PROPOSED RULES
Initiated After January 1, 1995

Unless exempted by A.R.S. § 41-1005, each agency shall begin the rulemaking process by first filing a Notice of Proposed Rulemaking, containing the preamble and the full text of the rules, with the Secretary of State's Office. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the *Arizona Administrative Register.*

Under the Administrative Procedure Act (A.R.S. § 41-1001 *et seq.*), an agency must allow at least 30 days to elapse after the publication of the Notice of Proposed Rulemaking in the *Register* before beginning any proceedings for adoption, amendment, or repeal of any rule. A.R.S. §§ 41-1013 and 41-1022.

TITLE 4. COMMERCE, PROFESSIONS, AND OCCUPATIONS
CHAPTER 16. BOARD OF MEDICAL EXAMINERS

PREAMBLE

1. Sections Affected — Rulemaking Action

Article 1.	
R4-16-101	Repeal
R4-16-102	Repeal
R4-16-103	Renumber
R4-16-104	Repeal
R4-16-105	Repeal
R4-16-106	Renumber
Article 2.	New Article
R4-16-201	New section
R4-16-202	New section
R4-16-203	New section
R4-16-204	New section
R4-16-205	New section

2. **The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**
Authorizing statute: A.R.S. §32-1403(A)(8)
Implementing statute: A.R.S. §32-1491(E)

3. **The name and address of agency personnel with whom persons may communicate regarding the rule:**
Name: Elaine Hugunin, Deputy Director
Address: 1651 East Morten, Suite 210, Phoenix, AZ 85020
Telephone Number: (602) 255-3751
Fax Number: (602) 255-1848

4. **An explanation of the rule, including the agency's reasons for initiating the rule:**
In 1989, the Arizona Legislature enacted A.R.S. § 32-1491 which authorized physicians to dispense drugs and devices. These rules are being proposed to implement subsection (E) of that Section, which mandates that the Board establish rules regarding labeling, recordkeeping, storage, and packaging of drugs consistent with the requirements of A.R.S. Title 32, Chapter 18. These rules set forth the requirements for the dispensing of controlled substances, prescription-only drugs, and medical devices. A current rule regarding anabolic-androgenic steroids is being repealed as it will be covered by the new dispensing rules. Principally, the proposed rules detail the requirements for all physicians who wish to dispense drugs and devices from their offices to be registered with the Board; address application for and renewal of registration; packaging, labeling, recordkeeping, prescribing, and dispensing requirements; inventory control of the drugs and devices; inspection by the Board; and self-reporting of drug thefts or shortages. Finally, three other current rules, which address the oral and written examinations required for physician licensure as well as limited licensure, are being repealed because they have been superceded by the enactment of more specific statuory provisions governing examination and licensure of physicians.

The Board believes that adoption of these rules will benefit the public health and safety by establishing clear standards governing the dispensing of drugs and devices by physicians. The Board further believes that, with this expanded component of a physician's practice, specific regulation and enforcement are necessary to regulate and control the dispensing of drugs and devices and to make physicians accountable for all activities related to dispensing.

5. **A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:**
Not applicable.

6. **The preliminary summary of the economic, small business, and consumer impact:**
The principal impact of these rules will be on physicians, pharmacies, and consumers. For physicians who elect to dispense, the rules will place additional responsibility on them for the dispensing and control of drugs and devices. The requirements are similar to those borne by pharmacists and will add only minimal costs. With authority to dispense, physicians will benefit by being provided clear guidelines for control of controlled substances and prescription-only drugs and devices dispensed from their practices, reducing risk of employee theft, disciplinary action and malpractice claims. It is anticipated that this could substantially reduce costs for a physician. Physicians who dispense will also benefit through increased revenues.

It is believed that the decrease in business and revenues for pharmacies, wherever located, is and will be minimal, as fewer than 10 percent of licensed physicians have undertaken to be registered to dispense.

For consumers, there will be a benefit from the physicians' ability to dispense controlled substances, prescription-only drugs, and medical devices in a more controlled environment. The consumer will, if the consumer's physician is registered to dispense, have the option to purchase required medications or devices from either the physician or a pharmacy, and will be assured of proper control and supervision in either case. It is anticipated that the rules will facilitate access for patients to drugs in some practice settings, particularly in rural areas where pharmacies may not be located nearby. Any cost impact on consumers is expected to be negligible.

The repeal of the three rules which address the oral and written examinations required for licensure as well as limited licensure will have no economic impact as these provisions have not been followed. Rather, the very different and more specific statutory provisions which have been enacted to address examination and licensure have been observed. There will be no change to the manner in which the Board carries out these responsibilities.

7. **The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:**
Name: Elaine Hugunin, Deputy Director
Address: 1651 East Morten, Suite 210, Phoenix, AZ 85020
Telephone Number: (602) 255-3751
Fax Number: (602) 255-1848

8. **The time, place, and nature of the proceedings for the adoption, amendment, or repeal of the rule or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:**
No public proceeding is scheduled. A person may submit written comments to or request that an oral proceeding be held on the proposed rules by submitting the comments or a written request for hearing no later than 5 p.m., March 20, 1995, to the following person:
Name: Elaine Hugunin, Deputy Director
Address: 1651 East Morten, Suite 210, Phoenix, AZ 85020
Telephone Number: (602) 255-3751
Fax Number: (602) 255-1848

9. **Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:**
Not applicable.

10. **Incorporations by reference and their location in the rules:**
None.

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

TITLE 4. COMMERCE, PROFESSIONS, AND OCCUPATIONS

CHAPTER 16. BOARD OF MEDICAL EXAMINERS

ARTICLE 1. GENERAL PROVISIONS

Section
R4-16-101. ~~Written examination~~
R4-16-102. ~~Oral examination~~
R4-16-1031. Continuing Medical Education
R4-16-104. ~~Continuing qualification for limited licensure~~
R4-16-105. ~~Anabolic-androgenic steroids~~
R4-16-1062. Rehearing or Review of Board Decision

ARTICLE 2. DISPENSING OF DRUGS AND DEVICES

Section
R4-16-201. Registration and Renewal
R4-16-202. Packaging and Inventory; Exception
R4-16-203. Prescribing and Dispensing Requirements
R4-16-204. Recordkeeping and Reporting Shortages
R4-16-205. Inspections; Denial and Revocation

ARTICLE 1. GENERAL PROVISIONS

R4-16-101. ~~Written examination~~
~~The written examination required by A.R.S. § 32-1425 shall be the FLEX examination of the Federation of State Medical Boards. All applications to take this examination shall be filed with the Board at least 90 days prior to the examination date and shall be accompanied by all required forms, allied papers and information as well as the examination fee.~~

R4-16-102. ~~Oral examination~~
~~The oral examination required by A.R.S. § 32-1426 shall be conducted at least semi-annually on dates and at times and places set by the Board. All applications to take this examination shall be filed with the Board at least 45 days prior to the examination date and shall be accompanied by all required forms, allied papers and information as well as the examination fee.~~

R4-16-1031. Continuing Medical Education
No Change.

R4-16-104. ~~Continuing Qualification for Limited Licensure~~
~~Continuing qualification, under A.R.S. § 32-1425.01(B)(3) for a limited license to practice medicine, requires that the licentiate attain a weighted grade average of not less than 70 percent on any written examination of the Board taken in accordance with A.R.S. § 32-1425.01(D). A limited licensee who fails to maintain a weighted grade average of 70 percent or above on his written examination shall be requested to attend an informal interview before the Board to show cause why his license should not be summarily suspended for medical incompetency and referred to a formal hearing for revocation of his license.~~

R4-16-105. ~~Anabolic-androgenic steroids~~
~~The Arizona Board of Medical Examiners has determined that the prescribing, dispensing or administering of anabolic-androgenic steroids by a duly licensed physician to a normal healthy person for other than therapeutic purposes is unprofessional conduct as that term is defined in A.R.S. § 32-1401(8)(j) and (o).~~

R4-16-1062. Rehearing or Review of Board Decision
No change.

ARTICLE 2. DISPENSING OF DRUGS AND DEVICES

R4-16-201. Registration and Renewal

A. A physician who wishes to dispense controlled substances and prescription-only drugs and devices shall be currently licensed to practice medicine in the State of Arizona and shall return to the Board, the following:
   1. A completed form for registration, furnished by the Board, which includes the following information:
      a. The physician's name, license number, and area of practice;
      b. A listing of the types of drugs and devices the physician desires to dispense, including prescription-only and controlled substances; and
      c. The location or locations where the physician desires to dispense.
   2. A copy of the physician's current Drug Enforcement Administration Certificate of Registration for each dispensing location from which the physician intends to dispense controlled substances.
   3. The statutorily required fee.

B. A physician shall renew a registration to dispense drugs and devices by complying with the requirements set forth in subsection (A) on or before June 30 of each year. When a physician has made timely and complete application for the renewal of a registration, the physician may continue to dispense until the application has been finally determined by the agency or as otherwise provided in A.R.S. § 41-1064(B).

C. If the completed annual renewal form, all required documentation, and the correct fee are not received in the Board's office on or before June 30, the physician shall not be permitted to dispense drugs and devices until newly registered. The physician shall register by filing for initial registration pursuant to subsection (A) and shall not dispense drugs and devices until receipt of a new registration.

R4-16-202. Packaging and Inventory; Exception

A. A physician shall dispense all drugs and devices in prepackaged containers or in light-resistant containers with a consumer safety cap, unless a patient or a patient's representative requests a non-safety cap.

B. All drugs and devices dispensed shall be labeled with the following information:
   1. The physician's name, address, and telephone number;
   2. The serial number and date the drug or device is dispensed;
   3. The patient's name; and
   4. The name and strength of the drug, the quantity dispensed, directions for its use, and any cautionary statement necessary for the safe and effective use of the drug.

C. A physician shall secure all controlled substances, prescription-only medications, and manufacturers' samples of such substances and medications in a locked cabinet or room and shall control access to the cabinet or room by a written procedure which shall include, at a minimum, designation of the persons who have access to the cabinet or room and procedures for recording requests for access to drugs. This written procedure shall be made available on demand to the Board or its authorized representatives for inspection or copying.

D. Drugs and devices not requiring refrigeration shall be maintained in an area where the temperature does not exceed 85° Fahrenheit.

E. A physician shall maintain an ongoing dispensing log for all drugs dispensed by the physician which includes separate inventory sheets for each controlled substance and the prescription-only medications nalbuphine hydrochloride (Nubain) and butorphanol tartrate (Stadol). The heading of a dispensing log shall include the following information:
   1. The date the drug is dispensed;
   2. The patient's name;
   3. The name and strength of the drug;
   4. The number of dosage units dispensed;
   5. A running total of medication dispensed; and
   6. The signature of the physician or the person authorized by the physician who dispensed the medication, written next to each entry.

F. Except as otherwise provided, this Section shall not apply to manufacturer samples of drugs and devices.

R4-16-203. Prescribing and Dispensing Requirements

A. A physician shall record on the patient's medical record the name and strength of the drug or device dispensed, the quantity or volume dispensed, the date the drug or device is dispensed, the medical reasons for dispensing the drug or device, and the number of refills authorized.

B. Prior to delivery to the patient, a physician shall review the prepared drugs and devices to ensure their compliance with the prescription and, additionally, ensure that the patient has been informed of the name of the drug or device, directions for its use, precautions, and storage requirements.

C. A physician shall purchase all dispensed drugs and devices from a manufacturer or distributor approved by the United States Food and Drug Administration.

D. The person who prepares drugs and devices for dispensing shall countersign and date the original prescription form for the drugs and devices.

R4-16-204. Recordkeeping and Reporting Shortages

A. All original prescription orders for drugs or devices dispensed from a physician's office shall be dated, consecutively numbered in the order in which they were originally dispensed, and filed separately from the patient medical records. Original prescription orders for Schedule II drugs or other substances shall be maintained separately from other prescription orders.

B. A physician shall maintain drug purchase orders, invoices of drugs and devices received, and original prescription orders for a period of three years from the date of the order. Dispensing logs and destruction records shall be maintained for ten years.

C. A physician who determines that drugs have been illegally removed from the physician's office, or that an inaccurate drug count or drug shortage exists in controlled substances maintained for dispensing, shall immediately notify a local law enforcement agency and the federal Drug Enforcement Administration. The physician shall also provide written notification to the Board within seven days of the discovery, including the name of the law enforcement agency notified.

D. For purposes of this Section, "Schedule II drugs or other substances" means the controlled substances identified, defined, or listed in A.R.S. § 36-2513 and the following hallucinogenic substances:

1. Dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a U.S. Food and Drug Administration-approved drug product.
2. Nabilone.

R4-16-205. Inspections; Denial and Revocation

A. A physician shall cooperate with and allow access by the Board or its authorized representatives to the physician's office and records during periodic inspections of dispensing practices by the Board. Failure to cooperate or allow access shall be grounds for revocation of a physician's registration to dispense or denial of renewal of registration.

B. Failure to comply with A.R.S. § 32-1491 or this Article shall constitute grounds for denial or revocation of registration.

C. A physician's registration to dispense drugs and devices shall be revoked by the Board upon occurrence of the following:

1. Suspension, revocation, or cancellation of the physician's license,
2. Placement of the physician's license on inactive status,
3. Failure to timely renew the physician's license, or
4. Restriction of the physician's ability to prescribe or administer medication.

D. A physician denied registration may request a hearing to appeal the decision by filing the request, in writing, with the Board, not later than ten days after receipt of the notice denying the registration.