

## 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 4. PROFESSIONS AND OCCUPATIONS

#### CHAPTER 23. BOARD OF PHARMACY

[R07-62]

#### PREAMBLE

**1. Sections Affected**

R4-23-110  
R4-23-1201  
R4-23-1202  
R4-23-1203  
R4-23-1204  
R4-23-1205  
R4-23-1206  
R4-23-1207  
R4-23-1208  
R4-23-1209  
R4-23-1210  
R4-23-1211

**Rulemaking Action**

Amend  
New Section  
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) and 32-1904(B)(3)

Implementing statutes: A.R.S. § 32-1909

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

Notice of Rulemaking Docket Opening: 12 A.A.R. 3812, October 13, 2006

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

Name: Dean Wright, Compliance Officer

Address: Board of Pharmacy  
4425 W. Olive Ave., Ste. 140  
Glendale, AZ 85302

Telephone: (623) 463-2727, ext. 131

Fax: (623) 934-0583

E-mail: rxcop@cox.net

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

The 47th Legislature passed H.B. 2382 to specify creation of a prescription medication donation program. The bill requires the Board to write rules, in consultation with the Director of the Department of Health Services, implementing a prescription medication donation program in Arizona. The proposed rules will add necessary new definitions to R4-23-110 (Definitions), including "health care institution" and "licensed health care professional." The proposed rules will include a new Article 12 (Prescription Medication Donation Program) and new Sections within the Article that specify the requirements described in A.R.S. § 32-1909. 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.

Notices of Proposed Rulemaking

The Board believes that approval of these rules benefits the public and the pharmacy community by clearly establishing the standards for a prescription medication donation program.

**6. A reference to any study that the agency proposes to rely on in its evaluation of or justification for the rules and where the public may obtain or review the study, all data underlying each study, any analysis of the study, and other supporting material:**

The agency did not review or rely on any study relevant to these rules.

**7. A showing of good cause why the rules are necessary to promote a statewide interest if the rules 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, pharmacies, physicians, health care institutions, and the public. The proposed rules' impact on the Board will be the usual rulemaking-related costs which are minimal. The Board estimates the proposed rules will have moderate economic impact on Board office operations through increased staff time to perform compliance inspections of prescription medication program participants.

The Board estimates the proposed rules have the potential to reduce the public's drug cost by allowing the use of previously dispensed but unused prescription medications that are donated to participating physician offices, pharmacies, or health care institutions for dispensing to uninsured qualifying individuals. The Board estimates that hundreds of thousands dollars worth of unused prescription medications are destroyed annually because the medication is stopped by the physician, the patient no longer needs the medication, or similar other reasons. The Arizona Legislature felt that patients should be allowed to donate these unused prescription medications to a program that would dispense the prescription medication to individuals who might not otherwise be able to afford prescription medication, thus reducing the needless loss of perfectly good prescription medication. The proposed rules allow a participating physician's office, pharmacy, or health care institution to charge a nominal (no more than \$3 based on the current AHCCCS dispensing fee) per prescription handling fee to cover the costs of inspecting, stocking, and dispensing the donated prescription medication. The proposed rules have no direct economic impact on the public. However, the public benefits from a program that provides otherwise unused prescription medication to individuals who otherwise could not afford treatment, and who without treatment could become a burden on the public health care system.

The public, Board, pharmacies, and pharmacists benefit from rules that are clear, concise, and understandable. The proposed rules benefit the public and the pharmacy community by clearly establishing the standards for a prescription medication donation program.

**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., Ste. 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 rules or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rules:**

Comments may be written or presented orally. Written comments must be received by 5:00 p.m., Monday, April 23, 2007. An oral proceeding is scheduled for:

Date: April 23, 2007  
Time: 10:00 a.m.  
Location: 4425 W. Olive Ave., Ste. 140  
Glendale, AZ 85302

A person may request information about the oral proceeding by contacting the person listed above.

**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 12. PRESCRIPTION MEDICATION DONATION PROGRAM**

R4-23-1201. Eligibility Requirements for Participation in the Program

R4-23-1202. Donating Medications

R4-23-1203. Eligible Prescription Medications

R4-23-1204. Eligibility Requirements to Receive Donated Prescription Medications

R4-23-1205. Donor Form

R4-23-1206. Recipient Form

R4-23-1207. Recordkeeping

R4-23-1208. Handling Fee

R4-23-1209. Policies and Procedures

R4-23-1210. Dispensing Donated Prescription Medications

R4-23-1211. Responsibilities of the Physician-in-charge or Pharmacist-in-charge of a Participating Physician's Office, Pharmacy, or Health Care Institution

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
- “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

*Arizona Administrative Register / Secretary of State*  
**Notices of Proposed Rulemaking**

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“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  
“Health care decision maker” has the same meaning as in A.R.S. § 12-2291.  
“Health care institution” has the same meaning as in A.R.S. § 36-401.  
“Immediate notice” No change  
“Inactive ingredient” No change  
“Internal test assessment” No change  
“ISO Class 5 environment” No change  
“ISO Class 7 environment” No change  
“Licensed health care professional” means a professional who is licensed and regulated under Title 32, Chapter 7, 11, 13, 14, 15, 16, 17, 18, 25, 29, or 35.  
“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  
“Prep area” 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
- “Sight-readable” No change
- “Single-drug audit” No change
- “Single-drug usage report” No change
- “Standard-risk sterile pharmaceutical product” No change
- “Sterile pharmaceutical product” No change
- “Strength” No change
- “Substantial-risk sterile pharmaceutical product” No change
- “Supervision” No change
- “Supervisory physician” No change
- “Supplying” No change
- “Support personnel” No change
- “Transfill” No change
- “Verified signature” or “signature verifying” No change
- “Wholesale distribution” No change
- “Wholesale distributor” No change

**ARTICLE 12. PRESCRIPTION MEDICATION DONATION PROGRAM**

**R4-23-1201. Eligibility Requirements for Participation in the Program**

A physician’s office, pharmacy, or health care institution may participate in the prescription medication donation program, under A.R.S. § 32-1909, if all of the following requirements, as applicable, are met:

1. The physician-in-charge of the participating physician’s office has a current license issued under A.R.S. Title 32, Chapter 13 or 17;
2. The pharmacy has a current permit issued under A.R.S. Title 32, Chapter 18;
3. The health care institution has a current license issued under A.R.S. Title 36, Chapter 4 and has a physician-in-charge or pharmacist-in-charge of dispensing; and
4. The physician’s office, pharmacy, or health care institution complies with all federal and state drug laws, rules, and regulations.

**R4-23-1202. Donating Medications**

**A.** The following may donate an eligible prescription medication, as specified in R4-23-1203, to a physician’s office, pharmacy, or health care institution that participates in the prescription medication donation program:

1. An individual who was legally prescribed the prescription medication on a patient-specific prescription order or that individual’s health care decision maker;
2. A manufacturer who has a current permit issued under A.R.S. Title 32, Chapter 18; or
3. A health care institution that has a current license issued under A.R.S. Title 36, Chapter 4.

**B.** An individual or health care decision maker electing to donate an eligible prescription medication shall not have taken possession of the prescription medication before the donation and shall make the donation through a medical practitioner, pharmacy, or health care institution.

**R4-23-1203. Eligible Prescription Medications**

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A prescription medication, other than a controlled substance or drug sample, may be donated to a physician's office, pharmacy, or health care institution that participates in the prescription medication donation program if the prescription medication:

1. Is in its original sealed and tamper-evident unit dose packaging that is unopened or has only its outside packaging opened and its single unit dose packaging undisturbed;
2. Has been in the possession of a licensed health care professional, manufacturer, pharmacy, or health care institution and not in the possession of the ultimate user;
3. Has been stored according to federal and state drug law and the requirements of the manufacturer's package insert;
4. Has an expiration date or beyond-use-date later than six months after the date of donation;
5. Is in packaging that shows the lot number and expiration date or beyond-use-date of the prescription medication;
6. Does not have any physical signs of tampering or adulteration; and
7. Is in packaging that does not have any physical signs of tampering.

**R4-23-1204. Eligibility Requirements to Receive Donated Prescription Medications**

**A. Before dispensing a donated prescription medication to an individual, a physician's office, pharmacy, or health care institution that participates in the prescription medication donation program shall determine if the individual is eligible to receive donated prescription medications.**

**B. To be eligible to receive donated prescription medication from the prescription medication donation program, an individual shall:**

1. Provide proof that the individual is a resident of Arizona that includes:
  - a. One of the following that shows the Arizona residential address included on the recipient form specified in R4-23-1206 and the name of the recipient or, if the recipient is a minor, the recipient's parent or guardian:
    - i. Documentation issued by a governmental entity related to participation in public assistance, dated within 60 calendar days before the date the donated prescription medication is dispensed;
    - ii. Current documentation from AHCCCS related to the recipient's eligibility for enrollment in AHCCCS;
    - iii. Current documentation from the Social Security Administration or the Department of Veterans Affairs related to the recipient's eligibility for benefits;
    - iv. Current documentation from the Arizona Department of Economic Security related to the recipient's eligibility for unemployment insurance benefits;
    - v. A property tax statement for the most recent tax year issued by a governmental entity;
    - vi. A homeowner's association assessment or fee statement, dated within 60 calendar days before the date the donated prescription medication is dispensed;
    - vii. A current lease agreement; or
    - viii. A mortgage statement for the most recent tax year;
  - b. If the recipient is unable to produce documentation that satisfies subsection (B)(1)(a), two of the following that show the Arizona residential address included on the recipient form specified in R4-23-1206 and the name of the recipient or, if the recipient is a minor, the recipient's parent or guardian:
    - i. A utility bill dated within 60 calendar days before the date the donated prescription medication is dispensed;
    - ii. A tax statement, other than a property tax statement, issued by a governmental entity for the most recent tax year;
    - iii. An Internal Revenue Service Form W-2 for the most recent tax year;
    - iv. A check stub or statement of direct deposit issued by an employer for the most recent pay period;
    - v. A bank or credit union statement dated within 60 calendar days before the date the donated prescription medication is dispensed;
    - vi. A non-expired Arizona driver license issued by the Arizona Department of Transportation's Motor Vehicle Division;
    - vii. A non-expired Arizona vehicle registration issued by the Arizona Department of Transportation's Motor Vehicle Division;
    - viii. A non-expired Arizona identification card issued by the Arizona Department of Transportation's Motor Vehicle Division;
    - ix. A tribal enrollment card or other type of tribal identification; or
    - x. A current immigration identification card issued by U.S. Citizenship and Immigration Services; or
  - c. If the recipient is unable to produce documentation that satisfies either subsection (B)(1)(a) or (b), two of the following that include the name of the recipient or, if the recipient is a minor, the recipient's parent or guardian:
    - i. A document listed in subsection (B)(1)(b)(i) through subsection (B)(1)(b)(x) that shows the Arizona residential address included on the recipient form specified in R4-23-1206;
    - ii. A letter issued by an entity providing non-permanent housing to the recipient, including the Arizona residential address of the non-permanent housing that is the same as the Arizona residential address for the recipient included on the recipient form specified in R4-23-1206;
    - iii. A written statement issued by a community service organization, verifying that the recipient is homeless and

- a resident of Arizona:
- iv. A department store, primary care provider's office, insurance company, or mobile telephone company billing statement dated within 60 calendar days before the date the donated prescription medication is dispensed, including the Arizona residential address included on the recipient form specified in R4-23-1206;
- v. A vehicle insurance card dated within 60 calendar days before the date the donated prescription medication is dispensed, including the Arizona residential address included on the recipient form specified in R4-23-1206;
- vi. An official document, such as an Arizona voter registration card, issued by a governmental entity and including the Arizona residential address included on the recipient form specified in R4-23-1206;
- vii. A written statement issued by the recipient's case manager indicating that the case manager has conducted a home visit with the recipient at the Arizona residential address included on the recipient form specified in R4-23-1206 within 30 calendar days before the date the donated prescription medication is dispensed; or
- viii. A written statement issued by the recipient's primary care provider, verifying that the recipient is a resident of Arizona;
- 2. Have no active third party prescription medication coverage for the prescription medication prescribed; and
- 3. Be ineligible for enrollment in AHCCCS as established by documentation issued by AHCCCS.

**R4-23-1205. Donor Form**

- A.** Before donating a prescription medication, a donor shall sign a form that includes:
- 1. A statement attesting that the donor is the owner of the prescription medication and intends to voluntarily donate the prescription medication to the prescription medication donation program;
  - 2. If the donor is an individual:
    - a. The individual's name and address;
    - b. The name of the individual's health care decision maker, if applicable;
    - c. The name of the medical practitioner, pharmacy, or health care institution through which the donation is being made;
    - d. A statement attesting that the individual has not had possession of the donated prescription medication;
    - e. A statement attesting that the medical practitioner, pharmacy, or health care institution through which the donation is being made has stored the donated prescription medication as required in R4-23-1203(3);
    - f. If the donation is an ongoing donation as authorized under subsection (B), a statement that conforms to subsection (B);
    - g. The dated signature of the individual or the individual's health care decision maker; and
    - h. The dated signature of the medical practitioner or of an authorized agent for the pharmacy or health care institution through which the donation is being made;
  - 3. If the donor is a manufacturer:
    - a. The name and address of the manufacturer; and
    - b. The dated signature of the manufacturer's authorized agent; and
  - 4. If the donor is a health care institution:
    - a. The name and address of the health care institution;
    - b. A statement attesting that the health care institution has stored the donated prescription medication as required in R4-23-1203(3); and
    - c. The dated signature of the health care institution's authorized agent.
- B.** An individual who resides in a health care institution, or the individual's health care decision maker, may elect to make an ongoing donation of future unused eligible prescription medication by indicating the following on a donor form that complies with subsection (A): "From this day forward, I wish to donate all my remaining unused prescription medications that are eligible, under R4-23-1203, to the prescription medication donation program."
- C.** In addition to obtaining a completed donor form as required in subsection (A), each physician's office, pharmacy, or health care institution that participates in the prescription medication donation program shall document, either on the original signed donor form or on an alternate record that includes the name of the donor, the following information:
- 1. The brand name or generic name of the prescription medication donated;
  - 2. If a generic medication, the name of the manufacturer or the national drug code number (NDC#) of the prescription medication donated;
  - 3. The strength of the prescription medication donated;
  - 4. The quantity of the prescription medication donated; and
  - 5. The date the prescription medication is donated.
- D.** To stop an ongoing donation, an individual who resides in a health care institution, or the individual's health care decision maker, shall submit written notice to the receiving physician's office, pharmacy, or health care institution indicating the individual's, or the health care decision maker's, desire to stop the ongoing donation.

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**R4-23-1206. Recipient Form**

Each recipient of a donated prescription medication from the prescription medication donation program shall sign a form stating that the recipient understands the immunity provisions of the program under A.R.S. § 32-1909(E) and (F) and including at least the following:

1. The recipient's name and address;
2. The dated signature of the recipient;
3. The brand name or generic name of the prescription medication received;
4. If a generic medication, the name of the manufacturer or the national drug code number (NDC#) of the prescription medication received;
5. The strength of the prescription medication received; and
6. The quantity of the prescription medication received.

**R4-23-1207. Recordkeeping**

A. A physician's office, pharmacy, or health care institution that participates in the prescription medication donation program shall:

1. Maintain the documents required under R4-23-1205 and R4-23-1206 for a minimum of three years; and
2. Make the documents required in subsection (A)(1) available upon request for inspection by the Board, its designee, or other authorized officers of the law.

B. Before transferring possession of a prescription medication donated by an individual or an individual's health care decision maker, a medical practitioner, pharmacy, or health care institution through which the donation is being made shall create an invoice that includes the following:

1. The name and address of the medical practitioner, pharmacy, or health care institution;
2. The name of the individual who made the donation;
3. The brand name or generic name of the prescription medication donated;
4. If a generic medication, the name of the manufacturer or the national drug code number (NDC#) of the prescription medication donated;
5. The strength of the prescription medication donated;
6. The quantity of the prescription medication donated;
7. The lot number of the prescription medication donated;
8. The expiration date or beyond-use-date of the prescription medication donated;
9. The date the prescription medication is transferred to a participating physician's office, pharmacy, or health care institution; and
10. The name and address of the participating physician's office, pharmacy, or health care institution to which the donated prescription medication is transferred.

C. A manufacturer that donates a prescription medication shall create an invoice that includes the manufacturer's name and address and the information described in subsections (B)(3) through (10).

D. A health care institution that donates a prescription medication shall create an invoice that includes the health care institution's name and address and the information described in subsections (B)(3) through (10).

E. A medical practitioner, pharmacy, health care institution, or manufacturer required to create an invoice under subsection (B), (C), or (D) shall:

1. Transmit a copy of the invoice to the participating physician's office, pharmacy, or health care institution to which a donated prescription medication is transferred;
2. Maintain a copy of the invoice for a minimum of three years from the date of the invoice; and
3. Make a copy of the invoice available upon request for inspection by the Board, its designee, or other authorized officers of the law.

F. A participating physician's office, pharmacy, or health care institution that receives a donated prescription medication shall:

1. Maintain each invoice received under subsection (E)(1) for at least three years from the date received; and
2. Make an invoice available upon request for inspection by the Board, its designee, or other authorized officers of the law.

**R4-23-1208. Handling Fee**

A physician's office, pharmacy, or health care institution that participates in the prescription medication donation program may charge a recipient of a donated prescription medication a handling fee of no more than 200 percent of the AHCCCS professional dispensing fee, per prescription, to cover inspection, stocking, and dispensing costs.

**R4-23-1209. Policies and Procedures**

A physician's office, pharmacy, or health care institution that participates in the prescription medication donation program shall:

1. Develop, implement, and comply with policies and procedures for the safe and efficient receipt, storage, and distribu-

- tion of prescription medications donated to the physician's office, pharmacy, or health care institution;
2. Review biennially and, if necessary, revise the policies and procedures required under this Section;
  3. Document the review required under subsection (2);
  4. Assemble the policies and procedures as a written manual or in a readily accessible electronic format;
  5. Make the policies and procedures available for reference by physician's office, pharmacy, or health care institution personnel and, upon request, for inspection by the Board or its designee; and
  6. Ensure that the written policies and procedures required under subsection (1) include provisions to ensure:
    - a. That each donor meets the eligibility requirements of R4-23-1202;
    - b. That each prescription medication to be donated meets the eligibility requirements of R4-23-1203;
    - c. That each individual who receives a donated prescription medication under the program meets the eligibility requirements of R4-23-1204;
    - d. Compliance with the requirements for donor and recipient forms in R4-23-1205 and R4-23-1206;
    - e. Compliance with the requirements for recordkeeping in R4-23-1207;
    - f. Compliance with the requirements of R4-23-1210; and
    - g. Compliance with the requirements of R4-23-1211.

**R4-23-1210. Dispensing Donated Prescription Medications**

- A.** Before dispensing a donated prescription medication under the program, a participating physician's office, pharmacy, or health care institution shall:
1. Obtain and maintain a current drug identification reference or text in hard-copy or electronic media format;
  2. Obtain a valid prescription order of a licensed medical practitioner for the recipient to receive the donated prescription medication;
  3. Properly label the donated prescription medications to be dispensed;
  4. Comply with all federal and state laws regarding storage and distribution of a donated prescription medication;
  5. Inspect the donated prescription medication to ensure that the prescription medication has not been adulterated; and
  6. Certify that the donated prescription medication has been stored in compliance with the requirements of the manufacturer's package insert.
- B.** Prescription medications donated under this Article shall not be resold, except for transfers between participating physician's offices, pharmacies, or health care institutions as specified in subsection (C).
- C.** A participating physician's office, pharmacy, or health care institution may transfer a donated prescription medication to another participating physician's office, pharmacy, or health care institution, when:
1. The transferring physician's office, pharmacy, or health care institution has available a prescription medication that the receiving physician's office, pharmacy, or health care institution needs;
  2. The transferring physician's office, pharmacy, or health care institution prepares an invoice that includes its name and address and the information described in R4-23-1207(B)(3) through (10);
  3. A copy of the invoice required in subsection (C)(2) is sent to the receiving physician's office, pharmacy, or health care institution with the transferred prescription medication; and
  4. The transferring physician's office, pharmacy, or health care institution and the receiving physician's office, pharmacy, or health care institution each keep a copy of the invoice required in subsection (C)(2) on file for three years from the date of transfer.

**R4-23-1211. Responsibilities of the Physician or Pharmacist-in-charge of a Participating Physician's Office, Pharmacy, or Health Care Institution**

The physician-in-charge of a participating physician's office; the pharmacist-in-charge of a participating pharmacy; or the physician-in-charge or pharmacist-in-charge of dispensing for a participating health care institution shall, either personally or through designees:

1. Coordinate the receipt of donated prescription medications from eligible donors;
2. Check each donated prescription medication against the donor form and any additional alternate record and resolve any discrepancies;
3. Store and secure donated prescription medications as required by federal and state law;
4. Inspect each donated prescription medication for adulteration;
5. Certify that each donated prescription medication has been stored in compliance with the manufacturer's package insert;
6. Ensure that expired, adulterated, or unidentifiable donated prescription medication is not dispensed;
7. Ensure that prescription medications identified under subsection (6) are destroyed within 30 days of identification as specified in subsection (9);
8. Ensure safety in drug recalls by destroying any donated prescription medication that may be subject to recall if its lot number cannot exclude it from recall;
9. Ensure destruction of expired, adulterated, unidentifiable, and recalled donated prescription medication by:

Notices of Proposed Rulemaking

- a. Following federal, state, and local guidelines for drug destruction;
- b. Creating a list of expired, adulterated, unidentifiable, or recalled donated prescription medications to be destroyed;
- c. Following the destruction, signing the list described in subsection (9)(b) and having the list signed by a witness verifying the destruction; and
- d. Keeping the list described in subsection (9)(b) on file for three years from the date of destruction;
10. Redact or remove all previous patient or pharmacy labeling on a donated prescription medication before dispensing the donated prescription medication;
11. Ensure that all dispensed donated prescription medications comply with the labeling requirements of A.R.S. § 32-1968(D); and
12. Place on the label of each dispensed donated prescription medication a beyond-use-date that does not exceed the beyond-use-date or expiration date from the original label of the donated prescription medication or, if the dispensed donated prescription medication comes from multiple packages, the earliest beyond-use-date or expiration date from the donated prescription medication packages.

NOTICE OF PROPOSED RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 22. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM  
ADMINISTRATION

[R07-64]

PREAMBLE

- |                                    |                                 |
|------------------------------------|---------------------------------|
| <b><u>1. Sections Affected</u></b> | <b><u>Rulemaking Action</u></b> |
| R9-22-1431                         | 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. § 36-2903.01  
Implementing statute: A.R.S. § 36-2907.04
- 3. A list of all previous notices appearing in the Register addressing the proposed rule:**  
Notice of Rulemaking Docket Opening: 13 A.A.R. 1053, March 23, 2007 (*in this issue*)
- 4. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:**
- |            |   |
|------------|---|
| Name:      | Mariaelena Ugarte   |
| Address:   | AHCCCS<br>Office of Legal Assistance<br>701 E. Jefferson, Mail Drop 6200<br>Phoenix, AZ 85034 |
| Telephone: | (602) 417-4232  |
| Fax:       | (602) 253-9115  |
| E-mail:    | AHCCCSRules@azahcccs.gov  |
- 5. An explanation of the rule, including the agency's reasons for initiating the rule:**  
The Administration is proposing amendments to revise and clarify the Family Planning rule language. The Centers for Medicare and Medicaid Services (CMS) approved the Section 1115 waiver on October 27, 2006. The Administration is to provide family planning services for up to 24 months, with an annual redetermination at 12 months. The Administration is updating the existing rules on Family Planning to make them consistent with the changes stipulated by the federal government in then Section 1115 waiver, as well as, to make the rules clear, concise, and understandable.
- 6. A reference to any study that the agency proposes to rely on in its evaluation of or justification for the rules and where the public may obtain or review the study, all data underlying each study, any analysis of the study, and other supporting material:**  
The Administration did not review any study relevant to these rules.

**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:**

It is anticipated that the contractors, private sector, members, providers, small businesses, political subdivisions, the Department, and the Administration will be minimally impacted by the changes to the rule language. The Family Planning rule describes how the Administration will enroll and reenroll individuals for Family Planning services. The Administration is proposing amendments to the rules to revise, reorganize, and clarify the Family Planning program as specified in the Section 1115 waiver with CMS.

**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: Mariaelena Ugarte  
Address: AHCCCS  
Office of Legal Assistance  
701 E. Jefferson, Mail Drop 6200  
Phoenix, AZ 85034  
Telephone: (602) 417-4232  
Fax: (602) 253-9115  
E-mail: AHCCCSRules@azahcccs.gov

Proposed rule language is anticipated to be available on the AHCCCS web site (www.azahcccs.gov) the week of March 5, 2007. Please send written or e-mailed comments to the above address by 5:00 p.m., May 7, 2007.

**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:**

Date: May 7, 2007  
Time: 10:00 a.m.  
Location: AHCCCS  
701 E. Jefferson  
Phoenix, AZ 85034  
Nature: Public Hearing

Date: May 7, 2007  
Time: 10:00 a.m.  
Location: ALTCS: Arizona Long-term Care System  
110 S. Church, Ste. 1360  
Tucson, AZ 85701  
Nature: Public Hearing

Date: May 7, 2007  
Time: 10:00 a.m.  
Location: ALTCS: Arizona Long-term Care System  
3480 E. Rte. 66  
Flagstaff, AZ 86004  
Nature: Public Hearing

**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 9. HEALTH SERVICES**

**CHAPTER 22. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM (AHCCCS)**

**ADMINISTRATION**

**ARTICLE 14. AHCCCS MEDICAL COVERAGE FOR FAMILIES AND INDIVIDUALS**

Section

R9-22-1431. Family Planning Services Extension Program (FPEP)

**ARTICLE 14. AHCCCS MEDICAL COVERAGE FOR FAMILIES AND INDIVIDUALS**

**R9-22-1431. Family Planning Services Extension Program (FPEP)**

**A.** ~~Except as under this Section, a person may receive family planning services as provided in A.R.S. § 36-2907.04.~~

**B.** ~~The Administration shall deny or terminate family planning services under this Section for any of the following reasons:~~

- ~~1. Voluntary withdrawal,~~
- ~~2. Loss of contact,~~
- ~~3. Failure to provide information,~~
- ~~4. Inmate of a public institution,~~
- ~~5. Move out of state~~
- ~~6. Sterility, or~~
- ~~7. Death.~~

**A.** A member who loses eligibility for AHCCCS Medical Coverage under R9-22-1430 after the postpartum period and who has no other creditable insurance may receive up to 24 months of family planning services as provided in this Section and A.R.S. § 36-2907.04.

**B.** Review of eligibility.

1. The Department shall complete a review of each member's continued eligibility for FPEP at least once every 12 months.
2. If a member continues to meet all eligibility requirements and conditions of eligibility, the Department shall authorize continued eligibility for family planning services and notify the member of continued eligibility.
3. The Department shall discontinue eligibility and notify the member of the discontinuance under R9-22-1415 if the member:
  - a. Has income that exceeds 133 percent of the FPL at the time of the 12 month review.
  - b. Fails to comply with a review of eligibility under this subsection, or
  - c. Meets any of the criteria under subsection (D).

**C.** Changes in the member's income after the initial or review eligibility determination shall not impact the member's eligibility during the following 12 month period.

**D.** The Administration or its designee shall deny or terminate FPEP under this Section if a member:

1. Voluntarily withdraws from the program.
2. Has whereabouts that are unknown.
3. Fails to provide information to the Administration or Department.
4. Becomes an inmate of a public institution.
5. Moves out-of-state.
6. Has creditable coverage under 42 U.S.C. 300gg(c).
7. Fails to meet the documentation requirements for U.S. citizenship or legal alien status under A.R.S. § 36-2903.03.
8. Becomes eligible under 9 A.A.C. Chapter 22, Chapter 28, or Chapter 31 for full services under Article 2 of this Chapter.
9. Becomes sterile, or
10. Dies.

**E.** The Administration or its designee shall not reinstate eligibility under this Section after the effective date of the discontinuance unless the discontinuance is overturned on appeal or resulted from an administrative error.

NOTICE OF PROPOSED RULEMAKING

TITLE 17. TRANSPORTATION

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

[R07-61]

PREAMBLE

- 1. Sections Affected**

R17-4-201	<b><u>Rulemaking Action</u></b>
R17-4-207	Amend
R17-4-208	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. § 28-2064
- 3. A list of all previous notices appearing in the Register addressing the proposed rules:**

Notice of Rulemaking Docket Opening: 12 A.A.R. 4904, December 29, 2006
- 4. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:**

Name: Celeste M. Cook, Administrative Rules Analyst  
Address: Administrative Rules Unit  
Department of Transportation, Motor Vehicle Division  
1801 W. Jefferson St., Mail Drop 530M  
Phoenix, AZ 85007  
Telephone: (602) 712-7624  
Fax: (602) 712-3081  
E-mail: ccook@azdot.gov

Please visit the ADOT web site to track progress of this rule and any other agency rulemaking matters at [www.mvd.azdot.gov/mvd/MVDRules/rules.asp](http://www.mvd.azdot.gov/mvd/MVDRules/rules.asp).
- 5. An explanation of the rules, including the agency's reasons for initiating the rules:**

This rulemaking action arises from a Five-Year Review Report approved by the Governor's Regulatory Review Council on December 10, 1999. The Arizona Department of Transportation, Motor Vehicle Division, proposes to amend the existing rules to conform to current statute, remove and update related citations. Changes are also made to ensure conformity to Arizona Administrative Procedures Act, Secretary of State, and Governor's Regulatory Review Council rulemaking format and style requirements.
- 6. A reference to any study that the agency proposes to rely on in its evaluation of or justification for the rules and where the public may obtain or review the study, all data underlying each study, any analysis of the study, and other supporting material:**

None
- 7. A showing of good cause why the rules are necessary to promote a statewide interest if the rules 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 anticipated economic impact of these rules on the Division is moderate, as the rules require the Division to mail the Arizona Certificate of Title to the lienholder of record and maintain electronic title lien records for members of the Electronic Lien and Title program.

The Division anticipates that the economic impact of these rules on small businesses is moderate to substantial as lenders as the rules require the lienholder to implement and maintain a filing system for the Arizona Certificate of Titles for which the lienholder is listed as the lienholder of record. Qualified lenders who opt to participate in the Electronic Lien and Title program will need to establish a computer system and connectivity with the Division's Electronic Lien and Title system for the transmitting of lien filing and lien release information.

Notices of Proposed Rulemaking

The Division anticipates that the economic impact of these rules on the consumer is minimal.

**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:**

See item #4.

**10. The time, place, and nature of the proceedings for the making, amendment, or repeal of the rules, or if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rules:**

Date: April 30, 2007  
Time: 1:00 p.m.  
Location: 1801 W. Jefferson St., Rm. 410  
Nature: Oral Proceeding  
Close of record: April 23, 2007

**11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rules 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 2. VEHICLE TITLE

Section

R17-4-201. Definitions  
R17-4-207. ~~Filing liens and encumbrances~~ Lien Filing  
R17-4-208. ~~Vehicle title lien clearance requirements~~ Lien Clearance Requirements

TITLE 17. TRANSPORTATION

CHAPTER 4. DEPARTMENT OF TRANSPORTATION

TITLE, REGISTRATION, AND DRIVER LICENSES

ARTICLE 2. VEHICLE TITLE

**R17-4-201. Definitions**

~~Unless otherwise indicated, the following definitions apply to this Article: In addition to the definitions prescribed under A.R.S. §§ 28-101, 28-2001, and 28-3001, the following definitions apply to this Article, unless otherwise specified:~~

- ~~“Authorized ELT Participant” means a lending institution or finance company authorized by the Division to electronically release a lien or encumbrance.~~  
~~“Date of lien” means the date identified by the lienholder as the date the loan was issued to the borrower.~~  
1. ~~“Division” or “MVD” means Motor Vehicle Division of the Arizona Department of Transportation, Transportation’s Motor Vehicle Division.~~  
2. ~~“Encumbrance” means a lien recorded, by the Division, on a vehicle or mobile home record and title that is released upon payment or cancellation of the obligation. the Arizona Certificate of Title.~~  
~~“ELT” means Electronic Lien and Title.~~  
3. ~~“EPA standards” means the emission standards of the Environmental Protection Agency standards, as prescribed under 40 CFR 86.~~  
4. ~~“FMVSS” means the Federal Motor Vehicle Safety Standards as prescribed under 49 CFR 571.~~  
5. ~~“GVWR” or “gross vehicle weight rating” has the meaning prescribed in A.R.S. § 28-3001(10).~~  
6. ~~“Joint tenancy with right of survivorship” means vehicle ownership by two or more people persons and with the share of a deceased joint tenant owner’s interest in the vehicle going is transferred to the surviving tenant owners.~~

"Lienholder" means a person or entity retaining legal possession of a vehicle or mobile home until the debtor has satisfactorily repaid the loan for which the vehicle or mobile home was designated as collateral.

"Lienholder Number" means the computer generated record number assigned by the Division to a lienholder.

7. "Low-speed vehicle" has the same meaning as prescribed in under 49 CFR 571.3.

8. "Multipurpose passenger vehicle" or "MPV" means a multipurpose passenger motor vehicle with motive power, except a low speed vehicle or a trailer designed to carry 10 persons or fewer, constructed either on a truck chassis or with special features for occasional off-road operation, which has the same meaning as prescribed under 49 CFR 571.3.

"MVD" means the Arizona Department of Transportation's Motor Vehicle Division.

9. "NHTSA" means the National Highway Traffic Safety Administration of the United States Department of Transportation.

"Primary lien" means the first of any multiple liens recorded on a vehicle or mobile home record.

10. "Registered importer" means a person who: registered by the NHTSA Administrator to import vehicles, as prescribed under 49 CFR 301.

a. Is registered by the NHTSA Administrator as prescribed under 49 CFR 592.5;

b. Is licensed under A.R.S. Title 28, Chapter 10, Article 2; and

e. Performs duties as prescribed under 49 CFR 592.6.

11. "Tenancy in common" means vehicle ownership by two or more people without the right of survivorship.

12. "Valid titling document" means one of the following documents showing a vehicle's compliance with federal vehicle equipment and emissions equipment standards: FMVSS and EPA standards:

a. A registered importer's certificate NHTSA Declaration,

b. A manufacturer's letter, or

e. A U.S. federal compliance label printed in English.

#### **R17-4-207. Filing liens and encumbrances Lien Filing**

A. Section 66-231, A.C.A. 1939, provides for the filing of liens and encumbrances upon motor vehicles with the Division of Motor Vehicles, which section provides, however, that the liens or encumbrances so deposited shall not constitute constructive notice until the issuance of a new certificate of title issued after the filing of said lien. Lien filing. When filing a lien with the Division, a person shall submit an application furnished by the Division, the most recently issued certificate of title, the fee or fees to be paid as provided by law, and any other documentation required pursuant to A.R.S. Title 28.

1. The Division shall record a statement of all liens and encumbrances on the vehicle or mobile home record when satisfied as to the authenticity of the application.

2. The Division shall immediately return a lien filing, with a letter stating why the lien filing was returned, when the lien filing does not meet the requirements prescribed in this subsection.

B. This Section further provides, upon the depositing of any lien or encumbrance, it shall be accompanied by the certificate of title last issued, and the fee or fees provided by law to be paid, whereupon the Division is required to file the application and documents, endorsing thereon the date and hour received and, when satisfied as to the genuineness and regularity of the application, shall issue a new certificate of title showing the name of the owner and statement of all liens and encumbrances, and the amount thereof. Multiple liens. The Division may record up to three liens on any one vehicle or mobile home record. Any additional liens are recorded through the County Recorder's office. The Division considers the primary lien recorded on the vehicle or mobile home record to be above all other subsequent liens or encumbrances.

C. In the past, liens and encumbrances have been submitted to the Division for filing that have not been accompanied by the documents and fees required by law to be filed therewith. Lien filing notice. The Division shall notify the lienholder of the recording of a lien.

1. The Division shall issue an Arizona Certificate of Title or, when the lienholder is an Authorized ELT Participant, transmit an electronic lien notification to the primary lienholder.

2. The Division shall issue a computer-generated Lienholder Record to each subsequent lienholder recorded on the vehicle or mobile home record. The Division shall not issue a duplicate Lienholder Record.

D. Effective immediately, any lien or encumbrance submitted for deposit with this Division, unless accompanied by certificate of title and the required fees, shall be immediately returned, without endorsing thereon the date or hour received, advising and instructing the person so depositing, that the law requires that there shall be deposited with every lien or encumbrance, the certificate of title to the motor vehicle, accompanied by the fee or fees required by law to be paid.

#### **R17-4-208. Vehicle title lien clearance requirements Lien Clearance Requirements**

A. A.R.S. § 28-325, subsection (G), reads: "When final payment is made on a lien or encumbrance recorded under this section, the holder thereof shall make and deliver to the lienor or encumbrancer a satisfaction thereof. Upon delivery to the vehicle division by the lienor or encumbrancer of the certificate of title to the vehicle on which the lien or encumbrance was given, together with satisfaction thereof, the division shall satisfy the lien or encumbrance on its records and on the certificate of title to the vehicle". Lien clearance. The Division shall remove the lien from the vehicle or mobile home

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record indicated on the lien clearance and issue a new Arizona Certificate of Title upon receiving either an electronic lien release or proof that the lien is satisfied and the items specified in R17-4-207(A). The Division considers the following instruments satisfactory proof that the lien or encumbrance recorded on a vehicle or mobile home record is satisfied:

1. The above quoted statute clearly requires that the lien holder shall make and deliver to the lienor a satisfaction. The transmission of an electronic lien release from an ELT Participant.
2. The act of stamping on the face of a title the words "Paid" or "Lien Satisfied" does not comply with the requirements of the Section referred to above. A certificate of title.
3. The Motor Vehicle Division does as a matter of policy furnish to each lien holder a lien filing receipt. An original lien filing receipt.
4. To give full effect to the provisions of the above quoted statute and for the best interests of all lien holders, IT IS ORDERED that either one of the two forms as indicated below must be furnished the division for the purpose of satisfying the lien on the division records and on the certificate of title to the vehicle. An original computer-generated Lienholder Record.
5. A lender copy of the original lien instrument indicating the lien is paid in full; or
  - a. The lien filing receipt furnished the lien holder by the motor vehicle division, on which receipt the lien holder may indicate by use of a rubber stamp that the lien has been paid or satisfied. Such stamp shall be validated by the full signature of the lien holder or his authorized agent. The date of the validation shall be indicated.
  - b. Any form of instrument giving a complete description of the vehicle, the date, amount and type of lien as recorded on the certificate of title and indicating that the lien has been paid or satisfied. The authorized signature of the lien holder or his authorized agent appearing on the instrument must be acknowledged before a Notary Public.
6. Any document giving a complete description of the vehicle and the date of lien, as recorded on the Arizona Certificate of Title, indicating that the lien is either "paid in full" or "satisfied".

**B. Lienholder satisfaction of lien requirements.**

1. The Division shall not accept a satisfaction of lien when the authorized signature of the lienholder or authorized agent of the lienholder, appearing on the lien clearance instrument, is not acknowledged before a Notary Public or witnessed by an authorized Division employee.
2. The lienholder shall deliver the Arizona Certificate of Title to the next lienholder or, if there is not another lienholder, to the owner of the vehicle or mobile home within 15 business days after receiving payment in full satisfaction of the lien.
3. A lienholder that fails to deliver the certificate of title within 15 business days may be assessed a civil penalty, as prescribed under A.R.S. § 28-2134.

**C. Lien release received in error. The Division is not responsible for any monetary damages that may occur when a lienholder issues a lien clearance to the Division in error.**

**D. Administrative hearing. A lienholder who is assessed a civil penalty, as prescribed under A.R.S. § 28-2134, may request a hearing according to the procedure prescribed under 17 A.A.C. 1, Article 5. The hearing is held in accordance with the procedures prescribed under A.A.C. R17-1-501 through R17-1-511 and R17-1-513.**