

NOTICES OF SUPPLEMENTAL PROPOSED RULEMAKING

After an agency has filed a Notice of Proposed Rulemaking with the Secretary of State's Office for *Register* publication and filing and the agency decides to prepare a Notice of Supplemental Proposed Rulemaking for submission to the Office, the Secretary of State shall publish the Notice under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.). Publication of the Notice of Supplemental Proposed Rulemaking shall appear in the *Register* before holding any oral proceedings (A.R.S. § 41-1022).

NOTICE OF SUPPLEMENTAL PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

PREAMBLE

1. **Register citation and date for the original Notice of Proposed Rule making:**
5 A.A.R. 1088, March 16, 1999
2.

<u>Sections Affected</u> R4-23-403	<u>Rulemaking Action</u> Amend
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3. **The specific authority for rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**
Authorizing Statute: A.R.S. § 32-1904
Implementing Statute: A.R.S. §§ 32-1904(B)(5) and (7).
4. **The name and address of agency personnel with whom persons may communicate regarding this rule:**
Name: Dean Wright, Compliance Officer
Address: Board of Pharmacy
5060 N. 19th Avenue, Suite 101
Phoenix, AZ 85015
Telephone: (602) 255-5125, Ext. 131
Fax: (602) 255-5740
5. **An explanation of the rule, including the agency's reasons for initiating the rules:**

This rule was initiated at the request of the Arizona Pharmacy Association. The Arizona Pharmacy Association represents pharmacies and pharmacists in the state of Arizona. In the fall of 1994, a committee consisting of members from the Arizona Pharmacy Association and the Board staff worked together to identify possible changes in existing rule that are formalized in these proposed rules.

The rule includes new definitions for "certified pharmacy technician", "other designated personnel", "pharmacy technician", and "support personnel". The rule amends the definition for "supervision" and deletes the definition for "supportive personnel". The rule also incorporates the use of "graduate intern". Recent statutory changes created the "graduate intern" designation and the rule incorporates the term where applicable. The rule addresses format and style changes necessary under the current administrative procedures act and other necessary language changes to provide a clear, concise, and understandable document.

The heading of R4-23-403 is changed from "Supportive personnel" to "Pharmacy Technicians and Certified Pharmacy Technicians". The rule makes changes to R4-23-403 that address the activities of pharmacy technicians and certified pharmacy technicians. Specifically, the rule adds language that:

 - a. Changes the minimum requirements for working as a pharmacy technician or certified pharmacy technician including age, education, training, and documentation;
 - b. Addresses off site training and includes a grandfather clause;
 - c. Addresses the current 2:1 ratio of technicians to pharmacists in the pharmacy area by allowing 3 technicians in the pharmacy area per pharmacist if at least 1 of the 3 technicians is certified;

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- d. Changes the list of permissible activities of a pharmacy technician by deleting items 1, 7, and 9 (accepting a new written prescription order, counting, pouring or reconstituting medications, and filing prescription orders);
- e. Renumbers the list to items 1 through 8 and makes changes that clarify technician activities;
- f. Defines the permissible activities of certified pharmacy technicians;
- g. Addresses the employment and termination notification requirements imposed on the pharmacist-in-charge of the pharmacy; and
- h. Requires development and implementation of written policies and procedures and a training program for pharmacy technicians and certified pharmacy technicians.

The rule makes changes to R4-23-610 that address community pharmacy personnel and security procedures. The rule expands and clarifies the duties of the pharmacist-in-charge related to the written policies and procedures for technicians, the technician training program, the designation of personnel permitted in the pharmacy, and the security of the drugs received by the pharmacy.

The Board believes that adoption of these rules will benefit the public health and safety by establishing clear standards governing community pharmacy practice. Specifically, the duties of pharmacy technicians, and certified pharmacy technicians. The Board further believes that regulation and enforcement are necessary to regulate and control the rapidly evolving role of pharmacists and technicians in a dynamic healthcare system.

6. An explanation of substantial change which resulted in this supplemental notice:

Comments received at a public hearing on the proposed rulemaking held on May 17, 1999, prompted the Board to make the substantive changes which required this notice. It was pointed out by the public that requiring a pharmacist-in-charge to develop or even cooperate in the development of policy and procedures and training programs was not feasible. Chain pharmacies (community, supermarket, deep-discount) comprise more than 85% of the pharmacies in Arizona. In real life, the pharmacist-in-charge in these chains has no input into pharmacy policy and procedures or training programs.

The rule is changed to require that the pharmacy permittee (in this case chain management) or the pharmacist-in-charge develop technician policy and procedures and technician training programs. These changes occur in subsections (A)(3), (E), and (H)(1). These changes include the strikeout of the words "in cooperation with the" from those same subsections.

In subsection (A)(3), the rule requires a copy of the training guidelines in the pharmacy. The training guidelines are actually a part of the training program and it was the intent of the Board to have a copy of the entire training program in the pharmacy for reference. Subsection (A)(3) is changed to add the words "program and" between the words "training" and "guidelines".

Other public comment questioned why a pharmacist-in-charge should be required, as in subsection (G), to notify the Board within specific time-frames of employing, terminating, or training a technician. Another question was what did the Board do with this information. Since the Board does not license or even have authority to license technicians and does not do anything with the information in question, the Board decided to repeal the employment notification requirements in subsection (G) and renumber subsequent subsections accordingly.

While reviewing the rule for these changes, Board staff noticed and inserted a missing word in subsection (I)(7)(e). The word "and" was left out by mistake in the proposed rulemaking. This grammatical error should be caught by GRRC staff on final review, but we have inserted it at this time.

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 economic, small business, and consumer impact:

The principal impact of the rule will be on pharmacists, technicians, pharmacies, and patients. For pharmacists-in-charge, the rule will place additional responsibility on them for writing and reviewing a policy and procedure manual and technician training program. The upside for the pharmacist-in-charge will be better control of their pharmacy practice through established written policy and procedure and better trained technicians. The actual impact on most pharmacists-in-charge will be minimal because most chain pharmacies already have established policies and procedures and technician training programs. The rule provides the means to increase the quality and training of technicians.

For staff pharmacists, the rule will provide more qualified and better trained technicians. This will give the pharmacist more time to evaluate drug use, counsel patients, and ultimately provide better health care for Arizona citizens.

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For technicians, the rule will define a definite career path through certification. Technicians who become certified can look forward to increased income and prestige. All technicians will benefit from the establishment of minimum standards of education and training. Job opportunity for technicians will increase with the increase in technician to pharmacist ratio.

The majority of pharmacies in Arizona are chain pharmacies. Chain pharmacy representatives helped write the new standards. The chain pharmacies have already moved to increase the number of certified pharmacy technicians they employ. These pharmacies realize that using better trained technicians will decrease costs by lowering employee turnover rates and increasing employee efficiency. When appropriate, the use of a 3 technician to 1 pharmacist ratio will decrease payroll costs and improve efficiency and patient care. These cost savings should offset the increased cost of higher wages for certified pharmacy technicians. The rulemaking allows for the continued employment of existing technicians who may not meet the new standards, thus not unduly penalizing either employee or employer. Most independent pharmacies will not use the 3 to 1 ratio, but they will receive the other benefits of using better trained technicians. Since using certified pharmacy technicians is not mandatory, except for the 3 to 1 ratio, the rulemaking will have minimal impact on independent pharmacies.

The rulemaking indirectly benefits consumers by establishing higher minimum standards for pharmacy technicians and certified pharmacy technicians. These minimum standards will provide more qualified and better trained technicians. The use of well trained technicians will give the pharmacist more time to evaluate drug use, counsel patients, and ultimately provide better pharmaceutical care for Arizona citizens.

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
5060 N. 19th Avenue, Suite 101
Phoenix, AZ 85015
Telephone: (602) 255-5125, Ext. 131
Fax: (602) 255-5740

10. **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:**

Comments may be written or presented orally. Written comments must be received by 5 p.m., Monday, August 16, 1999. An oral proceeding is scheduled for:

Date: August 16, 1999
Time: 10 a.m.
Location: Board of Pharmacy
5060 N. 19th Avenue, Suite 101
Phoenix, AZ 85015

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

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:**

Not applicable.

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

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 4. PROFESSIONAL PRACTICES

Sections

R4-23-403. Pharmacy Technicians and Certified Pharmacy Technicians ~~Supportive Personnel~~

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ARTICLE 4. PROFESSIONAL PRACTICES

R4-23-403. Pharmacy Technicians and Certified Pharmacy Technicians Supportive Personnel

- A.** ~~Prior to~~ Before working as a pharmacy ~~supportive person, technician or certified pharmacy technician,~~ an individual shall:
1. Be 18 years of age or older;
 2. Have a high school diploma or equivalent;
 3. Complete a training program at the pharmacy of employment. The training program shall be developed by the pharmacy permittee or in cooperation with the pharmacist-in-charge based on the needs of the individual pharmacy. The training program shall be implemented by the pharmacist-in-charge and include written guidelines that define the specific tasks the technician is expected to perform and how the technician's competency is to be assessed. A copy of the training program and guidelines shall be available within the pharmacy for reference by pharmacy technicians or certified pharmacy technicians and inspection by the Board or its designee. The pharmacist-in-charge shall certify that the technician has successfully completed the training program. Pharmacy technicians and certified pharmacy technicians shall perform only those tasks, listed in subsections (D) and (E), for which they have been trained and in which competency has been demonstrated;
 14. ~~Have~~ Read and discussed, with the pharmacist-in-charge of the pharmacy where employed, the Board rules concerning ~~supportive personnel pharmacy technicians and certified pharmacy technicians, the supportive personnel the pharmacy technician or certified pharmacy technician~~ job description, and policy and procedure manual of that pharmacy; and
 25. Date and sign a statement affirming their understanding of the Board of Pharmacy rules for pharmacy technician or certified pharmacy technician, supportive personnel and the pharmacy's job description and policy and procedure manual.
- B.** ~~Procedures. Supportive personnel shall function in accordance with written procedures prepared by the pharmacist in charge. These procedures shall specify functions and supervisory controls designed to assure the quality and safety of pharmaceutical service. A function is suitable to be performed by supportive personnel if written quality control procedures are developed, and a verification procedure is documented by the pharmacist in charge to assure the quality of product and service. Supportive personnel shall wear a badge indicating his or her name and title.~~
- B.** Nothing in subsection (A) shall prevent additional off site training of a pharmacy technician or certified pharmacy technician. Any pharmacy technician or certified pharmacy technician actively employed before the effective date of this rule shall be exempt from R4-23-403 (A)(1) and (2).
- C.** In accordance with the space requirement set forth at R4-23-609(A), the pharmacist-in-charge shall ensure that there are no more than 2 pharmacy technicians in the pharmacy area per pharmacist except if an additional 3rd pharmacy technician is certified, there may be three pharmacy technicians per pharmacist in the pharmacy area.
- ED.** Permissible activities of a pharmacy technician. Acting in compliance with R4-23-402(A) all applicable statutes and rules and under the supervision of a pharmacist, supportive personnel pharmacy technicians may assist a graduate intern, pharmacy intern, or a pharmacist in with the following:
1. ~~Accepting a new written prescription order;~~
 21. Receiving requests for refilling ~~Receive a request, from a patient or patient's agent, to refill a patient's prescription medication by serial number;~~
 32. ~~Recording~~ Record on the front of an original prescription order the prescription serial number and date dispensed;
 43. ~~Initiate or accept accepting~~ Initiate or accept verbal or electronic refill authorization from a medical practitioner or the medical practitioner's agent thereof and recording 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;
 54. ~~Recording~~ Record information in the refill record or ~~family prescription order record~~ patient profile;
 65. ~~Typing~~ Type and ~~affixing~~ affix labels for prescription medications; or ~~causing enter~~ information for new or refill prescription medication to be entered into a computer, provided ~~the a~~ a pharmacist shall verify the accuracy and personally initial in handwriting the finished label prepared by ~~supportive personnel a technician~~ a technician before the prescription medication is dispensed to the patient;
 7. ~~Counting, pouring or reconstituting medications, provided the pharmacist checks the ingredients and procedure prior to any reconstitution and provided the original containers are beside the medication for verification by the pharmacist;~~
 6. Reconstitute prescription medications, provided a pharmacist shall check the ingredients and procedure before reconstitution and verify the final product after reconstitution;
 7. Retrieve, count, or pour prescription medications, provided a pharmacist shall verify the contents of the prescription medication against the original prescription medication container or by alternative drug identification methods approved by the Board or its designee; and
 8. ~~Prepackaging~~ Prepackage drugs in accordance with R4-23-402(A); and,
 9. ~~Filing prescription orders.~~
- E.** Permissible activities of certified pharmacy technician. Acting in compliance with all applicable statutes and rules, after completing a compounding training program developed by the pharmacy permittee or in cooperation with the pharmacist-

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in-charge pursuant to subsection (A)(3), and under the supervision of a pharmacist, a certified pharmacy technician may, in addition to the activities listed in subsection (D), assist a pharmacist, graduate intern, or pharmacy intern in compounding prescription medications in accordance with written policies and procedures by which the preparation, accuracy, and safety of the final product is verified by a pharmacist before it is dispensed to the patient.

~~**DE.** Prohibited activities. Supportive personnel are Pharmacy technicians and certified pharmacy technicians shall not authorized to perform functions reserved for a pharmacist, graduate intern, or pharmacy intern in accordance with R4-23-402.~~

~~**E.** Notification. The pharmacist in charge shall notify the Arizona State Board of Pharmacy within ten days of employing a supportive person. Such notice shall indicate that the individual has signed the statement prescribed in R4-23-403(A) and the statement is available for review by a Board of Pharmacy Compliance Officer. At the discretion of the Executive Director of the Arizona State Board of Pharmacy, this notification may be by written statement, telephone, or personal appearance. The Executive Director shall maintain a file of supportive personnel.~~

~~**G.** Employment notification. On a form supplied by the Board, the pharmacist in charge shall notify the Board:~~

- ~~1. Within 30 days of employing or terminating a pharmacy technician or certified pharmacy technician, and~~
- ~~2. Within 10 days of a technician's satisfactory completion of the training requirements in R4-23-403(A).~~

~~**HG.** A pharmacy technician or certified pharmacy technician shall wear a badge indicating name and title while on duty.~~

~~**HI.** The pharmacy permittee or pharmacist-in-charge shall:~~

- ~~1. Develop or cooperate in the development of written policies and procedures specifying permissible activities a pharmacy technician or certified pharmacy technician may perform under R4-23-403(D) and (E) and supervisory controls and verification procedures ensuring the quality and safety of pharmaceutical service.~~
- ~~2. Implement the written policies and procedures.~~
- ~~3. Review and revise the policies and procedures biennially, and~~
- ~~4. Make the policies and procedures available as a manual or by other methods approved by the Board or its designee within the pharmacy for reference by pharmacy technicians or certified pharmacy technicians and inspection by the Board or its designee.~~

~~**II.** The policies and procedures shall include the following:~~

- ~~1. Performance expectations of pharmacy technician and certified pharmacy technician.~~
- ~~2. Prescription dispensing procedures for:
 - ~~a. Accepting a new written prescription.~~
 - ~~b. Accepting a refill request.~~
 - ~~c. Drug product selection.~~
 - ~~d. Counting and pouring.~~
 - ~~e. Labeling, and~~
 - ~~f. Refill authorization.~~~~
- ~~3. Computer data entry procedures for:
 - ~~a. New and refill prescriptions.~~
 - ~~b. Drug allergies.~~
 - ~~c. Drug-drug interactions.~~
 - ~~d. Drug-food interactions.~~
 - ~~e. Drug-disease state contraindications.~~
 - ~~f. Refill frequency.~~
 - ~~g. Disease or medical condition.~~
 - ~~h. Patient age or date of birth and gender, and~~
 - ~~i. Patient profile maintenance.~~~~
- ~~4. Compounding procedures for certified pharmacy technicians.~~
- ~~5. Supervisory controls and verification procedures.~~
- ~~6. Pharmacist and patient communication.~~
- ~~7. Quality management procedures for:
 - ~~a. Competency review and evaluation.~~
 - ~~b. Continuing education.~~
 - ~~c. Drug recall.~~
 - ~~d. Drug storage.~~
 - ~~e. Expired and beyond-use-date drugs, and~~
 - ~~f. Medication and dispensing errors.~~~~
- ~~8. Security procedures for:
 - ~~a. Confidentiality of patient prescription records, and~~
 - ~~b. The pharmacy area.~~~~
- ~~9. Automated medication distribution systems.~~
- ~~10. Support personnel.~~
- ~~11. Sanitation, and~~
- ~~12. Brief overview of state and federal pharmacy statutes and rules.~~

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FKJ. Hospital pharmacies. Nothing in this rule shall prevent hospital pharmacies from ~~utilizing supportive personnel~~ using pharmacy technicians and certified pharmacy technicians in accordance with regulations pertaining specifically to hospital pharmacies.