

SECRETARY OF STATE

AGENCY RECEIPT

2021 JUL 23 AM 10:26

NOTICE OF RULEMAKING DOCKET OPENING

FILED

1. Agency name: Board of Pharmacy

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)

R4-23-411

Amend

R4-23-1104

Amend

NOTICE OF RULEMAKING DOCKET OPENING
BOARD OF PHARMACY

SECRETARY OF STATE

2021 JUL 23 AM 10:26

FILED

1. Title and its heading: 4. Professions and Occupations

Chapter and its heading: 23. Board of Pharmacy

Article and its heading: 4, Professional Practices; 11, Pharmacy Technicians

Section numbers: R4-23-411 and R4-23-1104

2. The subject matter of the proposed rule:

The Board is amending its rules to allow pharmacy technicians to perform additional tasks, including administering vaccines, when the task is delegated by the pharmacist on duty. The Board is making minor changes needed to align the rules with statute or to incorporate changes implemented during the COVID19 emergency. An exemption from Executive Order 2021-02 was provided by Trista Guzman Glover of the Governor's Office in an e-mail dated May 18, 2021.

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: 1616 W Adams Street, Suite 120
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

SECRETARY OF STATE

2021 JUL 28 PM 2:42

FILED

AGENCY RECEIPT

NOTICE OF PROPOSED RULEMAKING

1. Agency name: Board of Pharmacy

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)

R4-23-411

Amend

R4-23-1104

Amend

AGENCY CERTIFICATE
NOTICE OF PROPOSED RULEMAKING

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:**

<u>Article, Part, or Section Affected (as applicable)</u>	<u>Rulemaking Action</u>
(in numerical order)	
R4-23-411	Amend
R4-23-1104	Amend
5. **The rules contained in this package are true and correct as proposed.**



7/23/2021

6. _____
Signature of Agency Chief Executive Officer in ink

Date of signing

Kamlesh Gandhi
Printed or typed name of signer

Executive Director
Title of signer

SECRETARY OF STATE

2021 JUL 28 PM 2:42

Trista Guzman Glover <tguzman@az.gov> Tue, May 18, 2021 at 10:12 AM To: Kamlesh Gandhi
<kgandhi@azpharmacy.gov>

Hi, Kam -

I am following up on the rulemaking allowing technicians to perform additional tasks delegated by Pharmacists. This email serves as approval to begin working on that rulemaking process. Please be sure to share the final draft of rules with me.

Best,

Trista

Trista Guzman Glover | Office of Arizona Governor Doug Ducey

Director, Boards and Commissions

O. (602) 542-1308

www.azgovernor.gov

FILED

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

2021 JUL 28 PM 2:42

FILED

PREAMBLE

1. Articles, Parts, and Sections Affected

Rulemaking Action

R4-23-411

Amend

R4-23-1104

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)

Implementing statute: A.R.S. §§ 32-1923.01, 32-1925, 32-1961, and 32-1974

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: 1616 W Adams Street, Suite 120

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:

The Board is amending its rules to allow pharmacy technicians to perform additional tasks, including administering vaccines, when the task is delegated by the pharmacist on duty. The Board is making minor changes needed to align the rules with statute or to incorporate changes implemented during the COVID19 emergency. An exemption from Executive Order 2021-02 was provided by Trista Guzman Glover of the Governor's Office in an e-mail dated May 18, 2021.

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 expects the rulemaking to have minor economic impact. Expanding the scope of work for pharmacy technicians will enable pharmacy permittees to serve the public more efficiently and effectively.

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
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: Tuesday, September 21, 2021

Time: 9:00 A.M.

Location: 1616 W Adams St, Suite 120, 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:

No rule in this rulemaking is more stringent than federal law. There are numerous federal laws with which individuals dealing with drugs must comply but none is directly applicable to this rulemaking.

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

R4-23-411. Pharmacist-administered or Inter-administered Immunizations

ARTICLE 11. PHARMACY TECHNICIANS

Section

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

ARTICLE 4. PROFESSIONAL PRACTICES

R4-23-411. Pharmacist-administered or Intern-administered Immunizations

- A.** Authorization to administer immunizations, vaccines, and emergency medications, as defined at A.R.S. § 32-1974(N), to an eligible adult patient or eligible minor patient. As used in this Section, “eligible adult patient” means an eligible patient 13 years of age or older and “eligible minor patient” means an eligible patient at least three years of age but less than 13 years of age. A pharmacist or an intern in the presence of and under the immediate personal supervision of a pharmacist, may administer, without a prescription, immunizations, vaccines, and emergency medications to an eligible adult patient or eligible minor patient, if:
1. Both the pharmacist and intern meet the qualifications and standards specified by A.R.S. § 32-1974 and this Section;
 2. The Board authorizes both the pharmacist and intern as specified in subsection (D);
 3. For an eligible adult patient, the immunization or vaccine is:
 - a. Recommended for adults by the United States Centers for Disease Control and Prevention; or
 - b. Recommended by the United States Centers for Disease Control and Prevention’s Health Information for International Travel;
 4. For an eligible adult patient, the immunization or vaccine is not on the Arizona Department of Health Services list specified in A.A.C. R9-6-1301 as required under A.R.S. § 32-1974(I);
 5. For an eligible minor patient, the immunization or vaccine is for influenza or a booster dose as described under A.R.S. § 32-1974(B)(2); and
 6. For an eligible minor patient, any immunizations or vaccines other than influenza or a booster dose as described under A.R.S. § 32-1974(B)(2) are administered in response to a public health emergency declared by the Governor under A.R.S. § 36-787.
- B.** A pharmacist or an intern in the presence of and under the immediate personal supervision of a pharmacist, may administer, with a prescription, any immunizations, vaccines, and emergency medications to an eligible adult patient or eligible minor patient, if:
1. Both the pharmacist and intern meet the qualifications and standards specified by A.R.S. § 32-1974 and this Section; and
 2. The Board authorizes both the pharmacist and intern as specified in subsection (D).
- C.** A pharmacist or intern who is authorized to administer immunizations, vaccines, and emergency medications to an eligible adult patient or eligible minor patient shall:
1. Not delegate the authority to any other pharmacist, intern, or employee not specifically authorized by rule; and

2. Maintain their current certificate for inspection by the Board or its designee or review by the public.

D. Qualifications to administer immunizations, vaccines, and emergency medications to an eligible adult patient or eligible minor patient. After receipt of a completed application form, the Board shall authorize the administration of immunizations, vaccines, and emergency medications to an eligible adult patient or eligible minor patient by a pharmacist or intern who meets the following qualifications:

1. Has a current license to practice pharmacy in this state,
2. Successfully completes a training program specified in subsection (E), and
3. Has a current certificate in basic cardiopulmonary resuscitation.

E. Immunizations training program requirements. A training program for pharmacists or interns to administer immunizations, vaccines, and emergency medications to an eligible adult patient or eligible minor patient shall include the following courses of study:

1. Basic immunology and the human immune response;
2. Mechanics of immunity, adverse effects, dose, and administration schedule of available vaccines;
3. Response to an emergency situation as a result of the administration of an immunization, vaccine, or medication including administering an emergency medication to counteract the adverse effects of the immunization, vaccine, or medication given;
4. Administration of intramuscular injections;
5. Other immunization administration methods; and
6. Recordkeeping and reporting requirements specified in subsection (F).

F. Recordkeeping and reporting requirements.

1. A pharmacist or intern authorized under this Section to administer immunizations, vaccines, and emergency medications to an eligible patient shall provide to the pharmacy the following information and documentation regarding each immunization, vaccine, or emergency medication administered:
 - a. The name, address, and date of birth of the patient;
 - b. The date of administration and site of injection;
 - c. The name, dose, manufacturer's lot number, and expiration date of the vaccine, immunization, or emergency medication;
 - d. The name and address of the patient's identified primary-care provider or physician;
 - e. The name of the pharmacist or intern administering the immunization, vaccine, or emergency medication;

- f. A record of the pharmacist's or intern's consultation with the patient determining that the patient is an eligible patient as defined in R4-23-110;
 - g. Consultation or other professional information provided to the patient by the pharmacist or intern;
 - h. The name and date of the immunization or vaccine information sheet provided to the patient; and
 - i. For an immunization or vaccine given to an eligible minor patient, a consent form signed by the minor's parent or guardian.
2. As required under A.R.S. § 32-1974(F)(1), the pharmacist or intern shall provide a written or electronic report to the patient's primary-care provider or physician containing the documentation required in subsection (F)(1)(a) through (d). The pharmacy shall document the time and date the report is sent and make the record of compliance with this subsection available in the pharmacy or on request, within 72 hours, for inspection by the Board or its designee.
 3. A pharmacy's pharmacist-in-charge or permittee shall maintain the records required in subsection (F)(1) in the pharmacy or database for a minimum of seven years from the administration date.
- G.** Confidentiality of records. A pharmacist, intern, pharmacy permittee, or pharmacist-in-charge shall comply with applicable state and federal privacy statutes and rules when releasing patient health information.
- H.** Pharmacist-administered or intern-administered adult immunizations that require a prescription order. A pharmacist or intern authorized by the Board to administer adult immunizations or vaccines shall not administer any immunization or vaccine listed in A.A.C. R9-6-1301 without a prescription order. In addition to filing a prescription order as required in A.R.S. § 32-1964, a pharmacist or pharmacy intern who administers an immunization or vaccine listed in A.A.C. R9-6-1301 shall comply with the recordkeeping requirements of subsection (F)(1).

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 ~~a graduate intern, pharmacy 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 ~~graduate or pharmacy~~ 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, ~~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 R4-23-1104.01(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);

5. Administer a vaccine when:
 - a. Authority to administer the vaccine is delegated by the pharmacist on duty;
 - b. Administration of the vaccine is done under a pharmacist's order that complies with A.R.S. § 32-1974 and R4-23-411;
 - c. Administration of the vaccine is done under the supervision of a pharmacist on duty who is certified by the Board under A.R.S. § 32-1974(D) to administer vaccines; and
 - d. There is evidence in the pharmacy file 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;
 - ii. Current certification in basic cardiopulmonary resuscitation; and
 - iii. Two hours of continuing education during each license renewal period that are about administration of vaccines and approved by the Accreditation Council for Pharmacy Education; and
6. Perform any task 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 evidence of the training exists in the pharmacy file. 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.
- 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, ~~graduate intern,~~ or pharmacy 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.