



How to Prepare for a Visit from the Drug Enforcement Agency (DEA) Regarding Buprenorphine Prescribing

The following document was prepared by the partner organizations of the Physicians' Clinical Support System-Buprenorphine. It provides background information regarding DEA inspection procedures and suggestions on how buprenorphine waived physicians can prepare for a DEA inspection of their office-based practice.

1. Regulations

Congress passed the Drug Addiction Treatment Act (DATA) on October 17, 2000. This act permits qualified physicians to administer or dispense Schedule III, IV, or V narcotic medications, that have been approved for the maintenance and detoxification treatment of a narcotic dependent person. Thus far, the Food and Drug Administration has only approved the use of buprenorphine (mono formulation) and buprenorphine/naloxone for this purpose. The DEA is authorized by the Controlled Substances Act (21 U.S.C. 822 (f) 880 and 21 CFR 1316.03 to enter controlled premises (registered locations) and conduct periodic inspections to ensure compliance with recordkeeping, security and other requirements of the Controlled Substances Act.

2. DEA Inspections of DATA-Waived Physicians

The Drug Enforcement Administration (DEA) is responsible for ensuring that physicians who are registered with DEA pursuant to the Drug Addiction Treatment Act of 2000 (DATA 2000) comply with recordkeeping, security, and other requirements for administering, dispensing or prescribing controlled substances under the CSA. As a result, they conduct on-site, unannounced inspections under the authority of the Controlled Substances Act (CSA). All physicians who administer, dispense, or prescribe Schedule III substances, including buprenorphine, are subject to these routine, random inspections.

3. Inspections vs. Audits

It is important to understand the difference between a DEA audit and a DEA inspection. An "audit" determines the accountability of the controlled substances received and dispensed. The audit is one component of the "inspection" process. With an "inspection," DEA will look only at the records required to be kept for patients receiving buprenorphine products. In most cases, the practitioner will be inspected, not audited. When they arrive, DEA inspectors will

issue a notice of inspection. If the practitioner dispenses buprenorphine products, then an audit will also be conducted of the controlled substances received and dispensed.

4. Required Records

Physicians prescribing buprenorphine and buprenorphine/naloxone should maintain the records required to be kept on every patient in treatment with documentation consistent with the recommendations of the DEA and Federation of State Medical Boards (TIP 40 Appendix F). Assessment Forms such as those available in TIP 40 Appendix B may also be included in patient records. All records must be kept for at least 2 years, and be available for inspection by the DEA and copying by officers and employees of the U.S. authorized by the Attorney General.

- Patients: Waivered physicians may treat up to 30 patients at any one time during the first year after the waiver has been granted to that physician, and thereafter the physician must submit a second notification to CSAT to increase their patient limit to 100 if they wish to increase the number of patients that they treat above 30. Notification forms are available at:
www.buprenorphine.samhsa.gov/howto.html
- Physicians' DEA certificates of registration indicate the patient limit to which they must adhere. The physicians should have a method to keep track of the number of patients for whom they are actively prescribing buprenorphine and/or buprenorphine/naloxone.
- Prescriptions: Prescriptions for buprenorphine and/or buprenorphine/naloxone must include full identification of the patient's name, address, and drug name, strength, dosage, form, quantity, and directions for use. Prescriptions for buprenorphine and/or buprenorphine/naloxone must be dated as of, and signed on, the day when issued [See 21 CFR 1306.05(a)]. Both the physician's regular DEA registration number and the physician's DATA 2000 identification number (which begins with the prefix X) must be included on the prescription [See 21 CFR 1301.28 (d)(3)].
- Records or Copies of the following records must be maintained at the location listed on the practitioner's DEA registration (office):
 - Copy of current DEA registration
 - Copy of state narcotics license (if applicable)
 - Copy of state medical license
- We also recommend the physician maintain:
 - Log of active buprenorphine patients
 - Prescription log

5. The Inspection Process - What to expect

- The investigation should be conducted by a DEA Diversion Investigator who will appear in professional attire (e.g. suit and tie) and will not carry a weapon. DEA policy is to have

at least 2 investigators visit any office. At least one investigator will be a Diversion Investigator, and the second may be a DEA Special Agent or Task Force Officer depending on their staffing for that day. While there is always a chance that the accompanying field personnel will be authorized to have a weapon, DEA has informed the DATA organizations that agents are instructed to be as discreet and professional as possible when arriving at a physician's office.

- The inspector(s) should present his/her DEA credentials and a "Notice of Inspection" which explains the process of the inspection and your rights. You have the right to refuse to consent to the inspection and insist that DEA obtain an administrative warrant. If you believe you require legal advice, you should contact a local attorney.
- The primary purpose of the inspection is to ensure compliance with the recordkeeping and security requirements under CSA and DATA 2000. They will likely verify your credentials including DEA registrations and state licensure and will ask to see three (3) months of records.
- The inspectors will verify the number of patients you are treating to ensure that they are in line with the limits in DATA 2000. **You must keep any log of patients who are treated with buprenorphine, as well as copies of prescriptions for each patient, in the location listed on your DEA registration** (i.e.: if you are treating patients at more than one practice location, you must bring copies of prescriptions/patient logs from each location and store those at the location listed on your DEA registration. This means that not only will you have information in an individual patient record for your buprenorphine-treated patients, but you will also need to keep a separate record of all patients/prescription copies at the location listed on your DEA registration. Failure to do this will result in problems during the inspection as DEA will not be able to easily determine your adherence to patient limits.
 - *NOTE: It is important to note that DEA does not stipulate the way the prescriptions records have to be maintained. A log or file would be an efficient way to maintain the record, but DEA cannot mandate this format. If you have kept a complete log of all of your patients receiving buprenorphine treatment, they should not need to look at individual patient records.*
 - If you have all of this information easily accessible, the inspection should be fairly rapid. You do not have to be with them as they check your logs. You can have a staff person/office manager, etc. do this. Typically inspection visits last between 1 and 2 hours.
- If you are dispensing or administering buprenorphine in addition to prescribing, they will probably take an inventory of the product on hand and reconcile that with the records of what was received/dispensed/administered. The investigator will also be checking to see that the drugs are properly secured within the facility.

- **Storage and Dispensing:** For those physicians dispensing medication directly from their office, 21 CFR 1301.75 stipulates that buprenorphine/naloxone and buprenorphine should be stored in a securely locked, substantially constructed cabinet. The physician must keep a record of the amount received and dispensed (21 CFR 1304.22) and a physical inventory of all stocks on hand pursuant to 21 CFR 1304.11. The individual practitioner must also include the identification number on all records when dispensing and on all prescriptions when prescribing these narcotic drugs. See 21 CFR 1301.28 (d)(3). The physician must notify the local DEA office, in writing, of the theft or significant loss of any buprenorphine or buprenorphine/naloxone, within one business day.

6. If there is a violation

If the DEA investigator finds that there are administrative violations, s/he can issue a “Letter of Admonition” outlining the problems found in the audit. The physician then has 30 days to respond to DEA with information about how the problem was corrected. If you receive an onsite inspection and experience any problems, please contact the Providers’ Clinical Support System – for Medication Assisted Treatment at pcssmat@aaap.org

7. References

- **TIP 40: Clinical Guidelines for the Use of Buprenorphine in the Treatment of Opioid Addiction**, Chapter 6, pp 79-85; Appendix F p 135; Appendix Band C p. 101-119. Laura McNicholas, Consensus Panel Chair M.D. Ph.D. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES. Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Treatment
<http://www.kap.samhsa.gov/products/manuals/index.htm>
- DEA Requirements for DATA-Waived Physicians Who Treat Narcotic Addiction Using Buprenorphine:
http://www.deadiversion.usdoj.gov/pubs/docs/dwp_buprenorphine.htm
- SAMHSA/CSAT Information on Record Keeping:
<http://www.buprenorphine.samhsa.gov/faq.html#A9>
- For additional information about the recordkeeping and security requirements for controlled substances, please see:
<http://www.deadiversion.usdoj.gov/faq/general.htm#rr-1>