

DRAFT RULES Article II. Dispensing of drugs and natural substances

R4-38-201 Definitions

In addition to the definitions in A.R.S. §§ 32-2901, 32-2933, and 32-2951, the following definitions apply in this Chapter:

1. "Administer" means the direct application of a controlled substance, prescription-only drug, dangerous drug as defined in A.R.S. 13-3401, narcotic drug as defined in A.R.S. 13-3401, homeopathic medication, natural substance, or non-prescription drug, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by a homeopathic physician, a homeopathic physician's nurse or assistant, or by the patient or research subject at a homeopathic physician's direction.
2. "Dispensing" means the prescribing, administering, packaging, labeling, and security to safeguard a drug or device for delivery by a homeopathic physician of a controlled substance, prescription-only drug, prescription-only device, homeopathic remedy, or natural substance to a patient for use outside the physician's office. Samples packaged for individual use by licensed manufacturers or repackagers of drugs are exempt.
- ~~2-3.~~ "Label" means a display of written, printed, or graphic matter on the immediate container of an article and, on the outside wrapper or container, if the display on the immediate wrapper or container is not easily legible through the outside wrapper.
- ~~3-4.~~ "Labeling" means all labels and other written, printed or graphic matter:
 - a. On an article or any of its containers or wrappers and
 - b. Accompanying the article.

~~4-5.~~ “Manufacturer” means each person who prepares, derives, produces, compounds, processes, packages or repackages, or labels a drug in a place devoted to manufacturing the drug, but does not include a pharmacy, pharmacist, or physician.

~~5-6.~~ “Natural substance” means an herbal phytotherapeutic or oxygen, carbon, or nitrogen-based therapeutic agent, vitamin, mineral, or food-factor concentrate isolated from animal, vegetable, or mineral sources for nutritional augmentation.

~~6-7.~~ “Official compendium” means the latest revisions of the Pharmacopoeia of the United States and the Homeopathic Pharmacopoeia of the United States, the latest revision of the National Formulary, or any current supplement.

~~7-8.~~ “Packaging” means the act or process of placing a drug in a container to dispense or distribute the drug.

~~8-9.~~ “Pharmaceutical drug” means a drug intended for use in preventing or curing disease or relieving pain.

R4-38-202 General Provisions

A. A homeopathic physician shall not dispense unless the physician obtains from the Board a permit to dispense. The physician may renew the permit annually at the same time the license is renewed. The physician shall include the following on the permit application or renewal form:

1. The classes of drugs the physician will dispense, including controlled substances, pharmaceutical drugs, homeopathic medications, prescription-only drugs, natural substances and non prescription drugs defined in A.R.S. § ~~32-1901(46)~~ 1901(52) and devices defined in A.R.S. § ~~32-1901(18)~~ 32-1901(20);
2. The location where the homeopathic physician will dispense; and

3. A copy of the physician's current Drug Enforcement Administration (DEA) registration or an affidavit averring that the physician does not possess a DEA registration and that the physician will not prescribe or dispense controlled substances.

B. If a homeopathic physician determines that a shortage exists in a controlled substance maintained for dispensing, the physician shall immediately notify the Board, the local law enforcement agency, and the Department of Public Safety by telephone. The physician shall also provide written notification to the Board within seven days of the date of the discovery of the shortage.

C. A physician who wishes to dispense a controlled substance, a prescription-only drug, or a prescription-only device as defined in A.R.S. 32-1901(75) shall be currently licensed to practice homeopathic 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 modality 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. § 32-2914.

D. A physician shall renew a registration to dispense a controlled substance, a prescription-only drug, a prescription-only device, a homeopathic medication or a natural substance by complying with the requirements in subsection (A) on or before the date of license renewal 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.

E. If the completed annual renewal form, required documentation, and the fee are not received in the Board's office on or before the date of license renewal, the physician shall not dispense any controlled substances, prescription-only drugs, prescription-only devices, homeopathic medication or natural substances 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, a prescription-only device, homeopathic medication, or natural substances until receipt of the re-registration.

R4-38-203 Storage, record-keeping and maintenance

A. 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.

B. Controlled substances and prescription-only drugs not requiring refrigeration shall be maintained in an area where the temperature does not exceed 85° F.

C. 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.

D. A physician may use a computer to maintain the dispensing log required in subsection (C) if the log is quickly accessible through either on-screen viewing or printing of a copy.

E. This Section does not apply to a prepackaged manufacturer sample of a controlled substance and prescription-only drug, unless otherwise provided by federal law.

F. This Section does not apply to homeopathic medications or natural substances.

R4-38-204 Prescribing and Dispensing Requirements for prescription-only drugs or devices, and controlled substances

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.

R4-38-205 Prescribing and Dispensing Requirements for homeopathic remedies or natural substances

A. A physician shall record on the patient's medical record the name, strength, dosage, and form, of the homeopathic remedy or natural substance, the quantity or volume dispensed, the date

the homeopathic remedy or natural substance is dispensed, the medical reasons for dispensing the homeopathic remedy or natural substance, and the number of refills authorized.

B. Before dispensing a homeopathic remedy or natural substance to a patient, a physician shall review the prepared homeopathic remedy or natural substance to ensure that:

1. The container label and contents comply with the prescription, and
2. The patient is informed of the name of the homeopathic remedy or natural substance, directions for use, precautions, and storage requirements.

C. The person who prepares a homeopathic remedy or natural substance for dispensing shall countersign and date the patient's medical record.

R4-38-206. Packaging

In addition to the requirements of A.R.S. § 32-2951, a dispensing homeopathic physician shall dispense a controlled substance or prescription-only pharmaceutical drug in a light-resistant container with a consumer safety cap, unless the patient or patient's representative and the physician agree otherwise. This section does not apply to homeopathic medications or natural substances.