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 3. AGRICULTURE

CHAPTER 2. DEPARTMENT OF AGRICULTURE
ANIMAL SERVICES DIVISION

[R06-292]

PREAMBLE

1. Sections Affected **Rulemaking Action**

R3-2-801 Amend

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. § 3-603 (A), A.R.S. § 3-605

Implementing statute: A.R.S. § 3-667

3. The effective date of the rules:

September 30, 2006

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

Notice of Rulemaking Docket Opening: 12 A.A.R. 486, February 17, 2006

Notice of Proposed Rulemaking: 12 A.A.R. 1302, April 21, 2006

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

Name: Rebecca A. Nichols, Rules Analyst

Address: Arizona Department of Agriculture
1688 W. Adams, Room 235
Phoenix, AZ 85007

Telephone: (602) 542-0962

Fax: (602) 542-5420

E-mail: rnichols@azda.gov

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

To update the reference from the 2001 revision to the 2003 Revision of the *Grade A Pasteurized Milk Ordinance – 1978 Recommendations of the United States Public Health Service/Food and Drug Administration, 2001 Revision.*

The PMO is a uniform standard of health and safety rules applicable to Grade A Pasteurized Milk. It is agreed upon and adopted by all 50 states to facilitate interstate commerce through the use of a uniform standard. The FDA oversees milk production ratings using this standard.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on in its evaluation of or justification for the rule 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:

A. *The Arizona Department of Agriculture*.

The Department does not anticipate any expenses associated with incorporating the new revision to the Pasteurized Milk Ordinance other than the direct resource costs associated with this rulemaking.

B. *Political Subdivision.*

None

C. *Businesses Directly Affected by the Rulemaking.*

None at this time. Potentially the milk producers could be affected by this rulemaking if Arizona instituted the PMO guidelines into their regulations. There are currently 123 dairy farms in Arizona and 19 processors. The dairy wholesalers licensed by ADA are not affected in any way by the PMO.

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

A change has been made between the Notice of Proposed Rulemaking and this Notice of Final Rulemaking. A citation for the statute that authorizes this rulemaking has been updated to include A.R.S. § 3-605. The additional reference has specific authority for rulemaking milk and milk products sold for human consumption.

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

None

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:

The *Grade A Pasteurized Milk Ordinance – 1978 Recommendations of the United States Public Health Service/Food and Drug Administration, 2001 Revision*, is incorporated by reference in the definition of "PMO."

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

No.

15. The full text of the rules follows:

TITLE 3. AGRICULTURE

CHAPTER 2. DEPARTMENT OF AGRICULTURE
ANIMAL SERVICES DIVISION

ARTICLE 8. DAIRY AND DAIRY PRODUCTS CONTROL

Section
R3-2-801. Definitions

ARTICLE 8. DAIRY AND DAIRY PRODUCTS CONTROL

R3-2-801. Definitions

In addition to the definitions in A.R.S. §§ 3-601 and 3-661, the following terms apply to this Article:

"3-A Sanitary Standards" and "3-A Accepted Practices," as published by the International Association for Food Protection, amended May 31, 2002, means the criteria for cleanability of dairy processing equipment. This material is incorporated by reference, does not include any later amendments or editions, and is on file with the Department and ~~the Office of the Secretary of State.~~ the USDA web site: http://www.cfsan.fda.gov/~ear/pmo03toc.html.

"C-I-P" means a procedure by which equipment, pipelines, and other facilities are cleaned-in-place as prescribed in the 3-A Accepted Practices.

"Converted" means the process by which a frozen dessert is changed from a frozen to semi-frozen form without any change in the ingredients.

"Fluid trade product" means any trade product as defined in A.R.S. § 3-661(5) that resembles or imitates milk, lowfat milk, chocolate milk, half and half, or cream.

"Food establishment" means any establishment, except a private residence, that prepares or serves food for human consumption, regardless of whether the food is consumed on the premises.

"Frozen desserts mix" or "mix" means any frozen dessert before being frozen.

"Grade A raw milk" means raw milk produced on a dairy farm that conforms to Section 7 of the PMO and the requirements of R3-2-805.
"Parlor" and "milk room" mean the facilities used for the production of Grade A raw milk for pasteurization.
"Plant" means any place, premise, or establishment, or any part, including specific areas in retail stores, stands, hotels, restaurants, and other establishments where frozen desserts are manufactured, processed, assembled, stored, frozen, or converted for distribution or sale, or both. A plant may consist of rooms or space where utensils or equipment is stored, washed, or sanitized and where ingredients used in manufacturing frozen desserts are stored. Plant includes:
"Manufacturing plant" means a location where frozen desserts are manufactured, processed, pasteurized, and converted.
"Handling plant" means a location that is not equipped or used to manufacture, process, pasteurize, or convert frozen desserts, but where frozen desserts are sold or offered for sale other than at retail.
"Plate line" means a horizontal structural member, such as a timber, that provides the bearing and anchorage for the trusses of a roof or the rafters.
"PMO" means the Grade A Pasteurized Milk Ordinance – 1978 Recommendations of the United States Public Health Service/Food and Drug Administration, ~~2001~~ 2003 Revision. This material is incorporated by reference, does not include any later amendments or editions, and is on file with the Department and ~~the Office of the Secretary of State.~~ the USDA web site: http://www.cfsan.fda.gov/~ear/pmo03toc.html.
"Retail food store" means any establishment offering packaged or bulk goods for human consumption for retail sale.

NOTICE OF FINAL RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

[R06-295]

PREAMBLE

1. Sections Affected — **Rulemaking Action**

R4-23-110	Amend
R4-23-205	Amend
R4-23-301	Amend
R4-23-408	Amend
R4-23-610	Amend
R4-23-611	Amend
R4-23-653	Amend
R4-23-654	Amend
R4-23-657	Amend
R4-23-658	Amend
R4-23-659	Amend
R4-23-671	Amend
R4-23-675	Amend
R4-23-682	Amend
R4-23-701	Amend
R4-23-701.02	Amend
R4-23-1104	Amend
R4-23-1105	Amend

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 32-1934

Implementing statutes: A.R.S. § 32-1904(B)(3), (5), and (7)

3. The effective date of the rules:

October 1, 2006

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

Notice of Rulemaking Docket Opening: 12 A.A.R. 691, March 3, 2006

Notice of Rulemaking Docket Opening: 12 A.A.R. 694, March 3, 2006

Notice of Proposed Rulemaking: 12 A.A.R. 1139, April 14, 2006

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

Name:	Dean Wright, Compliance Officer
Address:	Board of Pharmacy 4425 W. Olive Ave., Suite 140 Glendale, AZ 85302
Telephone:	(623) 463-2727, ext. 131
Fax:	(623) 934-0583
E-mail:	rxcop@cox.net

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

During the 2003 Legislative Session, the Legislature changed an intern license from a two-year license to a five-year license and mandated the Board to make rules for intern license renewal. The amended rules will amend R4-23-205 (Fees) by removing the fee for intern licensure renewal and R4-23-301 (Intern Licensure) by adding language to subsection (J) detailing the requirements for intern license renewal. Following the Board's intention to move to electronic records, the Board is making a new definition in R4-23-110 (Definitions). The new definition for "verified signature" or "signature verifying" would allow hand-written or electronic signatures on any license or permit application or any Board required report, form, or agreement. The Board is amending R4-23-611 (Pharmacy Facilities) to address the issue of licensed assistant animals that may be allowed inside a pharmacy and the addition of language that requires a pharmacy to comply with its policies and procedures. The Board is amending R4-23-408 (Computer Requirements), R4-23-610 (Community Pharmacy Personnel and Security), R4-23-653 (Personnel: Professional or Technician), R4-23-654 (Absence of Pharmacist), R4-23-657 (Security), R4-23-658 (Drug Distribution and Control), R4-23-659 (Administration of Drugs), R4-23-671 (General Requirement for Limited-service Pharmacy), R4-23-675 (Limited-service Sterile Pharmaceutical Products Pharmacy), R4-23-682 (Limited-service Nuclear Pharmacy), R4-23-701 (Long-term Care Facilities Pharmacy Services: Consultant Pharmacist), R4-23-701.02 (Long-term Care Facilities Pharmacy Services: Emergency Drugs), R4-23-1104 (Pharmacy Technicians and Pharmacy Technician Trainees), and R4-23-1105 (Pharmacy Technician Training Program) by adding language that requires a pharmacy to comply with its policies and procedures. The rules will include format, style, and grammar necessary to comply with the current rules of the Secretary of State and Governor's Regulatory Review Council.

The Board believes that approval of these rules benefits the public and the pharmacy community by clearly establishing the pharmacy practice standards for pharmacies, pharmacists, pharmacy interns, pharmacy technicians, and pharmacy technician trainees.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on in its evaluation of or justification for the rule 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 amended rules will impact the Board, pharmacies, pharmacists, pharmacy interns, pharmacy technicians, and the public. The amended rules' impact on the Board will be the usual rulemaking-related costs, which are minimal. The Board estimates the amended rules will have minimal economic impact on pharmacies, pharmacists, pharmacy interns, and pharmacy technicians. The amended rules have no economic impact on the public.

The public, Board, and pharmacies benefit from rules that are clear, concise, and understandable. The amended rules benefit the public and the pharmacy community by clearly establishing the pharmacy practice standards for pharmacies, pharmacists, pharmacy interns, and pharmacy technicians.

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. 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 rule and the agency response to them:

A public hearing was held on May 15, 2006. Janet Elliott representing the Arizona Community Pharmacy Committee attended the hearing. Ms. Elliott provided written and verbal comment in favor of the rulemaking. No other verbal or written comment was received.

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:
None

14. Was this rule previously made as an emergency rule?
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 2. PHARMACIST LICENSURE

Section
R4-23-205. Fees

ARTICLE 3. INTERN TRAINING AND PHARMACY INTERN PRECEPTORS

Section
R4-23-301. Intern Licensure

ARTICLE 4. PROFESSIONAL PRACTICES

Section
R4-23-408. Computer Records

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

Section
R4-23-610. Community Pharmacy Personnel and Security Procedures
R4-23-611. Pharmacy Facilities
R4-23-653. Personnel: Professional or Technician
R4-23-654. Absence of Pharmacist
R4-23-657. Security
R4-23-658. Drug Distribution and Control
R4-23-659. Administration of Drugs
R4-23-671. General Requirements for Limited-service Pharmacy
R4-23-675. Limited-service Sterile Pharmaceutical Products Pharmacy
R4-23-682. Limited-service Nuclear Pharmacy

ARTICLE 7. NON-PHARMACY LICENSED OUTLETS - GENERAL PROVISIONS

Section
R4-23-701. Long-term Care Facilities Pharmacy Services: Consultant Pharmacist
R4-23-701.02. Long-term Care Facilities Pharmacy Services: Emergency Drugs

ARTICLE 11. PHARMACY TECHNICIANS

Section
R4-23-1104. Pharmacy Technicians and Pharmacy Technician Trainees
R4-23-1105. Pharmacy Technician Training Program

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

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

"Active ingredient" No change
"Alternate physician" No change
"Approved course in pharmacy law" No change
"Approved Provider" No change
"Authentication of product history" No change
"Batch" No change
"Beyond-use date" No change
"Biological safety cabinet" No change
"Care-giver" No change
"Class 100 environment" No change
"Community pharmacy" No change
"Component" No change
"Compounding and dispensing counter" No change
"Computer system" No change
"Computer system audit" No change
"Contact hour" No change
"Container" No change
"Continuing education" No change
"Continuing education activity" No change
"Continuing education unit" or "CEU" No change
"Correctional facility" No change
"CRT" No change
"Current good compounding practices" No change
"Current good manufacturing practice" No change
"Cytotoxic" No change
"Day" No change
"DEA" No change
"Dietary supplement" No change
"Dispensing pharmacist" No change
"Drug sample" No change
"Drug therapy management" No change
"Drug therapy management agreement" No change
"Eligible patient" No change
"Extreme emergency" No change
"FDA" No change
"Immediate notice" No change
"Inactive ingredient" No change
"Internal test assessment" No change
"Limited-service correctional pharmacy" No change
"Limited-service long-term care pharmacy" No change
"Limited-service mail-order pharmacy" No change
"Limited-service nuclear pharmacy" No change
"Limited-service pharmacy permittee" No change
"Limited-service sterile pharmaceutical products pharmacy" No change
"Long-term care consultant pharmacist" No change
"Long-term care facility" or "LTCF" No change
"Lot" No change
"Lot number" or "control number" No change
"Materials approval unit" No change
"Mediated instruction" No change
"MPJE" No change
"NABP" No change
"NABPLEX" No change
"NAPLEX" No change
"Other designated personnel" No change
"Outpatient" No change

"Outpatient setting" No change
"Patient profile" No change
"Pharmaceutical patient care services" No change
"Pharmaceutical product" No change
"Pharmacist-administered immunizations training program" No change
"Pharmacy counter working area" No change
"Pharmacy law continuing education" No change
"Pharmacy permittee" No change
"Prepackaged drug" No change
"Proprietor" No change
"Provider pharmacy" No change
"Radiopharmaceutical" No change
"Radiopharmaceutical quality assurance" No change
"Radiopharmaceutical services" No change
"Red C stamp" No change
"Refill" No change
"Remodel" No change
"Remote drug storage area" No change
"Resident" No change
"Responsible person" No change
"Score transfer" No change
"Sight-readable" No change
"Single-drug audit" No change
"Single-drug usage report" No change
"Sterile pharmaceutical product" No change
"Strength" No change
"Supervision" No change
"Supervisory physician" No change
"Supplying" No change
"Support personnel" No change
"Transfill" No change
"Verified signature" or "signature verifying" means in relation to a Board license or permit application or report, form, or agreement, the hand-written or electronic signature of an individual who, by placing a hand-written or electronic signature on a hard-copy or electronic license or permit application or report, form, or agreement agrees with and verifies that the statements and information within or attached to the license or permit application or report, form, or agreement are true in every respect and that inaccurate reporting can result in denial or loss of a license or permit or report, form, or agreement.
"Wholesale distribution" No change
"Wholesale distributor" No change

ARTICLE 2. PHARMACIST LICENSURE

R4-23-205. Fees

A. Licensure fees:
1. No change
   a. No change
   b. No change
2. Pharmacy or graduate intern~~:~~.
   ~~a.~~ Initial licensure: $50.
   ~~b. Licensure renewal: $50.~~
3. No change
   a. No change
   b. No change
4. No change

B. No change
C. No change
D. No change
1. No change
2. No change
   a. No change

b. No change
c. No change
3. No change
4. No change
a. No change
b. No change
5. No change
6. No change

E. No change
1. No change
a. No change
b. No change
c. No change
d. No change
2. No change
3. No change

F. No change

G. No change
1. No change
2. No change

ARTICLE 3. INTERN TRAINING AND PHARMACY INTERN PRECEPTORS

R4-23-301. Intern Licensure

A. No change

B. No change
1. No change
2. No change
3. No change
4. No change

C. No change

D. No change
1. No change
2. No change
3. No change

E. No change

F. No change
1. No change
2. No change

G. No change

H. No change
1. No change
2. No change
a. No change
b. No change
c. No change
d. No change
e. No change
f. No change
g. No change
h. No change

I. No change

J. License renewal. ~~A pharmacy intern shall remain in good standing by payment of the biennial renewal fee specified in R4-23-205.~~ A pharmacy intern whose license expires before the intern completes the education or training required for licensure as a pharmacist but less than six years after the issuance of the initial pharmacy intern license may renew the intern license for a period equal to the difference between the expiration date of the initial intern license and six years from the issue date of the initial intern license by payment of a prorated renewal fee based on the initial license fee specified in R4-23-205. If a pharmacy intern fails to graduate from a Board-approved college or school of pharmacy within six years from the date the Board issues the initial intern license, the intern is not eligible for relicensure as an intern unless the intern

obtains Board approval as specified in A.R.S. § 32-1923(E). To remain in good standing, an intern who receives Board approval for relicensure shall pay a prorated renewal fee for the number of months of licensure approved by the Board based on the initial license fee specified in R4-23-205 before the license expiration date. If ~~the biennial renewal fee is not paid by November 1 of the renewal year specified in A.R.S. § 32-1925~~ an intern receives Board approval for relicensure and does not pay the renewal fee specified in this subsection before the license expiration date, the intern license is suspended and the ~~licensee~~ intern shall pay a penalty as provided in A.R.S. § 32-1925 to vacate the suspension.

K. No change
1. No change
2. No change

ARTICLE 4. PROFESSIONAL PRACTICES

R4-23-408. Computer Records

A. Systems manual. A pharmacy permittee or pharmacist-in-charge shall:
1. Develop, ~~and~~ implement, and comply with policies and procedures for the following operational aspects of a computer system:
   a. No change
   b. No change
   c. No change
   d. No change
   e. No change
2. No change
3. No change
4. No change
5. No change

B. No change
1. No change
2. No change
3. No change
4. No change
5. No change
   a. No change
   b. No change
   c. No change
   d. No change
   e. No change
   f. No change
6. No change

C. No change
1. No change
2. No change
3. No change
4. No change
   a. No change
      i. No change
      ii. No change
      iii. No change
   b. No change
      i. No change
      ii. No change
      iii. No change

D. No change

E. No change

F. No change
1. No change
2. No change

G. No change
1. No change
2. No change

H. Prescription records and retention.
1. No change
   a. No change
   b. No change
2. In lieu of filing the actual original hard-copy prescription, a pharmacy permittee or pharmacist-in-charge may use an electronic imaging recordkeeping system, if:
   a. No change
   b. No change
   c. No change
   d. Policies and procedures for the use of an electronic imaging recordkeeping system are developed, ~~and~~ implemented, reviewed, and revised in the same manner described in subsection (A) and complied with ~~in the same manner as specified in subsection (A)~~; and
   e. No change
3. No change

ARTICLE 6. PERMITS AND DISTRIBUTION OF DRUGS

R4-23-610. Community Pharmacy Personnel and Security Procedures

A. No change
1. No change
2. The pharmacist-in-charge shall:
   a. Ensure that all pharmacy policies and procedures required under 4 A.A.C. 23 are prepared, ~~and~~ implemented, and complied with;
   b. No change
   c. No change
   d. No change
   e. No change

B. No change
1. No change
2. No change

C. No change
D. No change
E. No change
F. No change
G. No change
1. No change
2. No change

R4-23-611. Pharmacy Facilities

A. No change
1. No change
2. No change
   a. No change
   b. No change
3. No change
4. No change
   a. No change
   b. No change
5. No change
6. No change
7. No animals, except ~~guide dogs for the blind~~ licensed assistant animals and guard ~~dogs~~ animals, are allowed in the pharmacy;
8. No change
9. No change

B. Supply of drugs and chemicals. A pharmacy permittee or pharmacist-in-charge shall ensure that:
1. No change
   a. No change
   b. No change
2. No change

3. Policies and procedures are developed, ~~and~~ implemented, and complied with to prevent the sale or use of a drug or chemical:
   a. No change
   b. No change
   c. No change
   d. No change
   e. No change
4. No change
   a. No change
   b. No change
      i. No change
      ii. No change
      iii. No change

R4-23-653. Personnel: Professional or Technician

A. Each hospital pharmacy shall be directed by a pharmacist who is licensed to engage in the practice of pharmacy in Arizona and is referred to as the Director of Pharmacy. The Director of Pharmacy shall be the pharmacist-in-charge, as defined in A.R.S. § 32-1901 or shall appoint a pharmacist-in-charge. The Director of Pharmacy and the pharmacist-in-charge, if a different individual, shall:
   1. No change
   2. Ensure that the policies and procedures required by these rules are prepared, ~~and~~ implemented, and complied with;
   3. No change
   4. No change
   5. No change
   6. No change

B. No change

C. No change

D. No change

E. No change
   1. No change
      a. No change
      b. No change
   2. No change
      a. No change
      b. No change
      c. No change
      d. No change
   3. No change
   4. No change
   5. No change
   6. No change
   7. No change
   8. No change
   9. No change
   10. No change
   11. No change
   12. No change
   13. No change
   14. No change

F. No change

G. No change

H. No change
   1. No change
   2. No change
      a. No change
      b. No change

I. No change

R4-23-654. Absence of Pharmacist

A. No change

B. No change
C. No change
D. Remote drug storage area. The Director of Pharmacy or pharmacist-in-charge shall, in consultation with the appropriate committee of the hospital:
1. No change
2. Develop, ~~and~~ implement, review, and revise in the same manner described in R4-23-653(A) and comply with policies and procedures ~~in the same manner described in R4-23-653(A)~~ that ensure proper storage, access, and accountability for drugs in a remote drug storage area.

E. No change
1. The Director of Pharmacy or pharmacist-in-charge shall, in consultation with the appropriate committee of the hospital, develop, ~~and~~ implement, review, and revise in the same manner described in R4-23-653(A) and comply with policies and procedures ~~in the same manner described in R4-23-653(A)~~ to ensure that access to the hospital pharmacy during the pharmacist's absence conforms to the following requirements:
   a. No change
   b. No change
   c. No change
   d. No change
2. No change
   a. No change
      i. No change
      ii. No change
      iii. No change
      iv. No change
   b. No change
   c. No change
   d. No change
3. No change

R4-23-657. Security

A. No change
1. No change
2. No change
3. No change

B. Prescription blank security. The Director of Pharmacy shall develop, ~~and~~ implement, review, and revise in the same manner described in R4-23-653(A) and comply with policies and procedures ~~in the same manner described in R4-23-653(A)~~ for the safe distribution and control of prescription blanks bearing identification of the hospital.

R4-23-658. Drug Distribution and Control

A. General. The Director of Pharmacy or pharmacist-in-charge shall in consultation with the medical staff, develop, ~~and~~ implement, review, and revise in the same manner described in R4-23-653(A) and comply with written policies and procedures ~~in the same manner described in R4-23-653(A)~~ for the effective operation of a drug distribution system that optimizes patient safety.

B. No change
1. No change
2. No change
3. No change

C. No change
1. No change
2. No change

D. No change
1. No change
   a. No change
      i. No change
      ii. No change
      iii. No change
   b. No change
      i. No change
      ii. No change
      iii. No change
      iv. No change

c. No change
i. No change
ii. No change
iii. No change
iv. No change
v. No change
vi. No change
vii. No change
viii. No change
2. No change

E. Controlled substance accountability. A Director of Pharmacy or pharmacist-in-charge shall ensure that effective policies and procedures are developed, ~~and~~ implemented, reviewed, and revised in the same manner described in R4-23-653(A) and complied with ~~in the same manner described in R4-23-653(A)~~ regarding the use, accountability, and recordkeeping of controlled substances in the hospital, including the use of locked storage areas when controlled substances are stored in patient care areas.

F. Emergency services dispensing. If a hospital permits dispensing of drugs from the emergency services department when the pharmacy is unable to provide this service, the Director of Pharmacy, in consultation with the appropriate department personnel and medical staff committee shall develop, ~~and~~ implement, review, and revise in the same manner described in R4-23-653(A) and comply with written policies and procedures ~~in the same manner described in R4-23-653(A)~~ for dispensing drugs for outpatient use from the hospital's emergency services department. The policies and procedures shall include the following requirements:
1. No change
2. No change
3. No change
4. No change
5. No change
6. No change
7. No change

R4-23-659. Administration of Drugs

A. Self-administration. A hospital shall not allow self-administration of medications by a patient unless the Director of Pharmacy or pharmacist-in-charge, in consultation with the appropriate department personnel and medical staff committee, develops, ~~and~~ implements, reviews, and revises in the same manner described in R4-23-653(A) and complies with policies and procedures for self-administration of medications by a patient ~~in the same manner described in R4-23-653(A)~~. The policies and procedures shall specify that self-administration of medications, if allowed, occurs only when:
1. No change
2. No change

B. Drugs brought in by a patient. If a hospital allows a patient to bring a drug into the hospital and before a patient brings a drug into the hospital, the Director of Pharmacy or pharmacist-in-charge shall, in consultation with the appropriate department personnel and medical staff committee, develop, ~~and~~ implement, review, and revise in the same manner described in R4-23-653(A) and comply with policies and procedures for a patient-owned drug brought into the hospital ~~in the same manner described in R4-23-653(A)~~. The policies and procedures shall specify the following criteria for a patient-owned drug brought into the hospital:
1. No change
a. No change
b. No change
2. No change
a. No change
b. No change

C. Drug samples. The Director of Pharmacy or pharmacist-in-charge is responsible for the receipt, storage, distribution, and accountability of drug samples within the hospital, including developing, ~~and~~ implementing, reviewing, and revising in the same manner described in R4-23-653(A) and complying with specific policies and procedures ~~in the same manner described in R4-23-653(A)~~ regarding drug samples.

R4-23-671. General Requirements for Limited-service Pharmacy

A. No change

B. No change
1. No change
2. No change
3. No change

4. No change

C. No change

D. No change

E. Before dispensing from a limited-service pharmacy, the limited-service pharmacy permittee or pharmacist-in-charge shall:

1. Prepare, ~~and~~ implement, and comply with written policies and procedures for pharmacy operations and drug dispensing and distribution,
2. No change
3. No change
4. No change
5. No change

R4-23-675. Limited-service Sterile Pharmaceutical Products Pharmacy

A. No change

B. No change

C. No change

D. No change

E. The limited-service pharmacy permittee or the pharmacist-in-charge shall ensure development, ~~and~~ implementation, review and revision in the same manner described in R4-23-671(E) and compliance with ~~of~~ policies and procedures for pharmacy operations, including pharmaceutical product compounding, dispensing, and distribution, that comply with the requirements of R4-23-402, R4-23-410, R4-23-670, and R4-23-671.

F. No change

R4-23-682. Limited-service Nuclear Pharmacy

A. No change

B. No change

1. No change
   a. No change
   b. No change
   c. No change
2. No change
3. No change

C. No change

1. No change
   a. No change
   b. No change
   c. No change
   d. No change
2. No change

D. No change

E. No change

1. No change
   a. No change
   b. No change
   c. No change
2. No change
   a. No change
   b. No change
   c. No change
   d. No change
   e. No change
   f. No change
   g. No change
3. No change
   a. No change
   b. No change
   c. No change
   d. No change
   e. No change
   f. No change

g. No change
h. No change

F. No change
1. No change
   a. No change
   b. No change
   c. No change
2. No change
   a. No change
   b. No change
   c. No change
   d. No change
   e. Prescription balance, Class A, and weights or an electronic balance of equal or greater accuracy;
   f. No change
   g. No change
   h. No change
   ~~i. Equipment to produce a typed or mechanically printed label;~~
   ~~j. Equipment to produce mechanically printed numbers;~~
   ~~k.~~ i. No change
   ~~l.~~ j. No change
   ~~m.~~ k. No change
   ~~n.~~ l. No change
   ~~o.~~ m. No change
3. No change
4. No change
   a. No change
   b. No change
   c. No change
5. No change
   a. No change
   b. No change
   c. No change
   d. No change
   e. No change
   f. No change

G. The pharmacist-in-charge of a limited-service nuclear pharmacy shall prepare, ~~and~~ implement, review, and revise in the same manner described in R4-23-671(E) and comply with written policies and procedures for pharmacy operations and drug distribution.

H. No change
1. No change
2. No change
   a. No change
   b. No change
   c. No change
   d. No change
   e. No change
3. No change
4. No change
5. No change
6. No change
7. No change
8. No change
9. No change
   a. No change
   b. No change
   c. No change
   d. No change
   e. No change
   f. No change

g. No change
h. No change
10. No change
11. No change
12. No change
13. No change
a. No change
b. No change
c. No change
d. No change
e. No change
14. No change

ARTICLE 7. NON-PHARMACY LICENSED OUTLETS - GENERAL PROVISIONS

R4-23-701. Long-term Care Facilities Pharmacy Services: Consultant Pharmacist

A. The long-term care consultant pharmacist as defined in R4-23-110, in cooperation with the pharmacist-in-charge of a provider pharmacy shall:
1. Prepare, implement, review, and revise in the same manner described in R4-23-671(E) and comply with written policies and procedures for the safe and efficient receipt, distribution, and storage of pharmaceutical products by the long-term care facility ~~in the manner specified in R4-23-671(E)~~;
2. No change
3. No change
a. No change
b. No change
c. No change
d. No change
i. No change
ii. No change
iii. No change
iv. No change
e. No change
f. No change
g. No change
h. No change
i. No change
j. No change
k. No change
l. No change
m. No change

B. No change
1. No change
2. No change
a. No change
b. No change
c. No change
d. No change
e. No change
f. No change
3. No change
4. No change
5. No change
a. No change
b. No change

C. No change
1. No change
2. No change
3. No change
4. No change

D. No change
1. No change
   a. No change
   b. No change
   c. No change
2. No change
   a. No change
   b. No change

R4-23-701.02. Long-term Care Facilities Pharmacy Services: Emergency Drugs
A. No change
B. No change
1. No change
2. No change
C. No change
1. No change
   a. No change
   b. No change
2. No change
3. No change
4. No change
D. The limited-service pharmacy permittee or pharmacist-in-charge of a provider pharmacy shall:
1. Prepare, ~~and~~ implement, review, and revise in the same manner described in R4-23-671(E) and comply with written policies and procedures for the storage and use of an emergency drug supply unit in a long-term care facility ~~in the manner specified in R4-23-671(E),~~;
2. Make the policies and procedures available in the provider pharmacy and long-term care facility for employee reference and inspection by the Board or its designee~~,~~; and
3. No change
   a. No change
      i. No change
      ii. No change
      iii. No change
   b. No change
      i. No change
      ii. No change
      iii. No change
      iv. The provider pharmacy's personnel restock the emergency drug supply unit within 48 hours of receiving the notification required in subsection (D)(3)(b)(ii), and
   c. Security and inspection procedures~~,~~; and
4. No change

ARTICLE 11. PHARMACY TECHNICIANS

R4-23-1104. Pharmacy Technicians and Pharmacy Technician Trainees
A. No change
1. No change
2. No change
3. No change
4. No change
5. No change
6. No change
7. No change
8. No change
B. No change
1. No change
2. No change
C. No change
D. No change
E. Before employing a pharmacy technician or pharmacy technician trainee, a pharmacy permittee or pharmacist-in-charge

shall develop, ~~and~~ implement, review, and revise in the same manner described in R4-23-653(A) and comply with policies and procedures ~~in the same manner described in R4-23-653(A)~~ for pharmacy technician and pharmacy technician trainee activities as specified in subsection (F).

F. No change
1. No change
   a. No change
   b. No change
   c. No change
   d. No change
   e. No change
   f. No change
      i. No change
      ii. No change
   g. No change
   h. No change
   i. No change
2. No change
   a. No change
      i. No change
      ii. No change
      iii. No change
      iv. No change
      v. No change
      vi. No change
   b. No change
      i. No change
      ii. No change
      iii. No change
      iv. No change
      v. No change
      vi. No change
      vii. No change
      viii. No change
      ix. No change
3. No change
   a. No change
   b. No change
   c. No change
   d. No change

R4-23-1105. Pharmacy Technician Training Program

A. No change

B. Pharmacy technician training program.
1. A pharmacy permittee or pharmacist-in-charge shall develop, ~~and~~ implement, review, and revise in the same manner described in R4-23-653(A) and comply with ~~in the same manner described in R4-23-653(A)~~ a pharmacy technician training program based on the needs of the individual pharmacy;
2. No change
   a. No change
   b. No change
   c. No change
3. No change
   a. No change
   b. No change
   c. No change
   d. No change

C. Drug compounding training program.
1. A pharmacy permittee or pharmacist-in-charge shall develop, ~~and~~ implement, review, and revise in the same manner described in R4-23-653(A) and comply with ~~in the same manner described in R4-23-653(A)~~ a drug compounding training program based on the needs of the individual pharmacy;
2. No change

a. No change
b. No change
c. No change
i. No change
ii. No change
iii. No change
iv. No change
v. No change
3. A pharmacist-in-charge shall:
a. Document a pharmacy technician's progress throughout the training program, ~~and~~
b. Date and sign a statement attesting that a pharmacy technician ~~trainee~~ has successfully completed the training program, and
c. No change

D. No change

NOTICE OF FINAL RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 24. DEPARTMENT OF HEALTH SERVICES
ARIZONA MEDICALLY UNDERSERVED AREA HEALTH SERVICES

[R06-291]

PREAMBLE

1. Sections Affected — **Rulemaking Action**

Article 1	Repeal
R9-24-101	Repeal
R9-24-102	Repeal
R9-24-201	Amend
R9-24-202	Amend
R9-24-203	Amend
Table 1	Amend
R9-24-204	Amend
R9-24-205	New Section
R9-24-301	Amend
R9-24-302	Amend

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. §§ 36-136(A)(7) and 36-136(F)

Implementing statutes: A.R.S. §§ 36-2352 and 36-2354

3. The effective date of the rules:

September 30, 2006

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

Notice of Rulemaking Docket Opening: 12 A.A.R. 489, February 17, 2006

Notice of Proposed Rulemaking: 12 A.A.R. 1081, April 7, 2006

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

Name: Patricia Tarango, Office Chief

Address: Office of Health Systems Development
Arizona Department of Health Services
1740 W. Adams, Room 410
Phoenix, AZ 85007

Telephone: (602) 542-1219

Fax: (602) 542-2011

E-mail: tarangp@azdhs.gov

Or

Name: Kathleen Phillips, Rules Administrator

Address: Office of Administrative Rules
Department of Health Services
1740 W. Adams, Suite 202
Phoenix, AZ 85007

Telephone: (602) 542-1264

Fax: (602) 364-1150

E-mail: phillik@azdhs.gov

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

A.R.S. § 36-2352 requires the Department to designate Arizona medically underserved areas (AzMUAs). A.R.S. § 36-2354 authorizes the Department to establish the functions of coordinating medical providers who supervise the medical care offered at a medical clinic in an AzMUA. The Department originally made AzMUA and coordinating medical provider rules in 1978. In 1994, the legislature changed the statutory scheme for AzMUA designation. The Department's AzMUA designation program has been consistent with the statutory scheme since 1994, although the rules were not changed until 2001.

In this rulemaking, the Department is revising the AzMUA and coordinating medical provider rules in 9 A.A.C. 24 that became effective in January 2001. The Department is making revisions in accordance with the five-year-review report approved by the Governor's Regulatory Review Council on December 7, 2004. Additionally, the Department is consolidating 9 A.A.C. 24, Articles 1 and 2 to simplify the structure and improve the accessibility of the AzMUA rules.

The Department is repealing 9 A.A.C. 24, Article 1, General, including R9-24-101, Definitions, and R9-24-102, Time-frames. Definitions of non-statutorily defined terms and the boundary change request time-frames are being moved to Article 2. The new AzMUA rules' structure will benefit the public by making the rules easier to use.

For 9 A.A.C. 24, Article 2, the Department is moving to R9-24-201 definitions of terms formerly defined in R9-24-101 that are not included in A.R.S. § 36-2351, is improving R9-24-201's definitions, and is adding to R9-24-201 definitions of previously undefined terms. These changes will make the rules more understandable to the public. The Department is making a new Section, R9-24-205, containing the R9-24-102 time-frames with technical changes. These technical changes will improve the rule, although the Department has not received any primary care area boundary change requests according to R9-24-204(C).

The Department is making technical changes to the AzMUA designation process in R9-24-202, R9-24-203, and Table1 and to the primary care area boundary determination process in R9-24-204. The Department also is:

- Correcting the text of R9-24-203(B)(13) to "or a full-time registered nurse practitioner as 0.8;"
- Providing in R9-24-203(B)(1)(c) and R9-24-203(B)(13)(c) for downward adjustment of the number of physicians, physician assistants, and registered nurse practitioners in a primary care area if the Department determines that a provider renders less than full-time health care to the primary care area's population;
- Adding to R9-24-203(B)(2)(a), for the census data publication year, data from the most recent decennial census;
- Adding to R9-24-203(B)(12)(a) data from the Population Estimates for Arizona's Counties, Incorporated Places and Balance of County;
- Conforming R9-24-203(B)(7)(b) to A.R.S. § 36-125.05 by changing "hospital discharge record data" to "hospital inpatient and emergency department services data;"
- Adding new R9-24-204(C) that specifically authorizes the Department's redetermination of primary care area boundaries without a boundary change request from a member of the public; and
- Moving the provisions for boundary change requests from members of the public to R9-24-204(D).

For 9 A.A.C. 24, Article 3, the Department is adding definitions of previously undefined terms to increase understandability. Additionally, the Department is making changes to R9-24-302, dealing with coordinating medical provider functions. Some of these changes result from the different scopes of practice of registered nurse practitioners and physician assistants. No AzMUA has ever had a coordinating medical provider.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on in its evaluation of or justification for the rule 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 Department did not review, rely on, or not rely on any study for this rulemaking.

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:

To clarify the structure and improve the accessibility of the AzMUA rules, the Department is repealing 9 A.A.C. 24, Article 1, General, including R9-24-101, Definitions, and R9-24-102, Time-frames. Definitions of non-statutorily defined terms and the boundary change request time-frames are being moved to Article 2. The Department believes that this structural change will benefit the public.

For 9 A.A.C. 24, Article 2, the Department is remaking in R9-24-201 definitions of terms formerly defined in R9-24-101 that are not included in A.R.S. § 36-2351, is improving the R9-24-201 definitions, and is adding to R9-24-201 definitions of previously undefined terms. The Department is making a new Section, R9-24-205, containing the R9-24-102 time-frames with technical changes. The Department also is making content changes to R9-24-203 and R9-24-204.

The content changes to R9-24-203 fully reflect the current AzMUA designation process. These changes generally will not result in AzMUA designations different from the AzMUA designations that would be obtained under former R9-24-203. The data source additions in the R9-24-203(B)(2) and R9-24-203(B)(12) criteria contribute to the accuracy of the Department's determinations. The data source modification in the R9-24-203(B)(7) criterion conforms the subsection to current statutory language. Correcting the R9-24-203(B)(13) text to "registered nurse practitioner," will not affect AzMUA designation. Along with physicians and physician assistants, the Department has always counted as primary care providers registered nurses with registered nurse practitioner certification from the Arizona State Board of Nursing according to 4 A.A.C. 19, Article 5. Therefore, the R9-24-203(B)(13) textual correction will not determine AzMUA designation. Finally, the effect, if any, on AzMUA designation from the possible downward adjustment in R9-24-203(B)(1) and R9-24-203(B)(13) of the number of primary care providers in a primary care area, would be an increase in the number of primary care areas designated as AzMUAs. Such an increase would indirectly benefit medical facilities and individuals as discussed in this summary of economic, small business and consumer impact.

The content change to R9-24-204 addresses the Department's ability to redetermine primary care area boundaries without a request from a member of the public. The Department has not received a primary care area boundary change request from a member of the public according to former R9-24-204(C). The Department believes that the technical changes and the changes to the content of the Article 2 rules will not have any additional economic impact on the Department and will not impose any direct costs on any other individual or entity.

For 9 A.A.C. 24, Article 3, the Department added definitions of previously undefined terms in R9-24-301 and made some changes to the content of R9-24-302. No AzMUA has ever had a coordinating medical provider. The Department believes that the technical changes and changes to the content of the Article 3 rules will not have any additional economic impact on the Department and will not impose any direct costs on any other individual or entity.

Under the former rules, the Department incurred substantial costs ($10,000 or more) to operate the AzMUA designation program, including preparation of the primary care index. The Department's AzMUA program and its rules indirectly result in substantial benefits or losses to a primary care area and to medical facilities or individuals in the primary care area. A.R.S. § 36-2172(E) gives priority for the primary care provider loan repayment program to rural areas with an AzMUA designation or assigned to a high-degree-of-shortage group according to federal regulations. These regulations are currently located at 42 CFR Part 5, Appendix A, Criteria for Designation of Areas Having Shortages of Primary Medical Care Professional(s). A primary care area with an AzMUA designation also is eligible for health crisis fund monies for "basic health services delivery disruptions, caused by unforeseen circumstances" under A.R.S. § 36-797. A primary care area with an AzMUA designation may receive the Department's assistance to recruit a coordinating medical provider under A.R.S. § 36-2353. To the Department's knowledge, this assistance has not occurred, and no AzMUA has used the rules in 9 A.A.C. 24, Article 3.

Non-Department programs that require AzMUA designation include the Arizona medical student loan program under A.R.S. Title 15, Chapter 13, Article 7; and priority consideration by the University of Arizona College of Medicine for applicants who indicate their willingness to practice in AzMUAs under A.R.S. § 15-1751. Additionally, under A.R.S. § 48-2201 a health service district may be established only in an area with an AzMUA designation. The Department is aware of only one health service district in the state, the Ajo-Lukeville Health Service District.

Under the revised rules, the Department's methodology for AzMUA designation under 9 A.A.C. 24, Article 2 will continue to result in some annual variation because the indicators established in A.R.S. § 36-2352(A) measure variable demographics.

Under the revised rules, benefits and losses to primary care areas and to medical facilities or individuals in primary care areas will remain indirect, resulting from the need for AzMUA designation for participation in programs under statutes other than A.R.S. § 36-2352. Direct costs related to designating AzMUAs will continue to arise from the Department's performance of its statutory functions under A.R.S. Title 36, Chapter 24.

The Department, external stakeholders, and members of the public might experience minimal costs and benefits (less than $1000) from the time-frame rule if the Department receives a primary care area boundary change request according to R9-24-204(D) [formerly R9-24-204(C)]. The Department, external stakeholders, and members of the public might experience undetermined costs and benefits from the coordinating medical provider rules if these rules are ever used. The benefits from 9 A.A.C. 24 as revised will continue to outweigh the costs.

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

The Department made the following technical changes:

- In R9-24-301(2)(a), the rule citation has been changed from A.A.C. R4-16-101 to A.A.C. R4-16-102;
- In R9-24-301(2)(c), the statutory citation has been corrected from A.R.S. § 32-1824 to A.R.S. § 32-1825 and the citation of A.A.C. R4-22-110 has been deleted;
- In R9-24-301(3)(a), the rule citation has been changed from A.A.C. R4-19-507 to A.A.C. R4-19-511 and "medication" has been changed to "drugs and devices;" and
- In R9-24-301(7) the rule citations have been changed from A.A.C. R9-4-505 and A.A.C. R9-4-507 to A.A.C. R9-4-508 and A.A.C. R9-4-511.

Other technical and grammatical changes were made at the suggestion of the staff of the Governor's Regulatory Review Council.

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

The Department did not receive any written or oral comments on the rules.

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:

None

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

The Department did not previously make the rules as emergency rules.

15. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 24. DEPARTMENT OF HEALTH SERVICES
ARIZONA MEDICALLY UNDERSERVED AREA HEALTH SERVICES

ARTICLE 1. ~~GENERAL~~ REPEALED

Section
R9-24-101. ~~Definitions~~ Repealed
R9-24-102. ~~Time-frames~~ Repealed

ARTICLE 2. ARIZONA MEDICALLY UNDERSERVED AREAS

Section
R9-24-201. Definitions
R9-24-202. Arizona Medically Underserved Area Designation
R9-24-203. Primary Care Index
Table 1. Primary Care Index Scoring
R9-24-204. Primary Care Area ~~Designation~~ Boundaries Determination
R9-24-205. ~~Repealed~~ Time-frames

ARTICLE 3. COORDINATING MEDICAL PROVIDERS

Section
R9-24-301. Definitions
R9-24-302. CMP Functions

ARTICLE 1. ~~GENERAL~~ REPEALED

R9-24-101. ~~Definitions~~ Repealed

~~In this Chapter, unless otherwise specified:~~

~~1. "Arizona medically underserved area" means a primary care area that is designated by the Secretary of the United~~

~~States Department of Health and Human Services as a health professional shortage area or that is designated by the Department using the methodology described in A.A.C. R9-24-203.~~

2. ~~"Days" means calendar days, excluding the day of the act, event, or default from which a designated period of time begins to run and excluding the last day of the period if it is a Saturday, a Sunday, or a legal holiday, in which event the period runs until the end of the next day that is not a Saturday, a Sunday, or a legal holiday.~~
3. ~~"Department" means the Arizona Department of Health Services.~~
4. ~~"Health professional shortage area" means a geographic region designated by the Secretary of the United States Department of Health and Human Services under 42 U.S.C. § 254e as a primary medical care health professional shortage area.~~
5. ~~"Physician" has the same meaning as in A.R.S. § 36-2351.~~
6. ~~"Physician assistant" has the same meaning as in A.R.S. § 32-2501.~~
7. ~~"Primary care area" means a geographic region designated as a primary care area by the Department under A.A.C. R9-24-204.~~
8. ~~"Registered nurse practitioner" has the same meaning as in A.R.S. § 32-1601.~~

R9-24-102. ~~Time-frames~~ Repealed

~~A.~~ ~~The overall time-frame described in A.R.S. § 41-1072 for a request for boundary change under A.A.C. R9-24-204 is 90 days. The person requesting a boundary change and the Department may agree in writing to extend the substantive review time-frame and the overall time-frame. An extension of the substantive review time-frame and the overall time-frame may not exceed 25% of the overall time-frame.~~

~~B.~~ ~~The administrative completeness review time-frame described in A.R.S. § 41-1072 for a request for boundary change under A.A.C. R9-24-204 is 30 days and begins on the date that the Department receives a request for boundary change.~~

1. ~~The Department shall mail a notice of administrative completeness or deficiencies to the person requesting a boundary change within the administrative completeness review time-frame.~~
   a. ~~A notice of deficiencies shall list each deficiency and the information and documentation needed to complete the request for boundary change.~~
   b. ~~If the Department issues a notice of deficiencies within the administrative completeness review time-frame, the administrative completeness review time-frame and the overall time-frame are suspended from the date that the notice is issued until the date that the Department receives the missing information from the person requesting a boundary change.~~
   c. ~~If the person requesting a boundary change fails to submit to the Department all of the information and documents listed in the notice of deficiencies within 30 days from the date that the Department mails the notice of deficiencies, the Department shall consider the request for boundary change withdrawn.~~
2. ~~If the Department issues an approval to the person requesting a boundary change during the administrative completeness review time-frame, the Department shall not issue a separate written notice of administrative completeness.~~

~~C.~~ ~~The substantive review time-frame described in A.R.S. § 41-1072 is 60 days and begins on the date of the notice of administrative completeness.~~

1. ~~The Department shall mail written notification of approval or denial of the request for boundary change to the person requesting a boundary change within the substantive review time-frame.~~
2. ~~During the substantive review time-frame, the Department may make 1 comprehensive written request for additional information, unless the Department and the person requesting a boundary change agree in writing to allow the Department to submit supplemental requests for information.~~
3. ~~If the Department issues a comprehensive written request or a supplemental request for information, the substantive review time-frame and the overall time-frame shall be suspended from the date that the Department issues the request until the date that the Department receives all of the information requested. If the person requesting a boundary change fails to submit to the Department all of the information and documents listed in the comprehensive written request or supplemental request for information within 30 days from the date that the Department mails the comprehensive written request or supplemental request for information, the Department shall consider the request for boundary change withdrawn.~~
4. ~~The Department shall approve a request for boundary change under A.A.C. R9-24-204 unless the Department determines that the resulting primary care area does not comply with A.A.C. R9-24-204(A).~~

ARTICLE 2. ARIZONA MEDICALLY UNDERSERVED AREAS

R9-24-201. Definitions

In addition to the definitions in A.R.S. § 36-2351, the following definitions apply in this Article, unless otherwise specified:

1. "Act, event, or default" means an occurrence or the failure of something to occur.
2. "Agency" has the same meaning as in A.R.S. § 41-1001.

~~1.~~ 3. "Ambulatory care sensitive conditions" means the illnesses listed ~~as ambulatory care sensitive conditions in Ambula-~~

~~tory Care Access Project, United Hospital Fund of New York, Final Code Specifications for "Ambulatory Care Sensitive" Conditions, "Marker" Conditions (July 30, 1991), which is incorporated by reference, on file with the Department and the Office of the secretary of State, and available from United Hospital Fund, 350 5th Avenue, 23rd Floor, New York NY 10118-2399. This incorporation by reference contains no future editions or amendments.~~ in the first table of Appendix B (entitled "Ambulatory Care Sensitive Conditions") to "Using Administrative Data to Monitor Access, Identify Disparities, and Assess Performance of the Safety Net," in *Tools for Monitoring the Health Care Safety Net*, AHRQ Publication No. 03-0027, September 2003, Agency for Healthcare Research and Quality, Rockville, MD, and available on the web site of the Agency for Healthcare Research and Quality, U.S. Department of Health and Human Services, at http://www.ahrq.gov/data/safetynet/billappb.htm.

4. "Arizona Medical Board" means the agency established by A.R.S. § 32-1402 to regulate physicians licensed under A.R.S. Title 32, Chapter 13.
5. "Arizona medically underserved area" means:
   a. A primary care area or part of a primary care area with the designation described in R9-24-202(1), or
   b. A primary care area with the designation described in R9-24-202(2).
6. "Arizona Regulatory Board of Physician Assistants" means the agency established by A.R.S. § 32-2502 to regulate physician assistants.
7. "Arizona State Board of Nursing" means the agency established by A.R.S. § 32-1602 to regulate nurses and nursing assistants.

~~2.~~ 8. "Birth life expectancy" means the average life span at the time of birth ~~as published in~~ according to the most recent ~~United States Life Tables by~~ U.S. life expectancy data in the National Vital Statistics Reports of the National Vital Statistics System, available on the web site of the National Center for Health Statistics, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, at http://www.cdc.gov/nchs/fastats/lifexpec.htm.

9. "Board of Osteopathic Examiners in Medicine and Surgery" means the agency established by A.R.S. § 32-1801 to regulate physicians licensed under A.R.S. Title 32, Chapter 17.
10. "Boundary change" means a re-determination of the geographic limits of a primary care area.
11. "Census block" means a geographic unit that is:
    a. The smallest unit of census geography established by the U.S. Census Bureau, and
    b. One of approximately 8 million similar units covering the entire nation.
12. "Day" means calendar day:
    a. Excluding the day of the act, event, or default that triggers the running of a time-frame;
    b. Excluding the last day of a time-frame if it is a Saturday, Sunday, or legal holiday; and
    c. If the last day of a time-frame is excluded under subsection (12)(b), including the next day that is not a Saturday, Sunday, or legal holiday.

~~3.~~ 13. "Family unit" means:
    a. ~~A group of~~ Two or more individuals ~~residing together~~ related by birth, marriage, or adoption who ~~are related by birth, marriage, or adoption~~ live at the same residence; or
    b. ~~An~~ One individual who does not ~~reside~~ live at the same residence with ~~any individual to whom the individual is~~ anyone related by birth, marriage, or adoption.
14. "First health care contact" means the initial telephone call or visit to a health care provider as defined in 45 CFR 160.103 for an individual's health issue.

~~4.~~ 15. "Full-time" means providing primary care services for at least 40 hours ~~during the 7-day period~~ between a Sunday at 12:00 ~~a.m.~~ midnight and the next ~~Saturday at 11:59 p.m.~~ Sunday at 12:00 midnight.

16. "Health organization" means:
    a. A person or entity that provides medical services;
    b. A third party payor defined in A.R.S. § 36-125.07(C); or
    c. A trade or professional association described in 501(c)(3), (4), (5), or (6) of the Internal Revenue Code, 26 U.S.C. 501(c), that is exempt from federal income taxes.

~~5. "Hospital" has the same meaning as in A.R.S. § 36-2351.~~
~~6. "HPSA" means health professional shortage area.~~

17. "Indian reservation" has the same meaning as in A.R.S. § 11-801.
18. "Legal holiday" means a state service holiday listed in A.A.C. R2-5-402.
19. "Local planning personnel" means individuals who develop programs related to the delivery of and access to medical services for places or areas:
    a. Under the jurisdiction of an Arizona city or county, or
    b. In an Arizona Indian reservation or less than 50 miles outside the boundaries of an Indian reservation.

~~7.~~ 20. "Low-weight birth" means the live birth of an infant weighing less than 2500 grams or 5 pounds, 8 ounces.
21. "Medical services" has the same meaning as in A.R.S. § 36-401.

~~8.~~ 22. "Mobility limitation" means ~~a~~ an individual's physical or mental condition that:
    a. Has lasted for ~~6 or more~~ at least six months,

b. ~~Makes it difficult~~ Impairs the individual's ability to go outside the ~~home~~ individual's residence alone, and
c. Is not a temporary health problem such as a broken bone that is expected to heal normally.

23. "Motor vehicle" has the same meaning as in A.R.S. § 28-101.
~~9. "Office of Vital Records" means the office of the Department that prepares, publishes, and disseminates vital records.~~
24. "Nonresidential" means not primarily used for living and sleeping.
25. "Person" has the same meaning as in A.R.S. § 41-1001.
26. "Physician assistant" has the same meaning as in A.R.S. § 32-2501.
27. "Political subdivision" means a county, city, town, district, association, or authority created by state law.
~~10.~~ 28. "Population" means the ~~total of permanent residents~~ number of residents of a place or an area, according to:
a. ~~the~~ The most recent decennial census ~~published~~ prepared by the ~~United States~~ U.S. Census Bureau and available at http://www.census.gov; or
b. ~~according to the~~ The most recent Population Estimates for Arizona's Counties ~~and~~, Incorporated Places and Balance of County ~~published~~ prepared by the ~~Arizona~~ Department of Economic Security and available at http://www.workforce.az.gov/?PAGED=67&SUBID=137.

~~11.~~ 29. "Poverty ~~level~~ threshold" means ~~the annual income for a family unit of a particular size in the poverty guidelines updated annually in the Federal Register by the United States Department of Health and Human Services~~ calendar year income relative to family unit size that:
a. Determines an individual's poverty status,
b. Is defined annually by the U.S. Census Bureau, and
c. Is available for the most recently completed calendar year at http://www.census.gov/hhes/poverty/threshld.html.

30. "Primary care area" means a geographic region determined by the Department under R9-24-204.
31. "Primary care HPSA" means primary care health professional shortage area designated by the U.S. Department of Health and Human Services under 42 U.S.C. 254e, 42 CFR 5.1 through 5.4, and 42 CFR Part 5, Appendix A.
~~12.~~ 32. "Primary care index" means the document in which the Department designates primary care areas as medically underserved ~~by using the methodology described in A.A.C.~~ according to R9-24-203 and Table 1.
~~13.~~ 33. "Primary care provider" means a physician, physician assistant, or registered nurse practitioner ~~providing direct patient care~~ who:
a. Except for emergencies, is an individual's first health care contact; and
b. Provides primary care services in general or family practice, general internal medicine, pediatrics, or obstetrics and gynecology.

~~14.~~ 34. "Primary care services" means health care provided by a primary care provider~~.~~, including:
a. Illness and injury prevention,
b. Health promotion and education,
c. Identification of individuals at special risk for illness,
d. Early detection of illness,
e. Treatment of illness and injury, and
f. Referral to specialists.

35. "Primary care services utilization pattern" means a distribution of the use of primary care services resulting from the factors listed in R9-24-204(A)(3)(a).
36. "Registered nurse practitioner" has the same meaning as in A.R.S. § 32-1601.
37. "Residence" means a structure or part of a structure where an individual lives and sleeps.
38. "Resident" means an individual who lives and sleeps in a place or an area more than one-half of the time.
39. "Residential" means primarily used for living and sleeping.
~~15.~~ 40. "Self-care limitation" means ~~a~~ an individual's physical or mental condition that:
a. Has lasted for ~~6 or more~~ at least six months;
b. ~~Makes it difficult to take care of personal needs~~ Impairs the individual's ability to perform activities such as dressing, bathing, or moving around inside the ~~home~~ individual's residence; and
c. Is not a temporary health problem such as a broken bone that is expected to heal normally.

41. "Specialist" means an individual who:
a. Is regulated under:
i. A.R.S. Title 32, Chapters 7, 8, 11, 13, 14, 15, 15.1, 16, 17, 18, 19, 19.1, 25, 28, 29, 33, 34, 35, 39, or 41;
ii. A.R.S. Title 36, Chapter 6, Article 7; or
iii. A.R.S. Title 36, Chapter 17; and
b. Meets the education, knowledge, and skill requirements generally recognized in the profession related to a specific service or procedure, patient category, body part or system, or type of disease.

42. "Street route" means a course of travel by road.
43. "Temporary" means lasting for a limited time.
44. "Topography" means the surface configuration of a place or region, including elevations and positions of the physical features.

45. "Travel pattern" means a prevalent flow of motor vehicles resulting from:
    a. The configuration of streets, and
    b. The location of residential and nonresidential areas.
46. "Value" means a number within a value range.
47. "Value range" means, for a criterion listed in R9-24-203(B) and Table 1, a measurement:
    a. Consisting of a scale between upper and lower limits, except for the supplementary criteria score under R9-24-203(B)(12); and
    b. To which Table 1 assigns points or 0 points.

~~16. "Vital records" has the same meaning as in A.R.S. § 36-301.~~

~~17.~~ 48. "Work disability" means ~~a~~ an individual's physical or mental condition that:
    a. Has lasted for ~~6 or more~~ at least six months,
    b. Limits ~~an~~ the individual's choice of jobs or ~~makes an~~ prevents the individual ~~unable to work for 35 or more~~ from working for more than 34 hours per week, and
    c. Is not a temporary health problem such as a broken bone that is expected to heal normally.

R9-24-202. Arizona Medically Underserved Area Designation

The Department shall designate as Arizona medically underserved areas:

1. ~~those~~ The primary care areas or parts of primary care areas designated as ~~HPSAs~~ primary care HPSAs by the ~~Secretary of the United States~~ U.S. Department of Health and Human Services, and
2. ~~those~~ The primary care areas ~~identified~~ designated as medically underserved by the ~~primary care index described in A.A.C.~~ the Department under R9-24-203 and Table 1.

R9-24-203. Primary Care Index

A. ~~Using the criteria in subsection (B), the~~ Every 12 months, the Department shall ~~generate~~ prepare, according to this Section, a primary care index ~~to designate~~ for designating primary care areas determined under R9-24-204 as Arizona medically underserved areas.

1. ~~The~~ For each primary care area determined under R9-24-204, the Department shall calculate the value for each criterion ~~as described~~ in subsection (B).
    a. After calculating the value for each criterion in subsection (B), the Department shall ~~determine the points to be assigned~~ assign points to each value ~~using~~ according to Table 1.
    b. ~~The total score for each~~ A primary care ~~area~~ area's score is the sum of~~:~~
        ~~i.~~ ~~The~~ the points ~~that the primary care area~~ received by the primary care area for each criterion ~~under subsections (B)(1) through (B)(11),~~ in subsection (B).
        ~~ii. The supplementary criteria score under subsection (B)(12), and~~
        ~~iii. The sole provider or no provider score under subsection (B)(13).~~
2. The Department shall designate as Arizona medically underserved ~~areas those~~:
    a. The primary care areas that, according to subsection (B) and Table 1, score within the top ~~25%~~ 25 percent on the primary care index or that ~~have point totals greater than or equal to 55~~ obtain more than 55 points, whichever results in the designation of more Arizona medically underserved areas~~.~~; and
    b. The primary care areas or parts of primary care areas with the designation described in R9-24-202(1).

B. ~~The~~ For each primary care area determined by the Department under R9-24-204, the primary care index shall include a score for each of the following ~~criteria for each primary care area~~:

1. Population-to-primary-care-provider ratio, determined by dividing the population of the primary care area by the number of primary care providers in the primary care area~~,~~:
    a. ~~using~~ Using primary care provider data from the ~~Board of~~ Arizona Medical ~~Examiners~~ Board, the Board of Osteopathic Examiners in Medicine and Surgery, the Arizona State Board of Nursing, and the ~~Joint~~ Arizona Regulatory Board ~~on the Regulation~~ of Physician Assistants~~,~~; ~~and~~
    b. ~~counting 1~~ Counting a full-time physician as 1.0 ~~and 1~~, a full-time physician assistant ~~or~~ as 0.8, and a full-time registered nurse practitioner as ~~.8~~ 0.8; and
    c. If the Department determines that a physician, physician assistant, or registered nurse practitioner practices less than full-time in the primary care area, lowering the number obtained under subsection (B)(1)(b) as follows:
        i. Creating a fraction with a numerator that represents the number of hours per week the physician, physician assistant, or registered nurse practitioner practices in the primary care area and with a denominator of 40;
        ii. Multiplying 1.0 or 0.8, whichever is appropriate, by the fraction obtained under subsection (B)(1)(c)(i);
        iii. Subtracting the result obtained under subsection (B)(1)(c)(ii) from 1.0 or 0.8, whichever is appropriate; and
        iv. Subtracting the result obtained under subsection (B)(1)(c)(iii) from the number obtained under subsection (B)(1)(b);
2. Travel distance to the nearest primary care provider, determined by:
    a. ~~estimating~~ Estimating the distance in miles:
        i. ~~from~~ From the center of the most densely populated area in the primary care area determined from the most

recent Population Estimates for Arizona's Counties, Incorporated Places and Balance of County identified in R9-24-201(28)(b) or, for the year in which the most recent decennial census is published, from the most recent decennial census prepared by the U.S. Census Bureau; and

ii. ~~to~~ To the nearest primary care provider determined from the data described in subsection (B)(1)(a); and

b. ~~by~~ Using the most direct street route;

3. Composite transportation score, determined by:
   a. Compiling data on the following ~~6~~ six indicators ~~using~~ from the most recent decennial census ~~published~~ prepared by the ~~United States~~ U.S. Census Bureau:
      i. Percentage of population with ~~annual~~ calendar year income less than ~~100%~~ 100 percent of the poverty ~~level~~ threshold;
      ii. Percentage of population older than age 65 ~~years of age~~;
      iii. Percentage of population younger than age 14 ~~years of age~~;
      iv. Percentage of population ~~that has~~ with a work disability, mobility limitation, or self-care limitation;
      v. Percentage of population without a motor vehicle; and
      vi. The ~~noncommercial vehicle-to-population~~ motor-vehicle-to-population ratio;
   b. Calculating the statewide average value for each of the ~~6~~ six indicators in subsection (B)(3)(a);
   c. Dividing the value of each indicator for each primary care area by the statewide average value for that indicator;
   d. Multiplying the figure calculated under subsection (B)(3)(c) for each indicator by 100; and
   e. Averaging the ~~6~~ six indicator values obtained under subsection (B)(3)(d) for each primary care area;
4. Percentage of population with ~~annual~~ calendar year income less than 200% of the poverty ~~level, as reported in~~ threshold, determined from data in the most recent decennial census ~~published~~ prepared by the ~~United States~~ U.S. Census Bureau;
5. Percentage of population with annual income between 100% and 200% of the poverty ~~level, as reported in~~ threshold, determined from data in the most recent decennial census ~~published~~ prepared by the ~~United States~~ U.S. Census Bureau;
6. Percentage of uninsured births, determined from ~~Office of Vital Records~~ Department birth records reporting payment source as "self-pay" or "unknown;"
7. Ambulatory care sensitive condition hospital admissions~~,~~:
   a. ~~based~~ Based on the number of hospital admissions for ambulatory care sensitive conditions per 1000 ~~resident~~ individuals living in the primary care area ~~aged~~ who are under age 65 ~~years or younger~~, and
   b. ~~determined~~ Determined from ~~hospital discharge record~~ hospital inpatient and emergency department services data provided by the ~~Bureau of Public Health Statistics~~ Department;
8. Percentage of low-weight births, determined from data provided by the ~~Office of Vital Records~~ Department;
9. ~~Sum~~ From data provided by the Department, the sum of the ~~following, determined from data provided by the Office of Vital Records~~ percentage of births for which the mothers reported:
   a. ~~Percentage of births for which the mothers reported having no~~ No prenatal care,
   b. ~~Percentage of births for which the mothers reported commencing prenatal~~ Prenatal care that began in the ~~2nd~~ second or ~~3rd~~ third trimester, and
   c. ~~Percentage of births for which the mothers reported having 4~~ Four or fewer prenatal care visits;
10. Percentage of deaths at ages younger than the birth life expectancy, determined from the ~~birth life expectancy~~ most recent U.S. life expectancy data and data provided by the ~~Office of Vital Records~~ Department;
11. Number of infant ~~mortalities~~ deaths per 1000 live births, determined from data provided by the ~~Office of Vital Records~~ Department;
12. Supplementary criteria score, ~~determined by assigning 2 points for each~~ based on the presence or absence in a primary care area of the following ~~indicators that exists in the primary care area~~:
   a. Percentage of minority population greater than the statewide average for all counties, determined from data in the most recent Population Estimates for Arizona's Counties, Incorporated Places and Balance of County identified in R9-24-201(28)(b) and from data in the most recent decennial census ~~published by the United States Census Bureau~~;
   b. Percentage of elderly population greater than the statewide average for all counties, determined from data in the most recent Population Estimates for Arizona's Counties~~, and~~ Incorporated Places and Balance of County ~~published by the Arizona Department of Economic Security~~ identified in R9-24-201(28)(b) and from data in the most recent decennial census ~~published~~ prepared by the ~~United States~~ U.S. Census Bureau; and
   c. Average annual unemployment rate greater than the average annual statewide rate, ~~determined~~ from data in the most recent ~~annual report issued~~ Arizona Unemployment Statistics Program Special Unemployment Report, prepared by the Arizona Department of Economic Security; Research Administration, in cooperation with the U.S. Department of Labor, Bureau of Labor Statistics, and available at http://www.workforce.az.gov; and
13. Sole provider or no provider score~~,~~:
   a. ~~determined by assigning 5 points if the~~ Based on whether a primary care area has only 1.0 or less than 1.0 pri-

mary care provider.;

b. ~~counting 1~~ Counting a full-time physician as 1.0 ~~and 1~~, a full-time physician assistant ~~or~~ as 0.8, and a full-time registered ~~nurses .8~~ nurse practitioner as 0.8.; and

c. If the Department determines that a physician, physician assistant, or registered nurse practitioner practices less than full-time in the primary care area, lowering the number obtained under subsection (B)(13)(b) as follows:

i. Creating a fraction with a numerator that represents the number of hours per week the physician, physician assistant, or registered nurse practitioner practices in the primary care area and with a denominator of 40;

ii. Multiplying 1.0 or 0.8, whichever is appropriate, by the fraction obtained under subsection (B)(13)(c)(i);

iii. Subtracting the result obtained under subsection (B)(13)(c)(ii) from 1.0 or 0.8, whichever is appropriate; and

iv. Subtracting the result obtained under subsection (B)(13)(c)(iii) from the number obtained under subsection (B)(13)(b).

C. ~~The Department shall generate a primary care index every 12 months to determine Arizona medically underserved area designations. The~~ Every 12 months, according to subsections (A) and (B) and Table 1, the Department shall:

1. ~~withdraw~~ Withdraw an Arizona medically underserved area designation,
2. ~~continue~~ Continue an Arizona medically underserved area designation, or
3. ~~designate~~ Designate a new Arizona medically underserved area ~~based on the criteria in subsections (A) and (B).~~

D. ~~The Department shall publish and keep on file a~~ A list of current Arizona medically underserved areas is available in the Department's annual Arizona Medically Underserved Areas (AzMUA) Report at http://www.azdhs.gov/hsd/.

Table 1. Primary Care Index Scoring

CRITERIA	VALUE RANGE	POINTS
Population-to-primary-care-provider ratio	≤ 2000:1 2001:1 to 2500:1 2501:1 to 3000:1 3001:1 to 3500:1 3501:1 to 4000:1 > 4000:1 or no provider	0 2 4 6 8 10
Travel distance to nearest primary care provider	≤ 15.0 miles 15.1-25.0 miles 25.1-35.0 miles 35.1-45.0 miles 45.1-55.0 miles > 55.0 miles	0 2 4 6 8 10
Composite transportation score	~~50th~~ 51st highest score and below 41st-50th highest scores 31st-40th highest scores 21st-30th highest scores 11th-20th highest scores 10 highest scores	0 2 4 6 8 10
Percentage of population with annual income less than 200% of poverty ~~level~~ threshold	≤ 15.0% 15.1-25.0% 25.1-35.0% 35.1-45.0% 45.1-55.0% > 55.0%	0 2 4 6 8 10
Percentage of population with annual income between 100% and 200% of poverty ~~level~~ threshold	≤ 10.0% 10.1-15.0% 15.1-20.0% 20.1-25.0% 25.1-30.0% > 30.0%	0 2 4 6 8 10

Percentage of uninsured births	≤ 6.0% 6.1-10.0% 10.1-14.0% 14.1-18.0% 18.1-22.0% > 22.0%	0 2 4 6 8 10
Ambulatory care sensitive condition hospital admissions	≤ 8.0 8.1-12.0 12.1-16.0 16.1-20.0 20.1-24.0 > 24.0	0 2 4 6 8 10
Percentage of low-weight births	≤ 6.0% 6.1-8.0% 8.1-10.0% 10.1-12.0% 12.1-14.0% > 14.0%	0 2 4 6 8 10
Sum of the ~~following~~ percentage of births with: a. ~~Percentage of births with no~~ No prenatal care, b. ~~Percentage of births with prenatal~~ Prenatal care begun in ~~2nd~~ second or ~~3rd~~ third trimester, and c. ~~Percentage of births with prenatal~~ Prenatal care visits ≤ 4	≤ 15.0% 15.1-25.0% 25.1-35.0% 35.1-45.0% 45.1-55.0% > 55.0%	0 2 4 6 8 10
Percentage of deaths at ages younger than birth life expectancy	≤ 40.0% 40.1-50.0% 50.1-60.0% 60.1-70.0% 70.1-80.0% > 80.0%	0 2 4 6 8 10
Number of infant ~~mortalities~~ deaths per 1000 live births	≤ 4.0 4.1-6.0 6.1-8.0 8.1-10.0 10.1-12.0 > 12.0	0 2 4 6 8 10
Supplementary criteria score	1 Criterion 2 Criteria 3 Criteria	2 4 6
Sole provider or no provider score	~~primary~~ Primary care provider ≤ 1.0 ~~primary~~ Primary care ~~provider~~ providers > 1.0	5 0
Key to Symbols ≤ represents "less than or equal to" > represents "more than"		

R9-24-204. Primary Care Area ~~Designation~~ Boundaries Determination

A. The Department shall ~~designate~~ determine the boundaries of primary care areas ~~within the~~ for the entire state. A primary care area's boundaries shall ~~that~~ meet the following ~~criteria~~ requirements:

1. ~~Each primary care~~ The geographic area within the boundaries ~~is not smaller than the smallest unit of census geography used on~~ corresponds to or is larger than a census block identified for the geographic area in the most recent

decennial census ~~published by the United States Census Bureau~~; ~~and~~

2. The boundaries ~~of each primary care area~~ are consistent with the population's primary care services utilization patterns ~~of its population for primary care services, determined by considering:~~; and
3. The primary care utilization patterns are determined by considering:
   a. The geographic area's:
      ~~a.~~ i. Topography~~;~~,
      ~~b.~~ ii. Social~~,~~ and cultural relationships of the people living within the geographic area,
      iii. ~~and geopolitical~~ Political subdivision boundaries~~;~~, and
      ~~c.~~ iv. Travel patterns ~~for the geographic area~~; and
   ~~d.~~ b. Data about the type, amount, and location of primary care services used by the geographic area's population, obtained from local planning personnel, government officials, health organizations, primary care providers, and residents of the geographic area ~~about the type, amount, and location of primary care services used by the population~~.

B. ~~The~~ In addition to the requirements for primary care area boundaries in subsection (A), the Department shall consider ~~the following additional factors in determining the boundaries of each primary care area~~:

1. ~~Boundaries of~~ Indian ~~reservations~~ reservation boundaries, and
2. ~~Boundaries of HPSAs~~ Primary care HPSA boundaries.

C. Without receiving a primary care area boundary change request under subsection (D), the Department may redetermine the boundaries of one or more primary care areas according to the requirements and considerations in subsections (A) and (B).

~~**C.**~~ **D.** ~~Local~~ A primary care area's local planning personnel, government officials, health organizations, primary care providers, or residents ~~of a primary care area~~ may submit to the Department a ~~request to change the boundaries of a~~ primary care area boundary change request.

1. ~~The request~~ A person requesting a boundary change shall:
   a. ~~be made~~ Make the request in writing ~~and~~,
   b. ~~shall include~~ Include documentation ~~to support~~ supporting the boundary change~~.~~, and
   c. ~~The request shall be submitted~~ Submit the request by October 1 to be considered for inclusion in the next calendar year's Arizona medically underserved area designation process ~~for the following calendar year~~.
2. The ~~time-frames for the request for change of boundaries are in A.A.C. R9-24-102.~~ Department shall review a primary care area boundary change request according to the time-frames in R9-24-205.

R9-24-205. ~~Repealed~~ Time-frames

A. The overall time-frame described in A.R.S. § 41-1072 for a primary care area boundary change request under R9-24-204(C) is 90 days.

1. A person requesting a boundary change and the Department may agree in writing to extend the substantive review time-frame and the overall time-frame.
2. An extension of the substantive review time-frame and the overall time-frame may not exceed 25 percent of the overall time-frame.

B. The administrative completeness review time-frame described in A.R.S. § 41-1072 for a primary care area boundary change request under R9-24-204(C) is 30 days and begins on the date the Department receives a boundary change request.

1. Within the administrative completeness review time-frame, the Department shall mail a notice of administrative completeness or a notice of deficiencies to the person requesting a boundary change.
   a. A notice of deficiencies shall list each deficiency and the information or documents needed to complete the boundary change request.
   b. A notice of deficiencies suspends the administrative completeness review time-frame and the overall time-frame from the date the Department mails the notice until the date the Department receives the missing information or documents.
   c. If the person requesting a boundary change does not submit to the Department all the information and documents listed in the notice of deficiencies within 60 days after the date the Department mails the notice of deficiencies, the Department considers the boundary change request withdrawn.
2. If the Department approves a boundary change request during the administrative completeness review time-frame, the Department does not issue a separate written notice of administrative completeness.

C. The substantive review time-frame described in A.R.S. § 41-1072 for a primary care area boundary change request under R9-24-204(C) is 60 days and begins on the date the Department mails the notice of administrative completeness.

1. Within the substantive review time-frame, the Department shall mail written notification of approval or denial of the boundary change request to the person requesting a boundary change.
2. During the substantive review time-frame:
   a. The Department may make one comprehensive written request for additional information; and

b. If the Department and the person requesting a boundary change agree in writing to allow one or more supplemental requests for information, the Department may make the number of supplemental requests for information agreed to.

3. A comprehensive written request for additional information or a supplemental request for information suspends the substantive review time-frame and the overall time-frame from the date the Department mails the request until the date the Department receives all the information and documents requested.

4. If the person requesting a boundary change does not submit to the Department all the information and documents listed in a comprehensive written request for additional information or a supplemental request for information within 60 days after the date the Department mails the request, the Department shall deny the boundary change request.

D. The Department shall approve a primary care area boundary change request under R9-24-204(C) unless:

1. The requested boundaries do not meet the requirements in R9-24-204(A),
2. The considerations required in R9-24-204(B) support the current boundaries and outweigh the information and documents submitted with the boundary change request, or
3. The person requesting the boundary change does not submit information and documents as stated in subsection (B)(1)(c) or subsection (C)(4).

ARTICLE 3. COORDINATING MEDICAL PROVIDERS

R9-24-301. Definitions

In addition to the definitions in A.R.S. § 36-2351 and 9 A.A.C. 24, Article 2, the following definitions apply in this Article, unless otherwise specified:

1. "CMP" means coordinating medical provider~~, as defined in A.R.S. § 36-2351~~.
2. "Continuing medical education" means instruction that meets the requirements in:
   a. A.A.C. R4-16-102 for a physician licensed under A.R.S. Title 32, Chapter 13;
   b. A.A.C. R4-17-205 for a physician assistant licensed under A.R.S. Title 32, Chapter 25; and
   c. A.R.S. § 32-1825 and A.A.C. R4-22-109 for a physician licensed under A.R.S. Title 32, Chapter 17.
3. "Continuing nursing education" means instruction that:
   a. Is required by A.A.C. R4-19-511 for authorization from the Arizona State Board of Nursing for a registered nurse practitioner to prescribe and dispense drugs and devices;
   b. Meets requirements for continuing education established by a nurse credentialing organization, such as the American Nurses Credentialing Center; or
   c. Provides training related to the performance of a nurse's job duties.
4. "Drug prescription services" means providing medication that requires an order by medical personnel authorized by law to order the medication.
5. "Durable medical equipment" means an item that:
   a. Can withstand repeated use;
   b. Is designed to serve a medical purpose; and
   c. Generally is not useful to an individual in the absence of a medical condition, illness, or injury.
6. "Governing authority" has the same meaning as in A.R.S. § 36-401.
7. "Independent decision" means a registered nurse practitioner's action without a physician's order according to A.A.C. R4-19-508 and A.A.C. R4-19-511.
~~2. "Medical clinic" has the same meaning as in A.R.S. § 36-2351.~~
8. "Medical direction" means guidance, advice, or consultation provided by a CMP to a registered nurse practitioner.
~~3.~~ 9. "Medical personnel" means a medical clinic's physicians, physician assistants, registered nurse practitioners, and nurses ~~of a medical clinic~~.
~~4.~~ 10. "Nurse" means an individual licensed as a graduate, professional, or registered nurse or as a practical nurse under A.R.S. Title 32, Chapter 15.
11. "Order" means a written directive.
12. "Practice requirements" means the standards for physicians established in:
   a. A.R.S. Title 32, Chapter 13 and 4 A.A.C. 16; or
   b. A.R.S. Title 32, Chapter 17 and 4 A.A.C. 22.
13. "Referral source" means a person who sends an individual to a third person for medical services.
14. "Social services" means assistance, other than medical services, provided to maintain or improve an individual's physical, mental, and social participation capabilities.
15. "Supervision" has the same meaning as in A.R.S. § 32-2501.
~~5.~~ 16. "Support services" means drug prescription services, social services, and provision of durable medical equipment.
17. "Work schedule coverage" means a medical clinic's system for ensuring that a sufficient number of medical personnel are present at the medical clinic.

18. "Written protocol" means an agreement that identifies and is signed by a CMP and a registered nurse practitioner or a physician assistant.

R9-24-302. CMP Functions

A. A CMP shall:

1. ~~Be involved~~ Participate in planning for the delivery of medical services and support services within the Arizona medically underserved area that includes ways to increase access to medical services and support services for the Arizona medically underserved area's residents;
2. ~~Ensure access to medical and support services, either directly or by referral, for the residents of the Arizona medically underserved area;~~
3. 2. Develop written protocols that:
   a. ~~identify areas in which~~ Describe the manner and frequency that a registered nurse ~~practitioners and~~ practitioner or a physician ~~assistants under the CMP's supervision may use independent judgment~~ assistant at a medical clinic will communicate with the CMP, in addition to the face-to-face meeting required in subsection (A)(5);
   b. Specify the criteria used by a registered nurse practitioner at the medical clinic in making an independent decision to refer an individual to a physician; and
   c. Specify procedures to be followed by a physician assistant at the medical clinic when the CMP's supervision of the physician assistant is by a means other than physical presence;
4. 3. ~~Have final approval in~~ Approve or disapprove the selection of registered nurse practitioners and physician assistants ~~working under the CMP's supervision~~ who will work at the medical clinic;
5. 4. ~~Have authority over and responsibility for the~~ Provide:
   a. ~~medical~~ Medical direction ~~of all~~ to the registered nurse practitioners ~~and physician assistants under the CMP's supervision;~~ at the medical clinic, and
   b. Supervision to the physician assistants at the medical clinic;
6. 5. ~~Evaluate~~ At least weekly, conduct a face-to face meeting with each registered nurse practitioner and each physician assistant at the medical clinic to evaluate the medical ~~care~~ services provided by the registered nurse ~~practitioners and~~ practitioner or physician ~~assistants~~ assistant ~~under the CMP's supervision through face-to-face contact at least once per week~~;
7. 6. For continuing medical education or continuing nursing education of a medical clinic's medical personnel:
   a. Recommend specific areas of ~~medical education~~ instruction, including instruction in referral sources~~,~~; and
   b. Develop a written plan for work schedule coverage to ~~allow for the~~ accommodate continuing medical education ~~of medical personnel at the medical clinic~~ or continuing nursing education; and
8. 7. ~~Meet at~~ At least annually, meet with the ~~organization that owns and operates the~~ medical ~~clinic~~ clinic's governing authority to evaluate the medical clinic's program and the medical care provided by the medical clinic's medical personnel ~~of the medical clinic~~.

B. ~~These~~ The requirements in subsection (A) do not replace ~~other requirements of practice~~ the practice requirements applicable to a CMP.

NOTICE OF FINAL RULEMAKING

TITLE 18. ENVIRONMENTAL QUALITY

CHAPTER 8. DEPARTMENT OF ENVIRONMENTAL QUALITY HAZARDOUS WASTE MANAGEMENT

[R06-294]

PREAMBLE

1. Sections Affected	Rulemaking Action
R18-8-260	Amend
R18-8-261	Amend
R18-8-262	Amend
R18-8-263	Amend
R18-8-264	Amend
R18-8-265	Amend
R18-8-266	Amend
R18-8-268	Amend
R18-8-270	Amend

R18-8-271	Amend
R18-8-273	Amend

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. §§ 41-1003 and 49-104

Implementing Statute: A.R.S. § 49-922

3. The effective date of the rules:

October 1, 2006

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

Notice of Rulemaking Docket Opening: 11 A.A.R. 4987, November 25, 2005

Notice of Proposed Rulemaking: 12 A.A.R. 1452, May 5, 2006

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

Name: Mark Lewandowski

Address: Arizona Department of Environmental Quality
Waste Programs Division
1110 W. Washington St.
Phoenix, AZ 85007

Telephone: (602) 771-2230, or (800) 234-5677, enter 771-2230 (Arizona only)

Fax: (602) 771-4138

TTD: (602) 771-4829

E-mail: lewandowski.mark@azdeq.gov

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

Summary The Arizona Department of Environmental Quality (DEQ) has revised the state's hazardous waste rules to incorporate changes in federal regulations implementing Subtitle C of the Resource Conservation and Recovery Act (RCRA), as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA). The amendments in this rule adopt changes to the federal regulations that became effective between July 1, 2004, and September 6, 2005. In addition, the rule will allow members of DEQ's newly established Performance Track Program to submit manifests to DEQ at less frequent intervals than other generators.

This rulemaking will help fulfill the United States Environmental Protection Agency's (EPA's) authorization requirements in 40 CFR 271 which provides that states implementing the federal hazardous waste management program must incorporate certain amendments promulgated in the federal regulations through adoption of those changes into the state's rules. A.R.S. § 49-922 requires DEQ to establish a hazardous waste management program that is equivalent to and consistent with federal hazardous waste regulations. This rulemaking helps implement A.R.S. § 49-922.

Arizona's hazardous waste rules, currently found in 18 A.A.C. 8, Article 2, have been effective since 1984. Due to the statutory requirement for equivalency, Arizona's rules incorporate the federal regulations by reference, with the result that Arizona's hazardous waste rules are largely identical to the federal hazardous waste management regulations. In 1985, EPA first authorized Arizona to operate its hazardous waste program, in lieu of the federal hazardous waste program in Arizona, subject to the limitations imposed by the Hazardous and Solid Waste Amendments of 1984 (Fed Reg, Nov. 20, 1985). EPA last approved revisions to Arizona's hazardous waste authorization on March 17, 2004. (Fed Reg, March. 17, 2004) The Arizona regulations are reviewed and amended regularly to incorporate new text from the applicable federal regulations and to comply with A.R.S. § 49-922 and to facilitate continued authorization. Without continued authorization, the EPA, rather than DEQ, would administer parts of the hazardous waste program in Arizona. DEQ seeks to continue administering Arizona's hazardous waste program, and therefore is adopting changes to the state rules that reflect the recent amendments to federal RCRA regulations.

In this final rule, different incorporation dates are used in different Sections, in order to incorporate four EPA regulations that became effective after June 30, 2005. The amendments automatically adopt all changes to the cited federal regulations that became effective from July 1, 2004, to June 30, 2005. DEQ has also incorporated four EPA regulations that became effective between July 1, 2005 and September 6, 2005. Because of these four EPA rules, various Sections in this rule package contain incorporation dates later than July 1, 2005. (July 14, August 5, August 23, and September 6, 2005)

All Sections now incorporated to at least July 1, 2005

In recent hazardous waste rulemakings, ADEQ did not change incorporation dates in Sections if EPA did not amend any regulations during the previous one or two year period. With this rulemaking, ADEQ has changed this practice, so that all Sections in Article 2 that use incorporation by reference are incorporated as of July 1, 2005, even if no changes were made to those parts by EPA. This is for practical reasons. ADEQ believes that this will allow CFR editions revised as of July 1, 2005 to be used as starting point text for all Sections, and result in the fewest number of

CFR volumes that have to be kept by regulated entities. For 2005, 40 CFR Parts 260-265 and Parts 266-299 continue to be in separate July 1, 2005 volumes, while 40 CFR Parts 100-135 are in a third July 1, 2005 volume. (40 CFR Part 124 is incorporated in R18-8-271.)

What EPA regulations are being incorporated?

In this rule, DEQ incorporates four federal rules that became effective at various times after July 1, 2005. The four rules are:

1. Methods Innovation (SW-846 testing rule) (70 FR 34538, June 14, 2005, effective July 14, 2005)
2. Mercury Containing Equipment (70 FR 45508, August 5, 2005, effective August 5, 2005)
3. Dye and Pigment Production Wastes Listing (70 FR 9138, February 24, 2005; correction 70 FR 35032, June 16, 2005; both effective August 23, 2005)
4. Hazardous Waste Manifests (70 FR 10776, March 4, 2005; correction 70 FR 35034, June 16, 2005; both effective September 6, 2005)

A fifth federal rule, creating standardized hazardous waste permits, was published September 8, 2005, but is not included for incorporation at this time for reasons discussed below. A sixth rule relating to hazardous waste combustors was published in the October 12, 2005 Federal Register, and will be covered, as appropriate, in the ADEQ's next hazardous waste rulemaking which should begin in late 2006.

Methods Innovation (SW-846 testing rule) In this rule, effective July 14, 2005, EPA amended a variety of testing and monitoring requirements in the RCRA hazardous and nonhazardous solid waste regulations, along with certain Clean Air Act (CAA) regulations that relate to hazardous waste combustors. The amendments allow more flexibility when conducting RCRA-related sampling and analysis by removing from the regulations a requirement to use the methods found in "Test Methods for Evaluating Solid Waste, Physical/Chemical Methods," also known as "SW–846," in conducting various testing and monitoring and by limiting required uses of an SW–846 method to circumstances where the method is the only one capable of measuring the particular property (*i.e.*, the method is used to measure a required method-defined parameter). The action was part of EPA's implementation of a performance-based approach, which is part of their efforts toward Innovating for Better Environmental Results. Additionally, EPA made certain other clarifications and technical amendments. EPA stated that the changes should make it easier and more cost effective to comply with the affected regulations, without compromising human health or environmental protection.

The EPA rule amended 40 CFR parts 63, 258, 260, 261, 264, 265, 266, 268, 270, 271 and 279. In this rule, DEQ has incorporated into state rule all of the amendments, without modification, to 260, 261, 264, 265, 266, 268, and 270.

Although EPA characterized the Methods Innovation rule as "equivalent to or less stringent than the existing provisions in the Federal regulations which they" amend, and as such, "[s]tates would not be required to adopt and seek authorization" for the rule, ADEQ agreed with EPA's conclusion that the rule nevertheless provides "significant benefits to EPA, the states, and the regulated community without compromising human health or environmental protection." EPA further stated that it "strongly encourages authorized states to amend their programs and seek authorization for" the rule. It takes effect in Arizona after it is adopted in Arizona law.

Mercury Containing Equipment In this rule, effective August 5, 2005, EPA added mercury-containing equipment (MCE) to the federal list of universal wastes regulated under the RCRA hazardous waste regulations. Handlers of universal wastes are subject to less stringent standards for storing, transporting, and collecting these wastes. EPA concluded that regulating spent mercury-containing equipment as a universal waste would lead to better management of this equipment and facilitate compliance with hazardous waste requirements.

The EPA rule amended 40 CFR parts 260, 261, 264, 265, 266, 268, 270, and 273. In this rule, ADEQ has incorporated into state rules all of these federal amendments, without modification.

Although EPA characterized the rule as "less stringent than the current Federal program" and as such, "states are not required to adopt" it, EPA "encourage[d] them to do so." EPA justified this position with three examples where mercury-containing equipment could be transported through different states with different regulations governing the waste. The MCE rule takes effect in Arizona after it is adopted in Arizona law. DEQ believes that full compliance with this rule will result in less mercury entering the environment in Arizona, and that the confusion that could result from states with different regulations would detract from that full compliance.

Dye and Pigment Production Waste Listing In this rule, effective August 23, 2005, EPA listed as hazardous nonwastewaters generated from the production of certain dyes, pigments, and FD&C colorants. EPA promulgated the regulation under the RCRA, which directs EPA to determine whether these wastes pose a substantial present or potential hazard to human health or the environment when they are improperly treated, stored, transported, disposed of or otherwise managed. The listing sets annual mass loadings for constituents of concern, such that wastes would not be hazardous if the constituents are below the regulatory thresholds. If the wastes meet or exceed the regulatory levels for any constituents of concern, the wastes must be managed as listed hazardous wastes, unless the wastes are either disposed in a landfill unit that meets certain liner design criteria, or treated in a combustion unit as specified in the listing description. The EPA rule also added five toxic constituents to the list of hazardous constituents that serves as the basis for classifying wastes as hazardous. In addition, the rule established Land Disposal Restrictions (LDR) treatment standards for the wastes, and designated the wastes as hazardous substances subject to the Comprehensive Envi-

ronmental Response, Compensation, and Liability Act (CERCLA). The rule did not adjust the one pound statutory reportable quantity (RQ) for the waste.

The EPA regulation, and the subsequent correction published June 16, 2005, amended 40 CFR parts 148, 261, 268, 271 and 302. In this state rule, ADEQ has incorporated all of EPA's amendments to 261 and 268, including the corrections, without modification.

Because the regulation was promulgated pursuant to EPA's authority under HSWA, it took effect in all states, including Arizona, on August 23, 2005. Although, as an authorized state, Arizona was required to adopt this rule, until Arizona adopted the rule, EPA, and not Arizona, was responsible for implementing it. Under 40 CFR 271.21(e)(2)(ii), Arizona, as an authorized state, was given until July 1, 2007 to adopt this rule.

Hazardous Waste Manifests In this rule, effective September 6, 2005, EPA established new requirements revising the Uniform Hazardous Waste Manifest regulations and the manifest and continuation sheet forms used to track hazardous waste from a generator's site to the site of its disposition. The revisions were made to standardize the content and appearance of the manifest form and continuation sheet (Forms 8700–22 and 22a), make the forms available from a greater number of sources and adopt new procedures for tracking certain types of waste shipments with the manifest. The latter types of shipments include hazardous wastes that destination facilities reject, wastes consisting of residues from non-empty hazardous waste containers, and wastes entering or leaving the United States.

The EPA regulation, and the subsequent correction published June 16, 2005, amended 40 CFR parts 260, 261, 262, 263, 264, 265, and 271. In this rule, ADEQ has incorporated into state rule all of these federal amendments, as corrected by EPA, without modification.

EPA published the final manifest rule with a delayed compliance date, so that after September 5, 2006, only the new manifest form and requirements established under the final rule will be valid and acceptable for use. All shipments of hazardous waste initiated by generators or offerors on or after this date must be accompanied by the revised manifest form. In addition, authorized states were required to adopt the revised Uniform Manifest form and requirements and EPA expected that those states would generally be able to revise their RCRA programs to include the revised manifest within the final rule's transition period. ADEQ has attempted to have this rule become effective as close to September 5, 2006 as possible, to minimize confusion, while emphasizing that the revised form and requirements will apply uniformly in all states on this rule's delayed compliance date, under the authority of the federal hazardous materials laws.

EPA's standardized permit rule (70 FR 53419, September 8, 2005, effective October 11, 2005), is not being incorporated into ADEQ rules at this time. EPA characterized the standardized permit rule to be neither more nor less stringent than the current standards. Therefore, authorized states were not required to modify their programs to adopt regulations consistent with and equivalent to the new rule. ADEQ has not incorporated this EPA rule by reference at this time for the following reasons:

1. Many facilities in Arizona would not eligible for the standardized permit, and none have indicated an interest in the new permit. To be eligible, a facility must:
   a. Generate hazardous waste and then store or non-thermally treat the hazardous waste onsite in containers, tanks, or containment buildings, or
   b. Receive hazardous waste generated from off-site by a generator under the same ownership as the receiving facility, and then store or non-thermally treat the hazardous waste in containers, tanks, or containment buildings.
2. ADEQ had not analyzed the Licensing Time-frames implications of adopting this rule.

Performance Track Program

In this rule at R18-8-262(I)(3), DEQ is allowing less frequent submission of manifests for Performance Track members. The Performance Track requirements of exemplary environmental compliance and implementation of an EMS (Environmental Management System) are beneficial to the environment. DEQ believes that offering this incentive to encourage participation in the program will provide better environmental protection in line with DEQ's overall mission. In exchange for this, DEQ is willing to receive manifests less often from companies with an excellent compliance record. These companies will be able to mail in manifests quarterly along with the generation fees required under R18-8-260(N) which will be less of an administrative burden to the company, but not affect DEQ's ability to ensure environmental protection. The definition for Performance Track Members was placed in R18-8-260 so that it can apply to other Performance Track options.

7. A reference to any study relevant to the rule that the agency reviewed and either relied on in its evaluation of or justification for the rule 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:

Identification of the final rulemaking

This rulemaking incorporates into Arizona hazardous waste rules changes in federal hazardous waste regulations promulgated between July 1, 2004 and June 30, 2005, and for several significant federal rules, changes promulgated later in 2005. It accomplishes this by amending rules codified in Arizona Administrative Code Title 18, Chapter 8, Article 2, with updated incorporation dates.

Background

A significant purpose of this state rulemaking is to continue and update Arizona's authorization to implement federal hazardous waste regulations in lieu of EPA.

State authorization is a federal rulemaking process through which EPA delegates the primary responsibility of implementing the RCRA hazardous waste program to individual states in lieu of EPA. This process ensures national consistency and minimum standards while providing flexibility to states in implementing rules. Currently, 50 states and territories have been granted authority to implement the base, or initial, program. Many also are authorized to implement additional parts of the RCRA program that EPA has since promulgated, such as Corrective Action and the Land Disposal Restrictions. State RCRA programs must always be at least as stringent as the federal requirements, but states can adopt more stringent requirements as well.

ADEQ periodically applies to EPA implement additional parts of the RCRA program so that it may continue to implement and receive EPA funding for the federal hazardous waste program. In the absence of this periodic updating of its authorization, EPA would continue to administer parts of the federal program in Arizona. As part of its authorization process, EPA requires DEQ to adopt rules that incorporate the changes promulgated in the federal regulations. DEQ adopts these rules under the authority in A.R.S. § 49-922, which requires DEQ: to adopt rules to establish a hazardous waste management program equivalent to and consistent with the federal hazardous waste regulations promulgated pursuant to subtitle C of RCRA. EPA first authorized DEQ to administer the federal hazardous waste program in Arizona in 1985. DEQ continues to apply for reauthorization and complies with changes to federal regulations.

This rulemaking incorporates EPA changes promulgated through June 30, 2005, and for several rules, later dates in 2005. DEQ has determined that the benefits of this rulemaking easily exceed the costs. The federal regulations incorporated by reference in this rulemaking are either, necessary for authorization and already effective in Arizona under federal law (the dye and pigment production rule and the manifest rule), or make sense from a regulatory standpoint because they promote flexibility, efficiency, and sound environmental practices (the methods innovation rule, the mercury containing equipment rule, and the performance track addition). Adoption of federal regulations, in general, benefits regulated entities by promoting regulatory consistency and predictability among states, and, for required state program modifications, by allowing hazardous waste regulations to be implemented by ADEQ from Arizona, rather than by EPA from San Francisco.

Limitations of the data

Adequate data was not reasonably available to fully comply with the requirements of A.R.S. § 41-1055(B). DEQ was unable to estimate the number of facilities that would be impacted by some of the changes made in the incorporated federal regulations. Two databases contain information on regulated facilities and entities: the Arizona Unified Repository for Informational Tracking of the Environment (AZURITE) and the Revenue Management System (RMS). These databases were not set up to track certain information, and updates do not always keep pace with all data needs. In this instance, DEQ could not determine the numbers of the following impacted entities:

a. Entities that were also state agencies;
b. Entities that were also subdivisions of the state;
c. Entities that were also small businesses.

Methods used to obtain data

DEQ used the AZURITE and RMS databases whenever possible to find the number of entities affected by the changes. DEQ then filled data gaps by using the knowledge of experienced DEQ staff. Some of the rule changes have no significant economic impact in Arizona. An explanation of why there is no impact is provided for these changes. For other incorporated changes, none of the impacted entities exist in Arizona, and thus, there was no economic impact.

Executive Order 12866 (58 FR 51735, October 4, 1993), requires the EPA to determine whether regulatory actions are significant. Only significant actions are subject to federal Office of Management and Budget review. A "significant regulatory action" is one that may:

(1) Have an annual effect on the national economy of $100 million or more, or adversely and materially affect a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities;
(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
(3) Materially alter the budgetary impact of entitlements, grants, user fees, loan programs, or the rights and obligation of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or through principles set out in Executive Order 12866.

The costs and benefits of implementing federal regulations on a national level are looked at by EPA during the federal rulemaking. These amendments are published in the *Federal Register*, and when the amendments constitute "significant regulatory actions," detailed economic impact information is included in the publication. DEQ staff reviewed the *Federal Register* notices in developing this economic impact statement. The *Federal Register* notices may be viewed online at http://www.gpoaccess.gov/fr/index.html, or by visiting DEQ's offices. Each federal rulemaking references its underlying data. Citations and summaries of the *Federal Register* notices are found in part 6 of this Notice. Further information related to the economic impact is provided below.

1. Methods Innovation rule. This regulation allows entities more flexibility in using a large federal database of analytical methods known as SW-846. As such, it potentially impacts nearly every entity in Arizona involved with hazardous waste. ADEQ was not required to adopt this federal rule, but did so because it determined that the flexibility that it would provide Arizona entities involved with hazardous waste would be a great benefit. ADEQ believes that there are no increased costs associated with this regulation and received no comments on incorporating it by reference.
2. Mercury containing equipment. This regulation moved mercury containing equipment from full regulation as a hazardous waste to a reduced level of regulation as a 'universal waste'. ADEQ believes the regulation impacts a moderate amount of Arizona entities, but because it reduces regulatory requirements, ADEQ did not create a detailed inventory of sources impacted. According to EPA, "Spent mercury-containing equipment is generated by a variety of industries or groups of industries. Electric and gas utilities generate the greatest amount of this waste, but mercury-containing equipment is used to regulate pressure and temperature or to conduct electricity in switches or regulators in many other fields, for example, medicine, farming, and automobile manufacture. Generators of spent mercury-containing equipment, therefore, are from a wide range of sectors, from utilities to manufacturers, commercial establishments, universities, hospitals, and households." (70 FR at 45510) EPA goes on, "Some examples are helpful in understanding what kind of devices fall into today's definition of mercury containing equipment. These devices vary in size and function, but, for the most part, the mercury (1) is a relatively small amount of the complete piece of equipment, (2) is encapsulated in some way in an ampule or other housing, and (3) is used for delicate measuring of temperature or pressure or for completing an electrical circuit. Some of the various types of MCE are manometers, barometers, flow meters, mercury light switches, mercury regulators, pressure relief gauges, water treatment gauges, and gas safety relays." (70 FR at 45512)

EPA promulgated the universal waste rule in 1995 to "establish a streamlined hazardous waste management system for widely generated hazardous wastes as a way to encourage environmentally sound collection and proper management of the wastes within the system. Hazardous waste batteries, certain hazardous waste pesticides, mercury-containing thermostats, and hazardous waste lamps are already included on the federal list of universal wastes." (70 FR at 45509)

ADEQ was not required to adopt this regulation and could have kept mercury containing equipment at full hazardous waste status. However, benefits were identified for a more streamlined status for this material. As stated in item #6 of the preamble, it simplifies requirements for transporters who are crossing state lines. Just as important, EPA has stated that it will reduce the amount of mercury incinerated or going to landfills and ADEQ agrees. One example is that universal waste characterization should make it easier for auto salvage yards and auto shredding facilities to remove, handle, store and arrange for transportation of mercury switches from end-of life vehicles to be sold, shredded or otherwise disposed of.

3. Dye and Pigment Production Waste Listing. ADEQ determined that there will be no direct impact from incorporation of this regulation because it was already effective as federal law in Arizona. The primary impact will be that, once Arizona receives authorization for the incorporated regulation, it will be enforced by ADEQ and not EPA. An economic impact summary for the federal regulation shows that EPA believed it would impact 31 synthetic organic dye facilities nationally. ADEQ is not aware of any of these facilities in Arizona.
4. Hazardous waste manifests. This regulation is required by EPA in every authorized state and will affect every generator, transporter, and disposal facility in Arizona. Although there will be some costs in migrating to a new system, EPA generated two paperwork reduction estimates for the purposes of its rulemaking, and ADEQ believes that the benefits will surpass the migration costs in a relatively short time. Like the dye and pigment production waste listing, ADEQ has determined that there will be no direct impact from incorporation of this rule, because it will be effective as federal law in all states on September 6, 2006. The primary impact will be that, once Arizona receives authorization for the incorporated regulation, it will be enforced by ADEQ and not EPA.
5. Performance track addition. In this final rule, ADEQ reduced the required manifest submittal frequency for members of the newly established Arizona Performance Track program. R18-8-262(I) requires generators to submit to ADEQ every month copies of manifests for hazardous waste shipped. For members of the newly established Arizona performance track program, the requirement is quarterly instead. There are currently three Arizona performance track companies.

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

cable):
Only minor grammatical and technical changes were made to the proposed rule to improve the rule's clarity, conciseness, and understandability.

11. A summary of the comments made regarding the rule and the agency response to them:
No comments were made regarding the rule.

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:

Federal Citation	State Citation
40 CFR 260	R18-8-260(A)
40 CFR 261	R18-8-261(A)
40 CFR 262	R18-8-262(A)
40 CFR 263	R18-8-263(A)
40 CFR 264	R18-8-264(A)
40 CFR 265	R18-8-265(A)
40 CFR 266	R18-8-266(A)
40 CFR 268	R18-8-268(A)
40 CFR 270	R18-8-270(A)
40 CFR 124	R18-8-271(A)
40 CFR 273	R18-8-273

14. Was this rule previously made as an emergency rule?
No.

15. The full text of the rules follows:

TITLE 18. ENVIRONMENTAL QUALITY

CHAPTER 8. DEPARTMENT OF ENVIRONMENTAL QUALITY
HAZARDOUS WASTE MANAGEMENT

ARTICLE 2. HAZARDOUS WASTES

Section

ARTICLE 2. HAZARDOUS WASTES

R18-8-260. Hazardous Waste Management System: General

A. No change

B. No change

C. All of 40 CFR 260 and the accompanying appendix, revised as of ~~July 1, 2002~~ September 6, 2005 (and no future editions), with the exception of 40 CFR 260.1(b)(4) through (6), 260.20(a), 260.21, 260.22, 260.30, 260.31, 260.32, and 260.33, is incorporated by reference, modified by the following subsections, and on file with the Department of Environmental Quality (DEQ). Copies of 40 CFR 260 are available at www.gpoaccess.gov/cfr/index.html.

D. No change
- 1. No change
- 2. No change
  - a. No change
    - i. No change
    - ii. No change
  - b. No change
    - i. No change
    - ii. No change
    - iii. No change
    - iv. No change
  - c. No change
    - i. No change
    - ii. No change
    - iii. No change
  - d. No change
    - i. No change
    - ii. No change
    - iii. No change
  - e. No change
    - i. No change
      - (1) No change
      - (2) No change
    - ii. No change
      - (1) No change
      - (2) No change
    - iii. No change
      - (1) No change
      - (2) No change
      - (3) No change
      - (4) No change
  - f. No change
    - i. No change
    - ii. No change
    - iii. No change
    - iv. No change
    - v. No change

E. No change
- 1. No change
- 2. No change
- 3. No change
- 4. No change
- 5. No change
- 6. No change
- 7. No change
- 8. No change
- 9. No change
- 10. No change
- 11. No change
- 12. No change
  - a. No change

b. No change
c. No change
d. No change
e. No change
f. No change
g. No change
h. No change
i. No change
13. No change
14. No change
15. No change
16. No change
17. No change
18. No change
19. No change
20. No change
21. No change
22. No change
a. No change
b. No change
23. No change
24. No change
25. No change
26. No change
27. No change
28. No change
29. No change
30. No change
31. No change
32. No change

F. No change
1. No change
2. No change
3. No change
a. No change
b. No change
c. No change
4. [“Member of the Performance Track Program” means a facility or generator that has been accepted by EPA for membership in its Performance Track Program (as described at http://www.epa.gov/performancetrack/) and by DEQ for membership in the Arizona Performance Track Program (as described at http://www.azdeq.gov/function/about/track.html) and is a member of both programs. The Performance Track Programs are voluntary programs that encourage continuous environmental improvement through the use of environmental management systems, local community outreach, and measurable results.]

~~4.~~5. No change
~~5.~~6. No change
~~6.~~7. No change
a. No change
b. No change

G. No change
H. No change
I. No change
J. No change
K. No change
L. No change
M. No change
1. No change
2. No change
3. No change

N. No change

R18-8-261. Identification and Listing of Hazardous Waste

A. All of 40 CFR 261 and accompanying appendices, revised as of ~~July 1, 2004~~ September 6, 2005 (and no future editions), is incorporated by reference, modified by the following subsections, and on file with the DEQ. Copies of 40 CFR 261 are available at www.gpoaccess.gov/cfr/index.html.

B. No change

C. No change

D. No change

E. No change

F. No change

G. No change

H. § 261.5, titled "Special requirements for hazardous waste generated by conditionally exempt small quantity generators," paragraph (j) is amended as follows:

(j) If a conditionally exempt small quantity generator's wastes are mixed with used oil, the mixture is subject to 40 CFR 279 [(as incorporated by A.R.S. § 49-802 into Arizona law)] ~~of this Chapter~~. Any material produced from such a mixture by processing, blending, or other treatment is also so regulated ~~under 40 CFR 279~~.

I. No change

J. No change

K. No change

R18-8-262. Standards Applicable to Generators of Hazardous Waste

A. All of 40 CFR 262 and the accompanying appendix, revised as of ~~July 1, 2004,~~ September 6, 2005 (and no future editions), ~~with the exception of subsection 40 CFR 262.34(j), which is incorporated by reference as of October 25, 2004,~~ is incorporated by reference, modified by the following subsections, and on file with the DEQ. Copies of 40 CFR 262 are available at www.gpoaccess.gov/cfr/index.html.

B. No change

1. No change
2. No change
3. No change

C. No change

D. No change

E. No change

F. No change

G. No change

H. No change

I. Manifests required in 40 CFR 262, subpart B, titled "The Manifest," (as incorporated by R18-8-262) shall be submitted to the DEQ in the following manner:

1. A generator initiating a shipment of hazardous waste required to be manifested shall submit to the DEQ, no later than 45 days following the end of the month of shipment, one copy of each manifest with the signature of that generator and transporter, and the signature of the owner or operator of the designated facility, for any shipment of hazardous waste transported or delivered within that month. If a conforming manifest is not available, the generator shall submit an Exception Report in compliance with § 262.42 (as incorporated by R18-8-262).
2. A generator shall designate on the manifest in item I "Waste No.," the EPA hazardous waste number or numbers for each hazardous waste listed on the manifest.
3. A member of the Performance Track Program, as defined in R18-8-260(F), that initiates a shipment of hazardous waste required to be manifested shall submit the manifest to DEQ as specified in subsections (1) and (2), except a manifest may be submitted to DEQ within 45 days following the end of the calendar quarter of shipment rather than within 45 days following the end-of-the month of shipment.

J. No change

K. No change

L. No change

M. No change

R18-8-263. Standards Applicable to Transporters of Hazardous Waste

A. All of 40 CFR 263, revised as of ~~July 1, 1999~~ September 6, 2005 (and no future editions), is incorporated by reference, modified by the following subsections of R18-8-263, and on file with the DEQ. Copies of 40 CFR 263 are available at www.gpoaccess.gov/cfr/index.html.

B. No change

C. No change

D. No change

E. No change

R18-8-264. Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities

A. All of 40 CFR 264 and accompanying appendices, revised as of ~~July 1, 2004~~ September 6, 2005 (and no future editions), with the exception of §§ 264.1(d) and (f), 264.149, 264.150, and 264.301(l), is incorporated by reference, modified by the following subsections, and on file with the DEQ. Copies of 40 CFR 264 are available at www.gpoaccess.gov/cfr/index.html.

B. No change

C. No change

D. No change

1. No change
2. No change

E. No change

F. No change

G. § 264.71, titled "Use of manifest system," paragraph (a)(4) is amended as follows:

Within 30 days after the delivery, send a copy of the signed and dated manifest or a signed and dated copy of the shipping paper (if the manifest has not been received within 30 days after delivery) to the generator [and submit one copy of each manifest to ~~the~~ DEQ, ~~in accordance with~~ according to R18-8-264(I).]

H. No change

I. No change

1. No change
2. No change

J. No change

K. No change

L. No change

M. No change

N. No change

O. No change

1. No change
2. No change
3. No change
4. No change
5. No change
6. No change

R18-8-265. Interim Status Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities

A. All of 40 CFR 265 and accompanying appendices, revised as of ~~July 1, 2004~~ September 6, 2005 (and no future editions), with the exception of §§ 265.1(c)(2), 265.1(c)(4), 265.149, 265.150, and 265.430, is incorporated by reference, modified by the following subsections, and on file with the DEQ. Copies of 40 CFR 265 are available at www.gpoaccess.gov/cfr/index.html.

B. No change

C. No change

D. No change

1. No change
2. No change

E. No change

F. No change

G. § 265.71, titled "Use of manifest system," paragraph (a)(4) is amended as follows:

Within 30 days after the delivery, send a copy of the signed and dated manifest or a signed and dated copy of the shipping paper (if the manifest has not been received within 30 days after delivery) to the generator [and submit one copy of each manifest to ~~the~~ DEQ, ~~in accordance with subsection~~ according to R18-8-265(I).]

H. No change

I. No change

J. No change

K. No change

L. No change

M. No change

1. No change
2. No change
3. No change

R18-8-266. Standards for the Management of Specific Hazardous Wastes and Specific Hazardous Waste Management Facilities

A. All of 40 CFR 266 and accompanying appendices, revised as of ~~July 1, 2004~~ July 14, 2005 (and no future editions), is incorporated by reference, modified by the following subsections, and on file with the DEQ. Copies of 40 CFR 266 are available at www.gpoaccess.gov/cfr/index.html.

B. No change

R18-8-268. Land Disposal Restrictions

All of 40 CFR 268 and accompanying appendices, revised as of ~~July 1, 2004~~ August 23, 2005 (and no future editions), with the exception of Part 268, Subpart B, is incorporated by reference and on file with the DEQ. Copies of 40 CFR 268 are available at www.gpoaccess.gov/cfr/index.html.

R18-8-270. Hazardous Waste Permit Program

A. All of 40 CFR 270, revised as of ~~July 1, 2004~~ August 5, 2005 (and no future editions), with the exception of §§ 270.1(a), 270.1(c)(1)(i), 270.3, 270.10(g)(1)(i), 270.60(a) and (b), and 270.64, is incorporated by reference, modified by the following subsections, and on file with the DEQ. Copies of 40 CFR 270 are available at www.gpoaccess.gov/cfr/index.html.

B. No change
1. No change
   a. No change
   b. No change
   c. No change
2. No change
   a. No change
   b. No change

C. No change

D. No change

E. No change

F. No change

G. No change
1. No change
   a. No change
   b. No change
   c. No change
   d. No change
2. No change
   a. No change
   b. No change
3. No change
   a. No change
   b. No change
   c. No change
   d. No change
4. No change
5. No change
6. No change
   a. No change
   b. No change
7. No change
   a. No change
   b. No change
   c. No change
   d. No change
   e. No change
   f. No change
   g. No change
   h. No change
   i. No change
   j. No change
8. No change
9. No change

H. No change
I. No change
J. No change
K. No change
L. No change
M. No change
N. No change
O. No change
P. No change
Q. No change
R. No change
S. No change

R18-8-271. Procedures for Permit Administration

A. All of 40 CFR 124 and the accompanying appendix, revised as of July 1, ~~2002~~ 2005 (and no future editions), relating to HWM facilities, with the exception of §§ 124.1 (b) through (e), 124.2, 124.4, 124.16, 124.20 and 124.21 is incorporated by reference, modified by the following subsections, and on file with the DEQ. Copies of 40 CFR 124 are available at www.gpoaccess.gov/cfr/index.html.
B. No change
C. No change
D. No change
E. No change
F. No change
G. No change
H. No change
I. No change
J. No change
K. No change
L. No change
M. No change
N. No change
O. No change
P. No change
Q. No change
R. No change
S. No change
T. No change

R18-8-273. Standards for Universal Waste Management

All of 40 CFR 273, ~~as amended~~ revised as of ~~July 1, 2000~~ August 5, 2005 (and no future editions), is incorporated by reference and ~~is~~ on file with the DEQ~~ and the Office of the Secretary of State~~. Copies of 40 CFR 273 are available at www.gpoaccess.gov/cfr/index.html.