

WHAT YOU MUST KNOW WHEN YOU HAVE AN ORAL CONSCIOUS SEDATION, PARENTERAL SEDATION, OR GENERAL ANESTHESIA PERMIT

READ ALL of the information on these pages. It is critical that you know what the Board of Dental Examiners, the Drug Enforcement Agency (DEA), and other governing bodies will require of you once you obtain one of these permits.

Maintenance of Controlled Substances Records and Inventory: Board Rule 270-X-2-.12 sets forth your responsibility to maintain accurate inventory and dispensing logs. Be advised that discrepancies between inventory logs and dispensing logs can result in your being directed to undergo a substance abuse evaluation at a Board-approved facility. A summary of that Rule:

Board Rule 270-X-2-.12: Maintenance of Controlled Substances Records and Inventory

- You must maintain a separate inventory log of schedule drugs. See discussion of federal requirements below.
- You must maintain a separate Dispensing log of schedule drugs that includes:
 - o Date Dispensed
 - o Method by which dispensed
 - o Name of Drug
 - o Name of Patient
 - o Quantity of Drug Dispensed
- Both logs must be maintained for five (5) years
- The logs shall be made available for inspection to the Board, the DEA, or other law enforcement—immediately upon request.

Sample log sheets are [here](#) and [here](#).

The Board Rules are available [here](#). You must be familiar with specific Board Rules governing the specific procedures you perform. Rule 270-X-2-.11 covers controlled substances generally, and requires that you register with Alabama's Prescription Drug Monitoring Program (PDMP) so that you can be compliant with Board Rule 270-X-2-.23, which requires you to employ certain risk and abuse mitigation strategies on behalf of your patients. Rule 270-X-2-.17 sets forth what criteria you, your clinic, and your staff must meet to obtain a permit to perform general anesthesia and parenteral sedation. Board Rule 270-X-2-.21 sets forth the criteria for obtaining a permit to perform oral conscious sedation.

The Alabama Dental Practice Act, Ala. Code (1975), §§ 34-9-1 *et seq.*, available [here](#), at Section 34-9-18(a)(13), prohibits:

. . . the prescribing, administering or dispensing of any controlled substances enumerated in Schedules I through V contained in the Alabama Uniform Controlled Substances Act, Chapter 2 of Title 20, or any amendment or successor thereto, or any drug not prescribed

for any dentally or facially related condition, and/or for any necessary medication during the course of treatment rendered directly by the dentist, for any person not under his or her treatment in the regular practice of his or her profession.

That passage echoes the Alabama Uniform Controlled Substance Act, Ala. Code (1975), Ala. Code (1975) §§ 20-2-1 *et seq.*, which also governs your practice. The Controlled Substances Act makes it a felony to “prescribe, administer, or dispense any controlled substance enumerated in Schedules I through V for any person not under his treatment in his regular practice of his profession.” Ala. Code (1975), § 20-2-74. That Act is available [here](#), but the Board of Dental Examiners cannot guarantee that that web page is fully up to date.

The DEA Practitioner’s Manual, available [here](#), was prepared to assist you in your understanding of the Federal Controlled Substances Act and its implementing regulations. That link brings up the most recent version of the Practitioner’s Manual, released in 2006. An updated manual is expected soon.

You must familiarize yourself with DEA [regulations](#) governing disposal of controlled substances and DEA [Form 41](#) (and other forms, including Form [222](#)). See also DEA’s Controlled Substances Security [Manual](#).

Here are some of the highlights from the DEA regulations:

Title 21, Code of Federal Regulations:

21 C.F.R. §1301.12: Separate Registrations for Separate Locations

- A separate DEA registration is required at each clinic where schedule drugs will be dispensed or administered.

§1301.75: Physical Security Controls for Practitioners

- Schedule II-IV drugs must be stored in a securely locked, substantially constructed cabinet.

§1304.04: Maintenance of Records and Inventory

- You must retain records for at least two (2) years.
- Schedule II inventory logs and records must be kept separate from other records.
- All logs must be readily retrievable for inspection.

§1304.11: Inventory Requirements

- You must have an initial inventory date on the inventory log (the date the log was started)
- You must have a biennial inventory date on the inventory log
- The inventory log shall include:
 - Name of Drug
 - Finished form of drug (e.g. 10mg tablet, 10mg/mL solution)
 - Number of units per commercial container (e.g. 100 tablet bottle, 3mL vial)
 - Number of commercial containers (e.g. four 100 tablet bottles, six 3mL vials)

§1304.22: Maintenance of Records and Inventory

- Records must be continuous
- Records must be complete

§1306.04: Purpose of issue of Prescription

- You cannot write yourself a prescription to fill at a pharmacy for the purpose of using the drugs in clinic stock for dispensing to patients.

§1317.95: Destruction Procedures

- Waste of schedule drugs must render the drug non-retrievable
- 2 witnesses must witness, and sign, when schedule drugs are wasted
- Destruction of schedule drugs that are expired or will no longer be used in stock must be noted in inventory/ dispensing logs as well as on a DEA Form 41.