Meeting DEA registration, inventory requirements

Oral and maxillofacial surgeons must follow certain steps in order to remain compliant with the Controlled Substances Act and the recommendations of the DEA's Diversion Control Division. According to the DEA, the mission of DEA's Diversion Control Division is to prevent, detect and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial and scientific needs.

Q What information must be included on inventory records for controlled substances?

A For an initial inventory, a practitioner must take an actual physical count of all controlled substances in a practitioner's possession on the date the practitioner first engages in the dispensing of controlled substances (21 CFR 1304.11(b), 21 U.S.C. 827(a)(1)). If there are no stocks of controlled substances on hand, a practitioner can make a record showing zero inventory. Pursuant to 21 CFR 1304.11(a), (b) and (e)(6) and 21 U.S.C. 827(a)(1), the inventory must include:

- The date of the inventory.
- Whether the inventory was taken at the opening or close of business.
- The name of each controlled substance inventoried.
- The finished form of each of the substances (e.g., 10 milligram tablet).
- The number of dosage units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial).
- The number of commercial containers of each finished form (e.g., four 100-tablet bottles).
- A count of the substance. In determining the number of units of each finished form of a controlled substance in a commercial container that has been opened, the practitioner shall do as follows:
  - If the substance is listed in Schedule II, an exact count or measure of the contents is required.
  - If the substance is listed in Schedule III, IV or V, an estimated count or measure of the contents is sufficient unless the container holds more than 1,000 tablets or capsules, in which case an exact count of the contents is required.

After the initial inventory is taken, the registrant must take a new inventory of all stocks of controlled substances on hand at least every two years. A practitioner must record the same information as included in the initial inventory of all controlled substances on hand (21 CFR 1304.11(c)). The biennial inventory may be taken on any date that is within two years of the previous inventory date (21 CFR 1304.11(c)).

Although it is not required by law, the DEA recommends registrants keep an inventory record that includes the name, address and DEA registration number of the registrant and the signature(s) of the person(s) responsible for taking the inventory.

Q How long are practices required to maintain inventory records of controlled substances?

A A registrant must maintain all inventories for at least two years at the registered location in a readily retrievable manner for copying and inspection (21 CFR 1304.04(a), 21 U.S.C. 827(b)). Inventory records of Schedule II controlled substances must be kept separate from all other records (21 CFR 1304.04(f)(1)). Inventory records of Schedules III through V must be maintained separate from all other records or in such a manner that the required information is readily retrievable (21 U.S.C. 827(b), 21 CFR 1304.04(f)(2)). There is no requirement to submit a copy of the inventory to the DEA.

Q I am closing my practice; do I need to notify the DEA?

A If a practitioner discontinues business or professional practice, the practitioner must promptly notify the DEA (21 CFR 1301.52(a)). The DEA also recommends that the practitioner contact the local Special Agent in Charge and seek authority and instructions to dispose of any controlled substances obtained under the authority of that registration in accordance with 21 CFR part 1317.

For additional information regarding DEA registration, inventory requirements or to contact the local DEA field office, visit DEAdiversion.usdoj.gov or email dea.registration.help@dea.gov.

The "Practitioner's Manual: An Informational Outline of the Controlled Substances Act" is available to download at DEAdiversion.usdoj.gov/GDP/(DEA-DC-071)(EO-DEA226)_Practitioner's_Manual_(final).pdf. ■

Content for this article was sourced from "Practitioner's Manual: An Informational Outline of the Controlled Substances Act," a resource prepared by the DEA to provide guidance and assist practitioners with their understanding of the federal Controlled Substances Act and its regulations. This article is provided for informational purposes and not intended as legal advice or as replacing consultation with an attorney.