

AMB Requesting Comments on Rules:

Article 3 Dispensing of Drugs

The Arizona Medical Board (AMB) is accepting comments on the rules in Article 3, related to Dispensing of Drugs.

Please email communications@azmd.gov with your comments.

DEADLINE FOR COMMENT SUBMISSION IS:

MARCH 15, 2021

A current version of the rules is attached or at the Secretary of State's website, azsos.gov

CHAPTER 16. ARIZONA MEDICAL BOARD

ARTICLE 3. DISPENSING OF DRUGS

R4-16-301. Registration and Renewal

- A. A physician who wishes to dispense a controlled substance as defined in A.R.S. § 32-1901(12), a prescription-only drug as defined in A.R.S. § 32-1901(65), or a prescription-only device as defined in A.R.S. § 32-1901(64) shall be currently licensed to practice medicine in Arizona and shall provide to the Board the following:
1. A completed registration form that includes the following information:
 - a. The physician's name, license number, and field of practice;
 - b. A list of the types of drugs and devices the physician will dispense; and
 - c. The location or locations where the physician will dispense a controlled substance, a prescription-only drug, or a prescription-only device.
 2. A copy of the physician's current Drug Enforcement Administration Certificate of Registration for each dispensing location from which the physician will dispense a controlled substance.
 3. The fees required in A.R.S. § 32-1436.
- B. A physician shall renew a registration to dispense a controlled substance, a prescription-only drug, or a prescription-only device by complying with the requirements in subsection (A) on or before June 30 of each year. If a physician has made timely and complete application for the renewal of a registration, the physician may continue to dispense until the Board approves or denies the renewal application.
- C. If the completed annual renewal form, all required documentation, and the fee are not received in the Board's office on or before June 30, the physician shall not dispense any controlled substances, prescription-only drugs, or prescription-only devices until re-registered. The physician shall re-register by filing for initial registration under subsection (A) and shall not dispense a controlled substance, a prescription-only drug, or a prescription-only device until receipt of the re-registration.

Historical Note

New Section adopted by final rulemaking at 6 A.A.R. 751, effective February 2, 2000 (Supp. 00-1). Former Section R4-16-301 recodified to R4-16-401; New Section R4-16-301 recodified from R4-16-201 at 11 A.A.R. 1283, effective March 25, 2005 (Supp. 05-1).

R4-16-302. Packaging and Inventory; Exception

- A. A physician shall dispense all controlled substances and prescription-only drugs in prepackaged containers or in light-resistant containers with consumer safety caps, that comply with standards specified in the official compendium as defined in A.R.S. § 32-1901(49) and state and federal law, unless a patient or a patient's representative requests a non-safety cap.
- B. All controlled substances and prescription-only drugs dispensed shall be labeled with the following information:
1. The physician's name, address, and telephone number;
 2. The date the controlled substance and prescription-only drug is dispensed;
 3. The patient's name;
 4. The controlled substance and prescription-only drug name, strength, and dosage, form, name of manufacturer, the quantity dispensed, directions for use, and any cautionary statement necessary for the safe and effective use of the controlled substance and prescription-only drug; and
 5. A beyond-use-date not to exceed one year from the date of dispensing or the manufacturer's expiration date if less than one year.
- C. A physician shall secure all controlled substances in a locked cabinet or room and shall control access to the cabinet or room by a written procedure that includes, at a minimum, designation of the persons who have access to the cabinet or room and procedures for recording requests for access to the cabinet or room. This written procedure shall be made available on demand to the Board or its authorized representatives for inspection or copying. Prescription-only drugs shall be stored so as not to be accessible to patients.

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- D. Controlled substances and prescription-only drugs not requiring refrigeration shall be maintained in an area where the temperature does not exceed 85° F.
- E. A physician shall maintain an ongoing dispensing log for all controlled substances and the prescription-only drug nalbuphine hydrochloride (Nubain) dispensed by the physician. The dispensing log shall include the following:
 1. A separate inventory sheet for each controlled substance and prescription-only drug;
 2. The date the drug is dispensed;
 3. The patient's name;
 4. The dosage, controlled substance and prescription-only drug name, strength, dosage, form, and name of the manufacturer;
 5. The number of dosage units dispensed;
 6. A running total of each controlled substance and prescription-only drug dispensed; and
 7. The signature of the physician written next to each entry.
- F. A physician may use a computer to maintain the dispensing log required in subsection (E) if the log is quickly accessible through either on-screen viewing or printing of a copy.
- G. This Section does not apply to a prepackaged manufacturer sample of a controlled substance and prescription-only drug, unless otherwise provided by federal law.

Historical Note

New Section adopted by final rulemaking at 6 A.A.R. 751, effective February 2, 2000 (Supp. 00-1). Former Section R4-16-302 recodified to R4-16-402; New Section R4-16-302 recodified from R4-16-202 at 11 A.A.R. 1283, effective March 25, 2005 (Supp. 05-1).

R4-16-303. Prescribing and Dispensing Requirements

- A. A physician shall record on the patient's medical record the name, strength, dosage, and form, of the controlled substance, prescription-only drug, or prescription-only device dispensed, the quantity or volume dispensed, the date the controlled substance, prescription-only drug, or prescription-only device is dispensed, the medical reasons for dispensing the controlled substance, prescription-only drug, or prescription-only device, and the number of refills authorized.
- B. Before dispensing a controlled substance, prescription-only drug, or prescription-only device to a patient, a physician shall review the prepared controlled substance, prescription-only drug, or prescription-only device to ensure that:
 1. The container label and contents comply with the prescription, and
 2. The patient is informed of the name of the controlled substance, prescription-only drug, or prescription-only device, directions for use, precautions, and storage requirements.
- C. A physician shall purchase all dispensed controlled substances, prescription-only drugs, or prescription-only devices from a manufacturer or distributor approved by the United States Food and Drug Administration, or a pharmacy holding a current permit from the Arizona Board of Pharmacy.
- D. The person who prepares a controlled substance, prescription-only drug, or prescription-only device for dispensing shall countersign and date the original prescription form for the controlled substance, prescription-only drug, or prescription-only device.
- E. For purposes of this Article, "dispensing" means the delivery of a controlled substance, a prescription-only drug, or a prescription-only device to a patient for use outside the physician's office.

Historical Note

New Section adopted by final rulemaking at 6 A.A.R. 751, effective February 2, 2000 (Supp. 00-1). Amended by final rulemaking at 6 A.A.R. 4585, effective November 14, 2000 (Supp. 00-4). Former Section R4-16-303 recodified to R4-16-403; New Section R4-16-303 recodified from R4-16-203 at 11 A.A.R. 1283, effective March 25, 2005 (Supp. 05-1).

R4-16-304. Recordkeeping and Reporting Shortages

- A. A physician who dispenses a controlled substance or prescription-only drug shall ensure that an original prescription dispensed from the physician's office is dated, consecutively numbered in the order in which it is originally dispensed, and filed separately from patient medical records. A physician shall ensure that an original prescription be maintained in three separate files, as follows:
 1. Schedule II controlled substances;
 2. Schedule III, IV, and V controlled substances; and
 3. Prescription-only drugs.
- B. A physician shall ensure that purchase orders and invoices are maintained for all controlled substances and prescription-only drugs dispensed for profit and not for profit for three years from the date of the purchase order or invoice. Purchase orders and invoices shall be maintained in three separate files as follows:
 1. Schedule II controlled substances only;
 2. Schedule III, IV, and V controlled substances and nalbuphine; and
 3. All other prescription-only drugs.
- C. A physician who discovers a theft or loss of a controlled substance or a dangerous drug, as defined in A.R.S. § 13-3401, from the physician's office shall:
 1. Immediately notify the local law enforcement agency.
 2. Provide that agency with a written report, and
 3. Send a copy to the Drug Enforcement Administration and the Board within seven days of the discovery.
- D. For purposes of this Section, controlled substances are identified, defined, or listed in A.R.S. Title 36, Chapter 27.

Historical Note

New Section recodified from R4-16-204 at 11 A.A.R. 1283, effective March 25, 2005 (Supp. 05-1).

R4-16-305. Inspections; Denial and Revocation

- A. A physician shall cooperate with and allow access to the physician's office and records for periodic inspection of dispensing practices by the Board or its authorized representative. Failure to cooperate or allow access shall be grounds for revocation of a physician's registration to dispense a controlled substance, prescription-only drug, or prescription-only device or denial of renewal of the physician's dispensing registration.
- B. Failure to comply with A.R.S. § 32-1491 or this Article constitutes grounds for denial or revocation of dispensing registration.
- C. The Board shall revoke a physician's registration to dispense a controlled substance, prescription-only drug, or prescription-only device upon occurrence of the following:
 1. Suspending, revoking, surrendering, or canceling the physician's license;
 2. Placing the physician's license on inactive status;
 3. Failing to timely renew the physician's license; or
 4. Restricting the physician's ability to prescribe or administer medication, including loss or expiration of the physician's Drug Enforcement Administration Certificate of Registration.
- D. If the Board denies a physician's dispensing registration, the physician may appeal the decision by filing a request, in writ-