

DEA Audits of DATA-Waived Prescribers

The Drug Enforcement Administration (DEA) has recently sent letters to psychiatrists and other physicians who are registered with DEA pursuant to the Drug Abuse Treatment Act of 2000 (DATA 2000) stating that they will be conducting 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 required to agree to submit to these random audits, which are a routine part of DEA surveillance. These inspections are intended to ensure compliance with recordkeeping, security, and other requirements for administering, dispensing or prescribing controlled substances under the CSA.

APA has been in contact with DEA and has expressed our concerns about these inspections. DEA has assured us that these inspections are routine and are not intended to intimidate or harass DATA-waived physicians or their patients. To assist you in the inspections, we are providing background information about what to expect and how to alert us if there is a problem.

What to Expect:

The audit 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. While there is always a chance he will be accompanied by a field agent who is authorized to have a weapon, DEA has informed us that this is very rare and that agents are instructed to be as discreet and professional as possible when arriving at a physician's office.

The inspector should present his DEA credentials and a "Notice of Inspection" which explains the process of the audit and your rights. You do have the right to refuse to consent to the inspection and insist that DEA obtain an administrative warrant. However, while we are pleased to provide information and analysis of the law and the review process, it is important for members to understand that this does not, and cannot, constitute binding legal advice. If you believe you require such 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. They will verify the number of patients you are treating to ensure that they are in line with the limits in DATA 2000.

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 dispensed/administered. The investigator will also be checking to see that the drugs are properly secured within the facility.

For additional information about the recordkeeping and security requirements for controlled substances, please see: <http://www.deadiversion.usdoj.gov/faq/general.htm#rr-1>

For additional information about the requirements for DATA-waived physicians please see: http://www.deadiversion.usdoj.gov/pubs/docs/dwp_buprenorphine.htm

If there is a violation:

If the DEA investigator finds that there are administrative violations, 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 audit and experience any problems, please contact APA through Jenny Tassler at (703) 907-7842 or Beatrice Eld at (703) 907-8598.