The Baltimore Buprenorphine Initiative

CLINICAL GUIDELINES FOR BUPRE诺PHINE TREATMENT OF OPIOID DEPENDENCE IN THE BALTIMORE BUPRE诺PHINE INITIATIVE

Revised June 2013
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INTRODUCTION

The following guidelines were developed to support enhanced standardization in the clinical services delivered by providers participating in the Baltimore Buprenorphine Initiative (BBI). This document draws from existing practice guidelines in the literature that are focused on the use of buprenorphine as well as on the Code of Maryland Regulations (COMAR) that require a set of minimum standards of operation for licensed outpatient substance abuse treatment facilities. In many cases, the Clinical Guidelines recommend a higher standard of practice than the requirements outlined in COMAR.

The guidelines contained in this document recommend the standard of care that participating BBI treatment providers should follow and contain specific documentation forms that are required for use by all participating BBI providers. The following are the required forms, which are explained in the document and can be found in the Appendices, that BBI providers are asked to utilize:

1. Worksheet for DSM-IV Criteria for Diagnosis of Opiate Dependence
2. Clinical Opiate Withdrawal Scale
3. Mental Health Symptom Screening Form and Scoring Sheet
4. Mental Health Referral and Treatment Form
5. Agreement for Treatment with Suboxone through the Baltimore Buprenorphine Initiative
6. Authorization for Release of Confidential Information about Alcohol or Other Substance Abuse Treatment
7. Admission Orders/Suboxone Induction Protocol
8. Take-Home Medication Labels
9. Transfer Disposition Form
10. Buprenorphine Client Transfer Summary

A quality improvement plan has been developed by Baltimore Substance Abuse Systems, Inc. (BSAS) to monitor BBI provider performance on a set of quality indicators which reflect priority clinical and operating practices and processes. The Clinical Guidelines support high levels of performance on the quality indicators. Regular reports will be provided to participating BBI providers to review their performance on the quality indicators and to work with BSAS to improve performance as necessary. The Clinical Guidelines will be reviewed on a regular basis and modified as needed.

SIGNIFICANCE AND BACKGROUND

Opioid addiction is a costly and very significant public health problem that is often portrayed in the nonprofessional media as a problem primarily facing the lower socioeconomic segment of the U.S. population. Epidemiologic studies, however, show that opioid addiction affects 810,000 people each year, representing all segments of American society, as well as their families and communities, with annual costs estimated at $21 billion.
Baltimore City has one of the most severe heroin addiction problems in the United States. This is evidenced by the number of admissions to substance abuse programs, emergency department visits and deaths from heroin overdoses. More than 10,000 Baltimore City residents were admitted for heroin treatment in fiscal year 2006. Some of the medical consequences of opioid dependence are the spread of HIV, hepatitis C, endocarditis, and osteomyelitis. Long term opioid dependence also contributes to the worsening of other chronic conditions such as diabetes, hypertension and asthma. Further consequences of untreated opioid dependence are premature death, increased crime and destroyed families. Despite increased substance abuse treatment in Baltimore over the last decade, the availability of treatment remains inadequate to meet the need for substance abuse treatment in the city.

The Baltimore Buprenorphine Initiative is an effort in Baltimore City aimed at expanding access to treatment for opioid addicted individuals using the medication buprenorphine. Buprenorphine can be prescribed by certified physicians in their offices and is a covered service by third party payers, including Medical Assistance and Maryland’s Primary Adult Care Program, which are the most prevalent payers for individuals affected by opioid addiction in Baltimore. Expanding physician participation in the treatment of addicted individuals using buprenorphine therefore expands access and offers a new funding stream to support substance abuse treatment services.

OVERVIEW

The Baltimore Buprenorphine Initiative (BBI) is a joint project of the Baltimore City Health Department, Baltimore Substance Abuse Systems, Inc. (BSAS), and HealthCare Access Maryland, Inc. (HCAM) that was launched in October of 2006. The BBI promotes individualized, patient-centered buprenorphine therapy in conjunction with behavioral treatment with a goal of recovery from opioid addiction. The model promotes a continuum of care that includes an outpatient treatment regimen, medication induction, as well as maintenance and stabilization in the medical care system (see Appendix 1).

The BBI aims to significantly increase access to substance abuse treatment for people addicted to opioids in Baltimore by bringing together substance abuse treatment centers, community health centers, primary care physicians, and mental health providers. The aim is to facilitate patients’ success with long term buprenorphine treatment and to provide medical care and mental health services as necessary.

There are three major components of the BBI:

- **Patients start buprenorphine in a substance abuse treatment center.** The BBI provides patients with buprenorphine as well as other therapeutic services including, but not limited to, individual and group therapy. Patients initiate services in one of the designated BSAS-funded outpatient treatment centers and receive intensive outpatient or outpatient counseling based on an assessment determining the appropriate level of care. Buprenorphine induction takes place through on-site physicians at each treatment center who perform individual physical examinations and assessments in order to prescribe the most appropriate buprenorphine dose for each patient. Patients are seen by the on-site physician and nursing staff on a regular basis as they are maintained on buprenorphine while receiving ongoing individual and group counseling services. Patients are provided with the services of an advocate from HealthCare Access Maryland, Inc. (HCAM) to help obtain health insurance so that the cost of the buprenorphine can be covered and that patients can obtain ongoing treatment by a buprenorphine-certified continuing care physician once stable.
Patients transition to the medical system for buprenorphine stabilization and medical care. The HCAM advocate works with the treatment center clinical team to identify patients who meet the criteria for transfer to the medical or mental health system for continuing care. Patients who meet the criteria are assisted by the HCAM advocate to obtain an appointment with their assigned continuing care provider to begin receiving buprenorphine treatment and regular medical care. The HCAM advocate facilitates the transfer process by sending designated clinical and other information to the assigned community physician and then continues to support the patient and the physician for an additional six months following transfer to assist the patient in maintaining stability and attending medical appointments.

Patients continue to receive substance abuse counseling. If interested or clinically recommended, patients continue to receive at least three additional months of counseling at the original substance abuse center after transfer to the assigned physician. Systems of communication between the counseling staff and physician facilitate continuity of care. The HCAM advocates continue to offer support to patients as necessary.

PARTNERS

The BBI has three partners each with a critical role in the development and success of the initiative.

Baltimore City Health Department – The mission of the Baltimore City Health Department is to advocate, lead, and provide services of the highest quality in order to promote and protect the health of the residents of Baltimore. In order to achieve this mission, the Department funds and operates a number of programs that strive to improve the health of the city’s residents. BCHD played a major role in helping develop the BBI in 2006 and continues to support BBI’s efforts.

Baltimore Substance Abuse Systems, Inc. (BSAS) – Baltimore Substance Abuse Systems, Inc. is the designated substance abuse treatment and prevention authority for Baltimore City. The organization is responsible for the administration of federal, state and local grant funds designated for substance abuse treatment and prevention services. BSAS administers funding, monitors treatment programs, collects patient demographic and treatment data, works in collaboration with other agencies to improve services, and plans for the development of new treatment, prevention, and recovery services. BSAS does not provide treatment services directly but does provide information and referral.

The role of BSAS in the BBI is oversight of the initiative as a whole and the development of contracts with and guidance to the substance abuse treatment programs. Quality improvement and outcomes reporting are also the responsibility of BSAS.

HealthCare Access Maryland, Inc. (HCAM) – HCAM is a quasi-public agency of the Baltimore City Health Department and was established in 1997 to assist with the transition from Medicaid fee-for-service to managed care - HealthChoice. HCAM provides health education, care coordination, outreach, eligibility determination for the Maryland Children’s Health Insurance Program and the Maryland Primary Adult Care Program, as well as ombudsman services to HealthChoice enrollees. HCAM has also expanded its services in Baltimore to include outreach to at-risk pregnant women and their families, to the homeless, and to individuals seeking substance abuse treatment services in the city.
HCAM provides a team of treatment advocates who work with patients, treatment center staff and physicians to facilitate patients’ access to health insurance and other benefits, patients’ transfer to the medical care system and engage in ongoing patient advocacy. HCAM uses IRIS, an internal database to track patient activities and insurance status.

**Participating Substance Abuse Treatment Centers:**

BSAS works with a number of treatment centers across the city that provide buprenorphine services. A list of available centers can be found on the BSAS- BBI website, [http://bbi.bsasinc.org/index.html](http://bbi.bsasinc.org/index.html).
SECTION 1: BASICS OF BUPRENORPHINE

WHAT IS BUPRENORPHINE?

Buprenorphine is a medication used to treat patients who are addicted to opioids such as heroin, morphine, Oxycontin, Vicodin and other opioids. It is a semi-synthetic opioid derived from thebaine, a naturally occurring alkaloid of the opium poppy, Papaver somniferum. It is classified by the United States Drug Enforcement Administration (DEA) as a Schedule III narcotic.

Buprenorphine has three United States Food and Drug Administration (FDA) indications: opioid detoxification, opioid maintenance, and pain management. Opioid detoxification describes the process in which a physically dependent individual is gradually tapered off all opioids, typically over a period of days to weeks. Opioid maintenance is the long-term (typically months to years) substitution with a regulated opioid with the goal of discontinuing or substantially decreasing illicit opioid use. The liquid form of buprenorphine (BUPRENEX) and transdermal patch (BUTRANS) are approved for pain management.

HOW DOES BUPRENORPHINE WORK?

Buprenorphine is a partial agonist that is active at the mu opioid receptors. This means that it attaches to the same receptor as other opioids but that it does not “turn on” or activate the receptor as much as other opioids do (See Figures 1 and 2). In addition to the primary effects on the mu opioid receptor, buprenorphine also appears to act as an antagonist at the kappa opioid receptor (possibly involved with spinal analgesia and anti-dysphoric effects), as an agonist at the delta receptor (clinical significance uncertain) and as a partial agonist at the opioid-receptor-like 1 (ORL-1).

Past a certain point, higher doses do not further intensify the pharmacological effects of buprenorphine but may increase the length of withdrawal suppression and opioid blockade. This is in contrast to full opioid agonists such as methadone and heroin, which exert greater opioid receptor activity as the dose is increased (see Figure 3). Nevertheless, buprenorphine can have strong opioid effects in non-opioid tolerant individuals.
Buprenorphine also has a high affinity for mu opioid receptors. This means that it binds very tightly to these receptors, preventing other opioids from attaching. This allows buprenorphine to block the effects of other opioids taken subsequent to buprenorphine. It also has slow dissociation (“letting go”) from these receptors, allowing the clinical effects of buprenorphine to last significantly longer than would be expected based solely on its elimination half-life.

Buprenorphine is readily absorbed through the gastrointestinal and mucosal membranes. However, due to extensive first-pass metabolism, buprenorphine has very poor oral bioavailability (10% of the intravenous route) if swallowed. Its availability is significantly increased with sublingual administration (30-50% of the intravenous route) making this a feasible route of administration for the treatment of opioid dependence. Absorption of buprenorphine from the film preparation is greater than that seen with the tablets leading to a slightly higher peak concentration in the blood.

WHAT FORMS DOES IT COME IN?
Buprenorphine is administered sublingually and is available in three formulations:

- **Subutex** - contains only buprenorphine.
- **Buprenorphine** (generic)
- **Suboxone** - contains buprenorphine & naloxone.
  
- **Generic Buprenorphine & naloxone**

- **Suboxone Film** - contains buprenorphine and naloxone.
Naloxone is an opioid antagonist (blocker). It is used to discourage the non-medical, intravenous use of buprenorphine. It reduces the euphoria that buprenorphine produces if it is injected. The buprenorphine/naloxone combination is preferable in all cases except when the patient is hypersensitive to naloxone or pregnant. (Hypersensitivity may be demonstrated by rashes, hives, itchiness, bronchospasm, swelling and anaphylactic shock). Two other forms of buprenorphine, Buprenex, (a liquid, injectable form) and Butrans (a dermal patch) are not approved for use in the treatment of opioid addiction. They are only approved for the management of pain.

BBI uses Suboxone formulations in the treatment of opioid dependence.

HOW IS BUPRENORPHINE METABOLIZED?

Buprenorphine is metabolized in the liver, primarily by the cytochrome P450 3A4 system, into norbuprenorphine and other products. Peak plasma concentrations are achieved 1-2 hours after sublingual administration. Peak clinical effects occur 1-4 hours after sublingual administration, with continued effects for up to 12 hours at low doses (2mg) but as long as 48-72 hours at higher doses (16-32 mg).

Buprenorphine has a distribution half-life of 2-5 hours. The metabolites are excreted in the biliary system, with enterohepatic cycling of buprenorphine and its metabolites. Most of the drug is excreted in the feces and urine. Buprenorphine has an elimination half-life of 24-37 hours.

WITHDRAWAL SYNDROME FROM BUPRENORPHINE

Because buprenorphine is a partial opioid agonist and because it is slower to dissociate from opioid receptors than full opioid agonists, buprenorphine has a milder withdrawal syndrome when treatment is discontinued than that seen with full opioid agonists such as methadone. Typically, the withdrawal syndrome following abrupt cessation of long-term buprenorphine treatment emerges 2-5 days after the last dose and mild withdrawal features can continue for several weeks.

DRUG INTERACTIONS

The principal drug interactions of buprenorphine relate to its opioid activity.

- **Other sedatives**- Buprenorphine exerts additive CNS and respiratory depressant effects when used in conjunction with other sedating medications. These include benzodiazepines, alcohol, tricyclic antidepressants, and sedating antihistamines. **Deaths have been reported involving the combination of buprenorphine with high doses of benzodiazepines.**

- **Opioid antagonists**- Buprenorphine treatment should not be combined with opioid antagonists (naltrexone). Buprenorphine has a higher affinity for mu opioid receptors than the opioid antagonists. In the event of overdose of buprenorphine high doses of naloxone (10mg or more) may be required to reverse its effects. Naltrexone can precipitate a delayed withdrawal reaction in patients on buprenorphine.
- **Opioid agonists**- Buprenorphine exerts a degree of blockade to the effects of full agonist opioids which may complicate the use of additional opioids for analgesia. The initial dose of buprenorphine can precipitate opioid withdrawal in patients with high levels of physical dependence to full opioid agonists.

- **Hepatic enzyme inducers and inhibitors**- Buprenorphine is metabolized by the hepatic microsomal enzyme system (CYP 3A4). Theoretically, the use of foods or medications that inhibit the 3A4 enzyme (such as fluconazole, metronidazole, indinavir, ritonavir, erythromycin) may lead to increased plasma levels of buprenorphine whereas exposure to substances that induce the 3A4 system (such as phenobarbital, rifampin, phenytoin, carbamazepine, nevirapine) may lead to decreased levels of buprenorphine. Clinically, these medications have relatively minimal impact on buprenorphine dosing requirements. Each patient should be managed on an individual basis.

**BUPRENORPHINE SAFETY**

Buprenorphine has a favorable safety profile. Because of the “ceiling effect” of mu opioid receptor activation (See Figure 3), respiratory and central nervous system depression is significantly less with buprenorphine as compared to full opioid agonists. In adults, overdoses on buprenorphine alone are almost never (if ever) fatal. However, it is possible for non-tolerant individuals to overdose on buprenorphine. Therefore, care should be taken in prescribing buprenorphine to individuals who are not fully tolerant to opioids. Fatalities have occurred primarily when buprenorphine was used intravenously along with intravenous benzodiazepines. It is important for a physician to be aware of the patient’s concomitant use of other sedative hypnotics such as benzodiazepines. However, benzodiazepines and other CNS depressants, at therapeutic doses, can be used safely in combination with buprenorphine. If the use of benzodiazepines or other CNS depressants is deemed medically appropriate, it is important to monitor closely for side effects, particularly sedation and respiratory depression.
SECTION 2: INTAKE AND ASSESSMENT PROCESS

OVERVIEW

The BBI aims to increase availability of buprenorphine maintenance treatment in Baltimore City. A key factor in successful outcomes is having treatment readily available for opioid addicted people when they seek help. The primary objective of the intake and assessment process is to determine appropriateness for buprenorphine treatment, evaluate patient needs, establish expectations of the program and patient, and develop a treatment plan to address individualized needs. The intake and assessment process is the first step in the medical and psychosocial management of opioid addiction and uses validated screening tools to identify patients with an opioid use problem and other assessment methods to identify the scope and severity of an opioid addiction so that the most appropriate treatment setting, approach, and intensity can be established. Throughout the intake and assessment process, decisions are based on a patient’s preferences, addiction history, presence of medical or psychiatric co-morbidities, and readiness to change various substance use-related behaviors.

Each potential patient receives an intake and assessment for opioid dependence by an addiction counselor, nurse or nurse practitioner, and physician within one week of their initial contact with the BSAS-funded treatment center. The intake and assessment process includes a minimum of a brief screening, focused physical examination, complete patient history, relevant laboratory testing and mental health screening to determine an individual’s recommended level of care according to the American Society of Addiction Medicine’s Patient Placement Criteria (ASAM PPC). The intake and assessment process may be conducted over several visits; however, buprenorphine induction should not be delayed. The intake and assessment process should be scheduled and conducted in a manner that allows patients to receive their first buprenorphine dosage within 48 hours of initial face-to-face contact with the treatment center. Preferably, buprenorphine induction should take place on the day of the first face-to-face contact.

SCREENING

A brief screening of potential patients can be conducted through a telephone call to BSAS or a treatment center, or walk-in at one of the participating BBI treatment centers. The purpose of the screening is to determine if the person is a potential candidate for treatment in the Baltimore Buprenorphine Initiative through assessment that the patient has an opioid use disorder. The screening should be used to collect basic clinical information from patients to determine if there is an opioid addiction and to understand individual preferences that can help guide patients to an appropriate referral to a treatment center that matches the patient’s needs and ability to attend treatment.

Other treatment options should also be explained to the potential patient so that he/she can make an informed decision regarding the optimal form of treatment. Other options include: 1). Methadone maintenance, 2). Naltrexone maintenance, and 3). “Medication-free” counseling. Factors that might make a potential patient more appropriate for buprenorphine include: relatively shorter duration of opioid addiction (less than 1 year), good response to buprenorphine treatment in the past, known QT prolongation, and a history of fainting/passing out. Patients with alcohol dependence may benefit from
naltrexone treatment as this medication has also been shown to help some individuals reduce/stop alcohol use. Buprenorphine therapy is contraindicated with naltrexone.

The following three questions should be asked first to establish if the patient is an appropriate candidate for buprenorphine treatment:

- Is patient at least 18 years of age?
- Is patient currently opioid addicted or does he/she have a history of opioid addiction?
- Is patient interested in buprenorphine treatment?

If the patient answers positively to each of these questions, then the counselor should ask the following questions to help make a decision on the most appropriate treatment center to refer the patient to meet individual needs. Before asking the questions, the counselor should explain that the BBI may require almost daily attendance for the first one to four weeks of treatment:

- Are there days/times when you are not available for counseling?
- Are there times when you are not available to obtain your medication on a daily basis at the treatment center? (This may only be necessary for one to four weeks.)
- Is child care an issue for you attending treatment?
- Where do you live? Do you prefer a center close to your home?
- What type of health insurance do you have?

Based on the answers to the above five questions, the BSAS referral counselor will make a referral to a substance abuse treatment center that can most appropriately accommodate the patient’s needs. If the patient walks in to one of the treatment centers for screening, the counselor will decide if the center can accommodate the patient’s needs and if not, will provide a referral to the BSAS intake and referral line for a different placement so that the patient’s needs can be more appropriately met.

During the initial screening, if a the patient is a potential BBI candidate and the center can meet the patient’s needs, an appointment should be made with the patient as soon as possible, and no more than one week following the intake screening contact.

**INDICATIONS FOR APPROPRIATENESS FOR BUPRENORPHINE TREATMENT**

In order to determine the appropriateness for opioid treatment, a comprehensive assessment must be conducted to establish a diagnosis of opioid use disorder and to establish the presence of other minimum criteria for acceptance. An appropriate candidate for the BBI should at a minimum be:

- Opioid Dependent according to the DSM-IV-TR diagnostic criteria. The Worksheet for DSM-IV Criteria for Diagnosis of Opiate Dependence must be completed on all patients before induction (see Appendix 2).
**DSM-IV-TR Diagnostic Criteria for Opioid Dependence:**

A maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by three (or more) of the following, occurring at any time in the same 12-month period:

- Tolerance, as defined by either of the following:
  - A need for markedly increased amounts of the substance to achieve intoxication or desired effect, or
  - Markedly diminished effect with continued use of the same amount of the substance.

- Withdrawal, as manifested by either of the following:
  - The characteristic withdrawal syndrome for the substance, or
  - The same (or closely related) substance is taken to relieve or avoid withdrawal symptoms.

- The substance is often taken in larger amounts or over longer period than was intended.

- There is a persistent desire or unsuccessful efforts to cut down or control substance use.

- A great deal of time is spent in activities necessary to obtain the substance (e.g., visiting multiple doctors or driving long distances), use the substance (e.g. chain-smoking), or recover from its effects.

- Important social, occupational or recreational activities are given up or reduced because of substance use.

- The substance use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance (e.g., current cocaine use despite recognition of cocaine-induced depression, or continued drinking despite recognition that an ulcer was made worse by alcohol consumption).

Patients presenting with a clear history of opioid addiction but who are not currently physiologically dependent (such as patients recently released from a correctional facility or in-patient hospital or treatment center) may be at high risk for relapse and can be started on buprenorphine maintenance. However, in the absence of current physical dependence the prescribing physician must clearly document potential benefits to the person’s health and well-being that outweigh the potential disadvantages of buprenorphine treatment.

1. The patient must be able to give informed consent for buprenorphine treatment.
2. The patient must be able to adhere to the treatment plan. Treatment centers should carefully consider a patient’s ability to attend counseling and medication dispensing sessions based on their work schedule, transportation, child care or other needs before accepting patients for treatment. As much as possible, treatment centers should be flexible in accommodating patients’ needs.

RELATIVE CONTRAINDICATIONS

There are several medical conditions, as well as concurrent abuse of other drugs that may be relative contraindications to buprenorphine treatment.

- **Concomitant Acute Psychiatric Conditions** - Buprenorphine treatment should not be initiated in anyone with acute psychosis or other severe presenting psychiatric conditions which severely compromise the patient’s ability to give informed consent for treatment.

- **Significant Current Pain** – The sublingual formulations of buprenorphine are not FDA-approved for the treatment of pain in the United States. Therefore, the BBI does not permit prescribing buprenorphine solely for treatment of pain. Patients with significant pain and opioid addiction must be evaluated on an individual basis. Some of these patients can achieve adequate pain control with buprenorphine (often dosed 2-4 times per day) along with other non-opioid medications such as NSAIDs. For patients with significant acute pain, it may be appropriate to transition them from opioids to buprenorphine as the acute pain improves.

PRECAUTIONS

Particular caution should be exercised when assessing the appropriateness of buprenorphine treatment for anyone with any of the following clinical conditions.

- **High-Risk Poly Substance Use** - The BBI recommends patients with poly drug dependencies be evaluated carefully to determine the other substances that are being used. Some patients who use other substances (see below) may not be appropriate for the BBI and/or may need an alternate level of care. Patients who occasionally drink alcohol can be started on buprenorphine.

- **Dependence on Benzodiazepines** - Buprenorphine has demonstrated synergistic sedative effects when used in combination with benzodiazepines. Deaths have been reported when buprenorphine has been used in combination with high doses of benzodiazepines. Therefore, the BBI does not generally advise programs to prescribe buprenorphine to people with significant current physical dependence on benzodiazepines. Patients presenting with a history or current use of benzodiazepines should be carefully evaluated to determine their pattern of use and potential for withdrawal. If the patient is currently physically dependent on benzodiazepines, they should be referred for detoxification and then re-evaluated as to whether they are appropriate for buprenorphine treatment. Patients with occasional illicit use of benzodiazepines or those taking prescribed benzodiazepines...
appropriately may be started on buprenorphine.

- **Alcohol Use**- Although there are no reports of death attributed solely to the combination of buprenorphine and alcohol, the potential for synergistic CNS and respiratory effects does exist. Patients with significant history of alcohol use should be evaluated carefully and referred for detoxification if necessary.

- **Severe Hepatic Impairment**- The BBI advises physicians to use their clinical judgment when prescribing buprenorphine to patients with significant hepatic impairment because buprenorphine is metabolized by the liver. The patient should be monitored closely (with liver function tests initially and every 3-6 months) if buprenorphine is prescribed. Simply being positive for hepatitis B or C does **not** indicate severe hepatic impairment.

- **Pregnancy**- Buprenorphine is classified as a Pregnancy Category C medication by the FDA (like methadone). Until recently, the recommended treatment for opioid dependent pregnant women was methadone maintenance. While methadone is still used, recent data from the Mother Study indicate that buprenorphine is safe and effective in pregnancy. The BBI recommends that any pregnant woman seeking treatment through the BBI receive a comprehensive assessment for appropriateness of buprenorphine vs. methadone. A BBI physician (Dr. Welsh or Dr. Olsen) can be contacted to discuss. Subutex should be used in these cases.

- **Breast Feeding**- There is limited literature available regarding the safety of buprenorphine by lactating women. Because of buprenorphine’s poor oral bioavailability in infants, low levels found in breast milk, and low levels found in the serum and urine of breastfed infants, its use is acceptable in nursing mothers.

- **Other Medical Conditions**- Buprenorphine is an opioid and caution should be used in the following situations: (1) Recent head injury with the possibility of increased intracranial pressure and (2) Severely compromised respiratory function.

- **Non-tolerant Patients**- Patients who are not fully tolerant to opioids but who are at high risk of relapse and wish to begin treatment should be started at the lowest possible dose (See Chapter 3)

- **Transfer from Methadone Maintenance**- Buprenorphine may precipitate withdrawal in patients transferring from methadone. This is most likely to occur in patients on higher doses of methadone. (See Chapter 3)

**ASSESSMENT OF PATIENT FOR BUPRENOPTINE TREATMENT**

Once a patient has been determined to be appropriate for buprenorphine treatment, a comprehensive assessment must be conducted to obtain an understanding of an individual patient for purposes of planning treatment. The assessment process can take place over a period of several sessions so that the COMAR regulation of assessment completion within one week of admission is met. (However, induction to buprenorphine should optimally occur no more than 48 hours after the first face to face contact with the
patient and preferably on the same day). It is recommended that intake is scheduled in the morning to allow time so that patients can begin induction and be monitored for several hours before going home.

The assessment process should be used to establish a comprehensive evaluation of the patient’s needs for purposes of ongoing treatment planning, medication management, and determination of the patient’s stage of change relative to his/her motivation to engage in the treatment process. Centers may use a variety of instruments and techniques to conduct the various components of the assessment including but not limited to the Addiction Severity Index.

A level of care is determined in the assessment process based on guidelines from the American Society of Addiction Medicine Patient Placement Criteria and the information obtained during the patient interview. Patients in the BBI should be placed in a level of care that meets their individual needs and has the best chance for promoting retention in treatment. **Every attempt should be made to meet the specific needs of the patient.** This may require more one-to-one individual intervention, not just increased group therapy time.

BBI patients are not required to enter at the Intensive Outpatient (IOP) level of care. Patients who have specific individualized issues that may prevent them from attending an intensive outpatient program may be more successful in the Outpatient level of care and should be started in this level.

Upon completion of the comprehensive assessment (completed by the addiction counselor, nurse, and physician or physician extender, if applicable) the treatment center should be able to:

- Establish a diagnosis of opioid dependence according to the DSM-IV-TR.
- Determine appropriateness of buprenorphine treatment. The patient should meet all of the following:
  - Be interested in treatment for opioid addiction.
  - Have no contraindications to buprenorphine.
  - Be expected to be reasonably compliant with treatment.
  - Understand the risks and benefits of buprenorphine treatment.
- Make initial treatment recommendations.
- Formulate a specific, initial individualized treatment plan including psychosocial treatment (standard outpatient or intensive outpatient care).
- Ensure that there are no contraindications to the recommended treatments.

**Components of the Assessment**

The comprehensive assessment should consist of the following general components:

- **Medical History**
  - Past medical/surgical history, including past mental health treatment.
  - Sexual history (focused on risk factors for HIV, Hepatitis B & C, and other sexually transferred diseases).
  - Current and past medications.
  - Details of medication and other allergies
  - A detailed review of systems.

- **Substance Use and Treatment History**
Past and current drug and alcohol use (age of first use, substances used, change in effects over time, history of tolerance/overdose/withdrawal, attempts to quit, current problems with compulsivity or cravings).

- Treatment history (previous treatments for addiction, types of treatment tried, outcomes of treatment attempts, 12-step program involvement)

- Social History
  - Family and social relationships and structure (substance use disorders in the family, family medical and psychiatric history, quality of recovery environment, family/living environment, substance use by members of support network).
  - Past and current employment (past and current employers, employment successes and issues, skills, interests).
  - Financial support needs (income level, insurance status, housing status, other public benefits, ability to meet basic needs).
  - Educational background (highest level of education completed, current educational programs, educational interests).
  - Past and current legal involvement (previous or current charges for criminal activity, result of charges, status of legal involvement, involvement with parole or probation, past or current court ordered treatment, etc.).

- Pain History
  - Significant acute pain.
  - Significant chronic pain.
  - Past and current treatments

- Focused Physical Examination
  - Focused physical examination of all major body organs with special attention to findings suggestive of complications of substance use (such as track marks, abscesses, perforated nasal septum, cellulites, etc.) or current liver impairment (jaundice, palmar erythema, etc.).
  - Assessment of opioid withdrawal using the Clinical Opiate Withdrawal Scale (COWS). **Physicians or nurses should complete the COWS Form in Appendix 3 to assess the level of opioid withdrawal and to start the induction to buprenorphine process.**
  - Assessment of other drug intoxication or withdrawal syndromes such as alcohol (CIWA-Ar Clinical Institute Withdrawal Assessment for Alcohol Revised) and benzodiazepines (CIWA-B Clinical Institute Withdrawal Assessment for Benzodiazepines) should also be conducted.

- HIV Risk Assessment
  - Patients must document that they have completed education on HIV, STD, TB, hepatitis and other infectious disease education (provider based form).
  - All BBI patients should be offered an HIV oral swab test or blood test.

- Mental Health Screening
  - Providers will use the BSAS Mental Health Symptom Screening Form (see Appendix 4) as the mental health screening instrument. This tool can be used during the assessment to determine a baseline and to identify emergency mental
health needs; however, it is recommended that it be repeated after 1-2 weeks of treatment to be most accurate as a screen for possible independent mental health issues.

- Patients who score positive on the check list, after review by the clinical supervisor should be recommended for referral for a mental health assessment within 30 days following the mental health screening if possible or once the patient has insurance.
- Patients who are diagnosed with a mental health problem as a result of the assessment should be recommended for a referral to mental health treatment within 14 days following assessment.
- The treatment center counseling staff is responsible for referrals for mental health assessments and tracking patient results to assure that patients who need mental health services are appropriately referred. HCAM treatment advocates may be available to assist in the referral and tracking process.

LABORATORY TESTING

When a patient requests treatment with buprenorphine, a toxicology screen can help establish whether a patient is using opioids. However, a negative screen does not mean that patient is not using an opioid. It may mean that the patient has not used opioids within a period of time sufficient to produce a positive screening or that he/she has used an opioid that is not detected by the test. Certain medications that patients are taking may also cause false positive results and therefore it is important to obtain a thorough history of the patient’s medication use as part of the medical history (see Appendix 5).

The following laboratory tests are required before induction:
- Urine Toxicology - During the intake, urine drug screening should be performed to confirm opioid use. Urine tests can also be used to screen for poly-drug use that might necessitate detoxification or another level of treatment.
- Pregnancy testing for female patients of childbearing age
- Liver function tests – copies of test results done within the prior 6 months will suffice.

The following laboratory tests are recommended but need not be completed before induction:
- HIV antibody testing: All patients in the BBI must be offered the opportunity for testing as part of their intake history and physical examination. All BBI treatment centers will obtain a federal CLIA waiver and a Maryland state public health laboratory waiver to be able to perform the Orasure HIV oral swab test. The BBI recommends that a designated staff member involved in completion of the history and physical examination or other components of the assessment process complete the Orasure test or a blood test at the time of the assessment unless arrangements for HIV testing are easily accessible to assure that patients receive testing. BBI treatment centers are required to have their nurses, physicians, physician extenders, and/or counselors become certified as pre and post-test counselors.
- HBV & HCV tests.
ORIENTATION AND INFORMED CONSENT

All patients entering buprenorphine treatment with the BBI must participate in an orientation to the treatment center that includes the following:

- Provision of the BBI Informed Consent to Treatment (see Appendix 6).
- Execution of a treatment agreement.
- Completion of an emergency contact sheet.
- Review of all expectations of treatment.
- Completion of consent form to allow providers to release patient information to HealthCare Access Maryland (HCAM) (see Appendix 7).

The participation of an informed patient in the clinical decision-making process is important in the treatment of opioid dependence. It is particularly important when incorporating buprenorphine into the treatment plan. During orientation the patient should be introduced to the treatment center, the counseling program and its expectations. There are specific rules and patient agreements that are part of buprenorphine treatment, which are signed by all patients during orientation. The orientation program can be completed in a group setting or by video.

The forms listed above will be reviewed and signed by the patient and treatment center staff during the orientation program. Opportunity for questions and discussion should be provided.

Patient must give written permission (in accordance with HIPAA and 42 CFR Part 2) for the provider to release confidential information to HealthCare Access Maryland, Inc. for the purpose of obtaining public health insurance benefits, transfer to continuing care physicians and to assist in obtaining other support services. Copies of the forms will be given to the patient and to HCAM. A third copy will remain in patient’s file at the treatment center.

Informed Consent

The BBI orientation will include an explanation of the expectations and requirements for being a patient receiving treatment through the BBI. Treatment center staff will utilize the BBI Informed Consent form (see Appendix 6) to explain these expectations and requirements. All patients in the BBI will be expected to sign the BBI Informed Consent Form and a copy will be placed in the patient’s record. Patients should be given an opportunity to read the form and have their questions answered. Individual treatment centers may have an additional consent form or treatment contract that they wish to use; however, the content should be consistent with the BBI Informed Consent.

Referral to HealthCare Access Maryland, Inc. (HCAM)

The role of the HCAM treatment advocate includes meeting with the patient and treatment center staff on a regular basis in order to assist the patient in obtaining health insurance as necessary, to link patients to other services in coordination with the counseling staff, to monitor the patient’s progress, and to facilitate the transfer to a continuing care provider. The HCAM treatment advocate will visit the treatment center on a weekly basis and may schedule appointments with patients as necessary. An assessment of each patient’s needs will be completed within the first two weeks after obtaining consent for HCAM services. Based on the assessment, the HCAM treatment advocate will assist the patient in obtaining health
insurance and work with the counseling staff to assist in linking the patient to other needed services. The HCAM treatment advocate will meet with the treatment center team or designated staff every 30 days once the patient has been in treatment for at least 60 days to determine the patient’s readiness for transfer to a continuing care provider and will work with the treatment center team and the patient to coordinate the transfer process. Once the patient transfers to a continuing care provider, the treatment advocate will continue to work with the patient to assure ongoing linkage to the continuing care provider and the treatment center for counseling (as necessary) for an additional six months.

The treatment advocate will assist the patient with the following:

- Completion of health insurance application forms and filing of forms with necessary agencies.
- Obtaining necessary documentation required for the insurance applications and other services.
- Choosing a Managed Care Organization (MCO) and a buprenorphine-certified physician.
- Understanding benefits of insurance program.
- Scheduling appointments and referral for transportation assistance, if necessary, to continuing care appointments.
- Transitioning from treatment center to continuing care provider.
- Monthly follow-up after transfer to confirm appointments are kept, prescriptions are filled, and psychosocial treatment is continued.
- Assistance with any ongoing health insurance or medical issues.
- Continuous support to assist with needed services to assure linkage to continuing care.
- Determination of need for prescription co-pay assistance.

Referring a Patient to HCAM:

All patients who enter one of the BSAS funded buprenorphine treatment centers and are identified for buprenorphine maintenance will be referred to HCAM. Treatment center staff will have patient sign the Release of Confidential Information (see Appendix 7) during the intake and assessment procedures. Treatment center staff will enter patient information into the BSAS Utilization Program (UP) system and fax the release form to the HCAM referral coordinator (410) 649-0528 within 24 hours of patient intake. It is BSAS policy that information is entered into UP by the treatment site the same day a patient is admitted into the treatment program. Referrals should not be handed to HCAM treatment advocates when they are at the treatment center. All releases must be faxed. Referrals should only be faxed once the patient information has been entered into the UP database.

The information necessary for entry into the UP system includes but is not limited to:

- Patient name.
- DOB.
- Social security number.
- Admission date – this is the date of the first face to face contact with the patient.
- Date of first buprenorphine dose.
- Check that the HCAM release form was signed.

The HCAM referral coordinator will process referrals daily, enter patient information into IRIS, pull MMIS screens, and give treatment advocates all information obtained. Treatment advocates will attempt to meet with the patient at the next scheduled site visit. Treatment advocates will not see patients who have not signed a release or patients whose release has not yet been processed through the HCAM referral.
coordinator. If the patient has not seen the treatment advocate by the third week of treatment, the counselor will make the visit with the treatment advocate a requirement for continuation on buprenorphine.

Measuring a Patient’s Stage of Change

The ability to understand a patient’s motivation to engage in treatment is an important aspect of the assessment process and the development of an individualized treatment plan that matches the patient’s willingness and/or commitment to change the addictive behaviors that are present. Prochaska and DiClemente have developed the “Stages of Change” model that addresses a person’s readiness for change across five stages. These five stages are as follows:

- Pre-contemplation: Person shows no evidence of intent to change the problem behavior and may be unaware that the behavior is a problem. The person may also be aware of the problem but be unwilling to change due to past failed attempts.

- Contemplation: Individuals are considering changing the behavior and might be considering specific personal implications of the problem and what the consequences of change might entail.

- Preparation: Individuals are ready to change in both attitude and behavior. These individuals intend to change soon and have incorporated their experiences of previous tries at change.

- Action: Behavior change has clearly begun. Individuals in this stage need skills to implement specific behavior change methods.

- Maintenance: Individuals sustain and strengthen changes they have made.

Several instruments to measure stage of change have been developed and the BBI suggests that clinicians use one of these instruments as part of the assessment process to identify a patient’s stage of change so that treatment planning can be appropriately individualized. The two methods of assessment for stage of change that are suggested are the following (see Appendix 8):

- University of Rhode Island Change Assessment Scale (URICA).

- Stages of Change Readiness and Treatment Eagerness Scale (SOCRATES).

It must be remembered that patients may be at different stages of change for various substances they use as well as other behaviors. For example, the patient may want to discontinue use of heroin but may not feel that marijuana or nicotine use is problematic. The patient’s readiness to change must be individually assessed for each substance or behavior. Behavior change is also often not a linear process so individuals may move back and forth between the different stages of changes over time. Center staff must be flexible in modifying their therapeutic approaches as their patients change.

It is also important to remember that many patients want to change various behaviors but do not feel that they will be successful. Time should be spent early in treatment trying to identify specific perceived barriers to change, both external (physical environment, finances, legal, etc.) and internal (lack of self-confidence, lack of knowledge, lack of skills, etc.).
TREATMENT PLAN

The treatment plan is based on information gathered during the assessment process. Formulated in collaboration with the patient, the treatment plan is designed to address mutually agreed upon treatment goals. The treatment plan organizes, integrates and prioritizes the information collected during the assessment and serves as the plan of action for pursuing the identified goals of treatment. It should prioritize short- and long-term goals, select the optimal interventions for the goals, identify barriers to achieving the goals, and provide for monitoring of progress over time.

Addiction occurs in the context of other problems that may either contribute to or result from substance use. While the initial treatment plan may focus on reducing substance use first, the master treatment plan should address all problem areas for which treatment is indicated. The treatment plan will be open-ended with a variable length of treatment with buprenorphine.

Treatment planning is a collaborative process in which a team of professionals and the patient develop a written document that:

- Is developed as a result of a comprehensive assessment and made to be easily modified over time.
- Reflects participation from all disciplines including, at a minimum, the primary counselor, the physician and nurse on site providing buprenorphine. It may also include mental health clinicians, vocational therapists, case managers, etc.
- Reflects the patient’s presenting needs and specifies the person’s strengths and limitations, (i.e., if a patient’s primary presenting need in addition to their addiction is housing, then this should be identified as a priority short-term goal).
- Identifies specific objectives that relate directly to treatment goals.
- Identifies the specific services and/or settings necessary for meeting the patient’s needs and goals. The identification of the level of care, such as “intensive outpatient services,” is not sufficient to delineate the specific services required.
- Specifies the frequency of treatment contacts (this should be individualized based on priority needs and patient barriers and should not be automatically assigned based solely on the ASAM Level of Care).
- Identifies criteria for determining whether goals have been achieved and for terminating various components of treatment.
- Designed to be easily modified over time.

The treatment plan will address the patient’s individualized needs and identify specific, individualized interventions. During the first several weeks of treatment, it is recommended that treatment plans focus on linking patients to concrete services that will promote engagement and retention such as housing, social services, health care, etc. if these are the client’s priority needs. This might be achieved through more frequent weekly individual counseling sessions or intensive case management during the first month of treatment. Simply adding more group sessions is generally not sufficient or appropriate.
Individualized problems/needs that are addressed should include but are not limited to the following:

- Alcohol and drug use
- Housing
- Legal
- Financial
- Vocational
- Educational
- Physical health
- Mental health
- Socialization
- Family

**Reviewing the Treatment Plan with Patient**

Once the treatment goals are written, the patient will be asked to review, discuss and agree to the recommendations in the prescribed treatment plan. The treatment plan should be signed by the patient, and the addiction counselor. Other team members should also sign the treatment plan as available and appropriate. In order to increase the likelihood of positive treatment outcomes, the treatment plan should be reviewed and discussed with significant others, and family members given the patient has given such consent. Each patient is given a copy of the treatment plan and a copy is placed in patient’s record. It is recommended that the treatment plan be updated and reviewed with the patient at 30, 60 and 90 days. The treatment plan should be updated more often if significant changes occur, per above.

**BBI TREATMENT AGREEMENT**

All patients in the BBI will sign a treatment agreement that outlines the responsibilities of the treatment center and the patient. Each BBI treatment program should develop a treatment agreement that is consistent with the individual program’s policies, procedures and expectations. The treatment agreement can be included as part of the program’s consent for treatment. A sample agreement is found in Appendix 9. All agreements in the BBI should include the following components:

- The treatment agreement will explain the patient’s responsibility for adherence with the various aspects of treatment, including attendance, and the consequences of non-adherence.

- The treatment agreement will include conditions under which a patient may be dismissed from the program and referred to another organization for care, such as a methadone or residential treatment facility.

- The treatment agreement will advise a patient that he/she must submit to random urine/saliva toxicology tests and that failure to submit may result in a modification of treatment.

- The treatment agreement will include a confidentiality statement that explains that experiences and discussions shared within the group is confidential and should not be shared with people outside of the group.
• It is recommended that the patient, physician, and counselor all sign the treatment agreement to indicate that all parties have reviewed and explained their responsibilities. The patient will be given a copy and a copy will be placed in patient’s file.

• The agreement will also address that the program strives to treat all patients with dignity and respect and expects that patient’s will conduct themselves in a way that also is respectful to program staff and other patients.
SECTION 3: INDUCTION TO BUPRENORPHINE TREATMENT

OVERVIEW

The induction phase is the medically monitored start-up of buprenorphine therapy. The purpose of the induction phase of treatment is to help patients begin the process of transitioning from the opioid of abuse to buprenorphine. The goals of induction are to safely suppress opioid withdrawal as rapidly as possible by determining the minimum dose of buprenorphine that permits patients to eliminate or significantly diminish illicit opioid use, experience no withdrawal symptoms, and minimize side effects.

All patients will be started on buprenorphine treatment in one of the participating BSAS treatment centers. An exception to this might be in the case of a patient who was started on buprenorphine in another program or healthcare facility and is already “induced.” The certified physician will use evidence-based protocols as a general guideline for determining the appropriate buprenorphine dose during induction. Each patient will be assigned to a counselor during the induction phase. Care is taken by prescribing physicians and nursing staff not to administer buprenorphine to patients who have recently used opioids.

Induction is initiated as observed therapy in the BBI treatment center, for all patients regardless of insurance status. Prescriptions should not be written for any BBI patient until the induction period is complete (generally after approximately 2 weeks). During induction, buprenorphine is administered when an opioid-addicted individual has abstained from using short-acting opioids for a minimum of 6-8 hours and is in the early stages of opioid withdrawal. If the patient is not in the early stages of withdrawal, the buprenorphine could precipitate acute withdrawal. During induction the patient is seen every day by the physician, physician extender or nurse.

Induction should take place within 48 hours after the first face-to-face contact with the patient but preferably on the same day.

BUPRENORPHINE CERTIFIED PHYSICIANS

The Baltimore Buprenorphine Initiative recruits physicians across Baltimore City to obtain a waiver to prescribe buprenorphine. DATA 2000 enables qualifying physicians to receive a waiver, which allows qualifying physicians to prescribe or dispense FDA approved Schedule III, IV and V “narcotic” medications for the treatment of opioid addiction.

To qualify for a DATA 2000 waiver, a physician must have completed at least 8 hours of approved training in buprenorphine treatment for opioid addiction (or have certain other qualifications defined in the legislation) and must attest that they can provide or refer patients to the necessary concurrent psychosocial services.

To receive a DATA 2000 waiver to practice opioid addiction treatment, a physician must notify the Center for Substance Abuse Treatment (CSAT) of their intent to begin prescribing or dispensing buprenorphine. Physicians who meet qualifications defined in DATA 2000 are issued a waiver by The Substance Abuse and Mental Health Services Administration (SAMHSA) and a special identification number by the Drug Enforcement Administration (DEA).

Baltimore Substance Abuse Systems, Inc. © 2013
Through an arrangement with the American Society of Addiction Medicine and Clinical Tools, Inc., the Baltimore City Health Department offers free on-line training to Baltimore City physicians so they can obtain a DATA 2000 waiver to prescribe buprenorphine. Information on how to apply for the on-line course is in Appendix 10.

ADMINISTRATION OF BUPRENORPHINE

Personnel and Documentation

There are a number of procedures that are recommended to be implemented at the treatment center in order to safely and effectively administer buprenorphine. All treatment centers should adhere to the following in the administration of buprenorphine:

- Only authorized staff members will administer buprenorphine:
  - Buprenorphine-certified physician.
  - Physician extender.
  - Registered nurse or licensed practical nurse.

- The identity of the patient should be checked.

- The clinician should assess for intoxication.

- The dose should be confirmed for the current day.

- The dose should be recorded in a log at the time of administration.

- The patient should sign or initial a log stating he/she has received the dose.

Scheduling Induction

- Induction should generally be scheduled Monday through Thursdays (if the program is closed Saturday and Sunday). This allows for several days of initial observation of dosing prior to the first non-observed dose.

- Induction should generally be scheduled for the morning. This may increase the likelihood that the patient does not use opioids prior to coming to the clinic. It also allows for the flexibility in dealing with other factors such as lateness, patient not in sufficient withdrawal, etc.

Sublingual Administration

Patients should be instructed on the proper procedure for taking buprenorphine. After each administration, nursing staff should visually inspect the patient’s mouth to ensure that the tablet/film has been fully dissolved. The same manner of administration is followed each time:

- Buprenorphine tablet or film is placed under the tongue. (See Figure 4).
- Patients should not eat, drink, chew gum, suck on candy or talk while the tablet/film is dissolving.
• Observation of patient by nursing staff is necessary until medication is sufficiently dissolved to eliminate potential for diversion (approximately 2-10 minutes).

Figure 4

Administration of Initial Buprenorphine Dose

Physicians participating in BBI treatment centers will use the BBI Suboxone Induction Protocol form (Appendix 11) as the orders and documentation for the induction of all patients seen in the BBI. The protocol addresses the following:

• The Induction Phase of buprenorphine treatment begins by assessing:
  ○ Last use of all opioids (including short- and long-acting).
  ○ Objective signs and subjective symptoms of withdrawal using the Clinical Opiate Withdrawal Scale (COWS).

• Patients should be in early stages of withdrawal when they receive their first dose of buprenorphine. Patients who are not in active withdrawal because they have not abstained from using opioids for a sufficient time period may experience opioid withdrawal as the buprenorphine displaces heroin from the mu receptors. Generally, induction should be delayed until opioid withdrawal is present. (Exceptions may include individuals who are currently abstinent from opioids but are at high risk for relapse and individuals who are using illicitly-obtained buprenorphine to manage withdrawal symptoms at the time of initial presentation to the clinic).

• Initial dosing of buprenorphine should be done based on clinical signs and symptoms of withdrawal as assessed by the COWS on the BBI Induction Protocol Form. Under-dosing during induction does not offer any clinical benefits. In fact, under-dosing may actually increase the risk of treatment failure because it fails to adequately control patient’s withdrawal symptoms and cravings.

• After the initial assessment using COWS, either a 4/1mg or 8/2mg dose is administered. The patient is observed by staff for 1-2 hours and is then reassessed for withdrawal symptoms using COWS.
• If opioid withdrawal symptoms are still present or subside and return within two hours, a dose of 4/1 mg should be administered, according to the COWS scores indicated on the BBI Induction Protocol Form.

• The total amount of Suboxone to be administered on day one should generally not exceed 12/3 mg.

• Additional medications may be used to treat specific symptoms, including:
  o Insomnia (Trazadone, amitriptyline).
  o Nausea (Compazine, Bentyl).
  o Muscle aches or spasms (ibuprofen, methocarbamol).
  o Diarrhea (Imodium, Kaopectate).

• **Patients not currently tolerant to opioids** -- Currently non-opioid tolerant individuals with a history of opioid dependence who are at high risk for relapse because of recent release from a controlled environment and who wish to receive treatment, should be started at no more than 2 mg daily. The dose should be increased slowly (by increments of no more than 2 mg every 5-7 days. This may vary, depending on the amount of time since the last use of an opioid.

• **Patients using Suboxone illicitly at the time of presentation to the clinic** -- These patients may not be in withdrawal as they are using Suboxone to help manage their withdrawal on their own. The physician should assess the amount and frequency with which the patient is using illicit Suboxone. Many patients using Suboxone in this way are only using whole tablets and have not tried intermediate doses of Suboxone such as 12mg. A rapid buprenorphine test should be performed to assess for the presence of buprenorphine in the urine. For these individuals, it is generally recommended to start at 8-12mg of Suboxone on the first day.

• **Patients transferring from Methadone Maintenance** -- Buprenorphine may precipitate withdrawal in patients transferring from methadone. This is most likely to occur in patients on higher doses of methadone. In coordination with the methadone program, the methadone dose should be gradually tapered to 30 mg per day and maintained at this dose (or lower) for 5-7 days. The patient should then abstain from any methadone for 48-72 hours prior to initiating buprenorphine. He/she should have clear objective signs of opioid withdrawal prior to receiving buprenorphine.

• The initial dose should be 2mg buprenorphine with additional 2-6mg dose given after an hour if withdrawal symptoms persist but were not worsened (“precipitated”) by the buprenorphine. Further induction should proceed as for other opioids (see following section). There is some evidence that the risk of inducing withdrawal may be further decreased by using buprenorphine alone (Subutex) for the initial dose.

**Induction Day Two and Forward**

**Day Two Re-Evaluation** -- The patient will return the second day for re-evaluation and continued titration of the buprenorphine dose. Clinicians will continue to use the BBI Induction Form.
• Patients should be asked about:
  o Symptoms of opioid withdrawal since the previous day, using COWS.
  o Side effects from buprenorphine.
  o Other opioid use since the previous day.

Patients who return on day two and who are not experiencing withdrawal symptoms and have not used other opioids are given the equivalent of the total dosage received on Day One over the next several days, per their COWS score and the BBI Induction Protocol.

• If side-effects occur, the buprenorphine dose is maintained or lowered until the side effects improve.
• Patients who return on Day Two and who are experiencing withdrawal symptoms, as assessed by the COWS, should receive a dose equivalent to the total dosage received on Day One plus 4/1 mg with a maximum initial dose of 16/4 mg, per the BBI Induction Protocol.
• The same procedure is used on Day Three for all patients.
• The patient should be maintained on the Day Three dose with a maximum of 16/4mg per day unless there are significant signs of opioid withdrawal at this dose.
• The patient should be reassessed with COWS at the beginning of Week 2. An additional 4/1mg dose can be given if signs of withdrawal or significant craving persist (maximum of 20/5mg per day during Week 2). This visit is not optional and should occur for all patients. COWS forms should be in the medical record and medication logs should reflect any changes in dose based on the BBI Induction Protocol.
• If the patient continues to use opioids, he/she may require increased psychosocial treatment to assist in dealing with environmental/social circumstances contributing to continued use. The patient should be seen by the counselor and the medical and counseling team should meet to discuss how to address continued opioid use by patients early in this phase of treatment.
• For patients taking more than 16/4 mg (2 tablets/film strips) of Suboxone per day, it is recommended that the patient not have more than 2 tablets/film strips under his/her tongue at a time.
SECTION 4: STABILIZATION AND MAINTENANCE PHASE OF BUPRENORPHINE TREATMENT

OVERVIEW

The objective of the stabilization and maintenance phase of buprenorphine treatment is to find the minimum dose necessary to facilitate discontinuation of opioid use, suppress opioid withdrawal, and suppress opioid cravings. This dose can be anywhere from 4/1 to 24/6 mg per day (rarely, 32/8 mg/day), depending on the individual. During the stabilization and maintenance phase of buprenorphine treatment, the patient's buprenorphine dose is "fine-tuned." In the context of the BBI, the length of this phase will vary depending on the needs of the patient but is generally over a course of 90-120 days until the time that the patient is able to be transferred to a continuing care provider. The prescribing physician should evaluate the patient at least monthly and adjust the dosage of buprenorphine as necessary.

DETERMINING OPTIMAL MAINTENANCE DOSE

After the induction phase, patients should be periodically evaluated by the nurse and physician at the treatment center to assess the patient’s response to the buprenorphine and adjust the dosage as necessary. Patient’s response to buprenorphine varies according to rates of absorption, levels of physical dependence, side-effects, and continued use of illicit opioids. As a result, the BBI nurse should see patients one to two times per week during the stabilization and maintenance phase to monitor dosage and response. It is recommended that the physician see patients a minimum of one time per month (or more frequently, as necessary) to review patient’s progress and any need for changes in the buprenorphine dosage.

Regular patient reviews (1-2 times per week) of withdrawal symptoms, side-effects and illicit opioid use will assist in establishing a maintenance dose. Doses are progressively adjusted in increments or decrements of 2/0.5 to 4/1 mg. Patients that initially continue to use opioids should always have a COWS completed for an objective assessment of withdrawal symptoms and need for a higher dose of buprenorphine. Nursing staff and physicians should collaborate on the determining if medication dose is a factor in the patient’s continued opioid use early in the stabilization phase. All dose adjustments after the end of week 2 should be discussed with the physician and require a physician order. For increased doses above 20/5mg per day, the patient should be seen and evaluated by the physician.

After each dose adjustment, 3 to 5 days should be allowed for steady-state blood levels to be achieved, before evaluating the need for further dose changes. For the vast majority of patients, withdrawal symptoms and opioid craving will be eliminated at a dose between 12/3 and 20/5 mg of Suboxone per day. Some patients may require 24/6 mg per day and, rarely, 28/7 or 32/8 mg per day (especially if the patient has concomitant pain). Although higher doses of Suboxone are very safe, the risk for diversion may be increased as patients take some of the pills and sell/give away the rest. Precautions should be taken to minimize this risk.
URINE TESTING

All BBI treatment centers will follow the BSAS Urinalysis Policy and Procedure for urine testing (see Appendix 12). In addition to the Panel A that is routinely collected, buprenorphine should be added to the panel for testing on a monthly basis. The urine testing should be done on a random/unannounced basis. Additional urine testing using in-center “dips” should be administered randomly and on a regular basis after patients receive medications for non-observed administration.

Programs should outline specific procedures for how urine toxicology results are initially received from the lab, discussed with the patient and documented in the chart. This may be done by a nurse, physician, counselor or other clinical staff. The urine toxicology results must be reviewed by all members of the team, including the physician, nurse and counselor, regardless of which team member receives the results.

UNOBSERVED MEDICATION

Unlike methadone, buprenorphine can be provided by prescription which is filled and kept by the patient. However patients in the Baltimore Buprenorphine Initiative receive their medication directly from the treatment center for the induction period at a minimum for all patients. This is done for several reasons. Given the potential for diversion of buprenorphine to illicit, “street” use, the initial dispensing of the buprenorphine is done by the treatment center, which allows the center staff to observe patient behavior and potential for misuse/diversion during the initial, induction phase. Also, because many of the patients do not initially have insurance, dispensing directly from the treatment center allows for the BBI to obtain buprenorphine at the most affordable cost.

In order to gradually prepare patients to receive and manage prescriptions for Suboxone, the number of unobserved doses should be gradually increased as the patient demonstrates progress in the program.

Unobserved doses must be dispensed by a nurse, physician extender or physician. The tablets must be placed in a child-proof medicine bottle that is labeled. Suboxone film already comes in a child-proof foil packet but is no longer child-proof once opened. The nurse should photocopy each of the packets that are being given to the patient for unobserved doses on a sheet of paper labeled or stamped with the patient’s identifying information. Patients will be required to sign and date the sheet with the photocopies. The sheet with the photocopies should be placed in the patient’s medical record and the medication log used by program’s nurse in the dispensing area. Patients will be provided their unobserved film packets in a child-proof medicine bottle that is labeled. Patients should be informed that they may be asked to bring back the used packets in the pill bottle on their next visit to the center and provide to the nurse. In those cases, the nurse should validate that packets returned are those that match the photocopies in the medication log and/or patient’s medical record.

The label on the container must contain the following (see sample in Appendix 13):

- Treatment center name, address, and telephone number.
- Physician’s name.
- Patient’s name.
- Medication name, strength, dose, and instructions for use.
- Number of tablets/film strips dispensed.
- Date dispensed.
• A warning label that states: “Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.”

The purpose of the labeling is to increase patient safety and decrease diversion. In addition, the information is also useful in emergency situations where someone other than the patient ingests the medication.

All patients should be instructed about proper storage of buprenorphine at home. The tablets/film should be kept in the container in which they were dispensed, tightly closed, and out of reach of children. The film strips should be kept in unopened packets until the actual time they are taken. If a half strip is to be used at a later time, it should be placed back in the foil strip and placed in a child-proof container. Tablets/film strips should be stored at room temperature and away from excessive heat and moisture. Because buprenorphine can be a target for people who abuse prescription medications or street drugs, it must be kept in a safe place to minimize chances of theft. If possible, non-substance abusing relatives should also be instructed on the above storage and safety issues.

• Initially unobserved medications are generally provided only for days that the clinic is closed (weekends and holidays).

• During the induction phase, unobserved doses are given for a maximum of 2-3 days without supervision.

• Additional unobserved doses can be given to patients who are adherent with treatment and are testing negative for illicit drugs on toxicology screens. It is recommended that patients who meet these criteria begin to receive additional unobserved doses after 2-4 weeks of treatment, if they are not receiving prescriptions.

• Unobserved doses are gradually increased as the patient shows ability to handle medication responsibly as demonstrated by:
  o Pill counts or film verifications.
  o Absence of “lost” or “stolen” medication.
  o Urine toxicology demonstrating the presence of buprenorphine.

• Once the patient has demonstrated the ability to responsibly handle unobserved medications and has obtained insurance, he or she can begin to receive prescriptions for Suboxone.

CALL-BACKS / PILL/FILM VERIFICATION

During these weekly visits adherence to dosing regimen should be monitored using urine toxicology and assessing for symptoms of drug use or withdrawal. The nurse should administer COWS if symptoms of withdrawal are present. Once the patient has a prescription for buprenorphine, random pill counts should be conducted to check adherence and minimize diversion, if patient continues to utilize the tablets. For patients that are using the film, random counts of unopened packages will also be performed. If diversion is suspected, the patient may be asked to return the opened packages of the film in order to validate against the copies of the packages in the patient’s medical record. Pill counts and film verification should occur at least twice during the first month that patients are given a prescription and progressively less frequently, but still on a regular random basis as patients progress in their treatment plan. Patients should be contacted and advised to bring the bottle with all of their buprenorphine tablets/unopened film.
packages to the program within 24-48 hours. The pill count or film verification should not be conducted on the day that a prescription is due to be renewed as this will not assist in detecting diversion of pills/film.

Patient’s progress in achieving non drug use treatment goals should be assessed periodically (see below).

**PRESCRIPTIONS**

For patients that are insured upon admission or become insured during the course of treatment, the program will need to provide a prescription for buprenorphine to the patient. BBI sites are not authorized to dispense buprenorphine to insured patients from their inventory after the two week induction period.

The physician will write the prescription for the patient’s medication indicating the tablet or film. (All patients should be receiving prescriptions for the film effective May 1, 2011). Patients that have been receiving prescriptions prior to May 1, 2011, should be changed to the film. The physician will give the prescription to the nurse to instruct the patient that they are required to bring the box of film packets back to the nurse within 72 hours following receipt of the prescription. Failure to return the box of film packets should be discussed with the treatment team.

The nurse will photocopy all of the unopened film packages in the box for each prescription and have the patient sign and date the sheet. The nurse will place the sheet with the photocopy in the patient’s medical record and medication log at the nurse’s dispensing station. The nurse will inform the patient that they may be requested to bring in the bottle with the un-opened packages on a random routine basis to verify against the photocopies in their medical record. This should be done more frequently when patients are first given prescriptions and then can be tapered to less frequent checks as patients demonstrate responsibility with the prescriptions.

It is recommended that physicians start with prescriptions for a one week supply of buprenorphine for a minimum of two weeks until the patient demonstrates a level of responsibility through the above procedures. Additional supplies of one week can be gradually prescribed until the patient is able to demonstrate the ability to safely and responsibly manage a one month supply.

**FEMALE PATIENTS WHO BECOME PREGNANT DURING TREATMENT**

If a woman is already on buprenorphine through the BBI and becomes pregnant during the course of treatment, it might be de-stabilizing to transfer the patient to a methadone program. The BBI physician-consultant (Dr. Welsh or Dr. Olsen) can be contacted to discuss the options in such cases. Available data indicate that buprenorphine is safe and effective in pregnancy and that babies of mother’s taking buprenorphine during pregnancy may have less severe withdrawal after delivery. A meeting between the patient and the program physician should then be held to discuss the risks and benefits of continuing on buprenorphine versus switching to a methadone maintenance program. Each case should be reviewed on an individual basis.
If the decision is made for the patient to remain on buprenorphine, the Suboxone should be switched to Subutex at the equivalent dose for the remainder of the pregnancy. The prenatal medical clinic should also be contacted to discuss the buprenorphine treatment and any potential impact on the pregnancy or delivery.

**PATIENTS WITH PAIN WHILE ON BUPRENORPHINE**

Management of acute pain in patients on buprenorphine can be difficult due to the high affinity of buprenorphine for the \( \mu \) opioid receptors, blocking other opioids from fully binding. Although there are few actual studies looking at pain management in these patients, clinical experience provides guidance on several possible strategies which can be employed. These will vary somewhat depending on whether the pain is anticipated (such as with a dental procedure, elective surgery) or unanticipated (such as with a major trauma, fracture, kidney stones).

**Anticipated Pain**

Patients should alert program staff as soon as they are aware that they have an upcoming elective procedure. Communication between the program physician and the surgeon/dentist/anesthesiologist is very important as many physicians are not familiar with buprenorphine and may not fully appreciate the difficulty it can cause in pain management. The possible use of nerve blocks and other regional interventions should be discussed. Pros and cons of various methods of pain management should be discussed with the patient and significant others who may be involved to help reduce the risk of misuse of opioids if they are to be prescribed. Methadone should be avoided as it may make it more difficult to switch back to buprenorphine following the procedure.

For most patients, temporary discontinuation of buprenorphine 24-36 hours prior to anticipated need for analgesia will allow for enough dissociation from the \( \mu \) opioid receptors to allow for adequate effect of full opioid agonists. Short-acting opioids should be used during and after the procedure, titrated to adequate analgesia. The prescribing physician should be informed that higher doses than usual may be required due to the patients opioid tolerance as a result of buprenorphine maintenance.

Opioids should be tapered as the acute pain resolves or can be managed with non opioid medications. The patient should be instructed not to resume buprenorphine until at least 8-12 hours following the last dose of opioid while the patient is experiencing mild to moderate opioid withdrawal.

Alternatively, especially for patients maintained on lower doses of buprenorphine, adequate pain relief may be achieved by a temporary increase in the buprenorphine dose as well as “split dosing” (every 6 or 8 hours) in addition to the use of NSAIDs.

**Unanticipated Pain**

Programs should be prepared to provide guidance to other physicians (Emergency Physicians, Surgeons, etc.) who may need to manage acute pain in buprenorphine-maintained patients. Patients can be provided information cards (available from Reckitt-Benckiser, the manufacturer of Suboxone) with contact information. As mentioned above, many physicians are not familiar with buprenorphine and its unique properties which can make pain management difficult.

In general, for severe, acute pain, it is advisable to discontinue buprenorphine and begin a high potency opioid (such as fentanyl) in an attempt to override the partial \( \mu \) receptor blockade of the buprenorphine.
This blockade can be significant, especially if the patient is maintained on a higher dose of buprenorphine or if the patient has recently taken his/her buprenorphine. Patients should be monitored closely as high doses of full agonist may be required and, as the buprenorphine’s partial blockade dissipates, the full agonist effect may lead to over sedation and respiratory depression. Additional interventions such as regional anesthesia should also be considered.

As with anticipated pain, opioids should be tapered as the acute pain resolves or can be managed with non-opioid medications. The patient should be instructed not to resume buprenorphine until at least 8-12 hours following the last dose of opioid while the patient is experiencing mild to moderate opioid withdrawal.

For less severe pain, adequate pain relief may be obtained by increasing the buprenorphine dose as well as “split dosing” (every 6 or 8 hours) in addition to the use of NSAIDs.

**ADDRESSING CONTINUING SUBSTANCE USE**

Regularly scheduled meetings of the team should be held to review and discuss the patient’s progress with the identified goals in the treatment plan. Team meetings, both formal and informal should be held when changes in the patient’s status occur that may require modifications to the treatment plan. For example, patients that have continued positive toxicology screens for opioid use, missed counseling or nurse visits, and/or concerns over diversion should prompt team communication and treatment planning revisions. These team meetings should be documented in the patient’s medical record to reflect the communication that occurred and the action that is recommended.

It is important that continued substance use be addressed with patients. During the 1st month of treatment, patients should meet at least weekly with a counselor to address specific triggers and other potential barriers to achieving abstinence. Throughout the course of treatment, positive urine toxicology results should be discussed with the patient in a timely manner. Substance use disclosed in a group therapy session should be communicated to the patient’s primary counselor in order that it can be further addressed outside of that therapy session.

Specific psychosocial stressors contributing to continued substance use should be addressed by the treatment program. Increasing the number of group therapy sessions may not be effective in addressing many of these issues. More individual attention to the specific issue is often necessary.

Because buprenorphine is a medication that specifically acts at the opioid receptors, it has little pharmacologic effect on other substance use. Because of this, it is important to address continued opioid use and continued use of other substances in different ways.

**Continued Opioid Use**

After the Induction Phase, the nurse, physician or counselor should specifically ask the patient questions to assess reasons for continued opioid-positive urine. This information should be shared with the physician and discussed with the team in order that appropriate adjustment to the medication can be made, if necessary.

*Sample questions for assessment of continued opioid use (See Appendix 14 for “Request for Increased Suboxone Dose “Worksheet”)*

*Baltimore Substance Abuse Systems, Inc. © 2013*
- “What were the circumstances when you used heroin (or opioid of choice)?”
  (e.g. “Did you use alone?”, “Were you spending time with someone who uses drugs?” etc.)
- “Are you continuing to crave heroin (or opioid of choice)?”
- “Did you feel the effects of the heroin (or opioid of choice) after the last time you used?”
- “Are you continuing to have withdrawal symptoms?”
  If so: “What specific symptoms?”
    “How long after your buprenorphine dose do you experience this?”
- “Are you experiencing significant pain?”
  If so: “Is this a new condition?”
    “Does the buprenorphine help relieve the pain?”
- “Are you taking any new medications?”

If the patient has a Suboxone prescription and takes the medication on his/her own, proper sublingual technique should be reviewed with the patient (SEE Section 3).

If a patient displays continuous opioid use (all or almost all urine toxicology positive for opioids) for more than 60-90 days despite adjustment to Suboxone dose, it may be necessary to consider another form of treatment.

- The program physician should meet with the patient to discuss the option of switching to a methadone program. If the decision is made to switch, BSAS can be contacted to help find a slot at BSAS-funded program. The staff at the BBI program should help facilitate the transfer to the methadone program.

- If severe, chronic pain is present, it may be necessary to consider referral to a pain program, if possible, through the patient’s insurance.

If the patient displays sporadic opioid use (approximately one urine toxicology positive for opioids per month), specific reasons for use should be explored and addressed (see above).

**Continued Use of Other Substances**
It is important that continued substance use be addressed with patients. As mentioned above, regularly scheduled meetings of the team should be held to review and discuss the patient’s progress with the identified goals in the treatment plan. During the 1st month of treatment, patients should meet at least weekly with a counselor to address specific triggers and other potential barriers to achieving abstinence. Throughout the course of treatment, positive urine toxicology results should be discussed with the patient in a timely manner. As with continued opioid use, use of other substances disclosed in a group therapy session should be communicated to the patient’s primary counselor in order that it can be further addressed outside of that therapy session.

Specific psychosocial stressors contributing to continued substance use should be addressed by the treatment program. Solely increasing the number of group therapy sessions may not be effective in addressing many of these issues. More individual attention to the specific issues is often necessary. Similarly, having the patient go to residential treatment may only be a temporary solution to the problem if underlying issues are not addressed.
Some use of other substances may be partially explained by an unidentified co-morbid psychiatric disorder (e.g. continued use of benzodiazepines despite adequate detoxification in a patient with an anxiety disorder). Referral for psychiatric evaluation should be facilitated if there is a possibility of this. Similarly, some use may be partially explained by complaints related to unidentified co-morbid medical conditions (e.g. use of marijuana for nausea or pain). Referral for further medical evaluation should be considered.

Use of “take-homes”/prescriptions should not necessarily be based on the absence of use of other substances. If there is concern that the patient might be selling some of the Suboxone in order to purchase other substances, smaller prescriptions and increased frequency of call-backs should be instituted.

In the case of alcohol and nicotine use, the patient should meet with the program physician for an evaluation of the appropriateness for pharmacologic treatments.

-Disulfiram (Antabuse)
Irreversibly inhibits the enzyme acetaldehyde dehydrogenase (the enzyme that catalyzes the oxidation of acetaldehyde to acetic acid) and causes an accumulation of acetaldehyde whenever alcohol is consumed. This accumulation can lead to an “acetaldehyde reaction” or “disulfiram-ethanol reaction” which is characterized by warmth and flushing of the skin, tachycardia, diaphoresis, dyspnea, blurred vision, nausea and vomiting. Most reactions last about 30 minutes and are self-limited. Occasionally, the reaction may result in cardiac problems, hypotension and death. These more serious disulfiram-ethanol reactions are generally associated with higher doses of disulfiram (over 500mg/day) combined with several ounces of alcohol but deaths have been reported with lower doses and small amounts of alcohol.

The knowledge of the potential for this extremely uncomfortable and potentially dangerous reaction can serve as a strong deterrent to the consumption of alcohol for some patients. Patients must be educated about the use of over-the-counter medications that may contain alcohol, foods that contain alcohol and some cosmetics and hygiene products that may contain alcohol. Its use is relatively contraindicated in pregnant women and patients with poor cardiovascular reserve.

Adherence is a big problem. Various methods can be used to improve adherence including having the patient “contract” with a significant other (who also receives counseling) to take the medication in their presence every day, directly observed therapy (such as is done at methadone programs), incentives (such as increased privileges, decreased probation, money), and enhanced counseling (with stimulus control training, role playing, communication skills). Some patients find it useful to use disulfiram only during particularly “high-risk” periods (such as visiting with family on holidays or going on an airplane).

It is important to note that disulfiram inhibits a number of other enzymes and can cause altered metabolism of various drugs including chlordiazepoxide, diazepam, desipramine, imipramine, phenytoin, and warfarin. Disulfiram also has a number of common side effects unrelated to the disulfiram-alcohol reaction. These include drowsiness, lethargy, hypertension, peripheral neuropathy and hepatotoxicity. Because of its effects on dopamine metabolism (through inhibition of dopamine beta-hydroxylase), it can cause or increase psychotic symptoms. Similarly, it may also cause or exacerbate depression.

Although disulfiram has been used in the treatment of alcoholism for many years, very few well-controlled studies have looked at its efficacy. In most of the controlled studies, the difference in alcohol consumption between medication and control groups has been minimal.
Because of the dose-related toxicity, the usual dose of disulfiram prescribed in the United States is 250-500mg/day. Some patients, however, do not seem to experience a disulfiram-ethanol reaction at doses lower than 1000mg/day. The use of a “challenge dose” of ethanol (to demonstrate to the patient the symptoms of the disulfiram-ethanol reaction) was used commonly in the past but is rarely used now.

-Calcium acetylhomotaurinate (Acomprosate; Campral)
Acamprosate was approved by the FDA in July, 2004 and is the first medication approved for the treatment of alcohol dependence in over a decade. It is a derivative of the amino acid homotaurine. It appears to have agonist effects on GABA receptors and complex, inhibitory effects at NMDA glutamate receptors but its exact mechanism of action is still unclear. It has been used extensively in many European countries and was recently approved in the U.S. as an enteric-coated tablet. It has been shown to positively affect length of total abstinence, time to relapse, number of non-drinking days, and retention in treatment. Positive effects have been observed in follow up 12 months after the cessation of active medication treatment. There have also been several studies in which acamprosate was no better than placebo on several measures of alcohol use.

Acamprosate is associated with few side-effects (primarily nausea, diarrhea, bloating and headache). There does not appear to be any serious organ toxicity. It is renally excreted and should be used cautiously in patients with renal insufficiency. Use in pregnancy has not been adequately studied. The recommended dose is 666mg three times per day. The recommendation to take medication three times per day may present a problem with compliance. There is no contraindication to combining acamprosate with naltrexone or disulfiram and the combination may increase efficacy. It is very important to remember that the patients in the studies of acamprosate were all receiving some sort of counseling in addition to the medication. Combining with naltrexone or disulfiram likely increases efficacy.

-Naltrexone (Revia)
(INCLUDED FOR COMPLETENESS; SHOULD NOT BE USED WITH PATIENTS WHO ARE TAKING BUPRENORPHINE)
A mu opiate receptor antagonist that is felt to effect alcohol consumption by inhibiting opiate modulation of the brain’s reward system in the nucleus accumbens. Most of the clinical evidence seems to support the theory that naltrexone helps reduce alcohol consumption by suppressing craving and by reducing the reinforcing properties of alcohol if it is consumed.

When combined with other psychosocial treatments, it has been shown to be effective in reducing the number of drinking days, reducing the chance of resuming “heavy drinking” (defined as consuming five or more drinks in a day), and increasing the rate of total abstinence. It appears to be more effective in those patients who reported stronger craving. Beneficial effects of naltrexone appear to diminish after cessation of the drug. A few studies have demonstrated no difference from placebo. As with the pharmacologic management of other chronic behavioral conditions, compliance with medication appears to be crucial in achieving efficacy and must be emphasized in the treatment. Directly observed therapy, “contracts”, incentives, and enhanced counseling may all help with this.

The usual dose of naltrexone used in the treatment of alcohol dependence is 50mg/day. At this dose, it is generally well tolerated by most patients. The most common side effects reported are nausea, headache, sedation and anxiety. Hepatotoxicity is an extremely rare complication and is generally associated with doses of 300mg per day. It should not be used in patients who have acute hepatitis or liver failure. Before
initiating treatment, it is essential to assess the patient for recent opioid use to avoid precipitating opioid withdrawal. It is also important to remind patients that the naltrexone will block the effects of opioids should they require them for the treatment of pain. Higher doses of opioid analgesics therefore may be needed to provide adequate analgesia for acute pain states. The effects typically dissipate within 72 hours of discontinuation. Because naltrexone is currently a pregnancy category C, it should not be prescribed to pregnant women.

-Naltrexone long-acting injection (Vivitrol)
(INCLUDED FOR COMPLETENESS; SHOULD NOT BE USED WITH PATIENTS WHO ARE TAKING BUPRENORPHINE)
An injectable “depot” formulation approved in 2006. Allows for dosing every 4 weeks and may lead to improved adherence. Typical dose is 380mg/month. Most common side effects are nausea, vomiting, headache, dizziness, fatigue and injection site reactions. Vivitrol may make pain management more difficult. Use cautiously in patients with history of opioid addiction; risk of inducing withdrawal or overdose if patient tries to “overcome” blockade.

URINE TOXICOLOGY NEGATIVE FOR BUPRENORPHINE
Monitoring for the presence of buprenorphine in a urine toxicology screen is an important part of the BBI Buprenorphine Diversion Plan. It is important that a test result negative for buprenorphine be addressed in a timely manner. Patients should meet with the prescribing physician to discuss the negative test result. It should be remembered that a negative toxicology result does not necessarily mean that a patient is diverting buprenorphine. There are various reasons that a patient may not be taking buprenorphine. He/she may have been hospitalized in a facility that does not provide Suboxone. He/she may have stopped Suboxone because of a painful condition. He/she may have had difficulty obtaining Suboxone prescription because of insurance/prior-authorization problems. The cut-off level for the buprenorphine “dip” test is also higher than that for the laboratory test so all initial negative screens should be confirmed by the lab.

Possible explanations for a negative toxicology screen:
- Patient is not taking Suboxone at all.
- Patient did not take the last dose of Suboxone prior to the test.
- Patient is on a lower dose of Suboxone that produces levels below the test cut-off level.
- Patient took his/her last Suboxone dose more than a day prior to the test.
- Patient is using a urine sample obtained from someone else who is not taking Suboxone.

Each incident of a negative toxicology result should be handled on an individual basis. Input from the entire treatment team should be considered in making a decision as to the action that should be taken. If there is some reasonable explanation (See Above) and the patient has otherwise been doing well in treatment, it may be advisable to continue the patient on Suboxone with more frequent call-back/pill/film counts. The duration of prescription can also be shortened with the use of multiple refills. (Prescriptions can be given for as little as a single pill/film).

If there has already been suspicion of possible diversion, discontinuation of Suboxone prescription should be considered. The program should help facilitate the patient seeking treatment in another program.
REMOVAL OF PATIENTS FROM BUPRENORPHINE

Patients who continue to use opioids consistently for 90 days despite an adequate dose of Suboxone may not be appropriate for buprenorphine treatment and alternative treatment options should be considered.

- If a patient is removed from medication for non-adherence, failure to keep medication appointment, and/or voluntary removal, this information should be entered into UP within 30 days indicating that the patient has been discharged.

- The HCAM treatment advocate is required to continue working with the patient if the patient has not secured insurance or enrolled with an MCO and chosen a PCP.

- If the patient is insured and connected to a medical home at the time of removal from buprenorphine, HCAM will close the case since transfer assistance will not be necessary.

PATIENT DISCHARGE FROM TREATMENT PROGRAM

- Treatment center staff are required to enter discharge information into UP within 30 days of the last face-to-face treatment contact.

- Treatment center staff will notify the HCAM treatment advocate verbally or by email if patients have been discharged so that the treatment advocate can stop outreach to the patient.

- HCAM will continue to track insurance applications even after someone is discharged. This will continue until a decision on the application is confirmed.

If more than 60 days pass from the time the patient was reportedly discharged and no information has been entered into UP, a reminder email will be sent by HCAM to the treatment center and the treatment center must enter the required information within 72 hours.
SECTION 5: ADDICTION COUNSELING

OVERVIEW

Pharmacotherapy alone is not generally believed to be sufficient treatment for opioid addiction for most individuals. To improve treatment outcomes, buprenorphine should generally be administered in conjunction with counseling (individual and/or group) and/or participation in mutual support groups (such as Narcotics Anonymous) as well as any necessary adjunctive social services. In counseling, patients address issues of motivation, build skills to resist drug use, replace drug-using activities with constructive and rewarding non-drug-using activities, and improve problem-solving abilities. A further goal of addiction counseling is to improve retention rates in The Baltimore Buprenorphine Initiative. Behavioral therapy may also facilitate interpersonal relationships and the individual’s ability to function in the family and community.

The BBI understands that no single treatment is appropriate or effective for everyone. During the induction phase of treatment each patient is assigned a counselor for addiction counseling based on his/her needs. Throughout the patient’s involvement in treatment with the BBI, counseling should be continued as necessary, based on individual patient needs.

THE ROLE OF COUNSELING IN BUPRENORPHINE MAINTENANCE TREATMENT

The counseling in the BBI should focus on:

- Providing support and guidance, especially to eliminate illicit substance use.
- Monitoring of other problematic behaviors (such as prostitution, unsafe sex, selling or assisting in the sale of drugs, etc.).
- Identifying problems that need extended services and referring patients for these services (such as physical health, mental health, housing, financial, legal, educational, vocational, etc.).
- Identifying and removing barriers to full treatment participation and retention.
- Providing motivational enhancement for positive changes in lifestyle.
- Education about relapse prevention strategies.
- Education about addiction and the effects of substance use.
- Identification of unexpected problems needing attention (such as sudden homelessness, sudden acquisition of money, etc.).
- Information about stress- and time-management techniques.
- Assistance in developing a healthy lifestyle involving exercise, good nutrition, smoking cessation, and avoidance of risky sexual practices.
- Assistance in locating and joining mutual support groups or peer support groups such as Narcotics Anonymous (NA).
- Assistance in joining socially constructive groups such as community organizations and faith-based groups.
- Continuing education on health issues (particularly HIV/AIDS and hepatitis).
- Assistance in complying with program rules and regulations.
Many patients and their families have a great deal of ambivalence and misunderstanding concerning maintenance treatments for opioid addiction. It is often useful to educate patients and family members about the rationale for the use of medications in the treatment of addiction. It is very important to clarify the distinction between “physical dependence” and “substance dependence” (according to DSM-IV) or “addiction.”

AMERICAN SOCIETY OF ADDICTION MEDICINE (ASAM) LEVELS OF CARE

The two levels of care that are used by the treatment centers participating in the BBI are Level II.1, Intensive Outpatient Treatment and Level I Outpatient Treatment.

Level II.1 Intensive Outpatient Treatment (IOP):

As required by the Code of Maryland Regulations (COMAR), IOP consists of at least 9 hours of counseling per week. The IOP level of care has several clinical and consumer advantages over residential treatment. The cost of IOP treatment is generally considerably less than the cost of inpatient treatment. As a result, IOP treatment often lasts for weeks to months rather than days or weeks. This allows patients more time to learn new behaviors, participate in self-help groups, and practice relapse prevention strategies. In an IOP program, patients can continue to function in already-established roles with minimal disruption to work and family life. In fact, work and family life may be better stabilized through the support and structure offered by IOP.

The intensity of the IOP level of care promotes close bonding among patients. Access to the world outside of the program increases opportunities to practice learned behaviors and new responses such as drug refusal skills, open communication, and stress reduction techniques. Patients who participate in treatment within a therapeutic setting while returning daily to their home environment can practice relapse prevention techniques in the milieu in which they live. These patients can also be assessed more accurately with regard to their problems and progress. There is a greater opportunity for treatment centers to strengthen patients’ psychosocial supports and to intensively intervene within their family systems.

Level I Outpatient Treatment (OP):

As required by COMAR, OP treatment is comprised of less than 9 hours of counseling per week. Stable patients may continue in less frequent counseling (such as once per month) indefinitely.

COUNSELING MODALITIES

Individual Counseling

The role of the counselor in addiction treatment is to provide support, education and identify discrepancies between the patient’s goals and behaviors. The counselor must establish a good rapport with the patient. The counselor wants to convey to the patient that he/she appreciates the struggle and the need for support in the recovery process. While the patient must take ownership of the recovery process, the counselor should be a trusted guide.
The content of individual therapy may primarily concern substance use directly, or it may focus on family issues or psychological/psychiatric problems. Cognitive behavioral therapy is goal oriented and focuses on immediate problems faced by patients entering treatment. It aims to help patients recognize situations in which they are most likely to use, avoid these situations when appropriate and cope more effectively with a range of problems related to substance abuse. Through its emphasis on short-term behavioral goals, individualized drug counseling helps the patient develop coping strategies and tools for abstaining from drug use and then maintaining abstinence.

When used in the context of a larger treatment program, individual counseling sessions are often used to fill gaps in the patient’s substance use and recovery education, explain the program, address behavior issues and expectations, review case management issues, re-establish and/or review goals of treatment, and examine long-term goals.

The BBI recommends that individual counseling sessions occur on a weekly (or more) basis during the first month of treatment as this is a particularly important period for engaging the patient and addressing various areas (housing, financial, etc.) important to the recovery process. Once the patient has stabilized, individual sessions can be decreased to bi-weekly or monthly.

In each session, the counselor should:

- Find out how the patient has been since last session.
- Inquire whether the patient has used drugs since last session.
  - If the patient has used opioids:
    - Assess for opioid craving and the potential need for an increased buprenorphine dose.
    - Analyze the relapse, and develop strategies to prevent future relapses.
  - If the patient has used other drugs:
    - Discuss why abstaining from all drugs is important, particularly when one is attempting to recover from chemical addiction.
    - Analyze the relapse and assist the patient in developing strategies to prevent further use.
- Inquire whether there are any urgent problems that need attention and, if so, work with the patient on tangible, practical, specific solutions.
- Provide feedback about whether recent urine tests have come back showing any opioid use and adherence with buprenorphine.
- Discuss the recovery topic that is most relevant to the patient's stage in recovery and his or her particular needs in treatment.

**Group Counseling**

Group counseling has some advantages over individual counseling and therapy. It can reduce patients' sense of isolation and help him/her cope with addiction and other life problems by providing feedback from peers, social skill training and practice, structure, discipline, and encouragement. Through peer interaction, patients contribute to one another's recovery. These groups should be led by trained individuals licensed as an addiction counselor, social worker or other health professional.
The following types of groups are commonly used:

- **Psycho-educational groups** in which patients learn factual information about various substances of abuse or other topics.
- **Skill development groups**, such as relapse prevention, stress management, and substance use cessation groups, which help patients learn skills to attain and maintain abstinence.
- **Cognitive behavioral groups**, in which patients learn to alter pervasive thoughts and actions.
- **Interpersonal-process groups**, which delve into developmental issues contributing to addiction or interfering with recovery.
- **Support groups**, which buoy members and provide a forum to share pragmatic information about maintaining abstinence and managing a day-to-day substance-free lifestyle.

Group membership can be linked to the phase of a patient's treatment. Some groups maintain the same membership but stay together for a short time. Others are longer term and have a rolling membership; that is, frequent membership changes, with new members entering when they are ready. Neither type of group needs a predetermined end point nor set timeframe.

Some patients are resistant to group counseling. It may be useful to meet with the patient to attempt to determine why he/she does not want to participate in this type of treatment. Offering smaller groups might ease their concerns while therapists explore the reasons for their resistance (e.g., fear of talking in groups or confidentiality concerns). In general, the treatment center should consider a group's patient mix. Some patients with co-occurring disorders do better in groups with members who have similar conditions. However, some patients with co-occurring disorders cannot participate effectively in groups, and may require individual counseling.

A patient's gender or sexual orientation can be important in choosing individual or group counseling. Some women are uncomfortable in mixed-gender groups and do better in women-only groups. Others feel embarrassed about personal subjects related to their addiction. Gay men, lesbians, and bisexual individuals might feel isolated in predominantly heterosexual groups. In such cases the treatment center should consider the best fit on an individual basis.

The optimal size of the group is also very important to consider. Purely educational groups can often be conducted with larger numbers of patients (20 or more) but therapy groups should generally be limited to 8-15 members so that all patients can participate and have their issues addressed.

**Family Counseling**

Addiction generally has profound effects on the members of the addicted individual’s family. Often, the family needs to be involved with treatment in order to assure optimal treatment outcomes. The involvement may include simple education about the nature of addiction as well as practical recommendations for family members as to how to handle behaviors of the addicted individual. Referral to groups such as Al-Anon and Nar-Anon can also be extremely helpful.
SECTION 6: TRANSITION TO CONTINUING CARE

OVERVIEW

Patients who have successfully participated in outpatient counseling and are stabilized on an appropriate dose of buprenorphine that promotes their abstinence from opioid use for an extended period of time will be considered candidates for transition from the outpatient treatment center to a continuing care provider for continued, long term buprenorphine treatment.

A main goal of the BBI is to transition stable patients from the outpatient treatment setting to a continuing care provider within approximately 90-120 days. Treatment center staff will work with patients and HCAM treatment advocates as well as with other necessary service providers to address the patient’s identified needs so that a transition to a continuing care provider can be achieved within this timeframe. Treatment center staff will plan for the transition of patients to a continuing care provider early in the treatment planning process and provide the necessary intensity of counseling and other referrals to services that may be required to assist patients in successfully participating in treatment and transitioning to continuing care. Patients who continue to use heroin consistently even after being in treatment for 90 days on a therapeutic dose of buprenorphine will be considered for referral to an alternate treatment setting. If patients are stable on buprenorphine and using other substances, they will be considered for transition to continuing care on a case by case basis. All patients who do not transition to continuing care within 120 days will receive a case review by the BSAS Clinical Oversight Team.

TRANSITION TO CONTINUING CARE PROVIDER

Criteria for Transition

Patients will be in the stabilization/maintenance phase of treatment and exhibit:

- No opioid withdrawal symptoms.
- Minimal side effects of buprenorphine.
- No uncontrolled cravings for illicit opioids.
- Adherence with independent buprenorphine prescriptions for at least two weeks.
- Adherence with counseling.
- Two consecutive weekly toxicology reports negative for opioids.
- Two consecutive weekly toxicology reports positive for buprenorphine.

In order for a patient to be considered for transition he/she must meet the above criteria and the following:

- Patient is willing to establish and maintain a relationship with a continuing care provider and has been counseled about making and keeping appointments.
- Patient has health insurance and has enrolled in a managed care organization.
- Patient has selected and been accepted by a continuing care provider who accepts his/her insurance.
• Patient understands the cost of medication, his/her responsibility in maintaining health insurance coverage, his/her responsibility for co-pays, and the re-authorization for prescriptions.

**Procedure for Transition**

The treatment center team or designated staff will meet every 30 days with the HCAM treatment advocate after the patient has been in treatment for 60 days to discuss the patient’s readiness for transition and a potential transition date. The meeting will be documented on a Transition Disposition Form (see Appendix 15) completed by the HCAM treatment advocate and filed in the HCAM patient file. The HCAM treatment advocate will communicate to the BSAS BBI Quality Improvement (QI) Director the names of patients that have not transitioned within 120 days of treatment initiation. The BSAS QI Oversight Team will review all cases that have not transitioned within 120 days and provide a recommendation to the treatment center staff. The HCAM treatment advocate and treatment center staff will continue to meet every 30 days on patients who do not transition after 120 days and send a report to the BSAS QI Oversight Team on the patient’s transition disposition.

The procedure for transitioning a patient from a treatment center to a continuing care provider is as follows:

- Based on the monthly meetings of treatment center staff and the HCAM treatment advocate, the HCAM treatment advocate will monitor the status of those patients identified for transition in a given month to identify a date for transition.

- Patients who are approved for transition by the treatment center staff will require a completed Transition Summary (see Appendix 16). The HCAM treatment advocate will send email notification to the authorized treatment center staff stating the names of patients requiring completed transition summaries to be completed by the next HCAM visit to the treatment center.

- The treatment center staff will complete the Transition Summary (see Appendix 16).

- The HCAM treatment advocate will meet with the patient to arrange an appointment with the patient’s continuing care provider and to verify that the selected continuing care provider is appropriate for their transition needs. The HCAM treatment advocate will also identify other patient needs, such as assistance with co-pays, transportation, etc.

- The HCAM treatment advocate will fax completed Transition Summary to the continuing care provider at least one to two days prior to the first appointment.

- If the patient does not meet the criteria for transition after the continuing care appointment has been made, the HCAM treatment advocate will contact the continuing care provider to cancel the appointment unless the patient has an existing medical condition warranting the visit. If the patient keeps the appointment, the HCAM treatment advocate will notify the provider of the patient’s status on buprenorphine.
• The HCAM treatment advocate will attempt to contact the patient prior to the appointment to remind the patient of the appointment and to help with any issues as necessary.

• The HCAM office assistant contacts continuing care provider’s office within 3-4 days after the first appointment date to determine if the appointment was kept and when next appointment is scheduled.

• The HCAM office assistant will maintain a “tickler file” of continuing care appointments for each patient who is transitioned.

• The HCAM treatment advocate will contact the patient prior to the next appointment and perform follow-up for up to six months after transition.

• HCAM treatment advocate will attempt to meet face to face with the patient at least one time during the three months after transition to help with any issues, as necessary.
SECTION 7: CONTINUING CARE

OVERVIEW

A second major goal of the BBI is to maintain patients in buprenorphine treatment for as long as possible in order to promote long term recovery from their addiction. Patients who have successfully accomplished the majority of treatment goals established in the BBI-participating treatment centers and are stabilized on a dose of buprenorphine will transition to a continuing care provider in the community to receive long term buprenorphine treatment and medical care. Patients who continue to require outpatient counseling will be eligible to continue to receive counseling at their referring treatment center for an additional three months or more following transition to a continuing care provider.

CONTINUING CARE PROVIDERS

In order to participate as a continuing care provider with the BBI, physicians must meet the following criteria:

- Have an active license to practice medicine in Maryland.
- Have a waiver to prescribe buprenorphine.
- Agree to accept BBI patients for continuing care and to work with BBI staff.
- Designate office staff member(s) to act as a liaison to HCAM for transition and ongoing patient tracking.
- Agree to provide maintenance therapy to BBI patients and not require patients to repeat induction or frequent visits that are not medically necessary for buprenorphine treatment.
- Coordinate care with counselors at treatment centers, as necessary.
- Provide services geographically accessible to BBI patients.
- Treat BBI patients with dignity and respect.
- Agree to accept the patient’s insurance.

The BBI will actively recruit continuing care providers of various specialties and from various geographic areas of the city to meet the individualized needs of patients who are being transitioned. HCAM and BSAS maintain a database of all Baltimore City physicians who have their waiver to prescribe buprenorphine and, who participate with the BBI. HCAM tracks the number of patients who are under a provider’s care for buprenorphine treatment. The following types of continuing care providers participate with the BBI:

- Private practice internal medicine and family practice physicians.
- Community health center affiliated internal medicine and family practice physicians.
- Private practice psychiatrists.
- Community health center affiliated psychiatrists.
- Community mental health center affiliated psychiatrists.
- Hospital outpatient clinic affiliated internal medicine and family practice physicians.
- Hospital outpatient mental health clinic affiliated psychiatrists.
- Internal medicine/infectious disease specialists in HIV specialty clinics.

Continuing care providers and their office staff who agree to accept patients for transition will receive an orientation to the BBI to understand the procedures for transition, to meet designated HCAM treatment advocates, and to establish any specific protocols that are necessary and unique to the continuing care site. BBI staff will continue to communicate with participating continuing care providers and be available on an ongoing basis to provide regular support and assistance.

Patients will work with HCAM treatment advocates to select a continuing care provider who is most appropriate for their individual medical care needs. For example, if a patient has a co-occurring psychiatric disorder and is receiving psychotropic medications, they may be more appropriate for transition to a psychiatrist. Patients with HIV may be best managed for long term maintenance by their HIV clinic physician.

**MEDICAL MANAGEMENT IN CONTINUING CARE**

Patients that are referred to a continuing care provider will receive a Transition Summary by fax from the HCAM treatment advocate prior to the patient’s first appointment. Recommended components of treatment include the following:

- Conduct a comprehensive history and physical examination as well as an assessment of appropriate buprenorphine dosage based on the patient’s clinical findings during the initial visit.
- See patient for a one week follow-up visit with subsequent reduction to monthly visits as patient remains stable and adherent.
- Encouragement of patient to continue in counseling and/or 12 step meetings.
- Conduct at least monthly urine toxicology tests for relevant illicit drug use and use of buprenorphine.
- Address other medical co-morbidities as necessary.

The physician should assess the patient for adherence to buprenorphine treatment and signs of potential instability:

- Patient misses physician visits frequently.
- Patient requests increase in dose or more frequent refills of buprenorphine.
- Drug screens are positive for opiates.
- Drug screens are negative for buprenorphine.
- Drug screens are positive for other substances.
If the patient appears to be unstable, the continuing care provider can do the following:

- Contact the HCAM treatment advocate to obtain information and assistance if patients have missed appointments.
- Contact a Buprenorphine Physician Mentor through the Physician Clinical Support System (PCSS) or contact the BBI Medical Consultant for guidance.
- Adjust dose and/or reduce length of prescription until re-stabilized.
- Refer patient back to the Outpatient addiction substance abuse treatment program for reassessment and intensified counseling.
- Consult with the treatment center program physician and/or staff.
- Consult the BSAS-BBI website community of practice page to ask a physician consult for guidance (See http://bbi.bsasinc.org/index.html)

Patients who remain non-adherent with their buprenorphine treatment may be eligible for readmission to their referring outpatient treatment program. The HCAM treatment advocate will work with the continuing care provider, patient, and the treatment center to coordinate the re-admission process.

**COORDINATION WITH THE TREATMENT CENTER**

Continued outpatient counseling after transition to continuing care is not required; however, it is strongly encouraged for all BBI patients. The recommendation for continued counseling will be communicated to the continuing care provider on the Transition Summary.

For those patients who continue to receive outpatient counseling after transition, the BBI recommends that the continuing care provider and counseling staff communicate on a regular basis regarding the progress of the patient. Continuing care providers can obtain a regular update on the patient’s attendance in counseling via the Treatment Center Patient Attendance Form (see Appendix 17). The HCAM treatment advocate can also help to facilitate and coordinate communication between the continuing care provider and the treatment center counseling staff as necessary.

**CO-PAYMENT ASSISTANCE**

The BBI has established a fund to assist patients to pay for the cost of co-payments for their monthly buprenorphine prescriptions if they meet eligibility criteria. The HCAM treatment advocate will determine eligibility and need for co-payment assistance prior to transition to the continuing care provider. If eligible, the HCAM treatment advocate will issue a voucher to the patient for a participating BBI pharmacy that is accessible to the patient. Patients will need to continue to meet monthly with their HCAM treatment advocate to obtain additional vouchers.
SECTION 8: DIVERSION OF BUPRENORPHINE

OVERVIEW

Although effective in treating opioid dependence, buprenorphine is a sublingual tablet or film that can be diverted by patients. Patients may try to avoid taking their buprenorphine as directed so they can take it at a later time, misuse it (inject or snort the medication,) or give/sell it to someone else. The BBI has developed a number of important measures to prevent patients from diverting buprenorphine.

DIVERSION PREVENTION

The BBI takes many steps to minimize diversion of buprenorphine:

- Patients are counseled and warned of consequences associated with misuse/diversion of buprenorphine:
  - Medical consequences.
  - Program consequences.
  - Legal consequences.

- Initial doses are taken under the supervision of clinical staff members and monitored for a minimum of five minutes to ensure that the tablet/film is dissolved.

- Early stage patients are not permitted to handle buprenorphine tablets/film prior to dosing.

- Explicit information, including patient’s name, is included on the container for unobserved doses. It is believed that this reduces the chances of diversion as the container can be traced back to the patient and may result in negative consequences from the treatment program.

- Step-wise increase of unobserved doses and prescription duration. Once a patient has reached the stabilization phase of treatment and has obtained health insurance, he/she can be given a prescription for buprenorphine to take to the pharmacy. The length of the prescription is increased as the patient demonstrates that he/she can appropriately handle the medication.

- Medication recall, pill counts and film verifications are used to identify a patient’s ability to properly handle medications. Having too few pills/film packets or too many pills/film packets are “red flags” for diversion and should be addressed with the patient immediately.

- Random urine toxicology is used to identify if a patient has buprenorphine in his/her system. No buprenorphine present is a “red flag” for diversion and should be addressed with the patient.

- Regular roundtable meetings that include representatives from the treatment programs as well as representatives from the Baltimore City Health Department, BSAS, HCAM and Maryland’s
Alcohol and Drug Abuse Administration. These meetings allow all involved parties to share information and discuss any problematic trends, including diversion, as they arise.

- Introductory briefings with continuing care physicians (primary care physicians and psychiatrists) and relevant clinical staff are provided by BBI personnel prior to transition of patients to that provider. Protocols, procedures, and clinical standards (including measures to minimize diversion) are discussed.

- Continued toxicology testing (including testing for buprenorphine) in the Maintenance Phase of treatment.
BALTIMORE BUPRENOPHINE INITIATIVE MODEL

The Baltimore Buprenorphone Initiative

Step 1: Uninsured patient starts buprenorphine in one of the following:
- Outpatient/Intensive Outpatient Treatment
- Physician Office
- Residential Treatment

Step 2: Patient receives assistance in obtaining health insurance

Baltimore HealthCare Access, Inc. Treatment advocates arrange insurance and transfer

Step 3: Insured, stable patient transfers to a continuing care provider

Baltimore City Health Department: Supports training for doctors in the medical system

Buprenorphine treatment in substance abuse treatment program now available for another uninsured patient

Baltimore Substance Abuse Systems, Inc. © 2011
### WORKSHEET FOR DSM-IV CRITERIA FOR DIAGNOSIS OF OPIATE DEPENDENCE

**Client’s Name:**

**Diagnostic Criteria**

(Dependence requires meeting 3 or more criteria)

<table>
<thead>
<tr>
<th>#</th>
<th>Criterion Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Tolerance, as defined by either of the following:</td>
</tr>
<tr>
<td></td>
<td>(a) a need for markedly increased amounts of the substance to achieve intoxication of desired effect</td>
</tr>
<tr>
<td></td>
<td>(b) markedly diminished effect with continued use of the same amount of the substance</td>
</tr>
<tr>
<td>2</td>
<td>Withdrawal, as manifested by either of the following:</td>
</tr>
<tr>
<td></td>
<td>(a) the characteristic withdrawal syndrome</td>
</tr>
<tr>
<td></td>
<td>(b) the same (or a closely related) substance is taken to relieve or avoid withdrawal symptoms</td>
</tr>
<tr>
<td>3</td>
<td>The substance is often taken in larger amounts or over a longer period of time than intended</td>
</tr>
<tr>
<td>4</td>
<td>There is a persistent desire or unsuccessful efforts to cut down or control substance use</td>
</tr>
<tr>
<td>5</td>
<td>A great deal of time is spent in activities necessary to obtain the substance, use the substance or recover from its effects</td>
</tr>
<tr>
<td>6</td>
<td>Important social, occupational, or recreational activities are given up or reduced because of substance use</td>
</tr>
<tr>
<td>7</td>
<td>The substance use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance</td>
</tr>
</tbody>
</table>

**Meets criteria**

**Yes** | **No**

**Notes/supporting information**

**Signature**

**Date**

# Clinical Opiate Withdrawal Scale (COWS)

For each item, circle the number that best describes the patient’s signs or symptom. Rate on just the apparent relationship to opiate withdrawal. Have the patient sit in a quiet, relatively stimulus-free room for 5-10 minutes prior to administering the scale.

<table>
<thead>
<tr>
<th>Client’s Name: ___________________________</th>
<th>Date of Birth: __________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date: ____________________</td>
<td>Time: __________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Resting Pulse Rate:</strong></th>
<th></th>
<th><strong>GI Upset:</strong> Over past ½ hour</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measured after patient is sitting or lying for 2-3 minutes</td>
<td></td>
<td>0 no GI symptoms</td>
</tr>
<tr>
<td>0 pulse rate 80 or below</td>
<td></td>
<td>1 stomach cramps</td>
</tr>
<tr>
<td>1 pulse rate 81-100</td>
<td></td>
<td>2 nausea or loose stool</td>
</tr>
<tr>
<td>2 pulse rate 101-120</td>
<td></td>
<td>3 vomiting or diarrhea</td>
</tr>
<tr>
<td>4 pulse rate greater than 120</td>
<td></td>
<td>5 Multiple episodes of diarrhea or vomiting</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Sweating:</strong> Over past ½ hour; not accounted for by room temperature or patient activity.</th>
<th><strong>Tremor</strong> Observation of outstretched hands</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 no report of chills or flushing</td>
<td>0 No tremor</td>
</tr>
<tr>
<td>1 subjective report of chills or flushing</td>
<td>1 tremor can be felt, but not observed</td>
</tr>
<tr>
<td>2 flushed or observable moistness on face</td>
<td>2 slight tremor observable</td>
</tr>
<tr>
<td>3 beads of sweat on brow or face</td>
<td>4 gross tremor or muscle twitching</td>
</tr>
<tr>
<td>4 sweat streaming off face</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Restlessness</strong> Observation during assessment</th>
<th><strong>Yawning</strong> Observation during assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 able to sit still</td>
<td>0 no yawning</td>
</tr>
<tr>
<td>1 reports difficulty sitting still, but is able to do so</td>
<td>1 yawning once or twice during assessment</td>
</tr>
<tr>
<td>3 frequent shifting or extraneous movements of legs/arms</td>
<td>2 yawning three or more times during assessment</td>
</tr>
<tr>
<td>5 Unable to sit still for more than a few seconds</td>
<td>4 yawning several times/minute</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Pupil size</strong> Observation during assessment</th>
<th><strong>Anxiety or Irritability</strong> Self report &amp; Observation during assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 pupils pinned or normal size for room light</td>
<td>0 none</td>
</tr>
<tr>
<td>1 pupils possibly larger than normal for room light</td>
<td>1 patient reports increasing irritability or anxiousness</td>
</tr>
<tr>
<td>2 pupils moderately dilated</td>
<td>2 patient obviously irritable anxious</td>
</tr>
<tr>
<td>5 pupils so dilated that only the rim of the iris is visible</td>
<td>4 patient so irritable or anxious that participation in the assessment is difficult</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Bone or Joint aches</strong> If patient was having pain previously, only the additional component attributed to opiates withdrawal is scored</th>
<th><strong>Gooseflesh skin</strong> Observation during assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 not present</td>
<td>0 skin is smooth</td>
</tr>
<tr>
<td>1 mild diffuse discomfort</td>
<td>3 piloerrection of skin can be felt or hairs standing up on arms</td>
</tr>
<tr>
<td>2 patient reports severe diffuse aching of joints/ muscles</td>
<td>5 prominent piloerrection</td>
</tr>
<tr>
<td>4 patient is rubbing joints or muscles and is unable to sit still because of discomfort</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Runny nose or tearing</strong> Not accounted for by cold symptoms or allergies</th>
<th><strong>Total Score</strong> (The total score is the sum of all 11 items)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 not present</td>
<td>Initials of person completing Assessment: __________</td>
</tr>
<tr>
<td>1 nasal stuffiness or unusually moist eyes</td>
<td></td>
</tr>
<tr>
<td>2 nose running or tearing</td>
<td></td>
</tr>
<tr>
<td>4 nose constantly running or tears streaming down cheeks</td>
<td></td>
</tr>
</tbody>
</table>

Withdrawal score severity: 5-12 = mild  13-24 = moderate  25-36 = moderately severe  >36 = severe
MENTAL HEALTH SYMPTOM SCREENING FORM (SSF) PROCEDURE

**General Information:** The Mental Health Symptom Screening Form (SSF) is generally used as a self-report form to screen for the possibility of mental illness. This means that patients are usually asked to complete this on their own but may also complete the form through an interview. Counselors need to determine if a client can complete the form him- or herself or needs to be interviewed. The grade level for the SSF is 4.7, so it is written simply and, we hope, in an easily understood fashion.

**Origin of SSF:** The SSF was developed by Dr. Marta Hopkinson, Baltimore Mental Health Systems (BMHS), for the work of the first Open Society Institute (OSI) grant on integrated services in Baltimore City. In this grant, three mental health and three addiction programs were identified. Together they developed models for providing integrated mental health and substance abuse treatment. The addiction programs used the SSF to identify mental health symptoms and determine the need for a referral for mental health services. The rate of identification of people with co-occurring disorders, using this instrument, increased significantly from an average of 11% to 30%. Several of the providers in the original grant continue to use this form and have found it to be clinically helpful and easy-to-administer.

**Purpose of SSF:** The SSF serves a two-fold purpose: (1) To screen for individuals who may have co-occurring disorders and who may need a mental health referral; (2) To identify a need for further development of integrated care services for individuals with co-occurring disorders and to use this information as an advocacy tool.

**Procedure:**

1. The SSF will be given to new patients at the time of intake. Programs can choose to have staff involved in administering the SSF or can give it to patients as a self-report. At this time, the score of the SSF will be considered a mental health baseline score.

2. Immediately after the SSF is completed by the client at the time of intake, the intake staff should score the instrument and note the score on the scoring sheet. If immediate intervention is needed based on the scores for question #5 and/or 18 or on other observations, the intake worker will immediately consult with his/her supervisor and intervene appropriately.

3. The completed SSF and scoring sheet should be placed in the client’s chart in the intake portion of the chart. (Supervisors should add the SSF to their chart audit form). A positive score (i.e., one leading to discussion with a supervisor) should be recorded as a “yes” on the SAMIS form (question #26) that asks about the presence of a mental health problem.

4. Staff who document a score that requires discussion with one’s supervisor regarding a possible mental health referral should do so within 48 hours and note the discussion and outcome in the client’s chart. If immediate intervention is needed, staff should take appropriate steps right away.

5. Referrals can be made to the outpatient programs listed on the BMHS outpatient mental health clinic list. Timing of the referral will be decided in consultation with the supervisor and noted in the chart.

6. Counselors should inform BSAS (410-637-1900) of any problems with referrals to mental health services.

7. Best practice would be for the SSF to be completed again approximately 2 weeks after the individual’s admission to the program as problematic mental health symptoms often improve seven to ten days after cessation of substance use.

(YMP-12/30/04; Revised 2/14/11-BC/BSAS)
Mental Health Symptom Screening Form

Many people in our programs have various symptoms and problems. For us to better serve you, please answer the questions on these pages. Place a check (✓) in the box to the right of each question to show how much this type of feeling has been bothering you for the last several days.

<table>
<thead>
<tr>
<th></th>
<th>0 Not at all</th>
<th>1 Rarely</th>
<th>2 Sometimes</th>
<th>3 A Lot</th>
</tr>
</thead>
<tbody>
<tr>
<td>D</td>
<td>1. Have you been feeling sad or blue?</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>2. Does your future seem lonely or hopeless?</td>
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<td></td>
<td>3. Do you feel worthless or not as good as other people?</td>
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<td></td>
<td>4. Have you lost interest in activities you used to enjoy?</td>
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<td></td>
<td>5. Do you feel life is not worth living or you’re better off dead?</td>
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<tr>
<td>A</td>
<td>6. Do you feel nervous, shaky, tense, or restless inside?</td>
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<tr>
<td></td>
<td>7. Do you feel afraid?</td>
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<td></td>
<td>8. Do you worry a lot?</td>
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<td></td>
<td>9. Do you have physical stress—tense muscles, headaches, trouble breathing, or upset stomach?</td>
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<td>P</td>
<td>10. Do you hear voices other people say they don’t hear?</td>
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<td></td>
<td>11. Do you believe others are against you or are watching you?</td>
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<td></td>
<td>12. Do you feel out of touch with other people or not close to them?</td>
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<td></td>
<td>13. Do you feel someone or something else controls you or your thoughts?</td>
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<td>H</td>
<td>15. Do you feel easily irritated or lose your temper?</td>
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<td></td>
<td>16. Do you feel like breaking or smashing things?</td>
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<td></td>
<td>17. Do you think about hurting other people?</td>
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<td></td>
<td>18. Do you hit or injure people?</td>
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<td>T</td>
<td>19. Do you ever have bad dreams or thoughts about troubling or harmful events that happened to you in the past?</td>
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<tr>
<td></td>
<td>20. Are you jumpy or easily startled by noises or movements?</td>
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<td></td>
<td>21. Do you have periods of time in your life that you can’t remember?</td>
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<td></td>
<td>22. Have you ever been through an event that involved a physical threat or harmed you?</td>
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<tr>
<td></td>
<td>23. Do you ever feel numb, apart, or without much feeling at all?</td>
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<tr>
<td>E</td>
<td>24. Do you or have you ever eaten a very large amount of food within 2 hours?</td>
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<tr>
<td></td>
<td>25. Have you worried about gaining weight or being fat even if you were underweight?</td>
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<tr>
<td>M</td>
<td>26. Do you have intense mood ups-and-downs?</td>
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<td></td>
<td>27. Do your thoughts seem to race, or do you feel too active?</td>
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<td></td>
<td>28. Do you ever go without sleep, sometimes even for a few days?</td>
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<tr>
<td></td>
<td>29. Do you do things without thinking about what will happen?</td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
## Symptom Screening Form
### Scoring Sheet

<table>
<thead>
<tr>
<th>Client Name</th>
<th>Client ID #</th>
<th>Date of 1st screening</th>
<th>Date of 2nd screening</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Section</th>
<th>1st score</th>
<th>2nd score</th>
<th>Instruction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Question 5 score</td>
<td>________</td>
<td>_______</td>
<td><em><strong>If 1 or more, do suicide assessment and emergency psychiatric evaluation.</strong></em></td>
</tr>
<tr>
<td>Question 18 score</td>
<td>________</td>
<td>_______</td>
<td>*** If 1 or more, refer to psychiatrist.***</td>
</tr>
</tbody>
</table>

For the scores below, if the score is as indicated or higher in one of the items, discuss with supervisor and consider mental health referral.

- **Depression section**: ________ ________
  - If 6 or more, discuss…
- **Anxiety section**: ________ ________
  - If 6 or more, discuss…
- **Psychotic section**: ________ ________
  - If 4 or more, discuss…
- **Hostility section**: ________ ________
  - If 3 or more, discuss…
- **Trauma section**: ________ ________
  - If 3 or more, discuss…
- **Eating disorders section**: ________ ________
  - If 3 or more, discuss…
- **Manic section**: ________ ________
  - If 5 or more, discuss…

(YMP – 12/04; Revised 2/14/11 BC)
Baltimore Substance Abuse Systems

*Mental Health Referral and Treatment Form*

Patient Name: _________________________ SAMIS Patient ID #: #________________

Date: _________________________________

(Circle appropriate response):

1. Referred off-site for mental health treatment; treatment received.
2. Referred off-site for mental health treatment, treatment NOT received.
3. Referred on-site for mental health treatment, treatment received.
4. Referred on-site for mental health treatment, treatment not received.
5. No referral made
6. Already in treatment—no referral needed

(YMP – 12/04; Revised 2/14/11)
MEDICATIONS THAT MAY CAUSE A FALSE POSITIVE URINE TOXICOLOGY RESULT

A “false-positive” result can occur on a drug screen for various reasons. It may be due to a technical or clerical error. It also may be due to cross-reaction of other substances with the testing assay. This primarily occurs with immunoassay tests (such as EMIT) that are used in some clinics for quick results or by some drug-testing labs. Usually, confirmation with GC/MS (gas chromatography/mass spectroscopy) will confirm the presence or absence of the substance being tested for. If there is a question, it is best to contact the lab or check with the manufacturer of the assay. Below is a list of some medications that can cross-react with drug screens. Some of these cross-reactions are not common but may be seen with a specific drug assay.

ALCOHOL (ETHANOL)
Ethanol-containing hand sanitizers (Purell®, Avagard D®, Nexcare®, Germ-X®)
*Isopropyl alcohol (rubbing alcohol)

AMPHETAMINE
Amantadine (Symmetrel®)
Bupropion (Wellbutrin®, Zyban®)
Chlorpromazine (Thorazine®)
Desipramine (Norpramin®)
Dopamine (Intropin®)
Ephedrine (Vasopress®, Metabolife 356®, etc)
Indomethacin (Indocin®)
Methylphenidate (Ritalin®)
Phenmetrazine (Preludin®)
Phentermine (Pro-Fast®, Adipex®, Ionamin®)
Phenylephrine (in Robitussin CF®, Dristan®, DayQuil®, Sufadef PE®, Neo-Synephrine®)
Phenypropanolamine (Acutrim®, Dexatrim®)
Promethazine (Phenergan®)
Pseudoephedrine (Sufadef®, Triaminic®)
Ranitidine (Zantac®)
Selegilene (Deprenyl®, Elderyl®, Emsam®)
Thioridazine (Mellaril®)
Trimethobenzamide (Tigan®)
Trimepramine (Surmontil®)
Trazadone (Desyrel®)
Tyramine

BENZODIAZEPINES
Diphenhydramine (Benadryl®)
Oxaproxin (Daypro®)
Sertraline (Zoloft®)
Zolpidem (Ambien®)

COCAINE
Coca leaf tea*
Topical anesthetics containing cocaine*

MARIJUANA
Ibuprofen (Motrin®, Advil®, Excedin IB®)
Dronabinol (Marinol®)*
Efavirenz (Sustiva®)
Hemp-containing foods
Naproxyn (Aleve®, Naprosyn®, Anaprox®)

METHADONE
Bupropion (Wellbutrin®, Zyban®)
Diphenhydramine (Benadryl®)
Venlafaxine (Effexor®)

OPIATES
Diphenoxylate (in Lomotil®)
Hordenin (in some barley beers)
Levofloxacin (Levaquin®)
Ofloxacin (Floxin®)
Popp seed*
Quinine
Rifampin (Rifadin®)

PHENCYCLIDINE (PCP)
Desmethylvenlafaxine (Pristiq®)
Dextromethorphan (Robitussin-DM®, Coricidin Cough & Cold®)
Diphenhydramine (Benadryl®)
Doxylamine (in Unisom® & NyQuil®)
Ibuprofen (Motrin®, Advil®, Excedin IB®)
Imipramine (Tofranil®, Deprenil®)
Ketamine (Ketalar®, Ketaset®, Ketanest®)
Meperidine (Demerol®)
Mesoridazine (Serentil®)
Thioridazine (Mellaril®)
Tramadol (Ultram®)
Venlafaxine (Effexor®)

* Is actually a “true positive” as the tested-for substance is present
Appendix 6

AGREEMENT FOR TREATMENT WITH SUBOXONE® THROUGH THE BALTIMORE BUPRENORPHINE INITIATIVE (BBI)

Name of patient: ____________________________________________ DOB:______________

ABOUT BUPRENORPHINE
Suboxone® (a tablet or film containing buprenorphine and naloxone) is an FDA approved medication for treatment of people with heroin or other opioid addiction. Buprenorphine can be used for detoxification or for maintenance therapy. Maintenance therapy can continue as long as medically necessary. There are other treatments for opiate addiction, including methadone, naltrexone, and some treatments without medications that include counseling, groups and meetings.

If you are dependent on opiates – any opiates such as heroin, methadone, codeine, Percocet, Lortab, Oxycontin, Tramadol etc., - you should be in as much withdrawal as possible when you take the first dose of buprenorphine. If you are not in withdrawal, buprenorphine can cause severe opiate withdrawal. For that reason, you should take the first dose in the clinic and remain in the clinic for at least 2 hours. We recommend that you arrange not to drive after your first dose, because some patients get drowsy until the correct dose is determined.

Combining buprenorphine with alcohol or other sedating medications is dangerous. The combination of buprenorphine with benzodiazepines (such as Valium®, Librium®, Ativan®, Xanax®, Klonopin®, etc.) has resulted in deaths.

Buprenorphine itself is an opioid, but it is not as strong an opioid as heroin or morphine. Buprenorphine treatment can result in physical dependence similar to other opiates. Buprenorphine withdrawal is generally less intense than with heroin or methadone. If buprenorphine is suddenly discontinued, some patients have no withdrawal symptoms; others have symptoms such as muscle aches, stomach cramps, or diarrhea lasting several days. To minimize the possibility of opiate withdrawal, buprenorphine should be discontinued gradually, usually over several weeks or more.

Buprenorphine tablets/film must be held under the tongue until they dissolve completely. You will be given your first dose at the clinic, and you will have to wait as it dissolves, and for two hours after it dissolves, to see how you react. It is important not to talk, eat, drink, chew gum or suck on candy until the tablet/film dissolves. This can take up to ten minutes. Buprenorphine is then absorbed over the next 30 to 60 minutes from the tissue under the tongue. Buprenorphine will not be absorbed from the stomach if it is swallowed. If you swallow the tablet/film, you will not have the important benefits of the medication, and it may not relieve your withdrawal.
CONSENT TO TREATMENT

By signing below, I agree to the following:

1. Buprenorphine treatment for opiate dependence is most effective when combined with drug abuse counseling, 12-step recovery work, and/or a recovery support group. During my treatment with buprenorphine, I agree to attend counseling and to work on a program of recovery.

2. I understand that buprenorphine itself is an opiate (or “narcotic”) and can produce “physical dependence,” meaning that stopping it suddenly is likely to cause physical withdrawal symptoms similar to stopping heroin or opiate pain medicine (but generally less severe).

3. I understand that on the day I start buprenorphine, I should come to the office already in opiate withdrawal. I will not use any opiate (heroin, methadone, codeine or other opiate containing medications) after 6:00 p.m. the evening before I am to begin induction. If I do not have observable signs of opiate withdrawal, induction onto buprenorphine may be delayed a day or more.

4. I understand that take home doses and frequency of visits will be determined by how well I am doing.

5. I agree to take buprenorphine as prescribed at the dosage determined by my physicians, and not to allow anyone else to take medication prescribed for me.

6. I understand that I must have a means to store take-home supplies or prescriptions of buprenorphine safely, where it cannot be taken accidentally by children or pets, or stolen by unauthorized users. I agree that if my buprenorphine pills or film are swallowed by anyone besides me, I will call 911 or Poison Control at 1-800-222-1222 immediately.

7. I agree that, if my doctor recommends that my home supply of buprenorphine should be kept in the care of a responsible member of my family or another third party, I will abide by such recommendations.

8. While on buprenorphine or otherwise in treatment for addiction I agree not to use any alcohol, any benzodiazepine medicine, sedatives, any illegal substances, or take any opiate medication without prior permission from my doctor (the doctor who prescribes my buprenorphine). If I have been taking regular long-term doses of benzodiazepines and are showing signs of addiction, a plan will be developed to slowly decrease these medicines with the goal of eventually discontinuing them, in a way that avoids any significant benzodiazepine withdrawal symptoms. If any opiate medicines may be needed, I agree to discuss this with my substance abuse doctor in advance, before accepting or filling any such prescription. If I take or am given any such medicines in an emergency (such as for acute pain or surgery) I will report this to the substance abuse doctor within 24 hours and bring the medication bottle with any remaining medication promptly to the treatment program.

9. I agree not to take other medications with buprenorphine without prior permission from my doctor. I understand that overdose deaths have occurred when patients have taken other medications (particularly medications like Librium®, Valium® or other benzodiazepines) with buprenorphine.

10. I understand that if I continue to consistently use opioids despite buprenorphine treatment, it will be taken as an indication that buprenorphine treatment has not been successful, and I will be tapered off of buprenorphine and/or transferred to another form of treatment.

11. I understand that a relapse or slip can cause a fatal overdose of heroin (or other opiate) which is more common during early recovery. This is because it takes only five days of abstinence to lose tolerance to heroin (the ability to tolerate a certain dose) or to methadone or pain pills. This means that if I use the same amount of heroin (or other opiate) that I used in the past, a fatal overdose can result.

12. I understand that the goal of buprenorphine treatment is abstinence from opioid use and that, if I continue to use opioids for more than 60-90 days while on buprenorphine, I may be detoxified and transferred to a more appropriate form of treatment.
13. I understand that the goal of treatment of opiate dependency is to learn to live without abuse of drugs. Buprenorphine treatment should continue as long as necessary to prevent relapse to opiate abuse/dependence.

14. I understand that there is no particular time limit for the duration of buprenorphine treatment; it should be continued as long as necessary to prevent relapse to opiate addiction. Decisions about if, when, or how rapidly to taper are made by the physician, based on input and discussion with the patient and the treatment team.

15. I consent to periodic, random testing for drugs of abuse in order to help detect early relapse and to document my progress in treatment. This may be done through a urine or saliva test.

16. I understand that, once I am receiving prescriptions for buprenorphine, it will be prescribed in quantities to last from visit to visit. The frequency of visits depends on how I am progressing.

17. I understand that routine and random pill counts are a practice of the BBI and I may be asked to bring in my medication. Lost prescriptions or buprenorphine tablets/films are serious issues and may result in discontinuation of buprenorphine therapy from this office. I have been informed that if I report that my supplies have been lost or stolen, that my doctors will not be requested or expected to provide me with make-up supplies. This means that if I run out of my medication supplies it could result in my experiencing symptoms of opiate withdrawal. Also, I agree that if there has been a theft of my medication, I will report this to the police and will bring a copy of the police report to my next clinic visit.

18. I understand that all staff has the responsibility to maintain my confidentiality. I agree not to share any information about other clients, including whether or not they attend this program, with anyone.

19. I understand that I have the right to be treated with dignity and respect, and the right to confidentially inform the treatment program of any instance where I feel I have not been treated with respect. I understand that the goal of treatment, including the goal of any changes in the frequency of visits or urine testing, is not for punishment but to help and support me in my goal of recovery. Women Only: I agree to an initial pregnancy test and, for the remainder of my treatment, to tell the physician, nurse or counselor if I become pregnant or even think that I may be pregnant. If I do become pregnant, the physician will discuss with me the options of switching to methadone or switching to another form of buprenorphine called Subutex® that does not contain naloxone.

It is acknowledged by my signature and date that I have read this agreement and understand these details about buprenorphine treatment. I wish to be treated with buprenorphine through the Baltimore Buprenorphine Initiative.

Signature of patient: ___________________________ Date: ______________

Signature of provider obtaining consent: _______________ Date: ______________
ACUERDO DE TRATAMIENTO CON BUPRENORFINA A TRAVÉS DE LA INICIATIVA DE BUPRENORFINA BALTIMORE (BBI)

Nombre del paciente: ___________________________ Fecha de nacimiento: __________________

ACERCA DE BUPRENORFINA
Suboxone® (una tableta o filme que contiene buprenorfina y naloxona) es un medicamento aprobado por la FDA para el tratamiento de personas con adicción a la heroína o el opio. Buprenorfina puede ser utilizado para la desintoxicación o para terapia de mantenimiento. La terapia de mantenimiento puede continuar siempre y cuando sea médicamente necesario. Existen otros tratamientos para la adicción a los opiáceos, como la metadona, naltrexona, y algunos tratamientos sin medicamentos, que incluyen consejería, grupos y reuniones.

Si usted es dependiente de los opiáceos - cualquier opiáceo como la heroína, metadona, codeína, Percocet, Lortab, Oxycontin, Tramadol etc. - usted debe estar en abstinencia tanto como sea posible cuando se toma la primera dosis de buprenorfina. Si no están en abstinencia, la buprenorfina puede causar grave abstinencia de opiáceos. Por esa razón, usted debe tomar la primera dosis en la clínica y permanecer al menos 2 horas. Le recomendamos que haga arreglos para no conducir después de su primera dosis, debido a que algunos pacientes pueden tener somnolencia hasta que la dosis correcta se determine.

Contraindication buprenorfina con alcohol u otros medicamentos sedantes es peligroso. La combinación de buprenorfina con benzodiacepinas (como Valium®, Librium®, Ativan®, Xanax®, Klonopin®, etc.) ha resultado en muertes.

La buprenorfina es en sí un opiáceo, pero no es tan fuerte un opiáceo como la heroína o la morfina. El tratamiento con buprenorfina puede producir dependencia física similar a otros opiáceos. Retirada de la buprenorfina es generalmente menos intenso que con la heroína o la metadona. Si la buprenorfina esta suspendida de repente, algunos pacientes no tienen síntomas de abstinencia; mientras que otras tienen síntomas tales como dolores musculares, dolor de estómago, o diarrea que dura varios días. Para reducir al mínimo la posibilidad de abstinencia de opiáceos, buprenorfina debe retirarse gradualmente, por lo general durante varias semanas o más.

Los comprimidos/filmes de buprenorfina deben mantenerse bajo la lengua hasta que se disuelve completamente. Usted recibirá su primera dosis en la clínica, y tendrá que esperar hasta que se disuelve y esperar dos horas después de que se disuelve, para ver cómo reaccionan. Es importante no hablar, comer, beber, mascar chicle o chupar un caramelo hasta que el comprimido/film se disuelve. Esto puede tomar hasta diez minutos. La buprenorfina se absorbe en los próximos 30 a 60 minutos después de ser administrado debajo de la lengua. La buprenorfina no se absorbe en el estómago si se ingiere. Si el comprimido/film, no es absorbido debajo de la lengua y usted lo traga no recibirá los beneficios de la medicina y no podrá aliviar su abstinencia.

CONSENTIMIENTO AL TRATAMIENTO

Al firmar este documento, estoy de acuerdo a cumplir lo siguiente:
1. El tratamiento con buprenorfina para la dependencia de opiáceos es más efectiva cuando se combina con el asesoramiento del abuso de drogas, 12 pasos para la recuperación y/o con un grupo de apoyo de recuperación. Durante mi tratamiento con buprenorfina, me comprometo a asistir a terapia y trabajar con un programa de recuperación.

2. Entiendo que la buprenorfina en sí misma es un opiáceo (o “narcótico”) y puede producir una “dependencia física”, lo que significa que al dejarla de repente podría causar síntomas físicos de abstinencia similares a los de la heroína o medicamentos para el dolor de opiáceos (pero por general menos graves).

3. Entiendo que el día que comience la buprenorfina, debo venir a la oficina ya en la abstinencia de opiáceos. No use ningún opiáceos (heroína, metadona, codeína u otros medicamentos que contienen opiáceos) después de las 6:00 pm de la noche antes de iniciar la inducción. Si no tengo señales visibles de la abstinencia de opiáceos, la inducción de buprenorfina debe retrasarse un día o más.

4. Estoy de acuerdo que la dosis para llevar a casa y la frecuencia de las visitas serán determinadas por el buen resultado de lo que estoy haciendo.

5. Estoy de acuerdo en tomar la buprenorfina según la dosis recetada y determinada por mi médico y no permitir que nadie más tome el medicamento recetado para mí.

6. Entiendo que debo tener un lugar seguro para almacenar los suministros o prescripciones de buprenorfina que llevo a casa, donde no puedan ser alcanzados accidentalmente por los niños o mascotas o robadas por usuarios no autorizados. Estoy de acuerdo en que si las tabletas/filme de buprenorfina son ingeridos por cualquier persona además de mi, debo llamar al 911 o al centro de Control de Envenenamientos al 1-800-222-1222.

7. Estoy de acuerdo que si mi médico recomienda que mi surtido doméstico de la buprenorfina debe mantenerse al cuidado de un miembro responsable de mi familia o un tercero, voy a cumplir con dichas recomendaciones.

8. Mientras estoy tomando la buprenorfina o de otra manera en el tratamiento para la adicción, me comprometo a no consumir nada de alcohol o cualquier medicamento de benzodiazepinas, sedantes, sustancias ilegales, o tomar cualquier medicamento opiáceos sin la previa autorización de mi médico (el médico que prescribe mi buprenorfina). Si he estado tomando regularmente una dosis de benzodiazepinas por largo plazo y estoy mostrando signos de adicción, se desarrollará un plan para disminuir poco a poco estos medicamentos con el objetivo de suspenderlos eventualmente, de manera que se evite cualquier síntoma significativo de abstinencia de benzodiazepinas. Si algún medicamento opiáceo llegue a necesitarse, estoy de acuerdo en discutir esto con mi médico que me trata por abuso de sustancias por adelantado, antes de aceptar o llenar cualquier receta. Si tomo o recibo algún medicamento de este tipo en caso de emergencia (por ejemplo, para el dolor agudo o cirugía) voy a consultar esto con el médico de abuso de sustancias dentro de las 24 horas y llevar el frasco del medicamento con el medicamento restante para la continuación del tratamiento.

9. Estoy de acuerdo en no tomar otro medicamento con buprenorfina sin la previa autorización de mi médico. Entiendo que las muertes por sobredosis han sucedido cuando los pacientes han tomado otros medicamentos (en especial medicamentos como Librium®, Valium®, o otras benzodiazepinas) con buprenorfina.

10. Entiendo que si continúo usando constantemente los opiáceos a pesar del tratamiento con buprenorfina, se tomará como en indicio de que el tratamiento con buprenorfina no ha tenido éxito, seré quitado del buprenorfina poco a poco y/o transferido a otra forma de tratamiento.

11. Entiendo que una recaída o deslizamiento puede causar una sobredosis fatal de heroína (u otros opiáceos), que es más común durante la recuperación temprana. Esto solo es porque se lleva cinco días de la abstinencia a perder la tolerancia a la heroína (la capacidad de tolerar una cierta dosis) o a pastillas de metadona o pastillas para el dolor. Esto significa que si yo uso la misma cantidad de heroína (u otros opiáceos) que he usado en el pasado, una sobredosis puede resultar mortal.

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12. Entiendo que el objetivo del tratamiento con buprenorfina es la abstinencia del uso de opiáceos y si continúo el uso de los opiáceos durante más de 60-90 días, mientras uso la buprenorfina, es posible que sea desintoxicado y transferido a un tratamiento más apropiado.

13. Entiendo que el objetivo del tratamiento de la dependencia de opiáceos es aprender a vivir sin el abuso de las drogas. El tratamiento con buprenorfina debe continuar mientras sea necesario para prevenir una recaída al abuso/dependencia de opiáceo.

14. Entiendo que no hay límite de tiempo particular para la duración del tratamiento con buprenorfina, debe continuar mientras sea necesario para prevenir una recaída a la adicción a los opiáceos. Las decisiones acerca de cuándo o con qué rapidez debe disminuirse la buprenorfina serán tomadas por el médico, basando en la información y la discusión con el paciente y el equipo de tratamiento.

15. Doy mi consentimiento para ser sometido a pruebas de abuso de drogas al azar por medio de la orina y saliva con el fin de ayudar a detectar la reversión temprana y documentar mi progreso en el tratamiento.

16. Entiendo que, una vez que estoy recibiendo recetas de buprenorfina, las recetas serán recetadas en cantidades que duren de visita a visita. Las frecuencias de las visitas dependerá de cómo este progresando.

17. Entiendo que la cuenta de drogas de rutina y al azar son una práctica de BBI y se me puede pedir traer mi medicación. La pérdida de recetas o comprimidos/filmes de buprenorfina son problemas serios y puede resultar en la suspensión del tratamiento con buprenorfina en esta oficina. Se me ha informado que si reporto que mis comprimidos se han perdido o han sido robados, que no se les solicitará a mis médicos, ni se esperará que reemplacen mis comprimidos. Esto significa que si se me acaban los suministros de medicamentos podría resultar en experimentar sufrir síntomas del síndrome de abstinencia de opiáceos. También, estoy de acuerdo en que si ha habido un robo de mis medicamentos, voy a reportar a la policía y traeré una copia del reporte de la policía a mi próxima cita en la clínica.

18. Entiendo que todo el personal tiene la responsabilidad de mantener mi confidencialidad. Estoy de acuerdo en no compartir ninguna información sobre otros clientes, incluyendo clientes que asisten o alguien que asiste con alguien a este programa.

19. Entiendo que tengo el derecho a ser tratado con dignidad y respeto, y tengo el derecho a informar en una forma confidencial al programa de tratamiento de cualquier caso en que yo sienta que no haya sido tratado con respeto. Entiendo que el objetivo del tratamiento incluyendo el objetivo de cualquier cambio en la frecuencia de las visitas o pruebas de orina, no es una forma de castigo, sino para ayudar y apoyar en mi objetivo de recuperación.

20. Solo para Mujeres: Estoy de acuerdo en hacer una prueba inicial de embarazo y durante el resto de mi tratamiento, decirle a mi médico, enfermera o consejero si quedo embarazada o si pienso que estoy embarazada. Si quedo embarazada, el médico discutirá conmigo las opciones de cambiar a metadona o cambiar a otra forma de buprenorfina llamada Subutex® que no contiene naloxone.

Se reconoce por mi firma y fecha que he leído este acuerdo y entiendo estos detalles sobre el tratamiento con buprenorfina. Quiero ser tratado con buprenorfina a través de la Iniciativa de Buprenorfina de Baltimore (BBI).

Firma del paciente: ____________________________  Fecha: ____________

Firma del proveedor que Obtiene el consentimiento_______________________   Fecha: ___________
Appendix 7

BALTIMORE BUPRENORPHINE INITIATIVE
AUTHORIZATION FOR RELEASE OF CONFIDENTIAL INFORMATION ABOUT ALCOHOL OR OTHER SUBSTANCE
ABUSE TREATMENT
Fax to (443) 455 -1549

I _______________________ (client name) authorize (1) __________________________ (treatment program name) and
(2) Baltimore Substance Abuse Systems, Inc., which administers the City of Baltimore’s treatment system for alcohol and
other substance abuse and (3) HealthCare Access Maryland, Inc., which assists Baltimore City residents to obtain health
care benefits and care, to communicate with and disclose to one another the following information:

1. My status as a patient in drug and/or alcohol treatment
2. Name
3. Social Security Number
4. Date of Birth
5. Date of admission to substance abuse treatment
6. Date of discharge from substance abuse treatment
7. Medical insurance information, as needed, to enable the agencies listed above to provide, coordinate and monitor
my treatment for alcohol or other substance abuse, and primary health care
8. Continuing care buprenorphine physician appointments, attendance and progress in care

The purpose of these disclosures is to enable the agencies listed above to:

1. Provide, coordinate and monitor the treatment I receive for alcohol or other substance abuse
2. Assist me with enrolling in available public benefits programs
3. Assist in accessing primary health care and other relevant community services

I understand that my alcohol and/or drug treatment records are protected under the federal regulations governing the
Confidentiality of Alcohol and Drug Abuse Patient Records, 42 C.F.R. Part 2, and the Health Insurance Portability and
Accountability Act of 1996 (HIPAA), 45 C.F.R. Pts. 160 & 164 and cannot be disclosed without my written consent at any
time unless otherwise provided for in the regulations.

I understand that I may revoke this consent, in writing, at any time except to the extent that action has already been taken in
reliance on it, and that in any event this consent expires automatically as follows: 18 months from the date of this consent –
or – six months after I am discharged from my current substance abuse treatment program if I do not transition to a
continuing care physician.

I understand that I may be denied services if I refuse to consent to a disclosure for purposes of treatment, payment, or
health care operations, if permitted by state law. I will not be denied services if I refuse to consent to a disclosure for other
purposes.

Date ___________ Signature of Client ___________

Date ___________ Witness ___________

Prohibition on Re-disclosure of Information Concerning Client in Alcohol and/or Drug Abuse Treatment: This notice
accompanies a disclosure of information concerning a client in alcohol/drug abuse treatment, made to you with the consent
of such client. This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR
Part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is
expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 CFR Part 2. A
general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules
restrict any use of the information to criminally investigate or prosecute any alcohol abuse patients.

(BSAS 10/27/06, Revised 5/29/12)
UNIVERSITY OF RHODE ISLAND CHANGE ASSESSMENT (URICA)

NAME: _______________________________
ID#: _______________________________
DATE: _______________________________

This questionnaire is to help us improve services. Each statement describes how a person might feel when starting therapy or approaching problems in their lives. Please indicate the extent to which you tend to agree or disagree with each statement. In each case, make your choice in terms of how you feel right now, not what you have felt in the past or would like to feel. For all the statements that refer to your "problem," answer in terms of what you write on the "PROBLEM" line below. In these questions, the word "here" refers to this program.

Upon completion, you may compute your "Single Continuum Readiness to Change" score http://www.vcu.edu/vattc/uricascoring.html

PROBLEM: ___________________________________________________________________

There are FIVE possible responses to each of the items in the questionnaire:
1 - Strongly Disagree
2 - Disagree
3 - Undecided
4 - Agree
5 - Strongly Agree

Circle the response that best describes how much you agree or disagree with each statement.

1. As far as I am concerned, I don't have any problem that needs changing.

   1             2                3             4            5
   Strongly  Disagree  Undecided   Agree   Strongly
   Disagree                                                  Agree

2. I think I might be ready for some self-improvement.

   1             2                3             4            5
   Strongly  Disagree  Undecided   Agree   Strongly
   Disagree                                                  Agree

3. I am doing something about the problems that have been bothering me.

   1             2                3             4            5
   Strongly  Disagree  Undecided   Agree   Strongly
   Disagree                                                  Agree
4. It might be worthwhile to work on my problem.

1 2 3 4 5
Strongly Disagree Undecided Agree Strongly Agree

5. I am not the one with a problem. It doesn't make much sense for me to be here.

1 2 3 4 5
Strongly Disagree Undecided Agree Strongly Agree

6. It worries me that I might slip back on a problem I have already changed, so I am here to seek help.

1 2 3 4 5
Strongly Disagree Undecided Agree Strongly Agree

7. I am finally doing some work on my problem.

1 2 3 4 5
Strongly Disagree Undecided Agree Strongly Agree

8. I've been thinking that I might want to change something about myself.

1 2 3 4 5
Strongly Disagree Undecided Agree Strongly Agree

9. I have been successful in working on my problem, but I'm not sure I can keep up the effort on my own.

1 2 3 4 5
Strongly Disagree Undecided Agree Strongly Agree

10. At times my problem is difficult, but I'm working on it.

1 2 3 4 5
Strongly Disagree Undecided Agree Strongly Agree
11. Being here is pretty much of a waste of time for me because the problem doesn't have to do with me.

1             2                3             4            5
Strongly Disagree  Undecided   Agree   Strongly Disagree
Disagree                                                  Agree

12. I'm hoping this place will help me to better understand myself.

1             2                3             4            5
Strongly Disagree  Undecided   Agree   Strongly Disagree
Disagree                                                  Agree

13. I guess I have faults, but there is nothing that I really need to change.

1             2                3             4            5
Strongly Disagree  Undecided   Agree   Strongly Disagree
Disagree                                                  Agree

14. I am really working hard to change.

1             2                3             4            5
Strongly Disagree  Undecided   Agree   Strongly Disagree
Disagree                                                  Agree

15. I have a problem and I really think I should work on it.

1             2                3             4            5
Strongly Disagree  Undecided   Agree   Strongly Disagree
Disagree                                                  Agree

16. I'm not following through with what I had already changed as well as I had hoped, and I'm here to prevent a relapse of the problem.

1             2                3             4            5
Strongly Disagree  Undecided   Agree   Strongly Disagree
Disagree                                                  Agree

17. Even though I'm not always successful in changing, I am at least working on my problem.

1             2                3             4            5
Strongly Disagree  Undecided   Agree   Strongly Disagree
Disagree                                                  Agree
18. I thought once I had resolved the problem I would be free of it, but sometimes I still find myself struggling with it.

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<td>Strongly</td>
<td>Disagree</td>
<td>Undecided</td>
<td>Agree</td>
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<td>Undecided</td>
<td>Agree</td>
<td>Strongly</td>
<td>Disagree</td>
<td>Agree</td>
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19. I wish I had more ideas on how to solve my problem.

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<td></td>
<td>Disagree</td>
<td>Agree</td>
<td>Strongly</td>
<td>Agree</td>
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20. I have started working on my problems, but I would like help.

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<td>Disagree</td>
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<td>Disagree</td>
<td>Agree</td>
<td>Strongly</td>
<td>Agree</td>
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21. Maybe this place will be able to help me.

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<td>Strongly</td>
<td>Disagree</td>
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<td></td>
<td>Disagree</td>
<td>Agree</td>
<td>Strongly</td>
<td>Agree</td>
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22. I may need a boost right now to help me maintain the changes I've already made.

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<td></td>
<td>Strongly</td>
<td>Disagree</td>
<td>Undecided</td>
<td>Agree</td>
<td>Strongly</td>
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<tr>
<td></td>
<td>Disagree</td>
<td>Agree</td>
<td>Strongly</td>
<td>Agree</td>
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</table>

23. I may be part of the problem, but I don't really think I am.

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<td>Strongly</td>
<td>Disagree</td>
<td>Undecided</td>
<td>Agree</td>
<td>Strongly</td>
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<tr>
<td></td>
<td>Disagree</td>
<td>Agree</td>
<td>Strongly</td>
<td>Agree</td>
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24. I hope that someone here will have some good advice for me.

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<td>Strongly</td>
<td>Disagree</td>
<td>Undecided</td>
<td>Agree</td>
<td>Strongly</td>
</tr>
<tr>
<td></td>
<td>Disagree</td>
<td>Agree</td>
<td>Strongly</td>
<td>Agree</td>
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</table>

25. Anyone can talk about changing; I'm actually doing something about it.

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<td></td>
<td>Disagree</td>
<td>Agree</td>
<td>Strongly</td>
<td>Agree</td>
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</tbody>
</table>

26. All this talk about psychology is boring. Why can't people just forget about their problems?
27. I'm here to prevent myself from having a relapse of my problem.

28. It is frustrating, but I feel I might be having a recurrence of a problem I thought I had resolved.

29. I have worries but so does the next guy. Why spend time thinking about them?

30. I am actively working on my problem.

31. I would rather cope with my faults than try to change them.

32. After all I have done to try to change my problem, every now and again it comes back to haunt me.

Upon completion, you may compute your "Single Continuum Readiness to Change" score
http://www.vcu.edu/vattc/uricascore.html
## SOCRATES 8D
### Personal Drug Use Questionnaire

**Agency Name:** ________________  
**ID #:** ________________  
**Site Name:** ________________  
**Date:** ___/___/_______

Please read the following statements carefully. Each one describes a way that you might (or might not) feel about your drug use. For each statement, check the box beside the number from 1 to 5 that indicates how much you agree or disagree with it right now. Please check one and only one box for every statement.

<table>
<thead>
<tr>
<th></th>
<th>NO Strongly disagree</th>
<th>No Disagree</th>
<th>Undecided or unsure</th>
<th>Yes Agree</th>
<th>YES Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>I really want to make changes in my use of drugs.</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2.</td>
<td>Sometimes I wonder if I am an addict.</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>3.</td>
<td>If I don't change my drug use soon, my problems are going to get worse.</td>
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<tr>
<td>4.</td>
<td>I have already started making some changes in my use of drugs.</td>
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<tr>
<td>5.</td>
<td>I was using drugs too much at one time, but I've managed to change that.</td>
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<tr>
<td>6.</td>
<td>Sometimes I wonder if my drug use is hurting other people.</td>
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<td>7.</td>
<td>I have a drug problem.</td>
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<td>8.</td>
<td>I'm not just thinking about changing my drug use, I'm already doing something about it.</td>
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<td>9.</td>
<td>I have already changed my drug use, and I am looking for ways to keep from slipping back to my old pattern.</td>
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<td>10.</td>
<td>I have serious problems with drugs.</td>
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<td>11.</td>
<td>Sometimes I wonder if I am in control of my drug use.</td>
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<tr>
<td>12.</td>
<td>My drug use is causing a lot of harm.</td>
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<td>13.</td>
<td>I am actively doing things now to cut down or stop my use of drugs.</td>
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<td>14.</td>
<td>I want help to keep from going back to the drug problems that I had before.</td>
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<td>15.</td>
<td>I know that I have a drug problem.</td>
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<td>16.</td>
<td>There are times when I wonder if I use drugs too much.</td>
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<td>17.</td>
<td>I am a drug addict.</td>
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<tr>
<td>18.</td>
<td>I am working hard to change my drug use.</td>
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<tr>
<td>19.</td>
<td>I have made some changes in my drug use, and I want some help to keep from going back to the way I used before.</td>
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_Baltimore Substance Abuse Systems, Inc. © 2013_
TREATMENT CONTRACT

This undersigned hereby requests admission to the Partners in Recovery Program and consents to such care and treatment as is considered to be necessary by the Counselor and Treatment Team.

If my request is granted, I agree to conform to the following guidelines. Failure to comply with these guidelines may result in termination.

I acknowledge that no guarantees have been made to me as to the result of treatment by this facility. This has been fully explained to me, and I am satisfied with its’ content and significance.

1. I agree to take Suboxone as prescribed by the doctor and nurse practitioner, I agree to remain abstinent from alcohol and other drugs.

2. I agree to attend group sessions and individual sessions as prescribed. I understand that excessive absences or inconsistent patterns of attendance may result in modification or termination of my treatment.

3. I agree to take all psychiatric medications as prescribed (if applicable) and report any side effects to the nurse, doctor, or my counselor immediately. I will keep all schedule and follow-up appointments with psychiatric clinicians.

4. I agree to submit to supervised random urine and breathalyzer testing. I understand that failure to submit to requests for testing will result in an automatic positive status. I understand that positive results from testing may result in modification of my treatment.

5. I agree to attend (3-7) AA/NA meetings per week, or other self-help organizations approved by my counselor and treatment team.

6. I agree, if I am on the buprenorphine maintenance program that any diversion, misuse or abuse of the medication will result in immediate discharge from the program.

___________________________________________________
Patient Signature

___________________________________________________
Witness

___________________________________________________
Date

Baltimore Substance Abuse Systems, Inc. © 2013
Baltimore Buprenorphine Initiative

INSTRUCTIONS FOR FREE ONLINE TRAINING COURSE & WAIVER APPLICATION

Step 1: Sign Up for the Online Training
- Contact Bonnie Campbell at Baltimore Substance Abuse Systems, Inc. via email at bcampbell@bsasinc.org or via phone at 410-637-1900 ext. 252
- State your interest in the training program as well as your practice location and/or hospital affiliation
- Provide your first and last name, and email address to Ms. Campbell at 410-637-1911 ext. 252
- A payment coupon code to access the training website will be emailed to you

Step 2: Complete the Online Training Course within Three (3) Months
- The training website can be accessed at: http://www.buppractice.com
- Complete the 10 modules of the course within 3 months
- For questions about your account, please contact Bonnie Campbell at Baltimore Substance Abuse Systems, Inc. via email at bcampbell@bsasinc.org or via phone at 410-637-1900 ext. 252

Step 3: Complete and Submit the DATA 2000 Waiver Application
- After completing the course, print out your certificate of course completion
- Complete and submit the DATA 2000 waiver application
- The DATA 2000 waiver application can be completed and submitted directly online at http://buprenorphine.samhsa.gov/pls/bwns/waiver
- Applications can also be completed on paper and mailed or faxed to SAMHSA. The form and the SAMHSA mailing/fax information are available at: http://buprenorphine.samhsa.gov/sma_167l.pdf

Step 4: Inform Baltimore Buprenorphine Initiative Staff upon Receipt of Your Waiver
- Please inform Buprenorphine Initiative staff once you have received your waiver by emailing bcampbell@bsasinc.org or calling 410-637.1900 ext. 252.
Appendix 11

BALTIMORE BUPRENORPHINE INITIATIVE
ADMISSION ORDERS/SUBOXONE INDUCTION PROTOCOL

PATIENT NAME______________________________    DOB_____________

<table>
<thead>
<tr>
<th>Date</th>
<th>Physician Orders</th>
<th>Nurse</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>General Orders:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Notify M.D. if :</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient appears drowsy or intoxicated</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient appears short of breath or Respiratory Rate &gt; 25 or &lt; 12/minute</td>
<td></td>
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<tr>
<td></td>
<td>Patient c/o severe pain/headache, abdominal pain, leg swelling or dizziness</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient displays jaundice, icterus</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient admits to opiate use within prior 6 hours</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient complains of continued/increased opioid craving</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Urine pregnancy test (for female patients)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Place PPD and read in @ 48 hours</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Initial urine toxicology screen</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Weekly random urine toxicology for 3 months</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(check urine for buprenorphine if patient receives &gt; 2 “Take Home” doses)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Additional Orders (check all that apply):</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Initial “Take Home” dose(s) every (circle): Friday Saturday Sunday Monday</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Check Breathalyzer for EtOH daily x ____days and notify M.D. if &gt; 0.0</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Check Breathalyzer for EtOH prn for signs/symptoms of EtOH use/intoxication</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Begin BBI SUBOXONE Induction Protocol:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Day 1: Administer COWS: If initial COWS score &lt; 5, no Suboxone (wait 1-2 hours).</td>
<td></td>
</tr>
<tr>
<td></td>
<td>If 5-8, give Suboxone 4mg/1mg sublingually</td>
<td></td>
</tr>
<tr>
<td></td>
<td>If &gt;8, give Suboxone 8mg/2mg sublingually</td>
<td></td>
</tr>
<tr>
<td></td>
<td>After 1-2 hours, re-administer COWS</td>
<td></td>
</tr>
<tr>
<td></td>
<td>If COWS score &gt; 5, give additional 4/1mg Suboxone sublingually x 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Day 2: Administer COWS: If COWS score &lt; 5, continue Suboxone Day #1 dose.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>If COWS score &gt; 5, give Suboxone Day #1 dose plus additional 4/1mg sl.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Day 3: Administer COWS: If COWS score &lt; 5, continue Suboxone Day #2 dose.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>If COWS score &gt; 5, give Suboxone Day #2 dose plus additional 4/1mg sl.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(if patient already taking 16mg/4mg daily, continue this dose until Day# 8)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Day 4-7: Suboxone Day #3 dose ______ sublingually daily</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Day 8: Administer COWS: If COWS score &lt; 5, continue Suboxone Day #7 dose.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>If COWS score &gt; 5, give Suboxone Day #7 dose plus additional 4/1mg sl.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(if patient already taking 20mg/5mg daily, continue this dose until Day# 14)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Day 9-13: Suboxone Day #8 dose ______ sublingually daily</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Stabilization Dose:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Day 14 onward: Continue Suboxone Day # 13 dose. If pt. complains of withdrawal, administer COWS: If COWS score &lt; 5, continue Suboxone Day #13 dose.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>If COWS score &gt; 5, give Suboxone Day #13 dose plus additional 4/1mg sl.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Reevaluation by physician if client requiring dose &gt; 20/5mg daily</td>
<td></td>
</tr>
</tbody>
</table>

_______________________________________

Physician Signature

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FREQUENCY
All patients in treatment will be tested as follows:
• Once per week for the first three months of treatment (this includes the intake urine screen).
• Two times per month for the remainder of the first year of treatment.
• Once per month after the first year of treatment.
• The frequency of testing may be increased at any time for unstable patients.

DRUG PANELS
PANEL A (Adult patients in all modalities of treatment)
1. Opioids  4. Marijuana 50 ng/ml  7. Suboxone
3. Amphetamines  6. Cocaine

Note: Patients in methadone and buprenorphine treatment must be tested for alcohol at least monthly. This may be done by breathalyzer or Alco-Sensor Test Strips. Positive breathalyzer or Alco-Sensor tests must be validated by urinalysis.

PANEL C (All youth patients)
1. Cocaine  4. Marijuana (w/level)
2. Opioids  5. Benzodiazepines
3. Amphetamines

PANEL D – INDIVIDUAL TESTS
01 Opioids  08 Methamphetamine
02 Methadone  09 Amphetamines
03 Alcohol  10 Phencyclidine (PCP)
04 Barbiturates  11 Benzodiazepines
05 Cocaine  12 Darvon (Propxyphene)
06 Marijuana (w/level)
07 Marijuana 50 ng/ml

DRUG SCREENS
1. Adult patients in all modalities of treatment will be screened using Panel A.
2. All youth patients will be screened using Panel C.
3. If deemed clinically necessary and at the Program or Clinical Director’s discretion, programs may screen patients using individual drug screens listed in Panel D.
4. Intake urines should follow the above guidelines and include an individual alcohol emit test.
5. Though it is not required that all urine collections be observed, due diligence should be taken to ensure specimen validity. In cases where the submission of urine specimens is not witnessed, the following precautions are suggested:
   a. Turn off hot water supply under sink and remove knob.
   b. Add bluing agent to toilet bowl.
   c. Designated bathroom should be within eyesight of staff to preclude use by more than one person at a time.
   d. Require that no water be run or toilet flushed in bathroom until after specimen has been submitted.
6. It is recommended that urine screens be witnessed in cases in which there is evidence or reasonable suspicion that specimens have been falsified and/or tampered with.

**LABELS**
1. Programs must use the patient’s Patient ID number on the urine label. The intake urine label should be marked with the prefix “X” plus the last four digits of the patient’s Social Security number. Care should be taken to enter the patient’s correct cost center code (see below) and the corresponding agency code on both urine specimen labels and test requisition forms. **Do not, under any circumstances, record any other identifying information such as name, full social security number, etc. on the urine label.**
2. The drug screen panel code (Panel A or C) and/or individual test codes must be indicated clearly on the label.
3. Any medications the patient is taking must be listed on the label. To minimize false-positive results, the specific names of medications must be listed. This applies particularly to medications, such as Sustiva, that are known to cause false-positive test results.

**LABORATORY TESTING REQUISITION FORM/CHAIN OF CUSTODY**
1. The drug screen panel code (Panel A or C) and/or individual test codes must be clearly written on the testing requisition form and specimen label.
2. Programs must include a cost center code on the testing requisition form as follows:
   - C1 – Managed Care Medicaid
   - C2 – Medicaid (non-managed, federally eligible)
   - C3 – Other Insurance
   - C4 – 100% Self Pay
   - **C5 – BSAS-funded uninsured patients**
   - C6 – BSAS Special Initiatives – Fee for Service Contracts
3. Under the funding included in this RFP, BSAS will only pay for drug screens appropriately coded as C5. Prior to using any other drug screen cost center code other than C5 for a particular patient, providers should ensure that Friends Laboratory has the ability to bill third-party payers for that lab service or providers should use a laboratory that is contracted with the specific patient’s insurer.

**URINE PICK-UP SCHEDULE**
The lab will pick up specimens at programs according to a schedule that is mutually agreed upon by the provider and lab.
URINE RESULT REPORTING
1. The lab will report results to the program within 48 hours of receipt of the urine specimen. If results are needed within 24 to 48 hours, they may be obtained by phoning the laboratory.
2. All urinalysis results will be transmitted from the laboratory to BSAS on the 15th of the month for the previous month.

BILLING
1. The lab will bill BSAS directly for all urinalysis completed for C5 BSAS uninsured.
2. The lab may bill treatment programs directly for urinalyses completed under cost center codes other than C5, unless individuals programs make proper arrangements with Friends Laboratory and provides Friends with all necessary billing information.

SUPPLIES
The lab will supply temperature strip cups, labels, specimen containers, syringes and vials for blood serum collection and Testing Requisition/External Chain of Custody forms.

Document history:
Effective: January 10, 2002
Revised: March 20, 2008
Revised for OP/IOP RFP Only: February 16, 2011
Revised: October 26, 2011
Revised Panel A Only: May 14, 2012
Revised Panel C Only: July 2, 2012
Dear Colleague:

The purpose of this letter is to emphasize that according to 42 C.F.R. 8.12(i)(5), the take-home medication bottles should be properly labeled with the opioid treatment program’s (OTP’s) name, address, and telephone number. The Substance Abuse and Mental Health Services Administration (SAMHSA) also recommends including the patient’s name, the medication name, the physician’s name, and the dispensing date. In addition, prescription labels for liquid methadone should include the dose and the directions of use such as “single dose” while prescription labels for Suboxone® or Subutex® and methadone dispersible tablets should include the strength, quantity dispensed, and the appropriate directions of use such as “Take [#] tablet(s) under the tongue once a day” or “Take [#] tablet(s) once a day,” respectively.

Appropriate cautionary statements should also appear on the take-home bottle. According to 21 C.F.R. 290.5, “[t]he label of any drug listed as a ‘controlled substance’ in schedule II, III, or IV of the Federal Controlled Substances Act shall, when dispensed to or for a patient, contain the following warning: ‘Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.’”

We believe that the inclusion of the above information on take-home bottle labels will help reduce diversion of methadone and buprenorphine and improve patient safety. The display of the patient’s name on the take-home bottle label should help reduce diversion since the label can lead back to the patient if the medication was diverted and the bottle was found. The inclusion of the medication name, dose or strength and quantity, direction of use, physician name, dispensing date, as well as the patient name, will improve patient safety by providing necessary information to the patient so that the patient can accurately identify the contents in the bottle, the direction of use, and the physician who prescribed the medication. This information is also useful in emergency situations where someone has ingested the contents in the bottle.

Enclosed are examples of take-home bottle labels that include the above required and recommended information. SAMHSA acknowledges that states may have specific requirements that may not be addressed by the SAMHSA sample label. The sample labels are for guidance purposes only. For additional information or questions, please contact Jennifer Fan, Pharm.D., J.D., Public Health Advisor, at (240) 276-1759 or by e-mail at Jennifer.fan@samhsa.hhs.gov.

Sincerely,

H. Westley Clark, M.D., J.D., M.P.H., CAS, FASAM Director
Center for Substance Abuse Treatment
Example 1:

[X Y Z]

1111 State Street
Sunshine, Alaska  00000
301.555.5555

[Patient Name]

Dispense Date: 01/02/2008

Methadone 60mg  Directions: Single Dose

[Name of OTP Medical Director or Physician]

CAUTION:
Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

Example 2:

[X Y Z]

1111 State Street
Sunshine, Alaska  00000
301.555.5555

[Patient Name]

Dispense Date: 01/02/2008

Suboxone 8 mg  QTY: 14  Directions: Take 2 tablets under the tongue once a day

[Name of OTP Medical Director or Physician]

CAUTION:
Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.
Appendix 14

BALTIMORE BUPRENORPHINE INITIATIVE

REQUEST FOR INCREASED SUBOXONE DOSE WORKSHEET

PATIENT NAME______________________________   DOB ______________
CURRENT SUBOXONE DOSE_______   STAFF MEMBER COMPLETING FORM____________

1) “Have you **recently used** heroin (or opioid of choice)?”
   YES   NO
   If so: “What were the **circumstances when you used?**” (e.g. “Did you use alone?”, “Were you spending time with someone who uses drugs?” etc.)

2) “Are you continuing to **crave** heroin (or opioid of choice)?”
   YES   NO

3) “Did you **feel the effects** of the heroin (or opioid of choice) after the last time you used?”
   YES   NO

4) “Are you continuing to have **withdrawal symptoms**?”
   YES   NO
   If so: “What specific symptoms (administer the COWS)?”
   “How long after your buprenorphine dose do you experience this?”________________

5) “Are you experiencing significant **pain**?”
   YES   NO
   If so: “Is this a new condition?”
   YES   NO
   “Does the buprenorphine help relieve the pain?”
   YES   NO

6) “Are you taking any **new medications**?”
   YES   NO
   If so: “Please list.”

__________________________________________

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Appendix 15

BALTIMORE BUPRENORPHINE INITIATIVE
TRANSFER DISPOSITION FORM

Date: _________ Site: ____________________ Treatment Advocate: ____________
Client Name: ____________________________________________________________
Program Representative: ________________________________________________

Type of Disposition Meeting (please circle): 60 90 120 150 180 180+
Client’s Current Level of Care (please circle): IOP OP

Response to Treatment:
• Please indicate the results of the two most recent urine specimens or dipstick results:

  Date of Specimen: ____________ Date of Specimen: ____________
  Please circle results (P = positive, N = negative) Please circle results (P = positive, N = negative)
  Opioids P N Opioids P N
  Cocaine P N Cocaine P N
  Amphetamines P N Amphetamines P N
  Marijuana P N Marijuana P N
  Methadone P N Methadone P N
  Benzodiazepines P N Benzodiazepines P N
  Other: _______ P N Other: _______ P N
  Buprenorphine P N Unk Buprenorphine P N Unk

Insurance Status:
• Does the client have insurance (please circle)? YES NO Type: ________________
  If NO, what is the status:
    o Uninsured
    o Not Eligible for Insurance

Transfer Readiness:
• Is the client ready to transfer to continuing care (please circle): YES NO

  If NO, why is the client not ready (please check most prominent reason and then the action step):
  □ Opioid Use
    o Assess for need of dosage change
    o Increase Counseling
  □ Use of other substances (specify) __________________________
    o Refer to higher level of care
    o Put on Contract
  □ Recently re-engaged after lapse in treatment
    o Reassess within 15 days
  □ Mental health issues impacting treatment (please specify) ________________
    o Refer for mental health care
    o Transfer to a mental health provider
  □ Pending Discharge
  □ Other (Please Specify): ____________________________

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(Updated 1/11/09)
Patient Information

Patient Name: ___________________________ DOB: _____ / _____ / _____
Patient Address: __________________________________________________________

Patient Phone: ( ) _______ - ____________
Name of Emergency Contact: ___________________________ Phone: ( ) _______ - _____
Continuing Care Provider: ___________________________ Phone: ( ) _______ - _____

Insurance Information

Type of Insurance: __________________________________________________________
Insurance Number: __________________________________________________________
Name of MCO: ___________________________________________________________________
Dates of Authorization for Suboxone Medication: _____ / _____ / _____ to _____ / _____ / _____

Please attach copy of notification form or authorization form if available

Transfer Criteria

Patient Meets the Following Transfer Criteria (check all that apply):

☐ No withdrawal symptoms
☐ Minimal or no side effects of buprenorphine
☐ No longer has uncontrollable cravings for opioid agonists
☐ Compliant with independent medication administration for at least 2 weeks
☐ Compliant with counseling and treatment appointments
☐ Last toxicology test is negative for opioid use
☐ Patient tested positive for buprenorphine within the last 30 days

Drug Testing Results

Attach LAST urinalysis/tox screen results and buprenorphine UA/dip stick results to this form

Date of Last Tox Screen: _____ / _____ / _____

Drugs Detected in Last Tox Screen:

☐ None ☐ Cocaine ☐ Marijuana ☐ Benzodiazepines ☐ Alcohol ☐ Analgesics ☐ Stimulants

Others: ___________________________
Medical History
Intake physical and/or copy of latest H&P attached: Yes □ No □
If NO, report medical history and current diagnoses:

Medications:

Allergies:

Psychiatric History
None □ Bipolar Disorder □ Major Depression □ OCD □ Schizophrenia □ PTSD □ Anxiety Disorder
□ Other:

Medications:

PCP Transfer Orders
Buprenorphine Prescription: ______ mg of buprenorphine ______ time(s) per day
Date of Last Rx: / ______ / ______
Number of Tablets Prescribed in Last Rx: ______
Date Patient Will Run Out of Medication: / ______ / ______

Recommended Follow-Up:
Frequency of Follow-Up PCP Visits:
Frequency & Duration of Counseling Sessions at Our Substance Abuse Treatment Program:

Signatures
Date: / ______ / ______
Phone Number of Referring Physician: Phone: ( ) ______ - ______
Name of Referring Physician (please print):
Signature of Medical Staff completing paperwork:

Phone Number of Treatment Counselor: Phone: ( ) ______ - ______
Name of Treatment Counselor (please print):
Signature of Treatment Counselor:
Client Signature: __________________________ Date: __________________________

(HCAM 3/23/11)
BALTIMORE BUPRENORPHINE INITIATIVE
ATTENDANCE VERIFICATION FORM

Client Name: ________________________________

Instructions: In order for your continuing care physician to be certain that you are attending required counseling sessions, you are responsible for taking this form to every counseling session and requesting that an authorized person sign the form. You are also responsible to bring the form to every physician visit to verify attendance.

Please confirm that the above client has attended:

Circle type(s):  Group Session     Individual Counseling      NA/AA     Other:_________
Date:           Phone:________________
Name:           Signature:_________Position:______

Please confirm that the above client has attended:

Circle type(s):  Group Session     Individual Counseling      NA/AA     Other:_________
Date:           Phone:________________
Name:           Signature:_________Position:______

Please confirm that the above client has attended:

Circle type(s):  Group Session     Individual Counseling      NA/AA     Other:_________
Date:           Phone:________________
Name:           Signature:_________Position:______

Please confirm that the above patient has attended:

Circle type(s):  Group Session     Individual Counseling      NA/AA     Other:_________
Date:           Phone:________________
Name:           Signature:_________Position:______
Please confirm that the above client has attended:
Circle type(s): Group Session     Individual Counseling     NA/AA     Other:__________
Date: _______________     Phone: _______________
Name: _______________     Signature:______________Position:_________

Please confirm that the above patient has attended:
Circle type(s): Group Session     Individual Counseling     NA/AA     Other:__________
Date: _______________     Phone: _______________
Name: _______________     Signature:______________Position:_________

Please confirm that the above client has attended:
Circle type(s): Group Session     Individual Counseling     NA/AA     Other:__________
Date: _______________     Phone: _______________
Name: _______________     Signature:______________Position:_________

Please confirm that the above client has attended:
Circle type(s): Group Session     Individual Counseling     NA/AA     Other:__________
Date: _______________     Phone: _______________
Name: _______________     Signature:______________Position:_________

I agree to stay involved in group and counseling sessions and utilize this form as evidence of my participation in such activities.

Effective Dates: ___________     to     ___________

__________________________     ________________________
Client Signature             Physician Signature

(11/24/08)