

NOTICES OF PROPOSED RULEMAKING

Unless exempted by A.R.S. § 41-1005, each agency shall begin the rulemaking process by first submitting to the Secretary of State's Office a Notice of Rulemaking Docket Opening followed by a Notice of Proposed Rulemaking that contains the preamble and the full text of the rules. The Secretary of State's Office publishes each Notice in the next available issue of the *Register* according to the schedule of deadlines for *Register* publication. 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 making, amending, or repealing any rule. (A.R.S. §§ 41-1013 and 41-1022)

NOTICE OF PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 22. BOARD OF OSTEOPATHIC EXAMINERS IN MEDICINE AND SURGERY

[R06-107]

PREAMBLE

- 1. Sections Affected**

R4-22-101	<u>Rulemaking Action</u>
R4-22-109	New Section
R4-22-207	Renumber
R4-22-207	Amend
- 2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**

Authorizing statute: A.R.S. § 32-1803(C)(1)
Implementing statute: A.R.S. §§ 32-1804(B)(9) and 32-1825
- 3. A list of all previous notices appearing in the Register addressing the proposed rule:**

Notice of Rulemaking Docket Opening: 12 A.A.R. 1179, April 14, 2006
- 4. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:**

Name:	Jack Confer, Executive Director
Address:	Board of Osteopathic Examiners in Medicine and Surgery 9535 E. Doubletree Ranch Rd. Scottsdale, AZ 85258-5539
Telephone:	(480) 657-7703
Fax:	(480) 657-7715
E-mail:	Jack.confer@azdo.gov
- 5. An explanation of the rule, including the agency's reasons for initiating the rule:**

The Board is renumbering and amending the rule that establishes approved continuing medical education requirements and the procedure for requesting a waiver of or extension of time in which to complete the requirements. It is also defining words regarding continuing medical education.
- 6. A reference to any study relevant to the rule that the agency reviewed and either proposes to rely on or not 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:**

None
- 7. 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
- 8. The preliminary summary of the economic, small business, and consumer impact:**

The economic impact of the rulemaking will be minimal. Statute requires that a licensee obtain 20 hours of Board-approved continuing medical education (CME) every year. In this rulemaking, the Board indicates that in addition to the CME previously approved, it approves certain CME provided by the Accreditation Council for Continuing Medi-

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cal Education. This may provide an economic benefit to the ACCME and will make it more convenient for a licensee to obtain required CME.

Statute provides that a licensee may, under certain circumstances, obtain a waiver of the continuing medical education requirement. It also provides that the Board may grant an extension of time in which to complete the required continuing medical education. This rulemaking provides instructions for applying for a waiver or an extension. Compliance with either procedure will have a minimal economic cost and will benefit the licensee who is able to obtain a waiver or extension.

9. 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: Jack Confer, Executive Director
Address: Board of Osteopathic Examiners in Medicine and Surgery
9535 E. Doubletree Ranch Rd.
Scottsdale, AZ 85258-5539
Telephone: (480) 657-7703
Fax: (480) 657-7715
E-mail: Jack.confer@azdo.gov

10. The time, place, and nature of the proceedings for the making, 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:

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

Date: Monday, May 15, 2006
Time: 1:00 p.m.
Location: Board of Osteopathic Examiners in Medicine and Surgery
9535 E. Doubletree Ranch Rd.
Scottsdale, AZ 85258-5539

The rulemaking record will close at 5:00 p.m. on May 15, 2006.

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

None

12. Incorporations by reference and their location in the rules:

None

13. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 22. BOARD OF OSTEOPATHIC EXAMINERS IN MEDICINE AND SURGERY

ARTICLE 1. GENERAL PROVISIONS

Section

R4-22-101. ~~Expired Definitions~~

R4-22-109. ~~Continuing Medical Education; Approval; Waiver~~ Renumbered

ARTICLE 2. LICENSING AND TIME-FRAMES

Section

~~R4-22-109; R4-22-207. Reserved~~ Continuing Medical Education; Approval; Waiver; Extension of Time to Complete

ARTICLE 1. GENERAL PROVISIONS

R4-22-101. ~~Expired Definitions~~

In addition to the definitions in A.R.S. § 32-1800, in this Chapter:

“ACCME” means the Accreditation Council for Continuing Medical Education.

“AOA” means the American Osteopathic Association.

“CME” means continuing medical education.

“Continuing medical education” means a course, program, or other training that the Board approves for license renewal.

“Executive Director” means the officer employed by the Board to perform administrative and delegated functions.

“Licensee” means an individual who holds a current license issued under A.R.S. Title 32, Chapter 17.

R4-22-109. Continuing Medical Education; Approval; Waiver Renumbered

ARTICLE 2. LICENSING AND TIME-FRAMES

~~R4-22-109, R4-22-207. Reserved~~ Continuing Medical Education; Approval; Waiver; Extension of Time to Complete

A. ~~Board approved continuing medical education programs required by Under A.R.S. § 32-1825(B) include; a licensee is required to obtain 20 hours of Board-approved CME in each of the two years preceding license renewal. The Board shall approve the CME of a licensee if the CME complies with the following:~~

1. ~~Programs At least 12 hours are obtained annually by completing a CME classified by the American Osteopathic Association (AOA) AOA as Approved-Category 1A Continuing Medical Education defined in the AOA Continuing Medical Education Guide dated 1983, incorporated herein by reference and on file in the Office of the Secretary of State; and~~

2. ~~No more than eight hours are obtained annually by completing a CME classified by the ACCME as Category 1.~~

2.B. ~~Residency During the first year that a licensee is licensed, the licensee may fulfill 20 hours of the CME requirement by participating in an approved residency, internship, fellowship, or preceptorship in a teaching institution approved by the AOA or the American Medical Association (AMA).~~

B.C. ~~The Board shall accept the following is acceptable evidence documentation as evidence of compliance with the CME requirement of continuing medical education for annual license renewal:~~

1. ~~An individual using AOA Approved Category 1A Continuing Medical Education shall submit either For a CME under subsection (A)(1), the AOA printout of the individual's continuing medical education or a certificate of attendance from the sponsor of the course; licensee's CME;~~

2. ~~For a CME under subsections (A)(1) and (A)(2), a copy of the certificate of attendance from the provider of the CME showing:~~

- a. ~~Licensee's name;~~
- b. ~~Title of the CME;~~
- c. ~~Name of the provider of the CME;~~
- d. ~~Category of the CME;~~
- e. ~~Number of hours in the CME; and~~
- f. ~~Date of attendance; and~~

~~2.3. Interns, residents, fellows or preceptors shall submit For a CME under subsection (B), either a letter from the Director of Medical Education or a certificate of completion for the approved internship, residency, fellowship, or preceptorship, or a copy of a certificate of completion of the internship, residency, fellowship or preceptorship.~~

C.D. ~~Requests for waiver Waiver of continuing medical education CME requirements. To obtain a waiver under A.R.S. § 32-1825(C) of the CME requirements, a licensee shall submit to the Board a written request that includes made pursuant to A.R.S. § 32-1825(C) must be in writing and must be accompanied by the following documentation depending upon the reason for waiver:~~

1. ~~The period for which the waiver is requested.~~

2. ~~CME completed during the current license period and the documentation required under subsection (C), and~~

3. ~~Reason that a waiver is needed and the applicable documentation;~~

4. ~~Disability – letter from treating physician stating nature of disability.~~

2-a. ~~Military – For military service. A copy of current orders or a letter on official letterhead from the licensee's commanding officer verifying type of service (administrative or practice of medicine);~~

3-b. ~~Absence For absence from the United States, – photocopy A copy of pages from the licensee's passport showing dates of exit and, if applicable, date of reentry dates; ;~~

c. ~~For disability. A letter from the licensee's treating physician stating the nature of the disability; or~~

4-d. ~~Circumstances For circumstances beyond the licensee's control, – A letter from the licensee stating the nature of the circumstances explaining why it is beyond the licensee's control to timely obtain the required continuing education. The letter must be supplemented with supporting documentation and any supporting documentation.~~

E. ~~The Board or its Executive Director shall grant a request for waiver of CME requirements that:~~

1. ~~Is based on the reason under subsection (D)(3).~~

2. ~~Is supported by the required documentation.~~

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- 3. Is filed no sooner than 60 days before and no later than 30 days after the license renewal date, and
- 4. Will promote the safe and professional practice of osteopathy in this state.
- F.** Extension of time to complete CME requirements. To obtain an extension of time under A.R.S. § 32-1825(C) to complete the CME requirements, a licensee shall submit to the Board a written request that includes the following:
 - 1. Ending date of the requested extension.
 - 2. CME completed during the current license period and the documentation required under subsection (C).
 - 3. Proof of registration for additional CME that is sufficient to enable the licensee to complete all CME required for license renewal before the end of the requested extension, and
 - 4. Licensee’s attestation that the CME obtained under the extension will be reported only to fulfill the current license renewal requirement and will not be reported on a subsequent license renewal application.
- G.** The Board or its Executive Director shall grant a request for an extension that:
 - 1. Specifies an ending date no later than May 1.
 - 2. Includes the required documentation and attestation.
 - 3. Is submitted no sooner than 60 days before and no later than 30 days after the license renewal date, and
 - 4. Will promote the safe and professional practice of osteopathy in this state.

NOTICE OF PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

[R06-103]

PREAMBLE

1. Sections Affected

- R4-23-110
- R4-23-205
- R4-23-301
- R4-23-408
- R4-23-610
- R4-23-611
- R4-23-653
- R4-23-654
- R4-23-657
- R4-23-658
- R4-23-659
- R4-23-671
- R4-23-675
- R4-23-682
- R4-23-701
- R4-23-701.02
- R4-23-1104
- R4-23-1105

Rulemaking Action

- Amend

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statutes: A.R.S. §§ 32-1904(A)(1) and 32-1934
 Implementing statutes: A.R.S. § 32-1904(B)(3), (5), and (7)

3. A list of all previous notices appearing in the Register addressing the proposed rule:

Notice of Rulemaking Docket Opening: 12 A.A.R. 691, March 3, 2006
 Notice of Rulemaking Docket Opening: 12 A.A.R. 694, March 3, 2006

4. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

Name: Dean Wright, Compliance Officer
 Address: Board of Pharmacy
 4425 W. Olive Ave., Suite 140
 Glendale, AZ 85302

Telephone: (623) 463-2727, ext. 131
Fax: (623) 934-0583
E-mail: rxcop@cox.net

5. An explanation of the rule, including the agency's reasons for initiating the rule:

During the 2003 Legislative Session, the Legislature changed an intern license from a two-year license to a five-year license and mandated the Board to make rules for intern license renewal. The proposed rules will amend R4-23-205 (Fees) by removing the fee for intern licensure renewal and R4-23-301 (Intern Licensure) by adding language to subsection (J) detailing the requirements for intern license renewal. Following the Board's directive to move to electronic records, the Board staff is proposing a new definition in R4-23-110 (Definitions). The new definition for "verified signature" or "signature verifying" would allow hand-written or electronic signatures on any license or permit application or any Board required report, form, or agreement. The Board staff is proposing changes to R4-23-611 (Pharmacy Facilities) addressing the issue of licensed assistant animals that may be allowed inside a pharmacy and the addition of language that requires a pharmacy to comply with its policies and procedures. The Board staff is proposing changes to R4-23-408 (Computer Requirements), R4-23-610 (Community Pharmacy Personnel and Security), R4-23-653 (Personnel: Professional or Technician), R4-23-654 (Absence of Pharmacist), R4-23-657 (Security), R4-23-658 (Dug Distribution and Control), R4-23-659 (Administration of Drugs), R4-23-671 (General Requirement for Limited-service Pharmacy), R4-23-675 (Limited-service Sterile Pharmaceutical Products Pharmacy), R4-23-682 (Limited-service Nuclear Pharmacy), R4-23-701 (Long-term Care Facilities Pharmacy Services: Consultant Pharmacist), R4-23-701.02 (Long-term Care Facilities Pharmacy Services: Emergency Drugs), R4-23-1104 (Pharmacy Technicians and Pharmacy Technician Trainees), and R4-23-1105 (Pharmacy Technician Training Program) to add language that requires a pharmacy to comply with its policies and procedures. The rules will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and Governor's Regulatory Review Council.

The Board believes that approval of these rules benefits the public and the pharmacy community by clearly establishing the pharmacy practice standards for pharmacies, pharmacists, pharmacy interns, and pharmacy technicians.

6. A reference to any study relevant to the rule that the agency reviewed and either proposes to rely on or not 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:

None

7. 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

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

The proposed rules will impact the Board, pharmacies, pharmacists, pharmacy interns, pharmacy technicians, and the public. The proposed rules' impact on the Board will be the usual rulemaking-related costs which are minimal. The Board estimates the proposed rules will have minimal economic impact on pharmacies, pharmacists, pharmacy interns, and pharmacy technicians. The proposed rules have no economic impact on the public.

The public, Board, and pharmacies benefit from rules that are clear, concise, and understandable. The proposed rules benefit the public and the pharmacy community by clearly establishing the pharmacy practice standards for pharmacies, pharmacists, pharmacy interns, and pharmacy technicians.

9. 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: Dean Wright, Compliance Officer
Address: Board of Pharmacy
4425 W. Olive Ave., Suite 140
Glendale, AZ 85302
Telephone: (623) 463-2727, ext. 131
Fax: (623) 934-0583
E-mail: rxcop@cox.net

10. The time, place, and nature of the proceedings for the making, 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:

Comments may be written or presented orally. Written comments must be received by 5 p.m., Monday, May 15, 2006. An oral proceeding is scheduled for:

Date: May 15, 2006

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Time: 11:00 a.m.
Location: 4425 W. Olive Ave., Suite 140
Glendale, AZ 85302

A person may request information about the oral proceeding by contacting the person in item #9.

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

12. Incorporations by reference and their location in the rules:

None

13. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 1. ADMINISTRATION

Section
R4-23-110. Definitions

ARTICLE 2. PHARMACIST LICENSURE

Section
R4-23-205. Fees

ARTICLE 3. INTERN TRAINING AND PHARMACY INTERN PRECEPTORS

Section
R4-23-301. Intern Licensure

ARTICLE 4. PROFESSIONAL PRACTICES

Section
R4-23-408. Computer Records

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

Section
R4-23-610. Community Pharmacy Personnel and Security Procedures
R4-23-611. Pharmacy Facilities
R4-23-653. Personnel: Professional or Technician
R4-23-654. Absence of Pharmacist
R4-23-657. Security
R4-23-658. Drug Distribution and Control
R4-23-659. Administration of Drugs
R4-23-671. General Requirements for Limited-service Pharmacy
R4-23-675. Limited-service Sterile Pharmaceutical Products Pharmacy
R4-23-682. Limited-service Nuclear Pharmacy

ARTICLE 7. NON-PHARMACY LICENSED OUTLETS - GENERAL PROVISIONS

Section
R4-23-701. Long-term Care Facilities Pharmacy Services: Consultant Pharmacist
R4-23-701.02. Long-term Care Facilities Pharmacy Services: Emergency Drugs

ARTICLE 11. PHARMACY TECHNICIANS

Section

- R4-23-1104. Pharmacy Technicians and Pharmacy Technician Trainees
R4-23-1105. Pharmacy Technician Training Program

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

In addition to definitions in A.R.S. § 32-1901, the following definitions apply to A.A.C. Title 4 Chapter 23:

- “Active ingredient” No change
- “Alternate physician” No change
- “Approved course in pharmacy law” No change
- “Approved Provider” No change
- “Authentication of product history” No change
- “Batch” No change
- “Beyond-use date” No change
- “Biological safety cabinet” No change
- “Care-giver” No change
- “Class 100 environment” No change
- “Community pharmacy” No change
- “Component” No change
- “Compounding and dispensing counter” No change
- “Computer system” No change
- “Computer system audit” No change
- “Contact hour” No change
- “Container” No change
- “Continuing education” No change
- “Continuing education activity” No change
- “Continuing education unit” or “CEU” No change
- “Correctional facility” No change
- “CRT” No change
- “Current good compounding practices” No change
- “Current good manufacturing practice” No change
- “Cytotoxic” No change
- “Day” No change
- “DEA” No change
- “Dietary supplement” No change
- “Dispensing pharmacist” No change
- “Drug sample” No change
- “Drug therapy management” No change
- “Drug therapy management agreement” No change
- “Eligible patient” No change
- “Extreme emergency” No change
- “FDA” No change
- “Immediate notice” No change
- “Inactive ingredient” No change
- “Internal test assessment” No change

“Limited-service correctional pharmacy” No change
“Limited-service long-term care pharmacy” No change
“Limited-service mail-order pharmacy” No change
“Limited-service nuclear pharmacy” No change
“Limited-service pharmacy permittee” No change
“Limited-service sterile pharmaceutical products pharmacy” No change
“Long-term care consultant pharmacist” No change
“Long-term care facility” or “LTCF” No change
“Lot” No change
“Lot number” or “control number” No change
“Materials approval unit” No change
“Mediated instruction” No change
“MPJE” No change
“NABP” No change
“NABPLEX” No change
“NAPLEX” No change
“Other designated personnel” No change
“Outpatient” No change
“Outpatient setting” No change
“Patient profile” No change
“Pharmaceutical patient care services” No change
“Pharmaceutical product” No change
“Pharmacist-administered immunizations training program” No change
“Pharmacy counter working area” No change
“Pharmacy law continuing education” No change
“Pharmacy permittee” No change
“Prepackaged drug” No change
“Proprietor” No change
“Provider pharmacy” No change
“Radiopharmaceutical” No change
“Radiopharmaceutical quality assurance” No change
“Radiopharmaceutical services” No change
“Red C stamp” No change
“Refill” No change
“Remodel” No change
“Remote drug storage area” No change
“Resident” No change
“Responsible person” No change
“Score transfer” No change
“Sight-readable” No change
“Single-drug audit” No change
“Single-drug usage report” No change
“Sterile pharmaceutical product” No change
“Strength” No change
“Supervision” No change
“Supervisory physician” No change

“Supplying” No change

“Support personnel” No change

“Transfill” No change

“Verified signature” or “signature verifying” means in relation to a Board license or permit application or report, form, or agreement, the hand-written or electronic signature of an individual who by placing their hand-written or electronic signature on a hard-copy or electronic license or permit application or report, form, or agreement agrees with and verifies that the statements and information within or attached to the license or permit application or report, form, or agreement are true in every respect and understand that inaccurate reporting can result in denial or loss of a license or permit or report, form, or agreement.

“Wholesale distribution” No change

“Wholesale distributor” No change

ARTICLE 2. PHARMACIST LICENSURE

R4-23-205. Fees

A. Licensure fees:

1. No change
 - a. No change
 - b. No change
2. Pharmacy or graduate intern: Initial licensure: \$50.
~~b. Licensure renewal: \$50.~~
3. No change
 - a. No change
 - b. No change
4. No change

B. No change

C. No change

D. No change

1. No change
2. No change
 - a. No change
 - b. No change
 - c. No change
3. No change
4. No change
 - a. No change
 - b. No change
5. No change
6. No change

E. No change

1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
2. No change
3. No change

F. No change

G. No change

1. No change
2. No change

ARTICLE 3. INTERN TRAINING AND PHARMACY INTERN PRECEPTORS

R4-23-301. Intern Licensure

- A. No change
- B. No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
- C. No change
- D. No change
 - 1. No change
 - 2. No change
 - 3. No change
- E. No change
- F. No change
 - 1. No change
 - 2. No change
- G. No change
- H. No change
 - 1. No change
 - 2. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 - g. No change
 - h. No change
- I. No change
- J. License renewal. ~~A pharmacy intern shall remain in good standing by payment of the biennial renewal fee specified in R4-23-205. A pharmacy intern whose license expires before the intern completes the education or training required for licensure as a pharmacist but less than six years after the issuance of the initial pharmacy intern license may renew the intern license for a period equal to the difference between the expiration date of the initial intern license and six years from the issue date of the initial intern license by payment of a prorated renewal fee based on the initial license fee specified in R4-23-205.~~ If a pharmacy intern fails to graduate from a Board-approved college or school of pharmacy within six years from the date the Board issues the initial intern license, the intern is not eligible for relicensure as an intern unless the intern obtains Board approval as specified in A.R.S. § 32-1923(E). To remain in good standing, an intern who receives Board approval for relicensure shall pay a prorated renewal fee for the number of months of licensure approved by the Board based on the initial license fee specified in R4-23-205 before the license expiration date. If the biennial renewal fee is not paid by November 1 of the renewal year specified in A.R.S. § 32-1925 an intern receives Board approval for relicensure and does not pay the renewal fee specified in this subsection before the license expiration date, the intern license is suspended and the licensee shall pay a penalty as provided in A.R.S. § 32-1925 to vacate the suspension.
- K. No change
 - 1. No change
 - 2. No change

ARTICLE 4. PROFESSIONAL PRACTICES

R4-23-408. Computer Records

- A. Systems manual. A pharmacy permittee or pharmacist-in-charge shall:
 - 1. Develop, ~~and implement, and comply with~~ policies and procedures for the following operational aspects of a computer system:
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change

2. No change
3. No change
4. No change
5. No change
- B.** No change
 1. No change
 2. No change
 3. No change
 4. No change
 5. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 6. No change
- C.** No change
 1. No change
 2. No change
 3. No change
 4. No change
 - a. No change
 - i. No change
 - ii. No change
 - iii. No change
 - b. No change
 - i. No change
 - ii. No change
 - iii. No change
- D.** No change
- E.** No change
- F.** No change
 1. No change
 2. No change
- G.** No change
 1. No change
 2. No change
- H.** Prescription records and retention.
 1. No change
 - a. No change
 - b. No change
 2. In lieu of filing the actual original hard-copy prescription, a pharmacy permittee or pharmacist-in-charge may use an electronic imaging recordkeeping system, if:
 - a. No change
 - b. No change
 - c. No change
 - d. Policies and procedures for the use of an electronic imaging recordkeeping system are developed, ~~and implemented, reviewed, and revised in the same manner described in subsection (A) and complied with in the same manner as specified in subsection (A);~~ and
 - e. No change
 3. No change

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-610. Community Pharmacy Personnel and Security Procedures

- A. No change
 - 1. No change
 - 2. The pharmacist-in-charge shall:
 - a. Ensure that all pharmacy policies and procedures required under 4 A.A.C. 23 are prepared, ~~and~~ implemented, and complied with;
 - b. No change
 - c. No change
 - d. No change
 - e. No change
- B. No change
 - 1. No change
 - 2. No change
- C. No change
- D. No change
- E. No change
- F. No change
- G. No change
 - 1. No change
 - 2. No change

R4-23-611. Pharmacy Facilities

- A. No change
 - 1. No change
 - 2. No change
 - a. No change
 - b. No change
 - 3. No change
 - 4. No change
 - a. No change
 - b. No change
 - 5. No change
 - 6. No change
 - 7. No animals, except ~~guide dogs for the blind~~ licensed assistant animals and ~~guard dogs~~ animals, are allowed in the pharmacy;
 - 8. No change
 - 9. No change
- B. Supply of drugs and chemicals. A pharmacy permittee or pharmacist-in-charge shall ensure that:
 - 1. No change
 - a. No change
 - b. No change
 - 2. No change
 - 3. Policies and procedures are developed, ~~and~~ implemented, and complied with to prevent the sale or use of a drug or chemical:
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - 4. No change
 - a. No change
 - b. No change
 - i. No change
 - ii. No change
 - iii. No change

R4-23-653. Personnel: Professional or Technician

A. Each hospital pharmacy shall be directed by a pharmacist who is licensed to engage in the practice of pharmacy in Arizona and is referred to as the Director of Pharmacy. The Director of Pharmacy shall be the pharmacist-in-charge, as defined in A.R.S. § 32-1901 or shall appoint a pharmacist-in-charge. The Director of Pharmacy and the pharmacist-in-charge, if a different individual, shall:

1. No change
2. Ensure that the policies and procedures required by these rules are prepared, ~~and~~ implemented, and complied with;
3. No change
4. No change
5. No change
6. No change

B. No change

C. No change

D. No change

E. No change

1. No change
 - a. No change
 - b. No change
2. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change

3. No change

4. No change

5. No change

6. No change

7. No change

8. No change

9. No change

10. No change

11. No change

12. No change

13. No change

14. No change

F. No change

G. No change

H. No change

1. No change

2. No change

a. No change

b. No change

I. No change

R4-23-654. Absence of Pharmacist

A. No change

B. No change

C. No change

D. Remote drug storage area. The Director of Pharmacy or pharmacist-in-charge shall, in consultation with the appropriate committee of the hospital:

1. No change

2. Develop, ~~and~~ implement, review, and revise in the same manner described in R4-23-653(A) and comply with policies and procedures ~~in the same manner described in R4-23-653(A)~~ that ensure proper storage, access, and accountability for drugs in a remote drug storage area.

E. No change

1. The Director of Pharmacy or pharmacist-in-charge shall, in consultation with the appropriate committee of the hospital, develop, ~~and~~ implement, review, and revise in the same manner described in R4-23-653(A) and comply with policies and procedures ~~in the same manner described in R4-23-653(A)~~ to ensure that access to the hospital pharmacy during the pharmacist's absence conforms to the following requirements:

- a. No change
- b. No change
- c. No change
- d. No change
- 2. No change
 - a. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - b. No change
 - c. No change
 - d. No change
- 3. No change

R4-23-657. Security

- A. No change
 - 1. No change
 - 2. No change
 - 3. No change
- B. Prescription blank security. The Director of Pharmacy shall develop, ~~and implement, review, and revise in the same manner described in R4-23-653(A) and comply with~~ policies and procedures ~~in the same manner described in R4-23-653(A)~~ for the safe distribution and control of prescription blanks bearing identification of the hospital.

R4-23-658. Drug Distribution and Control

- A. General. The Director of Pharmacy or pharmacist-in-charge shall in consultation with the medical staff, develop, ~~and implement, review, and revise in the same manner described in R4-23-653(A) and comply with~~ written policies and procedures ~~in the same manner described in R4-23-653(A)~~ for the effective operation of a drug distribution system that optimizes patient safety.
- B. No change
 - 1. No change
 - 2. No change
 - 3. No change
- C. No change
 - 1. No change
 - 2. No change
- D. No change
 - 1. No change
 - a. No change
 - i. No change
 - ii. No change
 - iii. No change
 - b. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - c. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - v. No change
 - vi. No change
 - vii. No change
 - viii. No change
 - 2. No change
- E. Controlled substance accountability. A Director of Pharmacy or pharmacist-in-charge shall ensure that effective policies and procedures are developed, ~~and implemented, reviewed, and revised in the same manner described in R4-23-653(A)~~

~~and complied with in the same manner described in R4-23-653(A)~~ regarding the use, accountability, and recordkeeping of controlled substances in the hospital, including the use of locked storage areas when controlled substances are stored in patient care areas.

- F. Emergency services dispensing. If a hospital permits dispensing of drugs from the emergency services department when the pharmacy is unable to provide this service, the Director of Pharmacy, in consultation with the appropriate department personnel and medical staff committee shall develop, ~~and implement, review, and revise in the same manner described in R4-23-653(A)~~ and comply with written policies and procedures ~~in the same manner described in R4-23-653(A)~~ for dispensing drugs for outpatient use from the hospital's emergency services department. The policies and procedures shall include the following requirements:
1. No change
 2. No change
 3. No change
 4. No change
 5. No change
 6. No change
 7. No change

R4-23-659. Administration of Drugs

- A. Self-administration. A hospital shall not allow self-administration of medications by a patient unless the Director of Pharmacy or pharmacist-in-charge, in consultation with the appropriate department personnel and medical staff committee, develops, ~~and implements, reviews, and revises in the same manner described in R4-23-653(A)~~ and complies with policies and procedures for self-administration of medications by a patient ~~in the same manner described in R4-23-653(A)~~. The policies and procedures shall specify that self-administration of medications, if allowed, occurs only when:
1. No change
 2. No change
- B. Drugs brought in by a patient. If a hospital allows a patient to bring a drug into the hospital and before a patient brings a drug into the hospital, the Director of Pharmacy or pharmacist-in-charge shall, in consultation with the appropriate department personnel and medical staff committee, develop, ~~and implement, review, and revise in the same manner described in R4-23-653(A)~~ and comply with policies and procedures for a patient-owned drug brought into the hospital ~~in the same manner described in R4-23-653(A)~~. The policies and procedures shall specify the following criteria for a patient-owned drug brought into the hospital:
1. No change
 - a. No change
 - b. No change
 2. No change
 - a. No change
 - b. No change
- C. Drug samples. The Director of Pharmacy or pharmacist-in-charge is responsible for the receipt, storage, distribution, and accountability of drug samples within the hospital, including developing, ~~and implementing, reviewing, and revising in the same manner described in R4-23-653(A)~~ and complying with specific policies and procedures ~~in the same manner described in R4-23-653(A)~~ regarding drug samples.

R4-23-671. General Requirements for Limited-service Pharmacy

- A. No change
- B. No change
1. No change
 2. No change
 3. No change
 4. No change
- C. No change
- D. No change
- E. Before dispensing from a limited-service pharmacy, the limited-service pharmacy permittee or pharmacist-in-charge shall:
1. Prepare, ~~and implement, and comply with~~ written policies and procedures for pharmacy operations and drug dispensing and distribution,
 2. No change
 3. No change
 4. No change
 5. No change

R4-23-675. Limited-service Sterile Pharmaceutical Products Pharmacy

- A. No change
- B. No change
- C. No change
- D. No change
- E. The limited-service pharmacy permittee or the pharmacist-in-charge shall ensure development, ~~and~~ implementation, review and revision in the same manner described in R4-23-671(E) and compliance with ~~of~~ policies and procedures for pharmacy operations, including pharmaceutical product compounding, dispensing, and distribution, that comply with the requirements of R4-23-402, R4-23-410, R4-23-670, and R4-23-671.
- F. No change

R4-23-682. Limited-service Nuclear Pharmacy

- A. No change
- B. No change
 - 1. No change
 - a. No change
 - b. No change
 - c. No change
 - 2. No change
 - 3. No change
- C. No change
 - 1. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - 2. No change
- D. No change
- E. No change
 - 1. No change
 - a. No change
 - b. No change
 - c. No change
 - 2. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 - g. No change
 - 3. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 - g. No change
 - h. No change
- F. No change
 - 1. No change
 - a. No change
 - b. No change
 - c. No change
 - 2. No change
 - a. No change
 - b. No change
 - c. No change

- d. No change
- e. Prescription balance, Class A, and weights or an electronic balance of equal or greater accuracy;
- f. No change
- g. No change
- h. No change
- i. ~~Equipment to produce a typed or mechanically printed label;~~
- j. ~~Equipment to produce mechanically printed numbers;~~
- ~~k. l.~~ No change
- ~~l. j.~~ No change
- ~~m. k.~~ No change
- ~~n. l.~~ No change
- ~~o. m.~~ No change
- 3. No change
- 4. No change
 - a. No change
 - b. No change
 - c. No change
- 5. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
- G.** The pharmacist-in-charge of a limited-service nuclear pharmacy shall prepare, ~~and~~ implement, review, and revise in the same manner described in R4-23-671(E) and comply with written policies and procedures for pharmacy operations and drug distribution.
- H.** No change
 - 1. No change
 - 2. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - 3. No change
 - 4. No change
 - 5. No change
 - 6. No change
 - 7. No change
 - 8. No change
 - 9. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 - g. No change
 - h. No change
 - 10. No change
 - 11. No change
 - 12. No change
 - 13. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change

14. No change

ARTICLE 7. NON-PHARMACY LICENSED OUTLETS - GENERAL PROVISIONS

R4-23-701. Long-term Care Facilities Pharmacy Services: Consultant Pharmacist

- A.** The long-term care consultant pharmacist as defined in R4-23-110, in cooperation with the pharmacist-in-charge of a provider pharmacy shall:
1. Prepare, implement, review, and revise in the same manner described in R4-23-671(E) and comply with written policies and procedures for the safe and efficient receipt, distribution, and storage of pharmaceutical products by the long-term care facility ~~in the manner specified in R4-23-671(E);~~
 2. No change
 3. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - e. No change
 - f. No change
 - g. No change
 - h. No change
 - i. No change
 - j. No change
 - k. No change
 - l. No change
 - m. No change
- B.** No change
1. No change
 2. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
 - f. No change
 3. No change
 4. No change
 5. No change
 - a. No change
 - b. No change
- C.** No change
1. No change
 2. No change
 3. No change
 4. No change
- D.** No change
1. No change
 - a. No change
 - b. No change
 - c. No change
 2. No change
 - a. No change
 - b. No change

R4-23-701.02. Long-term Care Facilities Pharmacy Services: Emergency Drugs

- A. No change
- B. No change
 - 1. No change
 - 2. No change
- C. No change
 - 1. No change
 - a. No change
 - b. No change
 - 2. No change
 - 3. No change
 - 4. No change
- D. The limited-service pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall:
 - 1. Prepare, ~~and implement, review, and revise in the same manner described in R4-23-671(E)~~ and comply with written policies and procedures for the storage and use of an emergency drug supply unit in a long-term care facility ~~in the manner specified in R4-23-671(E).~~
 - 2. Make the policies and procedures available in the provider pharmacy and long-term care facility for employee reference and inspection by the Board or its designee; and
 - 3. No change
 - a. No change
 - i. No change
 - ii. No change
 - iii. No change
 - b. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. The provider pharmacy's personnel restock the emergency drug supply unit within 48 hours of receiving the notification required in subsection (D)(3)(b)(ii), and
 - c. Security and inspection procedures; and
 - 4. No change

ARTICLE 11. PHARMACY TECHNICIANS

R4-23-1104. Pharmacy Technicians and Pharmacy Technician Trainees

- A. No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. No change
 - 6. No change
 - 7. No change
 - 8. No change
- B. No change
 - 1. No change
 - 2. No change
- C. No change
- D. No change
- E. Before employing a pharmacy technician or pharmacy technician trainee, a pharmacy permittee or pharmacist-in-charge shall develop, ~~and implement, review, and revise in the same manner described in R4-23-653(A)~~ and comply with policies and procedures ~~in the same manner described in R4-23-653(A)~~ for pharmacy technician and pharmacy technician trainee activities as specified in subsection (F).
- F. No change
 - 1. No change
 - a. No change
 - b. No change
 - c. No change

- d. No change
- e. No change
- f. No change
 - i. No change
 - ii. No change
- g. No change
- h. No change
- i. No change
- 2. No change
 - a. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - v. No change
 - vi. No change
 - b. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - v. No change
 - vi. No change
 - vii. No change
 - viii. No change
 - ix. No change
- 3. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change

R4-23-1105. Pharmacy Technician Training Program

- A. No change
- B. Pharmacy technician training program.
 - 1. A pharmacy permittee or pharmacist-in-charge shall develop, ~~and implement,~~ review, and revise in the same manner described in R4-23-653(A) and comply with in the same manner described in R4-23-653(A) a pharmacy technician training program based on the needs of the individual pharmacy;
 - 2. No change
 - a. No change
 - b. No change
 - c. No change
 - 3. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
- C. Drug compounding training program.
 - 1. A pharmacy permittee or pharmacist-in-charge shall develop, ~~and implement,~~ review, and revise in the same manner described in R4-23-653(A) and comply with in the same manner described in R4-23-653(A) a drug compounding training program based on the needs of the individual pharmacy;
 - 2. No change
 - a. No change
 - b. No change
 - c. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change

- v. No change
- 3. A pharmacist-in-charge shall:
 - a. Document a pharmacy technician's progress throughout the training program, ~~and~~
 - b. Date and sign a statement attesting that a pharmacy technician ~~trainee~~ has successfully completed the training program, ~~and~~
 - c. No change
- D. No change

NOTICE OF PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

[R06-102]

PREAMBLE

- | | |
|---|--|
| <u>1. Sections Affected</u>
R4-23-402 | <u>Rulemaking Action</u>
Amend |
|---|--|
- 2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**
Authorizing statutes: A.R.S. § 32-1904(A)(1)
Implementing statutes: A.R.S. § 32-1904(B)(5)
- 3. A list of all previous notices appearing in the Register addressing the proposed rule:**
Notice of Rulemaking Docket Opening: 12 A.A.R. 695, March 3, 2006
- 4. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:**
- | | |
|------------|--|
| Name: | Dean Wright, Compliance Officer |
| Address: | Board of Pharmacy
4425 W. Olive Ave., Suite 140
Glendale, AZ 85302 |
| Telephone: | (623) 463-2727, ext. 131 |
| Fax: | (623) 934-0583 |
| E-mail: | rxcop@cox.net |
- 5. An explanation of the rule, including the agency's reasons for initiating the rule:**
During the January 25, 2006 Board meeting, Board President Chuck Dutcher instructed Board staff to craft proposed rules that require the documentation of the name or initials of the pharmacist, graduate intern, or pharmacy intern who does or does not provide oral consultation on a new prescription. The Board feels that the existing rule is flawed because it does not require the identification of the person who does or does not counsel. The proposed rule will amend R4-23-402 (Pharmacist, Graduate Intern, and Pharmacy Intern) by adding language to subsection (H) requiring documentation of the identity of the pharmacist, graduate intern, or pharmacy intern who does or does not provide oral consultation on a new prescription. The rules will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and Governor's Regulatory Review Council.

The Board believes that approval of these rules benefits the public and the pharmacy community by clearly establishing the standards for patient counseling provided by pharmacists and pharmacy interns and graduate interns under pharmacist supervision.
- 6. A reference to any study relevant to the rule that the agency reviewed and either proposes to rely on or not 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:**
None
- 7. 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

Notices of Proposed Rulemaking

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

The proposed rules will impact the Board, pharmacies, pharmacists, pharmacy interns, graduate interns, and the public. The proposed rules' impact on the Board will be the usual rulemaking-related costs which are minimal. The Board estimates the proposed rules will have minimal economic impact on pharmacies, pharmacists, pharmacy interns, and graduate interns. The proposed rules have no economic impact on the public.

The public, Board, pharmacies, pharmacists, pharmacy interns, and graduate interns benefit from rules that are clear, concise, and understandable. The proposed rules benefit the public and the pharmacy community by clearly establishing the standards for patient counseling provided by pharmacists and pharmacy interns and graduate interns under pharmacist supervision.

9. 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: Dean Wright, Compliance Officer
Address: Board of Pharmacy
4425 W. Olive Ave., Suite 140
Glendale, AZ 85302
Telephone: (623) 463-2727, ext. 131
Fax: (623) 934-0583
E-mail: rxcop@cox.net

10. The time, place, and nature of the proceedings for the making, 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:

Comments may be written or presented orally. Written comments must be received by 5 p.m., Monday, May 15, 2006. An oral proceeding is scheduled for:

Date: May 15, 2006
Time: 11:30 a.m.
Location: 4425 W. Olive Ave., Suite 140
Glendale, AZ 85302

A person may request information about the oral proceeding by contacting the person in item #9.

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

12. Incorporations by reference and their location in the rules:

None

13. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 4. PROFESSIONAL PRACTICES

Section

R4-23-402. Pharmacist, Graduate Intern, and Pharmacy Intern

ARTICLE 4. PROFESSIONAL PRACTICES

R4-23-402. Pharmacist, Graduate Intern, and Pharmacy Intern

- A. No change
1. No change
 2. No change
 3. No change
 - a. No change
 - b. No change
 4. No change

5. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
6. No change
7. No change
8. No change
9. No change
 - a. No change
 - b. No change
 - c. No change
 - d. No change
 - e. No change
10. No change
11. No change
12. No change
13. No change
 - a. No change
 - b. No change
 - c. No change
14. No change
 - a. No change
 - b. No change
 - c. No change
15. No change
 - a. No change
 - b. No change
 - c. No change
16. No change
17. No change
- B.** No change
 1. No change
 2. No change
 3. No change
- C.** No change
 1. No change
 2. No change
 3. No change
 4. No change
- D.** No change
 1. No change
 2. No change
 3. No change
- E.** No change
 1. No change
 2. No change
 3. No change
 4. No change
- F.** No change
- G.** No change
- H.** Oral consultation documentation. When oral consultation is required as specified in subsection (B), a pharmacist, graduate intern, or pharmacy intern shall:
 1. Document, or assume responsibility to document, that oral consultation is provided; or
 2. When a patient refuses oral consultation or a person other than the patient or patient's care-giver picks up a prescription and oral consultation is not provided, document, or assume responsibility to document, that oral consultation is not provided; or
 3. When a pharmacist, graduate intern, or pharmacy intern determines to omit oral consultation under subsection (D)

Notices of Proposed Rulemaking

and oral consultation is not provided, document, or assume responsibility to document, both the circumstance and reason that oral consultation is not provided; and

4. Document, or assume responsibility to document, the name, initials, or identification code of the pharmacist, graduate intern, or pharmacy intern who did or did not provide oral consultation.

- I.** No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
 - 5. No change
- J.** No change
- K.** No change
- L.** No change