

NOTICES OF RULEMAKING DOCKET OPENING

The Administrative Procedure Act (APA) requires the publication of Notices of Rulemaking Docket Opening when an agency opens a rulemaking docket to consider rulemaking. Under the APA effective January 1, 1995, agencies must submit a Notice of Rulemaking Docket Opening before beginning the formal rulemaking process.

NOTICE OF RULEMAKING DOCKET OPENING

BOARD OF PHARMACY

[R04-544]

- 1. Title and its heading:** 4, Professions and Occupations
Chapter and its heading: 23, Board of Pharmacy
Articles and their headings: 1, Administration
6, Permits and Distribution of Drugs
As part of this rulemaking, the Board may add, delete, or modify additional Articles as necessary.

Section numbers: R4-23-110, R4-23-614 and R4-23-615
As part of this rulemaking, the Board may add, delete, or modify additional Sections as necessary.
- 2. Subject matter of the proposed rule:**
Automated storage and distribution systems, such as, Pyxis and mechanical counting devices, such as, Baker cells and cassettes have been used by pharmacies for many years. However, the Board does not have rules specifically addressing these systems or devices. R4-23-402(A)(9) addresses the issue of prepackaging by pharmacy technicians under pharmacist supervision, and although, this subsection has been used to partially address the use of mechanical counting devices, the subsection does not truly apply to mechanical counting devices. The proposed rules will add two new Sections of rule to address automated storage and distribution systems and mechanical counting devices. A new definition for "automated storage and distribution systems" will be added to R4-23-110 (Definitions). New Section R4-23-614 (Automated Storage and Distribution Systems) will establish the standards for the use of automated storage and distribution systems in Arizona. New Section R4-23-615 (Mechanical Counting Device for Drugs in Solid, Oral Dosage Forms) will establish standards for the use of mechanical counting devices by Arizona pharmacies. 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.

The agency docket number, if applicable:
R0502
- 3. A Citation to all published notices relating to the proceeding:**
None
- 4. Name and address of agency personnel with whom persons may communicate regarding the rule:**

Name:	Dean Wright, Compliance Officer
Address:	Arizona 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. The time during which the agency will accept written comments:**
The Board will accept written comments Monday through Friday, 8 a.m. to 5 p.m.

The time and place where oral comments may be made:

Time:	Monday through Friday, 8 a.m. to 4:30 p.m.
Location:	Arizona Board of Pharmacy 4425 W. Olive Ave., Suite 140 Glendale, AZ 85302
Nature:	Oral comments

Written and oral comments will be accepted until the close of record on a date and time as yet undetermined.

Notices of Rulemaking Docket Opening

6. **A timetable for agency decisions or other action in the proceeding:**

None

NOTICE OF RULEMAKING DOCKET OPENING

BOARD OF PHARMACY

[R04-543]

1. **Title and its heading:**

4, Professions and Occupations

Chapter and its heading:

23, Board of Pharmacy

Articles and their headings:

4, Professional Practices

6, Permits and Distribution of Drugs

As part of this rulemaking, the Board may add, delete, or modify additional Articles as necessary.

Section numbers:

R4-23-408 and R4-23-605

As part of this rulemaking, the Board may add, delete, or modify additional Sections as necessary.

2. **Subject matter of the proposed rule:**

Based on comments from licensees and permittees and issues of compliance, the Board staff identified possible changes to R4-23-408 (Computer Records) and R4-23-605 (Resident Drug Wholesaler Permit). R4-23-408(D), (E), and (G) require compliance with R4-23-408(A) and (B). The proposed rules will amend R4-23-408(D), (E), and (G) to require compliance with R4-23-408(A), (B), and (F). R4-23-408 (A) and (B) address a pharmacy's computer systems and data storage and retrieval, and R4-23-408(F) addresses the issue of security and confidentiality of a patient's records within a pharmacy's computer system. Although the rule does not specifically state it, the Board believes that a drug wholesaler shall not package, repackage, label, or relabel any drug or device. Since the Board rule for non-prescription drug retailers states specifically that a retailer shall not package, repackage, label, or relabel a drug or device, the Board intends to amend R4-23-605 to specifically state that a full-service or non-prescription drug wholesaler shall not package, repackage, label, or relabel a drug or device. It is the Board's contention that packaging, repackaging, labeling, and relabeling may only be done by a manufacturer or repackager properly permitted by the Board, by a pharmacist in performance of a pharmacist's duties in a properly permitted pharmacy, or by other persons specifically exempted by A.R.S. §32-1921. The proposed rules will amend R4-23-605(D)(2) and (3) with language that requires that a wholesaler shall sell a drug only in the original container packaged and labeled by the manufacturer and not package, repackage, label, or relabel any drug. 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.

The agency docket number, if applicable:

R0501

3. **A Citation to all published notices relating to the proceeding:**

None

4. **Name and address of agency personnel with whom persons may communicate regarding the rule:**

Name: Dean Wright, Compliance Officer

Address: Arizona 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. **The time during which the agency will accept written comments:**

The Board will accept written comments Monday through Friday, 8 a.m. to 5 p.m.

The time and place where oral comments may be made:

Time: Monday through Friday, 8 a.m. to 4:30 p.m.

Location: Arizona Board of Pharmacy
4425 W. Olive Ave., Suite 140
Glendale, AZ 85302

Nature: Oral comments

Written and oral comments will be accepted until the close of record on a date and time as yet undetermined.

6. **A timetable for agency decisions or other action in the proceeding:**

None