NOTICES OF PROPOSED RULEMAKING

Unless exempted by A.R.S. § 41-1005, each agency shall begin the rulemaking process by first submitting to the Secretary of State's Office a Notice of Rulemaking Docket Opening followed by a Notice of Proposed Rulemaking that contains the preamble and the full text of the rules. The Secretary of State's Office publishes each Notice in the next available issue of the *Register* according to the schedule of deadlines for *Register* publication. Under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.), an agency must allow at least 30 days to elapse after the publication of the Notice of Proposed Rulemaking in the *Register* before beginning any proceedings for making, amending, or repealing any rule. (A.R.S. §§ 41-1013 and 41-1022)

NOTICE OF PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

Editor's Note: The following Notice of Proposed Rulemaking was exempt from Executive Order 2012-03 as issued by Governor Brewer. (See the text of the executive order on page 1769.)

[R12-118]

PREAMBLE

1. Article, Part, or Section Affected (as applicable) — **Rulemaking Action**

R4-23-609	Amend
R4-23-621	Amend
R4-23-692	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 (2)

Implementing statute: A.R.S. §§ 32-1901(8) through (12), 32-1904(B) (3), 32-1929, and 32-1930

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: 18 A.A.R. 1348, June 15, 2012

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

Name:	Dean Wright, Compliance Officer
Address:	Board of Pharmacy 1616 W. Adams St. Phoenix, AZ 85007
Telephone:	(602) 771-2727
Fax:	(602) 771-2749
E-mail:	dwright@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 An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

During the Board's five-year rule review approved August 5, 2008, the Board determined that R4-23-609 Pharmacy Area of Community Pharmacy and R4-23-692 Compressed Medical Gas Distributor needed to be amended to correct inconsistencies with state law and R4-23-621 Shared Services needed to be amended to improve clarity, conciseness, and understandability.

The Governor imposed a rulemaking moratorium in 2009, which lasted until September 2011. We are now ready to proceed with this rulemaking. Because of changes made during the 48th Legislative session in 2007, there is an inconsistency with the statutory citation in subsection R4-23-609(G). R4-23-609(G) cites A.R.S. § 32-1901(52) and the citation should be A.R.S. § 32-1901(55). The rulemaking will amend subsection R-23-609(G) with the correct statutory citation. The August 5, 2008 five-year rule review found that the first sentence in subsection R4-23-621(E) is not completely clear and understandable. To make the sentence clear and understandable, the rulemaking will insert the word "that" between the words "permittee" and "provides" in subsection R4-23-621(E). While preparing to make this change to R4-23-621, the Board determined that subsection (C)(2)(a) and (b) should be amended to clarify that a

shared services filling pharmacy must provide phone numbers with a patient's filled prescription that enables the patient to speak with a pharmacist who has access to that patient's records. Subsections (C)(2)(a) and (b) current only required the filling pharmacies local or toll-free telephone number. The amended rules will add language that requires the local or toll-free telephone number of the pharmacy utilizing shared services that has access to the patient's records. Because of changes made during the 47th Legislative session in 2005, there is an inconsistency with the statutory citation in subsection 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.

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 agency did not review or rely on any study relevant to the rule.

7. A showing of good cause why the rules are necessary to promote a statewide interest if the rules 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 proposed rules will impact the Board, compressed medical gas distributors, and pharmacies. The proposed rule's impact on the Board will be the usual rulemaking-related costs, which are minimal.

The Board estimates the proposed 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.

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

Name:	Dean Wright, Compliance Officer
Address:	Board of Pharmacy 1616 W. Adams St. Phoenix, AZ 85007
Telephone:	(602) 771-2727
Fax:	(602) 771-2749
E-mail:	dwright@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:

Comments may be written or presented orally. Written comments must be received by 5:00 p.m., Monday, August 27, 2012. An oral proceeding is scheduled for:

Date:	August 27, 2012
Time:	10:00 a.m.

Location: 1616 W. Adams St., 1st Floor Board Room
Phoenix, AZ 85007

A person may request information about the oral proceeding by contacting the person listed above.

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:

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:
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

12. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rules:
21 CFR 210 through 211, April 1, 2011 in R4-23-692(B)

13. 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

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~~ 3 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~~ 3 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~~ 3 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~~ 3 square feet per person.

C. Working area for compounding and dispensing counter. The aisle floor area used by the pharmacist, graduate intern, phar-

macy 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.
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~~;~~, 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~~;~~, 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 iden-

tification 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;
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~~ 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.