# Regulations for Office Based Opioid Treatment

## Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulations for Office-Based Opioid Treatment</td>
<td>1</td>
</tr>
<tr>
<td>Goal:</td>
<td>1</td>
</tr>
<tr>
<td>After completing this module participants will be able to</td>
<td>1</td>
</tr>
<tr>
<td>Professional Practice Gaps</td>
<td>1</td>
</tr>
<tr>
<td>Module Introduction</td>
<td>2</td>
</tr>
<tr>
<td>Case Illustration</td>
<td>2</td>
</tr>
<tr>
<td>Source Information</td>
<td>3</td>
</tr>
<tr>
<td>FYI</td>
<td>3</td>
</tr>
<tr>
<td>Primary Care Role in Addiction Treatment</td>
<td>3</td>
</tr>
<tr>
<td>New Role and Responsibilities in Primary Care</td>
<td>3</td>
</tr>
<tr>
<td>Using a Team Approach</td>
<td>3</td>
</tr>
<tr>
<td>Managing Time in a Best Practice Model of Care</td>
<td>3</td>
</tr>
<tr>
<td>Poll: When do you plan to institute a team approach towards substance abuse treatment in your practice?</td>
<td>4</td>
</tr>
<tr>
<td>Staff Roles and Considerations</td>
<td>4</td>
</tr>
<tr>
<td>Intake and Clinical Staff</td>
<td>4</td>
</tr>
<tr>
<td>Billing Staff</td>
<td>4</td>
</tr>
<tr>
<td>Staff Training</td>
<td>5</td>
</tr>
<tr>
<td>Information to Convey</td>
<td>5</td>
</tr>
<tr>
<td>Principles of Staff Training</td>
<td>5</td>
</tr>
<tr>
<td>Other Topics to Cover in Training</td>
<td>6</td>
</tr>
<tr>
<td>Confidentiality Law</td>
<td>6</td>
</tr>
<tr>
<td>Goal of the Law</td>
<td>7</td>
</tr>
<tr>
<td>Scope of the Law</td>
<td>7</td>
</tr>
<tr>
<td>Confidentiality Rules for Communications</td>
<td>7</td>
</tr>
<tr>
<td>Restricted Communication</td>
<td>7</td>
</tr>
<tr>
<td>Internal Communications</td>
<td>8</td>
</tr>
<tr>
<td>Other Confidentiality Law Concerns</td>
<td>8</td>
</tr>
<tr>
<td>Consequences for Violation</td>
<td>8</td>
</tr>
<tr>
<td>State Confidentiality Laws</td>
<td>8</td>
</tr>
<tr>
<td>Additional Rights for Minors</td>
<td>8</td>
</tr>
</tbody>
</table>
# Disclosure Rules

- Exceptions to Disclosure Rules
- Qualified Service Organization Agreement
- Scientific Research
- Emergency Medical Reports
- Court Orders
- Child Abuse or Neglect Reports
- Consent Forms
- The Consent Form Must Contain
- Quiz: Disclosure of Information

# The Prescription

- What Goes on the Prescription
- Electronic Prescribing
- PRACTICE TIP

# Medical Records

- Organizing Your Buprenorphine Records
- Additional Requirements for In-Office Dispensing
- Role of State Medical Board
- KEY POINT

# DEA Oversight of Buprenorphine Prescribers

- SAMHSA Reporting if Approved to See Up to 275 Patients
- Quiz: Practice Implementation

# Billing

- Discussing Payment Prior to Services
- Health Insurance Coverage

# CPT and ICD Codes Related to Buprenorphine Treatment

- Coding for Induction and Maintenance
- Contributing Components
- Commonly Used Codes
- ICD Codes
- Private Health Insurers

# CPT Codes for Counseling (Primary Care)

# CPT Codes for Psychiatrists
Medicaid and Medicare Coverage.................................................................................................................. 20
Medicaid Coverage.............................................................................................................................................. 20
Medicaid Screening and Brief Intervention Codes............................................................................................ 20
Medicare............................................................................................................................................................. 20
FYI........................................................................................................................................................................ 20

Poll: Prior to this training, were you familiar with the billing codes associated with buprenorphine treatment?......................................................................................................................................................... 20

Setting Up a Cash-Only Buprenorphine Treatment Program................................................................................. 21
Running a Cash-Only Buprenorphine Treatment.................................................................................................... 21
Flat Rates.............................................................................................................................................................. 21

Cost of Buprenorphine Treatment to Patients...................................................................................................... 21
Cost of Buprenorphine to the Patient.................................................................................................................. 21
Help for Non-Insured Patients................................................................................................................................ 22

Quiz: Case Study – Mrs. Olsen............................................................................................................................ 22
Meet Your Patient.................................................................................................................................................. 22
One Week Later................................................................................................................................................... 22
Question: How should you handle this faxed request from the pharmacy? (Choose the best answer). . . . . . . . . . . . . . . 23

Mrs. Olsen – Discussion About Insurance.......................................................................................................... 23

Quiz: Mrs. Olsen – Billing Decision.................................................................................................................... 24
Question: How should you bill the time? (Choose the best answer)......................................................................... 24

Quiz: Mrs. Olsen – Continued Treatment............................................................................................................ 24
Insurance Confirmation....................................................................................................................................... 24
Continued Treatment......................................................................................................................................... 25
Subsequent Visits.................................................................................................................................................. 25
Question: What would you do about insurance authorization for continued treatment? (Choose the best answer). . . . .. 25

Further Staff Training.......................................................................................................................................... 26
Prepare the Other Clinicians.................................................................................................................................. 26
PRACTICE TIP...................................................................................................................................................... 26

Establishing a Relationship with a Pharmacy...................................................................................................... 26
Ensuring Your Patients Have Access to Medication.............................................................................................. 26
Guidelines to Consider......................................................................................................................................... 26
Have All Patients Sign a Pharmacy Consent........................................................................................................ 27
Summary and Key Points........................................................................................................................27

A Team Approach to Office-Based Treatment..........................................................................................27

Confidentiality of Patient Records..........................................................................................................27

Billing and Insurance..................................................................................................................................27

PRACTICE TIP...............................................................................................................................................27

Read THE NEXT PAGE for important info Then, return to the Activity Page and use the large blue buttons to complete..............................................................................................................................................28

Must Read on Finishing the Activity!..........................................................................................................28

What you need to know about finishing this activity & getting a waiver to prescribe buprenorphine:........................................................................................................................................................................28

Resources available through this module:..................................................................................................29

References used in this module:................................................................................................................31
REGULATIONS FOR OFFICE-BASED OPIOID TREATMENT

Goal:
To prepare providers to follow regulations, laws, and other requirements for office-based treatment of opioid use disorder

After completing this module participants will be able to:
• Prepare a practice staff team for office-based buprenorphine practice
• Determine the pertinent confidentiality regulations (and exceptions) for treatment of substance use disorder and specifically office-based treatment of opioid use disorder
• Follow the requirements for medical record-keeping in office-based opioid treatment
• Prepare an office-based opioid treatment practice to work with health insurance companies or patients to bill for buprenorphine treatment

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:

• 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). 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\(^5\), 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\(^5\). 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\(^6\) 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.


**MODULE INTRODUCTION**

Practices starting to provide office-based opioid treatment need to make a number of office and practice-related protocol changes. They also need to prepare staff to implement them. Minor changes in medical records, patient confidentiality, communications with pharmacies, and insurance billing are required.

**Case Illustration**

This module describes the changes needed in a new office-based opioid treatment practice. It will prepare you and your staff to make the required modifications. The following case study will be used to illustrate how these issues affect patients.

**MRS. OLSER**

Mrs. Olsen, whose family is seen in your practice, has been taking 10-12 tablets per day of hydrocodone and oxycodone for the past 6 months. She was referred by her therapist for buprenorphine treatment.

What communications are permitted with the therapist, regarding Mrs. Olsen? With her family?
Source Information
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.

FYI
This module communicates general information and is not intended to replace consultation with an attorney or to be a full discussion of privacy issues related to the Health Insurance Portability and Accountability Act (HIPAA).

PRIMARY CARE ROLE IN ADDICTION TREATMENT

New Role and Responsibilities in Primary Care

In years past, primary care providers (PCPs) referred patients with substance use disorders to:

- Psychiatrists
- Addiction specialists
- Other mental health professionals
- Substance abuse treatment centers

Times have changed; PCPs are now responsible for the:

- Detection
- Assessment
- And intervention of substance use disorders

At minimum, routine screening for alcohol use and substance misuse should be part of all primary care practices. Ideally, PCPs should be comfortable and competent in their ability to assess, intervene, and treat or refer substance-abusing patients

USING A TEAM APPROACH
Managing Time in a Best Practice Model of Care

Conducting substance abuse treatment via a team approach allows the practitioner to provide treatment within the time constraints of the current health care system. Patients struggling with addiction often require more time and support because of factors including, but not limited to:
Using a team approach helps in delivering addiction treatment within the time constraints typical of many primary care practices. Although only waivered providers can prescribe buprenorphine, staff can assist with many aspects of treatment. A study involving 400 buprenorphine patients found that collaborative care, that is, involving close cooperation among providers, is effective for opioid treatment in the primary care setting.\(^7\)

**POLL: WHEN DO YOU PLAN TO INSTITUTE A TEAM APPROACH TOWARDS SUBSTANCE ABUSE TREATMENT IN YOUR PRACTICE?**

1. My practice already uses a team approach for this purpose  
   - 47% (1941 votes)
2. In the near future  
   - 23% (928 votes)
3. My practice will need more training first  
   - 28% (1164 votes)
4. I will not use a team approach for this purpose  
   - 2% (73 votes)

### STAFF ROLES AND CONSIDERATIONS

Educate your staff on buprenorphine treatment and addiction. Proper training among staff members can have an immediate effect, as the more information and involvement that they have, the smoother your practice will run and the better care your patients will receive.\(^8,9\) Also, be sure to explain every staff member’s role to your patients so they know who to ask for help or if there is a problem during any phase of treatment.

**Intake and Clinical Staff**

Clinical staff can assist with most steps of buprenorphine treatment if a consistent plan is in place. The appropriate office staff need to:

- Be prepared to talk about Office-Based Opioid Treatment with prospective patients.
- Follow a standardized intake form or checklist available from which to ask questions and gather basic information over the phone. The intake checklist should include questions about opioid use and treatment history and can be administered via phone by administrative or clinical staff with minimal training.

**Billing Staff**

The appropriate office staff need to be:
• Familiar with what insurance plans your practice accepts
• Able to identify the requirements that various insurance plans have with respect to buprenorphine treatment. With this knowledge, they will be prepared to gather all required information and permissions so that there is no delay in treatment.
• Familiar with and able to describe for patients the cost of treatment. This is a significant concern to many patients.
• Familiar with the relevant diagnostic and treatment codes

STAFF TRAINING

Your staff will be assisting you with many of the tasks essential to conducting in-office buprenorphine treatment. Before starting office-based buprenorphine treatment, you should conduct formal training with your staff so that they will be more fully knowledgeable of both the benefits of substance use intervention and their roles within the treatment process. The brief guidelines below can help you structure your training in order to gain the most benefits.

Staff members need a firm grasp of the principles of addiction treatment and specifically buprenorphine treatment. They will need the corresponding clinical skills and an attitude conducive to working with this patient population. The staff’s attitudes will affect the way they treat patients, thus influencing the outcome of treatment.

Information to Convey

In the course of your staff trainings, try to cover the following topics:

• Addiction is a chronic medical illness, not a character flaw or weakness of will, and can be treated successfully
• The treatment philosophy your practice espouses
• Substance abuse screening skills
• The basic underlying principles of how buprenorphine treatment works
• The clinical pathway for buprenorphine treatment
• The proper ways in which to store, distribute, and administer buprenorphine
• Proper record keeping and compliance with confidentiality legislation
• Appropriate interaction with patients and how to handle negative situations that may arise
• Psychosocial issues that may occur among patients who are opioid-dependent
• Knowledge of other services and referral options

Principles of Staff Training

The setting and tone of the trainings and the methods of information delivery will influence learning. Keep the following principles in mind:

• Design hands-on activities that stress experience. Focus on skills by using role-playing, for example. This will be more effective for staff than simply being lectured. Start the training with a participatory activity and intersperse these activities throughout the training to keep attention levels high.
• Notice how the staff members learn, and try to do more things that enhance their learning.
• Provide additional resources so that learning can continue after training is complete.

OTHER TOPICS TO COVER IN TRAINING
Staff training is especially needed if your practice has done minimal or no previous substance abuse treatment, as staff may not know how or when to provide such treatment. Neither advanced degrees nor clinical experience will ensure appropriate behavior toward substance-using patients. For this reason, all staff members who have patient contact (both clinical and support staff) should be trained and educated about buprenorphine before launching an office-based opioid treatment practice.

All staff should be able to provide suitable general treatment for substance use disorders or buprenorphine treatment for opioid use disorder. Like clinicians, support staff should have positive, constructive attitudes toward patients having opioid use disorder and their treatment, as it will affect the overall interactions that patients have within your practice. In addition, staff training should include other concrete goals:
• Debunking myths about substance misuse and substance use disorders.
• Educating about substance use disorders in general and opioid use disorder. Include information on the role that medications and maintenance therapies play in the treatment of opioid use disorder.
• Reviewing patient confidentiality regulations and the use of treatment agreements.
• Reviewing clinic guidelines for in-office and/or at-home induction protocols and the clinic's treatment philosophy.

CONFIDENTIALITY LAW
The confidentiality law places limits on the disclosure and use of any information that will identify a patient as someone who:
• Has received substance abuse treatment
• Is currently receiving substance abuse treatment
• Has applied to a substance abuse treatment program

The substance abuse treatment confidentiality law, the Public Health Service Act, is Title 42 of the United States Code of Federal Regulations. Unlike HIPAA, which governs all medical treatment, this law applies specifically to substance abuse treatment.

Title 42 CFR prohibits releasing records without:
• Patient consent
• A court order
• A true medical emergency
• Or report of child abuse (Child abuse itself should be reported, but restrictions continue to apply to the original patient records.)
Goal of the Law
The goal of the confidentiality law is to prevent the disclosure of information identifying applicants/recipients of substance abuse treatment. The law was created, in part, to facilitate patients' entry into substance abuse treatment. The underlying rationale is that people will be more willing to access treatment if they are confident that information about their diagnosis and treatment will remain private.

Scope of the Law
Any type of substance abuse treatment, or referral for treatment must comply with the confidentiality law. The scope of the confidentiality law includes:

- Individual practitioners who are DEA-certified
- Substance abuse treatment programs
- Federally assisted programs that provide diagnoses of substance use disorder. This includes:
  - Operated by the federal government
  - Certified for Medicaid reimbursement
  - Receiving federal block grant funds
  - Licensed by the federal government
  - Exempt from paying taxes
- Health plans and health care clearinghouses

Occasionally, federal or state grant money will be given only under the condition that confidentiality laws are obeyed. Neglecting to comply with the law could result in loss of funding. Application of confidentiality laws in cases of substance abuse treatment is dependent on status and identification as a treatment facility.

CONFIDENTIALITY RULES FOR COMMUNICATIONS
As a substance abuse treatment provider, you must follow rules restricting communications to assure patient confidentiality. Examples of types of rules that restrict communications include internal communications, additional rights for minors, and disclosure rules.

Restricted Communication
There are limits on how much information you can communicate about patients.

Actions regarding a patient's information that are prohibited include:

- Giving information to family members (this is illegal unless the patient has consented in writing)
- Disclosure of a patient's medical record
- Use of a letterhead that identifies your office as a substance abuse treatment provider
- Receptionist confirmation of a person's status as a patient who is receiving substance abuse services

More specifically, your substance abuse treatment program may not communicate the following:
• Information regarding a patient’s past, present, or future participation in substance abuse treatment
• Information about those who have applied for treatment or have been interviewed, regardless of whether they actually commenced treatment
• Information about deceased patients
• Verification of information that inquirers already possess – in other words, a program can neither confirm nor deny that a patient was being treated there.

Internal Communications
Information may be shared among staff and may be disclosed to the record keeping and billing departments. Program staff with access to patient records may consult among themselves or otherwise share information if necessary to complete their duties.

OTHER CONFIDENTIALITY LAW CONCERNS

Consequences forViolation
Violating the confidentiality law carries a criminal penalty. Guilty parties may be fined $500 for the first violation and $5,000 for each successive violation. If the violation occurs at the program level, the program may have its license or certification revoked. Additionally, patients may file lawsuits if their confidentiality is violated.

State Confidentiality Laws
• State laws may differ from federal regulations.
• State laws that are more restrictive than federal regulations must be obeyed.
• State laws cannot decrease federal restrictions.

Check with your state governmental office or state medical association for complete information.

Additional Rights for Minors
Minors have additional rights. Under the confidentiality law, practitioners are prohibited from communicating with a minor patient's parents unless the patient authorizes such contact on a consent form. Some states require parental approval for the treatment of minors, in which case more regulations apply. If you plan to treat minors, you should familiarize yourself with your state’s laws regarding minors and consult an attorney if confusion remains. This module is not designed to teach about the treatment of opioid use in minors.

DISCLOSURE RULES
Providers must inform patients of their rights regarding confidentiality shortly after they enter treatment. The communication should include a written statement of relevant regulations.

With a proper consent form, you may disclose some patient information to third parties in certain instances.

• Information may be disclosed only for the purpose(s) outlined in the form.
• A patient may revoke his or her consent at any time, either verbally or in writing.
• If a patient revokes his or her consent, you have no obligation to retrieve information that was disclosed while the consent was effective.
• Whenever information is disclosed, you must provide a written statement informing the recipient that the information is protected by federal law. You must also state that it cannot be re-disclosed, unless otherwise specified.
• An activity is not allowed to disclose whether or not someone has received treatment for substance abuse. However, if the activity provides several kinds of services, it may disclose that the patient has been seen as long as it does not specify the reason for treatment.

EXCEPTIONS TO DISCLOSURE RULES
The following are allowable exceptions to disclosure rules:

Qualified Service Organization Agreement
An office-based opioid treatment program may disclose information to qualified service organizations (QSOs) that provide services that the program does not. An example would be an outside laboratory to conduct urine or hair analysis.

In addition to being DEA licensed, providers must fit additional criteria to meet the definition of a “program”:

1. "An individual or entity (other than a general medical care facility) who holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment;"
2. "An identified unit within a general medical facility which holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment or referral for treatment; or"
3. "Medical personnel or other staff in a general medical care facility whose primary function is the provision of alcohol or drug abuse diagnosis, treatment or referral for treatment and who are identified as such providers."

Providers are encouraged to refer to the detailed regulations outlined in 42 CFR or refer to SAMHSA’s FAQs on Applying the Applying the Substance Abuse Confidentiality Regulations to see if they meet all the criteria to be considered a program.

Scientific Research
You may choose to grant a researcher access to patient records, however:

• Outside evaluators (such as institutional review boards) must deem the rewards of the research greater than the risks
• Patient names and other identifiers should be stripped from the data before distributed
• Researchers must not re-disclose confidential information

Emergency Medical Reports
In emergencies, patient information may be disclosed to medical personnel but not to non-medical workers or the patient’s family. The working definition of a medical emergency is a situation that poses an immediate threat to someone’s health and requires immediate medical attention. Note that the person whose health is in jeopardy is not necessarily the patient; for example, it could be a child who may have overdosed on buprenorphine.
Court Orders
Only court orders (not subpoenas or warrants) are grounds for disclosure of patient information regarding substance abuse treatment. An order can only be issued if the court decides that there is good cause for the disclosure. The benefits of issuing such an order must outweigh the risks. The court must also deem that the information cannot be accessed in any other manner.

Child Abuse or Neglect Reports
Practitioners must report cases of child abuse or neglect, but the victim or perpetrator need not be identified as receiving substance abuse treatment. Regulations continue to protect confidentiality of the original patient records. This includes disclosure and use for civil or criminal proceedings, unless a court order (see above) overrides this protection. Each state requires reporting suspected child abuse or neglect and offers immunity to practitioners who comply; most penalize practitioners who do not report known cases of child abuse or neglect.

CONSENT FORMS
The Consent Form Must Contain...
Each of the following items must be contained in the consent form:

- The name or general description of your program(s)
- The name of the patient and the names of individuals/organizations that will receive the disclosure
- The purpose or need for the disclosure
- How much and what kind of information will be disclosed
- A statement that the patient may revoke the consent at any time
- The date, event, or condition upon which the consent expires if not previously revoked
- The signature of the client
- The date on which the consent is signed

QUIZ: DISCLOSURE OF INFORMATION
Can an office-based opioid treatment program disclose treatment information to a patient's spouse (but no one else) before the consent form has been signed?

1. Yes, the information can be shared with a spouse before the consent form is signed.
   - Feedback: Incorrect
   Until the patient has consented in writing about this treatment, addiction treatment information cannot be disclosed to anyone, including the patient's spouse.

2. No, a consent form about this addiction treatment is required for information to be shared with anyone (including a spouse).
   - Feedback: Correct.
   Until the patient has consented, in writing about this addiction treatment, treatment information can not be disclosed to anyone, including the patient's spouse.

3. Yes, information can be shared if there is a consent form on file from previous medical treatments.
• Feedback: Incorrect

Until the patient has consented, in writing about this addiction treatment, the patient's
treatment information cannot be disclosed to anyone, including the patient's spouse. 
General information about your treatment programs can be shared, however.

THE PRESCRIPTION

What Goes on the Prescription
PRACTICE NAME
Address
Phone Number | Fax Number
Provider Name
License Number | DEA Registration Number
DATA 2000 Identification Number

Patient Name:
Patient Address:
Patient DOB:
Patient Age:

Medication Name:
Medication Strength:
Medication Dosage:
Medication Quantity:
Directions For Use:

Provider Signature
XX/XX/XX
Date of Prescription

Note: The DATA 2000 identification number begins with the prefix “X” [Example: X555-555-55555]. Instructions should be provided with the prescription for the specific formulation prescribed, as they can vary.

Paper prescriptions should be manually signed, whether filled out with indelible ink, typed on a typewriter, printed on a computer, or faxed. The DEA recommends making a copy of each prescription.

Electronic Prescribing
All states currently allow e-prescribing of Schedule 2 narcotics, but the software to support these prescriptions may need to be upgraded in order to meet DEA standards before prescriptions can be
sent by provider or accepted by pharmacies. Additionally, there is no requirement that a provider must utilize e-prescribing in their practice, nor that pharmacies must accept e-prescriptions.

Electronic prescribing requires a two-step verification process:

1. send the prescription for fulfillment
2. apply a digital signature when the prescription is sent

The Department of Justice suggests the following, or an equivalent statement:

"By completing the two-factor authentication protocol at this time, you are legally signing the prescription(s) and authorizing the transmission of the above information to the pharmacy for dispensing. The two-factor authentication protocol may only be completed by the practitioner whose name and DEA registration number appear above."

The Department of Justice has created some General Questions and Answers that may be helpful in learning more about the regulations surrounding e-prescribing of narcotics. This information can be found in the resources section.

The Support for Patients and Communities Act (SPCA) of 2018 provides that “In general, prescriptions for controlled substances that are covered drugs under Medicare must be transmitted through electronic prescription programs.”

**PRACTICE TIP**

Be sure to explain the directions for use of the buprenorphine formulation you are prescribing. Patients typically are not used to taking a medication orally that is absorbed rather than swallowed.

**MEDICAL RECORDS**

When starting to treat substance abuse patients, you may need to adjust your charting habits. Accurate and up-to-date medical records protect both the provider and patient in the event of a legal challenge. Be sure to clearly document your decision-making process. Notes on the following should be included for each patient:

**Patient Information**

- Patient's demographics
- Patient pharmacy and contact information
- Other providers
- Insurance or private pay records

**History and Evaluation**

- Medical history including diagnoses, therapies being used, medications prescribed, actual or references to records from past treatment by other providers
- Substance use and treatment history
- Physical exam results including those relative to opioid use disorder
• Laboratory test results including baseline lab and urine test results
• Results of other assessments
• Initial diagnosis and criteria met that support this diagnosis

Treatment Plan
• Treatment plan information, including measurable treatment goals, updated as needed
• Documentation of consultation discussions
• Induction plan and maintenance dose
• Current medications, including patient's response, side effects, and record of all prescriptions orders
• Psychosocial services required/recommended

Patient Education, Agreements, and Consent
• Copies of signed consent forms
• Disclosure forms
• Treatment agreements, signed by both you and the patient
• Authorizations for release of information to other providers
• Document efforts taken to avoid diversion, including reviewing the patient's record on the Prescription Drug Monitoring data base
• Copies of patient education materials including how to use medications (or a list of materials distributed)
• Document discussion of proper and safe storage of medication

Maintenance
• Schedule for follow-up visits
• A record of each maintenance visit and reasons for any changes in the treatment plan
• Monitoring visits

ORGANIZING YOUR BUPRENORPHINE RECORDS
There is no standard requirement for organizing your buprenorphine records, but the DEA suggests the following:
• Keep a photocopy of each prescription
• Keep a separate log of prescriptions issued
• Make a note in patient chart with prescription data and amount
• Keep all prescribing records together so they can be readily obtained in case of a DEA inspection
• Efficient prescription logs should include patient name, specific medication and strength, quantity, and the number of refills.
Electronic medical records are permitted, as long as they are readily accessible.

**Additional Requirements for In-Office Dispensing**

Most pharmacies now stock buprenorphine, so dispensing tablets from the office is an uncommon practice. Buprenorphine "must be stored in a securely locked, substantially constructed cabinet". Providers who dispense buprenorphine directly from the office must keep additional records:

- An inventory of the amount of buprenorphine tablets that are received and dispensed (note: an inventory showing that no medication was dispensed may be required by the field office, even if you do not keep an inventory on site)
- Data about areas of dispensing, receipts, inventories
- Records of any theft/loss/ destruction of the controlled substances

**Role of State Medical Board**

State Medical boards determine whether prescribing practices are appropriate based on overall patient treatment and documentation of treatment plans and outcomes. They generally get involved if there has been a complaint. The patient's opioid addiction must be treated appropriately or appropriate referral made. Additionally, the patient's functioning should be addressed if there are co-occurring medical or psychiatric conditions or significant psychosocial issues.
KEY POINT
The following will help you prepare for a U.S. or state DEA site visit:

1. Making a copy of written prescriptions
2. Keeping a log of buprenorphine patient names
3. Keeping buprenorphine patient records together

DEA OVERSIGHT OF BUPRENORPHINE PRESCRIBERS
The U.S. DEA requires that all prescribers keep two years worth of medical records for their buprenorphine patients. DEA field officers conduct unscheduled site visits to randomly selected buprenorphine prescribers each year to ensure that they are keeping adequate records. The frequency of DEA visits is decreasing. Specifically, the DEA reviews:

- Prescribing records
- Dispensing records
- Adherence to patient limits (30 patients initially, however, you can apply to increase to 100 after one year and 275 after another year. Certain addiction specialists may qualify for the higher limits initially.)

Federal DEA record-keeping requirements include the following:

- Keep written (or electronic) records of all prescriptions written for buprenorphine detoxification or maintenance.
- Keep prescribing records at your DEA registered location. If you are registered with the DEA at your home address, that is where the DEA will conduct a site visit.
- If you work in multiple offices, you must copy and keep ALL records at your registered address. Remember, this is only for prescribing records, not all patient files.
- Some states have more stringent record keeping requirements. Check with your state medical board to see if you need to keep records longer than two years.
- Contact your DEA local field office with any questions about DATA 2000 record keeping guidelines.

*State DEA requirements may be more stringent and should be checked.

SAMHSA REPORTING IF APPROVED TO SEE UP TO 275 PATIENTS
Providers approved to see up to 275 patients must report to SAMHSA annually, within a month of the anniversary of their approval or face losing their approval to see the additional patients. This report is in addition to DEA audits. The required information is:

1. Their patient case-load presented by month
2. Frequency of referring patients to behavioral health services (or providing these services)
3. Description of the features in the practitioner's plan for diversion control (e.g. frequency of urine drug testing, pill count call-back's, and checking the prescription drug monitoring program (PDMP).
SAMHSA will provide a reporting form for this purpose, which will clarify any additional specific
details. Practitioners having questions should contact the Public Health Advisor, Center for Substance Abuse Treatment.

Note that there are no such reporting requirements for practitioners approved to prescribe to 30 or 100 patients. This reporting rule applies only to those approved to see 275 patients.

The purpose of the report is to help ensure that patients receive "the full array" of medication assisted
treatment evidence-based services and to help minimize misuse and diversion.

*Reminder - When you are first waivered, you may treat no more than 30 patients at the same time. After a year, you can apply to treat no more than 100 patients. After a year at the 100 limit, you can apply to treat no more than 275 patients. It is only those providers at the highest limit of 275 who must fulfill the above reporting requirement. Certain addiction specialists may qualify to treat 275 patients without going through these steps. The number of patients you are qualified to see will be determined during the submission of the waiver notification form.

QUIZ: PRACTICE IMPLEMENTATION

Question: Which of the following suggestions would you implement in your practice? Choose all that you think might apply then submit to see which ones are DEA recommendations.

1. Make a photocopy of each prescription.
   - Feedback: Correct. The DEA recommends making a photocopy of each prescription.

2. Keep a separate log of prescriptions issued.
   - Feedback: Correct. The DEA recommends keeping a separate log of prescriptions issued. Note that a separate log of prescriptions issued typically has to be done as a separate step because most electronic health records do not provide a way to search for or create reports to track or provide a census for buprenorphine prescriptions. You might search by diagnostic code (304) to first come up with patients who have opioid use disorder, but there is usually no way to keep a registry in EHRs.

3. Make a note in the patient record with prescription data and amount.
   - Feedback: Correct. The DEA recommends making a note in patient chart with prescription data and amount.

4. Keep all prescribing records together so they can be readily obtained in case of a DEA inspection Prepare for the DEA field officer once yearly visit.
   - Feedback: Correct. The DEA recommends keeping all prescribing records together so they can be readily obtained in case of a DEA inspection.

5. Prepare for the DEA field officer once yearly visit.
   - Feedback: Incorrect. This is the only option that does not apply. DEA field officers do not visit each buprenorphine prescriber on a yearly basis. Visits are random. Practices that dispense buprenorphine will also be audited. Providers who comply with federal record keeping and treatment guidelines have no need for concern.
BILLING

Discussing Payment Prior to Services
Prior to starting a patient on buprenorphine, you should discuss the
issue of payment for services. First determine who should be billed—
an insurance agency, the patient, or both.

Health Insurance Coverage
Private insurance companies tend to cover the cost of appointments
for buprenorphine treatment. Almost all major insurers also cover at
least a portion of the prescription expense. It can be time-consuming
to determine whether and to what extent insurance covers
buprenorphine. Certain factors should be considered:

- Health insurance plans may classify buprenorphine/naloxone as a "niche" medication,
because it is prescribed solely for opioid use disorder, which affects a limited number of
individuals.
- In some insurance plans, buprenorphine treatment is covered, but counseling is uncovered or
unavailable.22
- In a minority of insurance plans, buprenorphine may be off-formulary, resulting in higher co-
pays.
- Exorbitant co-pay costs for patients may require planning and foresight regarding dosing and
medication refills. For instance, some insurance provider co-pay amounts may be based on
the number of pills prescribed.
- Insurers may also limit their coverage regarding the number of doses received or the duration
that a patient may be permitted to receive treatment.23
- Insurance coverage also varies by region and state.22

Patients who plan to use insurance coverage for buprenorphine treatment should contact their
insurance company, or work with you to contact their insurance if you provide that service, prior to
starting treatment to see what expenses are covered.

CPT AND ICD CODES RELATED TO BUPRENOPHINE TREATMENT
Ask about patient insurance during the first visit even if they do not plan to file for office visits.
Buprenorphine may be covered as a pharmacy benefit. However, some patients may wish not to file
insurance, as it is recorded on their permanent health record.

Coding for Induction and Maintenance
There are few specific codes for billing for buprenorphine treatment. Primary care physicians have
been successfully using standard evaluation and management outpatient billing codes for both
induction and maintenance treatment stages.

Contributing Components
Coding is either based on complexity of service or time, with four contributing components:

- History
- Physical exam
• Complexity of decision-making
• Contributing factors (e.g., time)

In the event of an audit, the documentation for a single visit must stand alone, unless another record is specifically referenced.

**Commonly Used Codes**
The most commonly used CPT codes by Primary Care Physicians are as follows:

<table>
<thead>
<tr>
<th>Type of Visit</th>
<th>Code</th>
</tr>
</thead>
</table>
| Assessment Visit: Comprehensive evaluation of new patient or established patient for suitableness for buprenorphine treatment | New Patient: 99205  
Established Patient: 99215  
New Patient E/M: 99201-05  
Established Patient E/M: 99211-15  
Patient Consult: 99241-45  
Psychiatric Outpatient Counseling: 99251-55  
Add-on Codes:  
30-60 minutes: 99354;  
60+ minutes: 99355 |

**Induction Visits:**
Any of the new patient evaluation and management (E/M) codes might be used for maintenance visits. Codes listed are in order of increasing length of time with patient and/or severity of the problems. Psychiatric outpatient counseling code does not specify minutes. Prolonged visit codes (99354, 99355) may also be added onto E/M codes for services that extend beyond the typical service time, with or without face-to-face patient contact. Time spent need not be continuous.

**Maintenance Visits:**
Any of these established patient E/M codes might be used for maintenance visits.

Counseling codes are commonly used to bill for maintenance visits. Counseling and coordinating service with addiction specialists comprise the majority of these follow-up visits.

See the following page on counseling for more detailed information on how to bill for these visits.

**ICD Codes**
The current ICD code, ICD-10, for opioid related disorders is F11. This code replaces the old ICD-9 codes. The ICD-10 code must be used as of October 1, 2015. The ICD-9 Code for opioid use disorder was 304.0x. The "x" refers to these classifications: 0=unspecified, 1=continuous, 2=episodic, 3=in remission.

**Private Health Insurers**
Some private health insurers have developed standard billing codes for buprenorphine treatment services. For instance, the Healthcare Common Procedure Coding System (HCPCS) code for "Oral medication administration, direct observation" is H0033. Be sure to check with individual insurers, as they may have different policies.
CPT CODES FOR COUNSELING (PRIMARY CARE)
Counseling and Coordinating with Addiction Specialists

A large portion of maintenance visits consist of counseling and coordinating service with addiction specialists. You can provide counseling and bill for it without conducting a review of systems. In this case, you should use Counseling codes in place of E/M codes (99211-15).

Documenting a Counseling Visit

Documentation for a counseling visit should include:

- Total visit time
- Time spent counseling or coordinating care (must be face-to-face)
- The nature/content of the counseling

You can bill for counseling time rather than complexity in a visit when counseling or coordination of care take up more than 50% of the total visit time. Coding is then based on the total visit time, not just the time spent counseling or coordinating care. A statement such as the following serves as documentation of time spent: "A total of ___ minutes of a ______ minute visit was spent counseling the patient about ______."

<table>
<thead>
<tr>
<th>Level</th>
<th>New Patient Counseling</th>
<th>Established Patient Counseling</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10-19 minutes: 99201</td>
<td>5-9 minutes: 99211</td>
</tr>
<tr>
<td>2</td>
<td>20-29 minutes: 99202</td>
<td>10-14 minutes: 99212</td>
</tr>
<tr>
<td>3</td>
<td>30-44 minutes: 99203</td>
<td>15-24 minutes: 99213</td>
</tr>
<tr>
<td>4</td>
<td>45-59 minutes: 99204</td>
<td>25-39 minutes: 99214</td>
</tr>
<tr>
<td>5</td>
<td>60+ minutes: 99205</td>
<td>40+ minutes: 99215</td>
</tr>
</tbody>
</table>

CPT CODES FOR PSYCHIATRISTS
For psychiatrists, CPT codes for buprenorphine treatment are time-based:

- The time for each psychotherapy code is described as being time spent with the patient and/or family member.
- There are no separate codes for interactive psychotherapy. Instead there is an add-on code for interactive complexity. This code may be used when the patient encounter is made more complex by the need to involve people other than the patient (90785).
- There is no distinction made by setting. Psychotherapy codes are applied to all settings.
- The codes for "Psychotherapy for crisis" are CPT code: 90839, +90840.

Psychiatrists are encouraged to use the E and M codes starting with 99 for medication management when prescribing buprenorphine, with psychotherapy as an add-on.
MEDICAID AND MEDICARE COVERAGE

Medicaid Coverage
Medicaid provides substance abuse treatment as a state option. Therefore, Medicaid coverage for buprenorphine treatment varies significantly by state. Some states reimburse Medicaid patients for buprenorphine treatment, and others do not, even when it is listed on the formulary.

Medicaid coverage of buprenorphine depends on:

- Prior authorization and medical necessity
- If your state's Medicaid plan is offered through a managed care or HMO program
- If buprenorphine is on your state's formulary list, check online or call your state's Medicaid office to determine what coverage is available.

Medicaid Screening and Brief Intervention Codes
Screening and Brief Intervention (SBI) codes are in place in most states. These codes, H0049 - Alcohol and Drug Screening, and H0050 - Brief Intervention, enable physicians to be reimbursed for screening Medicaid-eligible patients for substance abuse.

Medicaid licensed providers who live in states where Medicaid pays for buprenorphine treatment should not charge cash for buprenorphine treatment. It is illegal and state attorneys general have been investigating such practices.

Medicare

- Buprenorphine treatment costs are typically not covered by Medicare unless the treatment is provided in an inpatient or outpatient treatment center.
- Buprenorphine treatment may be covered in some instances, such as during detoxification or early stage stabilization.
- Medicare benefits do not usually cover typical office-based buprenorphine induction or maintenance treatment visits.
- Medicare Part D may cover the cost of the buprenorphine medication itself, however, plans vary by zip code. Only some Medicare providers will reimburse, including Healthnet Orange, Silverscript, and Wellcare. Prior authorization is usually required.

FYI
Search by the formulation of combination buprenorphine that you prescribe in the online Medicare Formulary Finder for Prescription Drug Plans and Advantage Prescription Drug Plans to learn about coverage.

POLL: PRIOR TO THIS TRAINING, WERE YOU FAMILIAR WITH THE BILLING CODES ASSOCIATED WITH BUPRENORPHINE TREATMENT?

1. Fully familiar with all the billing codes
   - 5% (224 votes)
2. Partially familiar with the billing codes
   - 34% (1393 votes)
3. Not familiar with the billing codes
   • 60% (2458 votes)

SETTING UP A CASH-ONLY BUPRENORPHINE TREATMENT PROGRAM

Running a Cash-Only Buprenorphine Treatment
Some providers run a cash-only buprenorphine treatment practice. In a cash-only practice, providers set their own fees and costs for treatment. Fee-for-service treatment providers should have a clear policy and cost sheet regarding initial and ongoing expenses for treatment, including:

- Costs for assessment
- Induction
- Maintenance visits

The costs of providing services to your patients to take into account may include:

- Staff time spent with patients
- Administrative time (i.e., filling out paperwork, answering phone calls)
- Capital and operating expenses

Flat Rates
Most providers charge flat rates of several hundred dollars ($200-$400) for the induction visit and half as much for initial and follow-up visits. To get a better idea of reasonable rates to charge for buprenorphine treatment, you may want to consult with a more experienced provider in your local area. You can contact other buprenorphine providers via the PCSS or NAABT websites or SAMHSA's waived provider online discussion board.

COST OF BUPRENORPHINE TREATMENT TO PATIENTS

Cost of Buprenorphine to the Patient
The cost of buprenorphine can vary depending on the dose. Parties that determine the cost of a dose of buprenorphine include:

- The pharmaceutical companies
- The health insurer
- Retail pharmacies

Daily doses are normally from 8 mg to 24 mg (if using sublingual tablets), FDA approved generic combination buprenorphine/naloxone tablets are available. They cost approximately $6.54 for a 16 mg daily dose. Newer brand name formulations, like Zubsolv® and Bunavail™, are likely to cost more. These estimates are based on an average dose of 16 mg/day, not including the $100-$200 fee for office visits.

- Rates vary based on factors such as geographic location and proximity of other providers.
• Annual costs: Buprenorphine costs $4,000 to $5,000 per year and methadone costs $2,600 to $5,200 per year\textsuperscript{26}. Cost for the implant form of buprenorphine is $8,000 to $12,000 annually.
• Prior-authorization is often required, although this may be decreasing in frequency.
• Many private clinics accept only cash. Patients who pay cash have to seek reimbursement through their insurance carriers if they are insured.

Help for Non-Insured Patients
A cost savings is realized with the generic formulation. Additionally, formulations are sometimes introduced with a coupon that gives a significant savings. A variety of prescription discounts are available for low-income patients, such as Needy Meds and the Free Drug Card Program (see Related Resources). Also, AAA members can save an average of 20% off the retail price of prescriptions at participating pharmacies.

*We are using brand names when there is a difference in the product that is not reflected in the generic name. We are not advocating one brand or the other.

**QUIZ: CASE STUDY – MRS. OLSEN**

**MEET YOUR PATIENT**

**Name:** Mrs. Olsen  
**Age:** 29 years old  
**Reason for visit:** Mrs. Olsen came in to request buprenorphine treatment; she was referred by her therapist.

**Medical History:** Six-month history of opioid abuse. She has been taking 10-12 hydrocodone and oxycodone of varying dosages every day for the last six months. Before that she used them intermittently. Daily use began about six months ago when she realized she could not work without them. If she does not take the pills, she cannot concentrate, and she experiences nausea and diarrhea and aches all over.

**Treatment History:** Mrs. Olsen has been seeing a therapist for her depression for the past two years. She has been on Fluoxetine (Prozac\textregistered) for two years. Mrs. Olsen works as a staff support aide with developmentally delayed children. She got married one year ago. She said her husband will support her office-based treatment with buprenorphine and pay for her medication.

**One Week Later**
The day before induction, you complete patient education and the written, signed patient-provider treatment agreement.

A few days after meeting and evaluating Mrs. Olsen, you inducted her onto 16 mg/day of generic buprenorphine/naloxone. Induction went well with no problems.

Two days after induction, your office manager hands you a fax from the pharmacy asking for prior authorization from Mrs. Olsen’s insurance company. Mrs. Olsen did not mention having insurance. You had not asked because she said her husband was going to pay her bills. She paid by check for her induction visits.
Question: How should you handle this faxed request from the pharmacy? (Choose the best answer)
Choose one

1. You need a signed release from Mrs. Olsen before filling out the paperwork for the insurance company.
   - Feedback:
     This is the best option. Mrs. Olsen, in effect, disclosed her diagnosis of opioid use disorder to her pharmacy by submitting the buprenorphine prescription. However, she has not given you permission to discuss her medical problems with her insurance company, so you would need a signed release before filling out the paperwork for the insurance company or pharmacy. Some practices do not deal with insurance companies at all. If this is the case, you would have to clarify this with Mrs. Olsen and might need to make a referral to another waivered provider or program that does fill out insurance forms.

2. You should call her insurance company to request the prior authorization paperwork.
   - Feedback:
     This is not the best option. Mrs. Olsen has not given you permission to discuss her medical problems with her insurance company. You first need to get a signed release from her before filling out the paperwork for the insurance company or pharmacy. Some practices do not deal with insurance companies at all. If this is the case, you would have to clarify this with Mrs. Olsen and you might need to make a referral to another waivered provider or program that does fill out insurance forms.

MRS. OLSEN – DISCUSSION ABOUT INSURANCE

You have your office manager call Mrs. Olsen and ask her to explain her insurance status.

Mrs. Olsen: My insurance covers all my medications, so I want it to cover my buprenorphine, too.

Mrs. Olsen provides details of her insurance plan. Your office manager calls the 800 number for Mrs. Olsen's insurance plan's pharmacy benefits. They do cover generic buprenorphine for up to six months, but require that you send them the treatment plan and the tapering plan. You have your staff leave Mrs. Olsen a voicemail regarding this.

Message from Provider

Provider: Mrs. Olsen, we need you to come in to sign a release of information regarding your planned treatment so that we can communicate with the insurance company.

When Mrs. Olsen returns, you make it clear to her that the release document communicates opioid use disorder as a diagnosis to her insurance company. You obtain her plan number and contact the insurance company. They fax you a questionnaire.
QUIZ: MRS. OLSEN – BILLING DECISION
After obtaining a signed release from Mrs. Olsen, your office manager completes the insurance company's forms. She faxes the forms to them along with your notes, including toxicology screen results and plan of treatment. Under "tapering plan" you write: "when patient stabilizes, will discuss taper with her, she may need maintenance treatment." That day, Mrs. Olsen leaves you a distraught voicemail message.

Message from Mrs. Olsen

Mrs. Olsen: I just got notified that my insurance won't cover my buprenorphine. I can't take it otherwise, it's too expensive!

You call her back to explain the current situation.

Provider: I am calling regarding your insurance's recent rejection of coverage for your buprenorphine treatment. I will see if my staff can place an urgent request for coverage. But keep in mind that insurance companies may take some time to process requests.

By this time you and your office manager have spent about 30 minutes combined on phone calls and forms from various parties related to insurance coverage.

Question: How should you bill the time? (Choose the best answer)
1. You should not bill for this time.
   • Feedback: Correct. Some practices routinely communicate with insurance companies for utilization review. In general it is not legal to bill for this time, but rather it is considered part of practice overhead.
2. Bill this time as a consultation for an established outpatient
   • Feedback: Incorrect
   This is not the best option. Some practices routinely communicate with insurance companies for utilization review. In general it is not legal to bill for this time, but rather it is considered part of practice overhead.
3. Bill additional time for the maintenance visit
   • Feedback: Incorrect
   This is not the best option. Some practices routinely communicate with insurance companies for utilization review. In general it is not legal to bill for this time, but rather it is considered part of practice overhead.

QUIZ: MRS. OLSEN – CONTINUED TREATMENT
Insurance Confirmation
The insurance company handles fax requests within five days, but offers an 800 number for urgent requests. Your office manager calls the 800 number, reviews the case with the benefits manager, and learns that they cover up to six months of buprenorphine treatment. They will review the treatment
every three months, however. She obtained authorization over the phone for the first three months of medication.

**Continued Treatment**
Mrs. Olsen does well on 16 mg of combination buprenorphine sublingual tablets. After several weekly visits you decide she is stable enough to see you monthly.

**Provider:** *To get your medication covered without interruption, you will need to come in two weeks before your approved coverage expires. That will allow processing of your claim by fax. And please inform us of any change in your insurance in the meantime.*

**Subsequent Visits**
Mrs. Olsen misses this requested appointment. Furthermore, she comes in asking for a buprenorphine refill 3 weeks after the insurance re-authorization should have been submitted and one week after she should have run out of the medication.

*Mrs. Olsen:* *I couldn’t come in, so I stretched out the tablets by cutting them in half with a pill cutter.*

**Question:** What would you do about insurance authorization for continued treatment? (Choose the best answer)

1. Continue to submit requests for medication coverage by phone or fax.
   - **Feedback:**
   
   The response to this situation varies by practice. Some providers would continue to submit requests for medication coverage by phone or fax. Others would refuse to deal with her insurance because of her failed personal accountability by showing up late for her re-authorization. Insurance authorization requests are often confusing to patients, because they have heard that “everything is covered.”

2. Refuse to deal with her insurance because of her failed personal accountability by showing up late for her re-authorization.
   - **Feedback:**
   
   The response to this situation varies by practice. Some providers would continue to submit requests for medication coverage by phone or fax. Others would refuse to deal with her insurance because of her failed personal accountability by showing up late for her re-authorization. Insurance authorization requests are often confusing to patients, because they have heard that “everything is covered.”

3. Have a conversation about truthfulness.
   - **Feedback:**
   
   You need to respond to Mrs. Olsen's self-reduction in dosage. Review her signs and symptoms of withdrawal and craving, and her behavior, to evaluate her stability at this new dose. You need to talk about her long-term plan and if she intends to stay on buprenorphine indefinitely.

   In addition the insurance authorization problem, the clinical issue must be addressed.
You need to respond to Mrs. Olsen's self-reduction in dosage by reviewing her signs and symptoms of withdrawal and craving, and her behavior, to evaluate her stability at this new dose. You need to talk about her long-term plan and if she intends to stay on buprenorphine indefinitely.

**FURTHER STAFF TRAINING**

Once all of the confidentiality, medical record-keeping, and billing practices for office-based opioid treatment (OBOT) are established, your staff should also be trained in them prior to treating any patients. Staff members should be educated on any other changes to expect once you are treating patients with buprenorphine.

**Prepare the Other Clinicians**

Other clinicians in your practice may benefit from taking a buprenorphine training program. Even if they are not prescribing buprenorphine themselves, they may need to support the induction process and see patients during the maintenance phase. Additionally, they can review staff training materials that were published by CSAT’s Addiction Technology Transfer Center (ATTC) (see Resources).

**PRACTICE TIP**

Both administrative and clinical staff need to be trained about buprenorphine and practice changes you make for OBOT.

**ESTABLISHING A RELATIONSHIP WITH A PHARMACY**

**Ensuring Your Patients Have Access to Medication**

You should establish a relationship with at least one local pharmacy before starting a buprenorphine practice to ensure that they can stock adequate supplies of buprenorphine.

**Guidelines to Consider**

Consider the following guidelines when contacting a pharmacy:

- Describe your time requirements, if you need the prescription filled quickly. This is especially important during buprenorphine induction.
- Specify which formulation of the buprenorphine/naloxone combination you will be using — film or tablet, sublingual or buccal, and make sure it is available.
- For the rare patient who is taking the monotherapy formulation, ensure that their preferred pharmacy has access to these tablets.
- Verify that the pharmacy can fill prescriptions quickly. This is especially important during induction when patients will visit the pharmacy to pick up single doses of buprenorphine.
- Ask the pharmacists if they are familiar with buprenorphine treatment and dispensing the medication. If not, refer them to some educational materials.
- Ask the pharmacists to alert you if the patient is filling prescriptions for other controlled substances, requesting early refills, behaving inappropriately, claiming to have lost prescriptions, etc.
Have All Patients Sign a Pharmacy Consent
On a related note, you should have all patients sign a pharmacy consent form. Keep this on file in case the pharmacy requires it for communications about the patient.

SUMMARY AND KEY POINTS

A Team Approach to Office-Based Treatment
Using a team approach with trained staff is important for office-based opioid treatment, in order to:

- Provide patients who need it with additional time and support.
- Train staff to address prejudice and prepare them to deal with aberrant behavior by some patients.
- To assure that staff understand confidentiality rules and the rules for office based opioid treatment, such as refill policies.

Confidentiality of Patient Records
The Public Health Service Act, Title 42 of the United States Code of Federal Regulations, governs laws in substance abuse treatment. These regulations are meant to prevent the disclosure of information identifying applicants/recipients of substance abuse treatment. They prohibit the release of patient records without:

- Patient consent
- A court order
- A true medical emergency
- Or report of child abuse

It is very important to abide by the confidentiality regulations. Violation carries a criminal penalty of $500 for the first violation and $5,000 for each successive violation. Patients may also file lawsuits if their confidentiality is violated. Program-level violations may result in revoking of license or certification.

Billing and Insurance
Prior to starting a patient on buprenorphine, discuss the issue of payment for services, including who should be billed—an insurance agency, the patient, or both.

- Insurance: Become familiar with the billing codes, as well as what can and cannot be billed for service. Document billable hours.
- Patient: Arrange a payment schedule and note what costs the patient will incur for treatment. Provide an itemized estimate of medication plus office-visit costs.
- Both: Determine what costs will be billed to the insurance company vs. the patient. Clarify patient responsibilities versus what their insurance will cover.

PRACTICE TIP

Almost Done!
You must request a waiver from SAMHSA before you prescribe buprenorphine.
On behalf of the American Society of Addiction Medicine, we are glad you have chosen to take your training with us. Buprenorphine can offer a successful and viable treatment option for opioid addicted patients. It is an evidence-based pharmacological treatment that can change and, in some cases, save lives.

What you need to know about finishing this activity & getting a waiver to prescribe buprenorphine:

1. Fulfill Training Requirements - The DATA 2000 law requires an 8-hour equivalent training activity of physicians, and CARA 2016 requires 24 hours for nurse practitioners and physician assistants before applying for a waiver to prescribe buprenorphine. This activity fulfills the 8-hour requirement for physicians, as well as 8 hours of the 24-hour requirement for nurse practitioners and physician assistants, respectively.

2. Complete Post-Assessments - After you have worked through the content, there is a post-test, a post-survey, and a satisfaction/standard post-survey at the end of each activity. You will need to complete these measures and pass the test with a score of 70% or better. You will be able to take the post-test more than once, but we suggest you review the material if you are unable to achieve a passing score on the first attempt.

3. Request Credit - After you complete the modules thoughtfully, pass the post-test, and complete the survey, you will be able to request up to 9 hours of continuing education for the training on this website. Please request an amount of credit commensurate with your effort.

4. Receive Continuing Education Certificates - You must request credit in order for us to know that you have completed the activity. You will be able to get copies of your continuing education certificates or review the material and references at any time in the future. Physicians will get one certificate for the 8-hour activity. NPs and PAs will receive three certificates: one for each part of their 24-hour activity. We notify SAMHSA weekly with a list of providers who have successfully completed the activity, so please wait until that time to continue the waiver request process.

5. Request Your Waiver - If you want to prescribe buprenorphine, you must request your waiver from SAMHSA using their online form. Once you have completed the required training hours and requested continuing education credit, use the online Buprenorphine Waiver Notification form on SAMHSA’s website to make this request. "American Society of Addiction Medicine (ASAM)" is the official provider of this training activity. It may take up to 45 days for SAMHSA to process the request.
RESOURCES AVAILABLE THROUGH THIS MODULE:

- **AAA Prescription Discounts**
  Information on how AAA members can save money prescriptions at participating pharmacies.

- **Advancing access to addiction medications**
  Describes report by ASAM from 2013 on making addiction medications more accessible.

- **Applying the Substance Abuse Confidentiality Regulations 42 CFR Part 2**
  This document contains frequently asked questions and answers in reference to applying substance abuse confidentiality regulations.

- **Buprenorphine Treatment: Training for Multidisciplinary Addiction Professionals**
  This is a training package developed by the Buprenorphine Awareness Blending Team to create awareness about buprenorphine among non-physician addiction professionals.

- **Confidentiality of Substance Use Disorder Patient Records**
  DHHS Government Publishing Office document.

- **Consent to Release of Information Under Title 42, Part 2, Code of Federal Regulations**
  An example of the wording and structure necessary in a consent for release of information form.

- **Electronic Prescriptions for Controlled Substances (EPCS) General Questions and Answers**
  The questions and answers are intended to summarize and provide general information regarding the Drug Enforcement Administration (DEA) Interim Final Rule with Request for Comment "Electronic Prescriptions for Controlled Substances" (21 CFR Parts 1300, 1304, 1306 and 1311; October 19, 2011) [Docket No. DEA-360].

- **Formulary Finder for Prescription Drug Plans**
  This is a database that allows users to search Medicare Prescription Coverage and Medicare Advantage Prescription Drug Plans by State.

- **Free Drug Card Program**
  The Free Drug Card Program was developed to help uninsured and under insured Americans afford their prescription needs. It offers a free Prescription Drug Card that can be taken to a pharmacy to lower prescription drug costs.

- **Frequently Asked Questions Applying the Substance Abuse Confidentiality Regulations to Health Information Exchange (HIE)**
  An educational document from the Substance Abuse and Mental Health Services Administration (SAMHSA) and the U.S. Department of Health and Human Services on the frequently asked questions in regard to substance abuse confidentiality regulations.

- **FSMB Model Policy for the Use of Controlled Substances for the Treatment of Pain**
  This document, first published in 2004 and revised in July 2013, is a model policy for state medical boards to use in developing their guidelines for use of opioids in treating chronic pain. These Model Guidelines provide the FSMB's policy on proper treatment of pain and the use of opioids when necessary to manage pain. Source: Federal State Medical Boards (FSMB).

- **Healthcare Access in Rural Communities**
  This website offers information about rural health programs and providing access to treatment, as well as Medicare and Medicaid funding for certain services and treatments in order to increase patient access to health care.

- **Links to State Health Department Websites**
List of contact information and websites for all of the state health departments.

- **Medical Recordkeeping**
  A description of what should be included in a buprenorphine patient's medical record.

- **Medication Assisted Treatment for Opioid Use Disorders Reporting Requirements**
  Describes reporting rule for those approved to prescribe buprenorphine to up to 275 patients.

- **NAABT Coding Grid**
  Displays the appropriate CPT and HCPCS billing codes for the different phases of buprenorphine treatment.

- **NeedyMeds**
  The Needymeds website provides information on the Suboxone assistance program, a program that offers free suboxone medication to low-income patients who meet all eligibility requirements. It also includes important contact information, suboxone doses that are part of the program, the roles of the physician and patient in the application process, and application requirements.

- **Nursing Follow-up Visit**
  This form can be used by nurses to note the areas that should be covered during a follow-up visit for patients on buprenorphine treatment.

- **Nursing Intake Screener**
  This form provides a list and a place to document important information that should be recorded during the intake assessment, including whether the patient is pregnant, taking other drugs, on methadone or has other addiction behaviors.

- **Office-Based Treatment: Training Your Staff**
  Your staff will be assisting you with many of the tasks essential to conducting in-office buprenorphine treatment. Therefore, staff members need a firm grasp of the principles of addiction treatment and corresponding clinical skills and an attitude conducive to working with this patient population. The staff's attitudes will affect the way they treat patients, thus influencing the outcome of treatment. Before starting office-based buprenorphine treatment, you may wish to conduct formal training with your staff. The brief guidelines below can help you structure your training.

- **Patient Satisfaction Survey**
  Provides a downloadable patient satisfaction form. The survey assesses satisfaction with the health center and staff.

- **PCSS-MAT Guidance: Drug Enforcement Administration Requirements for Prescribers and Dispensers of Buprenorphine and Buprenorphine Naloxone**
  This clinical guidance provides information about the requirements for storing, dispensing, and maintaining records for physicians who provide office-based opioid treatment.

- **PCSS-MAT Mentoring Program**
  PCSS-MAT provides ongoing mentoring programs aimed at improving providers confidence in treating opioid use disorder. The PCSS-MAT program is designed to assist providers in incorporating the use of medications for prescription opioid addicted patients in their practices. The mentoring program is available, at no cost to providers. PCSS-MAT mentors are a national network of trained providers with expertise in medication-assisted treatment and skilled in clinical education. Mentors provide support by telephone, email, or in person if logistically possible. (From the website.)
• Pharmacy Consent Form for Buprenorphine Treatment

By signing this Appointed Pharmacy Consent Form, the patient authorizes a provider to disclose to the pharmacy that he or she is being treated for opioid dependence; the pharmacy is also authorized to contact the provider to discuss treatment.

• Physician Clinical Support System - Clinical Coaching

This website is designed to provide coaching for providers in treating chronic pain, and substance use disorders including opioid use disorder.

• SAMHSA Section II: Guidelines (Medical Records)

These guidelines include a "Medical Record" section of what should be included in a buprenorphine patient's medical record.

• The National Alliance of Advocates for Buprenorphine Treatment (NAABT)

This website is for both buprenorphine patients and providers. It provides education on opioid addiction and buprenorphine treatment, and also connects patients in need of treatment to qualified treatment providers.

REFERENCES USED IN THIS MODULE:

11. SAMHSA. Substance Abuse Confidentiality Regulations. 2015.
22. ASAM. Advancing access to addiction medications. 2013.
23. Szabo L. Addiction treatment hard to find, even as overdose deaths soar. USA Today. 2015.