

SECRETARY OF STATE

2021 AUG 12 PM 4: 06

FILED

**AGENCY RECEIPT**

**NOTICE OF PROPOSED RULEMAKING**

**1. Agency name:** Arizona Medical Board

**2. The Subchapters, if applicable; the Articles; the Parts, if applicable, and the Sections involved in the rulemaking, listed in numerical order:**

**Article, Part, or Section Affected (as applicable) Rulemaking Action**

(in numerical order)

R4-16-201	Amend
R4-16-201.1	Amend
R4-16-301	Amend
R4-16-302	Amend
R4-16-303	Amend
R4-16-304	Amend
R4-16-305	Amend

2021 AUG 12 PM 4:07

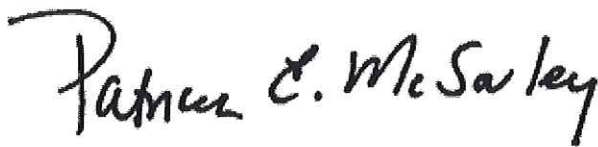
FILED

AGENCY CERTIFICATE  
NOTICE OF PROPOSED RULEMAKING

- 1. **Agency name:** Arizona Medical Board
- 2. **Chapter heading:** Arizona Medical Board
- 3. **Code citation for the Chapter:** 4 A.A.C. 16
- 4. **The Subchapters, if applicable; the Articles; the Parts, if applicable, and the Sections involved in the rulemaking, listed in numerical order:**

<u>Article, Part, or Section Affected (as applicable)</u>	<u>Rulemaking Action</u>
(in numerical order)	
R4-16-201	Amend
R4-16-201.1	Amend
R4-16-301	Amend
R4-16-302	Amend
R4-16-303	Amend
R4-16-304	Amend
R4-16-305	Amend

- 5. **The rules contained in this package are true and correct as proposed.**



8/11/21

6. \_\_\_\_\_  
Signature of Agency Chief Executive Officer in ink

\_\_\_\_\_  
Date of signing

Patricia McSorley  
Printed or typed name of signer

Executive Director  
Title of signer

NOTICE OF PROPOSED RULEMAKING  
TITLE 4. PROFESSIONS AND OCCUPATIONS  
CHAPTER 16. ARIZONA MEDICAL BOARD

PREAMBLE

**1. Articles, Parts, and Sections Affected**

**Rulemaking Action**

R4-16-201	Amend
R4-16-201.1	Amend
R4-16-301	Amend
R4-16-302	Amend
R4-16-303	Amend
R4-16-304	Amend
R4-16-305	Amend

**2. Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific):**

Authorizing statute: A.R.S. § 32-1404(D)

Implementing statute: A.R.S. §§ 32-1401(9), 32-1422, 32-1430, and 32-1491

**3. Citations to all related notices published in the Register as specified in R1-1-409(A) that pertain to the record of the proposed rule:**

Notice of Rulemaking Docket Opening: XX A.A.R. XX

**4. The agency's contact person who can answer questions about the rulemaking:**

Name: Patricia McSorley, Executive Director

Address: Arizona Medical Board

1740 W Adams Street, Suite 4000

Phoenix, AZ 85007

Telephone: (480) 551-2700

Fax: (480) 551-2704

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Web site: www.azmd.gov

**5. An agency's justification and reason why a rule should be made, amended, repealed, or renumbered, to include an explanation about the rulemaking:**

The rules in Article 3 are quite old. In 5YRRs completed in 2015 and 2020, the Board indicated it intended to amend the rules to address issues dealing with lack of clarity, incorrect cross references,

and inconsistencies with statute. However, higher priority work, turnover of staff, and scarce state resources prevented the Board from completing the plan rulemaking. This rulemaking addresses the issues identified in the previous 5YRRs.

A 5YRR of Article 2 was approved by the Council on February 2, 2021. This rulemaking addresses minor issues identified in that rulemaking.

Additionally, under Laws 2018, Chapter 1, the legislature amended A.R.S. § 32-1491(B) regarding dispensing a Schedule II controlled substance that is an opioid. R4-16-301 has been amended to reference that change.

Exemptions for this rulemaking from Executive Order 2021-02 were provided by Gabee Lepore of the Governor's Office by e-mails dated July 29, 2021.

**6. A reference to any study relevant to the rule that the agency reviewed and proposes either to rely on or not to rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:**

The Board reviewed and was informed by the following report on a study: *Physician, Heal Thy Double Stigma—Doctors with Mental Illness and Structural Barriers to Disclosure*, by Omar S. Haque, M.D., Ph.D., Michael A. Stein, J.D. Ph.D., and Amelia Marvit, New England Journal of Medicine, March 11, 2021. The article can be accessed at:

<https://www.nejm.org/doi/full/10.1056/NEJMp2031013>

**7. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state:**

Not applicable

**8. The preliminary summary of the economic, small business, and consumer impact:**

The Board believes that improving clarity and correcting references will have a minimal, positive economic impact on those required to comply with the rules. The amendments to R4-16-201 and R4-16-201.1 will benefit physicians who might be reluctant to obtain needed help for medical conditions that potentially impair practice.

**9. The agency's contact person who can answer questions about the economic, small business, and consumer impact statement:**

Name: Patricia McSorley, Executive Director

Address: Arizona Medical Board

1740 W Adams Street, Suite 4000

Phoenix, AZ 85007

Telephone: (480) 551-2700

Fax: (480) 551-2704

E-mail: patricia.mcsorley@azmd.gov

Web site: www.azmd.gov

**10. The time, place, and nature of the proceedings to make, amend, repeal, or renumber the rule, or if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:**

An oral proceeding regarding the proposed rules will be held as follows:

Date: Wednesday, October 6, 2021

Time: 10 A.M.

Location: The oral proceeding will be held electronically. Instructions for connecting to the oral proceeding will be posted on the Board's web site.

**11. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:**

None

**a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:**

The license, renewal, and registration addressed in this rulemaking are not general permits because the Board is required by statute (See A.R.S. §§ 32-1422, 32-1430, and 32-1491) to issue licenses and registrations only to individuals who meet criteria specified in statute and rule.

**b. Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:**

None of the rules is more stringent than federal law. There are numerous federal laws relating to the provision of health care but none is directly applicable to this rulemaking.

**c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:**

No analysis was submitted

**12. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rules:**

None

**13.** **The full text of the rules follows:**

**TITLE 4. PROFESSIONS AND OCCUPATIONS  
CHAPTER 16. ARIZONA MEDICAL BOARD**

**ARTICLE 2. LICENSURE**

Section

R4-16-201. Application for Licensure by Examination or Endorsement

R4-16-201.1. Application for Renewal of License

**ARTICLE 3. DISPENSING OF DRUGS**

Section

R4-16-301. Registration and Renewal

R4-16-302. Packaging and Inventory; Exception

R4-16-303. Prescribing and Dispensing Requirements

R4-16-304. Recordkeeping and Reporting Shortages

R4-16-305. Inspections; Denial and Revocation

## ARTICLE 2. LICENSURE

### **R4-16-201. Application for Licensure by Examination or Endorsement**

- A.** For purposes of this Article, unless otherwise specified:
1. “ABMS” means American Board of Medical Specialties.
  2. “ECFMG” means Educational Commission for Foreign Medical Graduates.
  3. “FCVS” means Federation Credentials Verification Service.
  4. “FLEX” means Federation Licensing Examination.
  5. “LMCC” means Licentiate of the Medical Council of Canada.
  6. “NBME” means National Board of Medical Examiners.
  7. “Primary source” means the original source or an approved agent of the original source of a specific credential that can verify the accuracy of a qualification reported by an applicant.
  8. “SPEX” means Special Purposes Examination.
  9. “USMLE” means United States Medical Licensing Examination.
- B.** An applicant for licensure to practice medicine by Step 3 of the USMLE or endorsement shall submit the following information on an application form available on request from the Board and on the Board’s web site:
1. Applicant’s full name, Social Security number, business and home addresses, primary e-mail address, business and home telephone numbers, and date and place of birth;
  2. Name of the school of medicine from which the applicant graduated and date of graduation;
  3. A complete list of the applicant’s internship, residency, and fellowship training;
  4. List of all licensing examinations taken;
  5. Names of the states, U.S. territories, or provinces in which the applicant has applied for or been granted a license or registration to practice medicine, including license number, date issued, and current status of the license;
  6. A statement of whether the applicant:
    - a. Has had an application for medical licensure denied or rejected by another state or province licensing board, and if so, an explanation;
    - b. Has ever had any disciplinary or rehabilitative action taken against the applicant by another licensing board, including other health professions, and if so, an explanation;
    - c. Has had any disciplinary actions, restrictions, or limitations taken against the applicant while participating in any type of training program or by any health care provider, and if so, an explanation;
    - d. Has been found in violation of a statute, rule, or regulation of any domestic or foreign governmental agency, and if so, an explanation;

- e. Is currently under investigation by any medical board or peer review body, and if so, an explanation;
  - f. Has been subject to discipline resulting in a medical license being revoked, suspended, limited, cancelled during investigation, restricted, or voluntarily surrendered, or resulting in probation or entry into a consent agreement or stipulation and if so, an explanation;
  - g. Has had hospital privileges revoked, denied, suspended, or restricted, and if so, an explanation;
  - h. Has been named as a defendant in a malpractice matter currently pending or that resulted in a settlement or judgment against the applicant, and if so, an explanation;
  - i. Has been subjected to any regulatory disciplinary action, including censure, practice restriction, suspension, sanction, or removal from practice, imposed by any agency of the federal or state government, and if so, an explanation;
  - j. Has had the authority to prescribe, dispense, or administer medications limited, restricted, modified, denied, surrendered, or revoked by a federal or state agency as a result of disciplinary or other adverse action, and if so, an explanation;
  - k. Has been found guilty or entered into a plea of no contest to a felony, a misdemeanor involving moral turpitude in any state, and if so, an explanation;
7. Whether the applicant is currently certified by any of the American Board of Medical Specialties;
  8. The applicant's intended specialty;
  9. Consistent with the Board's authority at A.R.S. § 32-1422(B), other information the Board may deem necessary to evaluate the applicant fully;
  10. Whether the applicant completed a training unit prescribed by the Board regarding the requirements of A.R.S. Title 32, Chapter 13 and this Chapter;
  11. In addition to the answers provided under subsections (B)(1) through (B)(10), the applicant shall answer the following confidential question:
    - a. Whether the applicant currently has ~~received treatment within the last five years for use of alcohol or a controlled substance, prescription only drug, or dangerous drug or narcotic or a physical, mental, emotional, or nervous disorder or a medical~~ condition that currently affects impairs the applicant's ability to ~~exercise the judgment and skills of a medical practice~~ medicine in a competent, ethical, and professional manner;
    - b. If the answer to subsection (B)(11)(a) is yes:
      - i. ~~A detailed description of the use, disorder, or condition~~ Provide an explanation of the medical condition; and



- D.** In addition to the requirements of subsections (B) and (C), an applicant for licensure to practice medicine by Step 3 of the USMLE or endorsement shall have the following submitted to the Board, electronically or in hard copy, by the primary source, ECFMG, Veridoc, or FCVS:
1. Official transcript or other authentication of graduation from a school of medicine;
  2. Verification of completion of postgraduate training;
  3. Verification of ECFMG certification if the applicant graduated from an unapproved school of medicine;
  4. Examination and Board history report scores for USMLE, FLEX, NBME, and SPEX;
  5. Verification of LMCC exam score or state written exam score;
  6. Verification of licensure from every state in which the applicant has ever held a medical license;
  7. Verification of all hospital affiliations during the five years before the date of application. Under A.R.S. § 32-1422(A)(11)(b), this verification is required to be on the hospital's official letterhead or the electronic equivalent; and
  8. Verification of all medical employment during the five years before the date of application. Under A.R.S. § 32-1422(A)(11)(b), this verification may be submitted by the employer.
- E.** As provided under A.R.S. § 32-1422(F), the Board may waive a documentation requirement specified under subsections (C)(5) and (D).
1. To obtain a waiver under this subsection, an applicant shall submit a written request that includes the following information:
    - a. Applicant's name;
    - b. Date of request;
    - c. Document required under subsection (C)(5) or (D) for which waiver is requested;
    - d. Detailed description of efforts made by the applicant to provide the document as required under subsection (C)(5) or (D);
    - e. Reason the applicant's inability to provide the document as required under subsection (C)(5) or (D) is due to no fault of the applicant; and
    - f. If applicable, documents that support the request for waiver.
  2. The Board shall consider the request for waiver at its next regularly scheduled meeting.
  3. In determining whether to grant the request for waiver, the Board shall consider whether the applicant:
    - a. Made appropriate and sufficient effort to satisfy the requirement under subsection (C)(5) or (D); and
    - b. Demonstrated that compliance with the requirement under subsection (C)(5) or (D) is not possible because:

- i. The entity responsible for issuing the required document no longer exists;
    - ii. The original of the required document was destroyed by accident or natural disaster;
    - iii. The entity responsible for issuing the required document is unable to provide verification because of armed conflict or political strife; or
    - iv. Another valid reason beyond the applicant's control prevents compliance with the requirement under subsection (C)(5) or (D).
  - 4. In determining whether to grant the request for waiver, the Board shall:
    - a. Consider whether it is possible for the Board to obtain the required document from other source; and
    - b. Request the applicant to obtain and provide additional information the Board believes will facilitate the Board's decision.
  - 5. If the Board determines the applicant is unable to comply with a requirement under subsection (C)(5) or (D) in spite of the applicant's best effort and for a reason beyond the applicant's control, the Board may grant the request for waiver and include the decision in the Board's official record for the applicant.
  - 6. The Board shall provide the applicant with written notice of its decision regarding the request for waiver. The Board's decision is not subject to review or appeal.
- F.** As provided under A.R.S. § 32-1426(B), the Board may require an applicant for licensure by endorsement who passed an examination specified in A.R.S. § 32-1426(A) more than ten years before the date of application to provide evidence the applicant is able to engage safely in the practice of medicine. The Board may consider one or more of the following to determine whether the applicant is able to engage safely in the practice of medicine:
- 1. ~~If an~~ Whether the applicant is board certified by one of the specialties recognized by the ABMS; ~~If the applicant holds a current ABMS certification, this criteria criterion is considered met.~~
  - 2. ~~If an~~ Whether the applicant ~~obtains a passing score on a~~ takes and passes the SPEX examination; ~~If the applicant obtains a passing score on the SPEX examination, this criteria criterion is considered met.~~
  - 3. The Board may also consider any combination of the following:
    - a. The applicant's records,
    - b. The applicant's practice history, and
    - c. A physical or psychological assessment of the applicant.

**R4-16-201.1. Application for Renewal of License**

- A.** Under A.R.S. § 32-1430(A), an individual licensed under A.R.S. Title 32, Chapter 13, shall renew the license every other year on or before the licensee's birthday.
- B.** To renew a license, a licensee shall submit the following information on an application form available on request from the Board and on the Board's web site:
1. The licensee's full name, license number, business and home addresses, primary e-mail address, and business and home telephone numbers;
  2. Identification of changes to medical specialties and fields of practice;
  3. A statement of whether, since the time of last license issuance, the licensee:
    - a. Has had an application for medical licensure denied or rejected by another state or province licensing board and if so, an explanation;
    - b. Has had any disciplinary or rehabilitative action taken against the licensee by another licensing board, including other health professions and if so, an explanation;
    - c. Has had any disciplinary action, restriction, or limitation taken against the licensee by any program or health care provider and if so, an explanation;
    - d. Has been subject to discipline resulting in a medical license being revoked, suspended, limited, cancelled during an investigation, restricted, or voluntarily surrendered, or resulting in probation or entry into a consent agreement or stipulation and if so, an explanation;
    - e. Has had hospital privileges revoked, denied, suspended, or restricted and if so, an explanation (do not report if the licensee's hospital privileges were suspended due to failure to complete hospital records and reinstated after no more than 90 days);
    - f. Has been subjected to disciplinary action including censure, practice restriction, suspension, sanction, or removal from practice by an agency of the state or federal government and if so, an explanation;
    - g. Has had the authority to prescribe, dispense, or administer medications limited, restricted, modified, denied, surrendered, or revoked by a federal or state agency as a result of disciplinary or other adverse action and if so, an explanation;
    - h. Has been found guilty or entered into a plea of no contest to a felony, a misdemeanor involving moral turpitude, or an alcohol or drug-related offense in any state and if so, an explanation; and
    - i. Has failed the SPEX;
  4. A statement of whether the licensee understands and complies with the medical records and recordkeeping requirements in A.R.S. §§ 32-3211 and 12-2297;

5. A statement of whether the licensee has completed at least 40 hours of CME as required under A.R.S. § 32-1434 and R4-16-102, including the hour of CME required under R4-16-102(A)(1);
6. A statement of whether the licensee requests that the license be inactivated or cancelled; and
7. A statement of whether the licensee completed a training unit prescribed by the Board regarding the requirements of A.R.S. Title 32, Chapter 13 and this Chapter.

C. Additionally, the licensee shall answer the following confidential question:

1. Whether the ~~applicant licensee currently has received treatment since the last renewal for use of alcohol or a controlled substance, prescription only drug, or dangerous drug or narcotic or a physical, mental, emotional, or nervous disorder or a medical~~ condition that currently affects impairs the applicant's licensee's ability to exercise the judgment and skills of a medical practice medicine in a competent, ethical, and professional manner;
2. If the answer to subsection (C)(1) is yes:
  - a. ~~A detailed description of the use, disorder, or condition~~ Provide an explanation of the medical condition; and
  - b. ~~An explanation of whether the use, disorder, or condition is reduced or ameliorated because the applicant receives ongoing treatment and if so, the name and contact information for all current treatment providers and for all monitoring or support programs in which the applicant is currently participating~~ If currently practicing under a monitoring agreement with a licensing board in another state, attach a copy of the monitoring agreement to the application; and
3. ~~A copy of any public or confidential agreement or order relating to the use, disorder, or condition, issued by a licensing agency or health care institution since the last renewal, if applicable.~~

D. To renew a license, a licensee shall submit the following with the required application form:

1. If the document submitted under R4-16-201(C)(3) was a limited form of work authorization issued by the federal government, evidence that the licensee's presence in the U.S. continues to be authorized under federal law;
2. The renewal fee specified under R4-16-205 and, if applicable, the penalty fee for late renewal; and
3. An attestation that all information submitted is correct.

### 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)~~ restricted under A.R.S. § 32-1491(B), a prescription-only drug as defined in ~~A.R.S. § 32-1901(65)~~, or a prescription-only device, as defined in ~~at A.R.S. § 32-1901(64)~~, shall be currently licensed to practice medicine in Arizona and shall ~~register with the Board by provide~~ providing the following to the Board the following:
1. A completed registration form, which is available on the Board's web site and 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; and
  3. ~~The fees fee~~ required in A.R.S. § 32-1436 under R4-16-205 unless the physician is exempt under A.R.S. § 32-1921(E) from paying the fee.
- B. A physician shall renew a registration to dispense a controlled substance, as restricted under A.R.S. § 32-1491(B), 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~~ makes 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~~ a physician fails to comply with subsection (B), the physician shall not dispense any controlled substances, prescription-only drugs, or prescription-only devices until re-registered the physician complies fully with subsection (A) and receives notice the Board approves the registration. 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.

**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 the patient's representative requests a non-safety cap.
- B. ~~All~~ A physician shall ensure a controlled substances and substance or prescription-only drugs drug dispensed ~~shall be~~ is labeled with the following information:
1. The physician's name, address, and telephone number;
  2. The date the controlled substance ~~and or~~ or prescription-only drug is dispensed;
  3. The patient's name and date of birth;
  4. The controlled substance ~~and or~~ or 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 or~~ or prescription-only drug; and
  5. A ~~beyond-use date~~ 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~~ The physician shall make the written procedure ~~shall be made~~ available on demand to the Board or its authorized representatives for inspection or copying.
- ~~D.~~ Prescription-only A physician shall store prescription-only drugs ~~shall be stored~~ so as ~~not to be~~ the prescription-only drugs are not accessible to patients.
- ~~D.E.~~ Controlled A physician shall store controlled substances and prescription-only drugs not requiring refrigeration ~~shall be maintained~~ in an area where the temperature does not exceed 85° F.
- ~~E.F.~~ 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 and date of birth;
  4. The ~~dosage,~~ controlled substance ~~and or~~ or 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.G.~~ A physician may use a computer to maintain the dispensing log required in subsection ~~(E)~~ (F) if the dispensing log is password protected and quickly accessible through either on-screen viewing or printing of a copy.

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

#### **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~~ a 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~~ therapeutic reason 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 order, 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~~ order 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.~~

#### **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 order for the controlled substance or prescription-only drug 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~~ The physician shall ensure that an original prescription orders are 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, whether for profit ~~and~~ or 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 the local law enforcement agency with a written report, and
  3. Send a copy of the report provided under subsection (C)(2) 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.

**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~~ constitutes 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~~ if any of the following occur:
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 timely; 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.** As specified under R4-16-103, If the Board denies a physician's physician who is denied a dispensing registration, ~~the physician~~ may appeal the decision by filing a request, in writing, with the Board, no later than 30 days after receipt of the notice denying the registration.