

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 23. BOARD OF PHARMACY

Editor's Note: The following Notice of Proposed Rulemaking was exempt from Executive Order 2011-05 as issued by Governor Brewer. (See the text of the executive order on page 1359.)

[R12-97]

PREAMBLE

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

R4-23-1101	Amend
R4-23-1102	Amend
R4-23-1104	Amend
R4-23-1105	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. § 32-1904(A)(1) and (B)(7)
Implementing statute: A.R.S. §§ 32-1901(66) and (67), 32-1923.01, 32-1924, 32-1925, 32-1926, and 32-1927.01
- 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, 18 A.A.R. XXXX, June 15, 2012 (*in this issue*)
- 4. The agency's contact person who can answer questions about the rulemaking:**

Name:	Dean Wright, Compliance Officer
Address:	Arizona Board of Pharmacy P.O. Box 18520 Phoenix, AZ 85005
Telephone:	(602) 771-2744
Fax:	(602) 771-2749
E-mail:	dwright@azpharmacy.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 An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:**

During the Board's five-year rule review approved May 5, 2009, the Board determined that R4-23-1101 Licensure and Eligibility, R4-23-1102 Pharmacy Technician Licensure, R4-23-1104, Pharmacy Technicians and Pharmacy Technician Trainees, and R4-23-1105 Pharmacy Technician Training Program needed to be amended to correct inconsistencies and improve clarity, conciseness, and understandability.

When the rules were made in 2004, the Board felt that the majority of applicants would follow the normal progression of licensure as a pharmacy technician trainee, proceed through the training required in R4-23-1105(B), pass the pharmacy technician examination, and apply for licensure as a pharmacy technician. However, we found that many applicants had already passed the pharmacy technician examination either before the law changed or in another state. These applicants may not have completed a pharmacy's training course, but had a job in a pharmacy and needed a license to work. The Board's staff licensed the applicants without the required proof of completing a pharmacy technician training program as required in R4-23-1101(A)(1). The Board is inconsistently enforcing a rule, which should

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be amended to reflect the real world situation. The Board also determined that R4-23-1104 should be amended to require technicians to “accurately” perform the functions listed in subsections (A) and (B).

The proposed rulemaking will amend R4-23-1101, R4-23-1102, and R4-23-1105 to make the rules work better and allow consistent enforcement. The rulemaking will amend R4-23-1104 by adding a new subsection with language that requires pharmacy technicians and pharmacy technician trainees to perform their permissible functions accurately. The rule will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and the Governor’s Regulatory Review Council.

The Board believes that approval of these rules will benefit the public health and safety by clearly establishing standards for the licensing and practice of pharmacy technician trainees and pharmacy technicians.

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 agency did not review or rely on any study relevant to the rule.

7. A showing of good cause why the rules are necessary to promote a statewide interest if the rules 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, pharmacy technician trainees, pharmacy technicians, pharmacists, and pharmacies. 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 pharmacy technician trainees, pharmacy technicians, pharmacists and pharmacies. The rulemaking is necessary to correct inconsistencies in the rules that have caused one subsection, R4-23-1101(A), to be inconsistently enforced and have created general confusion about training requirements and documentation. The rulemaking will reduce the paper work required of a pharmacist-in-charge and save her or him time. The rulemaking will clarify the training requirements for both pharmacy technician trainees and pharmacy technicians. The rulemaking will specify that pharmacy technician trainees and pharmacy technicians are responsible for performing their duties accurately. The Board estimates that the rulemaking will have minimal economic impact.

The Board believes that approval of these rules will benefit the public health and safety by clearly establishing standards for the licensing and practice of pharmacy technician trainees and pharmacy technicians.

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

Name: Dean Wright, Compliance Officer
Address: Arizona Board of Pharmacy
P.O. Box 18520
Phoenix, AZ 85005
Telephone: (602) 771-2744
Fax: (602) 771-2749
E-mail: dwright@azpharmacy.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:

Comments may be written or presented orally. Written comments must be received by 5:00 p.m., Monday, July 16, 2012. An oral proceeding is scheduled for:

Date: July 16, 2012
Time: 10:00 a.m.
Location: 1616 W. Adams St., 1st Floor Board Room
Phoenix, AZ 85007

A person may request information about the oral proceeding by contacting the person listed above.

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:

Not applicable

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 rule itself does not require a permit. However, the license required by statute arguably falls within the definition of general permit in A.R.S. § 41-1001.

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:

No

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

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 23. BOARD OF PHARMACY

ARTICLE 11. PHARMACY TECHNICIANS

Section

R4-23-1101. Licensure and Eligibility

R4-23-1102. Pharmacy Technician Licensure

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

R4-23-1105. Pharmacy Technician Trainee Training Program, Pharmacy Technician Drug Compounding Training Program, and Alternative Pharmacy Technician Training

ARTICLE 11. PHARMACY TECHNICIANS

R4-23-1101. Licensure and Eligibility

A. License required. A person shall not work as a pharmacy technician or pharmacy technician trainee in Arizona, unless the person:

- ~~1. Possesses~~ possesses a pharmacy technician or pharmacy technician trainee license issued by the Board;
- ~~2. Reads and discusses with the pharmacist in charge of the pharmacy where employed, the Board rules concerning pharmacy technicians and pharmacy technician trainees, the pharmacy technician and pharmacy technician trainee job description, and the policies and procedures manual of that pharmacy; and~~
3. Dates and signs a statement that the person has complied with subsection (A)(2).

B. Eligibility.

1. To be eligible for licensure as a pharmacy technician trainee, a person shall:
 - a. Be of good moral character,
 - b. Be at least 18 years of age, and
 - c. Have a high school diploma or the equivalent of a high school diploma.
2. To be eligible for licensure as a pharmacy technician, a person shall:
 - a. Meet the requirements of subsection (B)(1),
 - b. Complete a pharmacy technician training program that meets the standards prescribed in R4-23-1105, and
 - c. Pass the Pharmacy Technician Certification Board (PTCB) examination or another Board-approved pharmacy technician examination.

C. A pharmacy technician delinquent license. Before an Arizona pharmacy technician license will be reinstated, a pharmacy technician whose Arizona pharmacy technician license is delinquent for five or more consecutive years shall furnish to the Board satisfactory proof of fitness to be licensed as a pharmacy technician and pay all past due biennial renewal fees and penalty fees. Satisfactory proof includes:

1. For a person with a delinquent license who is practicing as a pharmacy technician out-of-state with a pharmacy technician license issued by another jurisdiction:
 - a. Proof of current, unrestricted pharmacy technician licensure in another jurisdiction; and
 - b. Proof of employment as a pharmacy technician during the last 12 months; or
2. For a person with a delinquent license who did not practice as a pharmacy technician within the last 12 months:
 - a. Take and pass a Board-approved pharmacy technician examination, and

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- b. Complete ~~120 hours of pharmacy technician training as a pharmacy technician trainee licensed under R4-23-1103~~ 20 contact hours or two CEUs of continuing education activity sponsored by an Approved Provider, including at least two contact hours or 0.2 CEUs of continuing education activity in pharmacy law; ~~or~~
- e. Complete ~~480 hours of pharmacy technician training as a pharmacy technician trainee licensed under R4-23-1103~~.

R4-23-1102. Pharmacy Technician Licensure

- A. Application. An applicant for licensure as a pharmacy technician shall:
 - 1. Provide the Board proof that the applicant is eligible under R4-23-1101(B)(2), including documentation that the applicant:
 - a. Completed a pharmacy technician training program that meets the standards prescribed in ~~R4-23-1105~~ R4-23-1105(B)(2); and
 - b. Passed the Pharmacy Technician Certification Board (PTCB) examination or another Board-approved pharmacy technician examination; or
 - c. Meets the requirements of R4-23-1105(D)(1) or (2);
 - 2. File an application on a form furnished by the Board, that includes:
 - a. Applicant's name, address, mailing address, if different, telephone number, and ~~social security~~ Social Security number;
 - b. Whether the applicant has ever been convicted of an offense involving moral turpitude, a felony offense, or any drug-related offense or has any currently pending felony or drug-related charge, and if so, indicate charge, charge date, conviction date, and jurisdiction;
 - c. Whether the applicant has ever had a pharmacy technician license revoked, suspended, or has a pending revocation or suspension action, or denied in this state or any other jurisdiction, and if so, indicate where and when;
 - d. Pharmacy name and address where the pharmacy technician will practice;
 - e. Date signed and applicant's verified signature; and
 - f. The wall license and initial licensure fees specified in R4-23-205.
- B. Licensure. Within seven business days of receipt of a completed application, fees, and other information specified in subsection (A), the Board office shall determine whether the application is complete. If the application is complete, the Board shall assess whether the applicant is qualified under statute and rule. If the applicant is qualified, the Board office shall issue a license number and mail a license to the applicant. An applicant who is issued a license number may begin practice as a pharmacy technician. The Board office shall mail a wall license to the licensee within 14 days of issuing the license number.
- C. License renewal. To renew a license, a pharmacy technician shall submit a license renewal form supplied by the Board with the biennial renewal fee specified in R4-23-205. The Board office will process the application for renewal in the same manner described in subsection (B).
- D. If the biennial renewal fee is not paid by November 1 of the renewal year specified in A.R.S. § 32-1925, the pharmacy technician license is suspended and the licensee shall pay a penalty as provided in A.R.S. § 32-1925 and R4-23-205 to vacate the suspension.

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

- A. Permissible activities of a pharmacy technician trainee. Acting in compliance with all applicable statutes and rules and under the supervision of a pharmacist, a pharmacy technician trainee may assist a graduate intern, pharmacy intern, or pharmacist with the following when applicable to the pharmacy practice site:
 - 1. Record on the original prescription order the prescription serial number and date dispensed;
 - 2. Initiate or accept verbal or electronic refill authorization from a medical practitioner or medical practitioner's agent and record, on the original prescription order or by an alternative method approved by the Board or its designee, the medical practitioner's name, patient name, name and quantity of prescription medication, specific refill information, and name of medical practitioner's agent, if any;
 - 3. Record information in the refill record or patient profile;
 - 4. Type and affix a label for a prescription medication or enter information for a new or refill prescription medication into a computer, if a pharmacist verifies the accuracy and initials in handwriting or by another method approved by the Board or its designee the finished label prepared by the technician before the prescription medication is dispensed to the patient;
 - 5. Reconstitute a prescription medication, if a pharmacist checks the ingredients and procedure before reconstitution and verifies the final product after reconstitution;
 - 6. Retrieve, count, or pour a prescription medication, if a pharmacist verifies the contents of the prescription medication against the original prescription medication container or by an alternative drug identification method approved by the Board or its designee;
 - 7. Prepackage drugs in accordance with R4-23-402(A); and

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8. Measure, count, pour, or otherwise prepare and package a drug needed for hospital inpatient dispensing, if a pharmacist verifies the accuracy, measuring, counting, pouring, preparing, packaging, and safety of the drug before the drug is delivered to a patient care area.
- B.** Permissible activities of a pharmacy technician. Acting in compliance with all applicable statutes and rules and under the supervision of a pharmacist, a pharmacy technician may:
 1. Perform the activities listed in subsection (A); and
 2. After completing a pharmacy technician drug compounding training program developed by the pharmacy permittee or pharmacist-in-charge under ~~R4-23-1105~~ R4-23-1105(C), assist a pharmacist, graduate intern, or pharmacy intern in compounding prescription medications and sterile or non-sterile pharmaceuticals in accordance with written policies and procedures, if the preparation, accuracy, and safety of the final product is verified by a pharmacist before dispensing.
- C.** When performing the activities listed in subsections (A) and (B) for which the pharmacy technician or pharmacy technician trainee has been trained, the pharmacy technician or pharmacy technician trainee shall perform those functions accurately.
- ~~**E.D.**~~ Prohibited activities. A pharmacy technician or pharmacy technician trainee shall not perform a function reserved for a pharmacist, graduate intern, or pharmacy intern in accordance with R4-23-402 or R4-23-653.
- ~~**D.E.**~~ A pharmacy technician or pharmacy technician trainee shall wear a badge indicating name and title while on duty.
- ~~**E.F.**~~ Before employing a pharmacy technician or pharmacy technician trainee, a pharmacy permittee or pharmacist-in-charge shall develop, implement, review, and revise in the same manner described in R4-23-653(A) and comply with policies and procedures for pharmacy technician and pharmacy technician trainee activities as specified in subsection ~~(F)~~ (G).
- ~~**F.G.**~~ The policies and procedures shall include the following:
 1. For all practice sites:
 - a. Supervisory controls and verification procedures to ensure the quality and safety of pharmaceutical service;
 - b. Employment performance expectations for a pharmacy technician and pharmacy technician trainee;
 - c. The activities a pharmacy technician or pharmacy technician trainee may perform as specified in R4-23-1104(A) and (B);
 - d. Pharmacist and patient communication;
 - e. Reporting, correcting, and avoiding medication and dispensing errors;
 - f. Security procedures for:
 - i. Confidentiality of patient prescription records, and
 - ii. The pharmacy area;
 - g. Automated medication distribution system;
 - h. Compounding procedures for pharmacy technicians; and
 - i. Brief overview of state and federal pharmacy statutes and rules;
 2. For community and limited-service pharmacy practice sites:
 - a. Prescription dispensing procedures for:
 - i. Accepting a new written prescription,
 - ii. Accepting a refill request,
 - iii. Selecting a drug product,
 - iv. Counting and pouring,
 - v. Labeling, and
 - vi. Obtaining refill authorization;
 - b. Computer data entry procedures for:
 - i. New and refill prescriptions,
 - ii. Patient's drug allergies,
 - iii. Drug-drug interactions,
 - iv. Drug-food interactions,
 - v. Drug-disease state contraindications,
 - vi. Refill frequency,
 - vii. Patient's disease and medical condition,
 - viii. Patient's age or date of birth and gender, and
 - ix. Patient profile maintenance; and
 3. For hospital pharmacy practice sites:
 - a. Medication order procurement and data entry,
 - b. Drug preparation and packaging,
 - c. Outpatient and inpatient drug delivery, and
 - d. Inspection of drug storage and preparation areas and patient care areas.

R4-23-1105. Pharmacy Technician Trainee Training Program, Pharmacy Technician Drug Compounding Training Program, and Alternative Pharmacy Technician Training

- A. Nothing in this Section prevents additional offsite training of a pharmacy technician.
- B. Pharmacy technician trainee training program.
1. A pharmacy permittee or pharmacist-in-charge shall develop, implement, review, and revise in the same manner described in R4-23-653(A) and comply with a pharmacy technician trainee training program based on the needs of the individual pharmacy;
 2. A pharmacy permittee or pharmacist-in-charge shall ensure that the pharmacy technician trainee training program includes training guidelines that:
 - a. Define the specific tasks a pharmacy technician trainee is expected to perform,
 - b. Specify how and when the pharmacist-in-charge will access the pharmacy technician trainee's competency, and
 - c. Address the policies and procedures specified in ~~R4-23-1104(F)~~ R4-23-1104(G) and the permissible activities specified in R4-23-1104(A) ~~and (B)~~;
 3. A pharmacist-in-charge shall:
 - a. Document ~~a pharmacy technician trainee's progress throughout the training program,~~
 - ~~b. Date and sign a statement attesting the date that a pharmacy technician trainee has successfully completed the training program, and~~
 - ~~e-b. Maintain the documentation required in this subsection and R4-23-1104(A)(3) for inspection by the Board or its designee, and~~
 - ~~d. Provide to the pharmacy technician trainee a copy of the statement required in subsection (B)(3)(b).~~
 4. A pharmacy technician trainee shall perform only those tasks, listed in R4-23-1104(A), for which training and competency has been demonstrated.
- C. ~~Drug~~ Pharmacy technician drug compounding training program.
1. A pharmacy permittee or pharmacist-in-charge shall develop, implement, review, and revise in the same manner described in R4-23-653(A) and comply with a pharmacy technician drug compounding training program based on the needs of the individual pharmacy;
 2. A pharmacy permittee or pharmacist-in-charge shall ensure that the pharmacy technician drug compounding training program includes training guidelines that:
 - a. Define the specific tasks a pharmacy technician is expected to perform,
 - b. Specify how and when the pharmacist-in-charge will access the pharmacy technician's competency, and
 - c. Address the following procedures and tasks:
 - i. Area preparation,
 - ii. Component preparation,
 - iii. Aseptic technique and product preparation,
 - iv. Packaging and labeling, and
 - v. Area clean up;
 3. A pharmacist-in-charge shall:
 - a. Document ~~a pharmacy technician's progress throughout the training program,~~
 - ~~b. Date and sign a statement attesting the date that a pharmacy technician has successfully completed the pharmacy technician drug compounding training program, and~~
 - ~~e-b. Maintain the documentation required in this subsection for inspection by the Board or its designee.~~
- D. Alternative pharmacy technician training.
1. A individual who has passed the required Board-approved pharmacy technician examination, but has not followed the normal path to pharmacy technician licensure by obtaining a pharmacy technician trainee license and working while completing a pharmacy technician trainee training program as specified in subsection (B), may obtain a pharmacy technician license, if the individual has employment in pharmacy and completes an in-store training program as part of the individual's employment orientation that includes: reading and discussing with the pharmacist-in-charge of the pharmacy where employed, the Board rules concerning pharmacy technicians and pharmacy technician trainees, the pharmacy technician and pharmacy technician trainee job description, and the policies and procedures manual of that pharmacy.
 - a. Board rules concerning pharmacy technicians and pharmacy technician trainees,
 - b. Pharmacy technician and pharmacy technician trainee job description, and
 - c. Policies and procedures manual of that pharmacy.
 2. An individual who has completed a pharmacy technician certificate program and has passed the required Board-approved pharmacy technician examination, but has not followed the normal path to pharmacy technician licensure by obtaining a pharmacy technician trainee license and working while completing a pharmacy technician trainee training program as specified in subsection (B), may obtain a pharmacy technician license, if the individual has employment in pharmacy and completes an in-store training program as part of the individual's employment orientation that includes: reading and discussing with the pharmacist-in-charge of the pharmacy where employed, the Board

rules concerning pharmacy technicians and pharmacy technician trainees, the pharmacy technician and pharmacy technician trainee job description, and the policies and procedures manual of that pharmacy.

3. A pharmacist-in-charge shall:

a. Document the date that an individual licensed under subsection (D)(1) or (2) has successfully completed the in-store training program as part of the individual's employment orientation as required under subsection (D)(1) or (2), and

b. Maintain the documentation required in this subsection for inspection by the Board or its designee.

~~D.E.~~ A pharmacy technician shall perform only those tasks, listed in R4-23-1104(B), for which training and competency has been demonstrated.