# Managing Patients in a Buprenorphine Practice

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MANAGING PATIENTS IN A BUPRENORPHINE PRACTICE

Goal
To prepare providers to manage problematic behaviors that may be encountered in patients with opioid use disorder and to use urine screening to measure treatment efficacy.

After completing this module participants will be able to:
• Summarize rules and regulations for a successful provider-patient relationship in office-based opioid treatment
• Determine what rules and regulations are needed to prevent and address patient problematic behavior in office-based opioid treatment
• Use a provider-patient treatment agreement to communicate expectations and responsibilities for both parties, and enforce consequences of not meeting expectations
• Explain concepts involved in the use of urine analysis for office-based treatment of patients with opioid use disorder

Professional Practice Gaps
The Substance Abuse and Mental Health Services Administration (SAMHSA), based on National Survey on the 2013 Drug Use and Health survey, found the following evidence of a continuing opioid epidemic and need for additional treatment among Americans age 12 and over:\n
• Current use:
  • 289,000 or 0.1 percent current users of heroin (similar to 2008 to 2012)
  • 4.5 million or 1.7% current users of non-medical use of pain relievers (similar to 2011 and 2012).

• New use:
  • 169,000 new initiates to heroin (similar to estimates from 2007 to 2012)
  • 1.5 million new initiates to nonmedical use of pain relievers (lower than 2002 to 2012, which was 1.9 million to 2.5 million).

• Receiving treatment: Only a small fraction of users needing treatment for an opioid use disorder receive it, especially for prescription pain relievers, but the numbers increased in 2013:
  • Past year receipt of treatment for heroin users rose from 277,000 persons in 2002 to 526,000 persons in 2013
  • Past year receipt of treatment for nonmedical users of prescription pain relievers increased from 360,000 in 2002 to 746,000 in 2013.

Buprenorphine is a safe and effective treatment for opioid use disorder that offers patients a more widely available, accessible, convenient treatment option as compared to traditional opioid treatment programs (OTP)\(^2-4\). The Drug Addiction Treatment Act (DATA) of 2000—an amendment to the Controlled Substances Act — allowed physicians who are not part of an OTP to prescribe buprenorphine with additional training and a waiver to the Controlled Substances Act. The Comprehensive Addiction and Recovery Act of 2016 (CARA) added nurse practitioners and physician assistants to the list of providers who can train to prescribe buprenorphine and become waivered.
The law requires physicians to complete an 8-hour buprenorphine training conducted by an approved organization in order to prescribe it; the required training for nurse practitioners and physician assistants is 24 hours. While buprenorphine is relatively safe, there are risks of overdose and death due to buprenorphine and there is a risk of diversion, which, in addition to skills needed to prescribe the medication effectively for each individual, are among the reasons for the mandatory training.

This buprenorphine training activity prepares providers to prescribe buprenorphine safely and effectively to address needs of the millions of Americans with opioid use problems. The activity has been developed to meet the DATA 2000 training guidelines as defined in Public Law 106-310-106th Congress as well as the Comprehensive Addiction and Recovery Act of 2016 (S 524, Title III, Section 303-114th Congress) and is endorsed by the American Society of Addiction Medicine, one of the approved training organizations named in DATA 2000. The activity content was initially based upon SAMHSA’s 2004 publication Treatment Improvement Protocol (TIP) #40: Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction and follow the Model Policy on DATA 2000 and Treatment of Opioid Addiction in the Medical Office. It has been edited to SAMHSA’s Sublingual and Transmucosal Buprenorphine for Opioid Use Disorder - Review and Update (2016), ASAM’s National Practice Guideline For the Use of Medication in the Treatment of Addiction Involving Opioid Use (2015), and the CDC’s guidelines on opioid treatment as well as CARA 2016. The courses are regularly reviewed and updated by ASAM members who are experts in the field of addiction medicine and buprenorphine treatment.

Specific Gap in Training:
Providers need to be able to manage patients with opioid use disorder as part of office-based opioid treatment with buprenorphine. Sections of TIP 40, describe the importance of non-pharmacological treatment and treatment monitoring and were updated in more recent guidelines. The FSMB Model policy describes critical aspects of patient assessment, including informed consent, treatment agreements, and patient education, which underscores the importance of providers who prescribe buprenorphine being familiar with patient management in treatment of opioid use disorder.

MODULE INTRODUCTION

Communicating the rules, expectations, goals, and boundaries of an office-based opioid treatment practice to the patients being treated is important. Patient-provider agreements, as well as regular patient monitoring, can help to ensure that patients are held accountable while receiving treatment. If patients are aware of this monitoring, it can help reduce the frequency of problematic behaviors, such as diversion or use of illicit drugs. Even with this structure in place, problematic patient behaviors may still be encountered, in which case the protocol described in advance in the patient-provider agreement can be followed. This module describes the structure needed to support patients in being successful in their buprenorphine treatment.

Case Illustrations
The following cases will be used to illustrate how to manage patients in a buprenorphine practice.

MRS. COPELAND

Mrs. Copeland has been seeing multiple providers in order to obtain Vicodin®.
Would Mrs. Copeland be a candidate for office-based buprenorphine treatment, despite her "doctor shopping"?

**MS. DAWSON**

Ms. Dawson is a 20 year old university student who has been smoking heroin for the past 15 months and wishes to begin buprenorphine treatment. How could a written, signed treatment agreement be used to help support her treatment?

**MS. CLARK**

Ms. Clark who is on buprenorphine maintenance recently had a slip up and used heroin to alleviate pain sustained from a back strain. Should you continue to provide buprenorphine treatment for Ms. Clark despite this relapse?

**Source**

This content was originally adapted from the Substance Abuse and Mental Health Services Administration's (SAMHSA's) Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction (TIP 40) (2004). Because it is the basis for the content, we do not cite the TIP 40 source in the text.

The content has been updated, as noted by citations, according to SAMHSA's (2016) Sublingual and Transmucosal Buprenorphine for Opioid Use Disorder - Review and Update, expert review, and other subsequent literature including The ASAM National Practice Guideline For the Use of Medication in the Treatment of Addiction Involving Opioid Use (2015).

*BupPractice* was created using NO pharmaceutical or other industry support.

**BUILDING RAPPORT**

**Importance of the Initial Visit**

The outcome of treatment for opioid use disorder has a great deal to do with the relationship between you and your patient. Setting a good precedent at the very first meeting will help you define this relationship in a positive manner. Be sure to:

1. **Establish trust**
   The primary purpose of the initial visit is to establish trust critical to the treatment's success. Your patient should feel comfortable disclosing any
anxieties or difficulties about treatment to you. To encourage future disclosures and build a partnership with your patients:

- Be open, understanding, empathetic, and willing to listen
- Maintain a nonjudgmental and straightforward response to patient concerns
- Use a patient-centered approach, respecting the patient's authority about their own experience, and avoid an overly authoritarian approach
- In the event of patient defensiveness, review your approach for whether you are using the above skills

2. Discuss confidentiality

To alleviate some of your patient’s concerns, discuss the confidentiality laws regarding addiction treatment as soon as the topic is broached. Many individuals with substance use disorders are anxious about seeking treatment, especially for illicit drug use. The laws ensuring confidentiality for opioid addiction treatment go above and beyond those protecting general medical patients, and patients commencing treatment should be aware of their rights.

TREATMENT STRUCTURE

The Benefits of Rules and Expectations for Patients and Your Practice

Unless you already treat addiction, you will most likely need to add practice policies that go beyond routine practice when starting Office-Based Opioid Treatment (OBOT). These additional policies promote a sense of security and confidence within the office-based opioid treatment. Patients often find such policies helpful, because they define the requirements and expectations placed on them in treatment and may answer potential questions. Multiple studies have shown that having policies that guide the patient toward behaviors that will improve outcomes (described in this module), results in better compliance and retention in OBOT maintenance.

Your patients and office staff should understand the rules and expectations, and consequences of breaking a rule. Determining policies in advance, ongoing monitoring for compliance, and enforcement of consequences are essential keys to success.

Research Supports Strong Treatment Structure

A study of heroin addicted patients in Sweden, theorized that a lenient policy toward lapses and use of other substances was resulting in a higher rate of overdose and treatment dropout. They adopted a policy of non-tolerance of such behaviors and enhanced treatment structure, including behavioral supports, to prevent such behaviors in the first place. Results support this approach:

2/3 were abstinent and employed after 7 years of this treatment approach and those who completed the program had no legal convictions. Problematic alcohol use was significantly reduced from baseline to follow-up (p < .001).

The increased risk of premature death associated with being discharged from a treatment program is the reason many programs avoid a policy of zero tolerance for substance use. In the above study, there was only one premature death among the 148 patients studied.
The psychosocial support met once per week for at least a year. Counseling aimed to change the patient’s behavior related to drug use and actively involve the patient in their own treatment.

**EXAMPLES OF EXPECTATIONS OF PATIENTS**

**Patient Expectations**
The following is a list of common expectations of patients in an office based opioid treatment practice. The list includes expectations for all patients, as well as additional expectations that may need to be imposed on specific individuals. Appropriate consequences, such as increased treatment structure or referral to a higher level of care, should accompany each expectation of the patient.

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<td><strong>Office Protocol</strong></td>
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<td>• The patient will call at least ___ hours before a scheduled appointment to say that he or she is unable to attend.</td>
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<td>• The patient will make satisfactory arrangements with the treating provider to pay for all services. (Alternatively, describe who handles insurance documents, etc.)</td>
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<td>• Lost prescriptions will not be rewritten.</td>
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<td>• New patients should only receive prescriptions for small amounts of buprenorphine.</td>
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<td>Buprenorphine prescriptions will be written for ___ days/weeks during the beginning of treatment. The patient must return to the office for a follow-up appointment in order to get a refill. If the provider determines there is acceptable progress, a prescription for longer length of time may be written.</td>
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<td>• Adherence to treatment may be a condition for prescriptions renewal.</td>
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<td><strong>Prescription Procedures</strong></td>
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<td>The patient will disclose to the clinician all opioid or other drug use.</td>
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<td>The patient agrees to come to the office for random urine drug testing when requested by the provider.</td>
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<td>• The patient will not adjust his or her own buprenorphine dose.</td>
<td>• The patient will participate in individual or group substance abuse counseling.</td>
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<td>• The patient will not share medication and will store it where others cannot obtain it.</td>
<td>• The patient will make a concerted effort to learn about community support and/or attend self-help groups and meetings.</td>
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EXAMPLE: OBOT POLICIES

Office-Based Opioid Use Disorder Treatment Policies - Example for One Practice

Practice: Steve Michael, MD, Anderson Health Center  Date: 01/18/2017

The following policies will be followed in this practice for opioid treatment. Note that in order to provide sufficient support for patients in this treatment program, some policies differ from our regular policies.

Office Policies

Communicating Our Opioid Treatment Policies to Patients:

- Review the policies in person with each patient, making sure that patients understand them. Offer an opportunity for questions.
- Present a written agreement between provider and patient that explains policies and expectations of the patient.
- The patient and provider must sign the written agreement.
- Review the policies with the patient again at the 2nd appointment.
- Update policies as needed according to patients' needs and behavior as outlined below.

Policies for Opioid Treatment Appointments

- Late for Appointments:
  - Patients who are later than 1 hour late for appointments must be rescheduled.
  - A limit of 2 times late will be tolerated. After being late twice, patients will not be rescheduled; they will be seen at the next regularly scheduled time.
  - Review these policies with the patient each time they are late for an appointment.
- Missed Appointments:
  - 24 hour notice is required for cancellations. Later notice is considered a missed appointment.
  - Patients may miss 1 appointment without penalty. Call to check on patient's status and reschedule.
  - For subsequent missed appointments, the patient will be charged for the missed appointment and seen at the next regularly scheduled appointment time.
  - Review these policies with patients each time they miss an appointment.

Patient/Provider Contact

To reach your provider or a designated representative, please call phone service at (555) 555-5555 and describe the nature of your problem. For all emergencies call 911.

Payment of Fees

- Payment is accepted in the form of cash only.
- Payment is expected on the day of treatment.
- We will provide records of treatment for patients to submit to insurance companies.
- Patients may have one appointment with non-payment and thereafter, treatment will be discontinued with a recommendation for a less expensive treatment, e.g., methadone clinic.
**Prescription Policies**

- Office visits are required for renewal of prescriptions for at least the first 3 months of treatment. Thereafter, prescriptions may be renewed regularly as long as patients attend follow-up appointments.
- Early renewal of prescriptions is not permitted.
- Lost prescriptions or medications will not be replaced.
- Requests for extra pills will not be honored.
- Patients are limited to using one pharmacy for their buprenorphine prescriptions.
- Patients who use more than one pharmacy will be warned for first instance. Further use of more than one pharmacy will result in discontinued treatment.
- The patient is limited to one prescribing provider. The Prescription Drug Monitoring program will be checked for each patient at least monthly and more often for patients who have been non-compliant.
- Patients who obtain buprenorphine from another provider/clinic will have their treatment at this clinic discontinued.

**Treatment Policies and Expectations of Patients**

This section describes policies for office based opioid treatment in this practice. Patients are expected to adhere to the following expectations. Non-compliance will result in the consequences described below:

**Treatment Goal:** The outcome of treatment for most patients in this practice will be long term maintenance on buprenorphine.

**Potential Benefits and Risks of Office-Based Opioid Treatment (OBOT):**

The potential benefits and disadvantages and risks that must be discussed with each patient include the following:

**Potential Benefits:**
1. Control of withdrawal symptoms when quitting opioid use
2. Supports patients with opioid use disorder in quitting other opioid use
3. Treatment can be conducted without regular attendance at a clinic to obtain medication

**Potential Disadvantages and Risks:**
1. Patients become physically dependent on buprenorphine
2. May experience some opioid-related side effects including constipation and, particularly when increasing dosage, mild sedation
3. Potential drug interactions with other substances, especially sedating drugs and alcohol

**Substance Use**

- Patients will be instructed to stop taking other opioid medications unless specifically instructed to take it.
- Patients are required to disclose the use of any psychoactive substance(s) to the provider. This means the use of consciousness altering drugs including narcotics, euphoriants, hallucinogens, marijuana, designer drugs whether illicit or licit.
  - If patients are discovered to have not disclosed the use of psychoactive substances:
    - Remind patients of the policy for the first instance and increase frequency of UDTs.
Discontinue treatment if there is a second instance of non-disclosure of use of psychoactive substance and refer to a higher level of care.

Patients are required to avoid use of substances that may cause an adverse interaction with prescribed medications. This includes psychoactive substances.

- If patients are discovered to have used substance(s) with adverse interactions:
  - Remind patients of the policy for the first instance and increase frequency of UDTs.
  - If there is a second instance, the patient will be referred to a higher level of care.

**Depression Screening**

- Patients will be asked a 2 question depression screening at each appointment and positive responses will receive further assessment.

**Urine Drug Screening Policies**

- Baseline urine drug tests (UDTs) are required for all patients in the opioid treatment program.
- Periodic UDTs are required for all patients.
- 1 to 2 UDTs will be performed per year for each patient. Additional UDTs will be completed for some patients having higher risk.
- UDTs may be scheduled or unannounced.
- Patients must bear the costs of UDTs. If they have insurance, they may seek reimbursement from insurance companies.
- The consequences of problematic UDT results include:
  - Increased frequency of UDT for the first episode.
  - Possible dose adjustment for opioid use.
  - Counseling referral if they are not already in substance use counseling.
  - Discuss the problem with the patient.
  - Second instances of problematic UDT results will result in discontinued treatment.

**Taking Medication as Instructed**

- Patients are required to take medication as instructed by the provider, for example, they may not crush or inject the medication.
  - If patients take medication other than as instructed:
    - Discuss the problem with the patient for the first episode.
    - Discontinue treatment with 2nd episode and refer to a higher level of care.
  - Patient dose changes are not permitted without consulting the provider.
    - If patients change their dosage on their own:
      - Remind the patient of the policy for the first episode.
      - Discontinue treatment if there is a 2nd episode and refer to a higher level of care.

**Safe Storage and Non-Sharing of Medications**

- Patients must agree to safe storage and non-sharing of medications.
  - Patients who share medications will have treatment discontinued immediately.
  - Patients who lose medication due to unsafe storage will be reminded of the policy for first instance, and have treatment discontinued if there is a second instance.
Mandatory Follow-up Visits

- Patients must return for follow-up visits as scheduled.
  - After the dose is stabilized, follow-up visits will be monthly for three months.
  - After 3 months of compliant, successful treatment, long-term follow-up visits will be biannual.

Criteria for Considering Treatment Successful

1. No intoxication from any substance use
2. Physical, psychosocial, and work-related functioning improved
3. No suffering from withdrawal
4. No experience of drug cravings
5. Following treatment protocol
6. Adherence to treatment agreement
7. Adherence to the treatment agreement and treatment plan

Relapse Policies

- Relapse to using opioids will not be grounds for stopping treatment the first time, but treatment structure will be increased, including more frequent appointments.
- A second episode of using opioids will result in the addition of further additional treatment structure, such as involving a third, responsible party. A pattern of non-compliance with treatment will plus continued use will result in discontinued treatment.
- If patients stop taking buprenorphine, they can have reinduction after an office visit where a revised treatment agreement is signed.
- Patients who have been dismissed from treatment and return with new motivation can be given one second chance with increased treatment structure.

Pill Counts

- Periodic pill counts are required of patients who are described as high risk at the initial or subsequent appointments.
- Schedule of pill counts: Twice per year, unannounced
- If the results of the pill count are problematic or if the patient fails to comply:
  - Discuss the problem with the patient for the 1st episode.
  - Discontinue treatment if there is a 2nd episode and refer to a higher level of care.

Counseling and Other Treatments

- Counseling and other treatment participation is required for patients with psychiatric diagnoses
- Consequences of not participating in recommended counseling or other treatments:
  - Warning 1st three instances
  - Discontinue treatment 4th instance and refer to a higher level of care

Patient Conduct

- Behaviors that will result in permanent dismissal from treatment include violence, stealing from the clinic, dealing drugs, or carrying weapons
- Other behavior that will not be tolerated:
  - Arriving intoxicated for appointments
  - Disruptive behavior
• Sustained payment problems
• Consequences for these behaviors include the following:
  • The patient will not be seen until the next regularly scheduled appointment for the first episode.
  • Discontinue treatment at 2nd instance and refer to a higher level of care.

Provider Signature:

Patient Signature:

**DISCUSSING RULES AND EXPECTATIONS**

The initial visit is an ideal time to discuss specific rules and expectations governing treatment. This helps patients understand what behaviors will most likely result in a successful treatment outcome and what you require in order for your practice to function smoothly. It also makes it easier to challenge problematic behaviors later that may occur during treatment.

- Discuss your general treatment philosophy, including your beliefs and your approach to treatment
- Communicate clear goals for the treatment
- Agree on the best way to approach those goals
- Present the expectations you have for the patient
- Clarify confusing points
- Explain to your patients that failure to comply will result in consequences.

**THINK AHEAD Question:**
What strategies would help ensure patient adherence to the opioid treatment program?

**HOW TO ADDRESS RULES AND REGULATIONS**

- Provide a printed copy of the rules, ideally, in the form of a written, patient-provider agreement. With a written, signed patient-provider treatment agreement, both parties have a resource to which they can refer.
- Both parties sign. Patient signatures verify that they understand and agree to the terms of treatment. The provider’s signature acknowledges a patient-centered rather than an authoritarian relationship.
- Re-review the rules soon after a patient has begun treatment as a reminder about what was agreed upon.
- Consider having a nurse or medical assistant help with patient orientation activities, such as refill policies and urine drug screen procedures.
- Use a patient education Appropriate Use Checklist to make sure you or a trained staff member discuss all aspects of buprenorphine treatment with every patient.
• Be sure to provide the written Medication Guide for the buprenorphine formulation you prescribe.

PRACTICE TIP
Don't make the mistake of being lax in your treatment structure in order to gain your patient's trust. It is possible to do both of the following:

1. Develop and maintain a foundation of trust in the practitioner-patient relationship.
2. Prior to treatment, establish an understanding of the treatment protocol. Identify behaviors that will not be tolerated and the consequences of such actions.

MOTIVATIONAL INTERVIEWING – RESISTANCE

Managing Patient Resistance
The interaction between the practitioner and the patient can produce resistance. For example, when the practitioner assumes the patient is more ready for change than is actually true, the patient may develop resistance to treatment.

To avoid building resistance

• Keep in mind that the patient is responsible for the decision to change.
• Monitor the patient's readiness for change, and do not push for change prematurely.
• Invite patients to consider a different perspective, but never impose that perspective on them.
• Affirm for patients that they have freedom of choice and self-direction.

To get back on track when a patient appears to be resistant:

• De-escalate resistance

Refocus on building rapport with the patient by using the basic skills of motivational interviewing, such as showing empathy, seeing the problem from the patient's view, affirming positive patient behavior or qualities, and practicing reflective listening. Re-establishing rapport with the patient will help him or her be open to engaging in a process that will move toward change. For example, a provider might say the following after getting off track:

Provider: Let's back up a second because I'd really like to understand how you are seeing this.

This could be followed by talking about a less-threatening health behavior, for example, with a heroin user, safe use of needles rather than quitting opioids.

• Work with the patient's resistance

  • Roll with the patient's resistance, that is, agree with it, rather than trying to counter it

Example:

  Patient: I just can't quit. I don't see it ever happening.

Provider: It seems to you like you'll never quit.
Patient: Well, I don’t know about ‘never.’

Provider: Tell me more about why it might not be ‘never.’

• Reframe the problem in a way that evokes less resistance from the patient.

Example:

Patient: I only know my sister and one or two friends who don’t smoke marijuana. Everyone else I know parties all the time.

Provider: That’s great that you already know three people who you can be around and count on not being tempted by their using marijuana in front of you.

CAUTION TIP
Keep safety in mind and the patient’s stability as you work with these skills. Their use assumes a certain degree of cognitive clarity on the part of the patient and emotional stability. If your sense is that the patient is not stable or capable of responding well to discourse such as the above, referral to a more structured treatment setting is indicated.

VIDEO: MANAGING PATIENT RESISTANCE

Motivational Interviewing - Managing Patient Resistance
A video that illustrates the use of Motivational Interviewing in response to resistant patient behavior can be found here: https://youtu.be/4_q9WPTnO4k.11

As you watch the video, notice how the provider alternates between skills that engage and connect with the patient and those that elicit his thoughts and feelings. She skillfully uses engaging skills, such as empathy, reflective listening, and agreeing with the patient (rolling with the resistance), in an attempt to diffuse his resistance. In further discussions, the provider would also need to respond to the patient’s repeated requests for vicodin, gathering more information as to whether or not it is actually needed. What is the patient's risk for opioids? If there is too much risk, the answer may be either alternative pain treatment or a high level of treatment structure. Is there moderate to severe pain that hasn't responded to first line treatments? If not, the answer to the patient's request may be "no." If the patient has opioid use disorder, buprenorphine treatment may be indicated. Sorting through all this complex information is a focus of this and other modules in this learning activity.

TREATMENT AGREEMENT PURPOSE

Written Patient-Provider Treatment Agreement Purpose
Treatment agreements between the provider and the patient communicate patient expectations and other information that will support successful buprenorphine treatment. They are particularly helpful in the beginning, during induction and later, if problems arise, but also serve a role of preventing problems. These agreements serve the following purposes5,12,13:

1. Improve communication
• Improve patient care through dissemination of information
• Act as a form of ongoing patient education
• Support open communication with not only the patient, but also the patient's family and other providers
• Avoid confusion during the treatment plan
• Clarify responsibilities when a patient is co-managed by more than one provider.

2. Enhance treatment
• Facilitate a mutually agreed-upon plan
• Enhance patient's adherence to the treatment plan
• Maintain accountability while taking these potentially hazardous medications
• Ensure the provider's ability to prescribe the drugs appropriately and safely

3. Communicate basic policies:
• Boundaries of treatment
• Expectations the provider has for the patient
• Role of the provider
• Objectives used to determine if treatment is a success or needs to be stopped and how to stop treatment

Treatment agreements relationship to informed consent: Written treatment agreements go beyond the goals, risks and benefits, and alternative treatments that are required in the informed consent. However, informed consent may be included within the agreement, because of overlapping purposes and content.

PRACTICE TIP
Note that some states, such as New Hampshire, require written treatment agreements when prescribing chronic opioids. They may be also called "Opioid Management Plans." These requirements may include buprenorphine. Be sure to check your state board's requirements for opioid prescribing, if any.

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**TREATMENT AGREEMENT: POLICIES**

To support smooth functioning of your practice, include your policies regarding:

• Cancelled appointments
• Contacting the provider during office hours and after hours
• Payment of fees
• Prescription procedures. Policy for prescription renewal and if there will be no early renewal.
• Courteous behavior, including behavior that cannot be tolerated, such as arriving intoxicated for appointments or being disruptive. Describe consequences
• Conditions regarding when treatment would be discontinued
• Patients who have relapsed to using opioids, for those who continued taking buprenorphine and for those who stopped treatment.

To support treatment success and safety, patients agree to\(^5,8\):

• Adhere to induction and maintenance protocols
• Obtain buprenorphine from only one provider and one pharmacy
• Participate in other recommended treatments, such as a support group or counseling
• Avoid use of illicit substances and those that might have an adverse interaction
• Disclose prescribed and non-prescribed psychoactive substances
• Participate in urine drug screens, pill counts, and/or periodic questionnaires about substance use when requested. Describe the schedule for these tests or describe if they are unannounced. Include information on costs of tests and the consequences of problematic results.
• (For women of child-bearing age) Disclose pregnancy or plans to try to get pregnant
• Attendance at follow-up visits. Describe the schedule.
• Authorization to communicate with your patient's other named providers, and, if needed, significant others
• Authorization to check your patient's record in the Prescription Drug Monitoring Program

INFORMED CONSENT OVERLAP, SAFETY
Information in Common with Informed Consent. There may be some overlap with informed consent issues in a written patient-provider agreement or they may intentionally be combined into one document. Overlapping elements include:

• Goal(s) of treatment
• Potential benefits and risks
• Voluntary nature of treatment

Child Safety
Treatment agreements should include information regarding safe storage of buprenorphine, including that medications should be kept in a locked container or otherwise made inaccessible to children. Even brief exposure of a child to buprenorphine can result in sedation, respiratory depression, cerebral anoxia, and death\(^8\). Following suspected or actual exposure of even a few seconds, call 911. The exposed child should have immediate medical attention and observation for 24 hours.

PRACTICE TIP
Treatment agreements should be completed in writing and signed prior to starting treatment and reviewed and updated periodically\(^8\). Many of the issues in the agreement are relevant to the maintenance phase, and so reviewing those elements at a followup appointment can help assure that the patient keeps them in mind.

CASE: TREATMENT AGREEMENT IN PRACTICE
Discuss the rules and regulations with each patient at the initial visit and have them sign the agreement which sums them up. Treatment agreements are between the patient and the provider. Patients are expected to agree to a treatment agreement and understand its contents. Providers can offer (and customize) standard treatment agreements. Agreements will include education on what the various components mean.

The treatment agreement can also be introduced to the patient along with screening tools using an online Patient Portal. Or they can be mailed to the patient or picked up at the office in advance so that patients come prepared and knowledgeable to the first appointment. If you do provide copies in advance, be sure that you still review them with the patient in person.

Case Illustration:
Ms. Allison Keville recently enrolled in a substance abuse program. As part of the standard procedures with new patients, the provider discusses the policies with her and asks her to sign a treatment agreement.
Provider: After we discuss the treatment agreement, I will provide you with a paper copy for you to sign. This will indicate that you agree to the terms of treatment.

Ms. Keville: This sounds like overkill. I’m not trying to break any rules.

Provider: I understand that this agreement seems extensive. However, these apply to every patient receiving buprenorphine treatment. I find that it is helpful since it defines the requirements placed on them in treatment and may answer potential questions.

The provider continues, using the practice’s policy checklist to make sure all the topics are covered with Ms. Keville. “In particular, she should understand that failure to comply will result in consequences. The provider next makes sure that Ms. Keville understands each component before she agrees to follow it.

Provider: Do you have any questions about what we covered?

Ms. Keville: No, I don’t think so. That sounds pretty reasonable to me. I can agree to that.

It is helpful to re-review the rules soon after a patient has begun treatment as a reminder about what was agreed upon.

QUIZ: STARTING TREATMENT

True or False: When starting office-based buprenorphine treatment, SAMHSA requires patients to sign a form stating that they understand the rules and expectations of treatment.

Choose one

1. True
   - Feedback: Incorrect. There is no SAMHSA regulation specifying that providers must have patients sign a form about the practice’s rules governing buprenorphine treatment. However, this is a very helpful step and is strongly advised.

2. False
   - Feedback: Correct. There is no SAMHSA regulation specifying that providers must have patients sign a form about the practice’s rules governing buprenorphine treatment. However, this is a very helpful step and is strongly advised.
MEET YOUR PATIENT

**Name:** Mrs. Copeland

**Age:** 45 years old

**Reason for visit:** Mrs. Copeland has concerns about possible adverse effects from her use of Vicodin®.

**Patient History:** Mrs. Copeland started taking Vicodin® for menstrual cramps but, after a hysterectomy two years ago, she no longer has pain. She has been taking about 10 Vicodin® a day for the past 6 months. She obtains them from a “pharmacist friend” and several doctors that she sees on a regular basis. You discover all this by reviewing her prescription drug monitoring report. None of the doctors are aware that she is taking 10 tablets/day.

*Mrs. Copeland:* I have tried to cut down my Vicodin® on my own a few times, but I cannot stand the insomnia and anxiety and diarrhea I get when I do. That forces me to go back on it, sometimes at a higher dose. But I’m getting worried because one of my doctors said that taking more than 8 Vicodin® a day could cause me to have liver damage.

**Question:** Despite her "doctor shopping", should you start Mrs. Copeland on buprenorphine today? (Choose the best answer.)

Choose one

1. Yes, start buprenorphine induction today.
   - **Feedback:** This is not the best answer. It is highly likely that Mrs. Copeland meets the criteria for opioid use disorder and is a good candidate for buprenorphine treatment. However, she has not even expressed interest in treatment yet and inducing her today would be premature. If she is interested in treatment, rather than turn her away because she has obtained drugs from multiple physicians, you can address your concerns and add a special provision into her treatment agreement. The agreement should specify that she will only obtain prescribed opioids from you and that you will inform the other healthcare providers of her treatment plan.

2. No, she is not a good candidate because she has shown she cannot be trusted.
   - **Feedback:** This is not the best answer. It is highly likely that Mrs. Copeland meets the criteria for opioid use disorder and is a good candidate for buprenorphine treatment. It would be premature to conclude that she can’t be trusted. However, she has not even expressed interest in treatment yet and inducing her today would be premature. If she is interested in treatment, rather than turn her away because she has obtained drugs from multiple physicians, you can address your concerns and add a special provision into her treatment agreement. The agreement should specify that she will only obtain prescribed opioids from you and that you will inform the other healthcare providers of her treatment plan.
3. No, she is not a good candidate at this point because she has not expressed interest in treatment.
   • Feedback: Correct. It is highly likely that Mrs. Copeland meets the criteria for opioid use disorder and is a good candidate for buprenorphine treatment. However, she has not even expressed interest in treatment yet and inducing her today would be premature. Her current clinical concern is side effects of Vicodin®. If she is interested in OBOT, rather than turn her away because she has obtained drugs from multiple physicians, you can address your concerns and add a special provision into her treatment agreement. The agreement should specify that she will only obtain prescribed opioids from you and that you will inform the other healthcare providers of her treatment plan.

MRS. COPELAND – FURTHER EVALUATION

Addressing Mrs. Copeland's Current Concern
To first address Mrs. Copeland's current concern, you give her information about physical opioid dependence, including reviewing the symptoms of withdrawal that seem to be affecting her life. You explain the effects on the liver of the acetaminophen component of Vicodin®. You conduct liver function tests and they are within normal limits.

Asking About Other Medications
Provider: Are there any other medications or drugs that you use?
   Mrs. Copeland: No, just the Vicodin.

Provider: Have you ever injected or snorted or smoked any opioids or other drugs?
   Mrs. Copeland: No, I'm not into anything like that.

Provider: I see that you have a history of alcohol and tobacco use.
   Mrs. Copeland: I drink about one to two glasses of wine a night on weekends and sometimes on weekdays. I also smoke a few cigarettes when I'm drinking.

Provider: Has your Vicodin® use has had any impact on your work or family or relationships?
   Mrs. Copeland: No, it hasn't. The Vicodin® costs more than I can afford sometimes, and my friends are concerned that I still use it, but I don't think it has caused any problems.

Outcome of Further Assessment
Further assessment confirms Mrs. Copeland has opioid use disorder related to her use of Vicodin. You decide to recommend buprenorphine treatment.

QUIZ: MRS. COPELAND – TREATMENT
Mrs. Copeland: Okay, I guess I'll try the buprenorphine treatment. To be honest, I'm surprised that none of my providers ever mentioned it. I guess I'll have to talk to them about it at my upcoming appointments.
Question: Which of these are issues to include in Mrs. Copeland's written, signed treatment agreement?
Choose all that apply

1. Past "doctor shopping"
   • Feedback: Correct. You should address the issue in her treatment agreement and set ground rules of no "doctor shopping" from this point forward. Also, be sure to check her Prescription Drug Monitoring report regularly until you feel confident that doctor shopping is no longer a problem for her.

2. Urine testing
   • Feedback: Correct. Urine testing should be described in the treatment agreement. It is important for any patient in OBOT.

3. Inappropriate office behavior and consequences
   • Feedback: Correct. Office guidelines and rules about treatment should be in the treatment agreement for an patient in OBOT.

4. Employment history
   • Feedback: Incorrect. Employment history is not typically part of the treatment agreement.

5. Goals of treatment
   • Feedback: Correct. Treatment goals are a good thing to include in the treatment agreement.

6. Diet and exercise habits
   • Feedback: Incorrect. Diet and exercise are not typically included in the OBOT treatment agreement, but treatment agreements can be effective in the treatment of other chronic conditions.

7. Patient confidentiality
   • Feedback: Partially Correct. Confidentiality is part of the patient consent form rather than the treatment agreement. Some offices may combine the treatment agreement and the consent form.

QUIZ: MRS. COPELAND - STARTING TREATMENT

Mrs. Copeland schedules her buprenorphine treatment and returns the following week for induction. She will use the buccal film combination formulation of buprenorphine/naloxone, and is started with no problems and stabilized on a dose of 8.4 mg buprenorphine/1.4 mg naloxone per day.

Three months pass without incident. Mrs. Copeland is compliant with treatment and attends all of her appointments with you and counseling sessions. Then one day you receive a phone call from another primary care physician, who says that Mrs. Copeland came to him for a buprenorphine refill. She said that she was not able to get in touch with you to refill her prescriptions. Your office does not have any record of Mrs. Copeland trying to contact the office, and you are unable to reach her by phone.

Question: Which of the following steps is an appropriate response? (choose the best answer)
Choose one
1. Discharge her from treatment since she has clearly violated her treatment agreement.
   - Feedback: This is not the best answer, but it is one possible choice. Mrs. Copeland's treatment agreement clearly defined rules regarding prescription refills — all prescriptions were supposed to be written by you only. It is up to your discretion if you want to discharge and terminate her treatment at this time, or give her another chance. If you do terminate, you should refer her to another waivered provider or program.

2. Give her a second chance to remain in your office-based opioid treatment program but increase her requirements.
   - Feedback: This is not the best answer, but it is one possible choice. Mrs. Copeland's treatment agreement clearly defined rules regarding prescription refills — all prescriptions were supposed to be written by you only. It is up to your discretion if you want to give her a second chance, or discharge and terminate her treatment at this time. If you do terminate, you should refer her to another waivered provider or program.

3. Refer her to a methadone maintenance program.
   - Feedback: This is not the best answer, but it is one possible choice. Mrs. Copeland's treatment agreement clearly defined rules regarding prescription refills — all prescriptions were supposed to be written by you only. It is up to your discretion if you want to discharge and terminate her treatment at this time, or give her another chance. If you do terminate, you should refer her to another waivered provider or program — a methadone maintenance program is one possible choice.

4. Give her a chance to explain herself before making a decision.
   - Feedback: Correct. This is the best possible answer. You should first talk to Mrs. Copeland and see if she admits visiting another doctor, and if she has an explanation for her action. Regardless, Mrs. Copeland's treatment agreement clearly defined rules regarding prescription refills — all prescriptions were supposed to be written by you only. It is up to your discretion if you want to discharge and terminate her treatment at this time, or give her another chance. If you do terminate, you should refer her to another waivered provider or program.

MRS. COPELAND – TREATMENT DECISION

Getting in Touch with Mrs. Copeland

It took a week to get in touch with Mrs. Copeland. When she finally called the office, she was scheduled for the next day. Because Mrs. Copeland has been in violation of her treatment agreement, the provider prescribes a small supply and schedules early follow-up.

Mrs. Copeland: I'm overdue for my buprenorphine refill. You told me that I had to come into the office to get one.

Provider: Yes, but first I would like to talk to you about a phone call we recently received. Another clinic advised us that you asked them for a refill because you couldn't get in touch with us. Our office doesn't have any record of you trying to contact us.

Mrs. Copeland: Well, I was in a hurry, and I didn't think I could get an appointment with you, so I saw a nurse practitioner who was close by.
**Provider:** Remember that not going to multiple providers was part of our treatment agreement, which you signed.

**Mrs. Copeland:** I don't think it's all that serious. Besides, I didn't get any medicine from the other provider, which is why I'm here.

**Provider:** For now, I will give you enough buprenorphine for a week and then I would like to see you back in the office to see how it is going.

**Discharge**

Mrs. Copeland scheduled an appointment, but she did not show up. A week later the provider sent a letter to her house officially discharging her from the office-based opioid treatment program. It included a list of other buprenorphine prescribers and addiction treatment centers in the local area. The provider did not hear from Mrs. Copeland again.

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**PRESCRIPTION DRUG MONITORING PROGRAMS**

**Recommendation for Use of Prescription Drug Monitoring Programs (PDMPs)**

The prescription drug monitoring programs (PMDPs are state-operated data bases containing information on controlled substances dispensed. Prescription Drug Monitoring Programs provide data on who has received prescriptions for certain controlled substances. You can order a report on the prescriptions a patient has filled.

Practice guidelines for prescribing opioids and buprenorphine recommend checking the prescription drug monitoring program data base as follows:

1. SAMHSA's *Sublingual and Transmucosal Buprenorphine for Opioid Use Disorder - Review and Update* (2016) recommends checking the PDMP before induction and prior to writing prescriptions.
2. The CDC's Guidelines for opioid prescribing, which includes buprenorphine, recommends checking PDMPs before prescribing and at least every 3 months and considering checking for every prescription.

**PDMPs in Your Area**

The state PDMPs vary, for example, by

- The schedules of drugs that are encompassed
- The number of times per month data is collected
- The way the data is submitted and disseminated

In some states you may be able to check prescriptions you have written in order to detect forged prescriptions and prescriptions that were modified. Check whether this is allowed in your state.

Currently, no national PDMP system exists, but many experts are calling for such a program. In some states, for example, Ohio, you can check the PMPs in adjacent states. The law, CARA 2016, provides supports each state sharing data with at least one adjacent state.

**CLINICAL USE OF PDMPS**

As a clinical tool, PDMPs can help you.
• Reduce abuse and diversion. Given the fairly frequent abuse of buprenorphine, a policy of checking the PDMP periodically throughout buprenorphine treatment is a good idea.
• Obtain an accurate picture of a patient's past and present pharmacological treatment with medications that are reported (narcotics) by
  • detecting patterns of excessive drug seeking, ie, obtaining narcotics from more than one provider and/or pharmacy. Look for buprenorphine or other narcotics being prescribed by other providers.
  • confirming compliance in taking prescribed medications, including your buprenorphine prescription
  • detecting any unreported use of other prescription medications, especially checking for opioids, buprenorphine, and benzodiazepines and other sedative-hypnotics to help prevent diversion and overdose.

Response to Finding Problematic PDMP Reports
In response to discovering via the PDMP that patients have irregularities or other problems with respect to their prescribed medications, such as obtaining the same medication from more than one provider or dangerous combinations of prescribed medications:
• Educate patients:
  • about risk of overdose
  • about potentially dangerous drug interactions
• Consider tightening treatment structure, for example, with:
  • more frequent visits
  • a smaller medication supply
  • more frequent pill counts
  • more frequent urine drug testing
  • required counseling
  • (if part of a consistent pattern of aberrant behavior) referral to a higher level of care

PRACTICE TIPS
• To maintain a patient-centered relationship, which includes transparency, patients should be informed that you check this data base.
• PMP reports might not be necessary for patients who have a long-standing relationship with you and are perceived to be at lower risk for diversion
• PMP reports can be a good resource when there is little history available or when there is concern based on clinical history, observation, or aberrant use of medication.

POLL: I CONSULT PRESCRIPTION DRUG MONITORING DATA BEFORE PRESCRIBING OPIOIDS:
Choices
1. Regularly/Always
   • 63% (2597 votes)
2. Sometimes
   • 21% (887 votes)
3. Never
   • 5% (206 votes)
4. Does not apply to me
   • 11% (453 votes)

PROBLEMATIC BEHAVIORS

Most of your patients will comply with office-based buprenorphine treatment programs and remain in good standing, but some might not. Substance use, including non-prescribed drugs, illicit drugs, or alcohol, increases the risk of both relapse and overdose. It is important to be aware of related problematic behaviors and have a plan in place for dealing with them. Common problematic behaviors include:

- Continued opioid use or other illicit drug use
- Intoxication at the office
- Diversion of medication
- Non-adherence to treatment (e.g., missing appointments, not taking medication as directed)

CONTINUED DRUG USE

Continued Opioid Use
Continued opioid use may indicate that your patient needs an increased dose or higher level of care. Some patients need the supportive system that methadone maintenance provides; they may struggle with the less intense (“casual”) treatment of simply having a bottle of pills and taking them as prescribed.

If urine drug screens are positive for opioids and negative for buprenorphine, assume that the patient is not taking the buprenorphine and is using other opioids.

Illicit Drug Use
Patients in opioid treatment may also abuse other illicit drugs. ASAM practice guidelines (2015) state that:

"The use of marijuana, stimulants, or other addictive drugs should not be a reason to discontinue buprenorphine treatment. However, evidence demonstrates that patients who are actively using substances during opioid use disorder treatment have a poorer prognosis. The use of benzodiazepines and other sedative hypnotics may be a reason to suspend agonist treatment because of safety concerns related to respiratory depression."

- Urge your patients to disclose drug use, especially sedating drugs.
- Remain watchful for signs of such use.
- Patients suspected of abusing benzodiazepines require careful evaluation, due to the risk of combining benzodiazepines and buprenorphine.
- Psychosocial treatment may need to be intensified for patients who continue to abuse other drugs while in buprenorphine treatment, especially if it interferes with treatment.
• With patients under the influence of other substances, first ensure the patient's safety and then address the issue at a later date. They may need to be referred to a higher level of care. Be sure to follow-up with patients who have been referred to other treatment settings.

Alcohol Intoxication
When dealing with patients who arrive at the office in a state of alcohol intoxication:

• Determine how the patient got to the office.
  • If the patient drove to the office, he/she should not be permitted to leave while intoxicated. Keep the patient in the office until he/she becomes sober or arrange other transportation.
  • If an intoxicated patient insists on driving, you should choose to contact the police. No information regarding the patient's status in a treatment program may be disclosed.
• Address the issue of alcohol abuse with the patient at a later date when the patient is no longer intoxicated.
• Do not administer any medication or bring up important decisions while the patient is intoxicated.
• Scheduling morning appointments may reduce the number of intoxication issues that arise.

MISUSE AND DIVERSION
Overview of Misuse and Diversion
Buprenorphine misuse and diversion do occur in office-based opioid treatment practices. Remember that prior to treatment, many of your buprenorphine patients were misusing opioids for months or years. Misuse is a common and learned behavior and one that can be a hard habit to break. Diversion is also on the rise as the street demand for buprenorphine rises. Continuing medical education (CME) is another approach for reducing buprenorphine diversion and misuse.  

• Misuse refers to the way a patient takes his/her buprenorphine - in any way different from how it was prescribed.
• Diversion refers to any manner in which people obtain buprenorphine other than by how it is prescribed.

Reasons for Misuse and Diversion
Common Reasons for Misuse
• Patient thinks he/she needs a higher dose
• To relieve opioid craving
• To relieve opioid withdrawal
• To get high

Common Reasons for Diversion
• To help addicted friends
• Peer pressure
• To make money

Reasons to misuse buprenorphine specifically also include a lack of sufficient funds to purchase a preferred opioid or a trusted source of preferred opioid not being available.
Signs of Misuse and Diversion

Signs of misuse and diversion may include:

- Missed appointments
- Claims that pills were lost, stolen, accidentally laundered, etc.
- Asking for early refills for reasons that cannot be proven, e.g., lost prescription
- Urine screens negative for buprenorphine, positive for opioids
- Physical signs of injection drug use
- Police reports of selling on the streets
- Calls from others to report diversion
- Claims of being allergic to or intolerant of naloxone, and requesting monotherapy
- Problems with keeping appointments or making payments - may signal a relapse
- Positive urine drug toxicology for illicit drugs or negative for buprenorphine
- Continued relationship with drug users not in treatment
- A sudden request for a dose increase after being stable

**MISUSE AND DIVERSION FREQUENCY**

**How frequent are buprenorphine misuse/abuse and diversion? What are the trends?**

Buprenorphine abuse/misuse and diversion is increasing. Analysis of national data involving buprenorphine abuse/misuse between 2005 and 2010 found increases in reports of:

- Poisoning
- Seizure of illegal supplies
- Visits to the emergency room

Awareness among drug users entering treatment that buprenorphine is used to get high and that it is being diverted has also increased in this time period. Of over 8,000 physicians surveyed, in 2009, 81% were of the opinion that it is easier to obtain buprenorphine illegally than methadone (compare 52% in 2005).

**Rate of increase in diversion/abuse is proportional to increase in prescribing in recent years.**

The increase in buprenorphine misuse and diversion holds true for raw numbers and in terms of the million pills prescribed when all forms of buprenorphine are considered. However, diversion of the combination form, buprenorphine/naloxone, has increased proportionally to an increase in unique recipients of a prescription. Pure buprenorphine diversion has increased faster than the increase in prescribing of the medication.

These trends underscore the need for strict adherence to buprenorphine prescribing guidelines especially careful establishment of the right dose, prescribing only the supply needed, and follow-up, as well as following the precautions described in this module.
DRUG DEALING AND THEFT
Illegal behavior related to drug use by your patients, such as drug dealing and theft from the office, could harm your practice and is also harmful to the patient, their families, and the community. It should be dealt with strictly.

Your practice’s credibility and integrity are at stake when your patients engage in illegal activity related to your practice. It is very important, though, that you not overreact to unsubstantiated claims. Direct evidence of drug dealing should elicit severe consequences, but indirect evidence (or rumors) should be addressed more subtly, such as by discussing the issue with the patient.

Drug Dealing
Staff, security personnel, and neighbors might report drug dealing. Red flags for possible drug dealing include the co-occurrence of:
- Loitering
- Frequently lost prescriptions

Stealing from the Office
Small discrepancies in inventories should be taken seriously and responded to with more careful storage and increased review of supplies. Items such as needles, syringes, and prescription pads are easily and commonly stolen.

Preventing Theft:
- Lock such items away and ensure they are not readily available to your patients
- Never leave patients unattended

When you suspect your patient of stealing from the office, the issue should be addressed directly and the necessary actions taken. It is recommended not to allow such acts to pass without consequences.

PRACTICE TIP
Talk to your patients to clear up any misinformation or to confirm rumors. Be direct without making assumptions or being judgmental, while still being firm about clinical structure agreed to in patient-provider agreements.

PREVENTING MISUSE, DIVERSION, & ACCIDENTAL EXPOSURE
Preventing Misuse and Diversion
There are some simple approaches that can be built into an office-based opioid treatment practice that will help prevent buprenorphine misuse and diversion.
- Prescribe a therapeutic dose of buprenorphine. Due to ceiling effects, there is very little clinical benefit to taking more than 16 mg/day. Be sure to question patients who come to the office who say they need significantly higher doses.
- Prescribe what is needed based on careful titration of dose. Don't routinely provide an additional supply "just in case."
• Make sure that the treatment agreement is clear about prescription guidelines—number of doses in each prescription, policies regarding refills, rules regarding "lost" prescriptions.
• Require your patients to use only one pharmacy for filling all prescriptions, buprenorphine and otherwise. Obtain consent for two-way communication with the pharmacist; if your patient doesn't consent, you have to question why.
• Monitor treatment through regular but random urine tests, pill/filmstrip counts in the office between writing prescriptions (if they sold the whole supply of medication immediately, they would not have the right count), state prescription monitoring system, feedback from family members, etc.
• Openly discuss misuse and diversion with your patients so they know that you are aware of the issues and have a plan to deal with these problems if they arise.

Children and Accidental Exposure and Overdose
Accidental exposure to buprenorphine by young children can cause central nervous system depression, respiratory depression, and death.

A recent study reviewed a total of 2,380 cases of unintentional exposure of buprenorphine by young children. Researchers found that exposure to the film formulations occurred at a significantly lower rate than to the tablet formulation. Many of the cases involved medication that was stored in sight, accessed from a bag or purse, or not stored in the original packaging.

PRACTICE TIP
Reevaluate patients who misuse or divert their medication and consider moving them to a more intensive level of treatment.

MANAGING MISUSE AND DIVERSION
Misuse and diversion must be addressed when suspected or verified. If not addressed, the patient's health and safety could be at risk. Additionally, the overall "reputation" of office-based opioid treatment (OBOT) could be damaged. Also, increase in diversion could lead to tighter DEA oversight of buprenorphine—and the oversight is already fairly substantial.

Misuse or diversion should not mean automatic discharge from your OBOT program. However, you should have a policy in place for how you deal with misuse and diversion. For instance, you may want to follow these steps when diversion or misuse occur:

• Reassess treatment plan and patient progress.
• Make changes as needed: alter dose, intensify psychosocial support requirement.
• Reassess the patient again after a short interval.
• Arrange for alternative treatment if needed.
• Injectable or implant formulations result in less supply of the medication lying around to be diverted.
PRACTICE TIP
To help avoid setting an adversarial tone in your doctor-patient relationship, be sure to acknowledge and reinforce with praise you patients’ adherence to treatment and any progress made, even if reduction in illicit substance use is only partial. Aside from verbal praise, other rewards for treatment progress may include reducing the frequency of office visits and other reduction in treatment structure, such as eliminating having the patient take their medication in front of you.

LOITERING AND AGGRESSION
Additional problematic behaviors that may not be common will still need rules and guidelines.

Loitering
Some of your patients might arrive significantly early for an appointment or stay after they have been seen. Methadone treatment programs report that some patients:

- Arrive hours before time for appointments or
- Remain in the vicinity of the office for hours subsequent to an appointment

Dealing with loitering involves a careful assessment. These patients could be:

- Trying to sell or purchase drugs illegally outside the treatment program or
- Trying to cope with unstructured time and wish to remain in a stable environment.

In the latter case, your strategy should be to:

1. Recognize the need of your patient to seek the comfort of a safe place
2. Discuss these feelings and other options with your patient

Aggressive Actions
Having a policy in place for aggressive behavior is important even if it is a rare occurrence. Aggressive actions may be grounds for discharge from the practice, based on the judgment of the individual clinician or practice. Neither vandalism nor threats should be tolerated. These acts are indisputably violations of any reasonable code of conduct. This should be clearly conveyed to your patient during the initial visit while discussing rules and expectations. The consequences must be well-defined and strictly enforced.

Examples:

- Threatening or harassing a staff member may lead to termination of office treatment.
- Threats toward other patients and accusations of vandalism should be carefully examined before action is taken:
  - If the threat or action is significant (has a high level of intent), then severe options, such as discharge from the treatment regimen, should be seriously considered.
  - Patients who have otherwise done well in the program yet have had an isolated aggressive incident with another office-based opioid treatment (OBOT) patient could be transferred to another program or rescheduled to avoid overlap of OBOT patients.
- Actions such as vandalism, for which there is little evidence, should be discussed with your patient. Closer monitoring may be a proportional response.
MANAGING PROBLEM BEHAVIORS
You must not ignore violation of the rules, since ongoing problematic behavior contributes to general disrespect for the rules and your authority. However, aberrant behaviors in many instances do not mean you should automatically discontinue treatment. It should at least prompt a discussion of the risks and consideration of ways to tighten treatment structure. The goal is to form a stronger doctor-patient alliance. The range of your responses to problematic behaviors might include the following:

- Evaluate whether the dose of buprenorphine is sufficient
- Increase the number of office visits per month
- Initiate or increase the intensity (frequency/duration) of psychosocial counseling services or group therapy or peer support programs
- Require supervised medication administration
- Alter the manner in which buprenorphine is provided
- Transfer the patient to more intensive level of treatment, such as an Opioid Treatment Program or a residential program

Evaluate deviance from accepted behaviors for each individual patient as it should not necessarily result in discharge from treatment. For patients who break rules, consider each violation in the context of that individual’s condition.

CASE STUDY – MS. DAWSON

Meet Your Patient

**Name:** Ms. Dawson  
**Age:** 20 years old  
**Reason for visit:** Needs treatment for her heroin use

**Patient History:** Ms. Dawson is a university student who has been smoking heroin occasionally for 15 months and daily for the past 3 months. She uses 1½ grams per day and requests help to quit.

**Relevant History:** She reports no prior history of treatment for drug use. She reports no alcohol or other drug use and the latter was later confirmed with urine drug testing.

Patient Discussion

**Provider:** Tell me more about why you’re here today.

**Ms. Dawson:** I use heroin, but it’s getting so expensive to maintain my habit. I need to get off of it.

**Provider:** I see you’re using 1½ grams per day?
**Ms. Dawson:** Yes, and it makes me feel good, but when I can't get any I feel awful. I'm anxious and I can't sleep. My muscles ache and I get diarrhea. I don't want to have to go through that every time I don't have enough money for heroin.

**Provider:** That makes sense; it sounds miserable. So, you've decided to get treatment at this point?

**Ms. Dawson:** Well, honestly, I was thinking of starting to shoot up to save money, because it takes less heroin that way, but I decided to give treatment a try instead. If I can stop using, I won't have to worry about paying for it.

**QUIZ: SUITABLE FOR TREATMENT**
You determine that Ms. Dawson is not pregnant and is taking oral contraceptives. She has no concurrent medical/psychiatric conditions and explore other psychosocial issues.

**Provider:** Having a good social support system helps treatment be successful. Do you have friends and family in the area that might be able to help you through treatment?

**Patient:** My parents live nearby. And I do have a couple of friends from school that have said they'd support me getting help. They've hated to see how the drugs have affected me.

**Provider:** And they are not users themselves, correct?

**Patient:** No, they're clean.

**Provider:** You said you have been finding it hard to pay street prices for drugs. Have those difficulties ever led to committing a crime or doing something that you find morally inappropriate in order to get the funds to pay for your drugs?

**Patient:** No, it hasn't come to that yet. In fact, that's one reason why I'm here. I want to make sure I don't get into a situation that I'll have to do something drastic just to keep my habit going.

**Question:** With this information in mind, is Ms. Dawson a good candidate for office-based buprenorphine treatment as a first line approach?

Choose one

1. Yes, she is suitable for office-based buprenorphine treatment as a first line approach
   - Feedback: Correct. Ms. Dawson is suitable for office-based buprenorphine treatment as a first line approach -- there is a clear diagnosis of opioid use disorder given the tolerance, withdrawal symptoms, and fear of how addiction could affect her financially. Office-based logistics may provide a suitable means for her to access treatment because she has school/classes to attend and daily attendance at an outpatient treatment facility could interfere with her attendance and improve the likelihood of running into people she associated with while using. If office-based treatment does not provide enough structure and support, then more intensive outpatient counseling treatments that could be considered.

2. No, she is not suitable for office-based buprenorphine treatment as a first line approach
   - Feedback: Incorrect. Ms. Dawson is suitable for office-based buprenorphine treatment as a first line approach -- there is a clear diagnosis of opioid use disorder given the tolerance, withdrawal symptoms, and fear of how addiction could affect her financially. Office-based logistics may provide a suitable means for her to access treatment because she has school/classes to attend and daily attendance at an outpatient
treatment facility could interfere with her attendance and improve the likelihood of running into people she associated with while using. If office-based treatment does not provide enough structure and support, then more intensive outpatient counseling treatments that could be considered.

3. There is not enough information available to determine whether or not Ms. Dawson is suitable for office-based buprenorphine treatment as a first line approach
   - Feedback: Incorrect. Ms. Dawson is suitable for office-based buprenorphine treatment as a first line approach – there is a clear diagnosis of opioid use disorder given the tolerance, withdrawal symptoms, and fear of how addiction could affect her financially. Office-based logistics may provide a suitable means for her to access treatment because she has school/classes to attend and daily attendance at an outpatient treatment facility could interfere with her attendance and improve the likelihood of running into people she associated with while using. If office-based treatment does not provide enough structure and support, then more intensive outpatient counseling treatments that could be considered.

SELECTING LEVEL OF TREATMENT

*Provider:* Office-based buprenorphine treatment fits your circumstances. Would you like to hear more about it?

*Ms. Dawson:* What about the outpatient clinic?

*Provider:* The outpatient clinic is a possibility, but I suggested office-based treatment because the logistics of an outpatient treatment facility could interfere with your class schedule. Outpatient treatment also increases the likelihood of you running into people that you were associated with while using, which can make it difficult to stay abstinent. If office-based treatment does not provide enough structure and support, then we can consider more intensive outpatient counseling treatment.

*Ms. Dawson:* That makes sense.

MAKING A TREATMENT PLAN

**Treatment Goals**

You determine that the goals for Ms. Dawson's treatment are:

- Cessation/reduction of illicit opioid use
- Participation in a comprehensive rehabilitation program (counseling for relapse prevention and possibly the issues surrounding her initial drug use)

**Induction Plan**

Ms. Dawson's evaluation and treatment plan for induction includes the following:

- Comprehensive psychosocial and medical assessment
- Discuss treatment plans (medical withdrawal or longer term treatment)
- Observation for signs and symptoms of opioid withdrawal before induction onto buprenorphine to avoid precipitating withdrawal
• Follow-up review by treating physician/PA/nurse practitioner
• Provide referrals for counseling

FIRST RETURN VISIT
Setting Up An Appointment

Ms. Dawson leaves a message that night:

**Ms. Dawson:** This is Rachel Dawson. I wanted to cancel my next appointment. I found a doctor that gives the same treatment but charges less.

Three days later she leaves you the following message in the evening after office hours:

**Message from Ms. Dawson**

**Ms. Dawson:** Hi doc. It's Rachel Dawson. I just wanted to let you know that I have been on 8 mg of bup over the past 4 days, working with another doctor. But that isn't working out. It's too far and he's not very flexible. Can I get an appointment with you as soon as possible?

You make time to see her the next day and convey the following the next morning:

**Provider:** Ms. Dawson, I can make time at 4 pm today. Please call to confirm.

Ms. Dawson does not confirm the appointment and shows up an hour late. You fit her into your schedule and have the following discussion:

**Provider:** Can you tell me a little bit about what's going on with your treatment? According to your phone call, you decided to get buprenorphine treatment with another doctor?

**Ms. Dawson:** Well, I know we set it all up when I was here last time, but the doctor I went to before costs less, so I decided to follow his plan instead. He had me on 8 mg of buprenorphine for the past four days, which seemed to be working, but he's not very flexible, like if I miss appointments. Maybe I should get treatment here instead.

**Provider:** Well you'll find we're all pretty strict about keeping appointments. That's part of my policy, too. Do you still want to make this switch?

**Ms. Dawson:** I guess I have to. They won't schedule me there any more.

**QUIZ: TREATMENT AGREEMENT**

**Provider:** First of all, before we start a formal treatment plan, I'll need you to sign a treatment agreement. It will include our policy on keeping appointments.

**Ms. Dawson:** What else is in the agreement?
Which of the issues that Ms. Dawson has demonstrated could be included in this treatment agreement? (Choose all that apply)

Choose all that apply

1. Seeing only one provider at a time for this treatment
   - Feedback: Correct! All of these issues could be described in a treatment agreement.

2. Keeping appointments or providing appropriate notice about breaking them
   - Feedback: Correct! All of these issues could be described in a treatment agreement.

3. Following treatment recommendations precisely
   - Feedback: Correct! All of these issues could be described in a treatment agreement.

4. Attending a relapse prevention seminar
   - Feedback: Correct! All of these issues could be described in a treatment agreement.

FOLLOW-UP

Follow-Up Appointment
Mrs. Dawson signs the treatment agreement. Because her withdrawal symptoms appear to be controlled at 8 mg, the provider prescribes a small supply of the same dose and tells her to be in touch regarding symptoms. The next appointment is scheduled in just a week because of her erratic behavior and to make sure this relatively low dose is sufficient for her.

Four Weeks Later
Ms. Dawson fails to show up for her follow-up appointment and does not attend a relapse prevention seminar. Without hearing from her for 4 weeks, Ms. Dawson returns during urgent care walk-in hours.

**Provider:** We haven't heard from you for four weeks. You were scheduled for an appointment 3 weeks ago and for a relapse prevention seminar. Can you tell me what's going on?

**Ms. Dawson:** It's just been a bad time. I just stopped the bup. I'm smoking more heroin and started dancing at a club on Parker Street so that I can afford it. I couldn't keep up with school so I dropped out. I feel like I've hit rock bottom.

**Provider:** I understand. I'd recommend getting back into treatment, but I'd need you to follow the agreement we made, including attending the seminar. What do you think?

**Ms. Dawson:** I just don't have the time to go to your seminar! Can't you just give me some buprenorphine and help me out?

**Provider:** If office-based treatment doesn't provide enough structure and support, then maybe it is time to consider the outpatient opioid treatment clinic.

**Ms. Dawson:** No, please. I can't afford to miss work, and I need the job to pay my bills. I'll agree to do it your way, just please help me here.

Patient Evaluation
You evaluate her mental and physical state and notice that she is in significant withdrawal. She says she last used heroin at midnight the night before, injected into her right arm.
QUIZ: CLINICAL CHOICE

Question: What would you do in terms of Ms. Dawson’s treatment at this point? (Choose the best answer.)

Choose all that apply

1. Schedule induction for next week.
   - Feedback: This is not the best answer. She is now in withdrawal so you can restart buprenorphine immediately and titrate the dose as needed over several days. Before induction you should require Ms. Dawson to sign a modified treatment contract in which she agrees to modifications providing additional treatment structure. These might include more frequent office visits, attending counseling, and attendance at 12-step meetings, in addition to the structure provided in the original agreement. She will likely also need support and assistance to set-up counseling appointments, finding 12 step meetings and their schedule, and appointment reminders.

2. Start buprenorphine now in your office and ask her to come in tomorrow to determine the correct dose for her.
   - Feedback: Correct if you are a more experienced prescriber and feel comfortable with her level of risk. You could start buprenorphine now and have her return the next day to titrate the dose. If you do decide to go ahead, because she is now in withdrawal, you can restart buprenorphine immediately and titrate the dose as needed over several days. Before induction you should require Ms. Dawson to sign a modified treatment contract in which she agrees to modifications providing additional treatment structure. Modifications might include more frequent office visits, attending counseling, and attendance at 12-step meetings, in addition to the structure provided in the original agreement. She will likely also need support and assistance to set-up counseling appointments, finding 12 step meetings and their schedule, and appointment reminders. If you are a new prescriber, however, or not comfortable with her level of risk, or if you are, but all of these details do not work out, it would be time for referral to the next level of care.

3. Tell her that office-based buprenorphine will not work for her, and refer her to a higher level care.
   - Feedback: Correct for many providers, especially new prescribers. However, if you are a more experienced prescriber and feel comfortable with her level of risk, you could start buprenorphine now and have her return the next day to titrate the dose. If you do decide to go ahead, before induction you should require Ms. Dawson to sign a modified treatment contract in which she agrees to modifications providing additional treatment structure. These might include more frequent office visits, attending counseling, and attendance at 12-step meetings, in addition to the structure provided in the original agreement. She will likely also need support and assistance to set-up counseling appointments, finding 12 step meetings and their schedule, and appointment reminders.
LESSONS LEARNED
The main teaching points from this case are the following:

1. Patients may be very motivated to take a medication, but resist engaging in counseling and groups. This may show up as late arrival, after hours calls, etc. Splitting between front desk, counseling staff, on call doctors, etc. can result, and the patient receives sub-optimal care.
2. Some users may progress from smoking heroin to IV use in order to save money or to have stronger drug effects.
3. Financial concerns and other effects of drug use may lead to quitting school, adopting a less safe lifestyle, or taking up criminal activity.
4. When a patient who has been non-compliant with counseling relapses, further treatment should attempt to engage that patient in counseling.
5. Before determining that there has been a failure of buprenorphine treatment, make sure that therapeutic doses have been tried.

URINE DRUG TESTING

Patient Centered Urine Drug Testing
A urine drug test (UDT) is recommended for monitoring patients during buprenorphine treatment. Its purpose is 1) to determine if the patient is taking their buprenorphine, and 2) to detect if they are taking illicit substances that could have adverse drug interactions with a prescribed medication. The UDT is for your patient's benefit and safety; it is not intended to root out people who lie or to be used as a trap. Discuss with your patients that periodic UDTs are:

- Part of routine care as a tool to optimize patient care, not for financial gain
- Used to support your patient's claims of stability and non-use of substances

Patients are more likely to accept the need for a UDT when the intent is therapeutic and the reasons for testing are communicated sensitively. It might even enhance your patient-provider relationship.

The treatment agreement should outline standard information on urine drug testing and include an explicit statement of the role of urine drug testing in the treatment plan.

Benefits of UDT to Patients

- Affirmation to your patient that they are in solid recovery
- Positive reinforcement
- Support of recovery
- Reassurance to your patient that you trust and have confidence in them
- Supports your patients’ claims of not using drugs
- Advocates for your patient to a third-party (e.g., workers comp, employer, insurer, or child protective services)
-Detects potential compounds that could interact with prescribed medication
Other Tests
Although other types of testing are available, urine testing is most common and convenient. Urine is usually tested for drug content because of the ease with which it can be obtained. Other less commonly tested specimens are:

- Blood
- Saliva
- Hair
- Sweat

If a positive result is obtained from one of these specimens, consider using urine testing for confirmation.

PRACTICE TIP
An excellent resource in drug testing is SAMHSA's TAP 32: Clinical Drug Testing in Primary Care.

URINE TESTING
Urine testing is an integral part of the office-based buprenorphine treatment program. Include a standard drug screen, buprenorphine, and its metabolites. It is essential to gauge accurately the current drug use by your office-based opioid treatment patients for their safety. Self-reports, family member reports, observation of attitude alteration, and behavior changes are generally insufficient. Testing for buprenorphine helps detect whether the drug is not being taken and has been diverted.

Considerations for Conducting Urine Testing

Timing of Testing
Decide between random and scheduled testing. Random testing increases the probability of detecting illicit drug usage: patients can no longer plan their drug usage around a schedule.

Frequency of Testing
Consider the frequency of testing. SAMHSA recommends monthly urine tests. These tests should screen not only for continued opioid use but also for use of other illicit drugs.

Collection Methods
Direct observation is the method that has the highest likelihood of preventing a doctored sample. To achieve this, have a same-sex staff member present. Require that your patients leave coats, purses, backpacks, etc., outside the bathroom.

If direct observation is not desired or possible, thermometers or testing machines that analyze urine temperature are an appropriate substitute. If patients have a substantial commute, consider testing the patient in a location outside the office that provides similar monitoring considerations.

Test Type
Urine testing for opioids can be done either by point of care or by laboratory testing.

- **Point of care:** The in-office test is an immunoassay which is fast, easy to use, and reliably detects any natural opioids (codeine, morphine, heroin) that are present. Oxycodone and buprenorphine are often included. The disadvantage is that most synthetic opioids, such as
fentanyl, are excluded. For in-office testing, be sure to use a testing kit that is waived from federal oversight under the Clinical Laboratory Improvement Amendments law (see sidebar). For example, some waived products, used in office testing, test for the following drugs: amphetamine, barbiturates, benzodiazepines, buprenorphine, cocaine, ecstasy, methadone, methamphetamine, opiates/morphine, oxycodone, phencyclidine (PCP), propoxyphene, and marijuana (THC)

- **Laboratory**: The laboratory tests include drug-specific identification using gas chromatography, mass spectrometry, high-phase liquid chromatography, or a similar technique. The advantage is that they are highly sensitive and specific and can detect any opioid. A disadvantage is the time involved and the expense.

**INTERPRETING URINALYSIS RESULTS**

All test results must be interpreted cautiously.

| Normal Urine Drug Testing Result | **Explanation**: The patient is taking buprenorphine as prescribed (see practice tip). Continue routine urine drug testing. |
| Urine Drug Testing Negative for Prescribed Opioid | **Explanation**: Non-adherence to regular intake of buprenorphine, diversion, or false negative results. Repeat the test using laboratory testing for the specific drug of interest. Increase adherence monitoring—monitor pill counts, prescribe fewer pills, discuss future termination of buprenorphine and referral to higher level of treatment if negative UDTs continue. **Explanation**: False positive, or the patient has acquired opioids elsewhere. |
| Urine Drug Testing Positive for Non-Prescribed Opioid or Benzodiazepines | Repeat the test with immunoassay and confirm with the laboratory. Review the prescription drug monitoring program or call the patient's pharmacy or other physicians. If the patient had surgery recently, they may have received benzodiazepines as a pre-operative sedative measure. |
| Urine Drug Testing Positive for Illicit Drugs | Reiterate the treatment agreement with the patient, and the consequences of continued use (e.g., termination from buprenorphine treatment and referral to higher level of treatment). |

With results other than what was expected, a non-confrontational approach might be to say, "We have used the best tests we have and they show that your urine has X (does not have X). That is what we have to work with in deciding next steps. I'm concerned because (state reasons). What are your thoughts?"

Keep in mind that false positives are possible. In cases where a patient strongly denies use of a drug for which they test positive, gather a thorough recent drug history. This includes over-the-counter drugs and other prescriptions. Inform the laboratory about these medications to see if they could be influencing the results.
Multiple variables affect the results of urine testing:

- Cut-off selection
- Pharmacokinetics
- Pharmacodynamics
- Pharmacogenetics
- Laboratory technology
- Subversion or adulteration of urine specimen

Key information to consider for interpretation includes the cutoff level for the test and minimum and maximum detection time in urine. Knowing when the drug is supposed to be detectable will help you determine if the patient's description of their drug use matches test results.

**POSITIVE RESULTS**

**Acting on a Positive Test Result**

When treatment plans include urine testing, they must also describe the consequences of a positive result.

- Office-based opioid treatment patients who have a positive urine toxicology screen are likely to be using opioids and probably need a higher dose of buprenorphine.
- A positive urine test later in the program suggests that more intensive nonpharmacological treatments are needed to address the patient's overall drug abuse.

The class of drug found in the patient's urine also affects the appropriate response:

- Drugs such as benzodiazepines present clear dangers.
- Alcohol and stimulants may indicate necessity for appropriate nonpharmacological treatment.

For the reasons discussed above, avoid stopping treatment as a response to drug test results only; rather, discuss test results and make subsequent adjustments in the treatment plan with the patient.

**Responding to Patients Who Deny Positive Results**

1. Positive test results from an Immunoassay should be confirmed by a laboratory test and consultation with the lab or a provider experienced in UDTs.
2. Indicate to the patient that you called the lab and that the tests are indeed correct.
3. Tell the patient that it is his or her job to provide a suitable sample for the clinic.
4. Refer the patient to the consequences provided in the treatment agreement.

**PRACTICE TIP**

Do not assume a negative test result means a patient is not taking drugs. Nor should it be assumed that a positive result means a patient is taking drugs. Contact your laboratory for help with test interpretation.

**POINT-OF-CARE TESTING**

Point-of-Care (POC) testing is performed outside of a clinical laboratory. POC testing uses single-use, non-instrument or instrumented,
immunoassay devices that are commercially available for testing some common individual drugs and classes of drugs. \(^{30}\)

- Immunoassay uses antibodies to find the presence of specific drugs or metabolites
- Immunoassay POC testing is the most common method used for the initial screening process

**Advantages:**

- Relatively low cost
- Small sample sizes
- Rapid turnaround
- Can be done at the point of care by minimally trained staff

**Disadvantages\(^{31}\):**

- Relatively low specificity
- Vary in the range of compounds detected
- Device may not come with independent scientific support
- Potential for false-positive results, which require a second test for confirmation (If the patient disputes the results. Be sure to advise the patient if a 2nd test will result in additional charges for them.)

**If you decide to use POC testing, consider\(^{30}\):**

- Regulatory requirements
- Safety, physical, and environmental requirements
- Benefits
- Costs
- Staffing
- Documentation

**LABORATORY TESTING**

Point of care immunoassay results that test positive need to be sent to the laboratory to confirm the specific drug (e.g., GC-MS or high-performance liquid chromatography)\(^{30}\). Note: This may not be needed if the patient does not dispute the result. Advise patients if there will be an additional cost for a confirmatory test.

When laboratory testing can be helpful\(^{30}\):

1. To identify a specific drug
2. To identify drugs not included in other testing methods
3. When results are disputed by the patient

**Gas Chromatography/Mass Spectrometry (GC-MS)**

- Highly specific
- Highly sensitive
- Can fail to identify a positive specimen (e.g., hydromorphone, fentanyl) if the test column is designed to detect only certain substances (e.g., morphine, codeine)
**SPECIMEN TAMPERING**

**Prevention**

The Providers’ Clinical Support System for Medication Assisted Treatment offers the following tips to improve chances of obtaining a good sample:

- Require that patients take nothing into the bathroom with them that could conceal a vial of liquid
- Avoid patient diluting of their sample by turning off running water in the room and adding color to the toilet water
- Monitor the bathroom door so that the patient is the only one in the room
- Check the specimen temperature, specific gravity, and creatinine immediately

**Detection: Sample Integrity Check**

The best way to prevent tampering is observed collection, however, if that cannot be obtained, observe the integrity of the specimen by checking:

To detect tampering pay attention to the specimen’s

- Temperature (hot or cold) - Within 4 minutes of voiding, with at least a volume of 30 ml, temperature should be between 90 and 100 °F
- Volume (small amount)
- Appearance (color) - look for dilution or concentration
- pH - Range should be 4.5 to 8.0

While a positive drug test is considered part of the disease and may require a higher level of care, tampering with the urine is generally considered more problematic behavior. It raises questions about diversion, and essentially makes the test useless. You can ask the patient for a new sample, collected under supervision, and send both samples to the lab.

If urine sample tampering is suspected, the lab can:

- Check the specific gravity of the sample (to ascertain if water has been added)
- Check the pH of the sample (in case the sample was made more acidic or basic in an attempt to throw off or invalidate the screening assays)
- Perform a creatinine analysis - while urinary creatinine varies with hydration, values less than 20 mg/dL are probably diluted and values of less than 5 mg/dL are not consistent with human urine.

**TESTING FOR BUPRENORPHINE IN URINE**

You should also screen for buprenorphine; a test that is negative for buprenorphine would suggest misuse or diversion.

However, a positive test result for buprenorphine does not always indicate buprenorphine is being taken. These samples can be positive with crumbs or pieces of buprenorphine tablets being dropped into the urine to falsify a test.

If you are concerned, you should test urine for the buprenorphine metabolite, norbuprenorphine. If it is present you can be assured that the patient is taking the medication.
Buprenorphine Metabolites\textsuperscript{29}:
- norbuprenorphine
- norbuprenorphine-3-glucuronide
- buprenorphine-3-glucuronide

Buprenorphine Cutoff Levels and Detection Times
For buprenorphine, in a typical point-of-care urine drug test these values are\textsuperscript{34}:
- Cutoff Level: 10 ng/ml
- Minimum Detection Time in Urine: 2-3 hours
- Maximum Detection Time in Urine: 1 day

\textbf{POLL: AFTER LEARNING ABOUT UDTS, DO YOU PLAN TO OBTAIN A UDT ON EVERY PATIENT BEFORE STARTING BUPRENORPHINE INDUCTION?}

\begin{itemize}
  \item 1. Yes
    \begin{itemize}
      \item 93\% (3794 votes)
    \end{itemize}
  \item 2. No
    \begin{itemize}
      \item 1\% (33 votes)
    \end{itemize}
  \item 3. Unsure
    \begin{itemize}
      \item 3\% (117 votes)
    \end{itemize}
  \item 4. Only some patients
    \begin{itemize}
      \item 2\% (74 votes)
    \end{itemize}
  \item 5. Does not apply to me
    \begin{itemize}
      \item 1\% (61 votes)
    \end{itemize}
\end{itemize}

\textbf{CASE STUDY – MS. CLARK}

\textbf{Meet Your Patient}

\textbf{Name:} Ms. Clark

\textbf{Age:} 42 years old

\textbf{Reason for visit:} Monthly buprenorphine check up

\textbf{Patient History:} Ms. Clark is a divorced mother of two school-aged children who works full-time as a waitress. She began having problems with prescription opioids after taking them for a back injury in her late 20s and was later introduced to heroin by her ex-husband. After a few years of heroin use and misuse of prescription opioids, she began to have problems at work and started methadone treatment.

\textbf{History at an Outpatient Opioid Treatment Program:} Ms. Clark has been in methadone treatment a few times and generally did well, except that she frequently missed doses, because she lived 50 miles from the nearest clinic. She left treatment several times due to travel time, child care responsibilities, and cost. She had been out of treatment and relapsed for several months, using mostly oxycodone, before visiting your practice four months ago.
**Treatment history in this office:** Ms. Clark came to your office, because it is much closer to where she lives. You determined her to be an appropriate OBOT patient and inducted her on generic buprenorphine/naloxone. Ms. Clark was stabilized on 8 mg buprenorphine/naloxone. She emphasized that she wanted to keep her dose low both to incur fewer expenses and because she has long-term plans of tapering off.

Prior to induction you reviewed the patient-provider treatment agreement with Ms. Clark and asked her to sign it. Since she is a high risk patient more frequent urine drug testing was added to the treatment agreement.

After induction she graduated to monthly visits. To date, she has provided 4 urine specimens, all negative for illicit drugs. She also has received occasional counseling from a social worker in her local area.

**QUIZ: MS. CLARK – CURRENT ISSUES**

**Provider:** How is your treatment going? Have you had any problems?

**Patient:** Treatment's going well. Nothing bad to report there, but I did recently strain my back and when I went to the ER I got some codeine. I just took it once because it didn't do much for my pain. I got better after a few days of rest and ibuprofen.

She provided a pill bottle that verifies the codeine prescription. You obtained a urine specimen, and prescribe her next month's supply of buprenorphine.

Two days later, her urine specimen comes back positive for both codeine, which she disclosed to you, and morphine, which she did not.

**Question:** How should you interpret the urinalysis results?

Choose one

1. Ms. Clark appropriately took codeine, and there is no cause for concern.
   - **Feedback:** This is not the best option. However, this interpretation is possible. Codeine is metabolized to morphine, and both compounds could appear in a urine specimen after ingestion of codeine. The best choice is to contact the lab and see if they can give you the morphine-to-codeine ratio. Although the result may not be completely definitive, a high morphine-to-codeine ratio suggests morphine or heroin use, whereas a low ratio would suggest codeine use alone.

2. Ms. Clark used morphine or heroin, and there is cause for concern.
   - **Feedback:** This is not the best option. However, this interpretation is possible. Codeine is metabolized to morphine, and both compounds could appear in a urine specimen after ingestion of codeine. The best choice is to contact the lab and see if they can give you the morphine-to-codeine ratio. Although the result may not be completely definitive, a high morphine-to-codeine ratio suggests morphine or heroin use, whereas a low ratio would suggest codeine use alone.

3. You should contact the lab and discuss the results of the specimen before making a final interpretation of the test.
   - **Feedback:** Correct. This is the best option. Codeine is metabolized to morphine, and both compounds could appear in a urine specimen after ingestion of codeine. The best
choice is to contact the lab and see if they can give you the morphine-to-codeine ratio. Although the result may not be completely definitive, a high morphine-to-codeine ratio suggests morphine or heroin use, whereas a low ratio would suggest codeine use alone.

**MS. CLARK – DISCUSSING URINE TEST RESULTS**

*Provider:* Your lab results show that you have a high morphine-to-codeine ratio in your blood work. That suggests that you may have been using morphine or heroin.

*Ms. Clark:* I had a slip-up and got some heroin from my ex-husband when the codeine wasn't working. But it was just when the pain was really bad. And I stopped and now I just take buprenorphine.

*Provider:* Okay. I just want to make sure you are not at risk for a full relapse. Have you had any cravings since you stopped?

*Ms. Clark:* Yes, I still do a little. I'm afraid I might relapse.

**QUIZ: MS. CLARK – TREATMENT DECISION**

Ms. Clark has violated her treatment agreement by using illicit drugs while in office-based opioid treatment. She is upset about this misstep and concerned that you are going to kick her out of treatment.

**Question:** Now that you have heard the facts from Ms. Clark, how should you proceed?

Choose all that apply

1. Congratulate Ms. Clark on her insight and tell her you will re-evaluate at her next scheduled appointment.
   - Feedback: This is not the best option. This clinical situation is urgent and you should intervene immediately. You can start by increasing the frequency of her counseling sessions as needed, which will probably help her stabilize. Also, increasing the buprenorphine dose in this situation is almost essential, both to reduce the cravings and to occupy more mu-opioid receptors so that the effects of heroin would be blunted if Ms. Clark uses it again. Furthermore, her treatment agreement should be reviewed and revised as needed so that it works better to support her in her treatment.

2. Encourage Ms. Clark to increase frequency of her counseling sessions.
   - Feedback: This is a good option. Increasing the frequency of her counseling sessions as needed will probably help her stabilize. Also, increasing the buprenorphine dose in this situation is almost essential, both to reduce the cravings and to occupy more mu-opioid receptors so that the effects of heroin would be blunted if she uses it again. Furthermore, her treatment agreement should be reviewed and revised as needed so that it works better to support her in her treatment.

3. Discharge her from your office-based opioid treatment program and refer her elsewhere.
   - Feedback: This is not the best option. Though she has violated the treatment agreement, she seems sincere about wanting to stay on buprenorphine. There are
several changes you can make. You can start by increasing the frequency of her counseling sessions as needed, which will probably help her stabilize. Also, increasing the buprenorphine dose in this situation is almost essential, both to reduce the cravings and to occupy more mu-opioid receptors so that the effects of heroin would be blunted if Ms. Clark uses it again. Furthermore, her treatment agreement should be reviewed and revised as needed so that it works better to support her in her treatment.

4. Consider increasing her dose of buprenorphine
   • Feedback: Due to the cravings she has been experiencing, she might benefit from increasing her buprenorphine dose. Also, increasing the frequency of her counseling sessions will probably help her stabilize and should be considered in this case.

**MS. CLARK – NEXT STEPS**
Together, you decide that Ms. Clark should:

- Increase her generic combination buprenorphine dose to 16 mg.
- Increase counseling frequency over the next several weeks in order to have the support she needs to remain abstinent
- Have more frequent office visits or more random urine screens during the next few months while she gets stabilized on her new dose.

**SUMMARY AND KEY POINTS**

**Recommendations for Defining Practice Rules and Expectations**

- Create a set of rules and expectations to apply to all patients that are mutually agreeable and defined during the initial visit.

**Recommendations Related to Buprenorphine Treatment**

- Discuss all aspects of buprenorphine treatment
- Prescribe only small amounts of buprenorphine for new patients and provide refills if they are compliant with treatment.
- Be aware of all drugs and medications currently being used by patients.

**Dealing with Problematic Behaviors**

- Most office-based opioid treatment patients are compliant with treatment, but be aware of problematic behaviors and have a plan for dealing with them.
- Patients who are taking buprenorphine but still abusing opioids or other drugs may need to be referred to a higher level of care.

**Dealing with Misuse and Diversion of Buprenorphine**

- Missed appointments, lost prescriptions, and inaccurate pill counts are among the signs that buprenorphine is being misused or diverted.
- Patients who misuse or divert their medication should be reevaluated and moved to a more intensive level of treatment if needed.
• Injectable or implant formulations result in less supply of the medication lying around to be diverted.

**Enforcing Consequences for Negative Behaviors**
- Violations of the treatment agreement or practice rules must be addressed
- Place each violation in the context of that individual's condition
- Consider if more intensive treatment is required
- Serious negative behaviors are grounds for discharge from the practice.

**Urine Testing in Buprenorphine Treatment**
- Urine drug testing should be routine in an opioid treatment program.
- Randomized testing with direct observation is most effective.
- Interpret results cautiously. Do not assume a negative test means a patient is not taking drugs. Likewise, a positive result is not necessarily definitive.

**RESOURCES AVAILABLE THROUGH THIS MODULE:**

- **A Closer Look at State Prescription Monitoring Programs (DEA FAQ's)**
  These FAQs address common questions regarding prescription drug monitoring programs.

- **Adherence, Diversion and Misuse of Sublingual Buprenorphine**
  This 2010 (update 2014) Physician Clinical Support System (PCSS) document written by Dr. Judith Martin discusses types of aberrant behavior associated with buprenorphine and steps that can be taken to reduce the risk of abuse and diversion.

- **Appropriate Use Checklist**
  Reminder of the safe use conditions and monitoring requirements for prescribing buprenorphine-containing transmucosal products for opioid dependence.

- **Behavioral Health Treatment Services Locator**
  The behavioral health treatment services locator is an on-line source of information for persons seeking treatment facilities in the United States or U.S. Territories for substance abuse/addiction and/or mental health problems.

- **Clinical Laboratory Improvement Amendments (CLIA) - Currently Waived Analytes**
  The following is a list of currently waived analytes that are used in laboratory test systems. The list provides the analyte name as well as a link to the waived test system.

- **Example of Office-Based Opioid Treatment Policies**

- **Hablando con su médico (Talking to Your Doctor (en Español)**
  This patient handout sheet discusses the importance of honesty from both the patient and the doctor when talking about drug use and treatment.

- **Medication Guide: Suboxone Sublingual Film (CIII)**
  Patient information sheet on buprenorphine plus naloxone sublingual film

- **Opioid Treatment Program Directory**
  Find Opioid Treatment Programs by state.

- **Prescription Drug Monitoring Program Training and Technical Assistance Center**
  PDMO TTAC at Brandeis University provides support and resources for multiple stakeholders regarding PDMPs/
• SAMHSA's Buprenorphine Physician and Treatment Program Locator
  A directory of treatment programs and physicians authorized to treat patients with buprenorphine.

• SAMHSA TIP 43, Chapter 9: Drug Testing as a Tool
  This chapter from TIP 43: Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs discusses the use of drug testing as a means of monitoring patient progress and treatment efficacy. This chapter details several methods for implementing drug testing, their effectiveness, and their pros and cons.

• Sample Treatment Agreement/Contract (TIP 40 Appendix H)
  Patient contract that can be used to set expectations and guidelines before beginning buprenorphine treatment.

• Talking to Your Provider
  This patient handout sheet discusses the importance of honesty from both the patient and the provider when talking about drug use and treatment.

• TAP 32: Clinical Drug Testing in Primary Care

REFERENCES USED IN THIS MODULE:


34. TransMed. CLIA Screen In-Vitro (CSI) 12-Panel Drug Test Screening Cup CLIA Waived TransMed Drug Test Lab Supplies. 2018.  