

If you are providing office-based treatment of opioid dependence, you should know that DATA 2000 requires the Drug Enforcement Agency to inspect physicians' office-based practices. The DEA has spent time in recent months preparing to inspect a greater number of these office-based settings, and several AAAP Board members recently had the opportunity to speak with DEA staff about the purpose of these visits and procedures to be used. The following information points are based on those discussions and are meant to assist you in preparing.

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

The following are a series of brief suggestions on how to prepare for a DEA inspection of waived physicians having an "X" number (modified DEA registration allowing them to engage in office-based treatment of opioid dependence) by the DEA based on a recent conversation (1/10) with officials at the DEA and AAAP Board members:

1. DEA is required by law to conduct regular inspections of physicians providing office-based treatment of opioid dependence. If you are contacted for such a visit, do not think it is because you have done something wrong; it is simply part of their process of carrying out DATA 2000 requirements.
2. It is important to understand the difference between an audit and an inspection. In most of these visits, the practitioner will be inspected not audited. With an "inspection," the DEA will issue a notice of inspection and will look only at the records required to be kept for patients receiving buprenorphine treatment. If the practitioner also dispenses buprenorphine products, then an audit will be conducted of the controlled substances received and dispensed. An "audit" determines the accountability of the controlled substances received and dispensed. The audit is one component of the "inspection" process.
3. DEA policy is to have at least 2 agents visit any office. At least one agent will be from DEA, the second agent may be from DEA or FBI depending on their staffing for that day. The presence of an FBI agent does not imply any suspicion of criminal activity.
4. DEA will not review clinical practices/procedures; their role is to determine that buprenorphine products are being used according to regulations.

5. DEA will specifically be looking at: prescription records, dispensing records, and adherence to patient limits.

6. Determination of 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.

- a. DEA will determine how many patients are being treated or have been treated at one time.
- b. If your state has a prescription monitoring program, DEA cannot directly access it. However, DEA might request access to those records as one means of determining your adherence to the law.
- c. It is recommended you keep any log of patients who are treated with buprenorphine, as well as copies or records 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 maintain 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 log 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.
- d. 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.

Comments or questions? Please email information@aaap.org.