



Notices of Final Rulemaking

rulemaking moratorium imposed by the Governor in 2009. Subsection (F) allows medical practitioners and pharmacies to request access to the monitoring program database, but in reality the program gives access to medical practitioners and pharmacists. Subsection (F) will be amended to remove references to a pharmacy obtaining access and insert pharmacists. The rulemaking will clean up the language to make it more clear, concise, and understandable. The rule will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and the Governor's Regulatory Review Council.

The Board believes that approval of the rules benefits the public and the pharmacy and medical communities by establishing a central repository of all prescriptions dispensed for Schedule II, III, and IV controlled substances in Arizona. The program improves the State's ability to identify controlled substance abusers or misusers and refer them to treatment, and to identify and stop diversion of prescription drugs in an efficient and cost effective manner that will not impede the appropriate medical utilization of licit controlled substances.

**7. A reference to any study relevant to the rules that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rules, 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 agency did not review or rely on any study relevant to the rule.

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

The amended rule will impact the Board medical practitioners, pharmacists, and pharmacies. The amended rule's impact on the Board will be the usual rulemaking-related costs, which are minimal.

The Board estimates the amended rules will have no economic impact on medical practitioners, pharmacists and pharmacies. The purpose of the existing rule R4-23-501 is to establish the registration requirements of A.R.S. § 36-2606. The registration requirements of A.R.S. § 36-2606 apply only to medical practitioners, not pharmacies. The changes to the rule remove the requirement in subsection (E) for pharmacies to register with the Controlled Substances Prescription Monitoring Program. It is not necessary to register pharmacies with the CSPMP, because every pharmacy is already issued a pharmacy permit by the Board to do business as a pharmacy. A.R.S. § 36-2604 defines to whom the monitoring program may give access to the information in the database. R4-23-501(F) gives access to a medical practitioner and pharmacy, but the program has always given access to medical practitioners and pharmacists. The program has never given access to a pharmacy, but does give access to the pharmacist in the pharmacy that dispenses the drug. The statute [A.R.S. § 36-2604(C)(1)] allows the Board to give access to "a person who is authorized to prescribe or dispense a controlled substance...", which means a medical practitioner or pharmacist. The proposed rule will amend R4-23-501(F) by taking out references to a pharmacy requesting access to the CSPMP database and inserting language for a pharmacist requesting access to the CSPMP database. None of these changes will have an economic impact on medical practitioners, pharmacists, or pharmacies.

The Board believes that approval of the rules benefits the public and the pharmacy and medical communities by establishing a central repository of all prescriptions dispensed for Schedule II, III, and IV controlled substances in Arizona. The program improves the State's ability to identify controlled substance abusers or misusers and refer them to treatment, and to identify and stop diversion of prescription drugs in an efficient and cost effective manner that will not impede the appropriate medical utilization of licit controlled substances.

**10. A description of any changes between the proposed rulemaking, to include supplemental notices, and the final rulemaking:**

There are no substantial changes in the final rules from the proposed rules. There are minor changes to style, format, grammar, and punctuation requested by GRRC staff.

**11. An agency's summary of the public stakeholder comments made about the rulemaking and the agency response to the comments:**

A public hearing was held August 27, 2012. Janet Underwood, representing the Arizona Community Pharmacy Committee, attended the public hearing. Ms. Underwood provided written comment from The Arizona Community Pharmacy Committee, voicing support for the rulemaking. No other comments were received.

**12. All agencies shall list any 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:**

**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 rule itself does not require a permit. However, the registration required by statute arguably falls within the definition of general permit in A.R.S. section 41-1001.

**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

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**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

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

None

**14. Whether the rule was previously made, amended or repealed as an emergency rule. If so, cite the notice published in the Register as specified in R1-1-409(A). Also, the agency shall state where the text was changed between the emergency and the final rulemaking packages:**

No

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

**TITLE 4. PROFESSIONS AND OCCUPATIONS**

**CHAPTER 23. BOARD OF PHARMACY**

**ARTICLE 5. CONTROLLED SUBSTANCES PRESCRIPTION MONITORING PROGRAM**

Section

R4-23-501. Controlled Substances Prescription Monitoring Program Registration

**ARTICLE 5. CONTROLLED SUBSTANCES PRESCRIPTION MONITORING PROGRAM**

**R4-23-501. Controlled Substances Prescription Monitoring Program Registration**

- A.** Under A.R.S. § 36-2606, a medical practitioner who is issued a license under A.R.S. Title 32, Chapter 7, 11, 13, 14, 15, 16, 17, 21, 25, or 29 and possesses a current DEA registration under the Federal Controlled Substances Act shall have a current CSPMP registration issued by the Board.
- B.** Application. To obtain a CSPMP registration, a person shall submit a completed application on a form furnished by the Board that includes:
1. Applicant's name, address, mailing address, if different, e-mail address, telephone number, facsimile number, license number issued under A.R.S. Title 32, Chapter 7, 11, 13, 14, 15, 16, 17, 21, 25, or 29, and DEA registration number;
  2. Whether the applicant's license and DEA registration listed in subsection (B)(1) are current and in good standing, and if not, the status of the license and registration; and
  3. Date signed and applicant's verified signature.
- C.** Registration. Within seven business days of receipt of a completed application specified in subsection (B), the Board office shall determine whether an application is complete. If the application is complete, the Board office shall issue a registration number and mail a current renewal receipt to the applicant. If the application is incomplete, the Board office shall issue a notice of incompleteness. An applicant with an incomplete application shall comply with the requirements of R4-23-202(F)(2) and (3).
- D.** Registration renewal. As specified in A.R.S. § 36-2606(C), the Board shall automatically suspend the registration of any registrant that fails to renew the registration on or before May 1 of the year in which the renewal is due. The Board shall vacate a suspension if the registrant submits a renewal application. A suspended registrant is prohibited from accessing information in the prescription monitoring program database.
- E.** Pharmacy registration and renewal. Each pharmacy with a current Board-issued pharmacy permit and a current DEA registration is automatically registered in the CSPMP. Existing pharmacy permittees who possess a current DEA registration will receive a registration receipt before the implementation date of the CSPMP. For pharmacy permits issued on or after the CSPMP implementation date, the Board will issue a registration receipt when issuing the pharmacy's permit. Each pharmacy shall renew the CSPMP registration on or before May 1 of the year in which the renewal is due. The Board shall automatically suspend the registration of any registrant that fails to renew the registration on or before the date on which the renewal is due. The Board shall vacate a suspension if the registrant submits a renewal application. A suspended registrant is prohibited from accessing information in the prescription monitoring program database.
- F.** CSPMP database access.
1. A medical practitioner ~~or pharmacy~~ that chooses to use the CSPMP database shall request ~~a user name and password in writing~~ access from the CSPMP Director on forms provided on the Board's web site. Upon receipt of the request, the CSPMP Director or designee shall issue ~~a user name and password~~ access credentials provided the medical practitioner ~~or pharmacy~~ is in compliance with the registration requirements of this Section and has completed the Board's CSPMP Online Training Program.
  2. A pharmacist that chooses to use the CSPMP database shall request access from the CSPMP Director on forms provided on the Board's web site. Upon receipt of the request, the CSPMP Director or designee shall issue access creden-



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section R4-23-692(A)(5). R4-23-692(A)(5) cites A.R.S. § 32-1932 and the citation should be A.R.S. § 32-1927.02. The review also determined that R4-23-692(B) uses an incorporation by reference for 21 CFR 210 through 211 published in April 1, 1996. The Board feels that the incorporation by reference should be updated to the most current edition of the Code of Federal Regulations. The rulemaking will amend R4-23-692(A)(5) with the correct statutory citation and amend subsection R4-23-692(B) to update the incorporation by reference for 21 CFR 210 through 211 to the edition published April 1, 2011. The rule will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and the Governor's Regulatory Review Council.

The Board believes that approval of these rules will benefit the public health and safety by clearly establishing standards for the pharmacy area of a community pharmacy, the provision of shared pharmacy services, and the distribution of compressed medical gases.

**7. A reference to any study relevant to the rules that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rules, 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 agency did not review or rely on any study relevant to the rule.

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

The amended rules will impact the Board, compressed medical gas distributors, and pharmacies. The amended rule's impact on the Board will be the usual rulemaking-related costs, which are minimal.

The Board estimates the amended rules will have minimal economic impact on compressed medical gas distributors and pharmacies. The changes are meant to improve the rules' clarity, conciseness, and understandability and will have no economic impact. The changes to R4-23-609 will correct incorrect citations caused by statutory changes from 2007. The changes to R4-23-621(E) will add the word "that" between the words "permittee" and "provides" to improve clarity. The changes to R4-23-621(C)(2)(a) and (b) will replace the telephone number of the filling pharmacy with the telephone number of the pharmacy utilizing shared services that has access to the patient's records, thus improving the patient's access to a pharmacist to answer questions specific to the patient's records. The changes to R4-23-692 will correct incorrect citations caused by statutory changes in 2005 and update incorporation by references to federal law. None of these changes cause increased costs for compressed medical gas distributors or pharmacies.

The Board believes that approval of these rules will benefit the public health and safety by clearly establishing standards for the pharmacy area of a community pharmacy, the provision of shared pharmacy services, and the distribution of compressed medical gases.

**10. A description of any changes between the proposed rulemaking, to include supplemental notices, and the final rulemaking:**

There are no substantial changes in the final rules from the proposed rules. There are minor changes to style, format, grammar, and punctuation requested by GRRC staff.

**11. An agency's summary of the public stakeholder comments made about the rulemaking and the agency response to the comments:**

A public hearing was held August 27, 2012. Janet Underwood, representing the Arizona Community Pharmacy Committee, attended the public hearing. Ms. Underwood provided written comment from The Arizona Community Pharmacy Committee, voicing support for the rulemaking. No other comments were received.

**12. All agencies shall list any 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:**

**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 rules require a permit. The Board does not issue a general permit, but issues the specific permit required under A.R.S. § 32-1930.

**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:**

Yes, federal law is incorporated by reference to ensure that the rules are not more stringent.

**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

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

21 CFR 210 through 211, April 1, 2011 in R4-23-692(B).

**14. Whether the rule was previously made, amended or repealed as an emergency rule. If so, cite the notice published in the Register as specified in R1-1-409(A). Also, the agency shall state where the text was changed between the emergency and the final rulemaking packages:**

No

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

**TITLE 4. PROFESSIONS AND OCCUPATIONS**

**CHAPTER 23. BOARD OF PHARMACY**

**ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS**

Section

R4-23-609. Pharmacy Area of Community Pharmacy

R4-23-621. Shared Services

R4-23-692. Compressed Medical Gas Distributor

**ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS**

**R4-23-609. Pharmacy Area of Community Pharmacy**

- A.** Minimum area of community pharmacy. The minimum area of a community pharmacy, the actual area primarily devoted to stocking drugs restricted to pharmacists, and to the compounding and dispensing of prescription medication, exclusive of office area or other support function area, shall not be less than 300 square feet. A maximum of three pharmacy personnel may practice or work simultaneously in the minimum area. The pharmacy permittee shall provide an additional 60 square feet of floor area for each additional pharmacist, graduate intern, pharmacy intern, pharmacy technician, pharmacy technician trainee, or support personnel who may practice or work simultaneously. All of the allotted square footage area, including adequate shelving, shall lend itself to efficient pharmaceutical practice and permit free movement and visual surveillance of personnel by the pharmacist.
- B.** Compounding and dispensing counter. On or after January 6, 2004, a pharmacy permit applicant or remodel or relocation applicant shall provide a compounding and dispensing counter that provides a minimum of three square feet of pharmacy counter working area of not less than 16 inches in depth and 24 inches in length for the practice of one pharmacist, graduate intern, pharmacy intern, pharmacy technician, or pharmacy technician trainee. For each additional pharmacist, graduate intern, pharmacy intern, pharmacy technician, or pharmacy technician trainee practicing simultaneously, there shall be an additional three square feet of pharmacy counter working area of not less than 16 inches in depth and 24 inches in length. The Board shall determine a pharmacy's total required compounding and dispensing counter area by multiplying the maximum number of personnel allowed in the pharmacy area using the requirements specified in subsection (A) by three square feet per person. A pharmacy permittee or pharmacist-in-charge may operate the pharmacy with a total pharmacy counter working area specified in subsection (A) that is equal to the actual maximum number of pharmacists, graduate interns, pharmacy interns, pharmacy technicians, and pharmacy technician trainees, working simultaneously in the pharmacy area times three square feet per person.
- C.** Working area for compounding and dispensing counter. The aisle floor area used by the pharmacist, graduate intern, pharmacy intern, pharmacy technician, or pharmacy technician trainee at the compounding and dispensing counter shall extend the full length of the counter and be clear and continuous for a minimum of 36 inches from any counter, fixture, or structure.
- D.** Area for patient counseling. On or after April 1, 1995, a pharmacy permit applicant or remodel or relocation applicant shall provide a separate and distinct patient counseling area that provides patient privacy. This subsection does not apply to a pharmacy exempt from the requirements of R4-23-402(B).
- E.** Narcotic cabinet or safe. To prevent diversion, narcotics and other controlled substances may be:
  - 1. Kept in a separate locked cabinet or safe, or
  - 2. Dispersed throughout the pharmacy's prescription-only drug stock.
- F.** Building security standard of community pharmacy area. The pharmacy area shall be enclosed by a permanent barrier or partition from floor or counter to structural ceiling or roof, with entry doors that can be securely locked. The barrier shall be designed so that only a pharmacist can access the area where prescription-only drugs, narcotics, and other controlled substances are stored, compounded and dispensed. The permanent barrier may be constructed of other than a solid material. If constructed of a material other than a solid, the openings or interstices of the material shall not be large enough to permit removal of items in the pharmacy area through the barrier. Any material used in the construction of the permanent barrier must be of sufficient strength and thickness that it cannot be readily or easily removed, penetrated, or bent. The pharmacy permittee shall submit plans and specifications of the permanent barrier to the Board for approval.
- G.** Drug storage and security.

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1. The pharmacy permittee shall ensure that drugs and devices are stored in a dry, well-lit, ventilated, and clean and orderly area. The pharmacy permittee shall maintain the drug storage area at temperatures that ensure the integrity of the drugs before dispensing as stated in the official compendium defined in A.R.S. § ~~32-1901(52)~~ 32-1901(55) or the manufacturer's or distributor's labeling.
  2. If the pharmacy permittee needs additional storage area for drugs that are restricted to sale by a pharmacist, the pharmacy permittee shall ensure that the area is contained by a permanent barrier from floor or counter to structural ceiling or roof. The pharmacy permittee shall lock all doors and gates to the drug storage area. Only a pharmacist with a key is permitted to enter the storage area, except in an extreme emergency.
- H. A pharmacy permittee or pharmacist-in-charge shall ensure that the pharmacy working counter area is protected from unauthorized access while the pharmacy is open for business by a barrier not less than 66 inches in height or another method approved by the Board or its designee.

**R4-23-621. Shared Services**

- A. Before participating in shared services, a pharmacy shall have either a current resident or non-resident pharmacy permit issued by the Board.
- B. A pharmacy may provide or utilize shared services functions only if the pharmacies involved:
1. Have the same owner~~s~~, or
  2. Have a written contract or agreement that outlines the services provided and the shared responsibilities of each party in complying with federal and state pharmacy statutes and rules~~s~~, and
  3. Share a common electronic file or technology that allows access to information necessary or required to perform shared services in conformance with the pharmacy act and the Board's rules.
- C. Notifications to patients.
1. Before using shared services provided by another pharmacy, a pharmacy permittee shall:
    - a. Notify patients that their orders may be processed or filled by another pharmacy; and
    - b. Provide the name of that pharmacy or, if the pharmacy is part of a network of pharmacies under common ownership and any of the network pharmacies may process or fill the order, notify the patient of this fact. The notification may be provided through a one-time written notice to the patient or through use of a sign in the pharmacy.
  2. If an order is delivered directly to the patient by a filling pharmacy and not returned to the requesting pharmacy, the filling pharmacy permittee shall ensure that the following is placed on the prescription container or on a separate sheet delivered with the prescription container:
    - a. The local, and if applicable, the toll-free telephone number of the ~~filling~~ pharmacy utilizing shared services that has access to the patient's records; and
    - b. A statement that conveys to the patient or patient's care-giver the following information: "Written information about this prescription has been provided for you. Please read this information before you take the medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions at (insert the ~~filling pharmacy's~~ local and toll-free telephone numbers of the pharmacy utilizing shared services that has access to the patient's records)."
  3. The provisions of subsection (C) do not apply to orders delivered to patients in facilities where a licensed health care professional is responsible for administering the prescription medication to the patient.
- D. A pharmacy permittee engaged in shared services shall:
1. Maintain manual or electronic records that identify, individually for each order processed, the name, initials, or identification code of each pharmacist, graduate intern, pharmacy intern, pharmacy technician, and pharmacy technician trainee who took part in the order interpretation, order entry verification, drug utilization review, drug compatibility and drug allergy review, final order verification, therapeutic intervention, or refill authorization functions performed at that pharmacy;
  2. Maintain manual or electronic records that identify, individually for each order filled or dispensed, the name, initials, or identification code of each pharmacist, graduate intern, pharmacy intern, pharmacy technician, and pharmacy technician trainee who took part in the filling, dispensing, and counseling functions performed at that pharmacy;
  3. Report to the Board as soon as practical the results of any disciplinary action taken by another state's pharmacy regulatory agency involving shared services;
  4. Maintain a mechanism for tracking the order during each step of the processing and filling procedures performed at the pharmacy;
  5. Provide for adequate security to protect the confidentiality and integrity of patient information; and
  6. Provide for inspection of any required record or information within 72 hours of any request by the Board or its designee.
- E. Each pharmacy permittee that provides or utilizes shared services shall develop, implement, review, revise, and comply with joint policies and procedures for shared services in the manner described in R4-23-610(A)(2). Each pharmacy permittee is required to maintain only those portions of the joint policies and procedures that relate to that pharmacy's operations. The policies and procedures shall:
1. Outline the responsibilities of each of the pharmacies;

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2. Include a list of the name, address, telephone numbers, and all license and permit numbers of the pharmacies involved in shared services; and
3. Include policies and procedures for:
  - a. Notifying patients that their orders may be processed or filled by another pharmacy and providing the name of that pharmacy;
  - b. Protecting the confidentiality and integrity of patient information;
  - c. Dispensing orders when the filled order is not received or the patient comes in before the order is received;
  - d. Maintaining required manual or electronic records to identify the name, initials, or identification code and specific activity or activities of each pharmacist, graduate intern, pharmacy intern, pharmacy technician, or pharmacy technician trainee who performed any shared services;
  - e. Complying with federal and state laws; and
  - f. Operating a continuous quality improvement program for shared services, designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.
- F. Nothing in this Section shall prohibit an individual pharmacist licensed in Arizona, who is an employee of or under contract with a pharmacy, or an Arizona-licensed graduate intern, pharmacy intern, pharmacy technician, or pharmacy technician trainee, working under the supervision of the pharmacist, from accessing that pharmacy's electronic database from inside or outside the pharmacy and performing the order processing functions permitted by the pharmacy act, if both of the following conditions are met:
  1. The pharmacy establishes controls to protect the confidentiality and integrity of patient information; and
  2. None of the database is duplicated, downloaded, or removed from the pharmacy's electronic database.

**R4-23-692. Compressed Medical Gas Distributor**

**A. Permit:**

1. A person shall not manufacture, process, transfill, package, or label a compressed medical gas before a compressed medical gas distributor permit is issued by the Board or its designee following a satisfactory final inspection by a Board compliance officer.
2. Before operating as a compressed medical gas distributor, a person shall register with the FDA as a medical gas manufacturer and comply with the drug listing requirements of the federal act.
3. To obtain a compressed medical gas distributor permit a person shall submit a completed application, on a form furnished by the Board, to the Board's office.
4. A compressed medical gas distributor permittee shall distribute a compressed medical gas only:
  - a. Pursuant to a compressed medical gas order; and
  - b. If the compressed medical gas is listed on the distributor's permit application. To receive approval to distribute an additional compressed medical gas, the permittee shall request that the permit application be amended.
    - i. The permittee shall send a written request to amend the permit application to the Board office.
    - ii. The request shall include documentation that the FDA has approved manufacture of the additional compressed medical gas not listed on the original permit application.
    - iii. If a request to amend an original permit application includes the documentation referenced in subsection (A)(4)(b)(ii) and if the Board or its designee determines that the amendment is in the interest of public health and safety, the Board or its designee shall approve the request to amend within 30 days of receipt.
5. A compressed medical gas distributor permit is subject to denial, suspension, or revocation under ~~A.R.S. § 32-1932~~ A.R.S. § 32-1927.02.

**B. Current Good Manufacturing Practice:** A compressed medical gas distributor permittee shall comply with the current good manufacturing practice requirements of 21 CFR 210 through 211, published ~~April 1, 1996~~ April 1, 2011, (and no future amendments or editions), incorporated by reference and on file with the Board ~~and the office of the Secretary of State~~.

**C. Records:** A compressed medical gas distributor permittee shall establish and implement written procedures for maintaining records pertaining to production, transfilling, process control, labeling, packaging, quality control, distribution, complaints, and any information required by federal or state law.

1. A permittee shall retain the records required by this Article and 21 CFR 210 through 211 for at least two years after distribution of the compressed medical gas or one year after the expiration date of the compressed medical gas, whichever is longer.
2. A permittee shall make the records required by this Article and 21 CFR 210 through 211 available within 48 hours for review by the Board, its compliance officers, or the FDA.

**D. Inspections:** A permittee shall make the compressed medical gas distributor's facility available for inspection by the Board or its compliance officers under A.R.S. § 32-1904.

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

[R13-06]

**PREAMBLE**

- 1. Articles, Parts, or Sections Affected**

	<b><u>Rulemaking Action</u></b>
R4-23-1101	Amend
R4-23-1102	Amend
R4-23-1104	Amend
R4-23-1105	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. §§ 32-1901(66) and (67), 32-1923.01, 32-1924, 32-1925, 32-1926, and 32-1927.01
  
- 3. The effective date of the rule:**

March 10, 2013
  
- 4. 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: 18 A.A.R. 1349, June 15, 2012  
Notice of Proposed Rulemaking: 18 A.A.R. 1340, June 15, 2012
  
- 5. The agency's contact person who can answer questions about the rulemaking:**

Name:	Dean Wright, Compliance Officer
Address:	Board of Pharmacy P.O. Box 18520 Phoenix, AZ 85005
Telephone:	(602) 771-2727
Fax:	(602) 771-2749
E-mail:	dwright@azpharmacy.gov
Web site:	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:**

During the Board's 5-Year Rule Review approved May 5, 2009, the Board determined that R4-23-1101, Licensure and Eligibility; R4-23-1102, Pharmacy Technician Licensure; R4-23-1104, Pharmacy Technicians and Pharmacy Technician Trainees; and R4-23-1105, Pharmacy Technician Training Program, needed to be amended to correct inconsistencies and improve clarity, conciseness, and understandability.

When the rules were made in 2004, the Board felt that the majority of applicants would follow the normal progression of licensure as a pharmacy technician trainee, proceed through the training required in R4-23-1105(B), pass the pharmacy technician examination, and apply for licensure as a pharmacy technician. However, we found that many applicants had already passed the pharmacy technician examination either before the law changed or in another state. These applicants may not have completed a pharmacy's training course, but had a job in a pharmacy and needed a license to work. The Board's staff licensed the applicants without the required proof of completing a pharmacy technician training program as required in R4-23-1101(A)(1). The Board is inconsistently enforcing a rule, which should be amended to reflect the real world situation. The Board also determined that R4-23-1104 should be amended to require technicians to "accurately" perform the functions listed in subsections (A) and (B).

The rulemaking will amend R4-23-1101, R4-23-1102, and R4-23-1105 to make the rules work better and allow consistent enforcement. The rulemaking will amend R4-23-1104 by adding a new subsection with language that requires pharmacy technicians and pharmacy technician trainees to perform their permissible functions accurately. The rule will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and the Governor's Regulatory Review Council.

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The Board believes that approval of these rules will benefit the public health and safety by clearly establishing standards for the licensing and practice of pharmacy technician trainees and pharmacy technicians.

- 7. A reference to any study relevant to the rules that the agency reviewed and either relied on or did not rely on in its evaluation of or justification for the rules, 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 agency did not review or rely on any study relevant to the rule.

- 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. The summary of the economic, small business, and consumer impact:**

The amended rules will impact the Board, pharmacy technician trainees, pharmacy technicians, pharmacists, and pharmacies. The amended rules' impact on the Board will be the usual rulemaking-related costs, which are minimal.

The Board estimates the amended rules will have minimal economic impact on pharmacy technician trainees, pharmacy technicians, pharmacists and pharmacies. The rulemaking is necessary to correct inconsistencies in the rules that have caused one subsection, R4-23-1101(A), to be inconsistently enforced and have created general confusion about training requirements and documentation. The rulemaking will reduce the paperwork required of a pharmacist-in-charge and save them time. The rulemaking will clarify the training requirements for both pharmacy technician trainees and pharmacy technicians. The rulemaking will specify that pharmacy technician trainees and pharmacy technicians are responsible for performing their duties accurately. The Board estimates that the rulemaking will have minimal economic impact.

The Board believes that approval of these rules will benefit the public health and safety by clearly establishing standards for the licensing and practice of pharmacy technician trainees and pharmacy technicians.

- 10. A description of any changes between the proposed rulemaking, to include supplemental notices, and the final rulemaking:**

There are no substantial changes in the final rules from the proposed rules. There is a correction in R4-23-1105(D)(2) due to incorrect formatting that added duplicative language at the end of the subsection. In R4-23-1105(D)(1), (2), and (3), the words "in-store" are changed to the words "on-the-job" to improve clarity. There are other minor changes to style, format, grammar, and punctuation requested by GRRC staff.

- 11. An agency's summary of the public stakeholder comments made about the rulemaking and the agency response to the comments:**

A public hearing was held July 16, 2012. No one attended the public hearing. The Board received one written comment from Janet Underwood, representing The Arizona Community Pharmacy Committee, voicing support for the rulemaking. No other comments were received.

- 12. All agencies shall list any 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:**

- 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 rule itself does not require a permit. However, the license required by statute arguably falls within the definition of general permit in A.R.S. § 41-1001.

- 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

- 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

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

None

- 14. Whether the rule was previously made, amended or repealed as an emergency rule. If so, cite the notice published in the Register as specified in R1-1-409(A). Also, the agency shall state where the text was changed between the emergency and the final rulemaking packages:**

No

- 15. The full text of the rules follows:**

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 11. PHARMACY TECHNICIANS

Section

- R4-23-1101. Licensure and Eligibility
- R4-23-1102. Pharmacy Technician Licensure
- R4-23-1104. Pharmacy Technicians and Pharmacy Technician Trainees
- R4-23-1105. Pharmacy Technician Trainee Training Program, Pharmacy Technician Drug Compounding Training Program, and Alternative Pharmacy Technician Training

ARTICLE 11. PHARMACY TECHNICIANS

**R4-23-1101. Licensure and Eligibility**

- A. License required. A person shall not work as a pharmacy technician or pharmacy technician trainee in Arizona, unless the person:
  - ~~1. Possesses~~ possesses a pharmacy technician or pharmacy technician trainee license issued by the Board;
  - ~~2. Reads and discusses with the pharmacist in charge of the pharmacy where employed, the Board rules concerning pharmacy technicians and pharmacy technician trainees, the pharmacy technician and pharmacy technician trainee job description, and the policies and procedures manual of that pharmacy; and~~
  - ~~3. Dates and signs a statement that the person has complied with subsection (A)(2).~~
- B. Eligibility.
  - 1. To be eligible for licensure as a pharmacy technician trainee, a person shall:
    - a. Be of good moral character,
    - b. Be at least 18 years of age, and
    - c. Have a high school diploma or the equivalent of a high school diploma.
  - 2. To be eligible for licensure as a pharmacy technician, a person shall:
    - a. Meet the requirements of subsection (B)(1),
    - b. Complete a pharmacy technician training program that meets the standards prescribed in R4-23-1105, and
    - c. Pass the Pharmacy Technician Certification Board (PTCB) examination or another Board-approved pharmacy technician examination.
- C. A pharmacy technician delinquent license. Before an Arizona pharmacy technician license will be reinstated, a pharmacy technician whose Arizona pharmacy technician license is delinquent for five or more consecutive years shall furnish to the Board satisfactory proof of fitness to be licensed as a pharmacy technician and pay all past due biennial renewal fees and penalty fees. Satisfactory proof includes:
  - 1. For a person with a delinquent license who is practicing as a pharmacy technician out-of-state with a pharmacy technician license issued by another jurisdiction:
    - a. Proof of current, unrestricted pharmacy technician licensure in another jurisdiction; and
    - b. Proof of employment as a pharmacy technician during the last 12 months; or
  - 2. For a person with a delinquent license who did not practice as a pharmacy technician within the last 12 months:
    - a. Take and pass a Board-approved pharmacy technician examination, and
    - b. ~~Complete 120 hours of pharmacy technician training as a pharmacy technician trainee licensed under R4-23-1103~~ 20 contact hours or two CEUs of continuing education activity sponsored by an approved provider, including at least two contact hours or 0.2 CEUs of continuing education activity in pharmacy law, ~~or~~
    - e. ~~Complete 480 hours of pharmacy technician training as a pharmacy technician trainee licensed under R4-23-1103.~~

**R4-23-1102. Pharmacy Technician Licensure**

- A. Application. An applicant for licensure as a pharmacy technician shall:
  - 1. Provide the Board proof that the applicant is eligible under R4-23-1101(B)(2), including documentation that the applicant:
    - a. Completed a pharmacy technician training program that meets the standards prescribed in ~~R4-23-1105~~ R4-23-1105(B)(2); and
    - b. Passed the Pharmacy Technician Certification Board (PTCB) examination or another Board-approved pharmacy technician examination; or
    - c. Meets the requirements of R4-23-1105(D)(1) or (2);
  - 2. File an application on a form furnished by the Board, that includes:
    - a. Applicant's name, address, mailing address, if different, telephone number, and Social Security number;

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- b. Whether the applicant has ever been convicted of an offense involving moral turpitude, a felony offense, or any drug-related offense or has any currently pending felony or drug-related charge, and if so, indicate charge, charge date, conviction date, and jurisdiction;
  - c. Whether the applicant has ever had a pharmacy technician license revoked, suspended, or has a pending revocation or suspension action, or denied in this state or any other jurisdiction, and if so, indicate where and when;
  - d. Pharmacy name and address where the pharmacy technician will practice;
  - e. Date signed and applicant's verified signature; and
  - f. The wall license and initial licensure fees specified in R4-23-205.
- B.** Licensure. Within seven business days of receipt of a completed application, fees, and other information specified in subsection (A), the Board office shall determine whether the application is complete. If the application is complete, the Board shall assess whether the applicant is qualified under statute and rule. If the applicant is qualified, the Board office shall issue a license number and mail a license to the applicant. An applicant who is issued a license number may begin practice as a pharmacy technician. The Board office shall mail a wall license to the licensee within 14 days of issuing the license number.
- C.** License renewal. To renew a license, a pharmacy technician shall submit a license renewal form supplied by the Board with the biennial renewal fee specified in R4-23-205. The Board office will process the application for renewal in the same manner described in subsection (B).
- D.** If the biennial renewal fee is not paid by November 1 of the renewal year specified in A.R.S. § 32-1925, the pharmacy technician license is suspended and the licensee shall pay a penalty as provided in A.R.S. § 32-1925 and R4-23-205 to vacate the suspension.

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

- A.** Permissible activities 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 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 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. Type and affix a label for a prescription medication or enter information for a new or refill prescription medication into a computer, if a pharmacist verifies the accuracy 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. Reconstitute a prescription medication, if a pharmacist checks the ingredients and procedure before reconstitution and verifies the final product after reconstitution;
  - 6. 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;
  - 7. Prepackage drugs in accordance with R4-23-402(A); and
  - 8. 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 activities of a pharmacy technician. Acting in compliance with all applicable statutes and rules and under the supervision of a pharmacist, a pharmacy technician may:
- 1. Perform the activities 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~~ 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.
- C.** When performing the activities listed in 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 accurately.
- ~~E.D.~~ Prohibited activities. A pharmacy technician or pharmacy technician trainee shall not perform a function reserved for a pharmacist, graduate intern, or pharmacy intern in accordance with R4-23-402 or R4-23-653.
- ~~D.E.~~ A pharmacy technician or pharmacy technician trainee shall wear a badge indicating name and title while on duty.
- ~~E.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

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procedures for pharmacy technician and pharmacy technician trainee activities as specified in subsection ~~(F)~~(G).

~~F.G.~~The policies and procedures shall 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 activities a pharmacy technician or pharmacy technician trainee may perform as specified in R4-23-1104(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,
    - ii. Accepting a refill request,
    - iii. Selecting a drug product,
    - iv. Counting and pouring,
    - v. Labeling, and
    - vi. Obtaining refill authorization;
  - 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.

**R4-23-1105. Pharmacy Technician Trainee Training Program, Pharmacy Technician Drug Compounding Training Program, and Alternative Pharmacy Technician Training**

A. Nothing in this Section prevents additional offsite training of a pharmacy technician.

B. Pharmacy technician trainee training program.

1. 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 a pharmacy technician trainee training program based on the needs of the individual pharmacy.
2. A pharmacy permittee or pharmacist-in-charge shall ensure that the pharmacy technician trainee training program includes training guidelines that:
  - a. Define the specific tasks a pharmacy technician trainee is expected to perform,
  - b. Specify how and when the pharmacist-in-charge will ~~access~~ assess the pharmacy technician trainee's competency, and
  - c. Address the policies and procedures specified in ~~R4-23-1104(F)~~ R4-23-1104(G) and the permissible activities specified in R4-23-1104(A) ~~and (B)~~.
3. A pharmacist-in-charge shall:
  - a. Document ~~a pharmacy technician trainee's progress throughout the training program,~~
  - b. ~~Date and sign a statement attesting the date~~ that a pharmacy technician trainee has successfully completed the training program, and
  - e.b. Maintain the documentation required in this subsection ~~and R4-23-1104(A)(3)~~ for inspection by the Board or its designee, ~~and~~
  - d. ~~Provide to the pharmacy technician trainee a copy of the statement required in subsection (B)(3)(b).~~

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4. A pharmacy technician trainee shall perform only those tasks, listed in R4-23-1104(A), for which training and competency has been demonstrated.
- C. ~~Drug~~ Pharmacy technician drug compounding training program.
1. 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 a pharmacy technician drug compounding training program based on the needs of the individual pharmacy;
  2. A pharmacy permittee or pharmacist-in-charge shall ensure that the pharmacy technician drug compounding training program includes training guidelines that:
    - a. Define the specific tasks a pharmacy technician is expected to perform,
    - b. Specify how and when the pharmacist-in-charge will ~~access~~ assess the pharmacy technician's competency, and
    - c. Address the following procedures and tasks:
      - i. Area preparation,
      - ii. Component preparation,
      - iii. Aseptic technique and product preparation,
      - iv. Packaging and labeling, and
      - v. Area clean up;
  3. A pharmacist-in-charge shall:
    - a. Document ~~a pharmacy technician's progress throughout the training program,~~
    - b. ~~Date and sign a statement attesting the date~~ that a pharmacy technician has successfully completed the pharmacy technician drug compounding training program, and
    - e-b. Maintain the documentation required in this subsection for inspection by the Board or its designee.
- D. Alternative pharmacy technician training.
1. An individual who has passed the required Board-approved pharmacy technician examination, but has not followed the normal path to pharmacy technician licensure by obtaining a pharmacy technician trainee license and working while completing a pharmacy technician trainee training program as specified in subsection (B), may obtain a pharmacy technician license, if the individual has employment in pharmacy and completes an on-the-job training program as part of the individual's employment orientation that includes: reading and discussing with the pharmacist-in-charge of the pharmacy where employed, the Board rules concerning pharmacy technicians and pharmacy technician trainees, the pharmacy technician and pharmacy technician trainee job description, and the policies and procedures manual of that pharmacy.
  2. An individual who has completed a pharmacy technician certificate program and has passed the required Board-approved pharmacy technician examination, but has not followed the normal path to pharmacy technician licensure by obtaining a pharmacy technician trainee license and working while completing a pharmacy technician trainee training program as specified in subsection (B), may obtain a pharmacy technician license, if the individual has employment in pharmacy and completes an on-the-job training program as part of the individual's employment orientation that includes: reading and discussing with the pharmacist-in-charge of the pharmacy where employed, the Board rules concerning pharmacy technicians and pharmacy technician trainees, the pharmacy technician and pharmacy technician trainee job description, and the policies and procedures manual of that pharmacy.
  3. A pharmacist-in-charge shall:
    - a. Document the date that an individual licensed under subsection (D)(1) or (2) has successfully completed the on-the-job training program as part of the individual's employment orientation as required under subsection (D)(1) or (2), and
    - b. Maintain the documentation required in this subsection for inspection by the Board or its designee.
- ~~D.E.~~ A pharmacy technician shall perform only those tasks, listed in R4-23-1104(B), for which training and competency has been demonstrated.