

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 2. ADMINISTRATION

CHAPTER 5. DEPARTMENT OF ADMINISTRATION PERSONNEL ADMINISTRATION

[R05-481]

PREAMBLE

- | | |
|------------------------------------|---------------------------------|
| 1. <u>Sections Affected</u> | <u>Rulemaking Action</u> |
| R2-5-502 | Amend |
- 2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**
Authorizing statute: A.R.S. § 41-778(A)
Implementing statutes: A.R.S. §§ 41-778(B) and 41-783
- 3. A list of all previous notices appearing in the Register addressing the proposed rule:**
Notice of Rulemaking Docket Opening: 11 A.A.R. 619, February 4, 2005
- 4. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:**
- | | |
|------------|--|
| Name: | Christine Bronson, Human Resources Consultant |
| Address: | Arizona Department of Administration
Human Resources Division
100 N. 15th Ave., Suite 261
Phoenix, AZ 85007 |
| Telephone: | (602) 364-1693 |
| Fax: | (602) 542-2796 |
| E-mail: | Christine.Bronson@azdoa.gov |
- 5. An explanation of the rule, including the agency's reasons for initiating the rule:**
The agency is complying with A.R.S. § 41-778, which requires the rules to include a procedure to allow state employees to voluntarily engage in activities that support mentoring, education and youth development of school age youths.
- 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 rulemaking affects state service employees only and will not have an impact on small businesses and consumers. Any financial impact or administrative expenses will be covered by ordinary operating funds.

Notices of Proposed Rulemaking

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: Christine Bronson, Human Resources Consultant
Address: Arizona Department of Administration
Human Resources Division
100 N. 15th Ave., Suite 261
Phoenix, AZ 85007
Telephone: (602) 364-1693
Fax: (602) 542-2796
E-mail: Christine.Bronson@azdoa.gov

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:

No oral proceeding is scheduled. To request an oral proceeding or to submit comments, please contact the human resources consultant listed in item 4 between the hours of 8:00 a.m. and 5:00 p.m., Monday through Friday, except Arizona legal holidays. If a request for an oral proceeding is not made, the public record in this rulemaking will close at 5:00 p.m. on January 30, 2006.

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

None

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

None

13. The full text of the rules follows:

TITLE 2. ADMINISTRATION

CHAPTER 5. DEPARTMENT OF ADMINISTRATION
PERSONNEL ADMINISTRATION

ARTICLE 5. CONDITIONS OF EMPLOYMENT

Section
R2-5-502. Hours of Work

ARTICLE 5. CONDITIONS OF EMPLOYMENT

R2-5-502. Hours of Work

- A.** State service work week. The state service work week is the period of seven consecutive days starting Saturday at 12:00 a.m. and ending Friday at 11:59 p.m. An agency head may apply to the Director for an exception from the work week period for all or part of an agency workforce. The Director may grant an exception from the work week period to promote efficiency in the state service.
- B.** Hours of employment.
1. An agency head shall determine the hours of employment in the work week for each agency employee.
 2. An agency head may provide for breaks during the work period consistent with carrying out the duties of the agency.
 3. An agency head may require an employee to work overtime.
- C.** Flexible work options.
1. An agency head may offer a flexible 40-hour work week option to an employee if the agency head determines the agency's existing services can be maintained.
 2. An agency head may offer flex time to an employee for the purpose of mentoring school age youths at a public school, private school, home school, or through a faith-based organization, if the agency head determines the agency's existing services can be maintained. Flex time for the purpose of mentoring shall not:
 - a. Exceed one hour per week per employee;
 - b. Exceed five hours in any calendar month per employee;
 - c. Be paid time;
 - d. Carry forward from one week to the next; or

- e. Count toward overtime.
- D. Attendance standards.
1. An agency head may establish a standard of attendance.
 2. Job abandonment. After an absence of three consecutive work days without approval, an agency head may dismiss the employee under R2-5-803 or may separate the employee without prejudice. The agency head shall provide written notice to the employee's last known address.

NOTICE OF PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

[R05-478]

PREAMBLE

- | | |
|------------------------------------|---------------------------------|
| 1. <u>Sections Affected</u> | <u>Rulemaking Action</u> |
| R4-23-110 | Amend |
| R4-23-614 | New Section |
| R4-23-615 | New Section |
- 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)
Implementing statutes: A.R.S. § 32-1904(B)(3)
- 3. A list of all previous notices appearing in the Register addressing the proposed rule:**
Notice of Rulemaking Docket Opening: 11 A.A.R. 5545, December 30, 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:**
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 R4-23-514 (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. 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

Notices of Proposed Rulemaking

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, January 30, 2006. An oral proceeding is scheduled for:

Date: January 30, 2006
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 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 rules 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 and accurately supplies the correct strength, dosage form, and quantity of the drug prescribed 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 in a wall of a properly permitted pharmacy;
 - 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 access to drugs or devices for the purposes of administration only by authorized licensed personnel based on a valid prescription order or medication order;
 4. Ensure adequate security to prevent unauthorized individuals from accessing or obtaining drugs or devices;
 5. Ensure that the filling, stocking, or restocking of all drugs or devices in the system is performed only by a Board licensee; and
 6. 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 and implemented;
 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 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

Notices of Proposed Rulemaking

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:

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 and implemented;

2. Review biennially and, if necessary, revise the policies and procedures required under this rule;

3. Document the review required under subsection (B)(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.

C. 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) and (B).

NOTICE OF PROPOSED RULEMAKING

TITLE 17. TRANSPORTATION

**CHAPTER 4. DEPARTMENT OF TRANSPORTATION
TITLE, REGISTRATION, AND DRIVER LICENSES**

[R05-468]

PREAMBLE

1. Sections Affected

R17-4-410

Rulemaking Action

Amend

2. The statutory authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statute: A.R.S. § 28-366

Implementing statute: A.R.S. §§ 16-101, 16-112

3. A list of all previous notices appearing in the Register addressing the proposed rule:

Notice of Rulemaking Docket Opening: 11 A.A.R. 5548, December 30, 2005

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

Name: Troy A. Walters, Rules Analyst

Address: Administrative Rules Unit
Department of Transportation
1801 W. Jefferson, MD 530M
Phoenix, AZ 85007

Telephone: (602) 712-8994

Fax: (602) 712-3081

E-mail: twalters@azdot.gov

Please visit the ADOT web site to track progress of this rule and any other agency rulemaking matters at www.azdot.gov/mvd/mvdrules/ruls.asp.

5. An explanation of the rule, including the agency's reasons for initiating the rule:

The Arizona Department of Transportation, Motor Vehicle Division "MVD" amends this Section to reflect current terminology used regarding voter registration through "MVD." This Section provides for voter registration through "MVD's" ServiceArizona program or through "MVD's" driver license system in accordance with A.R.S. § 28-112. Additionally, grammatical and technical changes will be made to make the rule more clear, concise, and understandable.

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:

The agency did not rely on any study for this rulemaking.

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 economic impact of this rulemaking is negligible. There are no costs to businesses resulting from this rulemaking. Private consumers will potentially benefit minimally in saved time and possibly also in mailing costs if opting for hardcopy voter registration. The rule merely makes changes to reflect the current terminology used and to make the rule more clear, concise, and understandable.

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: Troy A. Walters, Rules Analyst

Address: Administrative Rules Unit
Department of Transportation
1801 W. Jefferson, MD 530M
Phoenix, AZ 85007

Telephone: (602) 712-8994

Fax: (602) 712-3081

E-mail: twalters@azdot.gov

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:

No oral proceeding is scheduled for this rulemaking action. A request for an oral proceeding may be made to the agency official listed in item #4. If no oral proceeding is made, the public record for this rulemaking will close at 4:30 p.m. on January 30, 2006.

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

None

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

None

13. The full text of the rules follows:

TITLE 17. TRANSPORTATION

**CHAPTER 4. DEPARTMENT OF TRANSPORTATION
TITLE, REGISTRATION, AND DRIVER LICENSES**

ARTICLE 4. DRIVER LICENSES

Section

R17-4-410. ~~License Application-linked Easy~~ Voter Registration through the Motor Vehicle Division "MVD"

ARTICLE 4. DRIVER LICENSES

R17-4-410. ~~License Application-linked Easy Voter Registration~~ through the Motor Vehicle Division “MVD”

- A. For purposes of this Section, “license” has the same meaning as “Driver’s License” under A.R.S. § 16-111(2).
- B. To register to vote in Arizona through the Arizona Department of Transportation, Motor Vehicle Division “MVD,” as provided for in A.R.S. § 16-112, a person who completes a transaction listed in subsection (C) shall complete and return to MVD:
1. A Secretary of State-approved hardcopy voter registration form for the county of the person’s residence, or
 2. An Easy Voter Registration form on MVD’s Service Arizona web site at: www.servicearizona.ihost.com; and electronic voter registration form through MVD’s ServiceArizona program or through MVD’s driver license system along with an electronic verification of voter eligibility according to criteria prescribed under A.R.S. § 16-101.
 3. ~~An electronic verification of voter eligibility according to criteria prescribed under A.R.S. § 16-101.~~
- C. Subsection (B)(~~2~~) applies to the following license transactions:
1. Initial licensee application;
 2. License renewal;~~or~~
 3. Duplicate driver license; or
 4. Licensee personal information update.
- D. MVD shall transfer the voter registration forms and the data collected under this Section by:
1. Mailing the completed hardcopy forms to the appropriate county recorder; and
 2. Transmitting the data from completed ~~Easy Voter Registration~~ electronic voter registration forms and licensee personal information updates to the Secretary of State as prescribed under A.A.C. R2-12-605 for further distribution to the appropriate county recorder.
- E. MVD shall maintain confidential applicant information as required under A.R.S. Title 16, Chapter 1.