

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

[R05-295]

PREAMBLE

- 1. Sections Affected**

R4-23-651	<u>Rulemaking Action</u>
R4-23-653	Amend
R4-23-654	Amend
- 2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**

Authorizing statutes: A.R.S. §§ 32-1904(A)(1) and 32-1904(B)(3)
Implementing statute: A.R.S. § 32-1934
- 3. A list of all previous notices appearing in the Register addressing the proposed rule:**

Notice of Rulemaking Docket Opening: 11 A.A.R. 699, February 11, 2005
- 4. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:**

Name:	Dean Wright, Compliance Officer
Address:	Board of Pharmacy 4425 W. Olive Ave., Suite 140 Glendale, AZ 85302
Telephone:	(623) 463-2727, ext. 131
Fax:	(623) 934-0583
E-mail:	rxcop@cox.net
- 5. An explanation of the rule, including the agency's reasons for initiating the rule:**

A recent policy statement by the American Society of Health-System Pharmacists (ASHP) supporting a key proposed revision to the 2006 Medication Management Standards of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) took a historic step in recognizing pharmacists as essential to safe medication use. The proposed revision to the standards, announced on December 9, 2004, includes the requirement that "when an on-site licensed pharmacy is not open 24 hours a day, seven days a week, the organization must make arrangements for a pharmacist's review of medication orders during these hours." The current hospital standards require only that when the onsite pharmacy is closed, medication orders be reviewed by a health care professional determined by the organization to be qualified in the pharmacist's absence. While not every hospital can achieve 24-hour onsite pharmacy services, ASHP believes that all hospitals can accomplish this proposed requirement through various cost-effective mechanisms. With proper privacy and security protections, pharmacists can receive fax or computer-transmitted medication orders and access patient-specific information at home or other remote locations when the pharmacy is closed.

The Board agrees with the proposed standard and intends as part of its mission to protect the public health and safety to implement the proposed standard in Arizona. The Board proposes to amend the hospital rules, specifically R4-23-651 (Definitions), R4-23-653 (Personnel: Professional or Technician), and R4-23-654 (Absence of Pharmacist) to implement the standard requiring pharmacist review of medication orders during the hours an onsite pharmacy is closed. The rules will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and Governor's Regulatory Review Council.

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The Board believes that approval of these rules benefits the public and the pharmacy community by clearly establishing standards for medication management in hospitals that require a pharmacist's review of medication orders during the hours an onsite pharmacy is closed.

6. A reference to any study relevant to the rule that the agency reviewed and either proposes to rely on or not rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

None

7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule 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, pharmacists, hospital pharmacies, and the public. The proposed rules' impact on the Board will be the usual rulemaking-related costs that are minimal. The proposed rules will have substantial economic impact on hospital pharmacies and pharmacists. The proposed rules will clearly establish standards for medication management in hospitals that require a pharmacist's review of medication orders during the hours an onsite pharmacy is closed. The proposed rules will have a substantial economic impact on most Arizona hospital pharmacies, especially rural hospital pharmacies. Very few rural hospital pharmacies provide 24-hour pharmacy services, and the proposed rules will force the rural hospital pharmacies to either staff the pharmacy 24 hours or use remote access pharmacy services. The hospitals with 24-hour pharmacy services will experience little or no economic impact from the proposed rules. The annual cost to those affected hospital pharmacies is estimated to be from \$90,000 to over \$200,000 for personnel costs and from \$30,000 to over \$200,000 in system costs. The proposed rules have no direct economic impact on the public.

The public, Board, pharmacists, and hospital pharmacies benefit from rules that are clear, concise, and understandable. The proposed rules benefit the public, the Board, and the pharmacy community by clearly establishing standards for medication management in hospitals that require a pharmacist's review of medication orders during the hours an onsite pharmacy is closed. The public benefit stems from the increased health and safety afforded patients in hospitals where pharmacists review all medication orders before any medication is administered.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Dean Wright, Compliance Officer
Address: Board of Pharmacy
4425 W. Olive Ave., Suite 140
Glendale, AZ 85302
Telephone: (623) 463-2727, ext. 131
Fax: (623) 934-0583
E-mail: rxcop@cox.net

10. The time, place, and nature of the proceedings for the making, amendment, or repeal of 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 p.m., Monday, September 19, 2005. An oral proceeding is scheduled for:

Date: September 19, 2005
Time: 10:00 a.m.
Location: 4425 W. Olive Ave., Suite 140
Glendale, AZ 85302

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

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

12. Incorporations by reference and their location in the rules:

None

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

- R4-23-651. Definitions
- R4-23-653. Personnel: Professional or Technician
- R4-23-654. Absence of Pharmacist

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-651. Definitions

The following definitions apply to R4-23-651 through R4-23-659:

- “Administration” No change
- “Direct copy” No change
- “Dispensing for hospital inpatients” No change
- “Drug distribution” No change
- “Emergency medical situation” No change
- “Floor stock” No change
- “Formulary” No change
- “Hospital pharmacy” No change
- “Inpatient” No change
- “Intravenous admixture” No change
- “Medication order” No change
- “On-call” means a pharmacist is available to:
 - Consult or provide drug information regarding drug therapy or related issues; or
 - ~~Dispense a medication order and review~~ Review a patient’s medication order for pharmaceutical and therapeutic feasibility under R4-23-653(E)(2) before any drug is administered to a patient and if necessary, dispense a medication order; or ~~except~~ Remotely review and verify a patient’s medication order for pharmaceutical and therapeutic feasibility under R4-23-653(E)(2) before any drug is administered to a patient as specified in R4-23-653(E)(1)(b).
- “Patient care area” No change
- “Repackaged drug” No change
- “Satellite pharmacy” No change
- “Single unit” No change
- “Supervision” No change

R4-23-653. Personnel: Professional or Technician

- A. No change
- B. No change
- C. No change
- D. No change
- E. Pharmacists. A pharmacist or a pharmacy intern or graduate intern under the supervision of a pharmacist shall perform the following professional practices:
 - 1. Verify a patient’s medication order before administration of a drug to the patient, except:
 - a. In an emergency medical situation; or
 - b. In a hospital where the pharmacy is open less than 24 hours a day for pharmacy services, ~~a~~ an on-call pharmacist shall:
 - i. Have access to a patient’s medical record;
 - ii. Receive a patient’s medication order via facsimile or electronic transmission; and
 - iii. verify ~~Verify~~ a patient’s medication order ~~within four hours of the time the pharmacy opens for pharmacy services before administration of a drug to the patient, except for an emergency medical situation as defined in R4-23-651;~~
 - 2. No change

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- a. No change
- b. No change
- c. No change
- d. No change
- 3. No change
- 4. No change
- 5. No change
- 6. No change
- 7. No change
- 8. No change
- 9. No change
- 10. No change
- 11. No change
- 12. No change
- 13. No change
- 14. No change
- F. No change
- G. No change
- H. No change
- I. No change

R4-23-654. Absence of Pharmacist

- A. No change
- B. No change
- C. No change
- D. Remote drug storage area. The Director of Pharmacy or pharmacist-in-charge shall, in consultation with the appropriate committee of the hospital:
 - 1. Develop and maintain an inventory listing of the drugs to be included in a remote drug storage area; ~~and~~
 - 2. Develop and implement policies and procedures in the same manner described in R4-23-653(A) that ensure proper storage, access, and accountability for drugs in a remote drug storage area; and
 - 3. Develop and implement policies and procedures in the same manner described in R4-23-653(A) that ensure review and verification by a pharmacist of the medication order for any drug removed from the remote drug storage area before the drug is administered to a patient as specified in R4-23-653(E)(1)(b), except for an emergency medical situation as defined in R4-23-651.
- E. Access to hospital pharmacy. If a drug is not available from a remote drug storage area and the drug is required to treat the immediate needs of a patient whose health may be compromised, the drug may be obtained from the hospital pharmacy according to the requirements of this subsection.
 - 1. The Director of Pharmacy or pharmacist-in-charge shall, in consultation with the appropriate committee of the hospital, develop and implement policies and procedures in the same manner described in R4-23-653(A) to ensure that access to the hospital pharmacy during the pharmacist's absence conforms to the following requirements:
 - a. Access is delegated to only one supervisory nurse in each shift;
 - b. The policy and name of supervisory nurse is communicated in writing to the medical staff of the hospital;
 - c. Access is delegated only to a nurse who has received training from the Director of Pharmacy, pharmacist-in-charge, or Director's designee in the procedures required for proper access, drug removal, and recordkeeping; ~~and~~
 - d. Access is delegated by the supervisory nurse to another nurse only in an emergency; and
 - e. Before any drug is removed from the hospital pharmacy and administered to a patient, the patient's medication order is reviewed and verified by a pharmacist as specified in R4-23-653(E)(1).
 - 2. No change
 - a. No change
 - i. No change
 - ii. No change
 - iii. No change
 - iv. No change
 - b. No change
 - c. No change
 - d. No change
 - 3. No change