

AGENCY RECEIPT

SECRETARY OF STATE

NOTICE OF RULEMAKING DOCKET OPENING

2023 MAR 31 AM 9:32

1. **Agency name:** Board of Pharmacy

FILED

2. **The Subchapters, if applicable; the Articles; the Parts, if applicable, and the Sections involved in the rulemaking, listed in numerical order:**

Article, Part, or Section Affected (as applicable) Rulemaking Action
(in numerical order)

R4-23-1104

Amend

R4-23-1106

Amend

2023 MAR 31 AM 9:32

NOTICE OF RULEMAKING DOCKET OPENING

FILED

- 1. Title and its heading:** 4. Professions and Occupations
Chapter and its heading: 23. Board of Pharmacy
Article and its heading: 11. Pharmacy Technicians
Section numbers: R4-23-1104 and R4-23-1106 (Additional Sections may be made, amended, or repealed as necessary)

2. The subject matter of the proposed rule:

At the request of the Governor's Office and to enable a pharmacy permittee to determine business practices that are in the interest of public health and safety, the Board is amending its rules to allow a pharmacy technician to administer a vaccine when the pharmacy technician has completed specified training and the authority to administer the vaccine is delegated by and under the supervision of the pharmacist on duty. Authorizing a pharmacy technician to administer a vaccine is consistent with the evolving national landscape for pharmacy technicians. A 2023 survey of pharmacy law conducted by the National Association of Boards of Pharmacy found pharmacy technicians have vaccine administration authority under state law in 18 states and Guam. These states include Alabama, Colorado, Guam, Idaho, Illinois, Indiana, Iowa, Kentucky, Louisiana, Missouri, Nevada, North Carolina, North Dakota, Rhode Island, Utah, Virginia, Washington, Wisconsin, and Wyoming.

As required under A.R.S. § 41-1039, an exemption for this rulemaking was obtained from Zaida Dedolph, health policy advisor in the governor's office, in an e-mail dated March 3, 2023.

3. A citation to all published notices relating to the proceeding:

None

4. Name and address of agency personnel with whom persons may communicate regarding the rule:

Name: Kamlesh Gandhi

Address: 1110 W. Washington Street, Suite 260
Phoenix, AZ 85007

Telephone: (602) 771-2740

Fax: (602) 771-2749

E-mail: kgandhi@azpharmacy.gov

Website: www.azpharmacy.gov

5. The time during which the agency will accept written comments and the time and place where oral comments may be made:

The Board will accept comments during business hours at the address listed in item 4. Information regarding an oral proceeding will be included in the Notice of Proposed Rulemaking.

6. A timetable for agency decisions or other action on the proceeding, if known:

To be determined

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NOTICE OF PROPOSED RULEMAKING

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1. Agency name: Board of Pharmacy

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Article, Part, or Section Affected (as applicable) Rulemaking Action
(in numerical order)

R4-23-1104

Amend

R4-23-1106

Amend

**AGENCY CERTIFICATE
NOTICE OF PROPOSED RULEMAKING**

SECRETARY OF STATE

2023 MAR 31 AM 9:32

FILED

1. **Agency name:** Board of Pharmacy
2. **Chapter heading:** Board of Pharmacy
3. **Code citation for the Chapter:** 4 A.A.C. 23
4. **The Subchapters, if applicable; the Articles; the Parts, if applicable, and the Sections involved in the rulemaking, listed in numerical order:**

Article, Part, or Section Affected (as applicable) Rulemaking Action
(in numerical order)

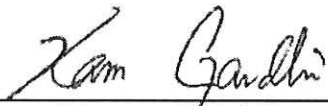
R4-23-1104

Amend

R4-23-1106

Amend

5. **The rules contained in this package are true and correct as proposed.**

6. 

Signature of Agency Chief Executive Officer in ink

March 29, 2023

Date of signing

Kamlesh Gandhi
Printed or typed name of signer

Executive Director
Title of signer

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>
R4-23-1104	Amend
R4-23-1106	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. §§ 32-1923.01 and 32-1925(H)

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: XX A.A.R. XX

4. The agency's contact person who can answer questions about the rulemaking:

Name: Kamlesh Gandhi

Address: 1110 W. Washington Street, Suite 260
Phoenix, AZ 85007

Telephone: (602) 771-2740

Fax: (602) 771-2749

E-mail: kgandhi@azpharmacy.gov

Website: 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:

At the request of the Governor's Office and to enable a pharmacy permittee to determine business practices that are in the interest of public health and safety, the Board is amending its rules to allow a pharmacy technician to administer a vaccine when the pharmacy technician has completed specified training and the authority to administer the vaccine is delegated by and under the supervision of the pharmacist on duty. Authorizing a pharmacy technician to administer a vaccine is consistent with the evolving national landscape for pharmacy technicians.

The need to increase the number of persons qualified to administer vaccines became critical when COVID19 reached the U.S. in early 2020. In March 2020, the Secretary of USDHHS issued guidance regarding the PREP Act, which provides qualified persons with liability protection when acting during a public health emergency. The guidance indicated that qualified pharmacy technicians acting under the supervision of a qualified pharmacist were “covered persons” under the PREP Act and authorized to administer both COVID19 vaccines and routine childhood vaccines (See <https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf>). The authorization provided under the PREP Act preempted state and local law prohibiting persons qualified under the PREP Act from administering COVID19 or routine childhood vaccines.

A recent study concluded that authorizing additional persons to administer vaccines during the COVID19 emergency worked. Hundreds of millions of vaccine doses were administered, averting millions of deaths and hospitalizations and saving trillions in healthcare costs (See <https://thehill.com/opinion/healthcare/3835860-getting-vaccinated-at-pharmacies-works-it-could-soon-disappear>). Outside of temporary and public health sites, approximately 90 percent of COVID19 vaccines were administered at pharmacies. In spite of this success, when the COVID19 health emergency ends on May 11, 2023, only persons authorized under state law will be able to administer vaccines. Pharmacy technicians are not authorized under Arizona law to administer vaccines and will have to cease doing so on May 11, 2023, unless the changes in this rule package are approved. A 2023 survey of pharmacy law conducted by the National Association of Boards of Pharmacy found pharmacy technicians have vaccine administration authority under state law in 18 states and Guam. These states include Alabama, Colorado, Guam, Idaho, Illinois, Indiana, Iowa, Kentucky, Louisiana, Missouri, Nevada, North Carolina, North Dakota, Rhode Island, Utah, Virginia, Washington, Wisconsin, and Wyoming.

To be a pharmacy technician in Arizona, a person must be licensed. A license is issued only if the person completes a training program that meets specified standards and passes a national examination. The licensed pharmacy technician is required to work under the supervision of a pharmacist and to complete 20 contact hours of continuing education every two years (See 4 A.A.C. 23, Article 11). In contrast, a medical assistant in Arizona is not licensed by the state. A medical assistant’s education may be obtained through on-the-job training (See A.R.S. § 32-1456(D)). An Arizona medical assistant is required to work under

the direct supervision of a physician, physician assistant, or nurse practitioner and is specifically authorized under A.R.S. § 32-1456(A)(2) to administer injections.

As required under A.R.S. § 41-1039, an exemption for this rulemaking was obtained from Zaida Dedolph, health policy advisor in the governor's office, in an e-mail dated March 3, 2023.

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:

Vaccines are one of the most cost-effective preventative health measures available and are largely responsible for the increase in life expectancy that occurred during the 20th century. However, infectious diseases remain a major cause of illness, disability, and death. Many of these infectious diseases can be prevented with a vaccine. In the U.S., approximately 42,000 adults and 300 children die each year from vaccine-preventable diseases other than coronavirus diseases (See <https://wayback.archive-it.org/5774/20220413183120/https://www.healthypeople.gov/2020/topics-objectives/topic/immunization-and-infectious-diseases>).

Because pharmacies in the U.S. are one of the most accessible health destinations for the public, pharmacies have served to increase vaccination rates and improve access to care. Both pharmacists and interns are authorized to administer vaccines in all 50 states and D.C. In the U.S. pharmacies are the second most common location for administering influenza vaccinations to adults, according to data from the 2018-2019 influenza season (See <https://www.pharmacytimes.com/view/how-pharmacy-technicians-can-be-certified-to-administer-immunizations-in-2020>).

In 2017, after completing a time study that showed a significant amount of a pharmacist's time was spent completing duties that did not require clinical judgment and could be safely performed by a pharmacy technician, Idaho became the first state to allow adequately trained pharmacy technicians to administer immunizations (See <https://info.nhanow.com/learning-leading-blog/the-first-pharmacy-technicians-to-give-immunizations-how-idaho-did-it>). By 2019, the Idaho board of pharmacy reported the

pharmacy technicians in Idaho had administered approximately 25,000 vaccinations with no reported adverse events or errors.

In the January 2022 issue of the Journal of the American Pharmacists Association, there is a report on a review of studies of the role of pharmacy technicians in vaccination services (See <https://www.sciencedirect.com/science/article/pii/S1544319121003861>). The review supported the effective deployment of pharmacy technicians in delivering vaccination services. The studies found pharmacy technicians delivering vaccination services produced pharmacy workflow efficiency, pharmacist clinical time, and pharmacy technician job satisfaction. The authors concluded that early adopters of professional practice advancements for pharmacy technician vaccine administration may expand vaccination service capacity efficiently and safely, allowing the pharmacy to reach more patients.

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 expects the rulemaking to have some economic impact on pharmacy permittees who choose to expand the permissible tasks of a pharmacy technician. Under the rulemaking, a pharmacy permittee is able to implement the authorized expanded permissible tasks for pharmacy technicians in a manner the pharmacy permittee determines is consistent with good business practice and the best interest of public health and safety. A pharmacy permittee that chooses to implement the authorized expanded permissible tasks for a pharmacy technician will incur the cost of ensuring the pharmacy technician is trained and working under the supervision of the pharmacist on duty. The pharmacy permittee will choose to incur these costs because the pharmacy permittee anticipates expanding permissible tasks of a pharmacy technician will be cost effective for the pharmacy permittee.

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

Name: Kamlesh Gandhi

Address: 1110 W. Washington Street, Suite 260
Phoenix, AZ 85007

Telephone: (602) 771-2740

Fax: (602) 771-2749

E-mail: kgandhi@azpharmacy.gov

Website: www.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:

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

Date: Monday, May 22, 2023

Time: 9:00 a.m.

Location: 1110 W. Washington Street, Suite 260, Phoenix, AZ 85007

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:

Under A.R.S. § 41-1037(A)(2), the license issued to a pharmacy technician under A.R.S. § 32-1923.01 is not a general permit. A.R.S. § 32-1923.01 requires the Board to assess individual qualifications before issuing the license.

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:

This rulemaking is not more stringent than federal law. Under guidance issued in early 2020, regarding the Public Readiness and Emergency Preparedness Act, the USDHHS indicated certain pharmacy technicians were qualified for liability protection when administering some FDA-authorized or licensed vaccines regardless of state-specific 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 11. PHARMACY TECHNICIANS

Section

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

R4-23-1106. Continuing Education Requirements

ARTICLE 11. PHARMACY TECHNICIANS

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

- A.** Permissible 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 an intern or pharmacist with the following when applicable to the pharmacy practice site:
1. Record on the original prescription order the serial number of the prescription medication 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. Enter information for a new or refill prescription medication as required under A.R.S. § 32-1964;
 5. Type and affix a label for the prescription medication. A pharmacist or intern working under the supervision of a pharmacist shall verify the accuracy of the label as described under R4-23-402(A)(11);
 6. Reconstitute a prescription medication, if a pharmacist checks the ingredients and procedure before reconstitution and verifies the final product after reconstitution;
 7. 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;
 8. Prepackage drugs in accordance with R4-23-402(A); and
 9. 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 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 tasks listed in subsection (A);

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 or 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 R4-23-1104.01(D);
4. If technology-assisted verification is performed, type and affix a label for the prescription medication. A pharmacist or intern shall verify the accuracy of the label as described under R4-23-402(A)(12);
5. Administer a vaccine when:
 - a. Administration of the vaccine is done under an order that complies with A.R.S. § 32-1974 and R4-23-411;
 - c. Administration of the vaccine is delegated by and done under the supervision of a pharmacist on duty who is certified under A.R.S. § 32-1974 to administer vaccines;
and
 - d. There is documentation by the permittee that the pharmacy technician has completed the following:
 - i. A practical training program that is approved by the Accreditation Council for Pharmacy Education and includes hands-on injection technique and recognition and treatment of emergency reactions to vaccines; and
 - ii. Current certification in basic cardiopulmonary resuscitation.
- 5.6. Perform a task not related to professional judgment if the task is delegated to the pharmacy technician by the pharmacist on duty after the pharmacist on duty ensures the pharmacy technician is trained to do the task and the evidence there is documentation by the permittee of the training exists in the pharmacy file.; and
- 6.7. A pharmacist on duty shall not delegate or attempt to delegate the following tasks to a pharmacy technician:
 - a. Administering an emergency medication,
 - b. Counseling a patient,
 - c. Conducting a drug utilization review,
 - d. Performing any task that requires the exercise of clinical judgment,
 - e. Issuing a prescription order,
 - f. Receiving a new prescription order for a controlled substance, or

g. Transferring by telephone an existing prescription order for a controlled substance;
and

~~7. The pharmacist on duty shall not delegate or attempt to delegate to a pharmacy technician the administering of an immunization or vaccine unless authority for the administration is specifically provided by statute or rule.~~

- C. A trained and licensed pharmacy technician or pharmacy technician trainee who performs a task as authorized under subsections (A) and (B) shall ensure the task is performed accurately.
- D. Prohibited activities. A pharmacy technician or pharmacy technician trainee shall not perform a professional practice reserved for a pharmacist or intern in accordance with R4-23-402 or R4-23-653 unless otherwise allowed by rule.
- E. A pharmacy technician or pharmacy technician trainee shall wear a badge indicating name and title while on duty.
- 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 manner described in R4-23-653(A) and comply with policies and procedures outlined in subsection (G) for pharmacy technician and pharmacy technician trainee tasks.
- G. A pharmacy permittee or pharmacist-in-charge shall ensure policies and procedures required under subsection (F) 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 tasks a pharmacy technician or pharmacy technician trainee may perform as specified under subsections (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 order,
 - ii. Accepting a refill request,
 - iii. Selecting a drug product,
 - iv. Counting and pouring,
 - v. Labeling, and
 - vi. Obtaining refill authorization; and
 - 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.

R4-23-1106. Continuing Education Requirements

A. General. According to A.R.S. § 32-1925(H), the Board shall not renew a pharmacy technician license unless the licensee has during the two years preceding the application for renewal:

1. Participated in 20 contact hours or two CEUs of continuing education activity sponsored by an Approved Provider, as defined in R4-23-110, and
2. A pharmacy technician licensee is exempt from the continuing education requirement in subsection (A)(1) between the time of initial licensure and first renewal.

B. Special continuing education requirement. During each license renewal period, a pharmacy technician shall not administer a vaccine under R4-23-1104(B)(5) unless the pharmacy

technician has participated in at least two contact hours of continuing education activity approved by the Accreditation Council for Pharmacy Education and related to administration of vaccines.

B.C. Valid CEUs. The Board shall:

1. Accept CEUs for continuing education activities sponsored only by an Approved Provider;
2. Accept CEUs accrued during only the two-year period immediately before licensure renewal;
3. Not allow CEUs accrued in a biennial renewal period to be carried forward to the succeeding biennial renewal period;
4. Allow a pharmacy technician who leads, instructs, or lectures to a group of health professionals on pharmacy-related topics in a continuing education activity sponsored by an Approved Provider to receive CEUs for a presentation by following the same attendance procedures as any other attendee of the continuing education activity; and
5. Not accept as a CEU a pharmacy technician's normal teaching duties within a learning institution if the pharmacy technician's primary responsibility is the education of health professionals.

C.D. Continuing education records and reporting CEUs. A pharmacy technician shall:

1. Maintain continuing education records that:
 - a. Verify the continuing education activities the pharmacy technician participated in during the preceding five years; and
 - b. Consist of a statement of credit or a certificate issued by an Approved Provider at the conclusion of a continuing education activity;
2. At the time of licensure renewal, attest to the number of CEUs the pharmacy technician participated in during the renewal period on the biennial renewal form; and
3. When requested by the Board office, submit proof of continuing education participation within 20 days of the request.

D.E. The Board shall deem a pharmacy technician's failure to comply with the continuing education participation, recording, or reporting requirements of this Section as unprofessional conduct and grounds for disciplinary action by the Board under A.R.S. § 32-1927.01.

E.F. A pharmacy technician who is aggrieved by any decision of the Board concerning continuing education units may request a hearing before the Board.