

NOTICE OF PROPOSED RULEMAKING
TITLE 4. PROFESSIONS AND OCCUPATIONS
CHAPTER 23. BOARD OF PHARMACY

PREAMBLE

- | <u>1. Articles, Parts, and Sections Affected</u> | <u>Rulemaking Action</u> |
|---|---------------------------------|
| R4-23-402 | Amend |
| R4-23-1104 | Amend |
| R4-23-1104.01 | New Section |
- 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)
Implementing statute: A.R.S. § 32-1961(A)
- 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: 22 A.A.R. 3196, November 11, 2016
- 4. The agency's contact person who can answer questions about the rulemaking:**
Name: Kamlesh Gandhi
Address: 1616 W Adams Street, Suite 120
Phoenix, AZ 85007
Telephone: (602) 771-2740
Fax: (602) 771-2749
E-mail: kgandhi@azpharmacy.gov
Web site: www.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 An agency's justification and reason why a rule should be made, amended, repealed, or renumbered, to include an explanation about the rulemaking:**
This rulemaking will create efficiencies in a pharmacy by enabling a licensed pharmacy technician working under the supervision of a pharmacist to use technology to verify the accuracy of medications prepared for dispensing. Current law requires a pharmacist do this verification. The technology required to verify the accuracy of medications prepared for dispensing exists and is simple to use. It involves scanning a bar code and visually comparing the prepared medication with the result on a computer screen. By enabling a licensed pharmacy technician to perform routine technology-assisted verification, this rulemaking will remove a regulatory burden and provide additional time in

which the pharmacist is able to perform tasks such as patient counseling that require the pharmacist's skills.

An exemption from Executive Order 2016-03 was provided for this rulemaking by Christina Corieri, Policy Advisor for Health and Human Services in the Governor's office, in an e-mail dated July 14, 2016.

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

The Board does not intend to review or rely on a study in its evaluation of or justification for any rule in this rulemaking.

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

Not applicable

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

The Board believes the economic impact will be positive for pharmacy permittees and pharmacy technicians. There will be cost savings for pharmacy permittees able to have pharmacy technicians perform technology-assisted verification of product. There may be a voluntary cost for pharmacy permittees to obtain equipment necessary to perform technology-assisted verification. Pharmacy technicians will benefit from the opportunity to expand their role. The rulemaking will have little or no economic impact on consumers.

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

Name: Kamlesh Gandhi

Address: 1616 W Adams Street, Suite 120

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

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

Date:

Time:

Location:

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

None

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

The rulemaking does not require a permit.

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:

There are federal laws relating to selling and dispensing of drugs. However, none is specifically applicable to this rulemaking. No rule in the rulemaking is more stringent than federal law.

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

No analysis was submitted.

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

None

13. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS
CHAPTER 23. BOARD OF PHARMACY
ARTICLE 4. PROFESSIONAL PRACTICES

Section

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

ARTICLE 11. PHARMACY TECHNICIANS

Section

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

R4-23-1104.01. Technology-assisted Verification of Product

ARTICLE 4. PROFESSIONAL PRACTICES

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

A. No change

1. No change
2. Obtain and record the name of ~~an~~ the individual who communicates an oral prescription order;
3. No change
 - a. No change
 - b. No change
4. No change
5. No change
 - a. ~~A patients'~~ The patient's allergies,
 - b. Incompatibilities with medications ~~a patient's~~ the patient currently ~~taken~~ medications takes,
 - c. ~~A~~ The patient's use of unusual quantities of dangerous drugs or narcotics,
 - 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
 - a. No change
 - b. No change
 - c. No change
 - d. No change
11. ~~Make~~ Except as provided in subsection (A)(12), make a final accuracy check ~~on~~ of the completed prescription ~~medication~~ label including verification of medication, accuracy of patient's name, consistency with prescription order, and drug utilization review and initial in handwriting or by another method approved by the Board or its designee the finished label-

~~Manual initialing of a finished label is not required if the pharmacy's computer system complies with the computer documentation requirements of R4 23 408(B)(4);~~

12. If a technology-assisted verification of product program is used, make a final accuracy check of the completed prescription label including accuracy of patient's name, consistency with prescription order, and drug utilization review and initial in handwriting or by another method approved by the Board or its designee the finished label. If a technology-assisted verification of product program is used, verification of product is not required.

~~12,13.~~ No change

~~13,14.~~ No change

a. No change

b. No change

c. No change

~~14,15.~~ No change

a. ~~Fa~~esimile, Fax

b. ~~Computer modem~~ E-mail, or

c. No change

~~15,16.~~ No change

~~16,17.~~ No change

~~17,18.~~ 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. When, in the professional ~~judgement~~ judgment of the pharmacist or graduate intern or pharmacy intern under the supervision of a pharmacist, or when circumstance precludes it, oral consultation may be omitted if the pharmacist, graduate intern, or pharmacy intern:

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.** No change
 - 1. No change
 - 2. No change
 - 3. No change
 - 4. No change
- 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

ARTICLE 11. PHARMACY TECHNICIANS

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

- A.** Permissible ~~activities~~ tasks 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 licensed under R4-23-1103 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 of the prescription medication and date dispensed;
 - 2. No change
 - 3. No change

4. ~~Type and affix a label for a prescription medication or enter~~ Enter information for a new or refill prescription medication ~~into a computer, as required under A.R.S. § 32-1964;~~
5. Type and affix a label for the prescription medication. if a ~~A pharmacist or graduate or pharmacy intern working under the supervision of a pharmacist~~ verifies shall verify the accuracy of the label as described under R4-23-402(A)(11) ~~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;~~

~~5.6.~~ No change

~~6.7.~~ No change

~~7.8.~~ No change

~~8.9.~~ No change

B. ~~Permissible activities~~ tasks of a pharmacy technician. Acting in compliance with all applicable statutes and rules and under the supervision of a pharmacist, a pharmacy technician licensed under R4-23-1102 may:

1. Perform the ~~activities~~ tasks 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(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-;
3. Perform a final technology-assisted verification of product if the pharmacy technician is qualified under R 4-23-1104.01(D); and
4. If technology-assisted verification is performed, type and affix a label for the prescription medication. A pharmacist or graduate or pharmacy intern shall verify the accuracy of the label as described under R4-23-402(A)(12).

C. ~~When performing the activities listed in~~ A trained and licensed pharmacy technician or pharmacy technician trainee who performs a task as authorized under 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~~ shall ensure the task is performed accurately.

D. Prohibited activities. A pharmacy technician or pharmacy technician trainee shall not perform a ~~function~~ professional practice reserved for a pharmacist, graduate intern, or pharmacy intern in accordance with R4-23-402 or R4-23-653.

E. No change

- 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 outlined in subsection (G) for pharmacy technician and pharmacy technician trainee ~~activities as tasks specified in subsection (G)~~.
- G.** ~~The~~ A pharmacy permittee or pharmacist-in-charge shall ensure policies and procedures ~~shall~~ required under subsection (F) include the following:
1. No change
 - a. No change
 - b. No change
 - c. The ~~activities~~ tasks a pharmacy technician or pharmacy technician trainee may perform as specified ~~in R4-23-1104~~ under subsections (A) and (B);
 - 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. Accepting a new written prescription order,
 - ii. No change
 - iii. No change
 - iv. No change
 - v. No change
 - vi. Obtaining refill authorization; and
 - b. Computer ~~data-entry~~ data-entry procedures for:
 - 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

R4-23-1104.01 Technology-assisted Verification of Product

A. By complying with this Section, the permittee of a retail, institutional, or limited-service pharmacy may implement a technology-assisted verification of product program that allows a pharmacy technician licensed under R4-23-1102 and qualified under subsection (D) to perform final product verification.

B. Written program description required. Before implementing a technology-assisted verification of product program the permittee of a retail, institutional, or limited-service pharmacy shall prepare a written program description that includes the following:

- 1. Responsibility of both the pharmacist in charge and permittee to ensure compliance with this Section;
- 2. Responsibility of the permittee to ensure the accuracy and safety of the product dispensed;
- 3. Duties of a verification technician;
- 4. The training necessary to qualify and remain qualified as a verification technician;
- 5. The monitoring and evaluation procedures to be used to ensure competency of the verification technician; and
- 6. Prohibition of a verification technician performing a final accuracy check of a completed prescription label.

C. The permittee of a retail, institutional, or limited-service pharmacy implementing a technology-assisted verification of product program shall:

- 1. Post the written program description required under subsection (B) in the pharmacy area;
- 2. Provide a copy of the written program description to the pharmacist in charge and verification technician;

3. Obtain the signature of the pharmacist in charge and verification technician on a copy of the written program description and place the signed copy in the personnel file of the pharmacist in charge and verification technician;
4. Ensure scanning technology used in the technology-assisted verification program captures both product and patient information; and
5. Update the written program description as needed and repeat subsections (C)(1) through (4) after each update.

D. Verification technician training: The permittee of a retail, institutional, or limited-service pharmacy implementing a technology-assisted verification of product program shall ensure a pharmacy technician does not perform the duties of a verification technician unless the pharmacy technician has the following qualifications:

1. Is licensed under R4-23-1102;
2. Has at least 1,000 hours of pharmacy technician work experience in the same kind of pharmacy practice site in which the technology-assisted verification of product will be performed;
3. Completes a training program that includes at least the following:
 - a. Role of a verification technician in the dispensing process,
 - b. Legal requirements of a verification technician,
 - c. How to use the technology-assisted verification system,
 - d. Primary causes of medication errors, and
 - e. Identifying and resolving dispensing errors; and
4. Completes at least four hours of the continuing education required under R4-23-1106 on patient safety.

E. The permittee of a retail, institutional, or limited-service pharmacy implementing a technology-assisted verification of product program shall ensure the pharmacy practice site has a computer data storage and retrieval system that meets the standards in R4-23-408(B).

F. The permittee of a retail, institutional, or limited-service pharmacy implementing a technology-assisted verification of product program shall ensure a verification technician verifies only the following:

1. A product with scanning technology that identifies product, or
2. A robotically prepared unit-dose product.

G. The permittee of a retail, institutional, or limited-service pharmacy implementing a technology-assisted verification of product program shall ensure a verification technician does not verify the following:

1. A product that involves a combination of drugs resulting from compounding or mixing two or more ingredients or products,
 2. A product that involves or results from an alteration of a drug, or
 3. A DEA schedule II controlled substance.
- H.** The permittee of a retail, institutional, or limited-service pharmacy implementing a technology-assisted verification of product program shall perform an unannounced evaluation of the competency of a verification technician at least twice a year and take steps to remediate any deficiencies identified including removing verification duties from the technician.
- I.** The permittee of a retail, institutional, or limited-service pharmacy implementing a technology-assisted verification of product program shall maintain the following records:
1. Date the pharmacy technician was designated as a verification technician,
 2. Date the pharmacy technician completed the training required under subsection (D)(3),
 3. Dates and results of the evaluations conducted under subsection (H), and
 4. Date and reason for any disciplinary action against the verification technician arising from performing the duties of a verification technician.
- J.** A verification technician shall wear identification that includes the title “Verification Technician” while on duty.
- K.** As used in this Section, the term “verification technician” means an individual who:
1. Is qualified under subsection (D),
 2. Uses a combination of scanning technology and visual confirmation to verify a product prepared to be dispensed is the product prescribed and indicated on the prescription label, and
 3. Performs verification of work performed by other pharmacy technicians before a pharmacist or graduate or pharmacy intern working under the supervision of a pharmacist performs the final accuracy check required under R4-23-402(A).