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

[R06-310]

PREAMBLE

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

Notice of Proposed Rulemaking: 12 A.A.R. 626, March 3, 2006

2.

Sections Affected	Rulemaking Action
R4-23-110	Amend
R4-23-607	Amend
R4-23-621	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), 32-1929, and 32-1930

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:

The Board has approved at least two pharmacies in Arizona to provide central filling for other pharmacies. There is at least one pharmacy in Arizona that is providing prescription order processing for other pharmacies, and there are other pharmacies from outside Arizona who are providing prescription order processing for Arizona pharmacies. The Board has no rules defining the practice of providing prescription order filling or processing by one pharmacy for another pharmacy. It has been the Board's practice to take each case individually. The rules define the practice of providing prescription order filling and processing by one pharmacy for another pharmacy. The rules include definitions added to R4-23-110 for: "order," "shared order filling," "shared order processing," and "shared services." The rules include a new Section R4-23-621 (Shared Services) that details the requirements for participating in shared services (order filling and order processing or both), including notifications to patients, labeling, recordkeeping, confidentiality, and policies and procedures. The Board feels that the public, pharmacists, and pharmacies benefit from rules that establish the standards for pharmacies that provide or utilize shared services.

Since many of the pharmacies involved in shared services are nonresident pharmacies, the Board determined that changes to R4-23-607 (Nonresident Permits) are required. R4-23-607(A)(3) will include changes specifying that a nonresident pharmacy shall employ a pharmacist-in-charge who has a current Board-issued pharmacist license. A new subsection R4-23-607(A)(4) will include language specifying that existing nonresident pharmacy permittees have until November 1, 2007 to comply with subsection R4-23-607(A)(3). R4-23-607(C)(d) is amended to add language to require the permit application contain the pharmacist-in-charge's current Arizona Board-issued pharmacist license number. Other changes to R4-23-607(E)(3) and (4) will specify that nonresident drug wholesalers like resi-

dent drug wholesalers shall not sell, distribute, give away, or dispose of, any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical to anyone in Arizona, except in the original container packaged and labeled by the manufacturer or repackager, or not package, repackage, label, or relabel any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical for shipment or delivery to anyone in Arizona. This change to R4-23-607(E)(3) and (4) will make the rules for resident and nonresident drug wholesalers equal and consistent. 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 the standards for pharmacies that provide or utilize shared services.

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

After fielding a few verbal and e-mail questions from nonresident pharmacies about how long they would have after the rules became effective to get their pharmacist-in-charge licensed in Arizona, the Board determined that language to specify a specific time for compliance with the requirement in R4-23-607(A)(3) that a nonresident pharmacy shall employ a pharmacist designated as the pharmacist-in-charge who possesses a current Arizona Board-issued pharmacist license is necessary. The words "on and after February 1, 2007" are added to R4-23-607(A)(3) and a new subsection (A)(4) is added that states: "for a nonresident pharmacy permit issued before February 1, 2007, complying with the requirement of subsection (A)(3) and submitting to the Board the pharmacist-in-charge's name, current Arizona Board-issued pharmacist license number, and telephone number by November 1, 2007." The changes specify that on or after February 1, 2007 a nonresident pharmacy shall employ a pharmacist-in-charge who has a current Arizona Board-issued pharmacist license. The changes further specify that any nonresident pharmacy permit issued before February 1, 2007 is allowed nine months to employ a pharmacist-in-charge who has a current Arizona Board-issued pharmacist license and submit that pharmacist-in-charge's name, current Board-issued pharmacist license number, and telephone number to the Board.

To improve clarity, the words "manual or electronic" and "initials, or identification code" were added to R4-23-621(D)(1) and (2) and the words "electronic or manual" were added to R4-23-621(E)(3)(d).

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 rules will impact the Board, pharmacies, and the public. The rules' impact on the Board will be the usual rulemaking-related costs, which are minimal. The Board estimates the rules will have minimal economic impact on pharmacies. Several pharmacies are already using or providing shared services. The Board's rules will not require a pharmacy to use or provide shared services, but will establish the minimum standards for using or providing shared services. The Board's rules will require nonresident pharmacies to employ a pharmacist-in-charge who has a Board-issued pharmacist license. The cost for nonresident pharmacies to comply with this requirement is minimal. The rules have no economic impact on the public.

The public, Board, and pharmacies benefit from rules that are clear, concise, and understandable. The rules benefit the public and the pharmacy community by clearly establishing the standards for pharmacies that provide or utilize shared services.

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, October 2, 2006. An oral proceeding is scheduled for:

Date:	October 2, 2006
Time:	11:00 a.m.
Location:	4425 W. Olive Ave., Suite 140 Glendale, AZ 85302

Nature: Public Hearing

Close of Record: 5 p.m. on October 2, 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
R4-23-607. Nonresident Permits
R4-23-621. ~~Reserved~~ Shared Services

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

"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
"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
"Order" means either of the following:
A prescription order as defined in A.R.S. § 32-1901; or
A medication order as defined in A.A.C. R4-23-651.
"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

"Refill" No change

"Remodel" No change

"Remote drug storage area" No change

"Resident" No change

"Responsible person" No change

"Score transfer" No change

"Shared order filling" means the following:

Preparing, packaging, compounding, or labeling an order, or any combination of these functions, that are performed by:

A person with a current Arizona Board license and located at an Arizona pharmacy on behalf of and at the request of another resident or nonresident pharmacy; or

A person located in a nonresident pharmacy on behalf of and at the request of an Arizona pharmacy; and

Returning the filled order to the requesting pharmacy for delivery to the patient or patient's care-giver or at the request of the requesting pharmacy, directly delivering the filled order to the patient.

"Shared order processing" means the following:

Interpreting the order, performing order entry verification, drug utilization review, drug compatibility and drug allergy review, final order verification, and when necessary, therapeutic intervention, or any combination of these order processing functions, that are performed by:

A pharmacist or intern, under pharmacist supervision, with a current Arizona Board license located at an Arizona pharmacy on behalf of and at the request of another resident or nonresident pharmacy: or

A pharmacist or intern, under pharmacist supervision, located in a nonresident pharmacy on behalf of and at the request of an Arizona pharmacy; and

After order processing is completed, returning the processed order to the requesting pharmacy for order filling and delivery to the patient or patient's care-giver or at the request of the requesting pharmacy, returning the processed order to another pharmacy for order filling and delivery to the patient or patient's care-giver.

"Shared services" means shared order filling or shared order processing, or both.

"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

R4-23-607. Nonresident Permits

A. Permit. A person, who is not a resident of Arizona, shall not sell or distribute any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical into Arizona without:

1. ~~A~~ Possessing a current Board-issued nonresident pharmacy permit, nonresident manufacturer permit, nonresident full-service or nonprescription drug wholesale permit, or nonresident nonprescription drug permit; ~~and~~
2. ~~A~~ Possessing a current equivalent license or permit issued by the licensing authority in the jurisdiction where the person or firm resides;
3. On and after February 1, 2007 for a nonresident pharmacy, employing a pharmacist designated as the pharmacist-in-charge who possesses a current Arizona Board-issued pharmacist license; and
4. For a nonresident pharmacy permit issued before February 1, 2007, complying with subsection (A)(3) and submitting to the Board the pharmacist-in-charge's name, current Arizona Board-issued pharmacist license number, and telephone number by November 1, 2007.

B. No change

C. In addition to the requirements of subsection (B), the following information is required:
1. No change
   a. No change
   b. No change
   c. No change
   d. Pharmacist-in-charge's name, current Arizona Board-issued pharmacist license number, and telephone number; and
   e. No change
2. No change
   a. No change
   b. No change
   c. No change
   d. No change
3. No change
   a. No change
   b. No change
   c. No change
   d. No change
4. No change
   a. No change
   b. No change
   c. No change

D. No change

E. No change
1. No change
   a. No change
      i. No change
      ii. No change
      iii. No change
   b. No change
      i. No change
      ii. No change
      iii. No change
   c. No change
   d. No change
2. No change
   a. No change
   b. No change
   c. No change
   d. No change
3. Nonresident full-service drug wholesaler. A nonresident full-service drug wholesale permittee shall:
   a. Not sell, distribute, give away, or dispose of, any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical to anyone in Arizona, except in the original container packaged and labeled by the manufacturer or repackager;
   b. Not package, repackage, label, or relabel any narcotic or other controlled substance, prescription-only drug or device, nonprescription drug, precursor chemical, or regulated chemical for shipment or delivery to anyone in Arizona;
   ~~a.~~c. Not sell, distribute, give away, or dispose of, any narcotic or other controlled substance, ~~or~~ prescription-only drug or device nonprescription drug, precursor chemical, or regulated chemical, to anyone in Arizona except a pharmacy, drug manufacturer, or full-service drug wholesaler currently permitted by the Board or a medical practitio-

ner currently licensed under A.R.S. Title 32;
~~b.~~ d. No change
~~c.~~ e. No change
~~d.~~ f. No change

4. Nonresident nonprescription drug wholesaler. A nonresident nonprescription drug wholesale permittee shall:
   a. Not sell, distribute, give away, or dispose of, any nonprescription drug, precursor chemical, or regulated chemical to anyone in Arizona, except in the original container packaged and labeled by the manufacturer or repackager;
   b. Not package, repackage, label, or relabel any nonprescription drug, precursor chemical, or regulated chemical for shipment or delivery to anyone Arizona;
   ~~a.~~ c. No change
   ~~b.~~ d. No change
   ~~c.~~ e. No change
5. Nonresident nonprescription drug retailer. A nonresident nonprescription drug permittee shall not:
   a. No change
   b. Package, repackage, label, or relabel any drug, precursor chemical, or regulated chemical for shipment or delivery to anyone in Arizona; or
   c. No change

F. No change

R4-23-621. ~~Reserved~~ 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 appropriate technology that allows access to sufficient 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 prescription order may be processed or filled by another pharmacy; and
   b. Give 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 prescription order, the patient shall be notified of this fact. Such notification may be provided through a one-time written notice to the patient or through use of a sign in the pharmacy.
2. If a prescription 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; and
   b. A statement that conveys to the patient or patient's care-giver the follow 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)."
3. The provisions of this subsection do not apply to prescriptions 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 meet the following requirements:
1. Maintain manual or electronic records identifying, individually for each order processed, the name, initials, or identification 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 identifying, 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 desig-

nee.

E. Each pharmacy permittee providing or utilizing 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. 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 prescription may be outsourced to another pharmacy for shared services and providing the name of that pharmacy;
   b. Protecting the confidentiality and integrity of patient information;
   c. Dispensing prescription orders when the filled order is not received or the patient comes in before the order is received;
   d. Maintaining appropriate 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 privacy and security of confidential records; and
2. None of the database is duplicated, downloaded, or removed from the pharmacy's electronic database.

NOTICE OF SUPPLEMENTAL PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

[R06-305]

PREAMBLE

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

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

Notice of Supplemental Proposed Rulemaking: 12 A.A.R. 1160, April 14, 2006

2.

Sections Affected	**Rulemaking Action**
R4-23-110	Amend
R4-23-614	New Section
R4-23-615	New Section
R4-23-616	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 three new Sections of rule to address automated storage and distribution systems, mechanical storage and counting devices, and mechanical counting devices. New definitions for "automated storage and distribution systems," "mechanical counting device for drugs in solid, oral dosage forms," and "mechanical storage and counting device for drugs in solid, oral dosage forms" 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 Storage and Counting Device for Drugs in Solid, Oral Dosage Forms) will establish standards for the use of mechanical storage and counting devices by Arizona pharmacies. New Section R4-23-616 (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, mechanical storage and counting devices, and mechanical counting devices in Arizona.

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

After reviewing public comment and additional changes requested by Board staff, the Board decided to make additional substantial changes. The first change adds a new Section for mechanical counting devices that only count medications and do not store the medications. The second change involves adding the words "storage and" between the words "mechanical" and "counting" in every instance they occur together in R4-23-615. This will change the heading of the Section to read (Mechanical Storage and Counting Device for Drugs in Solid, Oral Dosage Forms). This is necessary because these devices not only count medications, but also store medications and in many instances also package or label the medications. Whereas, the devices addressed by Section R4-23-616 only count medications, and do not store, package, or label medications. A third change is made by adding the words "placement into the automated storage and distribution system and subsequent" in R4-23-614(B)(2)(a)(ii) to improve the clarity of the subsection. A fourth change involves adding a new subsection (B) to R4-23-615 and renumbering the subsequent subsections. The new subsection R4-23-615(B) prohibits a pharmacy from returning a drug previously counted by a mechanical storage and counting device that has not left the pharmacy to the original cell, cassette or stock bottle. This prohibition is necessary to prevent restocking errors, as it is impossible to guarantee that the correct drug is placed in the correct cell, cassette, or stock bottle. The fifth change involves adding subsection (D) to R4-23-615 and subsection (B) to R4-23-616 requiring the pharmacy permittee or pharmacist-in-charge to make all documentation required under R4-23-615(C) and R4-23-616(A) available for inspection by the Board or its designee.

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, mechanical storage and counting devices, 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, October 2, 2006. An oral proceeding is scheduled for:

Date:	October 2, 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 October 2, 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 Storage and Counting Device for Drugs in Solid, Oral Dosage Forms
R4-23-616. ~~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
"Mechanical Counting Device for Drugs in Solid, Oral Dosage Forms" means a mechanical device that counts drugs in solid, oral dosage forms for dispensing and includes an electronic balance when used to count drugs.
"Mechanical Storage and Counting Device for Drugs in Solid, Oral Dosage Forms" means a mechanical device that stores and counts and may package or label drugs in solid, oral dosage forms for dispensing.
"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 prescriptions that:
i. Do not require oral consultation as specified in R4-23-402(B); and
ii. Are properly labeled and verified by a pharmacist before placement into the automated storage and distribution system and subsequent 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 designee; 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), or (C).

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

A. A pharmacy permittee or pharmacist-in-charge shall ensure that a mechanical storage and 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 that any drug previously counted by a mechanical storage and counting device for a drug in a solid, oral dosage form that has not left the pharmacy is not returned to its original cell, cassette, or stock bottle. This subsection does not prevent a pharmacy permittee or pharmacist-in-charge from using a manual or mechanical counting device to count and dispense such a previously counted drug that has not left the pharmacy provided that the previously counted drug is dispensed within its beyond-use-date.

C. A pharmacy permittee or pharmacist-in-charge shall ensure the accuracy of any mechanical storage and 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 storage and counting device for each employee who uses the mechanical storage and counting device;
2. Daily maintenance and calibration of the mechanical storage and counting device; and
3. Routine quality assurance and accuracy validation testing for each mechanical storage and counting device.

D. A pharmacy permittee or pharmacist-in-charge shall ensure that the documentation required in subsection (C) is available for inspection by the Board or its designee.

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

1. Ensure that policies and procedures for the performance and use of a mechanical storage and 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 subsection (E)(1);
3. Document the review required under subsection (E)(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.

F. The Board may prohibit a pharmacy permittee or pharmacist-in-charge from using a mechanical storage and 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), (C), (D), or (E).

R4-23-616. ~~Reserved~~ Mechanical Counting Device for Drugs in Solid, Oral Dosage Forms

A. 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 and accuracy validation testing for each mechanical counting device.

B. A pharmacy permittee or pharmacist-in-charge shall ensure that the documentation required in subsection (A) is available for inspection by the Board or its designee.

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 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 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), or (C).