NOTICES OF SUPPLEMENTAL PROPOSED RULEMAKING

After an agency has filed a Notice of Proposed Rulemaking with the Secretary of State's Office for *Register* publication and the agency decides to make substantial changes to the rule after it is proposed, the agency must prepare a Notice of Supplemental Proposed Rulemaking for submission to the Office, and the Secretary of State shall publish the Notice under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.). Publication of the Notice of Supplemental Proposed Rulemaking shall appear in the *Register* before holding any oral proceedings (A.R.S. § 41-1022).

NOTICE OF SUPPLEMENTAL PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

[R06-101]

PREAMBLE

1. *Register* citation and date for the original Notice of Proposed Rulemaking:

Notice of Proposed Rulemaking: 11 A.A.R. 5444, December 30, 2005

2. Sections Affected / Rulemaking Action

R4-23-110	Amend
R4-23-614	New Section
R4-23-615	New Section

3. 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)

Implementing statutes: A.R.S. § 32-1904(B)(3)

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

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:

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 and 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 Board believes that approval of these rules benefits the public and the pharmacy community by clearly establishing standards for the use of automated storage and distributions systems and mechanical counting devices in Arizona.

6. An explanation of the substantial change which resulted in this supplemental notice:

After receiving public comment from the Arizona Community Pharmacy Committee, the Board decided to make two substantial changes. The first change would clarify the required location of an automated storage and distribution system. The original proposed rule required that the automated storage and distribution system be located in a wall of a properly permitted pharmacy. The substantial change approved by the Board allows the location of an automated

storage and distribution system either in a wall of a properly permitted pharmacy or within 20 feet of a properly permitted pharmacy if the automated storage and distribution system is secured against a wall or floor in such a manner that prevents the automated storage and distribution system's unauthorized removal. The second change is the removal of language in R4-23-614(B)(1) that requires that the automated storage and distribution system "accurately supplies the correct strength, dosage form, and quantity of the drug prescribed." The Arizona Community Pharmacy Committee stated and the Board agreed that the language was unnecessary because accurately supplying the correct strength, dosage form, and quantity of prescribed drug is a function of a pharmacist not an automated storage and distribution system. The substantial change approved by the Board removes the following language from R4-23-614(B)(1): "and accurately supplies the correct strength, dosage form, and quantity of the drug prescribed."

On further review, the Board determined that additional language should be added to R4-23-615 to ensure the accuracy of mechanical counting devices used by pharmacies to count drugs in solid, oral dosage forms. The new language is added at subsection (B) and the remaining subsections are renumbered. The new language requires the pharmacy permittee or pharmacist-in-charge to ensure the accuracy of mechanical counting devices by requiring documentation of training in the maintenance, calibration, and use of mechanical counting devices by employees who use mechanical counting devices, daily maintenance and calibration of mechanical counting devices, and routine quality assurance testing of mechanical counting devices.

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, pharmacies, and the public. The proposed rules' impact on the Board will be the usual rulemaking-related costs that are minimal. The Board looked at the existing systems and devices in use within the state to develop the minimum standards established in the proposed rules. The existing systems and devices will meet or exceed the standards. The proposed rules will have no economic impact on pharmacies or pharmacists. The proposed rules have no economic impact on the public.

The public, Board, pharmacists, and pharmacies benefit from rules that are clear, concise, and understandable. The proposed rules benefit the public and the pharmacy community by clearly establishing standards for the use of automated storage and distributions systems and mechanical counting devices in Arizona.

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, May 15, 2006. An oral proceeding is scheduled for:

Date:	May 15, 2006
Time:	10:00 a.m.
Location:	4425 W. Olive Ave., Suite 140 Glendale, AZ 85302
Nature:	Public Hearing
Close of Record:	5 p.m. on May 15, 2006

A person may request information about the oral proceeding by contacting the person in item #9.

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 changes follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 1. ADMINISTRATION

Section
R4-23-110. Definitions

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

Section
R4-23-614. ~~Reserved~~ Automated Storage and Distribution Systems
R4-23-615. ~~Reserved~~ Mechanical Counting Device for Drugs in Solid, Oral Dosage Forms

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

In addition to definitions in A.R.S. § 32-1901, the following definitions apply to A.A.C. Title 4 Chapter 23:

"Active ingredient" No change

"Alternate physician" No change

"Approved course in pharmacy law" No change

"Approved Provider" No change

"Authentication of product history" No change

"Automated storage and distribution systems" means mechanical systems that perform operations or activities, other than counting, compounding, or administration, relative to the storage, packaging, or distributing of drugs or devices, and that collect, control, and maintain all transaction information.

"Batch" No change

"Beyond-use date" No change

"Biological safety cabinet" No change

"Care-giver" No change

"Class 100 environment" No change

"Community pharmacy" No change

"Component" No change

"Compounding and dispensing counter" No change

"Computer system" No change

"Computer system audit" No change

"Contact hour" No change

"Container" No change

"Continuing education" No change

"Continuing education activity" No change

"Continuing education unit" or "CEU" No change

"Correctional facility" No change

"CRT" No change

"Current good compounding practices" No change

"Current good manufacturing practice" No change

"Cytotoxic" No change

"Day" No change

"DEA" No change

"Delinquent license" No change
"Dietary supplement" No change
"Dispensing pharmacist" No change
"Drug sample" No change
"Drug therapy management" No change
"Drug therapy management agreement" No change
"Eligible patient" No change
"Extreme emergency" No change
"FDA" No change
"Immediate notice" No change
"Inactive ingredient" No change
"Internal test assessment" No change
"Limited-service correctional pharmacy" No change
"Limited-service long-term care pharmacy" No change
"Limited-service mail-order pharmacy" No change
"Limited-service nuclear pharmacy" No change
"Limited-service pharmacy permittee" No change
"Limited-service sterile pharmaceutical products pharmacy" No change
"Long-term care consultant pharmacist" No change
"Long-term care facility" or "LTCF" No change
"Lot" No change
"Lot number" or "control number" No change
"Materials approval unit" No change
"Mediated instruction" No change
"MPJE" No change
"NABP" No change
"NABPLEX" No change
"NAPLEX" No change
"Other designated personnel" No change
"Outpatient" No change
"Outpatient setting" No change
"Patient profile" No change
"Pharmaceutical patient care services" No change
"Pharmaceutical product" No change
"Pharmacist-administered immunizations training program" No change
"Pharmacy counter working area" No change
"Pharmacy law continuing education" No change
"Pharmacy permittee" No change
"Prepackaged drug" No change
"Proprietor" No change
"Provider pharmacy" No change
"Radiopharmaceutical" No change
"Radiopharmaceutical quality assurance" No change
"Radiopharmaceutical services" No change
"Red C stamp" No change
"Remodel" No change
"Remote drug storage area" No change

"Resident" No change
"Responsible person" No change
"Score transfer" No change
"Sight-readable" No change
"Single-drug audit" No change
"Single-drug usage report" No change
"Sterile pharmaceutical product" No change
"Strength" No change
"Supervision" No change
"Supervisory physician" No change
"Supplying" No change
"Support personnel" No change
"Transfill" No change
"Wholesale distribution" No change
"Wholesale distributor" No change

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-614. ~~Reserved~~ Automated Storage and Distribution Systems

A. Before using an automated storage and distribution system, a pharmacy permittee or pharmacist-in-charge shall:
1. Ensure that the automated storage and distribution system and the policies and procedures comply with subsection (B); and
2. Notify the Board in writing of the intent to use an automated storage and distribution system, including the type or name of the system.

B. A pharmacy permittee or pharmacist-in-charge shall establish policies and procedures for appropriate performance and use of the automated storage and distribution system that:
1. Ensure that the automated storage and distribution system is in good working order while maintaining appropriate recordkeeping and security safeguards;
2. Ensure that an automated storage and distribution system used by a pharmacy that allows access to drugs or devices by a patient:
   a. Only contains refilled prescriptions that are properly labeled and verified by a pharmacist before release to patients;
   b. Allows a patient to choose whether or not to use the system;
   c. Is located either in a wall of a properly permitted pharmacy or within 20 feet of a properly permitted pharmacy if the automated storage and distribution system is secured against a wall or floor in such a manner that prevents the automated storage and distribution system's unauthorized removal;
   d. Provides a method to identify the patient and only release that patient's prescriptions;
   e. Is secure from access and removal of drugs or devices by unauthorized individuals;
   f. Provides a method for a patient to obtain a consultation with a pharmacist if requested by the patient; and
   g. Does not allow the system to dispense refilled prescriptions if a pharmacist determines that the patient requires counseling as specified in R4-23-402(B);
3. Ensure that an automated storage and distribution system used by a pharmacy that allows access to drugs or devices for the purposes of administration only by authorized licensed personnel based on a valid prescription order or medication order;
   a. Provides for adequate security to prevent unauthorized individuals from accessing or obtaining drugs or devices; and
   b. Provides for the filling, stocking, or restocking of all drugs or devices in the system only by a Board licensee or other authorized licensed personnel; and
4. Implement an ongoing quality assurance program that monitors compliance with the established policies and procedures of the automated storage and distribution system and federal and state law.

C. A pharmacy permittee or pharmacist-in-charge shall:
1. Ensure that policies and procedures for the performance and use of an automated storage and distribution system are prepared, implemented, and complied with;
2. Review biennially and, if necessary, revise the policies and procedures required under subsection (C)(1);
3. Document the review required under subsection (C)(2);
4. Assemble the policies and procedures as a written manual or by another method approved by the Board or its desig-

nee; and

5. Make the policies and procedures available for employee reference and inspection by the Board or its designee within the pharmacy and at any location outside the pharmacy where the automated storage and distribution system is used.

D. The Board may prohibit a pharmacy permittee or pharmacist-in-charge from using an automated storage and distribution system if the pharmacy permittee or the pharmacy permittee's employees do not comply with the requirements of subsections (A), (B), and (C).

R4-23-615. ~~Reserved~~ Mechanical Counting Device for Drugs in Solid, Oral Dosage Forms

A. A pharmacy permittee or pharmacist-in-charge shall ensure that a mechanical counting device for a drug in a solid, oral dosage form that is used by a pharmacist or pharmacy intern, graduate intern, pharmacy technician, or pharmacy technician trainee under the supervision of a pharmacist complies with the following method to identify the contents of the device:

1. The drug name and strength are affixed to the front of each cell or cassette of the device;
2. A paper or electronic log is kept for each cell or cassette that contains:
   a. An identification of the cell or cassette by the drug name and strength or the number of the cell or cassette;
   b. The drug's manufacturer or NDC number;
   c. The expiration date and lot number from the manufacturer's stock bottle that is used to fill the cell or cassette. If multiple lot numbers of the same drug are added to a cell or cassette, each lot number and expiration date shall be documented, and the earliest expiration date shall become the expiration date of the mixed lot of drug in the cell or cassette;
   d. The date the cell or cassette is filled;
   e. Documentation of the identity of the licensee who placed the drug into the cell or cassette; and
   f. If the licensee who placed the drug in the cell or cassette is not a pharmacist, documentation of the identity of the pharmacist who supervised the non-pharmacist licensee who filled the cell or cassette; and
3. The paper or electronic log is available in the pharmacy for inspection by the Board or its designee for not less than two years.

B. A pharmacy permittee or pharmacist-in-charge shall ensure the accuracy of any mechanical counting device for a drug in a solid, oral dosage form that is used by a pharmacist or pharmacy intern, graduate intern, pharmacy technician, or pharmacy technician trainee under the supervision of a pharmacist by documenting completion of the following:

1. Training in the maintenance, calibration, and use of the mechanical counting device for each employee who uses the mechanical counting device;
2. Daily maintenance and calibration of the mechanical counting device; and
3. Routine quality assurance testing of each mechanical counting device.

C. A pharmacy permittee or pharmacist-in-charge shall:

1. Ensure that policies and procedures for the performance and use of a mechanical counting device for a drug in a solid, oral dosage form are prepared, implemented, and complied with;
2. Review biennially and, if necessary, revise the policies and procedures required under this rule;
3. Document the review required under subsection (C)(2);
4. Assemble the policies and procedures as a written manual or by another method approved by the Board or its designee; and
5. Make the policies and procedures available within the pharmacy for employee reference and inspection by the Board or its designee.

D. The Board may prohibit a pharmacy permittee or pharmacist-in-charge from using a mechanical counting device for a drug in a solid, oral dosage form if the pharmacy permittee or the pharmacy permittee's employees do not comply with the requirements of subsections (A), (B), and (C).