

How-To GUIDES: How to COMPLY WITH RULES, REGULATIONS, AND RECORDKEEPING

Clinical tips and advice about:

- Federal Drug Enforcement Administration (DEA) recordkeeping requirements for buprenorphine treatment
- Federal guidelines for dispensing buprenorphine tablets in the office
- Establishing a relationship with mental health professionals/facilities, laboratories, and pharmacies
- Guidelines for writing a prescription for buprenorphine
- DEA oversight and audits of buprenorphine treatment programs
- Patient privacy issues for buprenorphine treatment
- Medical recordkeeping guidelines for substance abuse patients
- Annual reporting if you treat over 275 patients (Updated 1/28/2019)

Plus resources on each page with additional tips and tools!

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FEDERAL (DEA) RECORDKEEPING REQUIREMENTS FOR BUPRENORPHINE TREATMENT



Providers who are conducting office-based buprenorphine treatment should adhere to specific DEA medical recordkeeping requirements. Note that some of these requirements go beyond the standard Schedule III requirements.

Buprenorphine treatment records should include a log identifying patients (by name or ID number), name of drug prescribed or dispensed, strength/quantity of medication prescribed, and date of issuance. One way to comply with this requirement is by keeping a photocopy of the prescription within each patient's record. These records should be kept for at least 2 years.

Practitioners can decide if they want to keep these records within standard patient charts or if they want to keep separate buprenorphine treatment records. When the physician keeps separate records then only these records would be subject to review during a DEA audit. The DEA does recommend keeping buprenorphine records separate, but it is not required.

State requirements should also be reviewed as they may be more stringent.

Related Resources:

- [Complete Text of the US Code, Title 21](#)
Description: This is the full text of Title 21, Chapter 13 of the US Code, which deals with drug abuse prevention and control.
- **Source:** Drug Enforcement Administration (DEA)
- [Practitioner's Manual: An Informational Outline of the Controlled Substances Act](#)
Description: Manual written by the DEA in 2006 to assist providers in understanding and complying with the Federal Controlled Substances Act. Topics covered include recordkeeping requirements, rules regarding prescription, and security requirements.
Source: US Drug Enforcement Administration (DEA)

FEDERAL GUIDELINES FOR DISPENSING BUPRENORPHINE MEDICATION IN THE OFFICE

When buprenorphine was first approved by the FDA in October 2003, few pharmacies consistently kept the medication in stock and thus many providers kept a supply of tablets on hand and dispensed them from their office. In-office buprenorphine dispensing is still a legal practice under DATA 2000.

However, providers who wish to dispense buprenorphine from their office must adhere to strict federal recordkeeping guidelines.

The Following Records Must Be Maintained For 2 Years:

- Inventories, including amounts of buprenorphine received and amounts dispensed
- Reports of theft or loss
- Destruction of controlled drugs
- Records of dispensing

Additionally, the buprenorphine tablets must be stored in a secure, locked cabinet. Note that providers who have their patients get their prescription filled at a pharmacy and return to the office for induction are NOT subject to the same recordkeeping guidelines as providers who store and dispense the tablets in-office.

- [Buprenorphine Inventory Form](#)

Description: This log can be used to keep track of office inventories of buprenorphine medication.

Source: California Society of Addiction Medicine (CSAM)

GUIDELINES FOR WRITING A PRESCRIPTION FOR BUPRENORPHINE

There are no special guidelines for writing a prescription for buprenorphine and giving it to a patient to get filled at the pharmacy of his/her choice. However, all prescriptions should have your DEA number plus the "X" DEA number if you are a physician (which denotes buprenorphine prescriber status) written on them or the pharmacy may not fill it.

Also note that under the Code of Federal Regulations Title 42 Part 4 (Confidentiality of Alcohol and Drug Abuse Patient Records) - you must receive full permission from the patient before you can fax the prescription to a pharmacy. Buprenorphine is a Schedule III drug and so DEA guidelines as well as state guidelines for Schedule III drugs must be followed; the stricter guideline always applies.



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^{1,2}. The DEA recommends making a copy of each prescription³.

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 providers or accepted by pharmacies⁴. Additionally, there is no requirement that a provider must utilize e-prescribing in their practice, nor that pharmacies must accept e-prescriptions². 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.

Additional Considerations:

- Providers who have their patients get their prescription filled and return to the office for induction are NOT subject to the same recordkeeping guidelines as providers who store and dispense the tablets or film in-office.
- Buprenorphine tablets and film (like other Schedule III medications) can be refilled up to 5 times. Most providers begin by prescribing limited initial quantities of medication and then write prescriptions for larger quantities and refills when the patient achieves stability (negative urines, psychosocial treatment adherence, etc.)

- If a buprenorphine prescription is written for an off-label use (i.e. not for opioid dependence), then no "X" number should appear on the prescription. Also, patients who are treated for with buprenorphine for pain are not considered to be part of the patient limit.
- The patient is considered to be under your care and is part of your roster for the duration of the last prescription issued. For example, if you write a prescription for a month's supply of buprenorphine then the patient will remain on your roster even if he/she misses all appointments and seems to have dropped out of treatment. When the last prescription that you wrote terminates, then you may remove the patient from your roster.

Related Resources:

- [Electronic Prescriptions for Controlled Substances \(EPCS\) General Questions and Answers](#)
Description: 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].
Source: DEA

DEA OVERSIGHT AND AUDITS OF BUPRENORPHINE TREATMENT PROGRAMS

The U.S. Drug Enforcement Administration (DEA) and state DEA oversee office-based buprenorphine treatment and have the right to inspect providers' buprenorphine practices at any time. Audits are random and usually unscheduled; a minority of buprenorphine practices are visited by the DEA annually. Providers who comply with federal recordkeeping and treatment guidelines have no need for concern.

According to a 2006 presentation by Denise Curry, Deputy Director from the DEA's Office of Diversion Control, most inspections are uneventful and the majority of practices are found to be in compliance with federal guidelines. When problems are cited, they generally involve administrative issues and require providers to make changes to their recordkeeping practices. However, if more serious violations are found then the DEA can revoke a physician's right to prescribe buprenorphine and take further legal action when necessary.

In Case Of A DEA Audit, You May Be Asked To Present The Following Information:

- documentation of your waiver to prescribe buprenorphine
- treatment logs, including information on how many patients are currently in treatment
- documentation of prescriptions given
- dispensing practices, for providers who are dispensing buprenorphine tablets from their offices

There are some exceptions to the disclosure laws, such as in case of medical emergencies or legal situations.

Related Resources:

- [Buprenorphine Inventory Form](#)
Description: This log can be used to keep track of office inventories of buprenorphine medication.
Source: California Society of Addiction Medicine (CSAM)
- [Complete Text of the US Code, Title 21](#)
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Source: Drug Enforcement Administration (DEA)

The Federal Laws Permitting Office-Based Opioid Use Disorder Treatment:

- [DATA 2000](#)
Description: This page provides links to the full text, summary, and physician waiver requirements under DATA 2000.
Source: SAMHSA
- [Comprehensive Addiction and Recovery Act of 2016](#)
Description: The House of Representatives Filing Copy
Source: U.S. Govt.
- [H.R.6 - SUPPORT for Patients and Communities Act: Nurse Practitioners and Physician Assistants Prescribing Buprenorphine](#)
Description: This is the full text of the law itself as it was signed into effect on 10/24/18.
Source: SAMHSA

REPORTING IF YOU ARE APPROVED TO SEE UP TO 275 PATIENTS

SAMHSA 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^{23*}. This report is in addition to DEA audits. 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 diversion²³. 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. 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 required information is:

- Their patient case-load presented by month
- Frequency of referring patients to behavioral health services (or providing these services)
- 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)).

Related Resources:

- [Image of an example blank 275-Patient Annual Report form](#)

Description: Example of the online form for the providers to submit annual reporting required if they are approved to see up to 275 patients per year.

Source: SAMHSA

- [SAMHSA Interface to Submit 275-Patient Annual Report](#)

Description: Links to the actual form for providers to submit annual reporting required if they are approved to see up to 275 patients per year.

Source: SAMHSA

PATIENT PRIVACY ISSUES FOR BUPRENORPHINE TREATMENT

Beyond HIPAA

In addition to standard HIPAA laws, federal regulations mandate strict confidentiality for information about patients being treated for substance use disorders (42 CFR Part 2). Additionally, the law requires written patient consent before information about substance abuse treatment can be disclosed to any other source. For buprenorphine treatment, this may include any communications with other providers, treatment centers, significant others, or pharmacies.

Specific actions that are prohibited (without consent) include the following:

- providing information regarding a patient's past, present, or future participation in substance abuse treatment
- disclosing or transmitting a patient's substance abuse-related medical records
- use of a letterhead that identifies the office as a substance abuse treatment provider
- providing information about those who have applied for treatment or have been interviewed, regardless of whether they actually commenced treatment
- providing information about deceased patients
- verifying information that inquirers already possess -- in other words, a program can neither confirm nor deny that a patient was being treated there⁵.

There are some exceptions to the disclosure laws, such as in case of medical emergencies or legal situations. Application of confidentiality laws in cases of substance abuse treatment is dependent on status and identification as a treatment facility. Review of the regulations should be made before determining when application is not required.

Related Resources:

- [Medical Records Privacy and Confidentiality](#)

Description: Information in support of protecting personal health information and supporting standards for privacy, consent, and sharing.

Source: Substance Abuse and Mental Health Services Administration (SAMHSA)

- [Federal Rules and Regulations on confidentiality of Substance Use Disorder Patient Records](#)

Description: DHHS Government Publishing Office document.

Source: Department of Health and Human Services (DHHS)

- [Substance Abuse Confidentiality Regulations FAQs](#)

Description: This document contains frequently asked questions and answers in reference to applying substance abuse confidentiality regulations

Source: SAMHSA

MEDICAL RECORDKEEPING GUIDELINES FOR SUBSTANCE ABUSE PATIENTS

In addition to the specific federal recordkeeping guidelines for buprenorphine patients, it is recommended that you document the following information:

History And Current Status

- Initial diagnosis and treatment plan information
- History and physical examination
- Comparisons with initial presentation
- Assessment of pharmacological efficacy
- Lab tests and results
- Compliance with treatment plan
- Urine and blood drug screening
- Medications prescribed
- Dispensing of controlled substances

Treatment Plan

- Diagnoses and how determined
- Treatment goals
- Determination of medication to be used
- How medication will be used
- Psychosocial services required/recommended

Other Information

Additionally, providers with an office-based buprenorphine practice may want to keep track of the following:

- Patient payment information (useful for fee-for-service practices)
- Induction, maintenance, discontinuation, and discharge information
- Instances of patient non-compliance and subsequent actions taken

Keeping the above information complete and organized will be useful if a patient relapses and then returns to treatment or when a referral is needed.

Related Resources:

- [Intake Checklist](#)

Description: This checklist provides a list of the forms that must be signed, the information that should be recorded for each patient (including current medications and allergies), and tests and labs that should be drawn during the intake assessment.

Source: Colleen LaBelle, RN/Boston Medical Center

MEDICAL RECORDKEEPING

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

Many portions of the medical record contain general information that is not specific to patients with substance use disorders or opioid dependence. An example of this is the history portion of the record.

The following sections of the medical record should be noted for all substance use patients:

- Initial diagnosis and treatment plan information
- History and physical examination
- Comparisons with initial presentation
- Assessment of pharmacological efficacy
- Lab tests and results
- Compliance with treatment plan
- Urine and blood drug screening
- Medications prescribed
- Dispensing of controlled substances

Treatment Plan

The treatment plan portion of the medical record should be a natural continuation of the previous portions of the medical record. The following information should be carefully documented and shared with the patient:

- Diagnoses and how determined
- Treatment goals
- Determination of medication to be used
- How medication will be used
- Psychosocial services required/recommended

When the practitioner reviews this information with the patient, he/she should include the patient in formulation of treatment goals. Following the patient-practitioner review, both parties should sign and date the information contained in the treatment plan. Information about buprenorphine -- such as its effects, what to expect, and what not to expect -- should be discussed with the patient, and this discussion should be documented as well. The practitioner must remember to put his or her DEA registration number on the patient's medical records, as well as the patient's prescriptions.

SUMMARY

- Providers must adhere to specific federal and state DEA medical recordkeeping requirements in their office-based buprenorphine practice; some requirements go beyond standard Schedule III requirements
- Providers who wish to dispense buprenorphine from their office must adhere to strict federal recordkeeping guidelines.
- All prescriptions for buprenorphine should have your U.S. DEA number plus the “X” DEA number (which denotes buprenorphine prescriber status) written on them or the pharmacy may not fill it. You must receive permission from the patient before you can fax the prescription to a pharmacy
- The Drug Enforcement Administration (DEA) conducts unscheduled audits of buprenorphine practices each year for a small minority of practices, but has the right to inspect practices at any time.
- In addition to standard HIPAA laws, federal regulations mandate strict confidentiality for information about patients being treated for substance use disorders, including written consent before disclosing information to any other source.
- In addition to the above, detailed documentation should include history and current status; treatment plan; induction, maintenance, discontinuation, and discharge information; and payment information

The End

REFERENCES

1. US Department of Justice. [Title 21 Code of Federal Regulations: PART 1306 — PRESCRIPTIONS](#). 2010.
2. US Department of Justice. [Title 21 Code of Federal Regulations: PART 1311 —REQUIREMENTS FOR ELECTRONIC ORDERS AND PRESCRIPTIONS](#). 2010.
3. Gallagher C. [What Waivered Physicians Need to Understand About DEA Requirements](#). 2010.
4. Lowes R. [e-Prescribing Controlled Substances Now Legal Nationwide](#). *MedScape*. 2015.
5. SAMHSA/CSAT. [Treatment for Alcohol and Other Drug Abuse: Opportunities for Coordination](#). Rockville, Md: Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration. 1994.