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

PREAMBLE

1. Articles, Parts, and Sections Affected
   Rulemaking Action
   R4-23-703  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)
   Implementing statute: A.R.S. §§ 32-1901(77)(b) and 32-1968(A)(5)

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: 22 A.A.R. 3415, December 9, 2016

4. The agency's contact person who can answer questions about the rulemaking:
   Name: Kamlesh Gandhi
   Address: Board of Pharmacy
            1616 W. Adams St., Suite 120
            Phoenix, AZ 85007
   Telephone: (602) 771-2740
   Fax: (602) 771-2749
   E-mail: kgandhi@azpharmacy.gov
   Web site: www.azpharmacy.gov
5. An agency's justification and reason why a rule should be made, amended, repealed, or renumbered, to include an explanation about the rulemaking:

The Board is making its rules consistent with standard practice of assisted living facilities (ALF), rules of the Department of Health Services (See R9-10-816(A)(2)), which licenses ALFs, and an advisory opinion of the Board of Nursing (https://www.azbn.gov/media/1067/ao-orders-accepting-transcribing-reviewing-orders.pdf). As a convenience to residents, personnel of ALFs, after obtaining verbal direction from a resident’s physician, call the prescription order into the resident’s pharmacy of choice. A confirming written prescription order is then generated by the physician’s office and sent to the pharmacy and ALF for their records.

A.R.S. § 32-1968(A)(5) allows a pharmacist to dispense a drug on an oral prescription order that is promptly reduced to writing and filed by the pharmacist. A.R.S. § 32-1901(77)(b) indicates a prescription order is one transmitted to a pharmacist through word of mouth, telephone, or other means of communication directed by a medical practitioner.

The Board has determined that as currently written, R4-23-703, which provides that a pharmacy shall dispense, sell, or deliver a prescription or nonprescription drug to an ALF resident only after receiving a prescription order from the resident’s medical practitioner, is inconsistent with the standard practice of ALFs, rules of the Department of Health Services, and the advisory opinion of the Board of Nursing. This rulemaking will make the Board’s rules consistent with the practices of other agencies.

An exemption from EO2016-03 was provided by Christina Corieri, Policy Advisor for Health and Human Services in the Governor’s Office, by e-mail dated July 14, 2016.

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

The Board does not intend to review or rely on a study in its evaluation of or justification for the rule in this rulemaking.

7. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

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

The Board believes making its rules consistent with standard practice of other agencies, as authorized by the Board’s statutes, will benefit residents of ALFs and the personnel who provide their care by enabling a pharmacist to fill many prescription orders on verbal direction from ALF personnel. The rulemaking will eliminate a regulatory burden caused by the Board’s rules being inconsistent with the practices of other agencies.

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

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Web site: www.azpharmacy.gov

10. The time, place, and nature of the proceedings to make, amend, repeal, or renumber the rule, or if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

An oral proceeding regarding the proposed rule will be held as follows:
Date: Monday, January 30, 2017
Time: 9:00 a.m.
Location: Board of Pharmacy
1616 W. Adams St., Suite 120
Phoenix, AZ 85007
11. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:

None

a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:
   The rulemaking requires no permit.

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:
   There are federal laws relating to selling and dispensing of drugs. However, none is specifically applicable to this rulemaking. No rule in the rulemaking is more stringent that federal law.

c. Whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:
   No analysis was submitted.

12. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rule:
   None

13. The full text of the rule follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 7. NON-PHARMACY LICENSED OUTLETS - GENERAL PROVISIONS

Section
R4-23-703. Assisted Living Facilities

ARTICLE 7. NON-PHARMACY LICENSED OUTLETS - GENERAL PROVISIONS

R4-23-703. Assisted Living Facilities

A. Assisted living facilities are licensed by the state Department of Health Services. Before dispensing, selling, or delivering a prescription or nonprescription drug to an assisted living facility resident, a pharmacy permittee shall obtain a copy of the current license issued by the Arizona Department of Health Services to the assisted living facility and make the copy available for inspection on request by a Board compliance officer.

B. A pharmacy permittee shall ensure that:
1. Only dispense, sell, or deliver a prescription or nonprescription drug to an assisted living facility resident after receiving a prescription order for the narcotic drug from the resident's medical practitioner; and
2. The narcotic drug is labeled in accordance with A.R.S. §§ 32-1963.01, 32-1968, and 36-2525, all drugs dispensed, sold, or delivered to an assisted living facility resident; and includes the following on the label:
   a. The name, strength, and quantity of the drug; and
   b. A beyond-use date.
3. Obtain a copy of the current Arizona Department of Health Services license issued to an assisted living facility before dispensing drugs to that facility's resident; and
4. Maintain, for inspection by a Board compliance officer, a file containing the license copy required in subsection (B)(3).

C. A pharmacy permittee may dispense, sell, or deliver to an assisted living facility resident a non-narcotic prescription or non-prescription drug if the pharmacy permittee:
1. Receives a written or oral prescription order for the non-narcotic prescription or non-prescription drug from:
   a. The resident's medical practitioner,
   b. An individual licensed by the Arizona Board of Nursing, or
   c. An assisted living facility manager or caregiver acting under the authority of R9-10-816(A)(2);
2. Determines the written or oral prescription order:
   a. Meets the requirements of R4-23-407, and
   b. Includes the name and title of the individual transmitting the prescription order; and
3. Labels the non-narcotic prescription or non-prescription drug in accordance with A.R.S. §§ 32-1963.01 and 32-1968 and includes the following on the label:
   a. The name, strength, and quantity of the drug; and
   b. A beyond-use date.

C. In addition to the labeling requirements of A.R.S. §§ 32-1963.01, 32-1968, and 36-2525, the label on a prescription medication for an assisted living facility resident shall include the name, strength, and quantity of the drug and a beyond-use date.
D. If the label on an assisted living facility resident's drug container becomes damaged or soiled, a pharmacist employed by the pharmacy permittee that dispensed the drug container, through the exercise of professional judgment, may relabel the drug container. Only a pharmacist is permitted to label a drug container or alter the label of a drug container.

E. A pharmacist may help assisted living facility personnel to develop written policies and procedures for the procurement, administration, storage, control, recordkeeping, and disposal of drugs in the facility and provide other information concerning drugs that assisted living facilities should have for safe and effective supervision of drug self-administration.

F. A pharmacy permittee shall not place an emergency drug supply unit as defined described in R4-23-701.02 or an automated dispensing system as defined described in R4-23-701.04 in an assisted living facility.

G. A pharmacist shall not repackage a drug previously dispensed to a resident of the assisted living facility resident by another pharmacy, and drugs previously dispensed by the provider pharmacy, shall not be repackaged.