CLINICAL GUIDELINES
FOR CONTINUING CARE PHYSICIANS IN THE
Baltimore Buprenorphine Initiative

May 2013
Preface
The introduction of the “Clinical Guidelines for Buprenorphine Treatment of Opioid Dependence in the Baltimore Buprenorphine Initiative” in 2009 (Rev. 2011) set clear and thorough expectations for clinical practices in the Baltimore Buprenorphine Initiative (BBI). Since that time, retention in treatment and the quality of care provided to patients in the BBI has increased such that the BBI now has become a nationally recognized model for how to deliver buprenorphine services to opioid dependent patients.

Over the last couple of years, it has become clear that while the clinical guidelines have set a standard of care for patients receiving buprenorphine as part of the BBI, the primary focus of that document has been outpatient substance abuse treatment providers. As a key component of the model, this focus has been critical.

However, as the network of physicians providing ongoing buprenorphine maintenance treatment as part of the BBI has grown, it has also become clear that there are unique challenges and questions that continuing care providers have in managing patients on buprenorphine. The current document, therefore, aims to provide focused and specific recommendations and guidelines for the effective management of patients maintained on buprenorphine as part of their overall health care. We hope that it will provide clinically useful tools for physicians in office-based settings where the focus is on supporting patients in their maintenance of recovery from substance use disorders, not necessarily on initiating that recovery.

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Section 1: Services in BBI Substance Abuse Treatment Programs

Patients seeking opioid dependence treatment from a BBI-participating substance abuse treatment program receive specific sets of services.

A. Buprenorphine Induction and Stabilization

Patients engaged in the BBI receive a standardized set of services to promote rapid and effective induction and stabilization onto buprenorphine as part of comprehensive substance abuse treatment.

B. Counseling Services

BBI treatment programs provide Intensive Outpatient (IOP) and traditional Outpatient (OP) levels of care as determined by the American Society of Addiction Medicine’s Patient Placement Criteria.¹

| American Society of Addiction Medicine (ASAM) Levels of Care for Substance Abuse Treatment |
|-----------------------------------------------|-----------------------------------------------|
| **ASAM Levels of Care** | **Description** |
| ASAM Level 0.5 | Early intervention services for people not meeting DSM-IV diagnostic criteria for a substance use disorder |
| ASAM Levels I and II | Outpatient treatment (OP) – 1-8 hours of treatment services weekly to monthly Intensive Outpatient Treatment (IOP) – at least 9 hours of treatment services weekly |
| ASAM Levels III.1 through III.7 | Clinically managed residential services, without medical staff unless detoxification services provided (the traditional “rehab”) |
| ASAM Level IV | Medically managed acute inpatient detoxification |

*Medications, such as methadone, buprenorphine, or others can be provided at any level of care

C. Case Management Services

Since inception of the BBI, HealthCare Access Maryland, Inc. (HCAM, formerly Baltimore HealthCare Access) has provided a team of addiction treatment advocates who work with patients, treatment center staff, and continuing care physicians. HCAM’s BBI Treatment Advocates’ functions:
• Help patients obtain all necessary documentation for enrollment into Medicaid’s HealthChoice or Primary Adult Care (PAC) programs or other health insurance, help patients enroll into a managed care organization, and assist patients with locating a buprenorphine-certified continuing care provider.
• Schedule primary care physician office visits and provide follow-up for six months.
• Link patients with community resources and other public benefits including food stamps, housing, clothing, utility assistance, transportation, and prescription medications.
Section 2: Transition to Continuing Care

The transition for patients stable on buprenorphine from a BBI substance abuse treatment program to a continuing care physician follows standardized, systematic procedures:

1. Transition Criteria

The stability of patients transitioning for continued buprenorphine and integrated care is critical. Patients are defined as stable for transition when they meet a specific set of five transition criteria.

<table>
<thead>
<tr>
<th>BBI Transition Criteria</th>
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<tbody>
<tr>
<td>1. Patient must be in the stabilization/maintenance phase of treatment and exhibit:</td>
</tr>
<tr>
<td>a. No opioid withdrawal symptoms.</td>
</tr>
<tr>
<td>b. Minimal side effects of buprenorphine.</td>
</tr>
<tr>
<td>c. No uncontrolled cravings for illicit opioids.</td>
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<tr>
<td>d. Adherence with independent buprenorphine prescriptions for at least two weeks.</td>
</tr>
<tr>
<td>e. Adherence with counseling.</td>
</tr>
<tr>
<td>f. Two consecutive weekly toxicology test results negative for opioids.</td>
</tr>
<tr>
<td>g. Two consecutive weekly toxicology test results positive for buprenorphine.</td>
</tr>
<tr>
<td>2. Patient is willing to establish and maintain a relationship with a continuing care provider and has been counseled about making and keeping appointments.</td>
</tr>
<tr>
<td>3. Patient has health insurance and has enrolled in a managed care organization.</td>
</tr>
<tr>
<td>4. Patient has selected and been accepted by a continuing care provider who accepts his/her insurance.</td>
</tr>
<tr>
<td>5. 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.</td>
</tr>
</tbody>
</table>

2. Patient Transition

The transition process includes a defined sequence of events and continued review.

- Once a patient has met the transition criteria, a potential transition date is set.
- The initial appointment with the continuing care provider is then scheduled. This becomes the transition date.
- The status of the patient is monitored as the transition date approaches.
- The HCAM BBI advocate faxes a completed Transition Summary to the continuing care physician prior to the transition date (see Appendix A). This Summary includes pertinent information, including insurance, medical, other provider contact information, and lab data.
• If the patient no longer meets the transition criteria by the transition date, the HCAM BBI advocate alerts the continuing care provider and cancels the appointment, unless the patient has a medical condition warranting the visit.

3. **Patient Follow-up**

HCAM BBI advocates continue to follow patients on buprenorphine for up to six (6) months after transition to continuing care:

• Monitor patient's adherence with continuing care provider appointments and provide assistance with barriers to continued engagement.

• Provide assistance with recovery-related supports as needed. This includes transportation, housing assistance, job training, and continued education.

• Assist patients to adhere to initial and subsequent continuing care appointments.

• Assist patients to adhere to ongoing counseling appointments at the BBI treatment program if patients are interested or it is clinically recommended by either the specialty treatment provider or the continuing care physician. For some patients, continued counseling is critical to strengthen recovery and help prevent relapse.

• Reconnect patients who became unstable after transition with specialty substance abuse treatment for re-stabilization.
Section 3: Addiction as a Chronic Disease

Addiction is defined as a chronic, long-term brain disease characterized by self-destructive behaviors and compulsive drug seeking and use, despite harmful consequences.²

Research shows that people with addiction can have a re-occurrence even after years of recovery.³

- Greater evidence has led many experts to compare addiction with other chronic diseases such as diabetes, depression, heart failure, and HIV.⁴
- All common, chronic diseases have behavioral components to their treatments in which the goal is disease management and recovery, not cure.
- This chronic disease approach is different than the historic treatment of addiction.
- Historically, addiction treatment followed an acute disease approach where those with the disease received a certain amount of treatment and then they were expected to be “cured.”
- A large and growing body of evidence demonstrates that recovery from addiction is a long-term process.⁵

Chronic Disease Management of Addiction

The BBI strongly embraces the chronic disease model of addiction. Its services follow evidence that integrated, comprehensive care for patients with addiction results in improved outcomes when compared with fragmented care.⁶ ⁷

BBI Continuing Care physicians play a critical role in helping patients on buprenorphine achieve long-term recovery.

Treating addiction is often a new experience for physicians, and each individual comes to it with different perspectives and experiences.

- All healthcare professionals may carry their own judgments, and biases about addiction.
- These attitudes are important to acknowledge since they may affect patient interactions.
- The BBI aims to promote positive experiences for patients and continuing care physicians.
- Positive experiences are ones in which patients feel respected and supported, and physicians express empathy and support, even when setting limits and addressing negative behaviors.

Patients also have a number of different perspectives about the health care system based on their lack of historical access and past negative experiences. Patients with addiction often mistrust the healthcare system based on past negative experiences.⁸
• This mistrust sometimes make patients “act out” when faced with new situations, new people, and unfamiliar procedures.9,10
• The stress of new situations and people may also trigger relapse.

To promote a positive experience for patients and physicians, the BBI focuses on three key areas in Continuing Care:

1. Management of the medication
2. Support of overall recovery maintenance (recovery management)
3. Integration of medication and recovery management with primary care, mental health treatment, and/or specialty HIV care through a medical or behavioral health home approach

The remainder of this guideline provides detailed information on the treatment of opioid dependence with buprenorphine in office settings with frequently asked questions that focus on the three areas key to Continuing Care.
Section 4: Buprenorphine Basics and Management of the Medication

Buprenorphine is a semi-synthetic, partial opioid agonist approved in a sublingual formulation by the U.S. Food and Drug Administration (FDA) for opioid detoxification and opioid maintenance therapy. In all patients except pregnant women, the BBI encourages use of Suboxone®, the combination product that includes naloxone.

1. What are the different formulations of buprenorphine?
   - Buprenex® - parenteral form only approved for pain management.
   - Butrans® - transdermal patch only approved for pain management.
   - Generic buprenorphine alone - tablet only approved for opioid abuse/dependence treatment.
   - Suboxone® - brand name buprenorphine/naloxone film and generic tablet only approved for opioid abuse/dependence treatment.

2. Why does Suboxone® contain naloxone?
   Suboxone® contains naloxone, a complete opioid antagonist, as a safety measure to decrease diversion and abuse. Naloxone is poorly absorbed through the sublingual route of Suboxone® administration but decreases any euphoria and may precipitate withdrawal if Suboxone® is injected.

3. How does Suboxone® work?
   Buprenorphine is a partial opioid agonist with primary activity at the mu opioid receptor.
   - The medication effectively treats opioid withdrawal at low doses.
   - Above 32mg there is generally no further pharmacological benefit. Most prescribers use 24mg as a practical upper limit.
   - Buprenorphine has high affinity for and slow dissociation from mu opioid receptors.
   - These properties allow for longer clinical effect (48-72 hours at therapeutic doses) than would be expected based solely on the medication’s elimination half-life (24-37 hours).
   - These properties also account for a relatively longer and milder opioid withdrawal syndrome compared to full agonist opioids such as methadone.
   - After abrupt cessation of buprenorphine, the opioid withdrawal syndrome typically begins after 2-5 days.

4. What is the therapeutic dose range for Suboxone®?
   At a therapeutic dose of Suboxone®, three goals are achieved:
   1) Alleviation of withdrawal symptoms
   2) Suppression of cravings
   3) Blockade of the euphoric effect of other opioids
The majority of patients experience good clinical effect without adverse side effects at doses of 12-24mg per day. Most patients are maintained on 12mg to 16mg daily but individual dosage needs may vary.

- There is relatively little additional pharmacological benefit beyond 24mg.\textsuperscript{11,12}
- Insurance companies may require more clinical rationale and information prior to authorizing payment for prescriptions beyond 24mg (see http://www.bsasinc.org for MCO specific information).

5. Why should Suboxone\textsuperscript{®} be taken sublingually?
Sublingual administration bypasses extensive first-pass metabolism that limits the bioavailability of the medication through the oral route.

- The film preparation is associated with a slightly higher peak serum concentration of Suboxone\textsuperscript{®} due to slightly better sublingual absorption compared to the tablet. The clinical significance of this difference is currently unclear.

6. What is the typical dosing regimen for Suboxone\textsuperscript{®}?
Once daily dosing is the typical dosing regimen for most patients.

7. Is it possible to overdose on Suboxone\textsuperscript{®}?
All buprenorphine formulations have a favorable safety profile in opioid tolerant individuals. Care should be taken in prescribing them to opioid-naïve or non-tolerant children and adults, as significant morbidity can result.

- Other sedating medications or substances exert additive CNS and respiratory depressant effects when taken along with any buprenorphine product.

- Deaths have been reported involving the combination of buprenorphine formulations with high doses of benzodiazepines.\textsuperscript{13}

- The BBI does not preclude patients from receiving combinations of Suboxone\textsuperscript{®} and prescribed benzodiazepines, but monitoring of use and coordination of care with other prescribers is essential. Consideration should be given to safer alternatives.

8. Are there clinically significant medication interactions with Suboxone\textsuperscript{®}?
Buprenorphine is primarily metabolized by the CYP450 3A4 hepatic enzyme system into active norbuprenorphine. This is a system often affected by foods and other medications. Clinically, these appear to have relatively minimal impact on Suboxone\textsuperscript{®} dosing requirements. Each patient should be managed on an individual basis. Other important interactions:

- Suboxone\textsuperscript{®} is contra-indicated in combination with naloxone or other opioid antagonists, unless in an overdose.
• Warn patients about taking full opioid agonists followed by Suboxone® as this will precipitate withdrawal.
• Physicians should caution patients about combining Suboxone® with other sedating medications, such as benzodiazepines, tricyclic antidepressants, and sedating antihistamines.

9. **What are typical side effects from Suboxone® and how should they be managed?**
Suboxone® is well tolerated but there are a few common side effects that patients either may report or that physicians should ask about since they may negatively affect adherence with the medication or serve as a trigger for relapse.

   a. **Headache** (reported in about 30% of study patients on doses up to and including 24mg daily)
   **Rx:** Suboxone®-induced headaches are usually easily relieved with standard doses of over-the-counter acetaminophen or ibuprofen as needed. A decrease in the Suboxone® dose may improve this side effect but should be balanced with any potential relapse risk.

   b. **Constipation** (reported in about 12% of study patients)
   **Rx:** Tolerance does not typically develop to opioid-induced, slow colonic transit that can result in chronic constipation. This may be less severe with Suboxone® than other opioids. Clinical approaches include both prevention and treatment.
   
   o **Prevention**
   - Ensure adequate daily non-caffeinated fluid intake.
   - Dietary, non-bulk forming fiber or prunes can help soften stool and improve bowel function.
   - Encourage physical activity as a healthy way to increase bowel motility.
   - Stool softening surfactants such as docusate sodium (Colace®) may help although may be less effective than other agents.[15]

   o **Treatment**
   - Short-term use of osmotic laxatives such as lactulose, milk of magnesia (MOM), or magnesium citrate, or stimulant laxatives such as bisacodyl (Dulcolax®) or senna-containing agents (Senokot® or Peri-Colace®) is recommended until the patient is having no fewer than one bowel movement every 2-3 days and has established preventive measures.
   - For severe constipation, osmotic laxatives such as polyethylene glycol (PEG) solutions with and without electrolytes (GoLytely® or MiraLAX®, respectively), sorbitol, and suppositories or enemas may be needed.
   - Use caution with all of these agents as all of the osmotic and stimulant laxatives may cause diarrhea and electrolyte abnormalities.
   - If the patient is on a Suboxone® dose of 20mg or higher and otherwise stable in recovery, a decrease in the dose by 2-4mg may improve constipation, but should be undertaken in combination with other remedies and re-assessed at regular intervals.
c. **Decreased sexual function** (reported in 18% of study patients)

**Rx:** Patients taking Suboxone® may report erectile dysfunction and decreased libido. It is unclear whether decreasing the dose of buprenorphine will improve sexual function; addressing other possible related factors, such as depression, partner relationships, other medication effects, smoking, testosterone deficiency, excessive alcohol intake, thyroid disorders, other systemic medical conditions, and obesity may be more beneficial.

d. **Nausea** (reported in about 10% to 15% of study patients)

**Rx:** Nausea may be due to the taste of the Suboxone® tablets or film, or as a GI side effect. This typically resolves spontaneously without need for intervention. Suboxone® has been associated with asymptomatic, transient elevations in hepatic transaminases and frank hepatitis and hepatic failure. The latter is rare and may be related to the concomitant use of other hepatotoxic medications or continued drug use in the presence of existing liver abnormalities. If nausea is severe and persistent, physicians should increase monitoring of liver function tests and further evaluate symptoms.

e. **Drowsiness**

**Rx:** Suboxone® can cause sedation and drowsiness, particularly in less tolerant or opioid-naïve individuals. A decrease in the daily Suboxone® dose may lessen this symptom. Patients should be cautioned about driving or operating heavy machinery if they are experiencing sedation. Changing the time of day when patients take the Suboxone® may also help.

f. **Dizziness** (reported in less than 10% of study patients)

**Rx:** Suboxone® can cause orthostatic hypotension and elevations of cerebrospinal fluid pressure. Blood pressure should be monitored in patients receiving Suboxone® and caution should be used in patients with head injury or other CNS lesions.

10. **How do I handle a patient’s request for an increase in his/her Suboxone® dose?**

Because patients transition from a BBI treatment program on a stable dose of Suboxone®, continuing care physicians should not expect to increase doses, particularly initially. However, through the course of care, patients may request an increase in their dose during a follow-up visit.

A request for an increase should prompt certain questions for the physician:

1. What is the reason for the request?
2. Has the patient missed doses of Suboxone®?
3. Is the current dose of Suboxone® already at the high end of the dose range?
4. Is the patient experiencing cravings, and if so, what might be triggering them?
5. Is the patient experiencing any withdrawal symptoms and if so, which ones?
6. What is the differential diagnosis for the symptoms described by the patient?
7. Is the patient exhibiting objective signs of opioid withdrawal?*1

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*1 Observable objective findings of opioid withdrawal confirm a primary physiologically based phenomenon but are not necessary for a dose increase to be considered.
8. Has the patient started any new medications or stopped any existing ones?
9. Are there any new stressors in the patient’s life?
10. Is there the presence of new, unrelieved pain?

After discussion with the patient, appropriate responses include:

- If the risk for relapse appears high (e.g. significant cravings, objective signs of opioid withdrawal, unrelieved pain, or new stressors are present), a trial period of increased dosage with close monitoring is warranted.
- BBI medical resources should be consulted prior to increasing doses beyond 24mg daily.
- Reinforce consistent adherence with the medication for best efficacy and to avoid the development of withdrawal symptoms.
- Evaluate for other potential causes of non-specific symptoms.

11. How do I manage patients who complain of withdrawal symptoms after having been on the same dose of Suboxone® for months?

- Obtain a thorough history and conduct a physical examination accordingly.
- Conduct appropriate symptom-guided laboratory and imaging testing.
- Refer for specialty consultations as needed.
- Explain the differential diagnosis for the reported symptoms with patients.
- Reassure patients that the symptoms are unlikely related to the Suboxone® dose – this can often reduce the patient’s anxiety and insistence on an increase in the medication.
- If the probability of opioid withdrawal or risk for relapse is high, small increases of 2-4mg can be considered, especially if the patient is on a lower dose of Suboxone®.
- If the daily dose is already 24mg daily, seek expert consultation prior to increasing the dose.
- The absence of significant cravings should provide some reassurance to the prescriber that the current dose is adequate.

12. Does the presence of withdrawal symptoms always mean withdrawal is present?

Patients with opioid dependence often equate a range of non-specific symptoms, such as sweating, nasal congestion, and nausea, with being in opioid withdrawal, even though a different phenomenon may be the cause.

- Sometimes the root cause is somatization of the psychological dependence that defines addiction.
- Other physical and/or psychiatric conditions may exist as well.

13. What do I do when my patient says the Suboxone® is “not holding”?

Before making any changes to the dose, it is crucial to understand what a patient means by a particular dose “not holding” since this will drive decision-making regarding the medication.

- Is the patient still experiencing cravings?
- How does the patient expect to feel with the Suboxone®?
If the patient expects to “feel” the medication the same way they may have “felt” full-agonist opioids in the past, educate the patient that the goal of Suboxone® is to stop withdrawal symptoms and improve functionality.

If these goals have been met, then the dose is appropriate.

- Are there other potential causes for the aches and pains or other non-specific symptoms patients may equate with a Suboxone® dose “not holding”?
  - Buprenorphine is effective as an analgesic when dosed multiple times a day.
  - The use of **sublingual** buprenorphine or Suboxone® for pain management is off-label at this point although the BBI recognizes the analgesic benefit of the medication when taken in divided doses.

- Is the patient addicted to prescription opioids, and psychologically conditioned to take a pill multiple times a day?
  - This is best addressed through specialty substance abuse counseling.

- Are there indications that the patient may be more rapidly metabolizing the Suboxone®, such as the presence of CYP 3A4 inducers?

### 14. How should I manage a patient who reports taking Suboxone® twice a day?

If a patient reports taking Suboxone® in divided doses, there is no need to discontinue prescribing it, even though once a day dosing is more of the norm. If there is concern for diversion, increase the frequency of visits and decrease the quantity of medication prescribed.

### 15. How do I manage a patient on Suboxone® who wants to switch to methadone?

Unlike switching from methadone to Suboxone®, there is no risk in precipitating withdrawal in patients switching from Suboxone® to methadone.

- Contact the patient’s HCAM BBI advocate who can help coordinate a referral to an opioid treatment program (OTP).
- Contact the OTPs medical director to provide pertinent clinical information on the patient, including the current Suboxone® dose and reason for the switch.

### 16. When should the dose of Suboxone® be decreased?

A decrease in the Suboxone® dose may be warranted if: 1) patients complain of sedation or describe functional limitations due to sedation or 2) if the physician or family members note significant sedation or 3) if the patient requests to taper off the medication.

### 17. Should I reduce the dosage of a new BBI patient who transitions to me on 32mg of Suboxone®?

Because there is relatively little long-term benefit of maintenance doses of Suboxone® above 24mg daily, and the risk of diversion increases at higher doses, the BBI recommends that continuing care physicians work with patients to reduce high transition doses to more typical therapeutic maintenance
levels. This also allows for more manageable pill or film burden, lowers cost, and may reduce side effects.

18. What if a patient does not want to decrease the Suboxone® dose?
Many patients express disagreement with any potential decrease in medication dose for a variety of reasons:

- Memories of intense, painful withdrawal that might recur with a lower dose
- Fear that the prescriber wants to taper the dose to zero
- Concern about relapse
- A sign that the patient is diverting some of their medication and is now afraid of loss of income

To minimize or pre-empt resistance from patients, tips to prescribers include:

- Explain the reason behind the recommended decrease and that the physician and patient together will monitor the response.
- Be sure to understand any fears or apprehension the patient may have about a dose decrease.
- Correct any misunderstanding the patient may have about the goal of the decrease (e.g. it is not to taper off).
- Begin discussing and implementing a decrease in the Suboxone® dose only after rapport has been established with the patient.
- Go slowly (e.g. decrease by 2mg per month or slower if needed).
Section 5: Recovery Facilitation

The BBI endorses the definition of recovery put forth by the federal Substance Abuse and Mental Health Services Administration (SAMHSA):

- A process of change through which individuals improve their health and wellness, live a self-directed life, and strive to reach their full potential.

The ultimate goal for patients with addiction is recovery and self-management of their chronic disease. This occurs through behavior change, just like self-management of diabetes involves behavior change.

1. **How should I think about behavior change as it relates to addiction?**

Understand that sustained behavior change is not a linear process, occurs in stages, and often occurs slowly.

- The Prochaska and DiClemente TransTheoretical Model of Behavior Change is a widely recommended model describing the different stages of behavior change.

- Behavior change has clearly begun. Individuals need skills to implement specific behavior change methods.

- Individuals sustain and strengthen changes they have made.

- No intent to change the problem behavior because unaware it is a problem or unwilling to change due to past failed attempts.

- Considering behavior change. May be considering specific personal implications of the problem and what the consequences of change might entail.

- Ready to change both attitude and behavior. Intend to change soon and have incorporated experiences of previous tries at change.

*Figure 2: Trans Theoretical Model of Behavior Change*
2. **What are the stages of change of BBI patients when they transition to continuing care?**

BBI patients are typically in the action or maintenance stage with regards to their problematic opioid use when they transition to continuing care.

- They may be at a different stage of change with respect to other, simultaneous substance use, including tobacco.
- The BBI strongly recommends that patients continue to receive outpatient counseling for 2-3 months after transition to continuing care to solidify and strengthen recovery skills gained and address all problematic substance use.
- Continuing care physicians can obtain a regular update on the patient’s attendance in counseling via the Counseling Confirmation Form (see Appendix B).
- If patients choose not to continue counseling and maintain abstinence from problematic opioid use and other substances, this may be appropriate.

3. **How does recovery relate to the duration of treatment with Suboxone®?**

Recent data suggests that retention in care and sustained recovery of at least 5 years reduces the risk of relapse to less than 15%.\(^3\)

- Significant evidence demonstrates that relapse rates to illicit opioid use exceed 50% within a year after patients taper off medications such as Suboxone® and methadone.\(^22,23\)
- The BBI expects that most patients be maintained on Suboxone® for at least one year, if not longer although this recommendation may be contrary to fixed notions held by patients, their family members, and even their physicians.

4. **How can I support patients on Suboxone® in their addiction self-management?**

One concrete way continuing care physicians can support the recovery management of their patients is through the recovery check-up. In addition, physicians can help patients identify concrete and realistic action steps for how they will sustain positive behavior change between visits. For example, how many counseling sessions will a patient attend or how many job applications will be submitted.

5. **What is the recovery check-up?**

The recovery check-up includes key questions that identify how and with whom patients are spending their time, what life stressors may be challenging their recovery, how they view their recovery overall, and what support systems are in place to help patients cope with life problems. It also includes noting and discussing any aberrant drug-taking behaviors.

6. **What are aberrant drug-taking behaviors?**

From time to time, patients may exhibit concerning behaviors such as complaining of non-specific problems requiring high dosages of medication, requesting more medication, requesting non-scheduled refills, etc. Many of these behaviors were previously known as “drug-seeking” behaviors.

- The preferred term now is aberrant drug-taking behaviors.
Aberrant drug-taking behaviors do not necessarily always equal prescription drug abuse or active addiction.
Aberrant drug-taking behaviors represent risk factors that warrant addressing, increased monitoring, and support.
There is a spectrum of aberrant drug-taking behaviors from less concerning (and less predictive of a substance use problem) to extremely serious (see Appendix C).

7. **What do I do if a patient exhibits aberrant drug-taking behaviors?**
If aberrant drug-taking behaviors occur, particularly a pattern of them or any of the more serious ones, respond as follows:
- Reduce the frequency and quantity of prescriptions and increase the frequency of visits.
- Evaluate for and help the patient manage any relapse.
- Help the patient re-connect to or increase amount of counseling at the BBI Treatment Program.

8. **What are risk factors for relapse?**
- Significant cravings, sometimes manifest as onset of vivid drug dreams
- Untreated depression or other psychiatric conditions
- Untreated pain
- Withdrawal (new onset of acute symptoms or protracted symptoms)
- Stress, such as loss of a loved one, becoming homeless, financial stress, or suffering abuse
- Associating with other people who are using drugs
- Lack of a recovery support network of people who do not use drugs (e.g. family, peer support)
- Idle, free time

9. **How do I respond when I identify risk factors for relapse in my patients on Suboxone®?**
- Encourage the patient to increase his/her use of recovery supports including:
  - Attending more AA/NA meetings, or other community-based support groups
  - Contacting peer mentors or a sponsor
  - Reaching out to supportive, non-drug using family and friends
  - Avoiding areas or people with whom he/she used to use drugs or drink
  - Increasing engagement in recovery-related activities
  - Increasing engagement in formal substance abuse counseling at the BBI treatment program
- Treat depression
- Work with patient on ways to minimize pain, if that is present
- Discuss any drug dreams with the patient and help him/her identify possible triggers for them
- For very intense cravings or drug dreams, it may be appropriate to increase the dose of Suboxone® temporarily, especially if the patient is on less than 24mg daily
- Explain and manage protracted withdrawal, preferably with non-pharmacological means
• Set specific, concrete goals with the patient for a realistic number of recovery contacts, supports, or activities he/she will achieve over a week or until the next visit
• See the patient again or have a telephone contact within 2-3 weeks for a recovery check-up, evaluate the risk factors, and re-assess the Suboxone® dose

10. What is protracted withdrawal?
Protracted withdrawal defines a constellation of symptoms that occurs in some patients for months to years beyond the cessation of acute withdrawal symptoms from a particular drug.

• Anhedonia and insomnia are two prominent symptoms often reported by patients and observed by their families and caregivers.
• There is no currently standardized or universally accepted diagnostic definition for protracted withdrawal due to limited research.24
• Reassurance and helping patients establish good sleep hygiene often helps. Judicious use of antidepressants may be warranted for unremitting symptoms.
Section 6: Integrating Suboxone® and Recovery Facilitation into the Office Setting

The Initial Visit

The initial visit is critical in beginning to develop relationships, build trust, and make the experience as positive as possible for the patient, the physician, and the whole practice. Starting off with a positive interaction in which the patient feels respected and supported makes the patient more likely to want to continue in care. It also makes for a more rewarding experience for the physician and the practice.

A. Goals for the initial visit:
   1. Introduce the patient to the practice, the continuing care physician, and other key personnel
   2. Address questions and concerns the patient may have
   3. Set clear expectations of and for patients
   4. Gather information
   5. Ensure adequate medication until next visit

B. Recommendations for the Initial Visit (See Appendix D for fillable checklist)
   1. Schedule as a new patient – this allows time to review Suboxone® and opioid addiction treatment and other aspects of the patient’s health.
   2. Review history and physical information from the BBI treatment program and complete or update as needed. Particularly review medication list and allergies.
   3. Assess current effectiveness of Suboxone® dose.
   4. Ask about counseling experience at or outside of the referring treatment program.
   5. Explain the recommended use of routine urine toxicology screens to monitor for the presence of Suboxone® and illicit drugs.
   6. Review, have patient sign, and provide patient with a copy of clinic policies and procedures for prescribing of Suboxone®. This could be part of any controlled substances policy or a separate document.
   7. Refer for laboratory testing as indicated by history and physical examination, including urine toxicology testing for opiates, buprenorphine, cocaine, and benzodiazepines, at a minimum.
   8. Ask the patient for the name and number or location of the pharmacy they use for their Suboxone® prescriptions.
   9. Check to make sure the Suboxone® prescription authorization with the patient’s insurance is current.
   10. Ensure the clinic has the correct name and contact information for the patient’s HCAM BBI advocate.
   11. Provide a prescription for 14 days of Suboxone® and schedule appointment to see back in two weeks for a shorter visit.
   12. Provide prescriptions and follow-up appointments for other aspects of the patient's overall medical care.
C. Dosing Tips:
- Since BBI patients transition from a BBI treatment program stabilized on Suboxone®, continuing care physicians should expect not to have to change the dose in the initial period after transition.
- The target dose of Suboxone® for an individual patient is the minimum dose at which the benefit outweighs risks and adverse side effects.
- Adequacy of the Suboxone® dose can be assessed by asking about the presence of cravings, including drug dreams, and presence of withdrawal symptoms.
- The BBI recommends not asking about specific withdrawal symptoms up-front, as patients may answer in the affirmative even if those symptoms are not truly present.
- Most patients are maintained on 12mg to 16mg daily but individual dosage needs may vary.
- Generally, patients should have one prescriber for all of their Suboxone® prescriptions and one pharmacy where they get all the prescriptions filled.

Follow-Up Visits
Over the course of follow-up visits, relationships build as the patient learns about and experiences the practice and the physician, and the physician and the practice learn about the patient.

A. Frequency of Visits and Prescriptions:
- The BBI recommends that physicians see patients and write prescriptions every two (2) weeks after the initial visit for one (1) or more visits.
- After one (1) or more every other week visits, physicians can see patients monthly for visits and prescriptions, with the frequency of visits and prescriptions adjusted according to clinical judgment.

B. Goals for Follow-up Visits:
1. Assess patient’s management of addiction and co-morbid medical conditions
2. Provide support and encouragement
3. Ensure adequate medication until next visit

C. Recommendations for Follow-up Visits: (See Appendix E for fillable checklist)
1. Fill in any needed history and physical examination such that by the end of the 3rd visit, the patient has received a complete history and physical examination, including medical, psychiatric, substance use history, and substance use disorder treatment history and response.
2. Assess effect of Suboxone® dose, including review of last visit’s urine toxicology test results.
3. Assess side effects from Suboxone®.
4. Conduct recovery check-up and help set realistic goal(s) for intervening period until next visit.
5. Note presence of any aberrant drug-taking behaviors.
6. Refer for necessary dental, preventive, psychiatric or specialty medical services.
7. Provide age-appropriate immunizations if needed.
8. Laboratory testing as needed and indicated by medical conditions, including urine toxicology testing for opiates, buprenorphine, cocaine, and benzodiazepines.
9. Schedule next visit.
10. Provide prescription for Suboxone® of duration to last until next visit.

<table>
<thead>
<tr>
<th>Key Don’ts for Buprenorphine Prescribers</th>
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<tr>
<td>1. Do not back date or forward date prescriptions.</td>
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<td>2. Do not use prescriber signature stamps on prescriptions.</td>
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<tr>
<td>3. Do not have a non-waivered physician or non-physician sign prescriptions for the primary prescriber.</td>
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1. **How does the office manage Suboxone® patients when the primary care physician is away?**

   The optimal alternative is to have a back-up prescriber -- document the reason for the alternate prescriber and how long the alternate prescriber will be responsible for Suboxone® prescriptions.

   1) In the event of a planned absence of the primary prescriber
      a. Have a back-up, waivered prescriber.
      b. If no back-up prescriber is available, the primary prescriber can write for or call in a refill of Suboxone®. Continuing care physicians should use this option sparingly to not lose connection with the patient.
      c. Alternatively, if no back-up prescriber is available, the primary prescriber can write out any needed future prescriptions, date them on the day they are being written but add to the prescription “Do not fill until XXXXX”. These can then either be given to the patient to take to the pharmacy or kept at the clinic and given to the patient closer to the appropriate fill date.

   2) In the event of an unplanned absence of the primary prescriber
      a. Have a back-up, waivered prescriber.
      b. If no back-up prescriber is available, the primary prescriber can call in a refill as Suboxone® is a Schedule III medication but some pharmacies will want a copy of the original script either by fax or via mail. No e-prescribing of controlled substances is available yet.

2. **How do I easily get Suboxone® authorization from Medicaid Managed Care Organizations (MCOs) or Medicare Part D?**

   While each payer establishes their own procedure for obtaining authorization, there are commonalities to the information they require and their procedures.
The BBI recommends that physicians track prescription authorization information for patients and obtain re-authorization prior to authorization expirations. Being familiar with the specific forms used and the information required by each payer, such as what other treatments have been tried, will help make the re-authorization process as smooth as possible. HCAM advocates can be consulted for assistance with any questions the office may have.

Note: By state regulation, pharmacies are allowed to provide 72 hours of medication to a patient with a bona fide prescription for Suboxone® while awaiting pre-authorization. Patients or the provider’s office likely will need to advocate for this with the pharmacist.

3. I wrote two prescriptions for the two different dosage strengths of Suboxone® -- will a patient with Medicaid have two co-payments? Yes -- if the physician writes two prescriptions or refills for the two dosage strengths of either brand name or generic Suboxone®, the pharmacy will charge the patient two separate co-payments.

4. How do I bill for visits with patients on Suboxone®? Billing for visits with patients on Suboxone® is no different than billing for other patient encounters.
   - Physicians should use the American Medical Association’s CPT coding system with which they are familiar.
   - The opioid dependence diagnosis code should be secondary.
   - The primary diagnosis code should be either a medication management or other medical or psychiatric code, depending on the content of the visit and the physician’s specialty.

Commonalities:

1) Most authorizations for Suboxone® are for specific blocks of time, after which the prescriber must obtain re-authorization.
2) Some payers ask for information on counseling services the patient is receiving in addition to the Suboxone®. However, each payer may define counseling differently. Primary care physician monitoring and support, formal counseling at an outpatient program, NA/AA meeting attendance, and other supportive activities may all be acceptable services for the purpose of prescription authorizations.
3) Most payers ask for urine toxicology test results as part of the authorization paperwork. Physicians should include at least two recent results, including tests demonstrating the presence of buprenorphine and the absence of illicit drugs.
Section 7: Alcohol, Illicit Drug, and Tobacco Use

1. What do I do if a patient relapses to drug or alcohol use?
In cases of relapse, the BBI recommends that the continuing care physician contact the HCAM Treatment Advocate for that patient to help facilitate a re-connection to counseling at the BBI treatment program.

- A relapse to drug or alcohol use does not necessarily mean that the continuing care physician should stop prescribing Suboxone®.
- Talk with the patient about the circumstances of the relapse.
- Assess the patient’s readiness to change their use as he/she may at this point be in pre-contemplation, contemplation, or even the action stage of change.
- Increase the frequency of visits and decrease the quantity of Suboxone® prescribed.

2. When should I transfer a patient to specialty substance abuse treatment for Suboxone®?
Continuing care physicians will vary in their comfort level with continuing to prescribe Suboxone® for patients who have relapsed or are exhibiting aberrant drug-taking behaviors.

- If patients have relapsed or are exhibiting serious aberrant drug-taking behaviors and have urine toxicology test results negative for buprenorphine, continuing care physicians should discuss with patients and transfer Suboxone® treatment back to the BBI treatment program or transfer the patient to methadone at an opioid treatment program.
- If patients have relapsed or are exhibiting serious aberrant drug-taking behaviors and have urine toxicology test results that are positive for buprenorphine, continuing care physicians should discuss the situation with the patient, assess readiness to change behaviors, and proceed as with other relapse or increased risk for relapse. Consider obtaining consultation from the BBI treatment program physician or BBI Medical Director.

Resources:

1) The HCAM BBI advocate assigned to the patient can provide information and assistance (410-649-0529)
2) Contact BBI Medical Consultants for guidance (For information, contact Bonnie Campbell, BSAS, bcampbell@bsasinc.org or 410-637-1900 ext. 252)
3) Consult with the BBI treatment program physician (BBI treatment programs are listed on the BSAS Buprenorphine website at www.bsasinc.org > select buprenorphine)
4) Consult the BSAS-BBI website Community of Practice page to ask for guidance (see www.bsasinc.org > select buprenorphine > Forums)
5) Contact a Buprenorphine Physician Mentor through the PCSS-Buprenorphine website (www.pcssb.org)
3. How do I manage a patient who relapses to cocaine use?
Discuss any positive urine toxicology test result for cocaine with the patient.

- Recognize that patients often feel significant shame and guilt after a relapse.
- Assess readiness to change cocaine use.
- Reinforce recovery management skills.
- Reduce the duration and quantity of Suboxone® prescriptions.
- Monitor patients more closely for aberrant drug-taking behaviors.
- If cocaine use persists, contact the patient’s assigned HCAM BBI advocate and refer the patient for counseling at the BBI treatment program.
- If cocaine use persists and serious aberrant drug-taking behaviors appear, a temporary return to a BBI treatment program may be warranted.

4. How do I manage a patient who is smoking marijuana?
- Assess whether the patient’s use and associated behaviors meet DSM-IV diagnostic criteria for abuse or dependence.
- Assess for aberrant drug-taking behaviors of Suboxone®.
- Assess readiness to change marijuana use at each visit and employ brief interventions to try to move the patient along the stages of change.
- Concurrent marijuana use does not necessitate discontinuing Suboxone®.
- Consult with the BBI medical director for additional recommendations.

5. How do I manage cigarette smoking in patients on Suboxone®?
Patients on Suboxone® may transition to a continuing care physician still in the precontemplative or contemplative stage of change with regards to smoking.

- Morbidity and mortality from nicotine significantly affects people with substance use disorders, even after they have achieved recovery from all other substances of abuse.26,27
- Effectively addressing nicotine dependence strengthens recovery and lengthens the time to relapse to other drugs.28,29
- Brief interventions and pharmacological therapies for smoking cessation are effective in patients with addiction.30
- At every visit, assess a patient’s stage of change and readiness to change nicotine use, provide brief interventions, and offer pharmacological therapies.
6. How do I manage a patient who drinks alcohol?
Alcohol use can significantly complicate Suboxone® treatment as it puts patients at risk for life-threatening respiratory depression.

- Identification of alcohol use by patients on Suboxone® should prompt intervention by continuing care physicians.
- The BBI strongly recommends treating alcohol abuse or dependence with combinations of counseling and medications, especially for patients in the contemplation or action stages of change.\(^3\)
- Disulfiram (Antabuse) and acamprosate (Campral®) are options for patients on Suboxone®.
- Oral and injectable naltrexone (ReVia® and Vivitrol®, respectively) are contra-indicated in patients on Suboxone® due their opioid antagonist properties.
- Some patients with severe alcohol dependence in addition to opioid abuse who have been unable to achieve recovery from alcohol may be effectively treated with oral or injectable naltrexone, after the patient is titrated off Suboxone®. This transition likely will require referral back to formal substance abuse treatment to more closely monitor the patient and minimize risk of relapse to opioids.
- Consider also involving peer support services.
- Screen for and treat depression and anxiety, common in patients with alcohol problems.

7. How do I manage a patient who takes benzodiazepines such as Klonopin®?
The combination of Suboxone® and any benzodiazepine increases a patient’s risk for morbidity and mortality. The initial step in addressing concurrent benzodiazepine use is determining whether diagnostic abuse or dependence is present and discussing concerns with the patient.

- Continuing care physicians should expect that patients transitioning to them on Suboxone® have already had an assessment and treatment for benzodiazepine abuse or dependence.
- If recurrent benzodiazepine abuse or dependence is suspected (excessive sedation and difficulty functioning, accidents, serious aberrant drug-taking behaviors), the BBI recommends several steps:
  - Quickly coordinate care with the benzodiazepine prescriber to share information regarding the possibility of relapse.
  - Decrease the frequency and quantity of Suboxone® prescriptions.
  - Increase visits, counseling sessions, and other contacts with the patient.
  - Consider temporary referral back to the BBI treatment program for higher intensity treatment and Suboxone® management.
- If the benzodiazepine use is consistent with less serious aberrant drug-taking behaviors or does not meet criteria for diagnostic abuse or dependence, the BBI recommends:
- Coordinate care with the benzodiazepine prescriber to share information regarding diagnoses, progress in treatment, and the development of aberrant drug-taking behaviors.
- Consider temporarily decreasing the frequency and quantity of Suboxone® prescribed.
- Consider assuming responsibility for prescribing the benzodiazepines after consultation with other prescribers and then gradually taper the medication, possibly by substituting longer-acting agents for short-acting ones.
- Tapering off benzodiazepines should be done concurrently with counseling and the introduction of non-benzodiazepine medications for underlying anxiety disorders.
Section 8: Mental Health Issues

1. How do I best manage anxiety among patients on Suboxone®?
Symptoms of anxiety are extremely common among patients with opioid dependence, and may persist despite adequate treatment with Suboxone®.

- The differential diagnosis includes anxiety disorders such as panic disorder, PTSD, obsessive-compulsive disorder, and generalized anxiety disorder.
- Also consider conditions such as hyperthyroidism or other substance use disorders.
- Symptom management may include pharmacological and non-pharmacological interventions including the avoidance of caffeine.
- Benzodiazepines should generally be avoided in patients on Suboxone®.
- A referral to a psychiatrist, psychologist, and mental health therapist may be necessary for diagnostic and treatment purposes.

2. Are there any special considerations for patients with depression?
Depression is a very common symptom experienced by patients with opioid dependence and if left untreated can adversely impact recovery from substance use disorders.

- The differential diagnosis includes psychiatric conditions such as major depression, bipolar disorder, situational depression (i.e. adjustment disorder with depression), and schizoaffective disorder.
- Also consider medical disorders such as hypothyroidism, neurosyphilis, or in association with neurological disorders, such as stroke, Parkinson’s, or traumatic brain injury.
- There is some evidence that buprenorphine alone may improve symptoms of depression but it is not FDA approved for the treatment of depression.
- First-line treatments for depression include SSRIs and SNRIs.
- A referral to a psychiatrist, psychologist, and mental health therapist may be necessary for diagnostic and treatment purposes.
Section 9: Surgery and Pain Management

1. **How do I manage a patient on Suboxone® undergoing an elective surgical procedure?**
   For acute, anticipated pain, such as pain associated with scheduled, elective procedures, coordination and planning is the key.
   - Before the procedure, coordinate with the providers involved (surgeons, anesthesiologists, and dentists) to ensure adequate anesthesia intra-operatively and post-procedure.
   - Include family/significant others as appropriate in discussions with patients before the procedure. Family can play a role in reducing the risk of misuse of any prescription opioids.
   - Patients should discontinue Suboxone® 24-36 hours prior to the procedure.
   - If withdrawal symptoms occur, treat symptomatically.
   - Include as many non-systemic, non-opioid interventions as possible intra-operatively, including nerve blocks and local or regional anesthesia.
   - If full-agonist opioids are needed post-op, provide short-acting formulations, titrated to adequate analgesia, preferably in combination with non-opioid analgesics. Prescribe limited quantities for short duration, and no refills.
   - Higher doses than usual of full-agonist opioids may be required due to the opioid tolerance resulting from Suboxone® maintenance.
   - Avoid methadone as it significantly complicates the resumption of Suboxone®.
   - See patients in follow-up soon after the procedure to assess pain, use of the prescription opioids, and develop a plan for tapering and returning to Suboxone®.
   - Taper the full-agonist opioid as pain improves. Cover remaining pain with non-opioid analgesics.
   - Patients can resume taking Suboxone® 8-12 hours after the last dose of the full agonist opioid, when he/she is experiencing mild to moderate withdrawal.
   - For minor procedures, especially for patients maintained on lower doses of Suboxone®, adequate pain relief may be achieved by a temporary increase in the Suboxone® dose and increasing the dose frequency to every 6 or 8 hours.

2. **How do I manage a patient on Suboxone® experiencing acute pain?**
   For acute, unanticipated pain, there is little time for planning.
   - Discontinue Suboxone® and begin a high potency opioid (such as fentanyl) in an attempt to override the mu receptor blockade of the Suboxone®.
   - Monitor patients closely as higher doses of full agonist may be required and, as the Suboxone®’s blockade dissipates, the full agonist effect may lead to over sedation and respiratory depression.
   - Consider additional interventions such as regional anesthesia.
   - Taper full-agonist opioids as the acute pain resolves or can be managed with non-opioid medications.
• Patients can resume taking Suboxone® 8-12 hours after the last dose of the full agonist opioid, when he/she is experiencing mild to moderate withdrawal.

3. How do I manage a patient on Suboxone® who develops chronic pain?
This is still an ambiguous area primarily because generic buprenorphine and Suboxone® are not currently FDA-approved for treatment of chronic pain.

• The first step is to target the particular type of pain with combinations of non-opioid agents and non-pharmacological therapies.
• Full-agonist opioids are contra-indicated in patients maintained on Suboxone® due to precipitated withdrawal that may occur if Suboxone® is taken shortly after the self-administration of full-agonist opioids.
• Full-agonist prescription opioids confer a significant risk of relapse in patients with opioid dependence so should not be first-line therapies for the management of chronic pain in these patients.33
• Suboxone® significantly blocks the efficacy of full-agonist opioids taken after Suboxone® administration because of its higher affinity for the mu-opioid receptor.
• Some physicians prescribe sublingual Suboxone® off-label in multiple doses to effectively treat concomitant chronic pain and opioid dependence.
• Some patients will have considerable improvement in chronic pain with an increase in Suboxone® dose.

4. Can I prescribe tramadol for pain management in patients on Suboxone®?
Tramadol is a centrally acting synthetic opioid analgesic34 with activity at the mu-opioid receptor and weak activity as serotonin and norepinephrine reuptake inhibitors. Continuing care physicians should exercise caution in prescribing tramadol for patients receiving Suboxone®:

• Early studies suggested less abuse and addictive potential with tramadol.35
• Reports are increasing of patient seeking treatment for tramadol abuse and dependence.
• Tramadol increases seizure risk and has led to life-threatening serotonin syndrome in combination with serotonergic agents, such as SSRIs.36
Section 10: Pregnancy

1. How do I manage a pregnant patient on Suboxone®?
The standard of care for opioid-dependent pregnant women has historically been methadone.

The Mother study, a multi-site randomized controlled trial of 175 pregnant, opioid-dependent women, has expanded treatment options to include Suboxone®. There is currently no evidence of long-term harm to children born to women treated during pregnancy with either methadone or buprenorphine.

Both methadone and Suboxone® are FDA pregnancy category C.

Recommendations:

1) Switch patient to mono-formulation buprenorphine when possible to avoid exposure of the developing fetus to any medically unnecessary naloxone.
2) Coordinate care with the obstetrician or mid-wife to monitor women for withdrawal symptoms as this needs aggressive treatment to prevent fetal intrauterine withdrawal.
3) Educate women that their newborn children will likely exhibit symptoms of neonatal abstinence syndrome but this is easily and effectively treated.
4) Switch women back to Suboxone® as soon as possible, either during the post-partum period for women who are not breastfeeding or shortly after breastfeeding ceases.

NOTE:

- Pregnant women transitioning from BBI treatment programs should already have been switched to the buprenorphine mono-product.
- The BBI strongly recommends that women use effective contraceptive methods if they are not interested in becoming pregnant.
Section 11: Discontinuing Buprenorphine

1. How do I respond to a patient who wants to come off Suboxone®?

The BBI supports long-term maintenance treatment with Suboxone® based on the evidence that retention in care and medication maintenance is associated with the best outcomes. At times, though, patients do not want to continue taking the medication.

Some patients believe, or are told by others, that taking Suboxone® means they are still addicted, or not fully in recovery. Continuing care physicians should provide accurate information regarding the risks of tapering off Suboxone® so patients can make informed decisions about their own health.

- Continuing care physicians should explain that Suboxone® causes physical dependence but this is not the same as addiction.
- Further explain that addiction is a chronic, long-term brain disease characterized by self-destructive behaviors and compulsive drug seeking and use, despite harmful consequences.²
- Patients maintained on Suboxone®, managing their addiction and other health issues, and living self-directed lives without the need for drugs or alcohol are completely in recovery.
- Ask how confident the patient is of maintaining recovery after tapering off.
- Explain that every year of sustained recovery increases the likelihood of sustaining recovery for an additional year.³
- Stress that after five years of sustained recovery, a person’s relapse risk drops below 15%.³

Despite explanation and education, some patients are adamant about tapering off the medication, and ultimately this decision is up to them. In preparing for this, continuing care physicians can help patients keep the focus on recovery:

- Explain the factors that increase the likelihood of sustaining recovery after tapering off Suboxone®
  - Stable housing
  - Employment or significant involvement in recovery-related activities
  - Stable medical and psychiatric conditions
  - Strong support network
  - No legal issues
  - Other substance use disorders in remission
- Encourage the patient to complete a tapering readiness assessment
  - This can provide the physician and the patient with information for collaborative discussion and decision-making around tapering off or, just decreasing, Suboxone®.
  - It can be completed by the patient alone for review with the physician, the physician and the patient together, or another clinical staff member and the patient (see Appendix F for Taper Readiness checklist).
- Use the information gathered to help the patient develop and implement a concrete plan to sustain recovery as he/she tapers off Suboxone®.
2. **How do I safely taper a patient off Suboxone®?**

The recommended approach is “go slow”, whether the patient is tapering off Suboxone® with the agreement of the continuing care physician or against medical advice. Tapering by 1-2mgs per month:

- Allows a patient to regain steady state between dose changes
- Minimizes opioid withdrawal symptoms
- Gives the patient time to solidify recovery areas that may require more attention

Allow the patient to stop or slow down the taper at any time and resume the therapeutic dose should cravings or withdrawal symptoms occur. Some patients eventually become more accepting of Suboxone® maintenance when they understand that they have the autonomy of deciding when and if to taper the medication.
Section 12: Urine Toxicology Testing

Toxicology testing is used as a tool for monitoring effectiveness of treatment and to identify potential relapse early. Revised terminology in describing toxicology test results aligns with the chronic disease model of addiction and removes stigma.

- “Positive” or “Unexpected” test results replace the colloquial term “dirty urine”.
- “Negative” or “Expected” results replace the term “clean urine”.

1. What are the goals of urine toxicology testing?
   - Confirm progress in recovery (toxicology test negative for substances of abuse, particularly opioids)
   - Confirm the therapeutic benefit of Suboxone® (toxicology test positive for buprenorphine)
   - Assess for the presence of other substances that may jeopardize recovery and require treatment or intervention (toxicology test positive for substances of abuse)

2. What should I test for in patients maintained on Suboxone®?
   Toxicology testing needs to take into account the substances which pertain to an individual based on:
   - Their substance use history
   - Any controlled medications the patient is prescribed (including Suboxone®)
   - Substances that are commonly found in the patient’s geographic area (e.g. cocaine, alcohol, oxycodone) even if the patient does not have a history of their use.
   - BBI recommends that continuing care physicians order urine toxicology tests for, at a minimum, opiates, buprenorphine, cocaine and benzodiazepines.

   Other testing recommendations:
   - Test for barbiturates or amphetamines if the patient has a history of their use or there is a clinical rationale. The prevalence of these substances in Baltimore City is very low.
   - Test for LSD, PCP, bath salts, and Spice/K2 only if the patient has a history of their use or if there is clinical rationale.
   - Test for methadone with a specific request if the patient has a history of methadone treatment, illicit methadone use, or resides with people taking methadone.

3. What are the different methods of urine toxicology testing?
   Initial testing typically relies on an immunoassay which uses antibodies to test for a parent compound and/or its metabolite(s).
   - Note that the immunoassay for opiates detects morphine metabolites so will be positive for any morphine-based substances (including heroin, codeine, or morphine).
   - The immunoassay for benzodiazepines similarly will be positive across several different benzodiazepines.
Specific requests are needed for testing of synthetic opioids such as methadone, oxycodone, fentanyl, and tramadol.

Gas or liquid chromatography and mass spectrometry (GC/MS or LC-MS/MS) can distinguish specific substances and quantify levels. They are not recommended for initial testing as they are much more expensive.

4. How frequently should I order urine toxicology testing?
The frequency of toxicology testing depends on the patient, their progress in recovery, and their overall health status.

- Monthly urine toxicology test for recommended substances and other prescribed controlled medications.
- If aberrant drug taking behaviors arise, increase the frequency of toxicology testing.
- Testing more than once a week is unlikely to provide significantly more information, adds to cost, and may be difficult for patients and clinic staff to achieve.
- Random testing is best.

5. How should I interpret toxicology test results for Suboxone®?
Look for both buprenorphine and its active metabolite norbuprenorphine. The ratio of the metabolite to the parent drug should be at least 2:1. If there is no metabolite present and only buprenorphine, then the specimen has likely been adulterated.

6. How do I manage a patient with a positive urine toxicology test result who adamantly denies using any illicit substances?

- Review foods and all medications, including over the counter and dietary supplements, with the patient to identify those that may cause false-positive test results (see Appendix G for a list).
- Contact the lab’s toxicologist for assistance with test interpretation.
- Consider ordering a GC/MS or LC-MS/MS for more specific substance identification, particularly if the immunoassay was positive for opiates or benzodiazepines.
- Consider the positive urine toxicology test result in the context of how the patient is doing otherwise, including presence or absence of other aberrant drug-taking behaviors.
- Strongly consider temporarily increasing frequency of visits for closer monitoring, to address risk factors for relapse, and obtain additional toxicology test results.

7. How do I interpret a urine toxicology test result that is negative for buprenorphine?
The reasons for a buprenorphine negative urine toxicology test result include:

1. Patient has missed doses of Suboxone®
2. Patient is diverting Suboxone®
3. Patient is on a lower dose of Suboxone® that produces levels below the test cut-off level
4. Patient is using a urine sample obtained from someone else who is not taking Suboxone®
If there is concern for diversion or falsification of the urine sample as reasons for the negative test result, then continuing care physicians should discuss this with patients and transfer Suboxone® treatment back to the BBI treatment program or transfer the patient to methadone at an opioid treatment program.

8. **Should I do point-of-care urine toxicology testing or send patients/urine specimens to the lab?**

BBI recommends the use of both monthly send out testing to a laboratory and point-of-care testing. Assays for point-of-care testing are commercially available, but requires a Maryland State Lab Permit in addition to a CLIA waiver. The BBI encourages point-of-care testing as it gives providers and patients immediate information and feedback. All point-of-care test kits employ immunoassay methods.

9. **How can I conduct random testing in a busy primary care practice?**

- Patients should be informed at the initial visit to expect to provide a urine sample at any time, even if that means having to come in only for this.
- Collect a urine sample at every visit, but only test a random number of them.
- Alternatively, call patients in for a random, unscheduled visit for a urine drug screen.
  - For greatest effectiveness, the time between the initial phone call to the patient and the visit should be fairly short such as 24 – 48 hours.

10. **How do I ensure that the patient is providing an accurate urine specimen?**

- Have a clinic policy that patients should leave coats, bags, and purses outside of the bathroom for any urine sampling.
- Consider the use of temperature sensitive cups that can help detect adulteration.

11. **What do I do with a patient who reports not being able to produce a urine sample?**

Patients may report an inability to provide a urine sample for many reasons, most of which can be overcome with extra fluid intake and waiting about 30 minutes.

- Persistent reports of an inability to void without a clear anatomical rationale can be considered an indication of relapse or diversion.
- For patients with documented legitimate reasons (e.g. severe BPH, neurological compromise, paraplegia, etc.), oral swabs are available for toxicology testing for some substances.

12. **Is urine the only acceptable specimen for toxicology testing?**

Toxicology testing of other bodily fluids is available but with limitations. The BBI encourages the use of urine testing if at all possible.

- Oral swab testing only detects very recent use (in some cases use only within hours).
- There may be limits on the substances that can be tested with oral swabs.
- For patients on hemodialysis, continuing care providers may be able to coordinate having toxicology testing done by the dialysis center.
Section 13: Buprenorphine Diversion Prevention

Although the public health impacts of abuse and diversion of Suboxone® are much less than that for other controlled prescription medications and illicit substances, it is important for physicians and practices to have policies and procedures in place to minimize diversion.

Components of such policies and procedures can include:

- Patient-physician/practice controlled medication agreements
- Random “call-backs” with pill/film counts
- Urine toxicology testing for buprenorphine
- More frequent prescriptions of smaller quantity
- Involvement of family members and significant others
- Prescription drug monitoring programs

Key Points on Controlled Medication Policies and Procedures for Suboxone®

- They can be separate policies/procedures or agreements for buprenorphine and other controlled medications
- Another option is to incorporate Suboxone® prescribing into existing controlled medication policies and procedures.
- Any controlled medication policy and procedures need to apply and be used practice-wide to minimize aberrant behavior.
- Physicians should inform patients on the initial visit that the purpose of the policies and procedures is to protect patients and their treatment and ensure consistency across all clinic staff.

A. Patient-Physician/Practice Controlled Medication Agreements

Agreements between the patient, the physician prescribing the Suboxone®, and the practice can help:

- Minimize diversion
- Set clear expectations for patients and practice staff
- Prevent conflict when aberrant drug-taking behaviors occur

Key Points on implementing a Controlled Substance Agreement:

- Have a practice staff member (physician or nurse typically), review the agreement with each new patient, have the patient and reviewer sign, and provide a copy to the patient. This ensures that patients and staff know what is being agreed upon.
- Periodically review the salient items in the agreement. This ensures that patients clearly understand what is expected of them (e.g. not to increase the Suboxone® dose on their own, importance of adhering with visit appointments, safekeeping their medication, etc.), and can help prevent misunderstandings or miscommunications.
- An annual review of the signed agreement with the patient may help reinforce appropriate medication management.
- If it is clear that the patient fully understands the expectations, then failure to adhere can be interpreted as an aberrant behavior.

Key components of an agreement include (see Appendix H for one example)²³

1. **Expectations of patients:**
   a. Appropriate follow-through with and behavior at appointments
   b. Storing of controlled medications at home in locked cabinets, particularly for patients residing in homes with children, adolescents or other adults
   c. Open communication and collaboration with the prescribing physician/practice
   d. Having one prescriber and one pharmacy

2. **Expectations of the prescriber and the practice:**
   a. Provide adequate doses and lengths of prescriptions to ensure continuity of medication
   b. Assist patients in case of problems at the pharmacy with prescriptions
   c. Conduct respectful interactions with patients
   d. Collaborate on care plan with the patient
   e. Provide effective care

3. **Actions the physician and/or clinic may take under the following situations**²:
   a. Patients are unable to follow expectations or
   b. The side effects of the controlled medication outweigh the benefit the patient may be achieving or
   c. The controlled medication is no longer effective for the condition it is meant to treat.

4. Identification of the prescriber responsible for the controlled medication

5. Identification of the pharmacy chosen by the patient as the only place where he/she will fill controlled medications

6. Identification of the patient’s preferred hospital and emergency department

7. A release of information to the patient’s chosen pharmacy

---

²² It is often helpful to include a menu of different options here that can be applied in a step-wise, progressive fashion and aligned with the seriousness of the aberrant behavior or clinical situation.
B. Pill/film Recall and Counts
Random Suboxone® pill or film counts done either by the physician or nurse can help minimize diversion. There are several ways to operationalize this and the practice will need to identify what works for them. Inform patients up-front that random pill or film counts are part of the expectation of the practice. Two common ways to operationalize pill/film counts are:

1. Have patients bring their bottles or containers of Suboxone® with them to every visit to the clinic for any reason (e.g. blood pressure check).
   - On a randomly chosen visit, in the presence of the patient, count the pills or film packages remaining in the container, preferably during a visit not at the end of their prescription.
   - If aberrant drug-taking behaviors of lower seriousness are present, consider also having the patient keep and bring back opened, empty film packets for counting.
2. Call patients in for a random, unscheduled visit for a pill or film count.
   - For greatest effectiveness, the time between the initial phone call to the patient and the visit should be fairly short, such as 24-48 hours.

For either of these approaches, the following information should be noted:
- The date of the count
- The number of pills or film packages remaining in the container
- The number of empty opened film packets, if applicable.
- Information from the bottle or film package container
  - The number of pills or film packages that was dispensed to the patient
  - The date the prescription was filled by the pharmacy
  - The name of the pharmacy
  - The number of tablets or film to be taken by the patient according to the instructions on the container

If there is a discrepancy in the count, this preferably should be addressed at that visit or as soon as possible, preferably in person.

C. Urine Toxicology Testing for Buprenorphine
Testing for the presence of buprenorphine adds another objective piece of information for patients and physicians. Random urine toxicology testing can be done at the same time as unscheduled visits for pill or film counts.

D. More Frequent Prescriptions of Smaller Quantity
If aberrant drug-taking behaviors appear or if there is concern regarding the patient’s ability to manage larger amounts of medication, more frequent prescriptions of smaller quantity can minimize the potential for diversion.
E. Involvement of Family Members and Significant Others
With the consent of the patient, continuing care physicians can engage willing, responsible family members and significant others in assisting patients manage their Suboxone®, including storing it, watching patients take the medication, counting doses, and providing collateral information on the patient’s progress in recovery.

F. Prescription Drug Monitoring Program (PDMP)
Maryland’s PDMP is to come online for prescribers with DEA certificates sometime in 2013. Once that occurs, BBI continuing care physicians should be able to verify the filling of controlled medications including Suboxone® and identify any additional prescriptions filled and the prescribers.
Section 14: Overdose Prevention

Because of its pharmacological properties as a partial opioid agonist with a ceiling effect, overdose from generic buprenorphine or Suboxone® by itself is uncommon, particularly in opioid-tolerant individuals.

- The most common effect of exposure to generic buprenorphine or Suboxone® alone in opioid-naive adults is sedation.
- In children, accidental exposure to generic buprenorphine or Suboxone® can result in significant sedation and respiratory depression that requires immediate medical intervention.
- Since FDA approval of Suboxone® and Subutex® in 2002, no definite fatalities from either formulation alone are known in the U.S.

To prevent unintentional ingestion of Suboxone®:

- Advise patients to store their medication in a safe place away from the reach of small children.
- Locked cabinets provide extra protection for controlled medications and are recommended for patients residing in homes with children, adolescents or other adults.

Alerts for patients to prevent overdose from other opioids:

- If a patient uses a large amount of a full-agonist opioid to try to overcome the blockade effects of Suboxone®, that large amount at some point after 24-72 hours may represent a lethal amount once the dose of Suboxone® is out of his/her system.
- A patient’s opioid tolerance may have decreased while on Suboxone®. This means if a patient misses 4 or 5 days of Suboxone® and then relapses to a full-agonist opioid, such as heroin, the same amount of that opioid that produced euphoria and/or relieved withdrawal symptoms prior to taking Suboxone® may now represent a lethal dose.

Alerts for physicians and patients to prevent overdose:

- The doses of Narcan™ that are used to reverse an overdose from a full-agonist opioid are typically too low to reverse significant sedation from Suboxone®.
- Higher doses of Narcan™ may be needed in cases of overdose where Suboxone® may have been ingested along with other opioids.
Appendix A: Suboxone® Patient Transition Summary Form

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: ________________________________

(BHCA 3/23/11)
Appendix B: Counseling Confirmation Form

Patient Name: ____________________________

Instructions: In order for you to confirm for your continuing care physician that you are attending counseling sessions, take this form to every counseling session and request that an authorized person sign the form. Then bring the form to every physician visit.

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 patient 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 patient 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 patient 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 patient 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 confirmation of my participation in such activities.

Effective Dates:          to          

________________________    ______________________________
Patient Signature           Physician Signature
### Appendix C: Spectrum of Aberrant Drug-Taking Behaviors

<table>
<thead>
<tr>
<th>Less Serious</th>
<th>Most Serious</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aggressively complaining about need for medication</td>
<td>Injecting an oral formulation</td>
</tr>
<tr>
<td>Asking for specific medications by name</td>
<td>Forging prescriptions</td>
</tr>
<tr>
<td>Asking for non-generic medication</td>
<td>Unwilling to sign controlled substances agreement</td>
</tr>
<tr>
<td>Request to have medication dose increased</td>
<td>Selling medications</td>
</tr>
<tr>
<td>Taking a few extra, unauthorized doses on occasion</td>
<td>Use of aliases</td>
</tr>
<tr>
<td>Failing to bring Suboxone® prescription containers to the visit, if this was an expectation</td>
<td>Refuse diagnostic workup or consultation</td>
</tr>
<tr>
<td>Claiming multiple pain medicine allergies</td>
<td>More concern about the drug than their medical problem that persists beyond the third clinic visit</td>
</tr>
<tr>
<td>Visiting multiple doctors for controlled substances</td>
<td>Obtaining controlled substance analgesics from illicit sources</td>
</tr>
<tr>
<td>Hoarding medication</td>
<td>Consistently calling outside of clinic hours or when a particular physician is on call who prescribes controlled substances</td>
</tr>
<tr>
<td>Frequent calls to clinic</td>
<td>Deterioration at home or work or reduction of social activities because of medication side effects</td>
</tr>
<tr>
<td>Using a controlled substance for non-pain relief purposes (e.g. to enhance mood, sleep aid)</td>
<td></td>
</tr>
<tr>
<td>Failing to provide a requested urine specimen for toxicology testing</td>
<td></td>
</tr>
<tr>
<td>Failing to keep a random, unscheduled visit as requested for a medicine check or urine specimen collection</td>
<td></td>
</tr>
<tr>
<td>Frequent unscheduled clinic visits for early refills</td>
<td></td>
</tr>
<tr>
<td>Consistent disruptive behavior when arrives in clinic</td>
<td></td>
</tr>
<tr>
<td>Obtaining controlled medications from family members</td>
<td></td>
</tr>
<tr>
<td>Pattern of lost or stolen prescriptions</td>
<td></td>
</tr>
<tr>
<td>Anger or irritability when questioned closely about pain</td>
<td></td>
</tr>
<tr>
<td>Unwilling to consider other medications or non-pharmacologic treatments</td>
<td></td>
</tr>
<tr>
<td>Frequent unauthorized dose escalations after being told that is inappropriate</td>
<td></td>
</tr>
<tr>
<td>Urine toxicology test result negative for buprenorphine</td>
<td></td>
</tr>
</tbody>
</table>

**Source:** Olsen Y and Alford DP ⁴⁰
Appendix D: Checklist for Initial Visit with Patient from BBI Treatment Program

Pt Name: _____________________________ DOB: _____________ Date: _____________

☐ Review history and physical examination information from BBI treatment program

☐ Conduct or update New Patient H+P

☐ Assess current effectiveness of Suboxone® dose
  1. How is your dose of Suboxone® working for you?
  2. Are you having any cravings or drug dreams?
  3. What do you do when you have cravings or drug dreams?
  4. Are you having any withdrawal symptoms? If so, what symptoms?

☐ Ask about counseling experience
  ☐ Recommend continued counseling at BBI treatment program
  ☐ Recommend NA/AA or other recovery support group

☐ Review with patient and have patient sign a copy of clinic policies and procedures for prescribing of Suboxone® (signed copy goes in the patient’s chart)

☐ Provide patient with a copy of the clinic’s policies and procedures for Suboxone®

☐ Order labs as recommended for all pertinent medical or psychiatric conditions, including urine toxicology tests

☐ Schedule appointment to see back in two weeks for shorter visit

☐ Provide a script for 14 days of Suboxone® (or enough to last until next visit)

☐ Ensure that patient has prior authorization that is active for new practice
Appendix E: Checklist for Follow-up Visits with Patient on Suboxone®

Pt Name: ___________________________ DOB: __________ Date: __________

Has the patient had a complete history and physical examination including medical, psychiatric, and substance abuse history, treatments and patient responses?  Yes ☐  No ☐ (if no, complete H+P)

☐ Assess effect of Suboxone®
1. How is your dose of Suboxone® working for you?
2. Are you having any cravings or drug dreams?
3. What do you do when you have cravings or drug dreams?
4. Are you having any withdrawal symptoms? If so, what symptoms?
5. Are you experiencing any side effects from the medication (such as decreased sexual function?)

☐ Conduct recovery check-up
1. How have you been spending your time since I last saw you, both with obligations and free time?
2. Who have you been spending most of your time with?
3. Have there been specific things (stressors or triggers) that have been making it difficult to sustain your recovery? If so, what have they been? How have you been managing them?
4. Have you used any illicit substances or ETOH since your last visit?
5. What recovery-related activities have you participated in since our last visit?
6. How concerned are you right now about your ability to maintain your recovery until our next visit?
7. What recovery-related activities are you going to participate in between now and our next visit?

☐ Note presence of any aberrant drug-taking behaviors and discuss with patient

☐ Refer for necessary dental, preventive, mental health, or other specialty medical services

☐ Order monthly urine toxicology tests and other labs as recommended for co-morbid medical or psychiatric conditions

☐ Schedule return visit (interval dependent on risk for relapse and presence of aberrant drug-taking behaviors)

☐ Provide a script for Suboxone® to last until next visit

☐ Check authorization for Suboxone®
Appendix F: Suboxone® Taper Readiness Checklist

Patient Name: _______________________  MR#: _______________ DOB: ______________

Instructions: Please truthfully answer all of the questions below. The answers you provide will help you and your doctor determine how safe it is for you to come off Suboxone® right now, and identify areas in your recovery that might need more work so you can decrease your risk of relapse.

1. Do you live in stable, permanent housing? □ Yes □ No

2. Are you employed? □ Yes □ No

3. Are you on parole or probation? □ Yes □ No

4. Do you have any outstanding charges or warrants? □ Yes □ No

5. If you have mental health problems, do your doctors consider them to be stable?
   □ Yes □ No □ N/A*

6. If you have medical problems, does your doctor consider them to be stable?
   □ Yes □ No □ N/A*

7. Have you used any drugs or alcohol within the last 30 days?
   □ Yes □ No

8. How many hours per week are you involved in recovery-related activities?
   □ 1-5 hrs/wk □ 5-10 hrs/wk □ 10-15 hrs/wk □ >15 hrs/wk

9. How do you spend your free, idle time (check all that apply)?
   □ Mostly alone □ With family who are in recovery or do not use drugs or alcohol
   □ With friends in recovery □ With people, including family, who are still using

*I do not have any of these problems
Appendix G: 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 specific 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 (Vasopro®, Metabolite 356®, etc)
Indomethacin (Indocin®)
Methylphenidate (Ritalin®)
Phenmetrazine (Preludin®)
Phentermine (Pro-Fast®, Adipex®, Ionamin®)
Phenylephrine (in Robitussin CF®, Dristan®, DayQuil®, Sudafed PE®, Neo-Synephrine®)
Phenylpropanolamine (Acetumin®, Dextromethorphan®)
Promethazine (Phenergan®)
Pseudoephedrine (Sudafed®, Triaminic®)
Ranitidine (Zantac®)
Selegiline (Deprenyl®, Eldepryl®, Emsam®)
Thioridazine (Mellaril®)
Trimethobenzamide (Tigan ®)
Trimipramine (Surmontil®)
Trazadone (Desyrel®)
Tyramine

**BENZODIAZEPINES**
Diphenhydramine (Benadryl®)
Oxaprozin (Daypro®)
Sertraline (Zoloft®)
Zolpidem (Ambien®)

**BUPRENORPHINE**
Tramadol (Ultram®)

**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®)
Poppy Seeds*
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 H: Example of a Patient-Physician/Clinic Controlled Medication Agreement  
(Adapted from agreement by Dr. Elinore F. McCance-Katz)

**Patient Name:** _______________________________  
**MR#:** ___________________  
**DOB:** _____________

I am requesting that my doctor prescribe Suboxone®, a controlled medication, to me for treatment of opioid addiction. I freely and voluntarily agree to accept this controlled medication agreement and I understand what is being expected of me and what I can expect of my doctor and my clinic as outlined below:

i. I agree to keep, and be on time for, all my scheduled appointments with the doctor and any of his/her assistants.

ii. I agree to call the clinic ahead of time if I cannot make an appointment or am running late.

iii. I agree to conduct myself in a courteous manner in the doctor’s or clinic’s office and, in return, I understand that my doctor and other clinic staff will treat me with respect and courtesy.

iv. I agree to have one doctor prescribe Suboxone® for me and I will not seek out other doctors other places for additional prescriptions. My primary Suboxone® prescriber is: ___________________

v. I agree to fill my prescriptions at one pharmacy, and I will give my doctor and clinic the name and phone number to this pharmacy. I agree to conduct myself in a courteous manner at the pharmacy, and, in return, I understand that my doctor and/or clinic will assist me if I have trouble there with my prescription.

vi. If I have to change pharmacies, I will let my doctor know and provide him/her with the new pharmacy’s information.

vii. I agree that the medication I receive is my responsibility and I will store it in a safe, secure place, away from children and teenagers. I agree that lost medication will not be replaced, unless I have a police report to document that it has been stolen.

viii. I agree not to sell, share, or give any of my medication to another person. I understand that such mishandling of my medication is very serious and likely will result in my being unable to receive any further Suboxone® from my doctor. Instead, I will likely be transferred to a substance abuse treatment program where I will need to attend every day to receive medication until I am stable.

ix. I agree that my doctor will only give me prescriptions for Suboxone® at my regular office visits. If I miss a visit, I likely will not be able to get a prescription until the next scheduled visit. If my doctor has to cancel my appointment, he/she will make sure I receive my prescription in time to not disrupt my treatment.

x. I agree not to obtain medications from any physicians, pharmacists, or other sources without informing my doctor who prescribes Suboxone®. I understand that mixing Suboxone® with other medications, especially benzodiazepines such as Xanax® (alprazolam) or Klonopin® (clonazepam), alcohol, and other drugs of abuse can be dangerous and even lead to death.

xi. I agree to communicate openly and honestly with my doctor and report any use of drugs or alcohol that may negatively affect my recovery. In return, I understand that my doctor will work with me to the utmost of his/her ability to help me maintain and strengthen my recovery.

xii. I agree to take my Suboxone® as my doctor has instructed, and not to change the way I take my medication without first consulting my doctor. I understand that my doctor will prescribe me Suboxone® at an effective dose that helps me with the least amount of side effects. If my doctor determines that Suboxone® is no longer effective for my opioid addiction, I understand that I may be transferred to a substance abuse treatment program where I will receive counseling and be offered other medication options, such as methadone or naltrexone.

xiii. I understand that my doctor or clinic may call me at any time to bring in my medication or provide a urine sample for testing. I understand that not adhering with this may be considered a risk factor for mishandling of my medication and likely will result in changes to my treatment.

xiv. I understand that medication alone is not sufficient treatment for my disease and I agree to participate in counseling and/or recovery-related activities that my doctor either recommends or that he/she and I agree on together.

**Patient Signature:** ___________________________________  
**Date:** ___________________
Patient Name: ____________________________  MR#: ___________________  DOB: ____________

My preferred hospital is: ___________________________________________________

My preferred emergency room is: ____________________________________________

The pharmacy where I fill all my Suboxone® prescriptions:

Name of pharmacy: _________________________________________________________

Address of pharmacy: _______________________________________________________

Phone number for pharmacy: ________________________________________________
REFERENCES


