NOTICES OF FINAL RULEMAKING

The Administrative Procedure Act requires the publication of the final rules of the state's agencies. Final rules are those which have appeared in the *Register* first as proposed rules and have been through the formal rulemaking process including approval by the Governor's Regulatory Review Council or the Attorney General. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the *Register* after the final rules have been submitted for filing and publication.

NOTICE OF FINAL RULEMAKING

TITLE 2. ADMINISTRATION

CHAPTER 5. DEPARTMENT OF ADMINISTRATION PERSONNEL ADMINISTRATION

[R08-388]

PREAMBLE

1. Sections Affected — **Rulemaking Action**

Article 4	Amend
R2-5-401	Amend
R2-5-403	Amend
R2-5-404	Amend
R2-5-405	Amend
R2-5-410	Amend
R2-5-411	Amend
R2-5-413	Amend
R2-5-414	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. §§ 41-763(2) and (6)

Implementing statute: A.R.S. § 41-783(17)

3. The effective date of the rules:

November 4, 2008

The Department requests an immediate effective date for these rules under A.R.S. § 41-1032. A.R.S. § 41-1032(A)(5) allows for an immediate effective date to adopt a rule that is less stringent than the rule that is currently in effect and that does not have an impact on the public health, safety, welfare or environment, or that does not affect the public involvement and public participation process. The amended rules are less stringent than the current rules because under the amended rules, a state employee will no longer lose any leave the employee earned as the result of working on a day on which a state holiday is observed. The rules only affect state service employees and do not have an impact on the public health, safety, welfare or environment, and do not affect the public involvement and public participation process.

4. A list of all previous notices appearing in the *Register* addressing the final rules.

Notice of Rulemaking Docket Opening: 13 A.A.R. 2447, July 6, 2007

Notice of Rulemaking Docket Opening: 14 A.A.R. 3184, August 8, 2008

Notice of Proposed Rulemaking: 14 A.A.R. 3154, August 8, 2008

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

Name: Christine Bronson, Employee Relations Manager

Address: 100 N. 15th Ave., Suite 261
Phoenix, AZ 85007

Telephone: (602) 542-1423

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E-mail: Christine.Bronson@azdoa.gov

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

This rulemaking primarily results from the Department's Five-year Review Report that was approved by the Governor's Regulatory Review Council (G.R.R.C.) in September 2006. Article 4, Benefits, explains the various types of employee benefits (leave and insurance), eligibility, and use. The Department is amending various rules in Article 4 by adding clarifying language regarding leave accruals, accumulation limits, Family and Medical Leave Act (FMLA) leave, and an employee's eligibility for continued participation in the employee insurance plans while on leave. Clarifications and housekeeping revisions are also being made along with the specific changes.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did 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 reviewed the "2007 Workforce Report" prepared by the Arizona Department of Administration (ADOA), September 2007, to prepare the economic impact statement. This report provides an overview of the ADOA Human Resources System and key demographical and statistical information about the state's workforce. There are 34 tables describing the workforce and key aspects of state employment, including the number of active employees, the percentage of employees in the state merit system, and the average salary for covered employees.

8. 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

9. The summary of the economic, small business, and consumer impact:

These rules affect only state agencies and state service employees and will not have an impact on small businesses or consumers. The changes in the rules will primarily benefit state agencies and state employees by adding clarifying language regarding leave accruals, accumulation limits, Family and Medical Leave Act (FMLA) leave, and an employee's eligibility for continued participation in the employee insurance plans while on leave. By amending R2-5-403, Annual Leave, so that additional annual leave earned by an employee for working on a day on which a state holiday is observed may be earned without limit and no longer subject to forfeiture if the employee's leave exceeds the maximum accumulation, some impact on the expenditure of state funds is anticipated. However, the rules already provide that leave earned for working on a holiday may be paid at any time by the agency head, and any associated costs should be managed with appropriate management of employee leave.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable).

Minor, non-substantive changes were made between the publication of the notice of proposed rulemaking and this notice of final rulemaking.

11. A summary of the comments made regarding the rules and the agency response to them:

As part of the initial rulemaking process, the agency solicited input from ADOA Human Resources/Personnel Managers and staff assigned to the satellite Human Resources (HR) offices.

Following submission of the Notice of Proposed Rulemaking and during the 30-day public comment period, one of the ADOA Human Resources Managers submitted written comments for consideration. A summary of these comments and the Department's response to them are provided below:

Comment: In the new language proposed under R2-5-401(B) regarding Family and Medical Leave Act (FMLA) leave, the commentator recommended using the term, "unpaid leave" instead of "leave without pay," questioned the reference to R2-5-412, and recommended replacing the language, "any other reason" with, "self or family member's serious health condition."

Department's response: The Department utilized the term "leave without pay" because this term is used throughout the rules and references the conditions in R2-5-413, Medical Leave without Pay, and R2-5-414, Leave Without Pay. R2-5-412, Leave for Serious Health Condition, is also included in Article 4, but since no revisions are being made at this time, R2-5-412 is not included in this rulemaking package. Since an employee may take FMLA leave for reasons other than the employee's serious health condition or serious health condition of a member of the employee's family, the Department elected to retain the language as originally proposed.

Comment: The commentator recommended including clarifying language regarding the term "disciplinary action" in several Sections in the rulemaking.

Department's response: The Department recognizes the benefit of including such a clarification; however, the commentator's suggested language and placement of the language were not applicable to the context of the rules. The Department will consider this comment for a future rulemaking under a separate Article.

Comment: The references to A.R.S. Title 41, Chapter 4 (formerly A.R.S. Title 38, Chapter 6), which appear in several subsections of R2-5-404, Annual Leave, was questioned by the commentator.

Department's response: This term is applicable to employees who entered state service during or prior to 1972, and therefore must be retained.

Comment: In reference to R2-5-404(E) regarding donation of annual leave, the commentator questioned whether donated leave should stop at six months if the employee was on intermittent FMLA leave.

Department's response: The limitation of six months is statutory. A.R.S. § 41-783(17) specifically provides: "an employee who receives transferred annual leave as provided in subdivision (a) of this paragraph is limited to using six consecutive months of transferred leave per occurrence" and provides an exception for an employee who has applied for long-term disability insurance, which is reflected in rule.

Comment: The commentator recommended adding/incorporating language relating to a domestic partner's child into Section R2-5-404, Sick Leave.

Department's response: Although the Department has extended eligibility to participate in the insurance plans to a domestic partner of an eligible state officer or employee, and the domestic partner's child(ren), the Department does not currently intend to extend leave benefits to domestic partners or their children. However, this may be considered at a later date.

Comment: The commentator questioned if any more thought had been given to increasing the amount of sick leave used for family sick leave from 40 hours to 80 hours.

Department's response: The Department had considered increasing the amount of sick leave an employee could use for family sick leave from 40 to 80 hours per calendar year; however, after further consideration, the Department has elected not to increase family sick leave at this time. This increase may be reconsidered in a future rulemaking.

Comment: In reference to accrual of sick leave, the commentator suggested replacing the language, "eight hours per month" with the accrual rate on a "per pay period" basis.

Department's response: R2-5-404, Sick Leave, currently provides that sick leave is accrued at the rate of eight hours per month and employees accrue the leave on a pay period or monthly basis, as determined by the agency head. The Department recognizes that revising the sick leave accrual to a per pay period basis would be consistent with the wording of R2-5-403, Annual Leave, which accrues each bi-weekly pay period. However, Laws 2008, Chapter 208 (HB2747), proposed to move the Arizona State Schools for the Deaf and Blind (ASDB) under the ADOA personnel system, and such a revision to the sick leave accrual would have a negative impact to ASDB. At this time, it is not known if ASDB will move to the ADOA personnel system, as Chapter 208 contained a conditional enactment clause which does not make the law effective until June 30, 2009, and only if the legislature appropriates sufficient funding. Thus, the Department will not be revising the sick leave accrual to a per pay period basis at this time.

Comment: In several Sections of the rulemaking referencing an employee being required to submit evidence substantiating the need for the leave, the commentator recommended adding the language, "at least every 30 days in advance and in writing before taking any leave, exception (sic) in unforeseen emergencies," and, "if the employee's leave was more than three consecutive days."

Department's response: Currently, the rules permit an agency head to require an employee to submit evidence substantiating the need for sick leave at any time, regardless of the length of the employee's absence. In some cases, it may be appropriate to request evidence if the employee has been absent for less than three days. In the same vein, adding language that would require an employee to submit evidence at least every 30 days and in advance may be unduly restrictive and may not be reasonable given the specific circumstances. In addition, for an employee on Family and Medical Leave Act (FMLA) leave, if the time period specified by the employee's health care provider for the duration of the incapacity or its treatment is longer than 30 days, an employer may not request recertification until the minimum duration has passed, except in certain circumstances.

Comment: The commentator suggested that if the evidence submitted by the employee to substantiate the need for sick leave was deemed inadequate, that the absence be charged to another category of leave or considered as unauthorized absence and provided a proposed definition of "unauthorized absence."

Department's response: The rules currently contain a provision permitting an agency to require an employee to submit evidence substantiating the need for sick leave. Under current rules, if the evidence is deemed inadequate, the employee's absence may be charged to another category of leave or considered absence without leave, which is a cause for dismissal or discipline of a state service employee under the provisions of A.R.S. § 41-770(A)(9). Thus, any reference to and definition of "unauthorized absence" is unnecessary.

Comment: The commentator recommended expanding the family relationships for which an employee may be absent with pay under R2-5-410, Bereavement Leave, to also include, "aunt, uncle, or niece and nephew related within the third degree of affinity (marriage) or consanguinity (blood)."

Department's response: As part of the Department's Five-year Rules Review, the Department considered expanding the family relationships for bereavement leave. However, after further consideration, the Department has elected not to expand the family relationships under bereavement leave at this time.

Comment: It was recommended that R2-5-411, Parental Leave, be revised to include language which would provide for leave on a proportional basis to employees who work less than full-time.

Department's response: Although language was added to R2-5-410, Bereavement Leave, to address the amount of leave available to an employee who works less than full-time, this leave category provides for an employee to be

absent with pay. The Department does not believe this clarification is necessary for R2-5-411, Parental Leave, which does not provide absence with pay, but instead permits an employee to use any combination of annual leave, sick leave, compensatory leave, or leave without pay due to conditions related to pregnancy or childbirth.

Comment: The commentator also recommended R2-5-413, Medical Leave without Pay, be further amended to include, "fails to provide agency with updated medical documentation as required by FMLA regulations" as a condition for terminating an employee's leave.

Department's response: R2-5-413, as amended by this rulemaking, provides that, "The leave terminates when the employee returns to work or when the employee is on leave without pay for 180 days, whichever occurs first." This language is consistent with the statutory language in A.R.S. § 41-783(17)(c). Further, there may be situations where an employee is on Medical Leave without Pay and either is not eligible for or otherwise does not qualify for FMLA leave.

An oral proceeding on the Notice of Proposed Rulemaking published August 8, 2008, was held on September 9, 2008. No one appeared to speak and no comments were received at the oral proceeding.

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

None

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

In R2-5-401: 29 CFR 825.100 through 29 CFR 825.312 (July 2007)

14. Was this rule previously made as an emergency rule?

No

15. The full text of the rules follows:

TITLE 2. ADMINISTRATION

CHAPTER 5. DEPARTMENT OF ADMINISTRATION PERSONNEL ADMINISTRATION

ARTICLE 4. ~~BENEFITS~~ LEAVE

Section
R2-5-401. ~~Benefit~~ Leave Administration
R2-5-403. Annual Leave
R2-5-404. Sick Leave
R2-5-405. Industrial Leave
R2-5-410. Bereavement Leave
R2-5-411. Parental Leave
R2-5-413. Medical Leave without Pay
R2-5-414. Leave Without Pay

ARTICLE 4. ~~BENEFITS~~ LEAVE

R2-5-401. ~~Benefit~~ Leave Administration

A. Eligibility for leave. All state service employees, except emergency, ~~seasonal,~~ clerical pool, and temporary employees, are eligible for any type of leave with pay from the date of appointment. Emergency, ~~seasonal,~~ clerical pool, and temporary employees are eligible only for holidays subject to the provisions of R2-5-402, ~~administrative leave, military leave, and~~ civic duty leave for the purpose of voting ~~only.~~, military leave, and administrative leave.

B. Family and Medical Leave Act (FMLA) leave. FMLA Regulations, 29 CFR 825.100 through 29 CFR 825.312 (July 2007), are incorporated by this reference and on file with the Department and available from the U.S. Government Printing Office at 710 N. Capitol St. N.W., Washington, D.C. 20401. This incorporation by reference contains no future editions or amendments. An employee who meets FMLA eligibility requirements and uses leave for any of the situations covered by the FMLA shall be subject to the following:

1. Counting FMLA leave. Periods of paid leave and periods of leave without pay shall count towards the employee's available FMLA leave.
2. Use of accrued paid leave. An employee shall use available paid leave for all or part of the employee's FMLA leave under the conditions in:
   a. R2-5-405 for an employee on industrial leave;
   b. R2-5-411 for an employee on parental leave;
   c. R2-5-412 for an employee on FMLA leave for any other reason.

C. Insurance benefits continuation. An employee remains eligible for continued participation in the employee insurance plans while on leave pursuant to this Article.

~~B.~~D. Requests for leave. Except in an emergency, an employee ~~must~~ shall obtain approval in advance and in writing ~~prior to~~ before taking any leave.

R2-5-403. Annual Leave

A. Definition. "Annual leave" means a period of approved absence with pay that is not chargeable to another category of leave.

B. Accrual.

1. All employees except temporary, emergency, clerical pool, and part-time employees shall accrue annual leave in accordance with the following schedule:

Credited Service	Hours Bi-weekly
Fewer than 3 years	3.70
3 years but fewer than 7 years	4.62
7 years but fewer than 15 years	5.54
15 years or more	6.47

2. Temporary, emergency, and clerical pool employees shall not accrue annual leave.
3. Part-time employees who:
   a. Work 1/4 time, 1/2 time, or 3/4 time shall accrue a proportional amount of annual leave;
   b. Work a percentage of full-time other than 1/4 time, 1/2 time, or 3/4 time shall accrue annual leave at the next lower rate;
   c. Work less than 1/4 time shall not accrue annual leave.
4. ~~Eligible employees accrue~~ Except as provided by R2-5-405 for an employee on industrial leave, an eligible employee accrues annual leave ~~on the last day of~~ each bi-weekly pay period if the employee is in pay status for at least ~~1/2~~ one-half of the employee's scheduled work hours in that pay period.
5. An annual leave accrual is credited on the last day of the bi-weekly pay period in which the accrual is earned and is available for use on the first day of the following pay period.
   a. Annual leave accrued during the last pay period that begins in a calendar year is not subject to forfeiture under subsection (D).
   b. An employee who is separating from state service is compensated in accordance with subsection (I) for leave accrued through the employee's last date of employment.

~~5.~~6. Service in a position that became covered in accordance with A.R.S. Title 41, Chapter 4 (formerly A.R.S. Title 38, Chapter 6), is considered credited service in determining accrual rate change dates.

~~6.~~7. The effective date for change in the accrual rate is the first day of the pay period immediately following the attainment of the required credited service.

C. Credited service.

1. Credited service shall be calculated from the first day of the first complete pay period worked.
2. Credited service shall include:
   a. A period of service as an employee of a state budget unit before a break in service of less than two years that is not the result of disciplinary action;
   b. A period of leave without pay of 240 hours or less;
   c. Family and Medical Leave Act (FMLA) leave;
   d. Military leave taken under A.R.S. §§ 26-168, 26-171, or 38-610; and
   e. Active military service of an employee who is restored to state service under A.R.S. § 38-298.

D. Accumulation.

1. Except as provided in subsections (D)(2), (D)(3) and (D)(4), an employee shall forfeit annual leave accumulated in excess of 240 hours as of the last day of the last pay period that begins in a calendar year.
2. An agency head may request an exception to the accumulation limit contained in subsection (D)(1) for an employee in an individual case.
   a. An agency head seeking an exception shall submit a written request to the Director that contains a plan to use the excess hours during the following calendar year, pay the employee for the excess hours, or a combination of both.
   b. The Director may approve, modify, or deny the request.
3. ~~An employee who earns additional annual~~ Annual leave earned for working on a day on which a state holiday is observed ~~may exceed the 240 hour limitation by up to 24 hours.~~ is not included in the accumulation limit specified in subsection (D)(1) and shall not be forfeited.
4. An employee may retain annual leave accumulated as a result of service that became covered in accordance with

A.R.S. Title 41, Chapter 4~~,~~ (formerly A.R.S. Title 38, Chapter 6), without regard to the accumulation limit ~~contained~~ specified in subsection (D)(1).

E. Donation of annual leave.

1. Definitions. For the purposes of this subsection ~~(E)~~:
   a. "Immediate family" means the recipient employee's parent, spouse, or child, whether natural, adopted, foster, or step.
   b. *"Family" means spouse, natural child, adopted child, foster child, stepchild, natural parent, stepparent, adoptive parent, grandparent, grandchild, brother, sister, sister-in-law, brother-in-law, son-in-law, daughter-in-law, mother-in-law, father-in-law, aunt, uncle, nephew, or niece.* A.R.S. § 41-783(17)(a)
   c. "Disability that is caused by pregnancy or childbirth" means, as certified by a licensed health care practitioner:
      i. An employee is unable to work due to the employee's pregnancy, childbirth, or medical care associated with the pregnancy or childbirth; or
      ii. A member of the employee's immediate family requires assistance to perform regular daily activities due to the immediate family member's pregnancy, childbirth, or medical care associated with the pregnancy or childbirth.
   d. "Extended" means a period of at least three consecutive weeks.
   e. "Seriously incapacitating" means~~, as certified by~~ a licensed health care practitioner certifies that an illness, injury, or disability that is caused by pregnancy or childbirth:
      i. ~~An illness, injury, pregnancy, or childbirth that involves~~ Involves in-patient care; or
      ii. ~~An illness, injury, pregnancy, or childbirth that involves~~ Involves continuing treatment.
2. Eligibility to receive donation of annual leave. An employee who has exhausted all available leave balances is eligible to receive donations of annual leave if, as certified by a licensed health care practitioner:
   a. The employee is unable to work due to:
      i. A seriously incapacitating and extended illness or injury, or
      ii. A seriously incapacitating and extended disability that is caused by pregnancy or childbirth; or
   b. The employee needs to care for a member of the employee's immediate family who has:
      i. A seriously incapacitating and extended illness or injury, or
      ii. A seriously incapacitating and extended disability that is caused by pregnancy or childbirth.
3. Eligibility to donate annual leave. An employee may donate annual leave to another employee who has exhausted all available leave balances if:
   a. The recipient employee is employed in the same agency as the donating employee~~;~~, or
   b. The recipient employee is a family member of the donating employee and employed in another agency.
4. Exhaustion of available leave. Before using donated annual leave, a recipient employee:
   a. ~~With~~ Who has a qualifying illness, injury, or disability caused by pregnancy or childbirth shall exhaust all available sick leave, compensatory leave, and annual leave; or
   b. Whose immediate family member has a qualifying illness, injury, or disability caused by pregnancy or childbirth shall exhaust sick leave granted in accordance with R2-5-404(A)(4), if available, and all available compensatory leave and annual leave.
5. Calculation of hours donated. An agency head shall adjust the number of hours of annual leave donated in proportion to the hourly rate of pay of the donating employee and the recipient employee. To calculate the number of hours of donated annual leave:
   a. Multiply the actual number of hours donated by the donating employee's hourly rate of pay~~;~~, and
   b. Divide the result by the recipient employee's hourly rate of pay.
6. Maximum duration. A recipient employee may use a maximum of six consecutive months of donated annual leave for each qualifying occurrence unless the recipient employee applies for Long-term Disability (LTD) by the end of the fifth month~~.~~ of the employee's leave, in which case ~~The~~ the recipient employee ~~then~~ may continue to use donated annual leave for up to 60 additional days or until LTD benefit payments begin, whichever is sooner.
7. Unused donated leave. If the recipient employee separates from state service, recovers before using all donated leave, attains the maximum donation of annual leave as permitted under ~~the provisions of~~ subsection (E)(6), or the need for the donated annual leave is otherwise abated, the agency head shall return unused donated leave to ~~contributors~~ employees who donated leave on a pro-rata basis.

F. Use of annual leave. An employee may take annual leave at any time approved by the agency head. An agency head shall not advance annual leave to an employee.

G. Payment of annual leave. Subject to funding availability:

1. An agency head may pay an employee at any time at the employee's current rate of pay for all or any portion of the employee's annual leave that was earned as the result of working on a day on which a state holiday is observed. ~~at the employee's current rate of pay.~~
2. An agency head may request and the ~~The~~ Director may approve pay to a non-separating employee for all or any portion of the employee's accumulated and unused annual leave at the employee's current rate of pay subject to the fol-

lowing:

a. Agency procedures. Before requesting approval to pay an employee under this subsection, ~~(G)(2),~~ an agency head shall develop written standards and procedures that provide for equal consideration of all employees similarly situated. The agency head shall submit proposed standards and procedures and any subsequent changes to the Director for approval. The agency's procedures shall include at minimum:
   i. Request and approval procedures;
   ii. Documentation required to support the request for payment;
   iii. Any limitations, as applicable, including, but not limited to: the maximum number of times an employee may receive payment under this subsection; ~~(G)(2),~~ the maximum number of hours an employee may be paid per occurrence; the minimum number of hours of annual leave an employee must have used in the previous 12 months; and the minimum balance an employee is required to maintain after payout, if any.

b. Restrictions. If payment would reduce the employee's annual leave balance to fewer than 240 hours, the agency head shall obtain the employee's concurrence.

H. Movement.

1. To another agency. If an employee moves from one agency to another state service agency, the employee's accumulated and unused annual leave shall be transferred to the employee's annual leave account in the new agency, unless the provisions of subsection (H)(2) apply.
2. To an employment status ineligible for leave accrual. If an employee becomes ineligible for accrual of annual leave under R2-5-401(A), the agency head~~,~~ or~~,~~ the agency head of the losing agency if the employee moves to another state service agency, shall pay the employee for all unused and unforfeited annual leave at the employee's regular rate of pay immediately before the change in status.

I. Separation. An agency head shall pay an employee who separates from state service for all unused and unforfeited annual leave at the employee's current rate of pay.

R2-5-404. Sick Leave

A. Definition. "Sick leave" is any approved period of paid absence granted an employee due to:

1. Illness or injury ~~which~~ that renders the employee unable to perform the duties of the employee's position. Minor, nondisabling injuries and illnesses do not qualify an employee for sick leave.
2. Disability of the employee that is caused by pregnancy, childbirth, miscarriage, or abortion.
3. Examination or treatment of the employee by a licensed health care practitioner.
4. Illness, injury, disability caused by pregnancy or childbirth, or examination~~,~~ or treatment by a licensed health care practitioner of an employee's spouse, dependent child, or parent. Sick leave granted for this purpose shall be charged to the employee's sick leave account and shall not exceed 40 hours per calendar year. For the purposes of this Section~~,~~:
   a. ~~the~~ The term "dependent child" ~~is defined as~~ means a natural child, an adopted child, a foster child, or a stepchild, ~~over 1/2~~ more than one-half of whose support is received from the employee.
   b. The term "parent" ~~is defined as~~ means a birth parent, adoptive parent, stepparent, foster parent, grandparent, parent-in-law, or ~~anyone who can be considered~~ an individual who stood "in loco parentis."~~, i.e., someone who assumed the responsibility of a parent. Sick leave granted for this purpose shall be charged to the employee's sick leave account and shall not exceed 40 hours per calendar year.~~

B. Accrual.

1. All state service employees, except ~~seasonal,~~ temporary, emergency, clerical pool, and part-time employees, shall accrue sick leave at the rate of eight hours per month.
2. Temporary, emergency, and clerical pool employees shall not accrue sick leave.
~~2.~~3. Part-time employees who:
   a. ~~work~~ Work 1/4 time, 1/2 time, or 3/4 time ~~will~~ shall accrue a proportional amount of sick leave~~.~~;
   b. ~~Part-time employees who work~~ Work a percentage of full-time other than 1/4 time, 1/2 time, or 3/4 time will accrue sick leave at the next lower rate~~.~~;
   ~~3.~~c. ~~Part-time employees who work~~ Work less than 1/4 time~~, and seasonal, temporary, emergency and clerical pool employees are not eligible for~~ shall not accrue sick leave.
4. Eligible employees accrue the appropriate number of hours of sick leave on a pay period or monthly basis, as determined by the agency head. Except as provided by R2-5-405 for an employee on industrial leave, an eligible employee ~~Accrued~~ accrues sick leave ~~is credited on the last day of the~~ each bi-weekly pay period or month ~~in which earned, provided~~ if the employee has been in a pay status for at least ~~1/2~~ one-half of the employee's ~~working days~~ scheduled work hours in that pay period or month.
5. A sick leave accrual is credited on the last day of the bi-weekly pay period or month in which the accrual is earned and is available for use on the first day of the following pay period or month. An employee who is separating from state service accrues leave through the employee's last date of employment for the purpose of determining the employee's accumulated sick leave at the time of the employee's separation pursuant to subsection (F).

C. Accumulation. Sick leave ~~credits are accumulated~~ accumulates without limit.

D. Use of sick leave.
1. Sick leave may be taken when approved by the agency head. An agency head shall approve sick leave requested as a part of a parental leave under R2-5-411.
2. The agency head may require submission of evidence substantiating the need for sick leave. If the agency head determines the evidence is inadequate, the absence shall be charged to another category of leave or considered absence without leave.
3. An agency head may require an employee to be examined by a licensed health care practitioner designated by the agency head.
   a. If the licensed health care practitioner determines that the employee should not work due to illness or injury, the agency head may place the employee on sick leave or, if the employee's sick leave is exhausted, charge the absence to another category of leave or leave without pay.
   b. The agency head may require the employee to obtain approval from the licensed health care practitioner ~~prior to~~ before returning to work.
   c. The agency shall pay for all examinations required pursuant to this subsection. The employee shall not be charged any leave while participating in or traveling to or from any examination required pursuant to this subsection.

E. Movement to another agency. An employee who moves to another state service agency shall transfer all accumulated and unused sick leave to the employee's sick leave account in the new agency.

F. Forfeiture. All sick leave credits are forfeited upon separation from state service except as otherwise provided by law. However, employees who re-enter ~~the~~ state service within two years after separation ~~will~~ shall be credited with all unused sick leave accumulated at the time of separation~~, provided~~ if:
1. ~~the~~ The separation was not the result of disciplinary action, and ~~provided~~
2. ~~the~~ The employee was not paid for accumulated sick leave pursuant to A.R.S. § 38-615.

R2-5-405. Industrial Leave

A. Use of leave.
1. An agency head shall place an employee who sustains a job-related ~~disability~~ illness or injury that is compensable under the Workers' Compensation Law, A.R.S. Title 23, Chapter 6 on sick leave.
2. If an employee exhausts all sick leave and does not request annual or compensatory leave, or has exhausted annual or compensatory leave, an agency head shall place the employee on leave without pay.
3. If an employee is on leave under the Worker's Compensation laws and ~~that~~ the leave qualifies for Family and Medical Leave Act (FMLA) leave, an agency head shall count it as FMLA leave. An agency head shall apply industrial leave and FMLA concurrently.

B. Payments.
1. An employee shall use leave in an amount necessary to receive total payments (leave payments plus Workers' Compensation payments) that do not exceed the gross salary of the employee.
2. If an employee receives a retroactive Workers' Compensation payment for any period of industrial illness or injury for which leave payments were received, the employee shall reimburse the agency for Workers' Compensation payments that exceed 100% of the employee's base pay before the illness or injury, and the agency shall restore the equivalent value of leave to the employee's appropriate leave account.

C. Light duty. If an employee has a job-related ~~disability~~ illness or injury that impairs performance on the former job, the agency head shall make every effort to place the employee in a suitable position within the agency, including a light duty assignment.

D. Restriction. An agency head shall not grant sick leave or leave without pay to an employee who fails to accept compensation available under the industrial injury and disease provisions of A.R.S. §§ 23-901 to 23-1091.

E. Insurance benefits continuation. An employee who is using leave with pay in accordance with subsections (A) and (B) remains eligible for continued participation in the employee insurance plans and the employee's share of premiums/contributions is paid through payroll deduction. An employee who is on leave without pay due to an industrial illness or injury may continue to participate in the employee insurance plans as follows:

~~E.~~1. Health benefit plan participation.

~~1.~~a. An employee ~~who is on leave without pay due to an industrial illness or injury~~ may continue to participate in the health benefit plan for a maximum of six months from the date of illness or injury by paying the employee ~~contribution~~ premium/contribution.

~~2.~~b. At the end of the ~~6-month~~ six-month period, an employee who remains on leave without pay due to industrial illness or injury may continue to participate in the health benefit plan by paying both the state and employee ~~contributions~~ premiums/contributions, until the employee returns to work or is determined to be eligible for Medicare coverage or Long-term Disability, whichever occurs first.

~~F.~~2. Life insurance plan participation. An employee who is on leave without pay continues to participate in the basic life and accidental death and dismemberment insurance plan without cost for six months after the month in which the illness or injury occurs. During this ~~time~~ six-month period, the employee may continue supplemental life and dependent

life coverages that were in effect at the start of the leave by paying the applicable ~~premium~~ premium/contribution.

~~C.~~3. Termination of insurance. The insurance coverage of an ~~individual~~ employee on leave without pay who fails to pay insurance ~~premiums or contributions~~ premiums/contributions when due shall terminate at 11:59 p.m. on the last day of the period covered by the last ~~premium or contribution~~ premium/contribution paid.

~~H.~~**F.** Accrual of leave. An employee shall continue to receive full leave accrual as long as the employee uses two or more hours of paid leave each day.

R2-5-410. Bereavement Leave

A. General. An employee may be absent with pay ~~for up to 24 regularly scheduled work hours~~ due to the death or funeral of a spouse, natural child, adopted child, foster child, stepchild, natural parent, stepparent, adoptive parent, ~~one who functioned~~ an individual who stood "in loco parentis,"~~,~~ grandparent, grandchild, brother, sister, brother-in-law, sister-in-law, mother-in-law, father-in-law, son-in-law, or daughter-in-law.

B. Amount of bereavement leave.

1. A full-time employee may be absent with pay for up to 24 regularly scheduled work hours. An agency head may extend the bereavement leave for up to 16 additional work hours if the employee travels out-of-state for the funeral.
2. A part-time employee who works 1/4 time, 1/2 time, or 3/4 time may be absent with pay for a proportional amount of bereavement leave. A part-time employee who works a percentage of full-time other than 1/4 time, 1/2 time, or 3/4 time may be absent with pay at the next lower rate. An employee who works less than 1/4 time is not entitled to bereavement leave.

R2-5-411. Parental Leave

A. "Parental leave" means any combination of annual leave, sick leave, compensatory leave, or leave without pay taken by an employee due to pregnancy, childbirth, miscarriage, abortion, or adoption of children.

B. An agency head shall approve a request for parental leave of an employee subject to the following conditions:

1. An employee may take sick leave only for periods of disability.
2. Parental leave for childbirth, miscarriage, abortion, or adoption shall not exceed 12 weeks, unless the agency head approves a request for a longer duration.
3. An agency head shall not require an employee to exhaust all annual leave, sick leave, or compensatory leave before taking leave without pay.
4. An employee shall specify the number of hours of annual leave, sick leave, compensatory leave, and leave without pay to be used when requesting parental leave.
5. If leave under this Section qualifies for FMLA leave and the employee meets FMLA eligibility requirements, an agency shall count ~~it~~ the leave as FMLA leave.
6. ~~An~~ Except for FMLA leave, an employee returning to work from leave without pay taken as part of a parental leave shall return to the position occupied at the start of the parental leave. If this position no longer exists, the agency shall conduct a reduction in force.
7. An employee returning to work from leave without pay taken as part of a parental leave and granted as FMLA leave shall be governed by the FMLA regulations incorporated by reference in R2-5-401.

C. Insurance benefits continuation. An employee who is using leave with pay remains eligible for continued participation in the employee insurance plans and the employee's share of premiums/contributions is paid through payroll deduction. An employee who is on leave without pay while on parental leave may continue to participate in the employee insurance plans as follows:

1. Health benefit plan participation.
   a. An employee who is on FMLA leave is eligible to continue to participate in the health benefit plan for the duration of the FMLA leave by paying the employee premium/contribution. An agency head may recover the state's portion of premium/contributions paid to maintain health coverage for an employee if the employee fails to return from FMLA leave under certain circumstances, in accordance with FMLA regulations incorporated by reference in R2-5-401.
   b. An employee who either does not meet FMLA eligibility requirements or has exhausted available FMLA leave and remains absent from work:
      i. For a health-related reason may continue to participate in the health benefit plan by paying both the state and employee premium/contribution. Authority to continue participation shall terminate in accordance with R2-5-414.
      ii. For other than a health-related reason may continue to participate in the health benefit plan for a maximum of six months by paying both the state and employee premiums/contributions.
2. Life insurance plan participation.
   a. An employee who is on FMLA leave continues to participate in the Basic Life and Accidental Death and Dismemberment Insurance Plan and may continue to participate in the supplemental life and dependent life insurance coverage by paying the full premium/contribution.
   b. An employee who either does not meet FMLA eligibility requirements or has exhausted available FMLA leave

and remains absent from work may continue to participate in the basic life insurance plan by paying the state premium/contribution. An employee who elects to continue to participate in the basic life insurance plan may also continue any supplemental or dependent life insurance coverage that is in force at the beginning of the leave without pay by continuing to pay the premium/contribution. Authority to continue in the life insurance plan shall terminate in accordance with the time limits specified in R2-5-414(E).

3. Termination of insurance. The insurance coverage of an employee on leave without pay who fails to pay insurance premiums/contributions when due shall terminate at 11:59 p.m. on the last day of the period covered by the last premium/contribution paid.

R2-5-413. Medical Leave without Pay

A. As specified in A.R.S. § 41-783, an ~~An~~ agency head shall place a permanent status employee on medical leave without pay if:
1. The employee is unable to work due to a non-job-related, seriously incapacitating and extended illness or injury;
2. A physician selected by the employee documents the seriousness and extensiveness of the incapacitating illness or injury, subject to confirmation by an agency-selected physician, at the expense of the agency, whose opinion shall be used to determine whether a medical leave without pay should be granted;
3. The employee exhausts all leave balances, including any leave donated to the employee; and
4. The leave terminates when the employee returns to work or the employee is ~~absent~~ on leave without pay for 180 days, whichever occurs first.

B. An agency head shall determine the status of an employee who returns to work from medical leave without pay in the manner specified in subsection ~~R2-5-414(D)(2)~~ R2-5-414(D).

R2-5-414. Leave without Pay

A. Approval. All leave without pay requires a written request by an employee in advance and approval by the agency head. An agency head shall approve leave without pay requested as a part of a parental leave.

B. Documentation of leave. A request for leave without pay in excess of 80 consecutive hours shall include the beginning date of the leave without pay, the reason for the request, the anticipated date of ~~the~~ return to work, and the signature or signatures of individuals at the appropriate level or levels of authority who ~~approving~~ approve the request.

C. Use of leave. Except for parental leave, ~~FMLA leave,~~ military leave, ~~or~~ leave granted to forestall a reduction in force, or if subsection (F) applies, an agency head shall not grant leave without pay in excess of 80 consecutive hours until all accrued annual leave and, if the leave without pay is for medical reasons, sick leave are exhausted.

D. Return to work.
1. An employee who returns to work after a period of leave without pay of 80 consecutive hours or less shall return to the same position occupied at the start of the leave without pay.
2. Except as provided in subsection ~~(D)(4)~~ (D)(5), an employee who returns to work after a period of leave without pay in excess of 80 consecutive hours is entitled to return to a position in the class held at the start of the leave without pay, if a position is available and funded, and if the leave without pay is terminated in one of the following ways:
   a. Expiration of its term and the employee's return to work;
   b. Rescission of the leave without pay by the agency head before its scheduled expiration~~,~~ due to an unforeseen need that results in an insufficient number of employees available to provide service and for which:
      i. The agency head ~~shall provide~~ provides written notice of the rescission to the employee's last known address at least 15 days before the date the employee is directed to return to work; or
      ii. If circumstances beyond the agency's control do not permit at least a 15-day notice, the agency head ~~shall provide~~ provides notice as soon as possible after becoming aware of the need for the employee to return to work; or
   c. Curtailment of the leave without pay before its scheduled expiration date~~,~~ upon request of the employee and with approval of the agency head.
3. An agency head may consider the failure or inability of an employee to return to work on the first work day after an approved leave without pay as a resignation, a separation without prejudice, or cause for dismissal.
4. If no funded position is available to accommodate an employee's return to work on the first working day following expiration of an approved leave without pay or any extensions, the agency head may separate the employee without prejudice.
5. An employee returning to work from leave without pay granted:
   a. ~~for~~ For military service, for industrial illness or injury for up to six months, or to forestall a reduction in force, ~~as part of a parental or FMLA leave, or to accept an uncovered position,~~ shall return to the position occupied at the start of the leave without pay. If this position or a position in the same class is not available and funded, the agency head shall conduct a reduction in force.
   b. As part of a parental leave is subject to the provisions of R2-5-411.
   c. As FMLA leave is subject to the provisions of the FMLA regulations incorporated by reference in R2-5-401.

E. ~~Health benefit plan participation.~~ Insurance benefits continuation. An employee who is on leave without pay may con-

tinue to participate in the employee insurance plans as follows:

1. Health benefit plan participation.
   a. An employee who is on FMLA leave is eligible to continue to participate in the health benefit plan for the duration of the FMLA leave by paying the employee premium/contribution. An agency head may recover the state's portion of premium/contributions paid to maintain health coverage for an employee if the employee fails to return from FMLA leave under certain circumstances, in accordance with FMLA regulations incorporated by reference in R2-5-401.
   ~~1.~~b. An employee who is on leave without pay for a health-related reason that is not an industrial illness or injury and who either does not meet FMLA eligibility requirements or has exhausted FMLA leave and remains absent from work may continue to participate in the health benefit plan by paying both the state and employee ~~contribution~~ premium/contribution. Authority to continue participation in the health benefit plan shall terminate on the earliest of:
      ~~a.~~i. Receipt of long-term disability benefits for which there is eligibility to continue health benefit plan participation under ~~R2-5-418(A)(3);~~ a state-sponsored retirement plan;
      ~~b.~~ii. A determination of eligibility for Medicare coverage; or
      ~~c.~~iii. 30 months after the incapacity began.
   ~~2.~~c. An employee who is on leave without pay for reasons other than ~~a health-related reason~~ those outlined in subsection (E)(1)(a), (E)(1)(b), or R2-5-405 pertaining to industrial leave, may continue to participate in the health benefit plan for a maximum of six months by paying both the state and employee ~~contributions~~ premiums/contributions.

~~F.~~2. Life insurance plan participation.
   a. An employee who is on FMLA leave continues to participate in the Basic Life and Accidental Death and Dismemberment Insurance Plan and may continue to participate in the supplemental life and dependent life insurance coverage by paying the full premium/contribution.
   b. An employee who is on leave without pay for a health-related reason that is not an industrial illness or injury and who either does not meet FMLA eligibility requirements or has exhausted FMLA leave and remains absent from work may continue to participate in the basic life insurance plan by paying the state ~~premium~~ premium/contribution. An employee who elects to continue to participate in the basic plan may also continue any supplemental or dependent life coverage that is in force at the beginning of the leave without pay by continuing to pay the ~~premium~~ premium/contribution. Authority to continue in the life insurance plan shall terminate in accordance with the time limits specified in subsection ~~(E)~~ (E)(1)(b).
   c. An employee who is on leave without pay for reasons other than those outlined in subsection (E)(1)(a), (E)(1)(b), or R2-5-405 pertaining to industrial leave, may continue to participate in the basic life insurance plan by paying the state premium/contribution. An employee who elects to continue to participate in the basic plan may also continue any supplemental or dependent life coverage that is in force at the beginning of the leave without pay by continuing to pay the premium/contribution. Authority to continue in the life insurance plan shall be available for a maximum of six months.

~~G.~~3. Termination of insurance. The insurance coverage of an individual on leave without pay who fails to pay insurance ~~premiums or contributions~~ premiums/contributions when due shall terminate at 11:59 p.m. on the last day of the period covered by the last ~~premium or contribution~~ premium/contribution paid.

~~H.~~**F.** Disposition of accrued leave.

~~1. If an employee is to be granted leave without pay by one agency to accept an uncovered position in another state service agency, the agency heads shall agree on whether the employee's accrued annual and compensatory leave is to be paid or transferred in whole or in part. Sick leave shall be transferred. The same procedure shall apply upon the return of the employee to covered service.~~

~~2.~~ The disposition of all current and future accrued leave of an employee who is to be granted leave without pay to accept a position in a non-state service agency or in another governmental jurisdiction shall be covered in the intergovernmental agreement ~~concluded~~ between the Director and the non-state service agency or other jurisdiction.

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

[R08-389]

PREAMBLE

1. Sections Affected — **Rulemaking Action**

R4-23-110	Amend
Article 12	New Article
R4-23-1201	New Section
R4-23-1202	New Section
R4-23-1203	New Section
R4-23-1204	New Section
R4-23-1205	New Section
R4-23-1206	New Section
R4-23-1207	New Section
R4-23-1208	New Section
R4-23-1209	New Section
R4-23-1210	New Section
R4-23-1211	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. The effective date of the rules:

January 3, 2009

4. A list of all previous notices appearing in the *Register* addressing the final rules:

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

Notice of Proposed Rulemaking: 13 A.A.R. 942, March 23, 2007

Notice of Termination of Rulemaking: 13 A.A.R. 4375, December 14, 2007

Notice of Rulemaking Docket Opening: 13 A.A.R. 4412, December 14, 2007

Notice of Proposed Rulemaking: 14 A.A.R. 2200, June 6, 2008

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

Name:	Dean Wright, Compliance Officer
Address:	Board of Pharmacy 1700 W. Washington St., Suite 500 Phoenix, AZ 85007
Telephone:	(602) 771-2744
Fax:	(602) 771-2749
E-mail:	dwright@azpharmacy.gov

6. 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 rules add necessary new definitions to R4-23-110 (Definitions), including "health care institution" and "licensed health care professional." The rules 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 criteria for determining economic need are based on existing state programs such as the eligibility criteria for participation in the Department of Health Services Primary Care Program and the Aids Drug Assistance Program. The definition of the terms "earned income" and "unearned income" also came from the Aids Drug Assistance Program, which are based on the federal Social Security system definitions. The use of these terms reduces the burden upon an individual who is applying for these programs, as the terms used are the same for all the programs, including

our medication donation program. Those individuals above 300 percent of federal poverty level are not considered to be in economic need. Those individuals who qualify for AHCCCS plan coverage pay no or very minimal co-payments for drugs and therefore do not have an economic need for this program. Those individuals with prescription drug coverage as part of an insurance package are not considered to have an economic need for this program, because they have prescription drug coverage. These rules target those individuals who are most at need, because those individuals have no other mechanism for drug coverage.

The rules 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 a prescription medication donation program.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did 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 review or rely on any study relevant to the rules.

8. 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

9. The summary of the economic, small business, and consumer impact:

The rules impact the Board, pharmacies, physicians, health care institutions, and the public. The rules' impact on the Board is the usual rulemaking-related costs, which are minimal. The Board estimates the 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 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 rules allow a participating physician's office, pharmacy, or health care institution to charge a nominal (no more than $4.50) per prescription handling fee to cover the costs of inspecting, stocking, and dispensing the donated prescription medication. 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, physicians, and health care institutions benefit from rules that are clear, concise, and understandable. The rules benefit the public and the pharmacy community by clearly establishing the standards for a prescription medication donation program.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

There are no substantial changes in the final rules from the proposed rules. Based on a request received from the public and to increase the clarity of the rules, R4-23-1205(A)(2) is changed by adding a new subsection (i) and renumbering the existing subsection (i) to subsection (j). The new subsection R4-23-1205(A)(2)(i) reads: "A statement by the medical practitioner, pharmacy, or health care institution attesting that the drugs being donated meet the specific requirements of R4-23-1203(1)." Based on a request received from the public and to increase the clarity of the rules, R4-23-1205(A)(4) is changed by adding a new subsection (d) and renumbering the existing subsection (d) to subsection (e). The new subsection R4-23-1205(A)(4)(d) reads: "A statement by the health care institution attesting that the drugs being donated meet the specific requirements of R4-23-1203(1)." There are minor changes to style, format, grammar, and punctuation requested by G.R.R.C. staff.

11. A summary of the comments made regarding the rules and the agency response to them:

A public hearing was held July 14, 2008. Colleen Chawla representing the Celgene Corporation attended the public hearing. Ms. Chawla provided written comment from The Celgene Corporation voicing support for the rulemaking, but also requesting that clarifying language be added to R4-23-1205(A)(2) and R4-23-1205(A)(4) to strengthen the patient protections placed in R4-23-1203(1)(c). Specifically, Ms. Chawla asked the Board to add language to R4-23-1205(A)(2) and R4-23-1205(A)(4) that would add to the donor form an attestation by donor that the drugs being donated meet the specific requirements of R4-23-1203(1)(c). This would require that the donor actively consider whether or not the drug being donated is subject to a restricted distribution system. While the Board believes that R4-23-1203(1)(c) very specifically states that drugs subject to restricted distribution programs shall not be donated under the Prescription Medication Donation Program, the Board agrees that it would improve the clarity of the rules to add the attestation requirement suggested by Ms. Chawla and Celgene Corporation. The Board believes it would be even better to not just cite subsection R4-23-1203(1)(c), but to cite subsection R4-23-1203(1), which includes subsections

(a) and (b) that deal with controlled substances and samples and subsection (c) that deals with a drug that can only be dispensed to a patient registered with the drug's manufacturer. The Board made changes in the final rules to R4-23-1205(A)(2) by adding a new subsection (i) and renumbering the existing subsection (i) to subsection (j). The new subsection R4-23-1205(A)(2)(i) reads: "A statement by the medical practitioner, pharmacy, or health care institution attesting that the drugs being donated meet the specific requirements of R4-23-1203(1)." The Board made changes in the final rules to R4-23-1205(A)(4) by adding a new subsection (d) and renumbering the existing subsection (d) to subsection (e). The new subsection R4-23-1205(A)(4)(d) reads: "A statement by the health care institution attesting that the drugs being donated meet the specific requirements of R4-23-1203(1)." The Board believes these non-substantive changes are necessary to improve the rule's clarity and protect the public health.

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

Not applicable

13. Any material incorporated by reference and its location in the rules:

None

14. Were the rules previously made as emergency rules?

No

15. 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

Section
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 4 A.A.C. 23:

"Active ingredient" No change

"AHCCCS" means the Arizona Health Care Cost Containment System.

"Alternate physician" No change

"Annual family income" means the combined yearly gross earned income and unearned income of all adult individuals within a family unit.

"Approved course in pharmacy law" No change

"Approved Provider" No change

"Authentication of product history" No change

"Automated storage and distribution system" 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
"CSPMP" 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
"Digital signature" No change
"Dispensing pharmacist" No change
"Drug sample" No change
"Drug therapy management" No change
"Drug therapy management agreement" No change
"Earned income" means monetary payments received by an individual as a result of work performed or rental property owned or leased by the individual, including:
    Wages,
    Commissions and fees,
    Salaries and tips,
    Profit from self-employment,
    Profit from rent received from a tenant or boarder, and
    Any other monetary payments received by an individual for work performed or rental of property.
"Electronic signature" No change
"Eligible patient" No change
"Extreme emergency" No change
"Family unit" means:
    A group of individuals residing together who are related by birth, marriage, or adoption; or
    An individual who:
        Does not reside with another individual; or
        Resides only with another individual or group of individuals to whom the individual is unrelated by birth, marriage, or adoption.
"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 an individual who is licensed and regulated under A.R.S. 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

"Low-income subsidy" means Medicare-provided assistance that may partially or fully cover the costs of drugs and is based on the income of an individual and, if applicable, the individual's spouse.

"Materials approval unit" No change

"Mechanical counting device for a drug in solid, oral dosage form" No change

"Mechanical storage and counting device for a drug in solid, oral dosage form" No change

"Mediated instruction" No change

"Medical practitioner-patient relationship" No change

"Medicare" means a federal health insurance program established under Title XVIII of the Social Security Act.

"MPJE" No change

"NABP" No change

"NABPLEX" No change

"NAPLEX" No change

"Order" 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

"Physician" means a medical practitioner licensed under A.R.S. Title 32, Chapter 13 or 17.

"Physician-in-charge" means a physician who is responsible to the Board for all aspects of a prescription medication donation program required in A.R.S. § 32-1909 and operated in the physician's office or in a health care institution.

"Poverty level" means the annual family income for a family unit of a particular size, as specified in the poverty guidelines updated annually in the *Federal Register* by the U.S. Department of Health and Human Services.

"Precursor chemical" No change

"Prepackaged drug" No change

"Prep area" No change

"Primary care provider" means the medical practitioner who is treating an individual for a disease or medical condition.

"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

"Regulated chemical" No change

"Remodel" No change

"Remote drug storage area" No change

"Resident" means:

~~a person~~ An individual admitted to and ~~residing~~ living in a long-term care facility,

An individual who has a place of habitation in Arizona and lives in Arizona as other than a tourist, or

A person who owns or operates a place of business in Arizona.

"Responsible person" No change

"Score transfer" No change

"Security paper" No change

"Shared order filling" No change

"Shared order processing" No change

"Shared services" 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

"Tourist" means an individual who is living in Arizona but maintains a place of habitation outside of Arizona and lives outside of Arizona for more than six months during a calendar year.

"Transfill" No change

"Unearned income" means monetary payment received by an individual that is not compensation for work performed or rental of property owned or leased by the individual, including:

Unemployment insurance;

Workers' compensation;

Disability payments;

Payments from the Social Security Administration;

Payments from public assistance;

Periodic insurance or annuity payments;

Retirement or pension payments;

Strike benefits from union funds;

Training stipends;
Child support payments;
Alimony payments;
Military family allotments;
Regular support payments from a relative or other individual not residing in the household;
Investment income;
Royalty payments;
Periodic payments from estates or trusts, and
Any other monetary payments received by an individual that are not:
As a result of work performed or rental of property owned by the individual,
Gifts,
Lump-sum capital gains payments,
Lump-sum inheritance payments,
Lump-sum insurance payments, or
Payments made to compensate for personal injury.

"Verified signature" or "signature verifying" No change
"Veteran" means an individual who has served in the United States Armed Forces.
"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, a pharmacy, or a 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, the pharmacy, or the 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, a pharmacy, or a health care institution that participates in the prescription medication donation program:
1. An individual for whom the prescription medication was prescribed on a patient-specific prescription order or that individual's health care decision maker;
2. A manufacturer that 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

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

1. Is not a:
   a. Controlled substance;
   b. Drug sample; or
   c. Drug that can only be dispensed to a patient registered with the drug's manufacturer, because donation could prevent the manufacturer from maintaining required patient registration data;
2. 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;
3. Has been in the possession of a licensed health care professional, manufacturer, pharmacy, or health care institution and not in the possession of the individual specified in R4-23-1202(A)(1);

4. Has been stored according to federal and state drug law and the requirements of the manufacturer's package insert;
5. Has an expiration date or beyond-use-date later than six months after the date of donation;
6. Is in packaging that shows the lot number and expiration date or beyond-use-date of the prescription medication;
7. Does not have any physical signs of tampering or adulteration; and
8. Is in packaging that does not have any physical signs of tampering, except for the outside packaging as specified in subsection (2).

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

An individual is eligible to receive donated prescription medications from the prescription medication donation program if the individual:

1. Is a resident of Arizona;
2. Has an annual family income that is less than or equal to 300% of the poverty level;
3. Satisfies one of the following:
   a. Has no health insurance coverage;
   b. Has health insurance coverage that does not pay for the prescription medication prescribed;
   c. Is an American or Alaska Native who:
      i. Is eligible for, but chooses not to use, the Indian Health Service to receive prescription medications; and
      ii. Either has no other health insurance coverage or has health insurance coverage that does not pay for the prescription medication prescribed; or
   d. Is a veteran who:
      i. Is eligible for, but chooses not to use, Veterans Health Administration benefits to receive prescription medications; and
      ii. Either has no other health insurance coverage or has health insurance coverage that does not pay for the prescription medication prescribed;
4. Is ineligible for enrollment in AHCCCS; and
5. If eligible for Medicare, is ineligible for a full low-income subsidy.

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 one of the entities identified in R4-23-1202(A) and intends to voluntarily donate the prescription medication to the prescription medication donation program;
2. If the donor is the individual named on the prescription or the individual's health care decision maker:
   a. The individual's name and address;
   b. The name of the individual's heath 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. The following information about the donated prescription medication:
      i. The brand name or generic name of the prescription medication donated;
      ii. If a generic medication, the name of the manufacturer or the national drug code number of the prescription medication donated;
      iii. The strength of the prescription medication donated;
      iv. The quantity of the prescription medication donated;
      v. The lot number of the prescription medication donated; and
      vi. The expiration date or beyond-use-date of the prescription medication donated;
   e. A statement attesting that the individual or the individual's health care decision maker has not had possession of the donated prescription medication;
   f. The dated signature of the individual or the individual's health care decision maker;
   g. If the donation is an ongoing donation as authorized under subsection (B), a statement that conforms to subsection (B);
   h. A statement by the medical practitioner, pharmacy, or health care institution 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(4);
   i. A statement by the medical practitioner, pharmacy, or health care institution attesting that the drugs being donated meet the specific requirements of R4-23-1203(1); and
   j. 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;
   b. The information about the donated prescription medication specified in subsection (A)(2)(d);
   c. A statement by the manufacturer that the manufacturer has stored the donated prescription medication as

required in R4-23-1203(4); and
d. 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. The information about the donated prescription medication specified in subsection (A)(2)(d);
c. A statement attesting that the health care institution has stored the donated prescription medication as required in R4-23-1203(4);
d. A statement by the health care institution attesting that the drugs being donated meet the specific requirements of R4-23-1203(1); and
e. 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:
1. When future unused eligible prescription medication is a result of the individual's prescription medication being changed or discontinued by the individual's primary care provider; and
2. 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. 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.

R4-23-1206. Recipient Form

Before receiving a donated prescription medication from the prescription medication donation program, a recipient of a donated prescription medication shall sign a form:
1. Identifying the physician's office, pharmacy, or health care institution that is dispensing the donated prescription medication;
2. Stating that the recipient has been advised of and understands the immunity provisions of the program under A.R.S. § 32-1909(E) and (F);
3. Attesting that the recipient meets the eligibility requirements specified in R4-23-1204: and
4. Including the following:
a. The brand name or generic name of the prescription medication received;
b. If a generic medication, the name of the manufacturer or the national drug code number of the prescription medication received;
c. The strength of the prescription medication received;
d. The quantity of the prescription medication received;
e. The recipient's name and address; and
f. The dated signature of the recipient.

R4-23-1207. Recordkeeping

A. 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 that has possession of the donated prescription medication and 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 that has possession of the donated prescription medication;
2. The name of the individual who made the donation;
3. The brand name or generic name of the prescription medication transferred;
4. If a generic medication, the name of the manufacturer or the national drug code number of the prescription medication transferred;
5. The strength of the prescription medication transferred;
6. The quantity of the prescription medication transferred;
7. The lot number of the prescription medication transferred;
8. The expiration date or beyond-use-date of the prescription medication transferred;
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.

B. Before transferring possession of a prescription medication donated by a manufacturer, the manufacturer shall create an invoice that includes the manufacturer's name and address and the information described in subsections (A)(3) through (10).

C. Before transferring possession of a prescription medication donated by a health care institution, the health care institution

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

D. A medical practitioner, pharmacy, health care institution, or manufacturer required to create an invoice under subsection (A), (B), or (C) shall:
1. Transmit a copy of the invoice and the donor form required under R4-23-1205 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;
3. Maintain a copy of the donor form for a minimum of three years from the date signed; and
4. Make a copy of the invoice or donor form available upon request for inspection by the Board, its designee, or other authorized officers of the law.

E. A physician's office, a pharmacy, or a health care institution that participates in the prescription medication donation program shall:
1. Maintain:
   a. The documents required under R4-23-1206 for a minimum of three years from the date signed; and
   b. Each invoice and donor form received under subsection (D)(1) for a minimum of three years from the date received; and
2. Make the documents required under R4-23-1206 and subsection (D)(1) 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, a pharmacy, or a health care institution that dispenses a donated prescription medication may charge a recipient of a donated prescription medication a handling fee of no more than $4.50 per prescription to cover inspection, stocking, and dispensing costs.

R4-23-1209. Policies and Procedures

A physician's office, a pharmacy, or a health care institution that participates in the prescription medication donation program shall:
1. Develop, implement, and comply with policies and procedures for the receipt, storage, and distribution of prescription medications donated to the physician's office, the pharmacy, or the 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 a 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 or electronic policies and procedures required under subsection (1) include provisions to ensure:
   a. That each transferred prescription medication meets the eligibility requirements of Sections R4-23-1202 and R4-23-1203;
   b. That each individual who receives a donated prescription medication under the prescription medication donation program signs the recipient form specified in R4-23-1206;
   c. Compliance with the applicable requirements for recordkeeping in Section R4-23-1207;
   d. Compliance with the requirements of Section R4-23-1210; and
   e. Compliance with the requirements of Section 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. Inspect the donated prescription medication to ensure that the prescription medication has not been adulterated;
3. Certify that the donated prescription medication has been stored in compliance with the requirements of the manufacturer's package insert;
4. Comply with all federal and state laws regarding storage and distribution of a donated prescription medication;
5. Obtain a prescription order of a licensed medical practitioner for the recipient to receive the donated prescription medication; and
6. Properly label the donated prescription medication to be dispensed.

B. As specified in subsection (C) a participating physician's office, pharmacy, or health care institution may transfer a prescription medication donated under this Article to another participating physician's office, pharmacy, or health care institution, but the donated prescription medication shall not be resold.

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, if:
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:
   a. Keep a copy of the invoice required in subsection (C)(2) on file for three years from the date of transfer; and
   b. Make the invoice records available, upon request, for inspection by the Board or its designee.

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 a designee:
1. Coordinate the receipt of prescription medications donated by manufacturers or health care institutions or through medical practitioners, pharmacies, or health care institutions from eligible donors;
2. Check each donated prescription medication against the invoice 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:
   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);
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; and
13. Maintain the records required in this Article.

NOTICE OF FINAL RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 22. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM ADMINISTRATION

[R08-390]

PREAMBLE

1. Sections Affected	Rulemaking Action
R9-22-501	Amend
R9-22-502	Amend

R9-22-503	Amend
R9-22-504	Amend
R9-22-505	New Section
R9-22-509	Amend
R9-22-512	Amend
R9-22-518	Amend
R9-22-521	Amend
R9-22-522	Amend

2. The specific 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

Implementing statute: A.R.S. §§ 36-2903, 36-2903.01, 36-2907

3. The effective date of the rules:

January 3, 2009

4. A list of all previous notices appearing in the *Register* addressing the final rules:

Notice of Rulemaking Docket Opening: 14 A.A.R. 2784, July 11, 2008

Notice of Proposed Rulemaking: 14 A.A.R. 2964, August 1, 2008

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

Name:	Mariaelena Ugarte
Address:	AHCCCS Office of Administrative Legal Services 701 E. Jefferson St., Mail Drop 6200 Phoenix, AZ 85034
Telephone:	(602) 417-4693
Fax:	(602) 253-9115
E-mail:	AHCCCSRules@azahcccs.gov

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

The Administration is proposing rule changes as a result of a Five-year Rule Review recently conducted. The topics requiring an update are: definitions, provision of member's medical records, completion of audits, and other technical updates.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did 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:

No study was reviewed during this rulemaking and the Agency does not anticipate reviewing any studies.

8. 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

9. The summary of the economic, small business, and consumer impact:

The Administration anticipates that there will be no economic impact as a result of the rule changes. The changes provide clarification of current processes and technical updates, therefore not requiring a change in practices for those affected by the rulemaking.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

Where R9-22-522 explains that a provider must provide medical records within 30 days, was not stricken and left as written due to the public comment received. No other changes have been made between the proposed rules and the final rules below except that the Administration made the rules more clear, concise, and understandable by making grammatical, verb tense, punctuation, and structural changes throughout the rules.

11. A summary of the comments made regarding the rule and the agency response to them:

The Administration received the following comments:

No.	Date/ Commentor:	Comment:	Response:
1.	08/19/08 Kathy Harris Health Choice Arizona	R9-22-522(D) The provision requiring providers, whose contract with a contractor has been terminated, to pass on medical records was stricken. This provision is needed to legally require terminated providers to pass on records.	The Administration agrees and will not strike the provision.
2.	08/30/08 Susyn Rasmussen AHCCCS member	R9-22-522(C) Provision where a PCP must also maintain medical records for ER services provided by non-contracting providers was stricken. 1. Member states her PCP was not notified of an ER service, therefore could not maintain an appropriate record, making it difficult for her to get continuing care. 2. Member states that she is denied her primary Medicare benefits since she is on Medicaid. And the contractor will not pay for her medical services since they were received out of network. Without the technical changes a contractor could not pick and chose what they want to treat.	The Administration does not have the authority to impose on an out of network provider to provide the PCP with medical records. It is recommended that the member obtain the member's records and provide the records to the member's PCP.
3.	08/30/08 Susyn Rasmussen AHCCCS member	The comment concerned changes made to R9-29-302 effective March 2006. Attachments refer to: Contractor Operations Manual Chapter 200 (A) Covered Services for QMB Duals and Non-QMB Duals. Chapter 201 Medicare Cost Sharing for Members in Medicare FFS Purpose and Definition section. Cost Sharing Matrix, Limits on Cost Sharing, Prior Authorization.	R9-29-302 is not within the scope of this rulemaking. The point made will be considered during any future rulemakings that include R9-29-302.

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

Not applicable

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

Not applicable

14. Was this rule previously adopted as an emergency rule?

No

15. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 22. ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM ADMINISTRATION

ARTICLE 5. GENERAL PROVISIONS AND STANDARDS

Section
R9-22-501. General Provisions and Standards – Related Definitions
R9-22-502. Pre-existing Conditions
R9-22-503. Provider Requirements Regarding Records
R9-22-504. Marketing; Prohibition ~~against~~ Against Inducements; Misrepresentations; Discrimination; Sanctions
R9-22-505. ~~Repealed~~ Standards, Licensure, and Certification for Providers of Hospital and Medical Services
R9-22-509. Transition and Coordination of Member Care
R9-22-512. Release of Safeguarded Information
R9-22-518. Information to Enrolled Members
R9-22-521. Program Compliance Audits
R9-22-522. Quality Management/Utilization Management (QM/UM) Requirements

ARTICLE 5. GENERAL PROVISIONS AND STANDARDS

R9-22-501. General Provisions and Standards – Related Definitions

In addition to definitions contained in A.R.S. § 36-2901, the words and phrases in this Chapter have the following meanings unless the context explicitly requires another meaning:

"Quality management" means a process used by professional health personnel through a formal program involving multiple organizational components and committees to:

Assess the degree to which services provided conform to desired medical standards and practices; and

~~Improve or maintain quality service and care.~~

Quality improvement or maintenance of care and services.

"Quality Improvement" means a process designed to achieve, through ongoing measurements and intervention, significant improvement that is sustained over time, in the areas of clinical care and non-clinical care and is expected to have a favorable effect on health outcomes and member satisfaction. Quality Improvement includes focusing organizational efforts on improving performance and utilizing data to develop intervention strategies to improve performance and outcomes.

"Utilization management/review" means a methodology used by professional health personnel to assess the medical indications, appropriateness, and efficiency of care provided. Utilization management applies to a contractor's process to evaluate and approve or deny the medical necessity, appropriateness, efficacy and efficiency of health care services, procedures, or settings. Utilization review includes processes for prior authorization, concurrent review, retrospective review, and case management.

R9-22-502. Pre-existing Conditions

A. Except as otherwise provided in ~~Article 3~~ Article 2 of this Chapter, a contractor shall be responsible for providing the full scope of covered services to each member from the effective date of eligibility until the termination of enrollment or transfer of the member to another contractor. A contractor shall not impose a pre-existing condition exclusion with respect to covered services.

B. A contractor or subcontractor shall not adopt or use any procedure to identify a person who has an existing or anticipated medical or psychiatric condition in order to discourage or exclude the person from enrolling in the contractor's health plan or encourage the person to enroll in another health plan.

R9-22-503. Provider Requirements Regarding Records

The provider shall maintain records that meet uniform accounting standards and generally accepted practices for maintenance of medical records, including detailed specification of all patient services delivered, the rationale for delivery, and the service date. A provider shall maintain and upon request, make available to a contractor and to the Administration, financial~~,~~ and medical records relating to payment for not less than five years from the date of final payment, or for records relating to costs and expenses to which the Administration has taken exception, five years after the date of final disposition or resolution of the exception. ~~The provider shall maintain records that meet uniform accounting standards and generally accepted practices for maintenance of medical records, including detailed specification of all patient services delivered, the rationale for delivery, and the service date.~~ Providers shall provide one copy of a medical record at no cost if requested by the member.

R9-22-504. Marketing; Prohibition ~~against~~ Against Inducements; Misrepresentations; Discrimination; Sanctions

A. A contractor or the contractor's marketing representative shall not offer or give any form of compensation or reward, or engage in any behavior or activity that may be reasonably construed as coercive, to induce or procure AHCCCS enrollment with the contractor. Any marketing solicitation offering a benefit, good, or service in excess of the covered services in Article 2 is deemed an inducement.

B. A marketing representative shall not misrepresent itself, the contracting health plan represented, or the AHCCCS program, through false advertising, false statements, or in any other manner to induce a member of another contractor to

enroll in the represented health plan.

~~1.~~ Violations of this subsection include, but are not limited to, false or misleading claims, inferences, or representations such as:

~~a.~~1. A member will lose benefits under the AHCCCS program or lose any other health or welfare benefits to which a member is legally entitled, if the member does not enroll in the represented contracting health plan;

~~b.~~2. Marketing representatives are employees of the state or representatives of the Administration, a county, or any health plan other than the health plan by which they are employed, or by which they are reimbursed; and

~~c.~~3. The represented health plan is recommended or endorsed as superior to its competition by any state or county agency, or any organization, unless the organization has certified its endorsement in writing to the health plan and the Administration.

C. A marketing representative shall not engage in any marketing or pre-enrollment practice that discriminates against a member because of race, creed, age, color, sex, religion, national origin, ancestry, marital status, sexual preference, physical or mental disability, or health status.

D. The Administration shall hold a contractor responsible for a violation of this Section resulting from the performance of any marketing representative, subcontractor, agent, program, or process under the contractor's employ or direction and shall impose contract sanctions on the contractor as specified in contract.

E. A contractor shall produce and distribute informational materials that are approved by the Administration to each enrolled member or designated representative after the contractor receives notification of enrollment from the Administration. The contractor shall ensure that the informational materials include, at a minimum:

1. A description of all covered services as specified in contract;
2. An explanation of service limitations and exclusions;
3. An explanation of the procedure for obtaining services;
4. An explanation of the procedure for obtaining emergency services;
5. An explanation of the procedure for filing a grievance and appeal; and
6. An explanation of when plan changes may occur as specified in contract.

R9-22-505. ~~Repealed~~ Standards, Licensure, and Certification for Providers of Hospital and Medical Services

A provider shall not provide hospital or medical services to a member unless the provider is licensed by the Arizona Department of Health Services and meets the requirements in 42 CFR 441 and 482, as of October 1, 2007, and 42 CFR 456 Subpart C, as of October 1, 2007, incorporated by reference, on file with the Administration and available from the U.S. Government Printing Office, 732 N. Capitol St. N.W., Washington, D.C., 20401. This incorporation contains no future editions or amendments. An Indian Health Service (IHS) hospital and a Veterans Administration hospital shall not provide services to a member unless accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

R9-22-509. Transition and Coordination of Member Care

~~**A.** The Administration shall coordinate and implement disenrollment and re-enrollment procedures when a member's change of residency requires a change in contractor.~~

~~**B.**~~**A.** A contractor shall assist in the transition of members to and from other AHCCCS contractors.

1. Both the receiving and relinquishing contractor shall:
   a. Coordinate with the other contractor to facilitate and schedule appointments for medically necessary services for the transitioned member within the Administration's timelines specified in the contract. If requested by the Administration, a contractor shall submit the policies and procedures regarding transition of members to the Administration for review and approval;
   b. Assist in the referral of transitioned members to other community health agencies or county medical assistance programs for medically necessary services not covered by the Administration, as appropriate; and
   c. Develop policies and procedures to be followed when transitioning members who have significant medical conditions; are receiving ongoing services; or have, at the time of the transition, received prior authorization or approval for undelivered, specific services.
2. The relinquishing contractor shall notify the receiving contractor of relevant information about the member's medical condition and current treatment regimens within the timelines defined in contract;
3. The relinquishing contractor shall forward medical records and other relevant materials to the receiving contractor. The relinquishing contractor shall bear the cost of reproducing and forwarding medical records and other relevant materials;
4. Within the ~~contract-specified~~ timelines specified in contract, the receiving contractor shall ensure that the member selects or is assigned to a primary care provider, and provide the member with:
   a. Information regarding the contractor's providers,
   b. Emergency numbers, and
   c. Instructions about how to obtain services.

~~**C.**~~**B.** A contractor shall not use a county or noncontracting provider health resource alternative to diminish the contractor's contractual responsibility or accountability for providing the full scope of covered services. The Administration may

impose sanctions as described in contract if a contractor makes referrals to other ~~health~~ agencies or programs to reduce expenses incurred by the contractor on behalf of its members.

R9-22-512. Release of Safeguarded Information

A. The Administration, contractors, providers, and noncontracting providers shall limit the release of safeguarded information to persons or agencies for the following purposes in accordance with 45 CFR ~~Part~~ 160 and 45 CFR ~~Part~~ 164, October 1, 2004, and 42 CFR 431.300 through 431.307, October 1, 2004, incorporated by reference, ~~and~~ on file with the Administration and available from the U.S. Government Printing Office, ~~Mail Stop: IDCC,~~ 732 N. Capitol ~~Street, NW~~ St. N.W., Washington, ~~DC~~ D.C., 20401. This incorporation by reference contains no future editions or amendments:

1. Official purposes directly related to the administration of the AHCCCS program including:
   a. Establishing eligibility and post-eligibility treatment of income, as applicable;
   b. Determining the amount of medical assistance;
   c. Providing services for members;
   d. Performing evaluations and analysis of AHCCCS operations;
   e. Filing liens on property as applicable;
   f. Filing claims on estates, as applicable; and
   g. Filing, negotiating, and settling medical liens and claims.
2. Law enforcement. The Administration may release safeguarded information without the applicant's or member's written or verbal consent, for the purpose of conducting or assisting an investigation, prosecution, or criminal or civil proceeding related to the administration of the AHCCCS program.
3. The Administration may release safeguarded member information to a review committee in accordance with the provisions of A.R.S. § 36-2917, without the consent of the applicant or member.

B. Except as provided in subsection (A), the Administration, contractors, providers, and noncontracting providers shall disclose safeguarded information only to:

1. An applicant;
2. A member;
3. An unemancipated minor, with written permission of a parent, custodial relative, or designated representative, if:
   a. An Administration employee, authorized representative, or responsible caseworker is present during the examination of the safeguarded information; or
   b. After written notification to the provider, and at a reasonable time and place.
4. Persons authorized by the applicant or member, or
5. A ~~lawful~~ court order or subpoena ~~accompanied by an authorization~~ compliant with 45 CFR ~~164.508~~ 164.512(e) ~~October 1, 2004, or qualified protective court order as defined by 45 CFR 164.512~~, October 1, 2004, incorporated by reference, ~~and~~ on file with the Administration and available from the U.S. Government Printing Office, ~~Mail Stop: IDCC,~~ 732 N. Capitol ~~Street, NW~~ St. N.W., Washington, ~~DC~~ D.C., 20401. This incorporation by reference contains no future editions or amendments.

C. The Administration, contractors, providers, and noncontracting providers shall safeguard ~~identifying~~ identifiable information, protected health information as specified in 45 CFR ~~Part~~ 160, and information obtained in the course of application for or redetermination of eligibility concerning an applicant or member, that includes, but is not limited to the following:

1. Name and address;
2. Social Security number;
3. Social and economic conditions or circumstances;
4. Agency evaluation of personal information;
5. Medical data and information concerning medical services received, including diagnosis and history of disease or disability;
6. State Data Exchange (SDX) tapes, and other types of information received from outside sources for the purpose of verifying income eligibility and amount of medical assistance payments; and
7. Any information received in connection with the identification of legally liable third-party resources.

D. The restriction upon disclosure of information in this Section does not apply to:

1. De-identified information as described by 45 CFR ~~Part~~ 164.514, October 1, 2004, incorporated by reference in subsection (A); or
2. A disclosure, in response to a request for information, that complies with 45 CFR ~~Part~~ 160 and 45 CFR ~~Part~~ 164, October 1, 2004, and 42 CFR 431.300 through 431.307, October 1, 2004, incorporated by reference in subsection (A).

E. A provider shall furnish records requested by the Administration or a contractor to the Administration or the contractor at no charge.

R9-22-518. Information to Enrolled Members

A. Each contractor shall produce and distribute printed informational materials to each member or family unit ~~within~~ no later than 10 days of receipt of notification of enrollment from the Administration. The contractor shall ensure that the informa-

tional materials meet the requirements specified in the contractor's current contract.

B. A contractor shall provide a member with the name, address, and telephone number of the member's primary care provider ~~within~~ no later than 10 days from the date of enrollment. The contractor shall include information on how the member may change primary care providers.

R9-22-521. Program Compliance Audits

A. The Administration shall conduct an onsite program compliance audit of a contractor at least once every ~~12 months~~ three years during the term of the Administration's contract with the contractor. ~~Unless the Administration determines that advance notice will render the program compliance audit less useful, the Administration shall notify a contractor approximately three weeks in advance of the date of an onsite program compliance audit.~~ The Administration may conduct, without prior notice, inspections of contractor facilities or perform other elements of a program compliance audit.

B. An audit team may perform any or all of the following procedures:

1. Conduct private interviews and group conferences with members, physicians, other health professionals, and members of the contractor's administrative staff including, but not limited to, the contractor's principal management persons;
2. Examine records, books, reports, and papers of the contractor and any management company, and all providers or subcontractors providing health care and other services. The examination may include, but need not be limited to: minutes of medical staff meetings, peer review and quality of care review records, duty rosters of medical personnel, appointment records, written procedures for the internal operation of the health plan, contracts and correspondence with members and with providers of health care services and other services to the plan, and additional documentation deemed necessary by the Administration to review the quality of medical care.

R9-22-522. Quality Management/Utilization Management (QM/UM) Requirements

A. A contractor shall comply with Quality Management/Utilization Management (QM/UM) requirements specified in this Section and in contract. The contractor shall ensure compliance with QM/UM requirements that are accomplished through delegation or subcontract with another party.

B. In addition to any requirements specified in contract, a contractor shall:

1. Submit to the Administration a written QM/UM plan that includes a description of the systems, methodologies, protocols, and procedures to be used in:
   a. Monitoring and evaluating the types of services provided,
   b. Identifying the numbers and costs of services provided,
   c. Assessing and improving the quality and appropriateness of care and services,
   d. Evaluating the outcome of care provided to members, and
   e. Determining the actions necessary to improve service delivery;
2. Submit the QM/UM plan to the Administration on an annual basis within timelines specified in contract. If the QM/UM plan is changed during the year, the contractor shall submit the revised plan to the Administration before implementation;
3. Receive approval from the Administration before implementing the initial or revised QM/UM plan;
4. Ensure that a QM/UM committee operates under the control of the contractor's medical director and includes representation from medical and executive management personnel. The committee shall:
   a. Oversee the development, revision, and implementation of the QM/UM plan; and
   b. Ensure that there are qualified QM/UM personnel and sufficient resources to implement the contractor's QM/UM activities; and
5. Ensure that the QM/UM activities include at least:
   a. Prior authorization for non-emergency or scheduled hospital admissions;
   b. Concurrent review of inpatient hospitalization;
   c. Retrospective review of hospital claims;
   d. Program and provider audits designed to detect over- or under-utilization, service delivery effectiveness, and outcome;
   e. Medical records audits;
   f. Surveys to determine satisfaction of members;
   g. Assessment of the adequacy and qualifications of the contractor's provider network;
   h. Review and analysis of QM/UM data; ~~and~~
   ~~i. Other activities necessary to improve the quality of care and the efficient, cost-effective delivery and utilization of services.~~
   i. Measurement of performance using objective quality indicators;
   j. Ensuring individual and systemic quality of care;
   k. Integrating quality throughout the organization;
   l. Process improvement;
   m. Credentialing a provider network;

n. Resolving quality of care grievances; and
o. Quality improvement activities focused on improving the quality of care and the efficient, cost-effective delivery and utilization of services.

C. A member's primary care provider shall maintain medical records that:
~~1. Are detailed and comprehensive and identify:~~
~~a. All medically necessary services provided to the member, and~~
~~b. All emergency services provided by a noncontracting provider for a member.~~
~~2.~~1. Conform to professional medical standards and practices for documentation of medical diagnostic and treatment data;
~~3.~~2. Facilitate follow-up treatment; and
~~4.~~3. Permit professional medical review and medical audit processes.

D. ~~A~~ Within 30 days following termination of the contract between a subcontractor and a contractor, the subcontractor or the subcontractor's designee shall forward to the primary care provider medical records or copies of medical records of all members assigned to the subcontractor or for whom the subcontractor has provided services~~, within 30 days following termination of the contract between the subcontractor and the contractor.~~

E. The Administration shall monitor each contractor and the contractor's providers to ensure compliance with Administration QM/UM requirements and adherence to the contractor's QM/UM plan.
1. A contractor and the contractor's providers shall cooperate with the Administration in the performance of the Administration's QM/UM monitoring activities; and
2. A contractor and the contractor's providers shall develop and implement mechanisms for correcting deficiencies identified through the Administration's QM/UM monitoring.

NOTICE OF FINAL RULEMAKING

TITLE 20. COMMERCE, FINANCIAL INSTITUTIONS, AND INSURANCE

CHAPTER 5. INDUSTRIAL COMMISSION OF ARIZONA

[R08-386]

PREAMBLE

1. Sections Affected **Rulemaking Action**
R20-5-602 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. § 23-405(4)

Implementing statute: A.R.S. § 23-410

3. The effective date of the rules:
December 30, 2008

4. A list of all previous notices appearing in the *Register* addressing the final rule:
Notice of Rulemaking Docket Opening: 14 A.A.R. 1147, April 11, 2008

Notice of Proposed Rulemaking: 14 A.A.R.1743, May 9, 2008

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

Name:	William M. Wright
Address:	Division of Occupational Safety and Health Industrial Commission of Arizona 800 W. Washington St., Suite 203 Phoenix, AZ 85007
Telephone:	(602) 542-1695
Fax:	(602) 542-1614
E-mail:	wright.william.m@dol.gov

6. An explanation of the rule, including the agency's reason for initiating the rule:
In order to conform to the Federal Occupational Safety and Health Standards as required by Section 18(c) of the Federal Occupational Safety and Health Act of 1970 requiring state-administered occupational safety and health pro-

grams to adopt standards that are at least as effective as those adopted by the U.S. Department of Labor, the Industrial Commission is amending R20-5-602 by the removal of several references to consensus standards that have requirements that duplicate, or are comparable to, other OSHA rules, and is making a technical change to 29 CFR 1910.107(c)(1)(iv). When removing duplicative references to consensus standards, OSHA has replaced them with cross references to existing OSHA standards that have requirements that are essentially identical to the consensus standards. The retention of duplicate references is unnecessary and may confuse the regulated community. In doing so, OSHA believes that existing compliance objectives and/or employee protection will not be altered. These changes are incorporated by reference as published in the *Federal Register* 72 FR 71061 – 71070, December 14, 2007.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on or did 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

8. 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

9. The summary of the economic, small business, and consumer impact:

The Federal Occupational Safety and Health Administration have determined that these amendments will have minimal financial impact on the general industry sector and has determined the amendments to be economically feasible for all industries including small business. Cost and benefit analysis of these amendments is available for inspection, review, and copying at the Industrial Commission of Arizona, Division of Occupational Safety and Health, 800 W. Washington St., Phoenix, AZ 85007.

10. A description of the changes between the proposed rules, including supplemental notices, and final rules (if applicable):

None

11. A summary of the comments made regarding the rule and the agency response to them:

The Arizona Division of Occupational Safety and Health did not receive any written or oral comments concerning this rule.

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

None

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

CFR 1910 Federal Occupational Safety and Health Standards for the General Industry with Amendments as of December 14, 2007. This incorporation by reference will appear in A.A.C. R20-5-602.

14. Was this rule previously made as an emergency rule?

No

15. The full text of the rules follows:

TITLE 20. COMMERCE, FINANICIAL INSTITUTIONS, AND INSURANCE

CHAPTER 5. INDUSTRIAL COMMISSION OF ARIZONA

ARTICLE 6. OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Section
R20-5-602. The Federal Occupational Safety and Health Standards for General Industry, 29 CFR 1910

ARTICLE 6. OCCUPATIONAL SAFETY AND HEALTH STANDARDS

R20-5-602. The Federal Occupational Safety and Health Standards for General Industry, 29 CFR 1910

Each employer shall comply with the standards in Subparts B through Z inclusive of the Federal Occupational Safety and Health Standards for General Industry, as published in 29 CFR 1910, with amendments as of ~~November 15, 2007,~~ December 14, 2007, incorporated by reference. Copies of these reference materials are available for review at the Industrial Commission of Arizona and may be obtained from the United States Government Printing Office, Superintendent of Documents, Washington, D.C. 20402. These standards shall apply to all conditions and practices related to general industry activity by all employers, both public and private, in the state of Arizona; provided that this rule shall not apply to those conditions and practices which are the subject of rule R20-5-601. This incorporation by reference does not include amendments or editions to 29 CFR 1910 published after ~~November 15, 2007,~~ December 14, 2007.