



KRISTIN K. MAYES
ATTORNEY GENERAL

OFFICE OF THE ARIZONA ATTORNEY GENERAL

May 2, 2023

Kamlesh Gandhi, PharmD
Arizona Board of Pharmacy
1110 W. Washington Street, Ste. 260
Phoenix, Arizona 85007

RE: A.G. Rule No. AGR23-0002; A.A.C. R4-23-1104 and 1106 (Amend)

Dear Dr. Gandhi,

We have reviewed the above-referenced emergency rules adopted by the Arizona Board of Pharmacy. We have determined that the rule is in proper form, is clear, concise and understandable, within the power of the agency to adopt, adopted within legislative standards, and was adopted in compliance with appropriate procedures. In addition, we have determined that the Board has demonstrated that the rules need to be effective immediately in accordance with A.R.S. § 41-1032.

Accordingly, pursuant to A.R.S. § 41-1026, I have affixed my signature to the original Approval of Emergency Rules and have forwarded it together with the original emergency rules, preamble, and three copies of each to the Secretary of State.

The Attorney General's approval of the emergency rules shall not be construed as an endorsement of policy issues relating to or resulting from rulemaking. Policy decisions relating to the rulemaking are those of the Arizona Board of Pharmacy and not the Office of the Attorney General.

We have enclosed a copy for your reference.

Sincerely,

A handwritten signature in black ink, appearing to read "Kristin K. Mayes".

Kristin K. Mayes
Attorney General

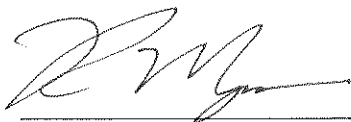
Enclosure

ATTORNEY GENERAL APPROVAL OF EMERGENCY RULES

1. **Agency Name:** Arizona Board of Pharmacy
2. **Chapter Heading:** Professions and Occupations
3. **Code Citation for the Chapter:** 4 A.A.C. 23
4. **The Articles and the Sections involved in the rulemaking, listed in numerical order:**

<u>Sections</u>	<u>Action</u>
R4-23-1104	Amend
R4-23-1106	Amend

5. **The rule contained in this package is approved as an emergency rule pursuant to the standards set forth in A.R.S. § 41-1026. The Attorney General's approval of the rule shall not be construed as an endorsement of policy issues relating to or resulting from the rulemaking. Policy decisions relating to the rulemaking are those of Arizona Board of Pharmacy and not the Office of the Attorney General. The rule is effective immediately upon filing.**



Kristin K. Mayes
Attorney General

MAY 3, 2023
Date

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

PREAMBLE

<u>1. Article, Part, or Section 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. The effective date of the rule:

The rule will be effective when filed with the Office of the Secretary of State.

a. If the agency selected a date earlier than the 60 day effective date as specified in A.R.S. § 41-1032(A), include the earlier date and state the reason or reasons the agency selected the earlier effective date as provided in A.R.S. § 41-1032(A)(1) through (5):

The Board has determined an immediate effective date is required under A.R.S. § 41-1032(A)(1) to preserve public health. Additionally, under A.R.S. § 41-1032(A)(4), the amendment in this rule package, which authorizes a licensed pharmacy technician to administer vaccines under the supervision of the pharmacist on duty, provides a benefit to the public and there is no penalty associated with violation of the rule.

Pharmacy technicians currently are authorized to administer vaccines under guidance issued by the USDHHS regarding the PREP Act in early 2020. The guidance provided qualified persons with liability protection when acting during a public health emergency such as that associated with the COVID19 pandemic. The guidance indicated 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. 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 go into effect before that date.

The need for an immediate effective date has not been caused by delay or inaction by the Board. Indeed, the Board previously attempted to amend R4-23-1104 to authorize pharmacy technicians to administer vaccines under supervision. However, in response to comments made by GRRC members at a study session on November 30, 2021, the Board withdrew the provision that would have authorized pharmacy technicians to administer vaccines under supervision. The need for this rule change became more urgent when President Biden announced on January 30, 2023, the pending termination of the current health emergency.

b. If the agency selected a date later than the 60 day effective date as specified in A.R.S. § 41-1032(A), include the later date and state the reason or reasons the agency selected the later effective date as provided in A.R.S. § 41-1032(B):

Not applicable

4. Citations to all related emergency rulemaking notices published in the Register as specified in R1-1-409(A) that pertain to the record of this notice of emergency rulemaking:

None

5. 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

6. 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)). Under the materials incorporated by reference at R4-16-402(A), a medical assistant working under direct supervision may 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.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did 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:

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>).

Pharmacists performed so well during the COVID19 pandemic that by the end of 2022 more than 178 bills were proposed across 36 states to permanently expand a pharmacist's scope of practice (See <https://www.dhinsights.org/news/pharmacists-scope-of-practice>). The goal is to allow pharmacists to become an integral part of patient care. Studies have shown that

pharmacists can have an important impact on health outcomes by improving medication adherence and outcomes in chronic conditions as well as preventing hospitalizations.

If pharmacists are to have an expanded scope of practice in patient care, they will need assistance performing the many other tasks required of a pharmacist, many of which do not require use of clinical judgment (For a list of pharmacists' responsibilities, see <https://www.liveabout.com/top-9-pharmacist-responsibilities-2663854>). However, a February 2023 report in Pharmanews Intelligence (See <https://pharmanewsintel.com>) indicated the COVID19 pandemic dramatically impacted the pharmaceutical workforce causing a significant decline in the number of pharmacists working in pharmacies. Even before the pandemic, many pharmacists were overworked and reported feelings of burnout. According to the US Bureau of Labor Statistics, these feelings were exacerbated by the pandemic and led to a six percent decline in pharmacists working in pharmacies between 2019 and 2021. This shortage is expected to continue for at least a decade. The Bureau of labor Statistics estimated the projected growth of pharmacy employment between 2021 and 2031 will be two percent, which is significantly slower than for other industries. This slow growth may leave many pharmacies looking for more employees or other solutions such as shorter hours to continue providing patient care. A February 2023 report on a survey by the National Community Pharmacists Association (See <https://www.uspharmacist.com/article/pharmacy-associations-weigh-in-on-socalled-staff-shortages>) found that pharmacy technicians were in highest demand among those responding to the survey. Overall, 67 percent reported difficulty filling open staff positions. Appropriate staffing and workplace conditions are essential for pharmacy teams to deliver quality patient care safely. Expanding the role of pharmacy technicians will facilitate expanding a pharmacist's scope of practice in patient care.

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.

8. 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

9. A summary of the economic, small business, and consumer impact:

Under A.R.S. § 41-1055(D), the Board is not required to prepare an economic, small business, and consumer impact statement with this Notice of Emergency Rulemaking. However, 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.

10. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules. When applicable, matters shall include but are not limited to:

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 2020 guidance regarding the Public Readiness and Emergency Preparedness Act, the USDHHS provided liability protection for certain pharmacy technicians to administer some FDA-authorized or licensed vaccines regardless of state-specific law. This authorization will end when the declared public health emergency ends on May 11, 2023.

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.

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

No material is incorporated by reference.

12. An agency explanation about the situation justifying the rulemaking as an emergency rule:

Pharmacy technicians currently are authorized to administer vaccines under guidance issued by the USDHHS regarding the PREP Act in early 2020. The guidance provided qualified persons with liability protection when acting during a public health emergency such as that associated with the COVID19 pandemic. The guidance indicated 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. 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 go into effect before that date.

13. The date the Attorney General approved the rule:

14. 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.