD MAP

- Initial Screening and Referral may occur via Primary Care Provider (PCP) or by Project RESPECT OB Team upon presentation to BMC's Emergency Department (ED) or Labor and Delivery Triage Unit.
- Medical Initiation
    - When a referral comes from PCP, initiation may occur on an outpatient basis
    - When initial referral comes from ED or Labor and Delivery Triage Unit, an inpatient admission for pharmacologic MOUD stabilization occurs
- MOUD/Outpatient RESPECT Intake: MOUD NCM visit with treatment agreement, consents, and RESPECT MOUD Provider comprehensive intake assessment, education, and support.
- Prenatal New Visit (PPN)
- MOUD Stabilization: weekly or biweekly joint prenatal and relapse prevention visits
- MOUD Maintenance: combined prenatal and relapse prevention visits as indicated throughout gestation and postpartum

CANDIDATES FOR MOUD/PROJECT RESPECT PROGRAM

- Patient must have a *DSM-5* diagnosis of OUD (see appendix)[3]
- Patient must be pregnant (the decision to continue or terminate the pregnancy does not change treatment options available at intake)
- Patient must agree with the goals of treatment, including: compliance with frequent perinatal-recovery clinical visits; prevention/reduction of withdrawal symptoms and cravings for opioids; addressing mental and behavioral health needs including follow through with necessary referrals and treatment
- Patient is able to come to visits during office hours of operation
- Patients seeking treatment with **agonist** medications must not have chronic pain requiring ongoing opioid management beyond buprenorphine/naloxone
- Patients seeking treatment with **antagonist** medications must not have chronic pain

requiring opioid management.

- The MOUD treatment team should carefully assess patient for appropriateness of medication treatment in an office-based setting. The patient must be able to be safely treated in an office-based setting without harm to self or others.

- Patient should be willing to address the use of other harmful and/or illicit substances.

- Patients should be willing to address possible changes in, or reductions to, prescribed psychoactive medications during pregnancy with the goal of reaching the lowest effective dose to maximize maternal health and mitigate NAS/NOWS.

Referral Process to Boston Medical Center's Project Respect Program

If the patient is currently prescribed buprenorphine, has a verified intrauterine pregnancy, and is willing to engage in the BMC Project RESPECT program, their provider can place a referral to Project RESPECT noting the patient's age, GsPs, best estimate of expected due date (EDD), and date on which the most recent MOUD prescription expires (to ensure the patient does not run out of medication prior to an intake). If the patient is not currently on buprenorphine and requires immediate stabilization, they can be referred to BMC's Emergency Department (if < 20 weeks gestation) or BMC's Labor and Delivery Triage Unit (if > 20 weeks gestation) for admission to our inpatient Maternal Fetal Medicine Service.

If the patient is safe and stable enough to wait for an outpatient appointment, they will be seen by Project RESPECT at the next available intake. Project RESPECT understands the necessity to avoid gaps in recovery care, and priority status is given to new patients to ensure care continuity.

The referring provider screen includes a review of obstetric, medical, social, and substance use history, including current or most recent substance use; determining the patient's demographics, living situation, current safety, and future treatment goals; trying to determine the EDD; and verifying the pregnancy via point-of-care urine pregnancy test or quantitative serum B-HCG level. Ultrasound confirmation of an intrauterine pregnancy is *recommended* for all patients.

*For any patient with a positive urine pregnancy test AND any pelvic pain and/or vaginal bleeding, ultrasound confirmation of an intrauterine pregnancy is *imperative*.

MOUD/Project RESPECT Intake

Upon receipt of referral, the MOUD NCM performs the initial screening to determine the potential appropriateness of the patient receiving medication for SUD in an office-based setting. This may be completed the same day as the MOUD/RESPECT provider visit in an effort to expedite care and simplify the appointment regimen.

MOUD NCM INTAKE

Initial screening and intake includes:

- **Laying the groundwork for a therapeutic relationship with the patient.** Assess patient goals for treatment, strengths for obtaining recovery, and risks to treatment success.

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

- **Provide an overview of medication for substance use disorder treatment:** what it is, how it works, medication administration, interactions, side-effects, and the induction and maintenance processes.

- **Harm reduction education**: provide overdose prevention education, including overdose reversal with naloxone, and rescue breathing. Ensure that the patient has access to naloxone.

- **Review of treatment agreement and program expectations**. Patient signs treatment agreement and consents for treatment. The NCM should also obtain appropriate signed consent forms to assist with collaboration of care with outside providers and supports.

Program expectations include:

- Appointment frequency with RESPECT NCM and RESPECT Provider/MOUD Provider

- Introduction to members of treatment team

- Counseling and psychiatric assessment and follow-up if warranted

- Medication refills

- Patient-centered treatment planning and review

- Discussion of responsibilities for safe medication storage

- Review of clinic hours and times available for scheduling visits, including after-hours emergency contact information

Appropriate candidates proceed to RESPECT Provider/MOUD Provider Intake visit within BMC's Project RESPECT program. If the site is unable to meet the patient's needs and the program requirements, the Project RESPECT team will assist in seamless referral of the patient to an appropriate treatment setting.

See Appendix 13 for RESPECT/MOUD NCM Responsibilities

RESPECT/MOUD Provider Intake

RESPECT/MOUD Provider initial screening and intake includes[3]:

- **Provider assessment visit with physical examination and review of laboratory test results.** Provider confirmation of *DSM-5* diagnosis of OUD or Alcohol Use Disorder (AUD) and assessment of appropriateness for medication treatment for SUD with either buprenorphine/naloxone or naltrexone.

- **Collects and reviews information to lay the groundwork for a therapeutic relationship with the patient.** Assess patient goals for treatment, strengths for obtaining recovery and risks/barriers to treatment success.

    - The RESPECT/MOUD Provider values the uniqueness of each individual and helps each patient define their own goals.

- **Assessment of substance use** including substance use history, current treatment status, prior recovery treatment, goals during pregnancy, postpartum and beyond.

- **Review of medical, mental health and social history.** If not already completed, obtain appropriate signed consent forms for care collaboration with outside providers and patient supports.

- **Education on MOUD treatment:** what it is, how it works, medication administration, interactions, side-effects, potential adverse reactions, and the induction and maintenance processes.

    - This includes discussing the likelihood of MOUD dose increases with advancing gestational age, potential fetal effects of NAS/NOWS, options for analgesics during labor and delivery, breastfeeding, and postpartum recommendations to continue MOUD for at least one year postpartum.

    - Clear communication is vital regarding mandated reporting laws for illicit drug use for patients who currently have custody of older children. Review of hospital and state regulations on reporting to child protective services (i.e., Department of Children and Families (DCF)) for all newborns exposed to illicit substances during pregnancy, as well as for all newborns exposed to prescribed MOUD during gestation, including methadone and buprenorphine, at the time of birth.

    - The RESPECT/MOUD Provider reinforces OUD as a chronic medical condition affecting numerous aspects of a person's wellbeing. The RESPECT/MOUD team ensures support of the patient throughout all phases of their recovery; throughout their pregnancy, postpartum period, and while parenting, even in the event of a relapse or any loss of custody.

- **Obtain laboratory tests as clinically indicated.**

    - Consider: type and screen, complete blood count, comprehensive metabolic panel, hepatic function panel; Syphilis, Rubella, Varicella and HIV antibodies; hepatitis A, B, and C serologies; STI screening; TB screening (quantiferon gold or PPD); and urine drug screening (UDS)

- **Harm reduction education and safety reviewed:** overdose prevention and reversal education, ensures access to naloxone.

- **The patient's treatment plan will be created to assist the patient in achieving disease remission and meeting their identified treatment goals.**

PRENATAL NEW VISIT

The Prenatal New Visit (PNN) includes the general prenatal assessment and a comprehensive physical examination. To streamline and standardize the prenatal information given and maximize MOUD provider productivity in the continuity clinics, the PNN is typically completed outside of the RESPECT program due to its time consuming nature. However, PNNs may be completed by a RESPECT Provider, NP, or CNM. The PNN has its own general prenatal assessment and checklist of tests, screenings, information sharing, and full physical examination.

PNN Intakes include:

- Complete history and physical, if not already done
- Confirmation of patient's due date (confirmation of intrauterine pregnancy/dating)
- Obtain PAP, GC/Chl screening, genetic (aneuploidy) screening, and SMA screening, as indicated
- Auscultate fetal heart rate and measure fundal height, as indicated
- Schedule dating ultrasound upon entry to care, if not previously done
- Discuss risks of tobacco use in pregnancy and plan for decreasing and/or ceasing smoking
- Obtain laboratory tests as clinicallyneeded/if any prenatal screening labs are missing, as above
- Overview of RESPECT/MOUD’s prenatal and postpartum care plan and curriculum for treatment

BUPRENORPHINE/NALOXONE TREATMENT

CHECKLIST: PRIOR TO INITIATING BUPRENORPHINE/NALOXONE

- ✓ 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 treatment.
- ✓ The goal is for the patient to establish counseling supports, but treatment will be initiated regardless of counseling placement. Counseling may be group-based or individual.
- ✓ UDS has been completed and reviewed by MOUD team.
- ✓ Patient's record has been checked within the Prescription Drug Monitoring Program (PDMP)
- ✓ After MOUD team review, coordinate induction per protocol in collaboration with patient, provider, and team, including date, time, prescription, and clinic schedule.

A note about buprenorphine formulations:

Historically, for patients with OUD who become pregnant while undergoing treatment with buprenorphine/naloxone, the recommendation has been to transition from the combination product (i.e. Suboxone) to the buprenorphine monotherapy (i.e., Subutex) product during pregnancy. This transition was intended to protect the fetus from any unnecessary exposure to naloxone and concern that if the patient were to inject the combination product they could experience precipitated withdrawal due to the parenteral bioavailability of naloxone [16]. However, in 2018 SAMHSA stated, "Evidence is now building that newborn outcomes are not negatively affected by using the combination product during gestation and that pregnant women may not need to transition to the buprenorphine-only product during pregnancy to protect the fetus." [2].

BMC's Project RESPECT team has made a clinical decision to switch from buprenorphine monotherapy treatment to the buprenorphine/naloxone film formulation throughout the peri-partum period. This decision was based upon a growing body of evidence supporting the safety of the combination product to both the mother and fetus during pregnancy [17, 18], along with recent shortages of buprenorphine monotherapy, increased risk of diversion with the monotherapy product [19], and increasing numbers of pregnant women reporting a preference for the buprenorphine/naloxone product [20]. Project RESPECT and BMC support shared decision-making between healthcare providers and pregnant patients in regard to the use of the buprenorphine/naloxone combination product during pregnancy. This clinical decision should be based upon the benefit versus the risk to the dyad.

BUPRENORPHINE/NALOXONE INDUCTION

- If the patient is not currently on MOUD, then the RESPECT Provider/MOUD Provider will determine if the patient is buprenorphine naive. The patient may be inducted in the clinic or in the hospital at the discretion of the Project RESPECT/MOUD provider.

- Candidates for office-based induction include but are not limited to:

    - Pregnant patients with OUD who were stable on buprenorphine and (by choice or lack of care access) abruptly stopped taking it due to pregnancy;
    - Pregnant patients with OUD who were tapered off of buprenorphine prior to their pregnancy but have since developed cravings, urges to use, and a risk of relapse;
    - Pregnant patients with OUD who recently completed an in-patient detoxification program, are not currently on MOUD, or who are seeking stability with MOUD; and
    - Pregnant patients with OUD who are able to adhere to the out-patient induction guidelines and contract for safety; have safe housing and access to next-day transportation; and those who are for some reason unable to be admitted but their buprenorphine induction is supported by the harm reduction model.

- Patient returns to clinic within three to five days of in-patient induction for assessment, prescription renewal, urine drug screening, counseling, education, support, and evaluation of mental health and other needs.

- If the patient is pregnant and on methadone, they *should not* be switched to buprenorphine/naloxone during pregnancy due to possible risks of recovery destabilization and the potential for maternal withdrawal inadvertently leading to potential fetal distress, pre-term labor, abruption or preterm delivery.

BUPRENORPHINE/NALOXONE INDUCTION AND STABILIZATION PHASE

Goal: stabilization of dosing. Target buprenorphine/naloxone dose = 8-16 mg/day or less with a maximum of 24 mg/day. Medication may be taken in divided doses.

- Opioid blockade is typically reached at 16 mg and is recommended in the early stages of recovery[3].

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

- Although buprenorphine has a long half-life, due to the increased metabolism of pregnancy divided dosing has been shown to be more effective at maintaining steady

state serum levels and is thus recommended for MOUD treatment during pregnancy[21]. Instead of the patient taking a full dose in the morning, the patient can take half of the dose in the morning and half later in the day. For some patients, smaller doses taken TID or QID might be necessary; this is based on individual patient and provider preference.

    - For patients who take buprenorphine/naloxone in divided doses, the prescription may need to be specifically written as twice daily dosing (or other frequency) to allow appropriate dispensing for those engaged in residential or day treatment programs for SUD or in other medical settings

- Increases in maternal MOUD doses may be expected throughout the pregnancy [22].
- Prescriptions are limited to no more than seven days during this phase of treatment.
- Patient sees Project RESPECT team member (the NCM, MOUD Provider, or CNM) weekly for four to six weeks until they are stable. If their urine drug screens are appropriate and the patient is adherent to the treatment plan, they may they progress to the maintenance phase.

BUPRENORPHINE/NALOXONE MAINTENANCE PHASE

Once stable, clinic visits occur once every two weeks, with medication refills coinciding with visits.

- Providing smaller prescriptions may help limit diversion and promote safety.
- If indicated for patient safety and structure, weekly to twice weekly follow-up visits should be scheduled.
- Limited information exists on dosing changes by trimester. It is common for patients to require dose increases for medications during pregnancy given physiological changes. Individualized assessment of withdrawal symptoms should be performed at each visit.
    - Options of changing daily dosing schedule can be employed prior to increasing dose.
    - Any increases in total daily dose should remain small (2 mg–4 mg), with the goal of finding the lowest effective dose to eliminate symptoms
- Frequent follow-up visits should include assessment, support, UDS, safety assessments, counseling, education, and social determinants of health screening.

Goal: Visits every two weeks until 36 weeks, then weekly until delivery per ACOG guidelines.

- Each decrease in visit frequency requires treatment team review.

- In rare cases, patients who enter treatment at <28 weeks pregnant who have been stable on maintenance buprenorphine prior to pregnancy may have office visits every two to four weeks. This should be determined by the treatment team and reviewed at each visit.

Clinic visits should include:

- Sample collection for UDS

- Assessment of status: medication dose, adherence, tolerance, side effects, cravings and withdrawal. Safe medication storage; recovery; relapse; and medical, social, and psychiatric issues should all be addressed as indicated

- Review of treatment plan: visit frequency, counseling, and assessment of need for additional support

- MOUD Provider notes should be documented in the clinical record and be made available to the entire clinical team.

- Liver Function: if LFTs were elevated at induction, consider rechecking within one to two months or sooner depending on degree of elevation

    - Elevations are more common in patients with hepatitis C and HIV infection.

    - Documentation of baseline LFTs < 20 weeks gestation will assist in differentiation between medication effects, liver disease, or the onset of pre-eclampsia after 20 weeks

    - Consider repeating LFTs prior to delivery (36-37 weeks).

    - In cases of co-occurring AUD, address concerns with patient and consider monitoring with Breathalyzer or urine EtG (ethyl glucuronide).

        - *Of note:* Patients managed on buprenorphine/naloxone are not candidates for naltrexone for AUD.

- Review and confirm contact information, including pharmacy of choice, at each visit.

- Refills for buprenorphine/naloxone will be given in quantities sufficient to maintain the patient until their next office visit.

- If MOUD provider is not also the OB, patient must also follow up with OB provider as recommended by ACOG guidelines or more often if needed.

- An effort should be made to schedule regular prenatal visit coinciding with MOUD visits (i.e., one right after another or concurrently).

- In addition to office visits, the patient can reach out to staff for any concerns.

- Follow-up with primary care provider may be warranted based on medical needs.

NALTREXONE TREATMENT

NALTREXONE INITIATION: PATIENT SELECTION

There has not been sufficient research to assess the safety or efficacy of naltrexone in pregnancy[3]. Naltrexone, both oral and injectable formulations, are Category C medications. The patient and the MOUD treatment team (as well as the prenatal provider, if different) need to evaluate the risks and benefits of continuing or initiating naltrexone treatment during pregnancy. Careful consent of unknown risk should be utilized.

Potential candidates for treatment with naltrexone include patients who:

- Are not currently using opioids, but have a history of OUD 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 AUD

CHECKLIST: PRIOR TO NALTREXONE CONTINUATION OR INITIATION

✓ Treatment agreement and consents are reviewed and signed.

✓ Reinforce the need for frequent appointment adherence with patient and establish whether this is realistic. If patient states that it is not manageable, this needs to be addressed with the team prior to treatment.

✓ The patient should have counseling or other support services in place or be working towards establishing counseling/support services. Counseling may be group-based or individual.

- ✓ Patient's record checked within the Prescription Drug Monitoring Program (PDMP).

- ✓ Labs ordered and reviewed:

    - UDS must be completed and reviewed by MOUD team, and the result must be negative for opioids.

    - If LFTs are >5x normal, appropriate medical evaluation should occur to determine the cause of transaminase elevation.

    - When deciding to start naltrexone treatment in pregnant patients or those with elevated LFTS, providers should utilize clinical judgment, carefully weighing the risks and benefits of initiating naltrexone and documenting an informed consent to treat the patient.

    - Detoxification from opioids should be fully complete prior to the administration of naltrexone to prevent precipitated or spontaneous withdrawal. The patient must not be experiencing withdrawal symptoms.

    - 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.

- ✓ After MOUD team review, coordinate initiation or continuation of naltrexone per protocol in collaboration with patient, provider and team: date, time, prescription, and clinic schedule.

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.

    - The first oral naltrexone dose should ideally be observed in the clinic.

    - 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 should be given an emergency card, bracelet, and/or dog tag.

- For the most up-to date information about administration of extended-release injectable naltrexone, please refer to the manufacturer's safety information, medication guide, and prescribing information. For Vivitrol: https://www.vivitrol.com/

NALTREXONE (ORAL OR INJECTABLE) STABILIZATION

- Patient should return to the clinic after one week for assessment; toxicology screening; counseling; education; support; and evaluation of mental health, medical, and other needs.

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

- Patient sees Nurse Care Manager weekly for four to six weeks until stable. If toxicology screens and Breathalyzer/EtG screens are appropriate and the patient is adherent to the treatment plan, they then may progress to the maintenance phase.

NALTREXONE MAINTENANCE

Once a patient is stable, clinic visits are extended to once every two weeks, with refills and visits coinciding.

- If indicated for patient safety and structure, weekly to twice weekly follow-up visits should be scheduled

- Frequent follow-up visits should include: assessment, support, UDS, safety assessment, counseling, education, and social determinants of health screening.

Goal: Visits every two weeks until 36 weeks, then weekly until delivery per ACOG guidelines

- Each decrease in visit frequency requires a treatment team review.

- In rare cases, patients who enter treatment <28 weeks pregnant and have been stable on maintenance naltrexone prior to pregnancy may have office visits every two to four weeks. This should be determined by the treatment team and reviewed at each visit.

Clinic visits to include:

- Sample collection for UDS

- Assessment of status: medication dose; adherence; tolerance; side effects; cravings and withdrawal; safe storage; recovery; relapse; and medical, social and psychiatric issues should all be addressed as indicated.

- Review of treatment plan: visit frequency, counseling, and need for additional support.

- MOUD/Project RESPECT NCM and MOUD Provider notes should be documented in the clinical record and available to the entire clinical team.

- If patient has a history of AUD, address any concerns with the patient and consider monitoring with Breathalyzer or urine EtG (ethyl glucuronide).

    - Acamprosate (Campral) and disulfiram (Antabuse) may also be offered to patients with problematic alcohol use with provider input and agreement.

- Liver Function: if LFTs were elevated at induction, consider rechecking within one to two months or sooner depending on the degree of elevation.

    - Elevations are more common in patients with hepatitis C and HIV infection.

    - Documentation of baseline LFTs <20 weeks gestation will assist in differentiation between medication effects, liver disease, or the onset of pre-eclampsia after 20 weeks.

    - Consider repeating LFTs prior to delivery (36-37 weeks).

- Review and confirm contact information at each visit.

- If MOUD provider is not also the OB, patients must also follow up with OB provider as recommended by ACOG guidelines, or more often if needed.

    - An effort should be made to schedule regular prenatal visits coinciding with MOUD visits (i.e., one right after another or concurrently).

- In addition to office visits, the patient should able to reach out to staff for any concerns.

- For management of pain in patients who are engaged in naltrexone treatment, refer to section titled “Pain Management throughout Pregnancy and during Delivery.”

Ongoing Patient Management: MOUD Agreement & Clinic Policies

MOUD in Pregnancy Treatment Agreement

Goal: To engage patients in the treatment plan, along with the RESPECT/MOUD team, individualize treatment to meet the needs of the patient, and encourage patients' involvement in their treatment.

- See 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 agreement, and give a copy to the patient to take home for their review.
    - Encourage patients to ask questions.
    - Review this agreement 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); the risks of transferring care from one form of MOUD to another; or patients' ambivalence about such changes.

The agreement reinforces that a SUD is a chronic medical condition that affects numerous aspects of a person's wellbeing. The RESPECT/MOUD 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, part 2.
- To have a means for contacting a member of the RESPECT/MOUD team or a

colleague for emergencies at night, on weekends, and when the office is closed.

ADHERENCE TO PROGRAM POLICIES AND TREATMENT PROTOCOLS:

- *Clinical Appointment Policy* (See Appendix 2): All patients who participate in the Office Based Addiction Treatment program are required to keep all appointments with their RESPECT/MOUD providers and, if separate, their prenatal provider. 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.

- Patients are expected to make an effort to arrive on time for scheduled appointments. They should understand that a late arrival in excess of 15 minutes may result in an extended wait time.

- If patients do not show up for medical appointments and do not call to inform RESPECT/MOUD 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 RESPECT/MOUD provider.

- Patients struggling to meet program requirements may need to be referred to a higher level of care (i.e., an intensive out-patient program or residential treatment). This should be discussed with the patient in person and should not surprise the patient. If necessary, a MOUD prescription should be written to bridge any necessary transition or alteration in care.

BEHAVIORAL 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 medical campus.

URINE DRUG SCREENING POLICY:

- Urine samples are required at each visit[3].

- All belongings (coats, bags, etc.) are left in the office of the medical assistant or outside the bathroom door. Patients may keep their wallet and cellphone with them.

- No washing of hands until the labeled urine sample is handed to the attendant in a bio-hazardous materials bag

- No flushing of toilet until urine sample is handed to the gloved attendant

- Observed UDS are discouraged

    - As an alternative, programs may wish to institute measures to reduce incidents of urine tampering, such as utilizing oral swabs, keeping the trash receptacle outside of the bathroom, having blue colored toilet water, and assessing characteristics of the urine (e.g., temperature, color, clarity, and creatinine concentration).

- Any questionable urine is repeated the same day.

    - In the event of receiving a questionable urine sample, a RESPECT/MOUD team member addresses concerns with the patient and reinforces that the RESPECT/MOUD team is available to work with the patient throughout their recovery process, especially in the event of recent use.

    - RESPECT/MOUD NCM and/or provider reviews the importance of UDS monitoring and honesty in treatment to ensure that the team has the ability to provide appropriate care.

- Patients will receive a buprenorphine/naloxone prescription, naltrexone prescription, or extended-release naltrexone injection after an acceptable toxicology sample is obtained.

BUPRENORPHINE/NALOXONE PRESCRIPTION POLICIES

The roles of the RESPECT/MOUD provider, MOUD NCM, the office staff, and the patient in the handling of prescriptions/medications are detailed below:

- Prescriptions will be processed by a RESPECT/MOUD nurse or provider who will review the medication record and consult with the prenatal provider (if separate providers), the pharmacy, and the PDMP if needed to confirm dosage, refill amounts, and timing of refill.

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

- Following confirmation, the NCM will generate an electronic prescription under the waivered provider's name. If not signed directly by the RESPECT/MOUD provider, the MOUD team (i.e., MOUD NCM) should forward the request to provider for co-signature as appropriate.

- Prescription records are maintained in the electronic medical record for review by

clinicians as needed and for DEA regulatory purposes.

Duration of buprenorphine/naloxone prescriptions:

Buprenorphine/naloxone prescriptions refills should generally coincide with visit frequency:

- At the time of treatment initiation, prescription duration should be limited to seven days or less and automatic refills should be avoided.

- After four to six weeks of weekly assessments and recovery treatment resulting in the patient moving into the stabilization phase, prescription refills will increase to two-week intervals.

- If a patient enters BMC's Project RESPECT program already in the maintenance phase and is receiving monthly prescriptions:

    - If the patient is <28weeks, the MOUD team should decide if continuation of monthly prescriptions is appropriate.
    - If appropriate, monthly prescriptions can continue until 28 weeks (however, this should be a rare occurrence).
    - The MOUD team should discuss with the patient that any concerns will necessitate more frequent office visits.

- Prescriptions are sent 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 RESPECT/MOUD team can make the decision to continue with shorter-interval prescriptions.

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

    - Write 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.
    - Make prescription safety lock-bags should be available for patient use.

Lost, stolen or destroyed buprenorphine/naloxone:

Special precautions should be taken when a patient reports that their buprenorphine/naloxone has been lost, stolen, or destroyed.

- Buprenorphine/naloxone prescriptions are generally not replaced; however, due to the

patient being pregnant, the medication will be refilled until they are able to see the MOUD provider.

- The patient may have to pay out-of-pocket for replacement medication due to insurance limitations.

- If more than a one-week supply of replacement prescription is needed, the prescription amount will go back to weekly prescriptions until such time that the team feels it is safe for the patient to be given a larger quantity of medication.

- In all of these events, prior to receiving a replacement prescription, the patient will be asked to return to the RESPECT/MOUD clinic for assessment and UDS. At this time, patients will receive additional education about safe handling and storage of buprenorphine/naloxone by the RESPECT/MOUD team to prevent these events from reoccurring. The treatment plan should be reviewed along with length of prescription and frequency of visits to further 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. For example, most methadone clinics offer daily dispensing of buprenorphine.

SAFE AND PROPER STORAGE OF MEDICATION[†]:

- ✓ Suggest to patients that they obtain a locked bag or a lock box to safely store buprenorphine/naloxone and any other controlled substances.

- ✓ Keep medication out of sight/reach of children.

- ✓ Do not put tablets/films in a purse or backpack, on counters, sinks, dresser, nightstands, or in any public, unsecure space.

- ✓ To prevent breakage, keep cotton or tissue in the bottle. (It is easier for children to put small pieces and crumbs in their mouth).

- ✓ Always keep in a labeled prescription bottle with child-proof cap.

- ✓ Patient's prescribed buprenorphine/naloxone film should be stored with an official pharmacy label at all times. Patients may request a second label from the pharmacy if they plan to carry a limited amount of medication on their person.

- ✓ **Call 911** if an accidental exposure occurs and/or go to the nearest emergency department.

[†]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

Clinical Decision-Making in the Event of Substance Use During Treatment

MOUD/Project RESPECT is a harm reduction model and therefore does not recommend discharge for patients who struggle with substance use while engaged in medication treatment[3]. When substance use is reported during an encounter, the treatment plan can be adjusted at the time of the visit. When this occurs, the MOUD NCM or MOUD provider should assess the circumstances surrounding the incident(s) (i.e., home environment, work environment, role of support persons and persons close to the patient). These details are helpful to effectively adjust the treatment plan to meet the evolving needs of the patient.

Clinical decisions to augment the treatment plan should be based upon the patient's overall well-being and standing within MOUD care and therefore based upon multiple data points including: patient engagement with the treatment plan; recent toxicology screens; and status of physical, mental, and social health.

- The MOUD treatment team's communication via in-person team meetings, telephone, and the electronic medical record is essential to ensure consistent and high-quality patient care.
- When a patient is struggling with ongoing substance use during treatment, MOUD NCMs and MOUD providers (and prenatal provider if separate) should review the case specifics and utilize shared decision making to adjust the treatment plan to best meet the needs of the patient.
- If illicit or harmful substance use occurs, the treatment plan should be revised to increase monitoring and supports.
- If the patient adheres with the intensive treatment plan and has had some improvement in substance use, the team will restructure treatment as needed and continue treatment with buprenorphine/naloxone.
- In a case of continued use despite additional support, the benefits of a referral to a more structured treatment environment should be considered.
    - When possible, ensure a "warm handoff" to providers at agency/program to which the patient has been referred.
    - For less urban areas, continued treatment despite their struggling may be the safest option for the mother-infant dyad. In this case, it is important to document

the reasons for continued efforts to mitigate risk and the ways it is reducing harm.

In every instance that the treatment plan is augmented, careful documentation should occur in the medical record to support either continuing the patient in current treatment program or referring them to another level of care.

Revision of treatment plan may include:

- More frequent visits
- Shortened prescription intervals
- Confirmation of counseling and team engagement with counselor
- Referral to relapse prevention groups or individual therapy
- Referral to Intensive Outpatient Program (IOP)
- Psychiatric evaluation and treatment per psychiatric assessment
- Residential treatment
- Increased collaboration with community providers
- Family/support involvement

Referral to a higher level of care may include:

- Detoxification: Crisis Stabilization Unit (CSS) or Treatment Stabilization Unit (TSS)
- Residential treatment; contacting the Institute for Health and Recovery (IHR) for screening and placement
- Methadone maintenance
- Dual diagnosis

BUPRENORPHINE/NALOXONE: RECURRENT USE AND UNEXPECTED URINE TOXICOLOGY SCREEN RESULTS

When substance use is reported during an encounter, the treatment plan can be adjusted at the time of the visit.

In cases of an unexplained urine drug screen result (i.e., patient did not report substance use at visit or reported inappropriate medication management at visit), the MOUD team will contact the patient to discuss the results of the urine drug screen and discuss revising their current treatment plan. The patient will be scheduled for a follow-up visit the same day or within less than two days to discuss an effort to address a potential relapse or medication concerns.

NEGATIVE BUPRENORPHINE

Buprenorphine adherence is necessary for successful treatment. Non adherence may be self-reported or found on a toxicology screen that is negative for buprenorphine. There are a variety of reasons why a patient may be non-adherent to buprenorphine and/or have a negative buprenorphine toxicology screen including:

- Self-increasing buprenorphine dose or a lost/stolen/destroyed medication, causing the patient to run out of medication early.
- Forms of diversion; diversion may be well-intended, such as sharing medication with a friend, or more salacious, such as selling medication for profit.
- Submission of a tampered urine sample.
- If a patient's dose is less than 4-6 mg, the toxicology sample may need to be sent for confirmatory testing due to the cut-off limits of the test; therefore, the patient has an inability to react positively to buprenorphine despite adherence to treatment.

In all cases of reported non adherence to buprenorphine, the MOUD NCM and MOUD providers should assess and reinforce medication adherence, including total daily buprenorphine dose, dosing schedule, proper administration, and safe storage. The treatment plan should be adjusted accordingly, including increased visit frequency. The MOUD treatment team should consider that the patient's buprenorphine/naloxone dose may need to be adjusted (i.e., increased if struggling, decreased if taking less than prescribed).

- If the patient provides adequate explanation regarding negative buprenorphine/naloxone, the MOUD team will establish a follow-up plan for the patient to return to clinic within one week.

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

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

    - Repeat UDS should be obtained and sent for confirmatory testing (i.e., buprenorphine level) that includes checking for the presence of buprenorphine's metabolite, norbuprenorphine.

    - If the patient denies any reason for negative buprenorphine/naloxone, and the repeat UDS is again negative, the patient may be struggling with their treatment. The MOUD team should confirm the validity of the UDS result with the lab facility used. The MOUD team should attempt to rule out urine sample tampering and assure (to best of ability) chain of command for urine specimen processing. If all of the above can be determined and the urine drug screen remains negative for buprenorphine and negative for opioids, then the patient may not qualify for buprenorphine/naloxone treatment.

    - Relapse prevention should be discussed along with continuation in the program without prescription for buprenorphine. The option of XR-Naltrexone (Vivitrol) treatment may be appropriate in this case and should be discussed with the patient.

    - If the UDS positive for unexpected opioid, the patient may benefit from a more structured treatment environment or additional supports in the MOUD clinic.

POSITIVE OPIOIDS

Report of opioid use or a positive opioid urine drug screen result is addressed by MOUD provider or nurse during the patient visit, and the treatment plan is intensified accordingly to meet the patient's needs.

A report of opioid use or a positive opioid UDS will result in intensification of the treatment plan potentially including increased frequency of clinic visits, increased buprenorphine dose, confirm attendance and increase frequency of counseling, encourage meetings, provide education on relapse prevention and overdose, and distribute naloxone or send naloxone prescription to pharmacy. This includes the patient returning to weekly clinic visits until they show improvement in their treatment.

If the patient has ongoing reports of opioid use or positive opioid urines, the patient will be assisted with a transfer to a higher level of care. 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, and referral to another treatment center should be supported and seamless.

POLYSUBSTANCE USE

The target of MOUD therapy is OUD, as the medications buprenorphine and naltrexone assist with opioid symptomology. MOUD does not treat other substance use. However, other substances can be part of the treatment plan. **It is not recommended to discontinue MOUD treatment purely as a result of other substance use.** Resumption of opioid use can have devastating effects, including the risk of death. Therefore, careful consideration is required in cases of polysubstance use. The frequency of MOUD office visits may be used as a means of contingency management, integrating a contingency management program, additional supports, resources, and risk reduction measures. Support of patients with intensified treatment engagement should be the goal.

Cocaine

A report of cocaine use or a positive cocaine UDS result is addressed by the MOUD nurse and/or provider during the patient's visit, and the treatment plan is intensified accordingly to meet the needs of the patient. In addition, a report of cocaine use or a positive cocaine UDS will result in relapse prevention education and increased support. This includes the patient potentially returning to weekly clinic visits. Contingency management combined with psychosocial support (CBT, counseling, etc.) has been shown to be an effective strategy for decreasing stimulant misuse and should be considered when possible.

Amphetamines

A report of illicit amphetamine use or positive amphetamine UDS result is addressed by MOUD nurse or provider during the patient's visit, and the treatment plan is intensified accordingly to meet the needs of the patient. In addition, a report of illicit amphetamine use or a positive amphetamine UDS will result in relapse prevention education and increased support. This includes the patient potentially returning to weekly clinic visits.

- 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.
    - Two to three consecutive UDS positive for illicit amphetamine 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 MOUD visits.
    - Contingency management combined with psychosocial support is an effective strategy for decreasing stimulant misuse and should be considered.

Benzodiazepines

A report of illicit benzodiazepine use or a positive benzodiazepine UDS result is addressed by the MOUD nurse or provider during the patient's visit, and the treatment plan is intensified accordingly to meet the needs of the patient. In addition, a report of illicit benzodiazepine use or a positive benzodiazepine UDS will result in relapse prevention education and overdose prevention education. This includes the patient returning to weekly clinic visits.

- If the patient reports that they are struggling with anxiety, offer a referral to psychiatry for evaluation. Providers should make every effort to avoid the use of benzodiazepines and other medications with potential for misuse.

- 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 an intensified treatment plan may result in referral to a higher level of care.

- It is not recommended to abruptly discontinue benzodiazepines; slowly tapering off this type of medication is necessary.

- Fetal risk associated with maternal benzodiazepine use or misuse is worsening of NAS/ NOWS

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, refer to institutional policies regarding safety concerns and mandated reporting.

Diversion

In cases of suspected diversion (i.e., suspicious negative buprenorphine urines, requests for early refills, reports of lost/stolen/destroyed medication, or requests for dose increase), the patient should be asked to come into the clinic for an urgent assessment. This assessment should include urine drug testing and a medication count. When possible, confirmatory testing (such as via buprenorphine and norbuprenorphine level) is recommended to confirm the 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 to be possibly discharged from the MOUD program for a seamless transition to methadone or another level of care.

DELIVERY: PATIENTS TREATED WITH BUPRENORPHINE

General Overview:

For patients on buprenorphine, there are some unique and important considerations for care during labor and delivery and in the immediate postpartum period.

- The partial blockade by buprenorphine can increase the dose of intravenous and parenteral pain medication needed for effective analgesia.

- Maintenance medication—in this case buprenorphine—does not treat pain. Hyperalgesia, a worsening of pain perception due to opioids, is associated with their use. **Continuation of maintenance medication is imperative.**

- Nalbuphine and butorphanol are **contraindicated** for patients on buprenorphine as they can precipitate withdrawal. If they are inadvertently given, fentanyl IVP should be administered until withdrawal symptoms abate.

- Intravenous (IV) access may be difficult; consider a consultation with the IV access team and, if needed, peripherally inserted central catheter (PICC) or central line. In general, it is recommended to **avoid central line** placement in laboring patients if at all possible.

- Please contact the RESPECT/MOUD clinic to notify team of admission.

- Review newborn testing recommendations with patients privately.

For Spontaneous Vaginal Delivery (SVD):

1. Continue buprenorphine at prescribed dose throughout labor and postpartum.
    - NOTE: While the patient is admitted to the hospital, a provider may legally order buprenorphine to maintain a patient's outpatient dose during her hospitalization. Documentation of this Federal regulation is available at: http //www.deadiversion.usdoj.go v/21cfr/cfr/1306/1306 07.htm

2. Confirm with the patient their plan *for receiving or avoiding* opioids for pain during hospitalization (including intrapartum and postpartum).

3. The most effective intrapartum pain control is an epidural.

- An epidural with low dose regional anesthetic plus fentanyl (or other opioid) in standard dosing is recommended and should be offered as early as possible.

4. Following a vaginal delivery: providers may give po NSAIDs (e.g., Motrin 600-800mg Q8hrs ATC). It is recommended to give this in scheduled dosing, *not* PRN.

5. For 3rd or 4th degree lacerations, or other significant pain, consider oral opioid analgesia at 1.5-2 times the increased opioid dose and/or more frequent intervals than non-opioid tolerant patients.

6. Avoid discharging a patient with a prescription for oral opioid pain medication, if possible.

For C-section deliveries:

1. Continue buprenorphine at pre-delivery dose.

2. Regional anesthesia is recommended unless there is a patient-specific contra-indication

3. Post-operatively: scheduled ketorolac 30mg IV Q6 for 72 hours is recommended, followed by Motrin 600-800mg orally every six hours until discharge.
    A. GI prophylaxis should be considered with scheduled NSAID use

4. Oral opioids, such as hydromorphone or oxycodone, may be added for breakthrough pain, unless the patient requests to avoid opioids.
    A. If they do not request to avoid opioids, it is recommended to order a dose q 3-4 hours (they can decline the medication).
    B. Orders for PRN pain medication dosing should be avoided.

5. For patients who receive general anesthesia, an opioid Patient-Controlled Analgesia (PCA) pump may be required for 12-24 hours; while IV opioids deliver rapid onset of analgesia, the half life is short and oral opioids will provide longer duration of analgesia.

6. Transition to oral opioid medication is recommended after 12-24 hours of PCA treatment.

7. Opioid tolerant patients experience increased opioid dose requirements to treat pain; scheduled dosing of 1.5-2 times the routine opioid dose with greater frequency should be considered.

8. PRN pain medication dosing has decreased efficacy and increased complexity

compared to scheduled dosing.

9. Prior to delivery, the RESPECT/MOUD team should review post-delivery pain management protocols with the patient. Remind the patient that they can refuse the scheduled pain medications, if their pain is well controlled. Declining a dose or partial dose should not change the availability of pain medication at the next scheduled dosing interval.

10. If available, a TAP block (or other transcutaneous anesthetic system) should be considered in appropriate cases.

11. On hospital discharge, adhere to one of the following two opioid prescribing guidelines.

    EITHER:

    A. Determine daily medication dosage required to control pain during the 24 hours prior to discharge and prescribe no more than this daily amount for five to seven days
        - Schedule a post-operative visit within 5-7 days to assess pain control and post-operative recovery

    OR:

    B. Limit total quantity of oral opioids to <20 doses and instruct the patient to call the RESPECT/MOUD program for post-partum pain management as needed.

Background:

These guidelines are designed for patients maintained on buprenorphine or buprenorphine/naloxone who are 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. 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.

- **If applicable,** all patients on buprenorphine/naloxone maintenance should be co-managed with their buprenorphine/naloxone provider during the pre- and post-procedure periods[23].

General Discharge Instructions:

- Patient should have three appointments with MOUD/RESPECT team scheduled before discharge (at one, three, and five weeks postpartum) for post-partum care and recovery follow up.

- Please remind the patient that Project RESPECT will continue prescribing buprenorphine/naloxone for six months to two years postpartum (individualized treatment plans will be developed as necessary). Transfer to a primary care/addiction medicine MOUD provider will be facilitated when appropriate for the patient.

- During discharge, review "My Pregnancy Plan" (BMC's version of CAPTA's Plan of Safe Care initiative) demonstrating that there is a plan for continued recovery support postpartum and a safe baby plan to ensure care for the baby (and other children, if applicable) in the event of a relapse.

- Remind the patient to bring any prescription bottles of pain medications given at time of hospital discharge to their follow-up appointment, even if they have used all of the medication.

THROUGHOUT PREGNANCY: ACUTE AND CHRONIC PAIN MANAGEMENT WITH BUPRENORPHINE

General principles for pain management on buprenorphine/naloxone[3]:

- Patients physically dependent on opioids require maintenance of daily equivalence before any pain relief is achieved with opioid analgesics (the "opioid debt").

- Scientific evidence 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 MOUD.

- Reassure patients that their OUD will not be an obstacle to aggressive pain management.

- Include patients in the 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., 24 mg per day changed to 8 mg every eight hours).
    - Consider a modest increase in the 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, SSRls, 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[24]. 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, 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.
- Kornfeld 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, Land R knee replacements, bilateral mastectomy, breast reconstruction, and/or X-Stop procedure)[25]. In all seven cases, daily buprenorphine maintenance dosing was uninterrupted. Full agonist opioids and non-opioid analgesics were used together with daily buprenorphine dosing. In all seven surgical cases, good to excellent pain control was achieved.

- Silca and 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[26]. Results showed that pain control was easier to achieve and functional recovery was greater when buprenorphine was maintained throughout the perioperative period compared to perioperatively using a full mu agonist opioid for chronic pain.

Delivery: Patients Treated With Naltrexone

Given the opioid antagonist property of naltrexone, discussions regarding the plan for anesthesia and pain management during childbirth should be reviewed throughout the peripartum period. If the mother wants the option to receive opioid medications during delivery and/or the postpartum recovery period, discussion as to when to stop naltrexone treatment, and reevaluation of the OUD treatment plan, must begin as soon as possible.

For planned or elective surgical procedures, extended release naltrexone must be discontinued four weeks prior, and oral naltrexone must be discontinued 72 hours prior to the procedure[3]. Given the often unpredictable and precipitous nature of childbirth, this timeframe of medication discontinuation may not be met. Consultation with the anesthesiologist is necessary to discuss effective analgesia and peri-operative anesthesia for non-scheduled or urgent surgical procedures for patients taking naltrexone.

When opioids are provided on top of naltrexone to manage acute pain:

- Irrespective 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.

- Patients should be monitored 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.

Neonate/Postpartum Care

- **Plan:** After delivery, it is essential for the mother to follow through with care for themselves and the infant.
- **Care for Baby:** Prior to being discharged from hospital, the infant will be observed for a minimum of seven days after birth for Neonatal Opioid Withdrawal Syndrome (NOWS)

- **Care for Mom**: The mother, in most instances, will be discharged from hospital within 2-4 days of delivery. The mother is expected to be seen for a postpartum check by the OB/ provider(s) at approximately one, three, and five weeks postpartum. Continued follow-up (Q 2-3 weeks) is recommended for the first six months to one year of the child's life.

SPECIFIC POPULATIONS

PATIENTS WITH HIV

Buprenorphine/naloxone use does not interfere with the clinical response to antiretroviral medications. Side effects from drug interactions between HIV medications and buprenorphine/naloxone are less severe and significant than those experienced with methadone. Reassure patients that treatment for their OUD 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.
    - Buprenorphine/naloxone may slightly increase protease inhibitor levels.
    - Decrease the buprenorphine/naloxone dosage until the symptoms disappear.

- Non-nucleoside reverse transcriptase inhibitors (NNRTls) may **decrease** buprenorphine/naloxone levels and may cause withdrawal symptoms. The buprenorphine/naloxone dose may need to be increased.
    - Efavirenz (Sustiva) can cause withdrawal symptoms. Increase the buprenorphine/naloxone dose accordingly.

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 can cause sedation and impaired thinking. Decrease the buprenorphine/naloxone dose accordingly.

PATIENTS WITH HEPATITIS C (HCV)

If a patient becomes pregnant while being treated for HCV, it is unknown whether it is better to continue with treatment or to stop treatment after delivery to ensure best outcomes for the pregnancy. It is best to discuss the options and possible effects with the patient. If a patient is found to be positive for HCV during pregnancy, guidelines currently are against HCV treatment because the effects of the medications on pregnancy are not known.

- Buprenorphine/naloxone is extensively metabolized by the liver.
- Most recent guidelines indicate that there are minimal concerns with the co-management of HCV and opioid use disorders utilizing buprenorphine/naloxone.
    - 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 an 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 versus buprenorphine when compared to healthy subjects[27].
    - Dose adjustment may be required for some patients with severe liver disease[3].
    - 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].
    - There are also case reports of seven patients with hepatitis C using buprenorphine/naloxone who had increased ALT 39 times the normal level[29].
        - All patients continued taking buprenorphine/naloxone, with a dose

reduction of 50% for three patients.

- All patients 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[3]. The MOUD prescriber can consult with Infection Disease provider if they are not comfortable preforming these assessments.

DUAL DIAGNOSIS

During pregnancy, it is important to continue treatment of psychiatric conditions in conjunction with opioid use disorder treatment. While there are psychiatric medications which are not recommended in pregnancy, acute discontinuation due to pregnancy is NOT recommended. Acute destabilization of maternal mental health is deleterious for both mother and fetus and can increase the risk of relapse. Alterations in psychiatric medications should be made in consultation with mental health providers.

Provider resources for dual diagnosis patients are listed in Appendix 12.

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 and psychiatric medications.

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.

APPENDIX 1: LIST OF ACRONYMS

ACME: Accreditation Commission for Midwifery Education
ACOG: American College of Obstetricians and Gynecologists
AUD Alcohol Use Disorder
BMC: Boston Medical Center
BSAS: Bureau of Substance Addiction Services
CFR-42: Code of Federal Regulations, Title 42
CMP: Certificate Maintenance Program
CNM: Certified Nurse Midwife
CNS: Central Nervous System
CSAT: SAMHSA's Center for Substance Abuse Treatment
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
FDA: Food and Drug Administration
HCG: Human Chorionic Gonadotropin
HIPAA: Health Insurance Portability and Accountability Act
IOP: Intensive Outpatient Program (counseling)
LFT: Liver Function Test
MOUD: Medication for Opioid Use Disorder
NAS: Neonatal Abstinence Syndrome
NICU: Neonatal Intensive Care Unit
NSAID: Non-steroidal Anti-inflammatory Drug
NSDUH: National Survey on Drug Use and Health
OB: Obstetrics
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
TSS: Transitional Stabilization Services (inpatient "holding" facility)
UDS: Urine drug screening

APPENDIX 2: CLINICAL APPOINTMENT POLICY

Clinical Appointment Policy:

- All patients who participate in the Boston Medical Center Office Based Addiction Treatment (MOUD) program are required to attend appointments with their obstetric, primary care provider, MOUD providers, and MOUD nurses as scheduled. These appointments are critical to effective comprehensive care.

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

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

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

APPENDIX 3: NALTREXONE INJECTION TREATMENT AGREEMENT

Treatment Agreement with Naltrexone Injection

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General Information:

Naltrexone is a drug used to treat individuals with opioid use disorder following detoxification from opioids and for alcohol use disorder. It is administered by an injection into your muscle.

Naltrexone is used with other activities and it does not take the place of other activities such as counselling.

Benefits and Risks:

The use of Naltrexone has been explained to me in terms that I understand. A booklet regarding this therapy has been given to me. I have been informed of the following:

- The nature and extent of Naltrexone.
- The benefits of Naltrexone.
- That I must stop the use of opioids prior to and while receiving Naltrexone.
- That I may experience acute opioid withdrawal symptoms if I still have opioids in my body. The symptoms may include runny nose, anxiety, nausea, vomiting, abdominal pain, diarrhea and/or muscle aches and pains.
- That the risks of Naltrexone include:
    - Pain, redness swelling at the injection site
    - Possible injury to my liver
    - Possible pneumonia-a lung infection
    - Possible severe allergic reaction including difficulty breathing and drop of blood pressure
    - Nausea, vomiting, headache, dizziness and tiredness
    - Possible depression and thoughts of suicide
    - Unintended opioid withdrawal

The risks and benefits of other treatment including no treatment at all have been discussed with me.

I understand that if I am or may be pregnant, it is my responsibility to notify my provider of this, for Naltrexone may not be safe for my baby.

I understand that I should notify my provider if I have ever tested positive for hepatitis. I **understand that if** I **use opioids while receiving** Naltrexone, I **run the risk of accidental overdose and death.** I understand that if I sustain a physical injury, it may be more difficult to treat my pain because of my use of Naltrexone.

I was given the opportunity to ask questions about Naltrexone therapy and all of my questions have been answered. I understand that I may see another provider regarding my opioid use disorder. I understand that I can refuse receiving Naltrexone.
I authorize my provider to provide additional treatment as needed in order to do what is best for me and my condition.

I know that medicine is not an exact science, and I agree that no one has given me any guarantees regarding Naltrexone therapy.

I have read (or had read to me) and understand the above information.

All of my questions and concerns regarding Naltrexone, including its benefits, risks, and alternatives have been explained to me, and I am satisfied with the explanation. I give my provider or a designated health care provider permission to administer Naltrexone to me.

Patient

Signature_____Date_____Time_____

Print _____

Patient DOB _____

Witness signature_____

Date_____ Time_____

Provider Signature_____Date_____Time_____

Naltrexone 380 mg

LOT# _____ Expiration Date_____

APPENDIX 4A: BUPRENORPHINE PROGRAM TREATMENT AGREEMENT

BUPRENORPHINE TREATMENT/PROGRAM REQUIREMENT AGREEMENT

As a patient in the MOUD program, I freely and voluntarily agree to accept this treatment agreement, as follows.

I agree to keep all my scheduled appointments with my provider 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 substances. If I do 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.

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

I agree not to tamper with urine screens and if I do so, this may be grounds to 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 will be given to me at my regularly scheduled times, typically following an office visit. Missed appointments may result in an intensified treatment plan including shorter prescriptions and loss of refills or referral to higher level of care.

I agree that the medication I receive is my responsibility and that I will keep it in a safe and secure place. I understand that lost medication may not be replaced. 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 prescribers, pharmacies, or other sources that I will inform my provider and/or MOUD nurse.

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 toxicology 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.

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 opioids or other substances, 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 result in a referral to more intense and supportive 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 or potentially transfer to another level of care.

MOUD providers will access the Prescription Drug Monitoring Program to review medication profiles on all patients. If patients are found to be accessing prescriptions from other providers, this finding will be reviewed by the MOUD team. If it is determined that the medications obtained by any other providers are in violation of the treatment agreement, the MOUD Team will evaluate the situation, address it with me, and adjust my treatment plan.

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

If I am female and of child bearing age it is 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.

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 taking medication 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 recovery services, as provided, to assist me in my treatment.

I understand that my medical records will be kept in an electronic medical record. These notes will be visible to any healthcare professional involved in my care at this institution.

The healthcare providers will only access your medical record if they are involved in your care.

Printed Name	Signature	Date
Witness Printed Name	Signature	Date

Buprenorphine Treatment for Pregnant Women

I understand that treatment with buprenorphine during pregnancy may result in neonatal abstinence syndrome (NAS) or Neonatal Opioid Withdrawal Syndrome (NOWS), a form of withdrawal from opioids in newborn babies.

- If I deliver at Boston Medical Center, I understand my baby will stay in the hospital for approximately 7 days to be observed for signs of withdrawal and longer if the baby's treatment team determines this to be necessary.
- I understand I can room-in with my baby until discharged from the hospital (unless there arises a safety concern for the baby; or a concern for my recovery stability)
- I recognize in-hospital monitoring is in the best interest of my baby and I and I will follow the behavioral expectations in this agreement when working with the providers caring for my baby in the hospital.

The state mandate regarding reporting of all *Substance Exposed Newborns* to the Department of Children and Families (DCF) has been explained to me.

I understand my providers are mandatory DCF reporters and I realize the filing of a 51A report to DCF is not a personal judgement but a legal requirement.

I also understand a 51A report may be made for any concerns for the health and safety of a child.

I have been able to ask questions regarding this policy.

I understand Project RESPECT/ MOUD treatment team will diligently advocate on my behalf to DCF highlighting my progress and success in my recovery during this pregnancy

Printed Name	Signature	Date
Witness	Signature	Date

BOSTON MEDICAL CENTER
Office Based Addiction Treatment (MOUD) Program
CONSENT FOR BUPRENORPHINE/NALOXONE TREATMENT IN PREGNANCY

Buprenorphine is a medicine that is used to treat opioid use disorder. Buprenorphine is an opioid which can help support recovery because it reduces craving and withdrawal symptoms, and blocks the effects of stronger and more dangerous opioids. Buprenorphine/naloxone is available as a daily sublingual film or pill.

Buprenorphine is used for maintenance therapy. Maintenance therapy can continue as long as medically necessary, it is recommended that buprenorphine treatment lasts for at least six (6) months.

Buprenorphine contains an opioid that can cause physical dependence. Do not stop taking buprenorphine suddenly. You may become sick with withdrawal symptoms because your body has gotten used to the medicine. Symptoms of withdrawal may include: muscle aches, stomach cramps, or diarrhea lasting several days. To decrease the possibility of opioid withdrawal, if you plan to stop Buprenorphine it should be done slowly over several weeks or longer under the direction of your care team.

It may take several days to get used the transition from the opioid that had been taken and using Buprenorphine. During this time any use of other opioids may cause an increase in symptoms. Combining Buprenorphine with alcohol or other sedating medications (such as benzodiazepines, pain medications, sleeping pills, anxiety medicines, antidepressants) may cause overdose and even death. **You should not take any other medications without first discussing with your health care provider.**

After becoming stabilized on Buprenorphine, the use of other opioid will have less effect. Attempts to override the Buprenorphine by taking more opioids could result in an opioid overdose.

The form of Buprenorphine that you will be taking is a combination of Buprenorphine and naloxone. If the Buprenorphine/Naloxone tablet or film were dissolved and injected by someone taking heroin or another strong opioid, it could cause life threatening infections and severe opioid withdrawal.

To fully absorb the medication, Buprenorphine/ Naloxone tablets must be held under the

tongue until they completely dissolve. Buprenorphine/Naloxone film must be completely dissolved either under the tongue or on the inside of your cheek. Your treatment team will discuss the proper technique to administer your medication.

It is recommended by the American College of Obstetrics and Gynecology (ACOG) and the American Academy of Pediatrics (AAP) that women with opioid use disorder who become pregnant should be offered medication for addiction treatment. Buprenorphine and methadone are considered first-line medications during pregnancy.

In the past, women with opioid use disorder who became pregnant while in treatment with buprenorphine/naloxone were changed to buprenorphine only medication (Subutex®). However, there are new studies showing that babies and mothers taking buprenorphine/naloxone did not have any negative affects compared to buprenorphine only medication (Subutex®). It has also been found that it was harder for expectant mothers to get Subutex® from pharmacies.

A known side effect of taking any opioid medication for treatment (such as methadone or buprenorphine) during pregnancy is that after birth the baby may suffer withdrawal called Neonatal Abstinence Syndrome (NAS). NAS is treated in the hospital by cuddling, skin-to-skin contact and swaddling. Often times NAS is also treated in the hospital by giving the baby small doses of morphine or methadone to treat withdrawal symptoms.

I have read this form or had it read to me. I understand what this says. I was given the opportunity to ask questions. All of my questions were answered. I have spoken to my health care team about the risk vs. benefit of starting or continuing buprenorphine/naloxone combination product during my pregnancy for me and my child. I believe I have enough information to consent to buprenorphine/naloxone treatment during my pregnancy. By signing this form I authorize my MOUD clinical team (physician, nurse practitioner, nurse), to treatment me with the medication buprenorphine/naloxone as medically appropriate.

Print Name	Sign name	Date

Witness	Date

APPENDIX 4B: 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 5: MOUD PATIENTS COUNSELING POLICY

Counseling Policy:

Patients of the Office Based Addiction Treatment (MOUD) program are strongly encouraged to engage in counseling and/or similar intensive recovery support programs. If needed, patients should receive assistance with referrals and linkages for counseling and recovery support services from MOUD 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 MOUD 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 MOUD team.

- Patients will agree to sign consent to release information so that MOUD 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 MOUD 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, and Online meetings.

APPENDIX 6: MOUD PROGRAM RANDOM CALLBACK POLICY

Random Callback Policy

- To monitor and verify the proper use of the buprenorphine/naloxone, the MOUD 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 tablets or films.

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

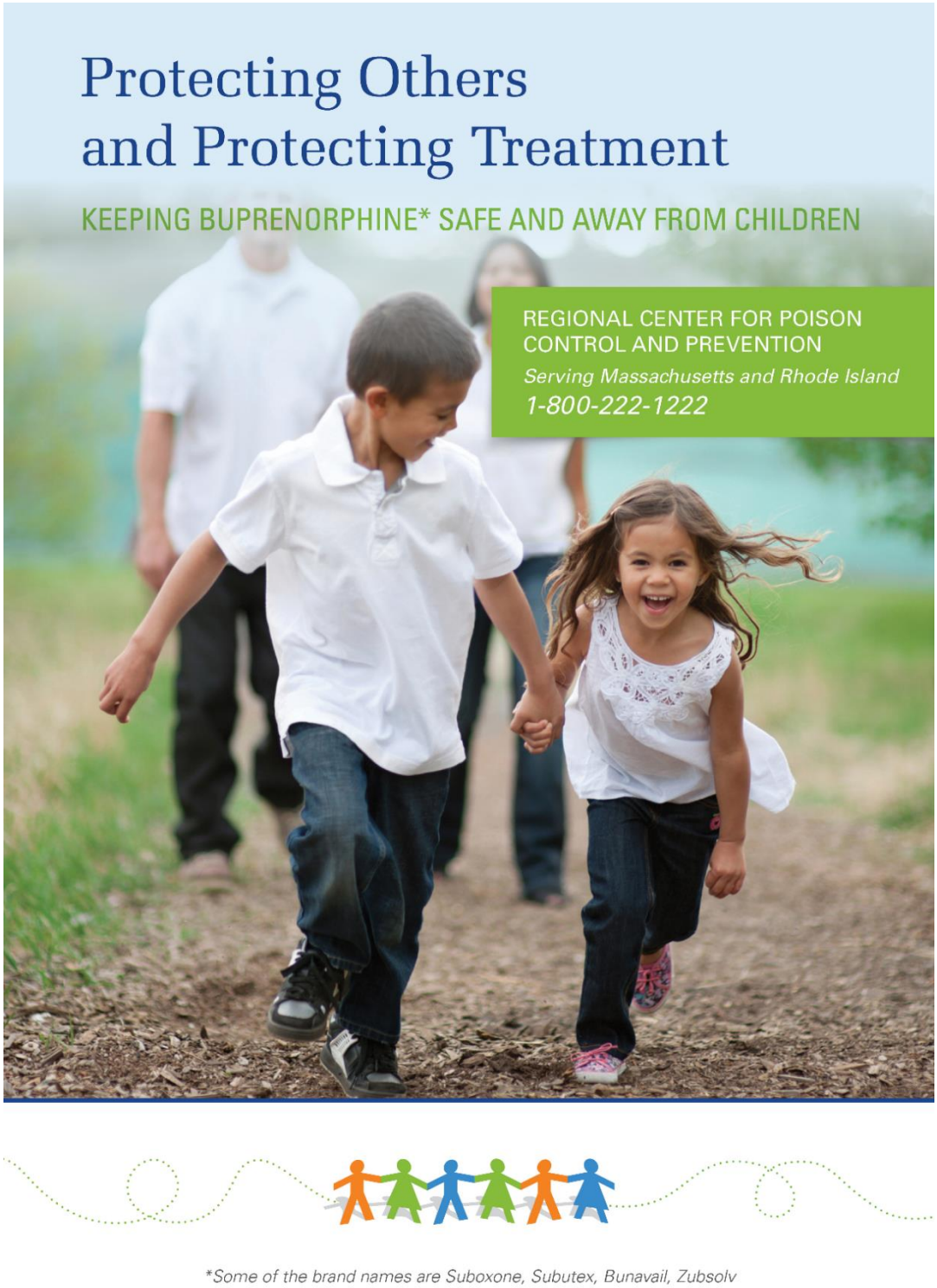
- For this policy to function, the patient must ensure that we have current and accurate contact information.

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

- If the patient does not return for a random callback monitoring visit the MOUD Team will meet and reassess the treatment plan with adjustments such as: shorter times between office visits, shorter prescriptions, no refills, etc.

APPENDIX 7: PATIENT HANDOUT: PEDIATRIC EXPOSURE TO BUPRENORPHINE/ NALOXONE

Handout can be ordered here: http://massclearinghouse.ehs.state.ma.us/product/SA1064kit.html



APPENDIX 8: DSM-V CRITERIA FOR DIAGNOSIS OF AN OPIOID USE DISORDER

Opioid Use Disorder is defined as 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:

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

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)

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

APPENDIX 9: MEMO FROM MASSACHUSETTS OFFICE OF HEALTH AND HUMAN SERVICES ON 51A REPORTS

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Children and Families
600 Washington Street, 6th Floor
Boston, MA 02111
Tel.: 617-748-2000 Fax: 617-261-7435
www.mass.gov/dcf

CHARLES D. BAKER
Governor

KARYN E. POLITO
Lieutenant Governor

MARYLOU SUDDERS
Secretary

LINDA S. SPEARS
Commissioner

TO: Mandated Reporters, Community Partners and Other Stakeholders
RE: 51A Mandated Reports regarding Substance Abused Newborns (SENs)
DATE: November 1, 2016

The Massachusetts Department of Children and Families (DCF) has received a number of questions regarding when to file a 51A report in circumstances involving Substance Exposed Newborns (SENs). In response, DCF is offering this guidance to hospitals and medical professionals as they update policies and practices to respond to SENs cases.

Mandated reporters should continue to report SENs as defined by both federal and state laws.[i] In Massachusetts, a 51A Report must be filed when a newborn is born physically dependent upon an addictive drug at birth and/or if there is a reasonable cause to believe that a child is suffering abuse/neglect. Federal law also requires that health care providers notify DCF when a newborn is identified as being affected by illegal substance abuse, experiencing withdrawal s symptoms or have Fetal Alcohol Spectrum Disorder.

Clinical considerations include:

- A diagnosis of withdrawal from a substance (Neonatal Abstinence Syndrome), including infants who experience NAS due to Medication Assisted Treatment or other prescribed medications;
- A diagnosis of fetal alcohol effects or fetal alcohol syndrome; and/or
- Newborns who were exposed to substances *in utero* and there is reasonable cause to believe that the child is suffering from abuse/neglect.

A newborn with a positive toxicology screen should prompt additional conversation and/or further information gathering to understand better if hospital or medical personnel believe there is reasonable cause to believe that the child is suffering from abuse/neglect.

If there are further questions regarding when to file a 51A, please contact your risk management office or legal department.

Newborns who are substance exposed are a highly vulnerable population that is at increased risk of abuse and/or neglect. DCF's role is to understand parental capacity and address related issues of risk, safety, health, and well-being.

When a 51A Report is filed related to substances, DCF will ask the mandated reporter:

- the substance(s) affecting the newborn, if known;
- if the newborn had a positive toxicology screen at birth;
- if the newborn is experiencing Neonatal Abstinence Syndrome;
- if the newborn is diagnosed with Fetal Alcohol Syndrome;
- if the substance affecting the newborn was prescribed and taken as directed by a medical professional; and
- if there are any concerns about the impact of the substance(s) use/misuse on the mother's capacity to safely care for her infant.

Upon receipt of the 51A report, DCF reviews all details of the report, including the allegations, the ages of the children in the family, family constellation, any information regarding the family's DCF's history, and current services to the family. Additionally, during the screening process DCF conducts a Criminal Offender and Sex Offender registry information check and many contact other collaterals. This information is then review to determine whether or not that report will be screened in for an investigation and if DCF needs to respond on an emergency basis to ensure the safety of the newborn.

DCF looks forward to continuing our partnership with mandated reporters and community stakeholders to best understand risk/safety concerns for all children. If you have further questions regarding filing a 51A report, please contact your local DCF Area Office.

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[i] ***Massachusetts General Law's ch. 119, sec 51 A Mandated Reporter Law:***

Legislates (a) mandated reporter who , in his professional capacity, has reasonable cause to believe that a child is suffering physical or emotional injury resulting from: (i) abuse inflicted upon him which causes harm or substantial risk of harm to the child's health or welfare, including sexual abuse; (ii) neglect, including malnutrition; (iii) physical dependence upon an addictive drug at birth, shall immediately communicate with the department orally and, within 48 hours, shall file a written report with the department detailing the suspected abuse or neglect; or (iv) being a sexually exposed child; or (v) being a human trafficking victim as defined by section 20M of chapter 233.

***Federal Child Abuse Prevention and Treatment Act (CAPTA*):**

Legislates that "(ii) policies and procedures (including appropriate referrals to child protection service systems and for other appropriate services) to address the needs of infants born with and identified as being affected by illegal substance abuse or withdrawal symptoms resulting from prenatal drug exposure, or Fetal Alcohol Spectrum Disorder, including a requirement that health care providers involved in the delivery or care of such infants notify the child protective services system of the occurrence of such condition in such infants."

APPENDIX 10: FDA PREGNANCY CATEGORY CLASSIFICATIONS

The FDA has a responsibility for ensuring that prescription drug and biological products (both referred to as ‘‘drugs’’ in this proposed rule) are accompanied by labeling (including prescribing information) that summarizes scientific information concerning their safe and effective use. Below are the current category designations:

Category A: Adequate and well-controlled studies have failed to demonstrate a risk to the fetus in the first trimester of pregnancy (and there is no evidence of risk in later trimesters).

Category B: Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women.

Category C: Animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.

Category D: There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.

Category X: Studies in animals or humans have demonstrated fetal abnormalities and/or there is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience, and the risks involved in use of the drug in pregnant women clearly outweigh potential benefits.

Source: Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling (Federal Register/Vol. 73, No. 104/Thursday, May 29, 2008)

APPENDIX 11: PROJECT RESPECT INTAKE PROCESS

1. Schedule an Intake with Nurse Care Manager (NCM)

   _____

2. Obtain Consents For MOUD Treatment In Pregnancy

   _____

3. Review and Sign Collaborative Treatment Agreement

   _____

4. Review Patient's Medication List

   _____

5. Review Rationale for, and Request of Medical and Behavioral Health Release of Information Forms

   _____

6. Prepare and Submit Prior Authorization (if indicated) for MOUD

   _____

7. Discuss Reporting Guidelines to The Department of Children and Families (DCF)

   _____

8. Add Patient to the Prescription Refill Calendar

   _____

9. Provide Patient with NAS/NOWS Information and Educational Brochure

   _____

10. Review the Hospital's NAS/NOWS Newborn Admission and Observation Protocols, including the Expected Newborn Length of Stay and Pediatric Treatment Protocols

    _____

11. Review Expectations And Frequency of Prenatal Visits

    _____

12. Discuss Postpartum Follow Up Care (Duration: up to 1 Year) and Resources Available for Parenting In Recovery

    _____

13. Review Pharmacy Utilization Guidelines: Record the Pharmacy Chosen by the Patient to be used (Name, Address, Contact Number and Fax Numbers)

    _____

14. Review Counseling Policy and the Importance of Behavioral Health Treatment in Conjunction with MOUD

    _____

15. Review the Clinic Appointment Policy

    _____

APPENDIX 12: PROVIDER RESOURCES FOR DUAL DIAGNOSIS PATIENTS

Massachusetts Child Psychiatry Access Program Form Moms: Promotes maternal and child health by building the capacity of providers serving pregnant and postpartum women and their children up to one year after delivery to effectively prevent, identify, and manage mental health and substance use concerns.

Website and more information: https://www.mcpapformoms.org/Default.aspx

Contact Number for Providers: 855-Mom-MCPAP (855-666-6272)

SAMHSA's National Helpline: 1-800-622-HELP (4357) (TTY: 1-800-487-4889)
SAMHSA's National Helpline is a free, confidential, 24/7. 365-day-a-year treatment referral and information service (in English and Spanish) for individuals and families facing mental and/or substance use disorders.

Website and more information: https://www.samhsa.gov/find-help/national-helpline

Massachusetts General Hospital Center for Women's Mental Health: Reproductive Psychiatry Resource and Information Center
The MGH Center for Women's Mental Health Reproductive Psychiatry Resource and Information Center can connect patients, providers, and family members to a variety of helpful resources.

Website and more information: https://womensmentalhealth.org/resource/

APPENDIX 13: RESPECT/MOUD NCM JOB DESCRIPTION AND RESPONSIBILITIES

RESPECT/ MOUD NURSE CARE MANAGER
JOB DESCRIPTION and RESPONSIBILITIES

Patient Care

1) Initial assessment and intake will include;
    - Obstetric history
    - Medical history
    - Mental health history
    - Substance use / treatment history
    - Social history
    - Triage for behavioral health needs with referral to LICSW and/or psychiatry
    - Review of prenatal care: coordination for gestational age appropriate testing as needed
    - Reviews clinical expectations re: appointments, urine screens, counseling, prescription refills
    - Ensures Narcan Rx for every patient
    - Ensures scheduling of weekly follow up visits (x 4) at end of intake appointment
    - Provides patients with recovery meeting list: Recommend 3-5 meetings per week

2) Reviews intake assessment with RESPECT clinical team
    - Present new patients at weekly behavioral health rounds and RESPECT am clinical rounds
    - Maintain list of active buprenorphine and naltrexone patients

3) Completes appropriate documentation with excellent record keeping in EPIC with clear treatment plan
4) Collects specimens (urine screens); evaluates results and takes clinical actions per protocol
5) Reviews MassPAT for each patient with every prescription
6) Maintain the buprenorphine refill calendar and prep buprenorphine Rx for respective prescriber (e-prescribing)
7) Counsels patients regarding relapse prevention and pharmacotherapy
8) Provides follow up care in person and via telephone when needed, proactively, including assistance scheduling clinical visits.
9) Manages RESPECT phone line: (active and VM messages) addressing prescription refills as needed, follow up of test results, critical values and medical issues.

Clinic Organization

1) Maintain list of all buprenorphine, naltrexone, and injectable naltrexone patients (how they were referred to RESPECT, starting dose, positive urine screens and date, housing, counseling, #no shows)
2) Attend every RESPECT am rounds with the active list (above)
3) Attends weekly behavioral health rounds
4) Attends monthly RESPECT team meetings (3rd Tuesday of month at noon)
5) Ensures collaboration, communication, and participates in meetings with OBAT team as needed and required
6) Provides ongoing education and proactive support of patients and coordination of services.
7) Assists in creation of clinical forms.
8) Engages in OB/GYN departmental nursing meetings and other communication methods as needed
9) Consistently uses clear concise and effective communication written/oral and comply with departmental policies when sharing/documenting relevant patient care data
10) Provides follow up care in person and via telephone when needed, proactively, including assistance scheduling clinical visits
11) Collect data for the bureau of substance addiction services on new patients, quarterly and at discharge: submit this data as required

Training and Education:

- Completes Certified Addiction Registered Nurse (CARN) course/ training and pursues certification

- Attends Annual MA-CARN Education Conference
- Attends PNQIN (Perinatal Neonatal Quality Improvement Network) or MPQC Annual Conference
- Completes OBAT TTA "Understanding Addiction" free on-line course
    - https://cmeonline.hms.harvard.edu/courses/course-v1:HarvardMedGlobalAcademy+OUDEP1+1T2017/about?utm_source=bmcobat&utm_medium=link&utm_campaign=OUDEP

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