

FEDERAL LAWS AND REGULATIONS (CASES ONLY)

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.

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).

Goal

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

After completing this module (didactic + cases), participants will be able to:

- Describe buprenorphine's status as a controlled substance and the laws governing the prescribing of this medication
- 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

Specific Training Gap: DATA 2000, CARA, 2016, TIP 40¹, SAMHSA (2016) and ASAM (2015) guideline updates, and FSMB 2013 describe rules, regulations, and requirements that providers who prescribe buprenorphine must follow.

CASE ILLUSTRATION – MRS. OLSEN

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. 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?

There are three major federal laws that, among other provisions, permit the prescribing of buprenorphine in the office-based setting and describe the requirements and limitations:

- The Drug Addiction Treatment Act (DATA 2000)²
- The Comprehensive Addiction and Recovery Act of 2016 (CARA)³
- The Support for Patients and Communities Act⁴



QUIZ: CASE STUDY – MRS. OLSEN

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®) 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.

How Should You Handle This Faxed Request From The Pharmacy? (Choose Best Answer)

1. You need a signed release from Mrs. Olsen before filling out the paperwork for the insurance company.
2. You should call her insurance company to request the prior authorization paperwork.



Case Study – Mrs. Olsen Quiz Feedback

(1) You Need A Signed Release From Mrs. Olsen Before Filling Out The Paperwork For The Insurance Company.

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 waived provider or program that does fill out insurance forms.

(2) You Should Call Her Insurance Company To Request The Prior Authorization Paperwork.

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 waived 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: 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.
2. No, a consent form about this addiction treatment is required for information to be shared with anyone (including a spouse).
3. Yes, information can be shared if there is a consent form on file from previous medical treatments.

Disclosure of Information – Quiz Feedback

(1) Yes, The Information Can Be Shared With A Spouse Before The Consent Form Is Signed.

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).

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.

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.

QUIZ: PRACTICE IMPLEMENTATION

Which Of The Following Suggestions Would You Implement In Your Practice? (Choose All That Apply)

- Make a photocopy of each prescription.
- Keep a separate log of prescriptions issued.
- Make a note in the patient record with prescription data and amount.
- 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.
- Prepare for the DEA field officer once yearly visit.



Practice Implementation Quiz Feedback

(1) Make A Photocopy Of Each Prescription.

Correct. The DEA recommends making a photocopy of each prescription.

(2) Keep A Separate Log Of Prescriptions Issued.

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.

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.

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.

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 recordkeeping and treatment guidelines have no need for concern.