FIVE-YEAR REVIEW REPORT

TITLE 9. HEALTH SERVICES
CHAPTER 10. DEPARTMENT OF HEALTH SERVICES
HEALTH CARE INSTITUTIONS: LICENSING
ARTICLE 2. HOSPITALS

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FIVE-YEAR REVIEW REPORT SUMMARY

Arizona Revised Statutes (A.R.S.) § 36-405(A) requires the Director of the Arizona Department of Health Services (Department) to adopt rules establishing minimum standards and requirements for the construction, modification, and licensure of health care institutions necessary to assure the public health, safety, and welfare. It further requires that the standards and requirements relate to the construction; equipment; sanitation; staffing for medical, nursing, and personal care services; and record keeping pertaining to the administration of medical, nursing, and personal care services according to generally accepted practices of health care. A.R.S. § 36-405(B)(1) allows the Director to classify and sub-classify health care institutions according to character, size, range of services provided, medical or dental specialty offered, duration of care, and standard of patient care required for the purposes of licensure.

Presently, there are 110 licensed hospitals in Arizona, of which 83 are accredited. The hospital industry currently utilizes several accreditation bodies. The 83 hospitals are accredited as follows: 67 hospitals are only accredited by Joint Commission on Accreditation of Healthcare Organizations (JCAHO); 1 hospital is only accredited by The American Osteopathic Association; 10 hospitals are only accredited by Det Norske Veritas Healthcare Inc.; 4 hospitals are accredited by Det Norske Veritas Healthcare Inc. and JCAHO, and 1 hospital is accredited by The American Osteopathic Association and JCAHO.

Three subclasses were established under the hospital class: general hospital, rural general hospital, and special hospital. Specific rules for the general hospital subclass were contained in Arizona Administrative Code (A.A.C.) Title 9, Chapter 10, Article 2, effective February 23, 1979; rules for the rural general hospital subclass were contained in 9 A.A.C. 10, Article 3, effective February 4, 1981; and rules for the special hospital subclass were contained in 9 A.A.C. 10, Article 4, effective January 28, 1980. The hospital rules were subsequently repealed in their entirety and replaced with new requirements for hospitals with specific requirements for each subclass in 9 A.A.C. 10, Article 2, effective October 1, 2002. The hospital rules were later amended to be consistent with industry standards and Departmental policy, effective March 5, 2005, and to revise the qualification requirements for a hospital administrator, effective December 5, 2006.

Since the 12007 Five-year Review Report, the Department amended the rules, effective December 2, 2008, to permit more than one organized service in a single hospital unit and to remove an unclear

1 Final submission of the 2007 Five-Year Review Report was in August 2008.
provision regarding informed consent. Most recently the rules were amended, effective June 30, 2012, to eliminate the dual licensing requirements for hospitals that provided organized psychiatric services.

The Department is currently implementing Laws 2011, Chapter 96, which requires the Department to facilitate the licensure of integrated health programs that provide both behavioral health and physical health services. Health Care Institutions licensure rules in 9 A.A.C. 10 will be revised to allow for the provision of behavioral health services, which are currently licensed under rules in 9 A.A.C. 20. This exempt rulemaking will involve the review and revision of all Articles in Chapter 10 and Chapter 20. The Department has convened several meetings to work with representatives of the hospital industry, the behavioral health system, advocates, and other affected stakeholders in the drafting of the new rules. Future dates for additional meetings will be scheduled for the remainder of this year and for early 2013. The Department plans to post drafts of each Article upon revision and obtain comments continuously from the public through electronic surveys located on the Department’s website. This rulemaking will be finalized by June 30, 2013.

Through the aforementioned rulemaking, the Department anticipates all rule amendments as identified in this Five-year Review Report will be completed by June 30, 2013.
**TABLE OF IDENTICAL INFORMATION**

This chart complies with the requirements of R1-6-111(B), which prescribes that information shall be provided only once for any group of rules for which the information on a particular issue is the same.

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8. **Economic, small business, and consumer impact comparison**

Effective October 2002, the hospital rules which were previously located in three separate Articles were repealed in their entirety and set forth in one Article. The rules were placed in Arizona Administrative Code (A.A.C.) Title 9, Chapter 10, Article 2 and amended to be comparable to Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards and Centers for Medicare and Medicaid Services (CMS) Conditions of Participation. The revised rules emphasized performance and patient outcome rather than process. An economic impact statement was prepared and submitted to the Governor's Regulatory Review Council as a part of the rule package.

The Department predicted the 2002 rules would benefit hospitals and consumers by providing clear and consistent requirements that reflected national patient care standards. Although most of the proposed changes to the rules were current hospital practice, these changes were considered important at the time because an increasing number of hospitals were relinquishing JCAHO accreditation. The Department expected the costs imposed on hospitals to be minimal to moderate, with the benefits of the rules outweighing the costs.

The Department also predicted the 2002 rules would benefit hospitals by adding a requirement that medical staff be screened for tuberculosis (TB). The Department expected the new requirement would cause a minimal to moderate increase in costs for hospitals that were already providing TB screening to medical staff. However, the Department expected the administrative costs of monitoring, tracking, and documenting TB testing information could result in a substantial increase in costs to hospitals. Overall, the Department expected the costs imposed on hospitals would be outweighed by the benefits.

Effective March 2005, several technical or clarifying changes were made to the existing rules, and the nurse to patient ratio in an Intensive Care Unit was adjusted. An economic impact statement was prepared and submitted to the Governor's Regulatory Review Council as a part of the rule package.

The Department predicted the 2005 rules would benefit hospitals by providing rules that are clear and understandable. The Department expected the new rules would cause a minimal increase in
costs for hospitals. The Department expected the costs to implement the new staff ratios would be minimal to substantial, depending on whether a hospital needed to add staff to comply with the new requirements. Overall, the Department expected the costs imposed on hospitals would be outweighed by the benefits.

Effective December 2006, the Department amended the minimum qualifications for a hospital administrator in R9-10-203. An economic impact statement was prepared and submitted to the Governor's Regulatory Review Council as a part of the rule package.

The Department predicted the 2006 rules would benefit hospitals and individuals seeking to be hospital administrators because the effect of the rule was to increase the number of individuals who are qualified to be hospital administrators. The Department expected the costs imposed on hospitals to be minimal to moderate, with the benefits of the rules outweighing the costs.

Effective December 2008, the Department revised the rules to amend the requirements for an organized service in a hospital. Previously, a hospital could only provide one organized service in a unit of a hospital. The rule revision permits a hospital to provide more than one organized service in a single hospital unit. This arrangement eliminated the need to physically transfer a patient to different organized service units during an individual’s recovery. An economic impact statement was prepared and submitted to the Governor's Regulatory Review Council as a part of the rule package.

The Department predicted the 2008 rules would benefit hospitals and consumers by becoming more efficient and effective with patient services. A hospital patient who previously had to be physically relocated as the patient recovered could recover more quickly when receiving all necessary organized services in one physical location. The Department expected a hospital that decided to have a multi-organized service unit may experience a minimal to substantial increase in physical plant costs. The Department expected a hospital that decided to have a multi-organized service unit may have a minimal to moderate decrease in costs due to a more efficient use of staff and physical plant. Overall, the Department expected the costs imposed on hospitals would be outweighed by the benefits.

Effective June 2012, the Department revised the rules through exempt rulemaking to eliminate the dual licensing requirements for hospitals that provide organized psychiatric services. Prior to
this rulemaking a hospital providing organized psychiatric services was required to be licensed as a hospital under 9 A.A.C.10, Article 2, and as a behavioral health service agency under 9 A.A.C. 20. Because this was an exempt rulemaking, the Department was not required to submit an economic impact statement. Since this rule was recently adopted, the Department cannot determine the costs and benefits of the rulemaking at this time.

The Department believes the 2002, 2005, 2006 and 2008 economic impact statements accurately predicted the costs and benefits of each rulemaking. The benefits of the amended rules outweigh any costs associated with their implementation.
INFORMATION THAT IS IDENTICAL FOR GROUPS OF RULES

3. **Analysis of effectiveness in achieving the objective**
   All rules are effective or mostly effective in achieving their objectives; however, R9-10-206, R9-10-207, and R9-10-229 should be amended to reflect current recommendations for tuberculosis infection control according to the Centers for Disease Control and Prevention, *Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005.*

4. **Analysis of consistency with state and federal statutes and rules**
   All rules are consistent with statutes, other rules made by the Department, and current Department policy; however, R-9-10-206 and R9-10-207 should be amended to be consistent with the Department’s Guidance Document, GD-008-DLS-MED, Clarification of Standards for Infectious Pulmonary Tuberculosis Screening, which allows health care institutions to utilize tuberculosis blood tests, also known as interferon-gamma release assays, as described in the Centers for Disease Control and Prevention, Division of Tuberculosis Elimination, *Testing for TB Infection, April 30, 2012.*

10. **Status of the completion of action indicated in the previous five-year review report**

14. **Analysis of whether a general permit is applicable**
    Except for R9-10-224, all rules were adopted before July 29, 2010 and do not issue permits or licenses. A.R.S. § 36-405 authorizes the Department to issue licenses to specific applicants based on specific circumstances, so a general permit is not appropriate according to § 41-1037(A)(3).
R9-10-201. Definitions

2. Objective

The objective of the rule is to define terms and phrases used in the Article to enable a reader to have a better understanding of the requirements contained in the Article.

4. Analysis of consistency with state and federal statutes and rules

Except for the following, the rule is consistent with state statutes, other rules and Department policy:

Subsection (1), the reference to A.R.S. § 36-422(J)(1) is incorrect. The reference should be to A.R.S. § 36-422(N)(1).

Subsection (5) states that the term "administrator" means a "chief administrative officer." The definition should reference A.R.S. § 36-425(I) for consistency with R9-10-202(C)(1).

Subsection (35) states that the term "diversion" means notification to an emergency medical services provider, as defined in A.R.S. § 36-2201. The term "diversion" is no longer defined in A.R.S. § 36-2201.

Subsection (105), the reference to A.R.S. § 36-422(J)(2) is incorrect. The reference should be to A.R.S. § 36-422(N)(2).

Subsection (110) refers to a "social worker" as an individual who "has at least a baccalaureate degree in social work from a program accredited by the Council on Social Work Education or who is certified according to A.R.S. Title 32, Chapter 33. " Laws 2003, Ch. 65, § 22, effective July 1, 2004 requires a social worker to be licensed in order to engage in the practice of social work.

Subsection (122) states that the term "vital records" has the same meaning as in A.R.S. § 36-301. The term "vital record" is only defined in A.R.S. § 36-301.

Subsection (123) states that the term "vital statistics" has the same meaning as in A.R.S. § 36-301. The term "vital statistics" is no longer defined in A.R.S. § 36-301.

6. Analysis of clarity, conciseness, and understandability

Except for the following, the rule is clear, concise, and understandable:

Subsection (53), because the term "risk" is used in the definition of "infection control risk assessment" the definition is not clear.

Subsection (95), the term "mental illness" is not defined.
Subsection (98), the term "rehabilitation services" is defined. The term "rehabilitative services" is used in subsection (17), and it is unclear whether "rehabilitation services" has a different meaning than "rehabilitative services."

Subsection (108), the rule should read "(F) or (G)" rather than "(F) and (G)."

The definition of "special hospital" in subsection (111) uses the term "specific branch of medicine" and the definition of "specialty" in subsection (112) uses the term "specific area of medicine" and it is unclear whether the terms "specific branch of medicine" and "specific area of medicine," both of which are undefined, have the same meaning or refer to different subjects.

10. **Status of the completion of action indicated in the previous five-year review report**

The Department partially completed the course of action in the previous Five-year Review Report by amending the lead sentence, using the current Arizona Administrative Code citation format. Other issues identified in the 2007 Five-year Review Report remain unchanged.

R9-10-202. **Application Requirements**

1. **Authorization of the rule by existing statute**

The rule has A.R.S. §§ 36-422, 36-424, and 36-425 as additional specific authority.

2. **Objective**

The objective of the rule is to establish specific hospital license application requirements.

4. **Analysis of consistency with state and federal statutes and rules**

Except for the following, the rule is consistent with state statutes, other rules and Department policy:

In subsection (B) the term "accredited facility" is not consistent with A.R.S. § 36-422(F) and (G). Laws 2003, Chapter 193, § 1 repealed the requirement that a facility be "accredited" and the term currently used in A.R.S. § 36-422(F) and (G) is "facilities."

6. **Analysis of clarity, conciseness, and understandability**

Except for the following, the rule is clear, concise, and understandable:

Subsection (A)(3) states that a hospital's governing authority may submit a copy of an accreditation report if the hospital is accredited and chooses to submit a copy of the report instead of receiving a license inspection but does not state that the provision is only applicable to a renewal license. Accrediting organizations do not accredit a hospital until the hospital is licensed so a hospital could not submit an accreditation report with an initial license application.

10. **Status of the completion of action indicated in the previous five-year review report**
The Department partially completed the course of action in the previous Five-year Review Report by correcting a statutory reference to A.R.S. 36-425(E). Other issues identified in the 2007 Five-year Review Report remain unchanged.

R9-10-203  Administration
2.  **Objective**  
The objective of the rule is to establish minimum requirements for a hospital’s governing authority and administrative office.

R9-10-204.  Quality Management
1.  **Authorization of the rule by existing statute**  
The rule has A.R.S. § 36-445 as additional specific authority.

2.  **Objective**  
The objective of the rule is to establish minimum requirements for a hospital’s quality management program.

6.  **Analysis of clarity, conciseness, and understandability**  
Except for the following, the rule is clear, concise, and understandable:
Subsection (B)(1)(b) requires the quality management plan to include a method to evaluate "hospital services and environmental services related to patient care." Subsection (B)(1)(c) contains requirements for evaluating the data collected to identify a concern about hospital services, and subsection (B)(1)(d) contains requirements to make changes or take action as a result of the identification of a concern about hospital services. Neither (B)(1)(c) or (B)(1)(d) requires the quality management plan to evaluate a concern about environmental services.

R9-10-205.  Contracted Services
2.  **Objective**  
The objective of the rule is to establish minimum requirements for hospital services provided by a person who contracts with the licensee to provide hospital services to ensure that the contractor complies with applicable requirements.

R9-10-206.  Personnel
2.  **Objective**  
The objective of the rule is to establish minimum standards for hospital personnel.
R9-10-207. Medical Staff

1. Authorization of the rule by existing statute
   The rule has A.R.S. §§ 36-445, 36-445.01, 36-445.02, and 36-445.03 as additional specific authority.

2. Objective
   The objective of the rule is to establish minimum requirements for a hospital’s medical staff.

R9-10-208. Nursing Services

2. Objective
   The objective of the rule is to establish minimum requirements for nursing services in a hospital.

4. Analysis of consistency with state and federal statutes and rules
   Except for the following, the rule is consistent with state statutes, rules and Department policy:
   Subsection (C)(7) requires a special hospital licensed to provide behavioral health services to comply with the staffing requirements in A.A.C. Title 9, Chapters 10 and 20. This rule is inconsistent with the implementation of Laws 2011, Chapter 43 which required the Department to eliminate dual licensing requirements for hospitals that provide organized psychiatric services. This rulemaking incorporated specific requirements, including staffing requirements, for the provision of psychiatric services in a hospital that were previously contained in 9 A.A.C. 20. In addition, the Department implemented Laws 2011, Chapter 231, § 3 which required the removal of requirements for hospitals from the behavioral health service agency licensing rules in 9 A.A.C. 20, effective June 30, 2012. Therefore, the requirements in subsection (C)(7) are no longer applicable.

6. Analysis of clarity, conciseness, and understandability
   Except for the following, the rule is clear, concise, and understandable:
   In subsections (C)(5) and (6) the term "on duty" may need to be defined. Subsection (C)(2)(a)(b)(c) requires an acuity plan to be established, documented and implemented and includes several requirements. The rule does not consider all levels of hospital personnel or require patient care assignments to be made according to the acuity plan. The acuity plan does not contain information necessary for the Department to ensure that the health and safety of the patient is not jeopardized.
R9-10-209  Patient Rights

2. **Objective**
   The objective of the rule is to establish minimum standards for patient rights.

R9-10-210  Admission

2. **Objective**
   The objective of the rule is to establish minimum requirements for an individual’s admission to a hospital.

R9-10-211  Discharge Planning; Discharge

2. **Objective**
   The objective of the rule is to establish minimum requirements for discharge and discharge planning.

R9-10-212.  Transport

2. **Objective**
   The objective of the rule is to establish minimum transport requirements to ensure that the patient’s health and safety are not compromised as a result of the transport.

4. **Analysis of consistency with state and federal statutes and rules**
   Except for the following, the rule is consistent with state statutes, other rules and Department policy:
   In subsection (B)(1)(b) the phrase "…the receiving hospital is a satellite facility, as defined in A.R.S. § 36-422" is inconsistent with the definition of "satellite facility" in A.R.S. § 36-422, which means "an outpatient facility at which the hospital provides outpatient medical services." According to the definition a "satellite facility" is an outpatient facility not a hospital.

6. **Analysis of clarity, conciseness, and understandability**
   Except for the following, the rule is clear, concise, and understandable:
   In subsections (A)(2)(f) and (B)(2)(f) terms such as "professional" and "assisting" may need to be defined.
R9-10-213. Transfer

2. **Objective**
   The objective of the rule is to establish minimum requirements for the transfer of a patient to ensure that the health and safety of the patient are not compromised as a result of the patient’s transfer.

6. **Analysis of clarity, conciseness, and understandability**
   Except for the following, the rule is clear, concise, and understandable:
   In subsection (A)(3)(e) terms such as "professional" and "assisting" may need to be defined.

R9-10-214. Surgical Services

2. **Objective**
   The objective of the rule is to establish minimum requirements for surgical services in a hospital.

6. **Analysis of clarity, conciseness, and understandability**
   Except for the following, the rule is clear, concise, and understandable:
   Subsection (A)(14)(a) requires a surgeon to document specific information regarding the surgical procedure. It does not state where the documentation is maintained so surveying for compliance with the requirement may not be possible. A surgeon may document the surgical procedure but maintain the documentation in the surgeon's private office instead of the hospital. Subsection (A)(14)(b) requires a postoperative follow-up report. It does not establish criteria for content, documentation, or maintenance of the postoperative report so surveying for compliance with the requirement may not be possible. There may be a postoperative follow-up report but it may not be available for review or it may not contain any of the information necessary for the Department to ensure that the health and safety of the patient was not jeopardized.

R9-10-215. Anesthesia Services

2. **Objective**
   The objective of the rule is to establish minimum requirements for anesthesia services in a hospital.

R9-10-216. Emergency Services

2. **Objective**
   The objective of the rule is to establish minimum requirements for emergency services.
R9-10-217. Pharmaceutical Services

2. **Objective**
The objective of the rule is to establish minimum requirements for pharmaceutical services.

6. **Analysis of clarity, conciseness, and understandability**
Except for the following, the rule is clear, concise, and understandable:
In subsection (1) an Arizona Administrative Code citation uses an outdated format. In subsection (3)(d), the term "categories" may need to be defined.

R9-10-218. Clinical Laboratory Services and Pathology Services

2. **Objective**
The objective of the rule is to establish minimum requirements for clinical laboratory services and pathology services.

6. **Analysis of clarity, conciseness, and understandability**
Except for the following, the rule is clear, concise, and understandable:
In subsection (5) the term "on duty" may need to be defined. In subsection (8) the rule requires notification to the ordering medical staff member or a registered nurse in the patient’s assigned unit if a test result is obtained that indicates a patient may have an emergency medical condition, as defined by medical staff. The rule should either define an emergency medical condition or require a definition of an emergency medical condition by medical staff at each facility.

R9-10-219. Radiology Services and Diagnostic Imaging Services

2. **Objective**
The objective of the rule is to establish minimum requirements for radiology services and diagnostic imaging services.

6. **Analysis of clarity, conciseness, and understandability**
Except for the following, the rule is clear, concise, and understandable:
In subsection (A) (1) an Arizona Administrative Code citation uses an outdated method.
Subsection (5) uses the terms "on duty" and "on call." Definitions may be needed to clarify the difference.

R9-10-220. Intensive Care Services

2. **Objective**
The objective of the rule is to establish minimum requirements for intensive care services provided by a hospital.
4. **Analysis of consistency with state and federal statutes and rules**

Except for the following, the rule is consistent with state statutes, other rules and Department policy:

Subsection (A) prohibits a rural general hospital from providing intensive care services and is inconsistent with A.R.S. § 36-425(F) added by Laws 2007, Chapter 128, § 2, which added a provision that states, "A hospital licensed as a rural general hospital may provide intensive care services."

6. **Analysis of clarity, conciseness, and understandability**

Except for the following, the rule is clear, concise, and understandable:

In subsection (B)(9) the term "advanced cardiopulmonary resuscitation" is undefined and is unclear because the term used by the industry is "advanced life support." Subsection (B)(5) is unclear because it requires staffing in an intensive care unit, in addition to the requirements in R9-10-208(C), according to an acuity plan as required in R9-10-208. The acuity plan is required by R9-10-208(C)(2) and it is unclear whether the requirement is an additional requirement or just repetitive.

R9-10-221. **Respiratory Care Services**

2. **Objective**

The objective of the rule is to establish minimum requirements for respiratory care services.

R9-10-222. **Perinatal Services**

2. **Objective**

The objective of the rule is to establish minimum requirements for perinatal services.

6. **Analysis of clarity, conciseness, and understandability**

Except for the following, the rule is clear, concise, and understandable:

Subsection (A)(11)(b) requires hospital policies and procedures that specify how the hospital determines to whom a neonate may be discharged. The subsection does not mention "authorization" for an individual to whom a neonate may be discharged. Subsection (A)(12)(a) requires that a neonate be discharged only to an individual who is authorized according to subsection (A)(11), which makes it unclear whether subsection (A)(11)(b) is an authorization process in addition to the determination. The term "on duty" in subsection (A)(16) may need to be defined.
R9-10-223. Pediatric Services

2. **Objective**
   The objective of the rule is to establish minimum requirements for providing pediatric services in a hospital.

7. **Summary of written criticisms of the rule**
   In May 2012 the Department received written criticism of this rule from Arizona Hospital and Healthcare Association stating the requirements are problematic for hospitals in rural Arizona. Hospitals without licensed pediatric beds can admit pediatric patients in an emergency situation, but in non-emergent cases must transfer the patient to a hospital with licensed pediatric beds. For rural hospitals this often results in a patient being sent to Phoenix or Tucson. This transport is costly and is inconvenient for the family. Rural hospitals typically do not have an organized pediatric unit because they have limited resources and are unable to accommodate the physical plant changes necessary to meet the requirements of licensed pediatric beds.

   **Response:**
   Concurrent with the Department's rulemaking to implement Laws 2011, Chapter 96, which requires the Department to review all Articles in Chapter 10, the Department will work with hospitals and other interested stakeholders to determine whether the rule should be amended. If determined, an amendment to this rule will be completed by June 30, 2013.

R9-10-224. Psychiatric Services

2. **Objective**
   The objective of the rule is to establish minimum requirements for providing psychiatric services in a hospital.

3. **Analysis of effectiveness in achieving the objective**
   Because this rule was adopted June 30, 2012, the Department plans to gather information as to whether the rule is effective in achieving its objective.

5. **Status of enforcement of the rule**
   Because this rule was adopted June 30, 2012, the Department plans to gather information as to whether the rule is enforced as written.

6. **Analysis of clarity, conciseness, and understandability**
   Because this rule was adopted June 30, 2012, the Department plans to gather information as to whether the rule is clear, concise and understandable.
R9-10-225. Rehabilitation Services

2. **Objective**
   
The objective of the rule is to establish minimum requirements for rehabilitation services.

R9-10-226. Social Services

2. **Objective**
   
The objective of the rule is to establish minimum requirements for social services.

R9-10-227. Dietary Services

2. **Objective**
   
The objective of the rule is to establish minimum requirements for dietary services.

6. **Analysis of clarity, conciseness, and understandability**
   
Except for the following, the rule is clear, concise, and understandable:

   The rule contains Arizona Administrative Code citations that use an outdated format in subsections (1) through (3). Although the rule requires a "current" diet manual in subsection (10) and "current" is defined as "up-to-date and extending to the present time" it is unclear whether the date of the publication or the content of diet manual would demonstrate that the diet manual is "up-to-date and extending to the present time."

R9-10-228. Medical Records

2. **Objective**
   
The objective of the rule is to establish minimum requirements for patients’ medical records.

4. **Analysis of consistency with state and federal statutes and rules**
   
Except for the following, the rule is consistent with state statutes, other rules and Department policy:

   In subsection (A)(11) for the maintenance of vital records and vital statistics according to A.R.S. § 36-343 which, after legislative changes, does not contain any record maintenance requirements.

6. **Analysis of clarity, conciseness, and understandability**
   
Except for the following, the rule is clear, concise, and understandable:

   Subsection (A)(10)(b) is missing a verb.

   Specific subsections are not included in cites in the following subsections: (C)(15)(a) and (b), and (D)(7)(a) and (b).
R9-10-229  Infection Control

2. **Objective**

   The objective of the rule is to establish minimum requirements for infection control in a hospital.

R9-10-230.  Environmental Services

2. **Objective**

   The objective of the rule is to establish minimum requirements for a hospital’s environmental services.

6. **Analysis of clarity, conciseness, and understandability**

   Except for the following, the rule is clear, concise, and understandable:

   The rule contains an Arizona Administrative Code citation using an outdated format in subsection (5).

   Although subsection (2)(a) requires the hospital premises and equipment to be cleaned according to policies and procedures designed to prevent or control illness or infection, it does not require the policies and procedures to be developed and adopted. In addition, R9-10-203(C)(2)(f) requires that policies and procedures be established, documented, and implemented for infection control and R9-10-229(A)(2)(a) requires that there be policies and procedures to prevent or minimize, identify, report, and investigate infections and communicable diseases. It is unclear whether the reference in subsection (2)(a) refers to the policies and procedures required in R9-10-203(C)(2)(f) or R9-10-229(A)(2)(a).

R9-10-231.  Disaster Management

2. **Objective**

   The objective of the rule is to establish minimum requirements to ensure that a hospital is prepared for a disaster.

R9-10-232.  Physical Plant Standards

2. **Objective**

   The objective of the rule is to establish physical plant requirements for the construction or modification of a hospital’s physical plant.

4. **Analysis of consistency with state and federal statutes and rules**

   Except for the following, the rule is consistent with state statutes, rules and Department policy:

   Subsection (A)(6) states that hospital premises are not licensed as more than one health care institution except as provided in A.R.S. Title 36, Chapters 4 and 5, and 9 A.A.C. 20. This rule is
inconsistent with the implementation of Laws 2011, Chapter 43 which required the Department to eliminate dual licensing requirements for hospitals that provide organized psychiatric services. This rulemaking incorporated specific requirements for the provision of psychiatric services in a hospital that were previously contained in 9 A.A.C. 20. In addition, the Department implemented Laws 2011, Chapter 231, § 3 which required the removal of requirements for hospitals from the behavioral health service agency licensing rules in 9 A.A.C. 20, effective June 30, 2012. Therefore, the reference to 9 A.A.C. 20 in subsection (A)(6) is no longer applicable.

R9-10-234. Multi-organized Service Unit

2. Objective

The objective of the rule is to establish minimum requirements for a multi-organized service unit in a hospital.
FIVE-YEAR-REVIEW REPORT

TITLE 9.  HEALTH SERVICES

CHAPTER 23.  DEPARTMENT OF HEALTH SERVICES

ORAL HEALTH

ARTICLE 1.  DEFINITIONS

ARTICLE 2.  ARIZONA DENTAL SEALANT PROGRAM

ARTICLE 3.  ARIZONA FLUORIDE MOUTHRINSE PROGRAM

November 2012
Arizona Revised Statutes (A.R.S.) § 36-104(1)(c)(i) requires the Arizona Department of Health Services (Department) to administer community health services, including preventive dental care. A.R.S. § 36-132(A)(10) requires the Department to encourage, administer, and provide dental health care services, and to help coordinate local dental public health programs, in cooperation with the Arizona Dental Association. A.R.S. § 36-138 establishes the oral health fund consisting of money received by the Department as reimbursement from the Arizona Health Care Cost Containment System (AHCCCS) for dental services provided by the Department.

The Department has adopted in Arizona Administrative Code (A.A.C.) Title 9, Chapter 23, effective January 8, 2008, rules to implement these statutes. Article 1 of 9 A.A.C. 23 contains definitions for the Department's oral health programs. The rules for the Arizona Dental Sealant Program are contained in 9 A.A.C. 23, Article 2. Under the Arizona Dental Sealant Program, the Department contracts with county health departments and other entities to arrange for licensed dentists and dental hygienists to provide dental sealants and dental screenings at participating schools. The rules in 9 A.A.C. 23, Article 3 are for the Arizona Fluoride Mouthrinse Program. The Arizona Fluoride Mouthrinse Program is a school-based program that supplies participating schools with fluoride mouthrinse for its students. For the Arizona Fluoride Mouthrinse Program, the Department purchases the fluoride mouthrinse under the direction of a licensed dentist or medical director and sends it to the participating schools.

After an analysis of the rules in 9 A.A.C. 23, the Department has determined that all but one rule are effective or mostly effective; all but two rules are clear, concise, and understandable or mostly clear, concise, and understandable; and all but one rule impose the least burden and costs on regulated persons. The Department has received no written criticism of the rules. The Department believes the rules are sufficient to protect public health and does not plan to amend the rules in 9 A.A.C. 23 unless a threat to public health or safety arises that would require amending the rules.
### TABLE OF IDENTICAL INFORMATION

This chart complies with the requirements of R1-6-111(B), which prescribes that information shall be provided only once for any group of rules for which the information on a particular issue is the same.

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INFORMATION THAT IS IDENTICAL FOR ALL OF THE RULES

8. Economic, small business, and consumer impact comparison

The rules in 9 A.A.C. 23 were adopted by final rulemaking published in the Arizona Administrative Register (A.A.R.) at 13 A.A.R. 4190, effective January 8, 2008. An economic, small business, and consumer impact statement (EIS) was submitted to GRRC as part of the final rulemaking. The EIS stated that the rules were adopted using the practices the Department was already using to implement the Arizona Dental Sealant Program and the Arizona Fluoride Mouthrinse Program. During the 2005-2006 school year, the Arizona Dental Sealant Program provided approximately 8,461 children with dental sealants at 160 participating schools, and the Arizona Fluoride Mouthrinse Program provided approximately 20,875 children with fluoride mouthrinse at 85 participating schools. During the 2011-2012 school year, the Arizona Dental Sealant Program provided approximately 11,411 children with dental sealants at 321 participating schools, and the Arizona Fluoride Mouthrinse Program provided approximately 15,628 children with fluoride mouthrinse at 33 participating schools.

The EIS designated annual costs/revenues changes as minimal when less than $1,000, moderate when between $1,000 and $10,000, and substantial when $10,000 or greater in additional costs or revenues. The Department anticipated that the rules would impose a minimal burden on the following groups: county health departments and other entities contracted with the Department for the Arizona Dental Sealant Program, schools that voluntarily participate in the Arizona Dental Sealant Program, schools that voluntarily participate in the Arizona Fluoride Mouthrinse Program, and the Department. The EIS stated that these groups would receive a benefit from clear, concise, and understandable rules. The Department believed that the cost to a child participating in the Arizona Dental Sealant Program or the Arizona Fluoride Mouthrinse Program or the child’s parent would be minimal and that children receiving dental sealants or fluoride mouthrinse through the programs would benefit from better oral health as a result of tooth decay prevention. The parents of these children, participating schools, the general public, and the state's health care system would benefit from healthier Arizona children.

The EIS further stated that, during the 2005-2006 school year, the Department used approximately $290,000 from the Maternal and Child Health Block Grant and state funds for the programs and received approximately $240,000 in AHCCCS reimbursement for services provided to AHCCCS-enrolled children participating in the Arizona Dental Sealant Program. During the 2011-2012 school year, the Department used approximately $375,529 from the Maternal and Child Health Block Grant and state funds for the programs and received
approximately $241,136 in AHCCCS reimbursement for services provided to AHCCCS-enrolled children participating in the Arizona Dental Sealant Program.

The Department believes that the costs and benefits identified in this EIS are generally consistent with the actual costs and benefits of the rules.

12. Planned rulemaking action
The Department believes the rules are sufficient to protect public health and does not plan to amend the rules in 9 A.A.C. 23 unless a threat to public health or safety arises that would require amending the rules.

INFORMATION THAT IS IDENTICAL FOR GROUPS OF RULES

6. Analysis of clarity, conciseness, and understandability
The following rules contain minor grammatical or formatting errors that could reduce the clarity of the rules:
ARTICLE 1. DEFINITIONS

R9-23-101. Definitions

2. **Objective of the rule**
   The objective of the rule is to define terms used in the Chapter to enable the reader to understand clearly the requirements of the Chapter and allow for consistent interpretation.

3. **Analysis of effectiveness in achieving the objective**
   The rule is mostly effective in achieving its objective but would be more effective if the rule defined the “Arizona Dental Sealant Program” and “Arizona Fluoride Mouthrinse Program.”

6. **Analysis of clarity, conciseness, and understandability**
   The rule is mostly clear, concise, and understandable but could be clearer if the meaning of the term “in charge of” in subsection (2) were better explained and the definition of “dental sealant services” were removed, since the phrase is only used in R9-23-201(A) and could be described in that location.

ARTICLE 2. ARIZONA DENTAL SEALANT PROGRAM

R9-23-201. Application Process

2. **Objective of the rule**
   The objective of the rule is to specify the application requirements for participation in the Arizona Dental Sealant Program.

3. **Analysis of effectiveness in achieving the objective**
   The rule is mostly effective in achieving its objective but would be more effective if the rule required a school to provide the number of children in each grade in the school, rather than the number attending second and sixth grades. Although seven-to-eight-year-olds and eleven-to-twelve-year-olds, typically second and sixth grade students, are the target population for the Arizona Dental Sealant Program, many schools do not have both second and sixth grades. In addition, a small school may want to combine first or third grade students with second grade, or seventh grade students with sixth grade, to include a sufficient number of children in the pool of children eligible for participation.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is mostly clear, concise, and understandable but could be improved if, in addition to the issue described under *Information that is Identical for Groups of Rules*, the phrase “and receive dental sealant services” were removed from subsection (A) since a child, not a school, receives
dental sealant services. Alternatively, the phrase “for its students to” could be used before the word “receive.” The rule would also be improved if subsection (B) used the phrase “Department shall accept,” rather than “Department accepts.”

R9-23-202. Approval Criteria for Participation

2. Objective of the rule
   The objective of the rule is to specify the criteria used by the Department in determining whether to approve an application for participation in the Arizona Dental Sealant Program.

3. Analysis of effectiveness in achieving the objective
   The rule is mostly effective in achieving its objective but would be more effective if the rule included in the criteria the Department uses to determine whether to approve a school’s participation: the availability of resources, other than funding, for the Arizona Dental Sealant Program; and the number of children eligible for participation, rather than specifying a minimum number.

6. Analysis of clarity, conciseness, and understandability
   The rule is mostly clear, concise, and understandable but could be improved if, in addition to the issue described under Information that is Identical for Groups of Rules, the lead-in to the rule used the phrase “Department shall use ...”, rather than “Department uses.”

R9-23-203. Participation Requirements

2. Objective of the rule
   The objective of the rule is to specify the requirements for schools participating in the Arizona Dental Sealant Program.

3. Analysis of effectiveness in achieving the objective
   The rule is mostly effective in achieving its objective but would be more effective if the rule stated that the parental consent form indicated permission “for the child” to participate. The rule could also be improved by including a threshold for the number of children who have parental consent and are eligible to receive dental sealant services. In addition, the rule would be improved by requiring the consent form to include the school name, the identification number assigned to a participating school by the Department, and date of parent signature.

6. Analysis of clarity, conciseness, and understandability
   The rule is not clear, concise, and understandable because the rule states that the consent form is “on file at the school,” but a consent form is collected by the school and given to the
representatives of the Arizona Dental Sealant Program at the time the dental sealant services are provided.

ARTICLE 3. ARIZONA FLUORIDE MOUTHRINSE PROGRAM

R9-23-301. Application Process

2. **Objective of the rule**
The objective of the rule is to specify the application requirements for participation in the Arizona Fluoride Mouthrinse Program.

3. **Analysis of effectiveness in achieving the objective**
The rule is mostly effective in achieving its objective but would be more effective if the rule required a school to provide the estimated number of children in each grade in the school who would be participating in the Arizona Fluoride Mouthrinse Program, rather than the information in subsections (A)(4) and (5).

6. **Analysis of clarity, conciseness, and understandability**
The rule is mostly clear, concise, and understandable but could be improved if, in addition to the issue described under *Information that is Identical for Groups of Rules*, subsection (A)(7) specified the flavor and amount of fluoride mouthrinse a school was “requesting” and subsection (B) used the phrase “Department shall accept ...”, rather than “Department accepts.”

R9-23-302. Approval Criteria for Participation

2. **Objective of the rule**
The objective of the rule is to specify the criteria used by the Department in determining whether to approve an application for participation in the Arizona Fluoride Mouthrinse Program.

3. **Analysis of effectiveness in achieving the objective**
The rule is mostly effective in achieving its objective but could be more effective if subsection (4) specified that the water is “below optimally fluoridated levels,” since a fluoride rinse program would not be required in a community where the fluoride levels in the water are already above those recommended to prevent tooth decay.

6. **Analysis of clarity, conciseness, and understandability**
The rule is mostly clear, concise, and understandable but could be improved if, in addition to the issue described under *Information that is Identical for Groups of Rules*, the lead-in to the rule used the phrase “Department shall use ...”, rather than “Department uses.”
R9-23-303. Participation Requirements

2. **Objective of the rule**
   The objective of the rule is to specify the requirements for schools participating in the Arizona Fluoride Mouthrinse Program.

3. **Analysis of effectiveness in achieving the objective**
   The rule is mostly effective in achieving its objective but would be more effective if the rule stated how long a parental consent form was required to be maintained at a school, required the consent form to include a description of the program, and required permission “for the child” to participate. The rule would also be more effective if subsection (3) specified how to request fluoride mouthrinse.

R9-23-304. Continuing Participation

2. **Objective of the rule**
   The objective of the rule is to specify requirements related to a school’s continuing participation in the Arizona Fluoride Mouthrinse Program.

3. **Analysis of effectiveness in achieving the objective**
   The rule is not effective in achieving its objective. For a school continuing participation in the Arizona Fluoride Mouthrinse Program, the March 15 date in subsection (A) should be replaced with a requirement that the written program evaluation be submitted as part of documentation for continuing participation or application for a new three-year period. The Department accepts applications beginning on March 1 for the next school year. The rule could also specify requirements for submission of information for the current school year from a school that is discontinuing participation during the next school year. The rule could also be improved by including in the written program evaluation in subsection (A) the time period during which the school administered the program. Without requiring this information, it is unclear how the Department would evaluate whether to discontinue participation under subsection (B)(3). In addition, since the purpose of requiring the information in subsections (A)(10) and (11) is to ensure that the amount of fluoride mouthrinse being requested for the next school year takes into account the residual mouthrinse on hand at the school, the rule should be amended to require a school continuing its participation to specify the number of packets or boxes needed, number left over from the current school year, and number being requested.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is not clear, concise, and understandable but could be improved by amending subsection (A) to make clear that the written program evaluation is being required as part of documentation.
for continuing participation and by specifying in subsection (A)(6) whether the rule requires the reporting of only the grades that participated during the current school year or includes the grades that participated in previous years as well. It is also unclear how the requirements in subsection (B) could be “In addition to the requirements in R9-23-304” since they are part of this rule. Subsection (B)(2) should also be amended to add “during the current school year” to be consistent with subsection (A)(8). Subsection (C) could be clarified by specifying that it is the contact person for a school, rather than the school, that needs to apply under R9-23-301 at the end of the third year of participation.

11. **Analysis of burden and costs to persons regulated by the rule**

The issues described in paragraphs 1 and 5 make it more difficult for a person regulated by the rule to understand requirements and to comply with the rule. This would especially be true for a school that is discontinuing participation in the program.
FIVE-YEAR-REVIEW REPORT

TITLE 9. HEALTH SERVICES
CHAPTER 5. DEPARTMENT OF HEALTH SERVICES
CHILD CARE FACILITIES

DECEMBER 2012
FIVE-YEAR-REVIEW REPORT

TITLE 9. HEALTH SERVICES
CHAPTER 5. DEPARTMENT OF HEALTH SERVICES
CHILD CARE FACILITIES

1. FIVE-YEAR-REVIEW SUMMARY Page 3
2. TABLE OF IDENTICAL INFORMATION Page 4
3. INFORMATION THAT IS IDENTICAL FOR ALL THE RULES Page 6
4. INFORMATION THAT IS IDENTICAL FOR GROUPS OF RULES Page 14
4. INFORMATION FOR INDIVIDUAL RULES Page 15
5. CURRENT RULES Attachment A
6. GENERAL AND SPECIFIC STATUTES Attachment B
7. WRITTEN CRITICISM OF THE RULES Attachment C
Arizona Revised Statutes (A.R.S.) § 36-883 requires the Arizona Department of Health Services (Department) to “define and prescribe reasonable rules regarding the health, safety and well-being of the children to be cared for in a child care facility.” A.R.S. § 36-883.04 requires the Department to “prescribe reasonable rules and standards regarding the health, safety and well-being of children cared for in any public school child care program.”

Arizona Administrative Code (A.A.C.) Title 9, Chapter 5 contains rules for the licensing of child care facilities (“facilities”). The rules contain definitions, requirements for the licensing of a facility, facility administration requirements, facility staff requirements, facility program and equipment requirements, and requirements for the physical plant of a facility.

The Department’s previous five-year-review report for this Chapter was approved in 2008 and proposed amending the rules by January 2009. All rules in the chapter were amended by exempt rulemaking in 16 Arizona Administrative Register (A.A.R.) 1564, effective September 30, 2010, and two Sections were further amended by exempt rulemaking in 16 A.A.R. 2350, effective December 3, 2010.

Overall, the rules in Chapter 5 are effective, clear, concise, and understandable. The Department plans to conduct exempt rulemaking as required in Laws 2012, Ch. 188 by August 1, 2013 to add provisions to the Child Care Facilities rules requiring licensees to verify the status of employees with the Department of Economic Security’s (DES) Central Registry. In the course of this exempt rulemaking, the Department may address A.R.S. § 28-907, as amended by Laws 2012, Ch. 314, § 1. The Department does not plan to amend the remaining rules until further substantive issues arise.
TABLE OF IDENTICAL INFORMATION

This chart complies with the requirements of R1-6-111(B), which prescribes that information shall be provided only once for any group of rules for which the information on a particular issue is the same.

Paragraph Legend:
2. The rule is effective or mostly effective in achieving its objective.
3. The rule is consistent with listed state and federal statutes and other rules.
4. The Department enforces the rule as written.
5. The rule is clear, concise, and understandable.
6. The Department did not receive any written criticisms of the rule in the last five years.
7. No business competitiveness analysis for the rule has been received by the Department.
8. The Department completed the proposed course of action in its previous five-year-review report.
9. The rule imposes the least burden and costs upon stakeholders necessary to achieve its objective.
10. The rule relates to a state program and does not have a related federal law or rule with which to compare it for its degree of stringency.
14. A.R.S. §§ 36-881 through 36-893 require the licensure of child care facilities to specific individuals for facilities at specific addresses, so a general permit is not appropriate and is not used.

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6. **Analysis of clarity, conciseness, and understandability**

The rules are clear, concise, and understandable, but potentially could be improved in some instances by minor technical or grammatical adjustments.

8. **Analysis of estimated economic, small business, and consumer impact**

As discussed in the summary, the rules in Chapter 5 were most recently amended by exempt rulemakings, and no economic impact statement (EIS) was filed.

For fiscal year 2012, there were 204 new facilities opened during the year, and 235 licensing applications received. The Department approved a total of 950 applications for licensing, counting initial licenses, renewals, and amended licenses. The Department did not deny any applications, but 38 initial applications were withdrawn. At the end of the fiscal year, 70 applications were in a pending status awaiting the completion of licensing review. During the fiscal year, 253 facilities elected to close. In FY 2012, the Department performed 2034 regular annual inspections and 1008 complaint-based inspections on facilities. These figures are in addition to the inspection accompanying each application for licensing indicated above. The Department performed 119 enforcement actions, some of them consolidating multiple complaints. This is the lowest enforcement figure since the previous five-year-review report was approved, with enforcement actions totaling as low as 171 and as high as 194 since 2008. As of November 30, 2012, 21 enforcement actions have occurred in FY 2013, which began July 1, 2012.

The rules in Chapter 5 establish minimum health and safety standards for the licensing of facilities. Licensees are required by the rules to meet prescribed standards at all times. The Department believes that some degree of non-compliance by licensees may result from aspects of the rules that could be clarified, streamlined, or simplified. Through rulemaking, the Department hoped to minimize or eliminate non-compliance, if there is any, resulting from these factors. Any failure of a licensee to meet prescribed standards poses a threat to the welfare of an enrolled child.

The Department has identified as stakeholders the Department, entities that own or operate facilities (“businesses”), individuals employed by or at facilities (“employees”),
and members of the public (“consumers”), in particular enrolled children and their families. This analysis of estimated economic impact designates annual costs and benefits as minimal when less than $1,000; moderate when $1,000 to $10,000; and substantial when greater than $10,000. Costs and benefits are designated as significant when meaningful or important but not readily subject to quantification. Only costs resulting from the rulemaking are considered, rather than costs imposed by legislation, such as fee increases. In general, the rules imposed some new costs upon stakeholders while conferring benefits upon all stakeholders, as discussed in the following summary of economic impact:

All Articles
Change: All Sections – Streamlining, reorganization, and clarification of requirements. Reduced administrative requirements by deleting submission form and bookkeeping requirements where feasible, such as the Applicant, Staff, and Resident Report Form and Director’s Qualification Form in R9-5-201 and R9-5-207 and the change of child care services in R9-5-302; eliminating submission of proof of insurance in R9-5-308, the schedule or lesson plan in specified indoor spaces on the premises in R9-5-501, and information received from a parent about an enrolled child receiving medical treatment in R9-5-514; reduction of redundancy by use of an existing record from the Arizona State Immunizations System in R9-5-305; clarification of when Department approval is required before a facility takes action, such as implementation of a facility change under R9-5-208; and more examples too numerous to list here. Also includes corrections to cross-references and other technical changes with no additional economic implications other than the benefit of making the rules clearer and easier to use and thus reducing the difficulty of compliance.

Effect: The Department and businesses experienced a significant benefit, and this benefit may have been passed on to consumers in the form of lower costs if the reduced administrative burden freed up business resources to be allocated in other ways.

Change: R9-5-514 – Changed requirements for submission to the Department of information received from a parent about an enrolled child receiving medical treatment for an accident, injury, or emergency at the facility to documentation of the information maintained at the facility.

Effect: Businesses are believed to have experienced a minimal benefit.

Article 2. Facility Licensure
Change: R9-5-201 – Changed the age requirement for an applicant from age 18 to age 21.
Effect: Any potential applicants aged 18 to 20 were no longer able to apply for licensure, reducing the number of applications to an unknown extent (because the Department may never know about a party who might otherwise have applied and did not.) By definition, however, that number is either zero or a positive number. The Department is believed to have experienced no economic impact from the reduction in applicants, if any. Under previous statutes, licensing fees did not meet the full cost of Department oversight of licensees, so a reduction in licensee applications would have saved more money in operational costs than the amount not collected in licensing fees. However, due to the December 2010 rulemaking correlating licensing fees to oversight costs, there is no longer any economic disadvantage to the Department licensing additional facilities. Businesses may have experienced substantial economic impact from lost revenue if the business was owned by an individual aged 18 to 20 who intended to apply for licensure and could not, but in that case the business would also have experienced reduced costs from not operating a child care facility. Consumers are believed to have experienced no change in costs and a significant benefit of having slightly older and presumably wiser individuals licensed to operate facilities.

Change: R9-5-201 – Provided alternate floor plan and site plan requirements for facilities located in public schools, and added more options for showing that a building is safe for occupancy.
Effect: Businesses are believed to have experienced a none-to-moderate benefit from reduced administrative costs as a result of having additional ways to meet plan submission requirements.

Article 3. Facility Administration
Change: R9-5-301 – Added requirements for attendance record retention.
Effect: Businesses are believed to have experienced a minimal cost.

Change: R9-5-301 – Amended tuberculosis screening requirements consistent with recommendations from the Department’s screening program.
Effect: Businesses are believed to have experienced a minimal cost. Consumers are believed to have experienced a significant benefit from reduced exposure to disease.

Change: R9-5-301 – Added language allowing administration of prescription medications that may be defined as controlled substances or dangerous drugs, in the manner prescribed.
Effect: Businesses are believed to have experienced a significant benefit by gaining the flexibility to care for enrolled children who may need to be administered such medications. Consumers are believed to have experienced a significant benefit by having the option of enrolling a child at a facility knowing the child could receive certain prescription medications while attending the facility.
Change: R9-5-301 – Added a requirement for a licensee to provide parents each September with information related to the recommendations for influenza vaccinations for children.
Effect: Businesses are believed to have experienced a minimal cost.

Change: R9-5-301 – Consolidated administrative requirements, including restricting a staff member’s presence in the facility during an outbreak of disease if the staff member does not have proof of immunity to the disease and licensee notification of the Department if a child dies at the facility during hours of operation.
Effect: Businesses are believed to have experienced no economic impact from this change.

Change: R9-5-302 – Added a requirement for the facility’s address and telephone information to appear on the statement of child care services.
Effect: Businesses are believed to have experienced no cost or a minimal cost, because this information was often, but not always, present on the statement of child care services even when not required. Consumers are believed to have experienced a significant benefit from improved reference and identification of the facility in which their child is enrolled.

Article 4. Facility Staff
Change: R9-5-401 – Three changes: Added teacher-caregiver aide as a category of staff and as a way to qualify for becoming an assistant teacher-caregiver, added that serving as a volunteer at a child care facility for 12 months would also fulfill one of the requirements to become an assistant teacher-caregiver, and changed the age requirement for a volunteer from 16 to 15 years old.
Effect: Businesses are believed to have experienced no benefit to a moderate benefit, depending whether the business utilized the availability of additional staff members in cases where such a staff member would not have qualified to be an assistant teacher-caregiver under the previous rules. Employees are believed to have experienced moderate to substantial benefit if qualifying as a teacher-caregiver aide allowed an employee who did not qualify as an assistant teacher-caregiver to work at a child care facility. Consumers are believed to have experienced a minimal benefit in cases where the offered price of child care was more competitive as a result of a child care facility being able to utilize employees at a lower qualification level while still meeting the Department’s standards of health and safety.

Change: R9-5-403 – Increased training requirements from 12 to 18 hours per year, and added requirements for training in specific subjects dependent on experience or job duties.
Effect: Businesses are believed to have experienced none or minimal costs. Because of common practices within the child care industry, many facilities were already training staff on the subject
areas added to the requirements, and training to proficiency for normal operations for a staff member could already take more than 12 hours per year. For a business that limited training to the bare minimum required, there could be additional costs to provide more training in accordance with the rule. Also, an extensive amount of web-based training in the required subject areas is available online free of charge.

Article 5. Facility Program and Equipment

Change: R9-5-501 – Added a requirement that the schedule and lesson plan be implemented.
Effect: Businesses that implemented the schedule and lesson plan are expected to have experienced no economic impact from this change. Most facilities are believed to have been in this category as it seems intuitive and obvious that a schedule and lesson plan are made to be implemented. However, some facilities in the past have created schedules and lesson plans to meet the literal requirement but not implemented them. For businesses so situated, the economic impact could have been a cost of any degree from minimal to substantial, depending on the facility’s size and scope of operations.

Change: R9-5-502 – Added a requirement that a facility develop policies and procedures for an infant to spend time on the infant’s stomach, for placing an infant on an infant’s back to sleep, restricting use of positioning devices for sleeping infants, requiring sanitary feeding, and prohibiting screen time in an infant room.
Effect: Businesses are expected to have experienced none to minimal costs, because infant “tummy time,” infants sleeping on their backs, particulars on the use of positioning devices, sanitary feeding, and infant rooms without screen time were already best practices within the child care industry and many facilities already had such procedures in place, and for those that may not have, the additional logistics were not especially cumbersome. Consumers are expected to have experienced a significant benefit from improved health and safety for infants.

Change: R9-5-504 – Prohibited screen time for a one-year-old.
Effect: Businesses are expected to have experienced none to minimal costs, because for any facility not already eliminating screen time for a one-year-old, the incremental additional logistics of staff supervision were not especially cumbersome.

Change: R9-5-507 – Added requirements related to usage of wheelchairs in a motor vehicle.
Effect: Businesses are expected to have experienced no costs in most cases as many facilities do not have any enrolled children who use wheelchairs. Most facilities that do have enrolled children who use wheelchairs already adhered to the requirements as best practices. Any facility that had
an enrolled child who used a wheelchair that did not already adhere to the requirements could have incurred up to a moderate cost to do so.

Change: R9-5-509 – Added a requirement that a facility obtain a food establishment permit if required by the local health department.
Effect: Businesses are believed to have experienced none or a minimal cost due to the additional administrative burden.

Change: R9-5-509 – Added a provision allowing single-use paper towels for washing a child’s hands.
Effect: Businesses are believed to have experienced minimal to substantial benefits from being able to use less expensive textiles.

Change: R9-5-509 – Added requirements related to family-style meals.
Effect: Businesses are believed to have experienced none to moderate benefits from the economy of scale offered by family-style meal service.

Change: R9-5-509 – Added a provision that a child’s parent may request the type of milk provided to the child.
Effect: Consumers are believed to have experienced a significant benefit.

Change: R9-5-509 – Added minimum food service requirements consistent with recommendations by Department sanitation personnel.
Effect: Businesses are believed to have experienced none to moderate costs, depending on the degree to which a facility’s food service processes were already sanitary and consistent with the new requirements.

Change: R9-5-512 – Added a provision allowing hand-washing sinks outside a toilet room if an enrolled child can access the sink without crossing space used for an activity.
Effect: Businesses are believed to have experienced no benefit or up to a substantial benefit, with the typical contractor rate to construct a restroom in a commercial space exceeding $10,000 in some instances as of August 2012. For businesses that could meet the requirement with modification of existing fixtures but now do not face that cost, the savings would be less.

Change: R9-5-516 – Added a provision to allow medication for an individual’s life-threatening symptoms to be in the activity area where the individual is present, but inaccessible to enrolled children.
Effect: Businesses and consumers are believed to have experienced a significant benefit. For businesses, the benefit is practical, while for consumers, any better accessibility to medicine for staff or an enrolled child represents improved health and safety.

Change: R9-5-518 – Added a provision requiring a written field trip plan to be taken on a field trip.
Effect: Businesses are believed to have experienced a minimal cost due to the added administrative burden.

Article 6. Physical Plant of a Facility
Change: R9-5-601 – Added a provision exempting activity areas used only for food service or for a specific activity for children older than 2 years of age from the requirement for having a diaper changing area.
Effect: Businesses are believed to have experienced no benefit or a minimal to moderate benefit based on the potential elimination of the incremental cost of building a diaper changing area in a given activity area during facility buildout. Consumers may have experienced a minimal or greater benefit if the cost abatement to businesses resulted in more competitive pricing.

Change: R9-5-602 – Consolidated provisions involving outdoor activity area requirements, substituting indoor for outdoor activity areas, and clarifying that impact-protective ground cover requirements still apply when an indoor activity area is substituted.
Effect: Businesses are believed to have experienced no benefit or a minimal to moderate benefit based on the elimination of duplicative requirements and the consolidation of requirements that existed before but were unintuitive because it was unclear that they applied even in cases where an indoor activity area was substituted. Consumers may have experienced a minimal or greater benefit if the cost abatement to businesses resulted in more competitive pricing.

Change: R9-5-603 – Prohibited outdoor play equipment from being located in the fall zone of another piece of outdoor play equipment.
Effect: Businesses are believed to have experienced no cost in most cases, but may have incurred a minimal to moderate cost to relocate outdoor play equipment if such equipment was already installed in a manner not meeting the requirement. Businesses that already had clear fall zones surrounding outdoor play equipment as an industry best practice would not have incurred any cost. Consumers are believed to have experienced a significant benefit from increased safety.

Change: R9-5-605 – Added an exemption from the requirement for outlet covers for activity areas used only by school-aged children.
Effect: Businesses are expected to have experienced a minimal benefit from cost reduction.

Change: R9-5-605 – Added requirements for smoke detectors and sprinkler systems.
Effect: Businesses are believed to have experienced no cost or up to a moderate cost. Local jurisdictions often require fire detection and suppression fixtures in ordinance, so a facility already required by local law to have smoke detectors or a sprinkler system in place would experience no cost from this change, while a business that had to install one or both to meet the requirement could have incurred up to a moderate cost to do so. Consumers are believed to have experienced a significant benefit from increased safety.

Change: R9-5-605 – Added documentation requirements for smoke detector testing, sprinkler system testing and servicing, and fire extinguisher testing.
Effect: Businesses are believed to have experienced a minimal administrative cost.

There is no direct effect on public or private employment from the rulemaking. Indirectly, if reduced costs help licensees to realize greater revenue, licensees may be able to expand their businesses and thus employ more individuals, while increased costs may have the opposite effect.

The Department believes that many licensees are small businesses as defined in A.R.S. § 41-1001, and of those that are not, most such entities are chains operating multiple child care facilities and as such perform operations at the customer level in a manner effectively the same as if they were small businesses. The rules impose administrative and other costs on small businesses, as discussed in the summary, but the 2010 rulemaking consolidated and simplified compliance and reporting requirements throughout Chapter 5, and these changes generally applied to all licensees. Facilities are required to maintain reasonable standards for the health and safety of enrolled children at all times. The compliance and reporting requirements in rule are established accordingly, and apply to all licensees. The Department does not believe that any further reduction in the cost or stringency of compliance or reporting is possible at this time, and believes that it would be inappropriate to establish separate performance standards for small businesses or exempt small businesses from having to meet minimum requirements to protect the health and safety of enrolled children. There are no schedules or deadlines for compliance because maintaining minimum standards for the health and safety of enrolled children is an ongoing requirement.
The licensing fees imposed by the rules result in a 10% portion of collections being deposited to the state general fund. Licensing fees fund the Department’s administrative activities under Chapter 5.

**INFORMATION THAT IS IDENTICAL FOR GROUPS OF RULES**

4. **Analysis of consistency with listed state and federal statutes and rules**
   Laws 2012, Ch. 188 requires the Department to engage in exempt rulemaking by August 1, 2013 to add provisions to the Child Care Facilities rules requiring licensees to verify the status of employees with the Department of Economic Security’s (DES) Central Registry. The Central Registry is a confidential database maintained by DES of substantiated reports of child abuse and neglect. The Department’s preliminary evaluation of the requirements in Laws 2012, Ch. 188 indicates that amending R9-5-203 and R9-5-402 may meet the legislative requirements. Provided the Department completes the exempt rulemaking by August 1, 2013, R9-5-203 and R9-5-402 will remain consistent with listed state and federal statutes and rules.

5. **Enforcement of the rules**
   For the reasons described in paragraph #4 above, if the Department completes an exempt rulemaking by August 1, 2013, R9-5-203 and R9-5-402 will continue to be enforced as written. If the Department does not amend the two sections accordingly, the Department will most likely enforce the statutory requirements enacted in Laws 2012, Ch. 188, as they are more stringent than the rules.

12. **Proposed course of action**
   Overall, the rules in Chapter 5 are effective, clear, concise, and understandable. The Department plans to conduct exempt rulemaking as required in Laws 2012, Ch. 188 by August 1, 2013 to add provisions to the Child Care Facilities rules requiring licensees to verify the status of employees with the Department of Economic Security’s (DES) Central Registry. In the course of this exempt rulemaking, the Department may address A.R.S. § 28-907, as amended by Laws 2012, Ch. 314, § 1. The Department does not plan to amend the remaining rules until further substantive issues arise.
INFORMATION FOR INDIVIDUAL RULES

R9-5-101. Definitions
2. Objective
The objective of the rule is to define terms used in the Chapter so that a reader can consistently interpret requirements in the Chapter.

R9-5-102. Individuals to Act for Applicant or Licensee Regarding Document, Fingerprinting, and Department-provided Training Requirements
2. Objective
The objective of the rule is to identify the individuals who are required to act in representation of an applicant or licensee when the Chapter requires the applicant or licensee to provide information to the Department, a signature, a fingerprint clearance card, or Department-provided training.

R9-5-201. Application for a License
2. Objective
The objective of the rule is to establish:
   a. Requirements for an entity to apply for a license to operate a child care facility,
   b. When a separate license is required for entities operating multiple or shared locations, and
   c. The criteria by which multiple structures may be encompassed within a single facility license.

R9-5-202. Time-frames
2. Objective
The objective of the rule is to establish administrative provisions related to licensing time-frames, such as application deadlines.

Table 2.1. Time-frames (in days)
2. Objective
The objective of the rule is to present a tabular chart of the time-frames in R9-5-202.
R9-5-203. **Fingerprinting Requirements**

2. **Objective**
   
The objective of the rule is to establish requirements for a facility to have and maintain in its records valid fingerprint clearance cards for the facility’s staff members.

R9-5-204. **Child Care Service Classifications**

2. **Objective**
   
The objective of the rule is to require a facility to classify service categories according to the applicable characteristics of enrolled children and notify consumers of the classifications.

R9-5-205. **Submission of Licensure Fees**

2. **Objective**
   
The objective of the rule is to establish fee submission requirements for licensees.

R9-5-206. **Licensure Fees**

2. **Objective**
   
The objective of the rule is to establish licensure fees for child care facility licenses, including provisions for fee applicability and discounting.

R9-5-207. **Invalid License**

2. **Objective**
   
The objective of the rule is to inform a licensee what will happen if the licensee does not submit the required fee as specified in R9-5-205.

R9-5-208. **Changes Affecting a License**

2. **Objective**
   
The objective of the rule is to:
   
a. Establish requirements and provisions for a licensee to submit applicable information to the Department to change an existing facility license,
   
b. Establish how the Department will review a request for a change in a facility license,
   
c. Prohibit licensees from implementing a change until the Department has issued an approval or amended license, and
d. Establish other requirements for submission of materials applicable to specific changes that a licensee may request for a facility’s license.

R9-5-209. Inspections; Investigations
2. **Objective**
The objective of the rule is to establish requirements for licensees to cooperate with and provide appropriate access to the Department for inspections and investigations.

R9-5-210. Denial, Revocation, or Suspension of License
2. **Objective**
The objective of the rule is to inform a licensee of the criteria by which the Department may deny, revoke, or suspend a license.

R9-5-301. General Licensee Responsibilities
2. **Objective**
The objective of the rule is to establish requirements for a licensee with regard to a facility’s facility director, facility policies and procedures, access to and supervision of applicable individuals, emergency evacuation drills, and related matters.

R9-5-302. Statement of Child Care Services
2. **Objective**
The objective of the rule is to require a licensee to prepare a written statement of child care services containing specified items and to disseminate the statement to specified parties at established times.

R9-5-303. Posting of Notices
2. **Objective**
The objective of the rule is to establish requirements for a licensee to post specified information in specified locations in a facility.

R9-5-304. Enrollment of Children
2. **Objective**
The objective of the rule is to establish requirements for a licensee for the enrollment of children at a facility to receive child care services.
R9-5-305. Child Immunization Requirements

2. Objective
   The objective of the rule is to establish requirements for when a licensee must exclude an enrolled child from attending a facility and the applicable documentation.

R9-5-306. Admission and Release of Children; Attendance Records

2. Objective
   The objective of the rule is to establish requirements for:
   a. When and how a licensee may admit or release an enrolled child,
   b. Additional procedures required when admitting or releasing an enrolled child, and
   c. Applicable documentation.

R9-5-307. Suspected or Alleged Child Abuse or Neglect

2. Objective
   The objective of the rule is to require a licensee to document and report all suspected or alleged cases of child abuse or neglect.

R9-5-308. Insurance Requirements

2. Objective
   The objective of the rule is to establish requirements for a licensee to maintain and make available documentation of insurance coverage for the facility and any applicable motor vehicles.

R9-5-309. Gas and Fire Inspections

2. Objective
   The objective of the rule is to establish requirements for a licensee to obtain and document inspection and repair of gas and fire fixtures and equipment at a facility.

R9-5-310. Pesticides

2. Objective
   The objective of the rule is to require a licensee to notify a parent about pesticide application in accordance with the provisions in A.R.S. § 36-898.
R9-5-401. **Staff Qualifications**

2. **Objective**
   The objective of the rule is to establish the qualifications required for each category of staff members at a facility.

R9-5-402. **Staff Records and Reports**

2. **Objective**
   The objective of the rule is to establish requirements for a licensee to maintain and produce upon Department request a file containing specified contents for each staff member at the facility.

R9-5-403. **Training Requirements**

2. **Objective**
   The objective of the rule is to establish requirements for the completion and documentation of training for the staff members of a facility.

R9-5-404. **Staff-to-Children Ratios**

2. **Objective**
   The objective of the rule is to establish how many and what type of staff members a licensee is required to have supervising a specified number of enrolled children in specified locations or conditions.

R9-5-501. **General Child Care Program, Equipment, and Health and Safety Standards**

2. **Objective**
   The objective of the rule is to establish program, equipment, and health and safety requirements that apply to the entirety of a facility.

R9-5-502. **Supplemental Standards for Infants**

2. **Objective**
   The objective of the rule is to establish program, equipment, and health and safety requirements that apply to specified locations or conditions involving enrolled children who are infants.
R9-5-503.  Standards for Diaper Changing

2.  Objective
The objective of the rule is to establish safety and sanitary requirements for diaper changing at a child care facility.

R9-5-504.  Supplemental Standards for 1-year-old and 2-year-old Children

2.  Objective
The objective of the rule is to establish program, equipment, and health and safety requirements that apply to specified locations or conditions involving enrolled children who are one or two years of age.

R9-5-505.  Supplemental Standards for 3-year-old, 4-year-old, and 5-year-old Children

2.  Objective
The objective of the rule is to establish program, equipment, and health and safety requirements that apply to specified locations or conditions involving enrolled children who are three, four, or five years of age.

R9-5-506.  Supplemental Standards for School-age Children

2.  Objective
The objective of the rule is to establish program, equipment, and health and safety requirements that apply to specified locations or conditions involving enrolled children who are school-age children.

R9-5-507.  Supplemental Standards for Children with Special Needs

2.  Objective
The objective of the rule is to establish program, equipment, and health and safety requirements that apply to specified locations or conditions involving enrolled children who are children with special needs.

6.  Analysis of clarity, conciseness, and understandability
The rule is mostly clear, concise, and understandable, but could be improved if subsection (A) were rephrased to more explicitly state that an individualized plan “implemented by the licensee when providing child care services” is not considered the
same plan as an individualized education plan or “IEP” typically used for educational accommodation of a child with special needs. Some school districts have been unable to provide copies of an enrolled child’s individualized plan to the Department, citing requirements in the federal Family Educational Rights and Privacy Act (FERPA), 20 USC § 1232g that an IEP be kept confidential. While the FERPA provides exceptions to its IEP confidentiality requirements, none appear applicable to an individualized plan with the characteristics indicated in the requirements in subsection (A) of the rule. The interchangeable use of the abbreviation “IEP” by Department staff and licensees alike in colloquial reference to either type of plan may contribute to the difficulty in distinction. The individualized plan required by the Department for child care contains no educational elements and should not fall within any requirements of FERPA, so the rule would be improved by more clearly differentiating it.

R9-5-508. General Nutrition Standards

2. Objective
The objective of the rule is to establish requirements specifying the meal serving times, meal types, and additional provisions for meals at a facility.

Table 5.1. Meal Pattern Requirements for Children

2. Objective
The objective of the rule is to establish requirements specifying meal contents at a facility.

R9-5-509. General Food Service and Food Handling Standards

2. Objective
The objective of the rule is to establish safety and sanitary requirements for meal service at a facility, including provisions for permit credentialing, food ingredients and preparation, and food storage.

R9-5-510. Discipline and Guidance

2. Objective
The objective of the rule is to establish requirements for the safe and appropriate administration of corrective actions to an enrolled child.
R9-5-511. Sleeping and Napping
2. **Objective**
   The objective of the rule is to establish safety, sanitary, and supervision requirements for enrolled children sleeping and napping at a facility, including provisions for maintenance and storage of related items.

R9-5-512. Cleaning and Sanitation
2. **Objective**
   The objective of the rule is to establish environmental requirements and sanitary procedures for a facility.

R9-5-513. Pets and Animals
2. **Objective**
   The objective of the rule is to establish requirements that apply to pets or animals present at a facility.
7. **Written criticism of the rule received in the last five years**
   **Criticism:** Subsection (B)(2) requires a licensee to ensure that a staff member “[p]rohibits reptiles, such as turtles, iguanas, snakes, and lizards, in the facility.” The Department received written criticism (included in this report as Attachment C) asking for the rule prohibiting reptiles to be changed.
   **Response:** The Department will evaluate the feasibility of a change to the rule the next time the Department conducts rulemaking in accordance with A.R.S. Title 41, Chapter 6, Article 3.

R9-5-514. Accident and Emergency Procedures
2. **Objective**
   The objective of the rule is to establish requirements for:
   a. A facility’s first-aid kit;
   b. A facility’s fire and emergency plan and evacuation plan;
   c. A facility’s communications system;
   d. Reporting and documentation of accidents, injuries, or emergencies at a facility and notification of other appropriate parties; and
   e. Reporting and documentation of accidents, injuries, or emergencies involving an enrolled child not occurring at a facility.
R9-5-515. Illness and Infestation

2. **Objective**

The objective of the rule is to establish requirements regarding the exclusion, documentation of the exclusion, and reporting of the exclusion of an individual from the facility because of an illness or infestation.

R9-5-516. Medications

2. **Objective**

The objective of the rule is to establish requirements regarding the storage, administration, and documentation of administration of medication at a facility.

R9-5-517. Transportation

2. **Objective**

The objective of the rule is to establish requirements for:

a. Motor vehicles kept at or used by the facility, and

b. The transportation of enrolled children of a facility.

4. **Analysis of consistency with listed state and federal rules and statutes**

Subsection (A)(8) requires a licensee to use “a child passenger restraint system, as required by A.R.S. § 28-907, for each enrolled child who is younger than five years old.” Laws 2012, Ch. 314, § 1 amended A.R.S. § 28-907 to require the use of a child passenger restraint system additionally for a child “who is at least five years of age, who is under eight years of age and who is not more than four feet nine inches tall.” The Department enforces subsection (A)(8) consistent with statute. The remainder of the rule is consistent with listed state and federal rules and statutes.

5. **Enforcement of the rules**

For the reasons described in paragraph #4 above, the Department enforces subsection (A)(8) consistent with statute. The remainder of the rule is enforced as written.

11. **Analysis of whether the rule imposes the least burden and costs to stakeholders**

The rule may not impose the least burden upon stakeholders because of issues discussed in paragraphs #4 and #5. The burden results from any time or cost incurred by the stakeholder to reconcile the requirements in the rules with the requirements of other listed state and federal statutes and rules, where undergoing such time and cost would not be necessary if the rules were consistent.
R9-5-518. Field Trips

2. **Objective**
   The objective of the rule is to establish requirements for field trips involving the enrolled children of a facility.

R9-5-601. General Physical Plant Standards

2. **Objective**
   The objective of the rule is to establish physical plant construction, maintenance, and safety requirements that apply to the entirety of a child care facility.

R9-5-602. Facility Square Footage Requirements

2. **Objective**
   The objective of the rule is to establish requirements for:
   a. The square footage per enrolled child required for a facility based on the facility’s classification,
   b. The method of computing square footage,
   c. The substitution or allocation of indoor or outdoor square footage for an activity area for a facility that does not have or is not using its exterior space to meet outdoor activity area requirements, and
   d. Department approval of a substitution or allocation by a facility.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is mostly clear, concise, and understandable, but could be improved if subsection (C) were rephrased to make it clearer that if a facility’s total capacity is limited based on outdoor space to, for example, 25 enrolled children, the facility cannot have more than 25 children inside the facility even if there are no children outside, regardless of whether the facility’s indoor square footage would otherwise qualify it for a capacity higher than 25 enrolled children.

R9-5-603. Outdoor Activity Areas

2. **Objective**
   The objective of the rule is to establish the construction, maintenance, and safety requirements of an outdoor activity area at a facility.
R9-5-604.   **Swimming Pools**

2. **Objective**

   The objective of the rule is to establish the physical plant construction, maintenance, and safety requirements of a swimming pool at a facility.

R9-5-605.   **Fire and Safety**

2. **Objective**

   The objective of the rule is to establish requirements for:
   
   a. A facility’s fire detection and suppression equipment;
   
   b. Fixtures, appliances, and other items relevant to the fire safety practices of a facility; and
   
   c. Documentation of a facility’s fire safety compliance.

3. **Analysis of effectiveness of the rule**

   The rule is mostly effective, but could be improved if subsection (B) allowed the non-mounted use of fans that do not present a bare-blade hazard, such as bladeless magnetic induction fans and “tower” form-factor fans in which the blades are not externally accessible. The Department will assess at the time of any future rulemaking whether this is a prudent and feasible change.
FIVE-YEAR-REVIEW REPORT

TITLE 9. HEALTH SERVICES
CHAPTER 21. DEPARTMENT OF HEALTH SERVICES
BEHAVIORAL HEALTH SERVICES FOR PERSONS WITH SERIOUS MENTAL ILLNESS

JULY 2013
FIVE-YEAR-REVIEW REPORT

TITLE 9. HEALTH SERVICES
CHAPTER 21. DEPARTMENT OF HEALTH SERVICES
BEHAVIORAL HEALTH SERVICES FOR PERSONS WITH
SERIOUS MENTAL ILLNESS

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Arizona Revised Statutes (A.R.S.) §§ 36-104(3), 36-136(A)(7), 36-136(F), 36-502(A), 36-550.01(C), 36-3402, and 36-3403(A)(4) authorize the creation of the Division of Behavioral Health Services (“DBHS”) within the Arizona Department of Health Services (“ADHS” or the “Department”) and the promulgation of rules governing the provision of services to individuals with serious mental illness.

Arizona Administrative Code (A.A.C.) Title 9, Chapter 21 contains rules governing the provision of services to individuals with serious mental illness. The rules were adopted in 1992 by exempt rulemaking under Laws 1992, Ch. 301, § 61. Portions of 9 A.A.C. 21 were amended under the same exemption and became effective September 30, 1993. Portions of 9 A.A.C. 21 were further amended by exempt rulemaking in 2001 under Laws 2000, Ch. 261, § 3 and again amended by another exempt rulemaking in 2003 under Laws 2001, Ch. 367 (SB 1353).

The rules in 9 A.A.C. 21 were originally developed based on a stipulation reached in the lawsuit Arnold v. Sarn, Maricopa County No. C-432355. Arnold was a class-action lawsuit against the state and Maricopa County alleging failure to provide adequate mental health care to certain indigent, chronically mentally ill persons. The Arizona Supreme Court upheld the trial court’s ruling that the Department breached its statutory duty to provide a broad range of care to the class members. The Arnold v. Sarn Joint Stipulation on Exit Criteria and Disengagement (“Exit Agreement”) is included in this report as Attachment D.

The Department’s DBHS administers a statewide comprehensive mental health system including the Arizona State Hospital, a community-based residential and mental health system, and programs for addictive behaviors such as alcohol or drug abuse. DBHS and Maricopa County are also responsible for implementing the Exit Agreement from Arnold v. Sarn.

Since the previous five-year-review report on Chapter 21 was approved in early 2009, several legislative and judicial actions have occurred. In most cases the legislative actions amounted to syntax changes or provisions not affecting the substantive effect of the statute(s) amended. Legislation with substantive implications is addressed in this report. However, following a state budget crisis from 2009 to 2011 and legislative budget prerogatives, the Department and the Arnold Plaintiffs jointly stipulated to stay litigation and related Arnold orders, reflected in an
order dated March 9, 2010, (the “2010 Court Order”), and a successor agreement effective July 1, 2012 (the “2012 Agreement”). Both are included in this report as Attachments E and F, respectively. The 2012 Agreement terminates June 30, 2014, unless extended before that date. For reasons discussed below, the existence of the agreements affects the rules in 9 A.A.C. 21.

Overall, although some of the rules in Chapter 21 are functional in and of themselves, the rules taken in their totality are not effective; not clear, concise, or understandable; in many cases unenforceable; too-often ultra-detailed or process-oriented in a manner that inhibits service providers from adapting to changing models of service delivery; inconsistent with other statutes and rules; and otherwise inadequate or confusing as described in this five-year-review report. The necessity of adapting the service delivery process to new developments in the behavioral health industry while overcoming deficiencies in the rules has given rise to a labyrinthine library of policies and procedures that have become increasingly convoluted with each passing year. The Department believes rewriting the rules in 9 A.A.C. 21 is necessary to ensure that individuals with serious mental illness are provided services in accordance with statutory authority, in a functional, properly structured system, and in a manner that adequately safeguards clients’ rights.

The Exit Agreement contained a broad limitation on Departmental rulemaking, as follows:

Notwithstanding anything herein to the contrary, the Department may propose a modification of its rules at any time provided that such modifications do not impair the rights of class members or substantially undermine the principles or the purposes of those provisions of the Implementation Plan… unless agreed to by the Monitor. [Attachment D, page 4.]

In practice, virtually any modification could be interpreted by the Court Monitor as “impair[ing] the rights of class members or substantially underm[ining] the principles or purposes of […] the Implementation Plan.” As such, the Department refrained from commencing with a rulemaking on its own initiative, instead proposing that it would collaborate with the Court Monitor to amend the rules by January 2012. As described in this report, that rulemaking never occurred. Because the 2012 Agreement requires instead the Department’s best efforts in implementation of rules, rather than a proscriptive limitation on rulemaking, the Department has the discretion to proceed with rulemaking under A.R.S. Title 41, Chapter 6. Accordingly, the Department plans to conduct rulemaking for 9 A.A.C. 21, and because of the substantial allocation of staff and resources expected to be necessary to complete the rulemaking, the Department plans to file a Notice of Final Rulemaking with the Governor’s Regulatory Review Council by December 31, 2016.
TABLE OF IDENTICAL INFORMATION

This chart complies with the requirements of R1-6-111(B), which prescribes that information shall be provided only once for any group of rules for which the information on a particular issue is the same.

Paragraph Legend:
1. General authority: A.R.S. §§ 36-104(3), 36-136(F), 36-502(A), 36-550.01(C), and 36-3403(A)(4).
3. The rule is effective or mostly effective.
4. The rule is consistent with referenced state and federal statutes and other rules.
5. The Department enforces the rule as written.
6. The rule is clear, concise, and understandable.
7. The Department did not receive any written criticisms of the rule in the last five years.
9. The Department did not receive any business competitiveness analysis for the rule.
10. The Department did not complete the proposed course of action in its previous five-year-review report.
11. The rule imposes the least burden and costs upon stakeholders necessary to achieve its objective.
14. The rules govern operation of a program providing services and do not establish licensing, certification, or permit requirements. Accordingly, there is no instance in the rules where a general permit or other permit is administered.

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4. **Analysis of consistency with referenced state and federal statutes and rules**

Laws 2010, Ch. 272 changed language in A.R.S. §§ 36-501, 36-514, and other statutes not relating to rulemaking authority over Chapter 21, with the following effects:

a. “Psychiatric and mental health nurse practitioner” is defined to mean “a registered nurse practitioner as defined in section 32-1601 who has completed an adult or family psychiatric and mental health nurse practitioner program and who is certified as an adult or family psychiatric and mental health nurse practitioner by the State Board of Nursing.”

b. The definitions of “admitting officer,” “independent evaluator,” and “professional” are expanded to include psychiatric and mental health nurse practitioners, where previously only physicians and other specified health professionals met the definition.

Throughout the Chapter, as a result of Laws 2010, Ch. 272, some functions that the rules were promulgated on the assumption a physician would be performing, may be performed instead by a psychiatric and mental health nurse practitioner.

Laws 2012, Ch. 334 changed language in A.R.S. §§ 36-501, 36-526, 36-540, 36-542, 36-543, and other statutes not relating to rulemaking authority over Chapter 21, with the following effects that relate to enforcement of the Chapter and have implications throughout:

a. The definition of “evaluation” has been expanded to include observations made via remote interactive audiovisual media.

b. The definition of “examination” has been struck and its characteristics included in the definition of “evaluation.”

c. An evaluation an appropriate health professional performs on a person presenting for admission or being discharged is specified to include the person’s psychiatric and physical condition.

d. Multiple new requirements exist for reporting on the status of a patient being treated under an expiring court order.

e. Multiple new due process requirements are imposed upon providers, and due process rights attach to a patient.
5. **Enforcement of the rule**

Entries specific to particular rules are included in this report in the information for individual rules. Overall, however, the rules are focused on ensuring that a process is carried out, not on achieving a positive outcome for a client. In practice, providers place achieving a positive outcome for a client as the prevailing concern. Accordingly, the Department takes outcomes into context when assessing provider compliance, rather than enforcing the rules literally in all cases.

Throughout the Chapter, as a result of Laws 2010, Ch. 272, some functions that the rules were promulgated on the assumption a physician would be performing, may be performed instead by a psychiatric and mental health nurse practitioner. The Department enforces such provisions consistent with statute in any case where a conflict arises.

The changes implemented by Laws 2012, Ch. 334 are enforced consistent with statute in any case where a conflict arises or, as is more likely, in any case where the current rules simply do not reach the substantive matter encompassed by the statutory changes.

6. **Analysis of clarity, conciseness, and understandability of the rule**

In addition to issues discussed elsewhere in this report for particular rules, the Chapter as a whole is not clear, concise, and understandable. The rules in 9 A.A.C. 21 are replete with undefined words or phrases that are ambiguous, vague, or industry jargon. The rules are confusing to the average person and especially confusing for those behavioral health clients desiring to act as their own advocates.

7. **Summary of written criticisms of the rules**

The Department did not solicit in the last five years, and did not receive, any written criticisms of the rules. The Department did and does receive appeals, pleadings, and other adjudicatory actions on a regular basis in litigation. However, the Department does not include such material here because such material is more accurately characterized as a criticism of the Department’s, or a subcontractor’s, implementation of the rules on a specific case basis than as a criticism of the rules in and of themselves on the basis of general applicability.

8. **Analysis of estimated economic, small business, and consumer impact**

The analysis of the rules’ economic, small business, and consumer impact is included in this report as Attachment C.

9. **Status of the completion of action indicated in the previous five-year-review report**

In its 2008 five-year-review report for 9 A.A.C. 21, the Department proposed to collaborate with stakeholders and the Court Monitor to develop rules amendments that
would meet the requirements of the Exit Agreement. The Department anticipated submitting final rulemaking to GRRC by January 2012. However, in the interim, the state government imposed a hiring freeze, the Department’s staff of rules analysts decreased from 13 FTEs to 5 FTEs, and multiple consecutive rules moratoria went into effect. Further, available resources in general were allocated to legislatively mandated rulemakings and Five-year-review Reports for which the Department was required to finish in a discrete time-frame. Accordingly, the Department has been precluded from, and unable to allocate resources in any case to, developing rules amendments for 9 A.A.C. 21 as originally proposed in 2008.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

The rules govern operation of a state program that provides behavioral health services to individuals with serious mental illness. The operation of this program is required under the statutory authority identified in this report and the Exit Agreement and its successor agreements. The economic analysis in attachment C indicates the amount of state and federal funds spent to operate the program, and the number of clients served thereby.

Although several rules do not impose the least burden and costs to stakeholders necessary to achieve the underlying regulatory objective, as discussed in this report, the rules do not otherwise provide benefits or impose costs separately from the benefits and costs imposed by statutory authority and the legal requirements in the Exit Agreement and its successor agreements.

12. **Proposed course of action**

The Exit Agreement contained a broad limitation on Departmental rulemaking, as follows:

Notwithstanding anything herein to the contrary, the Department may propose a modification of its rules at any time provided that such modifications do not impair the rights of class members or substantially undermine the principles or the purposes of those provisions of the Implementation Plan… unless agreed to by the Monitor. [Attachment D, page 4.]

In practice, virtually any modification could be interpreted by the Court Monitor as “impair[ing] the rights of class members or substantially underm[ing] the principles or
purposes of [...] the Implementation Plan.” As such, the Department refrained from
commencing with a rulemaking on its own initiative, instead proposing that it would
collaborate with the Court Monitor to amend the rules by January 2012. As described in
this report, that rulemaking never occurred. Because the 2012 Agreement requires
instead the Department’s best efforts in implementation of rules, rather than a
proscriptive limitation on rulemaking, the Department has the discretion to proceed with
rulemaking under A.R.S. Title 41, Chapter 6. Accordingly, the Department plans to
conduct rulemaking for 9 A.A.C. 21, and because of the substantial allocation of staff and
resources expected to be necessary to complete the rulemaking, the Department plans to
file a Notice of Final Rulemaking with the Governor’s Regulatory Review Council by
December 31, 2016.

13. **Analysis of stringency compared to federal laws**
   The rules govern operation of a state program that operates independently of any federal
   program. However, since many providers are reimbursed through federal funding, the
   Department consulted state and federal laws and regulations in developing the rules.
   Despite these efforts, due to the changing landscape of health law, conflicts do at times
   occur. For example, R9-21-204(K) requires a face-to-face evaluation of a client to be
   performed by a physician or licensed independent practitioner. 42 CFR 482.13(e)(12)(i)
   would also allow trained registered nurses or physician assistants to perform the
evaluation. The rule is somewhat more stringent than the federal regulation, though the
Department only enforces the state rule, and the federal regulation is only pertinent to a
provider seeking federal reimbursement. Nevertheless, because this change would
probably reduce costs for some providers while not conflicting with the Department’s
statutory mandate to ensure the health and safety of clients, in the rulemaking proposed in
paragraph 12, the Department will consider making this change.
INFORMATION THAT IS IDENTICAL FOR GROUPS OF RULES

1. **Authorization of the rule by existing statute**
   All the rules in Article 4 have specific authority in A.R.S. § 36-3413.

3. **Analysis of effectiveness in achieving the objective**
   The rules in Article 3 set forth a service planning process that appears to presume that, if followed, it will result in a favorable outcome for the client. There is no empirical evidence that, if the processes set forth in Article 3 are followed, a favorable outcome will indeed result. The rules in Article 3 are more focused on ensuring that the process is followed than on achieving any particular result for a client. In practice, conversely, providers are oriented toward achieving a positive outcome for a client more than ensuring strict adherence to process. The rules in Article 3 would be more effective if they required providers to focus on the individual circumstances and needs of a client rather than micromanaging adherence to process.

4. **Analysis of consistency with referenced state and federal statutes and rules**
   Article 4 contains cross-references to A.R.S. §§ 36-112 and 36-113, which were repealed in 1997, for example in R9-21-401 and R9-21-408.
   Also, the rules in Article 4 do not seem clear in distinguishing the grievance and appeal process in A.R.S. Title 36, Chapter 34 from the formal appeal process in A.R.S. Title 41, Chapter 6, Article 10 that follows exhaustion of the RBHA grievance and appeal process.

6. **Analysis of clarity, conciseness, and understandability of the rule**
   The following rules are clear, concise, and understandable in and of themselves and without regard to how they function in a Chapter that is overall not clear, concise, and understandable when taken in its totality: R9-21-103; R9-21-106; R9-21-206.01; the Exhibits A and B following R9-21-211; R9-21-303; R9-21-304; R9-21-306; R9-21-308; R9-21-310; R9-21-311; R9-21-402; R9-21-410; and all the rules and exhibits in Article 5 except R9-21-507 and R9-21-510.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Several rules do not impose the least burden upon stakeholders because part or all of the rule is not effective. The burden results from any time or cost incurred by the stakeholder for taking inappropriate or unnecessary actions to follow the rule as written. The applicable rules are: R9-21-101; R9-21-104 through R9-21-209; R9-21-301 through R9-
Several rules do not impose the least burden upon stakeholders because part or all of the rule is not consistent with referenced state and federal statutes and laws. The burden results from any time or cost incurred by the stakeholder to reconcile the conflict and determine the appropriate action to achieve compliance. The applicable rules are: R9-21-101; R9-21-105; R9-21-201; R9-21-202; R9-21-204; R9-21-205; R9-21-208; R9-21-301; R9-21-312; R9-21-401; R9-21-405; R9-21-406; and R9-21-408.

Several rules do not impose the least burden upon stakeholders because part or all of the rule is not enforced as written. The burden results from any time or cost incurred by the stakeholder to discover how the rule is enforced, generally through communication with the Department, and any time or cost reconciling situations in which enforcement occurred in a manner the stakeholder was not aware to expect based on the rule as written. The applicable rules are: R9-21-101; R9-21-102; R9-21-104 through R9-21-202; R9-21-204; R9-21-205; R9-21-208; R9-21-301 through R9-21-303; R9-21-305; R9-21-307; R9-21-308; R9-21-311; R9-21-312; R9-21-401; R9-21-403; and R9-21-405 through R9-21-409.

Several rules do not impose the least burden upon stakeholders because part or all of the rule is not clear, concise, and understandable. The burden results from any time or cost incurred by the stakeholder to understand the rule. The applicable rules are: R9-21-101; R9-21-102; R9-21-104; R9-21-105; R9-21-201 through R9-21-206; R9-21-207 through R9-21-211; R9-21-301; R9-21-302; R9-21-305; R9-21-307; R9-21-309; R9-21-312 through R9-21-401; R9-21-403; R9-21-405 through R9-21-409; R9-21-507; and R9-21-510.
INFORMATION FOR INDIVIDUAL RULES

R9-21-101. Definitions

2. Objective
The objective of the rule is to define terms used in the Chapter so that a reader can consistently interpret requirements in the Chapter.

3. Analysis of the effectiveness in achieving the objective
Parts of the rule are not effective, as follows:
The definition for “Human Rights Advocate” in subsection (B)(36) incorrectly states that the Department appoints human rights advocates. The rule would be more effective if it accurately stated that the Department hires human rights advocates because human rights advocates are employed by the Department to advocate on behalf of clients.
The definition of “authorization” in subsection (B)(6) does not allow for an electronic authorization.
The definition of “case manager” in subsection (B)(10) does not accurately reflect current industry practice. According to the definition, the case manager is a single individual, but a team-based “case management” approach has become an industry best practice in order to avoid relegating case dependencies to a single individual. The rules impose a number of obligations on a single case manager and do not contemplate the team-based case management approach.
The definition of “client who needs special assistance” in subsection (B)(13) may allow clients who are not in need of special assistance to qualify as a “client who needs special assistance.” Under the definition, a client qualifies as “a client who needs special assistance” if the client requires 24-hour supervision. There are clients, however, who require 24-hour supervision but are able to effectively act as their own self-advocate and therefore do not need special assistance.

4. Analysis of consistency with state and federal statutes and rules
The definition for “ASH” in subsection (B)(5) (“Arizona State Hospital”) is not consistent with A.R.S. § 36-201(7), which defines “State hospital” as “Arizona state hospital.”
The definition of “community services” in subsection (B)(15) requires the Department to provide services (such as housing) not required in statute.
The definition of “seriously mentally ill” in subsection (B)(58) is not consistent with R9-21-105 because the definition limits the application of Chapter 21 to persons 18 years of age or older while R9-21-105(A), (B), (G) and (H) include provisions that apply to
enrolled children. Under R9-21-101(B)(29) enrolled children are under the age of 18. Also, it references the definition in A.R.S. § 36-550 but adds additional characteristics, making it overall inconsistent with the statutory definition of the same term. The remainder of the rule is consistent with referenced state and federal statutes and rules.

5. **Status of enforcement of the rule**

As discussed in paragraph 3, the definition of “client who needs special assistance” in R9-21-101(B)(13) allows clients who do not need special assistance to qualify as a “client who needs special assistance.” Because the Department lacks the resources to provide special assistance to every client that satisfies that definition, the Department allows those clients who are capable of self-advocacy to advocate on their own behalf and assists only those clients who truly need special assistance.

6. **Analysis of clarity, conciseness, and understandability**

Parts of the rule are not clear, concise, and understandable, as follows:

Subsection (B)(1), the definition of “Abuse,” is unclear because it is devoid of any language indicating that abuse occurs only when there is unwarranted or improper physical pain or injury. The definition improperly contains regulatory language and also contains numerous words or phrases that are vague or ambiguous, such as “with respect to a client,” “impairment of bodily function,” “serious emotional damage,” “severe,” “withdrawal,” “untoward aggressive behavior,” “under the care of,” and “personnel.”

Subsection (B)(2), the definition of “Agency Director” is ambiguous because the definition’s sentence structure does not allow the reader to determine who the “agency director” actually is.

The definition of “authorization” in subsection (B)(6) contains the ambiguous phrase “permission expires” and improperly includes regulatory requirements in subsections (B)(6)(a) through (h).

Subsection (B)(13), the definition of “client who needs special assistance,” uses ambiguous or vague terms or phrases such as “deemed,” “qualified,” “supervision,” “in fact,” “difficulties,” “prepare,” “participate,” and “ITP.” Further, the definition uses the improper phrase “including but not limited to.”

The definition of “Clinical Team” in subsection (B)(14) is unclear because it contains the ambiguous term “vocational specialist” and cites “Laws 1992, Ch. 310,” which was repealed in 1994.

The definition of “community services” in subsection (B)(15) uses ambiguous terms or phrases such as “required to be provided” and “housing and residential services.”
The definition of “emergency safety situation” in subsection (B)(28) contains ambiguous words or phrases including “imminent risk” and “reasonable fear.” The definition of “frivolous” under subsection (B)(31)(c) contains the ambiguous phrase “substantially similar.” Although the rule may have been intended to dismiss only those unsubstantiated grievances arising out of the same specific set of facts, subsection (c) appears to be overly broad.

The definition of “grievance” in subsection (B)(33) is unclear with regard to whether a specific administrative rule must be cited for a party to file a grievance.

The definition for “Human Rights Advocate” in subsection (B)(36) contains an incorrect rule citation. The rule should cite to R9-21-104(B) instead of R9-21-105.

Subsection (B)(41), “inpatient facility” refers to the “County Annex,” which does not exist in Arizona.

Subsection (B)(51), the definition of “PRN order” limits the application of PRN orders to orders for medication even though the term is used in R9-21-204 (Restraint and Seclusion) with regard all types of restraints or seclusion.

Subsection (B)(54), the definition of “region” is unclear because it implies that a region’s designation is dependent on the existence of a contract with a regional authority. Logically, the regions would have been designated as a necessary step for the Department to solicit contract bids from the “regional authorities,” before the Department formed contracts with “regional authorities.” Further, the definition is an unclear circular definition because it uses the term being defined as part of the definition (“Region means . . . region . . .”)

The definition of “seriously mentally ill” in subsection (B)(58) is unclear because specific sections of Chapter 21 apply to children (See R9-21-105(A), (B), (G) and (H)) even though the definition of “seriously mentally ill,” “means a person 18 years of age or older . . . .”

R9-21-102. Applicability

2. Objective

The objective of the rule is to clarify the scope of Chapter 21 by specifying the specific persons to whom Chapter 21 applies and by listing a specific exclusion.

3. Analysis of the effectiveness in achieving the objective

As discussed in paragraph 6, it is unclear whether the Department has the authority to enforce the rule against Arizona Long-Term Care System (“ALTCS”) providers, and thus
as discussed in paragraph 5, the Department does not enforce the rule against those providers, making the rule to that extent not effective.

5. **Status of enforcement of the rule**
The rule is currently not being enforced against entities that are part of Arizona Long-Term Care System ("ALTCS") because, as discussed in paragraph 6, it is unclear whether the Department has the authority to do so.

6. **Analysis of clarity, conciseness, and understandability**
Parts of the rule are not clear, concise, and understandable, as follows:
The phrase "This Chapter shall not . . ." should be re-worded "This Chapter does not . . ."
The rule appears to include ALTCS providers, since they receive funds under Title XIX, but ALTCS providers do not provide services to clients under A.R.S. Title 36, Chapter 5.

R9-21-103. **Computation of Time**
2. **Objective**
The objective of the rule is to provide the reader with a method by which to calculate any period of time contained in Chapter 21.

R9-21-104. **Office of Human Rights; Human Rights Advocates**
2. **Objective**
The objective of the rule is to ensure that clients have the option of seeking assistance in pursuing recourse for an alleged rights violation by:
a. Establishing the Office of Human Rights ("OHR");
b. Identifying the required ratio of human rights advocates to clients; and
c. Establishing the roles and responsibilities of a human rights advocate.

3. **Analysis of the effectiveness in achieving the objective**
Parts of the rule are not effective for the reasons stated in paragraphs 5 and 6, and as follows:
Subsection (B) uses the incorrect term "region." Subsection (B) requires that there be one human rights advocate for each 2,500 clients in each "region."
Subsection (F)(2) fails to clearly state the roles and responsibilities of OHR. This subsection fails to state when and how OHR must "provide" the list or what information the list must contain.
Subsection (F)(2) and (G) lack specific time-frames as to when OHR must take specific actions with regard to dealing with clients who need special assistance.
5. **Status of enforcement of the rule**

Parts of the rule are not enforced as written, as follows:

Because A.R.S. § 36-103(A) allows the Director to organize the positions or organizational units within the Department to make the operation of the Department more efficient and effective, the Department does not organize the OHR according to subsection (A). Subsection (A) requires OHR’s “chief officer” to report to the Director. Rather, the manager (not chief officer) of OHR reports to the Branch Chief, who reports to the Deputy Director, who reports to the Director. This organization differs from what was reported in the 2008 Five-year-review Report for this Chapter. The internal organization of the Department is inappropriate for inclusion in rule.

Subsection (B) also requires OHR to assist “all clients” who request assistance in resolving appeals and grievances under Article 4 of Chapter 21. Because of limited resources, OHR provides varying levels of assistance to “all clients” who make requests. OHR allows those clients who are capable of self-advocacy to advocate on their own behalf, while answering client inquiries as resources permit.

6. **Analysis of clarity, conciseness, and understandability**

The rule is not clear, concise, and understandable.

The rule contains words, phrases, and abbreviations that are undefined, such as “behavioral services” and “residential program.”

Subsection (A) contains the provision, “the director shall establish an Office of Human Rights for clients within the Department.” The phrase “clients within the Department” in subsection (A) is unclear because according the definition of “client” in R9-21-101(B)(11), clients are “treated for a mental disorder by or through a regional authority,” not the “Department.”

Subsection (B) also requires that “the chief officer shall appoint at least one human rights advocate for each 2,500 clients in each region.” It is unclear whether the chief officer’s obligation to appoint an additional human rights advocate is triggered when there are 2,501 clients or when there are 5,000 clients.

R9-21-105. **Human Rights Committees**

1. **Authorization of the rule by existing statute**

The rule has specific authority under A.R.S. §§ 41-3803(C) and 41-3804(A). The Department lacks statutory authority to write rules for enrolled children.

2. **Objective**
The objectives of the rule are to ensure that there are independent entities charged with ensuring that clients’ human rights are protected by:

a. Establishing human rights committees ("HRCs") across Arizona;
b. Identifying the composition of an HRC;
c. Establishing when HRCs meet;
d. Establishing the duties of an HRC, and
e. Specifying the level of training and support the Department must provide HRCs.

3. **Analysis of the effectiveness in achieving the objective**

Parts of the rule are not effective, as stated in paragraphs 4, 5, and 6, and as follows:

In practice, HRCs continue to function even when they do not satisfy the requirements contained in subsections (A) and (B). Subsection (A) requires that there be one HRC for every 2,500 clients. It is difficult to satisfy this requirement in Maricopa County because of the population growth. It is also difficult for HRCs to find qualified volunteers to satisfy the composition requirements contained in subsection (B) in the less populated areas, especially because of the rigid composition and expertise requirements in the rule. As a result, there is currently only one HRC for each geographical service area, and the only functioning HRCs are for Maricopa County, Pima County, and the Arizona State Hospital, and therefore there are fewer HRCs than the rule requires.

The broad conflict of interest provision in subsection (E) prohibits any “individual under contract with the Department, regional authority, or service provider” from being a voting member of an HRC, compounding the existing difficulty in finding qualified volunteers to serve on an HRC to satisfy the rule’s ratio and membership requirements, but is necessary because employee contract restrictions alone are insufficient to fully allay conflict-of-interest concerns. Adding to the difficulty, the rule is not sufficiently definitive on who is responsible for finding volunteers.

The rule includes within its scope “enrolled children.” According to the definition of “seriously mentally ill” only persons who are aged 18 years or older are considered “seriously mentally ill” in Chapter 21. The rule cannot be effective for enrolled children because the Department lacks the statutory authority for the rule to reach them.

4. **Analysis of consistency with state and federal statutes and rules**

Parts of the rule are not consistent, as follows:

Subsection (G) is broader than the statutory equivalent, A.R.S. § 41-3804(E)(1), because subsection (G)(6) requires an HRC to provide, among other things, “independent oversight and review of . . . any other issue affecting the human rights of clients and
enrolled children.” A.R.S. § 41-3804(E)(1), by contrast, requires each HRC to “ensure that the rights of clients are protected.”

Subsection (H) allows the Committee to make site visits, meet with clients, and inspect client records. Many clients, such as those in need of special assistance, lack the capacity to consent to meet with Committee representatives. Further, the Committee’s oversight is limited to client rights, so no apparent authority exists to access a client’s record without the consent of the client or the legally authorized individual acting for the client.

Further, the reporting requirements for HRCs contained in rule and statute are not consistent. Subsection (K) requires each HRC to issue a quarterly report. A.R.S. § 41-3804(G), however, requires each HRC to issue an annual report.

The remainder of the rule is consistent with referenced state and federal statutes and rules.

5. **Status of enforcement of the rule**

Parts of the rule are not enforced as written, as follows:

As discussed in paragraph 3, it is difficult to find qualified volunteers to serve on HRCs. As a result, subsections (A) and (B) are not enforced.

The reporting requirements contained in statute and rule are not consistently followed by the HRCs. Subsection (K) requires each HRC to issue a quarterly report and A.R.S. § 41-3804(G) requires each HRC to issue an annual report. The HRCs do not consistently submit the requisite quarterly or annual reports but are not penalized for failing to do so.

6. **Analysis of clarity, conciseness, and understandability**

Parts of the rule are not clear, concise, and understandable, as follows:

Subsection (A) requires that “. . . if more than 2,500 clients reside within a region, the Department shall establish additional human rights committees until there is one human rights committee for each 2,500 clients in a region.” It is unclear whether the Department’s obligation to establish an additional human rights committee is triggered when there are 2,501 clients or when there are 5,000 clients.

Finally, the rule does not clearly specify HRC jurisdiction. For example, a client of a RBHA may be receiving services at the State Hospital. Both entities have an HRC. It is unclear which HRC would have jurisdiction.

R9-21-106. **State Protection and Advocacy System**

2. **Objective**
The objective of the rule is to require mental health agencies to cooperate with the State Protection and Advocacy System in its investigations and advocacy for clients, as required by federal law, 42 U.S.C. 10801 through 10851.

3. **Analysis of the effectiveness in achieving the objective**
   The rule is not effective, because federal law already imposes the requirements contained in the rule upon the parties specified in the rule, and the rule does not provide an additional enforcement mechanism.

5. **Status of enforcement of the rule**
   The rule does not have an enforcement provision, and thus is not enforced.

13. **Analysis of stringency of the rule compared to applicable federal law**
   While the rule references the requirements in 42 U.S.C. 10801, et seq., the rule does not have substantive effect due to its lack of an enforcement mechanism, and therefore neither reiterates the federal requirements nor expands upon them.

R9-21-201. **Civil and Other Legal Rights**

1. **Authorization of the rule by existing statute**
   This rule has specific authority under A.R.S. §§ 36-504, 36-506, 36-507, 36-508, 36-514, 36-550.03, and 36-550.05.

2. **Objective**
   The objectives of the rule are to:
   a. Itemize the rights of an individual that arise by virtue of the individual being a person with serious mental illness and a citizen of Arizona; and
   b. Ensure that mental health agencies providing behavioral health services in Arizona do not infringe those rights.

3. **Analysis of the effectiveness in achieving the objective**
   Parts of the rule are not effective for the reasons in paragraphs 4, 5, and 6, and as follows:
   Subsection (A) is overbroad and unclear because it requires that clients “have all rights accorded by applicable law” and prohibits “any” party providing behavioral health services from violating those rights. The rule fails to account for the circumstance where a provider violates a client’s right as a necessary step of the client’s treatment plan.
   Subsection (A)(5) apparently provides a client with the absolute right to perform religious practices, limited only by the client’s subjective “preferences.” Similarly, subsection (A)(16) is not effective because a client’s treatment plan may limit a client’s activities,
including the client’s religious practices and choice of residence and may limit the providers’ ability to provide the necessary behavioral health services. Subsection (B)(3) requires the reader to have knowledge of the rights “already present” to accurately interpret the rule. Further, this exception effectively renders the rule meaningless because, if the rights protected by the rule are only those rights “already present,” there is no reason to restate the rights in Article 2. Subsection (A)(1) cross-references A.R.S. § 36-506, which is duplicative of subsection (A). Subsection (A)(15) cross-references A.R.S. §§ 36-504 through 514, which is redundant of subsections (A) and (A)(1).

4. **Analysis of consistency with state and federal statutes and rules**

Parts of the rule are not consistent, as follows:

Subsection (A)(10), while consistent in its reference to A.R.S. § 36-507(2), may be inconsistent with A.R.S. § 41-1750(U)(1), because A.R.S. § 41-1750(U)(1) requires a person to be fingerprinted as part of the booking process upon arrest. While A.R.S. § 36-507 does not specify that it applies in instances when there has been an arrest, under A.R.S. §§ 36-520 through 36-531, some clients subject to A.R.S. § 36-507 may be receiving treatment pursuant to a court order, which typically occurs consequent to an arrest. Whether the two statutes conflict may be a matter for a court to decide, and whether subsection (A)(10) is consistent would then depend on that determination. The remainder of the rule is consistent with referenced state and federal statutes and rules.

5. **Status of enforcement of the rule**

Parts of the rule are not enforced as written, as follows:

As discussed in paragraphs 3 and 6, the plain language of the rule provides clients with absolute rights regardless of the clients’ treatment plans. In practice, clients’ rights are not viewed as absolute, but restricted in the context of the client’s treatment plan and individual circumstances so that the appropriate behavioral health services can be effectively provided. For example, subsection (A)(5) provides clients “the right to religious freedom and practice, without compulsion and according to the preference of the client.” If a client has an absolute right to engage in activities that are part of his religion, a provider cannot intervene when a client engages in conduct under the guise of religious practice that is harmful to the client’s well-being (e.g., ingesting peyote). Providers do not allow clients complete religious freedom, but might limit religious activities if those activities interfere with the provision of behavioral health services required by a client’s treatment plan.
6. **Analysis of clarity, conciseness, and understandability**

Parts of the rule are not clear, concise, and understandable, as follows:

The rule uses words or phrases that are undefined and that have meanings that are dependent on the subjective criteria of the reader. Subsection (A)(6) uses “reasonable assistance;” subsection (A)(7) uses “reasonable access,” “reasonable opportunity,” and “reasonable amounts;” subsection (A)(8) uses “reasonable restrictions;” subsections (A)(8) and (A)(9) contain “serious disruptions;” subsection (A)(9) uses “normal functioning;” and subsection (A)(11) uses “appropriate language.”

Subsection (A)(3) is not concise because it is a single sentence containing 92 words and numerous requirements.

It is unclear whether subsections (A)(7) (the right to communicate) and (A)(8) (the right of visitation) apply only to residential settings.

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R9-21-202. **Right to Support and Treatment**

1. **Authorization of the rule by existing statute**

   This rule has specific authority under A.R.S. §§ 36-504(A), 36-507, 36-508, 36-511, 36-550.03, 36-550.05 and 36-3407.

2. **Objective**

   The objective of the rule is to ensure that a client receives the necessary support and treatment from a provider of behavioral health services by:
   a. Identifying the support and treatment a client is entitled to receive; and
   b. Establishing clients’ rights with regard to the services that they are provided.

3. **Analysis of the effectiveness in achieving the objective**

   Parts of the rule are not effective for the reasons in paragraphs 4 and 6, and as follows:

   Many of the “rights” itemized in the rule are not quantifiable and therefore not enforceable by any mechanism.

   Subsection (A)(7) is impracticable because it might require a provider to absorb the costs of a client’s living expenses or recreational activities.

   Subsection (A)(8) gives a client “the right to be informed, in advance, of charges for services.” It can be difficult to inform a seriously mentally ill patient of the charges since the patient might be incapable of comprehending the charges. This rule would be more effective by clarifying the means for complying with the rule instead of broadly stating the desired end.
Subsections (A)(9) through (A)(11) give a client the right to “a continuum of care” with respect to various programs. This absolute right does not account for the fact that there are a number of examples where an interruption in care is due to the client’s actions or inactions. Holding a different party responsible for a client’s inactions is not effective in ensuring that a client receives proper support and treatment.

Subsection (A)(13) would be improved if, instead of requiring a “least restrictive” setting, required instead the “least restrictive setting available.” Otherwise, the rule might be virtually impossible to comply with.

Subsection (A)(15) would be more effective if it did not grant an absolute right, but accounted for the fact that a person with a serious mental illness might be incapable of participating in the decision process.

Subsection (B) is similar to R9-21-201(B)(3), which is an overbroad exception that renders much of the rules meaningless and is therefore ineffective.

4. **Analysis of consistency with state and federal statutes and rule**

Parts of the rule are not consistent, as follows:

The rule is not consistent with R9-21-201(B)(3). R9-21-201(B)(3) states that “[n]othing in [Article I] shall be interpreted to . . . construe this rule to confer constitutional or statutory rights not already present.” Similarly, subsection (B) states that “[Subsection (A)] shall not be construed to confer constitutional or statutory rights not already present.” Subsection (A), however, as permitted by A.R.S. § 36-504(A), sets forth numerous rights that are not provided for by the state or federal constitution or statute, including:

- Subsections (A)(1)(c)(i) through (A)(1)(c)(vii), (A)(6), (A)(7), and (A)(13) require that behavioral health services or community services must be provided so as to maximize the physical and mental well-being of the client;
- Subsection (A)(1)(d) requires that providers maximize the client’s freedom to choose to live in the client’s preferred physical and social environment;
- Subsection (A)(3) provides “the right to be provided with a reasonable explanation of one’s condition and treatment;”
- Subsection (A)(5) provides the right not to participate in experimental research without informed consent; and
- Subsection (A)(8) provides “the right to be informed, in advance, of charges for services.”
The remainder of the rule is consistent with referenced state and federal rules and statutes.

5. **Status of enforcement of the rule**

Parts of the rule are unenforceable in any functional or practical sense, as discussed in paragraphs 3 and 6. Also, requirements such as the rights in subsection (A)(13) are ambiguous and unclear as to who is required to enforce the rule, and by what means such enforcement would be quantified.

6. **Analysis of clarity, conciseness, and understandability**

Parts of the rule are not clear, concise, and understandable, as follows:

The rule uses dozens of undefined words or phrases that have meanings that are dependent on the subjective criteria of the reader. Limiting to only a few examples:

- **Subsection (A)(1)(a):** “personal liberty;”
- **Subsection (A)(1)(c):** “human dignity,” “respect,” “individuality,” “self-determination,” “freedom of choice,” “discomfort,” “distress,” “unresponsive and inhumane environment,” “clearly defined,” “as much as possible,” “ordinary community experiences,” and “humane and adequate support;”
- **Subsection (A)(7):** “wholesome,” “tasteful,” “appropriate,” “normal,” “adequate,” and “neat;” and
- **Subsection (A)(13):** “most normal,” “least restrictive” and “least restrictive means appropriate to the client’s needs.”

The rule also uses many words or phrases that are undefined and otherwise attempt to convey ideas that are indefinite or indistinct in nature. Citing a few examples:

- **Subsection (A)(1)(b):** “flexible service system;”
- **Subsection (A)(1)(c):** “preserves,” “encourages,” “participation,” “fullest capacity,” “deprivation,” “protects,” “promotes,” “maximizes,” “recognizes,” and “adjusting;”
- **Subsection (A)(7):** “arrangements,” “family planning services,” “opportunities,” “social contact,” “daily activities,” and “individual storage space;” and
- **Subsection (A)(10):** “continuum of care,” “clinical case management,” “housing and residential services,” “crisis intervention and resolution services,” “mobile crisis teams,” “vocational training and opportunities,” “day treatment,” “rehabilitation services,” “peer support,” “social support,” “recreation services,” “advocacy,” “family support services,” “outpatient counseling and treatment,” “transportation,” and “medical evaluation and maintenance.”
The rule also contains provisions that are not concise. The phrase “receive services on a voluntary basis to the maximum extent possible and entirely if possible” in subsection (A)(1)(d)(iii) is not concise. The phrase “entirely if possible” is redundant because the previous phrase “maximum extent possible” already subsumes that concept. Subsection (A)(17) is not concise because it repeats the requirements contained in Articles 3 and 4 of Chapter 21. Subsection (A)(4) is unclear because it is stated in broad, general requirements, but R9-21-206.01 contains more specific informed consent requirements. It is unclear whether the broader provision in subsection (A)(4) applies over the more specific R9-21-206.01.

R9-21-203. Protection from Abuse, Neglect, Exploitation and Mistreatment

2. Objective
The objective of the rule is to establish requirements for protecting a client from mistreatment, abuse, neglect, and exploitation by:
   a. Establishing sanctions for mistreating a client or failing to report mistreatment of a client, and
   b. Requiring that the identity of an individual who reports abuse, neglect, exploitation, or mistreatment remains confidential.

3. Analysis of the effectiveness in achieving the objective
Parts of the rule are not effective for the reasons in paragraph 6 and as follows:
The rule does not state whether a mental health agency is responsible for harm to a client that is inflicted by another client and thus fails to clearly state the responsibilities of a mental health agency in protecting its clients.

6. Analysis of clarity, conciseness, and understandability
Parts of the rule are not clear, concise, and understandable, as follows:
The rule contains undefined words or phrases that are ambiguous because they have meanings that are dependent on the subjective criteria of the reader or attempt to convey ideas that are indefinite and indistinct in nature, including: “mistreat,” “serious risk,” “unreasonable,” “verbal abuse,” “ridicule,” “punitive reasons,” and “convenience” in subsection (A); “mistreatment” in subsection (B); “appropriate” in subsection (C); “reasonable cause,” and “relevant” in subsection (D); “necessary” and “mistreatment” in subsection (E); “encouragement,” “coercion,” “retaliation,” and “commercial exploitation” in subsection (A); “mistreatment” and “directly operated” in subsection
(B); “exploitation” in subsection (C); and “identity” and “mistreatment” in subsection (E). Also, subsection (A) uses the passive voice.
Subsection (B) contains an incorrect citation to “9 A.A.C. 10, Article 10.”

R9-21-204. Restraint and Seclusion

1. **Authorization of the rule by existing statute**
The rule has specific authority under A.R.S. § 36-513.

2. **Objective**
The objective of the rule is to ensure that the health, safety, and welfare of clients are protected by establishing when and where seclusion or restraint may be used with respect to clients by:
   a. Establishing staffing requirements for the use of restraint and seclusion;
   b. Identifying those service providers who may use restraint or seclusion;
   c. Establishing a process for authorizing and initiating restraint or seclusion;
   d. Specifying documentation requirements for restraint or seclusion;
   e. Establishing timelines governing the amount of time that a client may be restrained or secluded; and
   f. Establishing a process for the reporting and review of restraint or seclusion to the Office of Human Rights (“OHR”).

3. **Analysis of the effectiveness in achieving the objective**
Parts of the rule are not effective for the reasons in paragraphs 4, 5, and 6, and because the rule does not clearly state which facilities are permitted to use restraint or seclusion.

4. **Analysis of consistency with state and federal statutes and rules**
Since the rule was last amended, the Centers for Medicare and Medicaid Services (CMS) enacted new federal rules regarding restraint and seclusion. Under the rules promulgated by CMS, the current requirement of a “face-to-face” evaluation by a physician or licensed independent practitioner in subsection (K)(1) has been expanded to include a trained registered nurse or physician assistant. See 42 CFR 482.13(e)(12)(i). Subsection (K)(1) is not consistent with the requirements in the new federal rules.
The remainder of the rule is consistent with referenced state and federal statutes and rules.

5. **Status of enforcement of the rule**
Parts of the rule are not enforced, as follows:
Subsections (H) and (O) are not enforced because “clinical necessity” is more properly reviewed by the licensing boards of qualified medical practitioners, not the Department.

6. Analysis of clarity, conciseness, and understandability

Parts of the rule are not clear, concise, and understandable, as follows:

The rule contains undefined words or phrases that have meanings that are dependent on the subjective criteria of the reader or that otherwise attempt to convey ideas that are indefinite, indistinct in nature, or are industry jargon, such as:

Subsection (B): “less restrictive methods,” “mental distress,” and “ceases;” Subsection (C): “coercion,” and “discipline;”

Subsection (I): “least restrictive,” “staff member,” “available” and “time-released drug;”

Subsection (M): “less restrictive alternatives,” “monitoring,” “observations,” “justifying it,” and “measurable criteria;”

Subsection (P): “comfort and safety,” “continued well-being,” “supervision,” “supervise,” “nutritious” and “opportunity;” and

Subsection (X): “Division for remedial action.”

Subsections (G), (H), and (K) are not entirely clear because they use the terms “level 1 psychiatric acute hospital,” “level 1 sub-acute agency,” and “level 1 RTC,” which are not defined in Chapter 21 or R9-20-102, even though the rule indicates that R9-20-102 clarifies these terms.

Subsection (U) is unclear because it is written in the passive voice.

Subsection (F) is unclear because it does not indicate the personnel at the facility that are required to participate in the training.

Subsections (G)(1) and (2) are unnecessarily duplicative of each other.

R9-21-205. Labor

1. Authorization of the rule by existing statute

The rule has specific authorization under A.R.S. § 36-510.

2. Objective

The objective of the rule is to ensure that clients are not exploited by a mental health agency by:

a. Identifying the requirements and conditions under which a person with a serious mental illness may perform labor at a mental health agency; and

b. Establishing when and how a client performing labor will be compensated.

3. Analysis of effectiveness in achieving the objective
Parts of the rule are not effective for the reasons in paragraphs 4, 5, and 6, and because a provider may not be able to allow a client to perform ANY labor available when some labor may be contraindicated in the patient’s ISP or ITDP developed under Article 3.

4. **Analysis of consistency with state and federal statutes and rules**
   Subsection (B) provides that “any client may voluntarily perform any labor available,” but unlike A.R.S. § 36-510, the rule does not require that the labor be in the “patient’s interest.” (“Patient” in A.R.S. § 36-501 is broader than “client” in R9-21-101, but in this context refers to the same category of individuals.) The remainder of the rule is consistent with referenced state and federal statutes and rules.

5. **Status of enforcement of the rule**
   The Department does not enforce the rule as written; rather, it enforces the rule based on the language in related statutes and a client’s ISP or ITDP, as discussed in paragraph 4.

6. **Analysis of clarity, conciseness, and understandability**
   Parts of the rule are not clear, concise, and understandable, as follows:
   Subsection (A) begins with “No client shall be required . . . .” The rule should be reworded not to use the negative subject with affirmative “shall.”

R9-21-206. **Competency and Consent**

1. **Authorization of the rule by existing statute**
   The rule has specific authority under A.R.S. § 36-506(A).

2. **Objective**
   The objectives of the rule are to:
   a. Establish that clients are presumed to be competent and that admission to a mental health agency, by itself, is insufficient to overcome this presumption;
   b. Require that an applicant or client must be competent to provide informed consent; and
   c. Delineate a process for determining when a guardianship, temporary guardianship, conservatorship, or guardian ad litem should be established or removed for an applicant or client.

3. **Analysis of the effectiveness in achieving the objective**
   Parts of the rule are not effective, as discussed in paragraph 6 and because the rule does not address the situation where the fiduciary is not necessarily engaging in improprieties, but is clearly not acting in the best interests of the client.

6. **Analysis of clarity, conciseness, and understandability**
Parts of the rule are not clear, concise, and understandable, as follows:

The rule contains undefined words or phrases that are vague or dependent on the subjective criteria of the reader, such as “serious risk” in subsection (C).

R9-21-206.01. Informed Consent

2. Objective

The objective of the rule is to ensure that clients agree to treatment only after demonstrating an appreciation and understanding of the facts and implications of an action by establishing a procedure that must be followed before a client or his representative can provide consent for treatment.

3. Analysis of the effectiveness in achieving the objective

Parts of the rule are not effective for the reasons in paragraph 6 and because it is not always necessary for the medical practitioner or registered nurse to have one year of behavioral health experience as required in subsection (C) in order to provide the client with the information.

6. Analysis of clarity, conciseness, and understandability

The rule is mostly clear, concise, and understandable, but could be improved as follows:

The rule should define or change the following undefined words or phrases that are industry jargon or otherwise set forth concepts that are indefinite in nature:

“psychotropic medication,” “electro-convulsive therapy” and “telemedicine” in subsection (A); “behavioral health experience” and “punitive action” in subsection (C); and “avoid any harmful effects” in subsection (G).

The rule also contains provisions that could be further clarified in context. For example, it is unclear under subsection (C) whether the medical practitioner and the registered nurse must have one year of behavioral health experience, or only the registered nurse.

R9-21-207. Medication

2. Objective

The objective of the rule is to ensure that clients take prescribed medications consistent with the prescribing physician’s orders by:

a. Setting forth when a client may be given medication,

b. Listing the client’s rights regarding medication,

c. Setting forth the manner in which medication is administered to a client,
d. Listing the circumstances and requirements for a client’s self-administration of medication, and

e. Setting forth the conditions pertinent to storing medication.

3. **Analysis of the effectiveness in achieving the objective**

Parts of the rule are not effective for the reasons in paragraph 6 and as follows:

The rule does not contain an exception to address when a client needs medication because of an emergency or crisis situation. Without such an exception, the rule is not effective in ensuring that a client receives the necessary medications at the necessary times.

Subsection (D)(2) is problematic because the frequency in which a client must be “seen” is not always indicated in the client’s ISP. If the client’s ISP does not indicate such, then the rule loses its effectiveness because the rule gives the reader a choice to see the client “monthly” or as indicated in the ISP and the client might need to be seen more often than once every month.

It is ineffective to have subsection (B) in this section and not in R9-21-201 (Civil and Other Legal Rights) or R9-21-202 (Right to Support and Treatment). Further, enforcement of this rule is problematic because only a physician can determine what is necessary and the proper amount, and the standard of care applicable to physicians would require that clients be given only necessary medications in the right amounts. In a similar respect, subsection (C) requires that medication “be given in the least amount medically necessary . . .”

Subsection (D)(2) is not consistent with good clinical practice. It could be more effective if it required the frequency of examinations to be based on the need of the client.

6. **Analysis of clarity, conciseness, and understandability**

Parts of the rule are not clear, concise, and understandable, as follows:

The rule uses undefined words or phrases that have meanings that are vague, dependent on the subjective criteria of the reader, or are industry jargon, such as: “appropriateness” in subsection (D); “proper” in subsection (F); “Title 36 guardian” in subsection (A); “particular emphasis,” in subsection (C); and “psychotropic medication,” “experienced,” and “tardive diskinesia” in subsection (D).

The rule also contains provisions that are unclear when read in context. Subsection (A) requires that medication be administered only after securing the informed consent of the client or the client’s “Title 36 guardian.” A “Title 36 guardian” does not exist. Further, it is unclear whether informed consent must be secured before each individual dosage, before the first dosage following a new prescription cycle, before the first dosage of a
prescription with a change of the dosage amount, or only after starting a new prescription. Further, because the rule is silent with regard to how the informed consent must be memorialized, the rule could be clearer if it cited R9-21-206.01(D).

R9-21-208. Property and Possessions.

1. **Authorization of the rule by existing statute**
The rule has specific authority under A.R.S. §§ 36-507 and 36-508.

2. **Objective**
The objective of the rule is to establish requirements for:
   a. When a client is entitled to acquire, retain, and dispose of personal property; and
   b. Management of client funds by a mental health agency.

3. **Analysis of effectiveness in achieving the objective**
Parts of the rule are not effective for the reasons in paragraphs 4, 5, and 6, and also subsection (A)(3) is diminished in effectiveness because it does not account for the circumstances where there are materials or objects that do not pose an imminent threat of serious physical harm to the client or others, but the client is nevertheless prohibited from possessing according to the client’s treatment plan.

4. **Analysis of consistency with state and federal statutes and rules**
Subsection (B)(1) is not consistent with A.R.S. § 36-507(5), which states that the client may “spend a reasonable sum of his own money for his own needs and comfort.” A.R.S. § 36-507 grants the facility some authority to limit spending while the rule denies the facility any such authority.
The remainder of the rule is consistent with referenced state and federal statutes and rules.

5. **Status of enforcement of the rule**
Although the rule seems to provide a client with the absolute right to possess property that is not a threat to the client or others, mental health agencies do not allow a client to possess property that is prohibited by the client’s treatment plan, such as, for example, pornography or gambling paraphernalia.

6. **Analysis of clarity, conciseness, and understandability**
Parts of the rule are not clear, concise, and understandable, as follows:
The rule contains undefined words and phrases that have meanings that are dependent on the subjective criteria of the reader, such as “serious physical harm” in subsection (A)(3);
“fair allocation” in subsection (B); “within reason” in subsection (B)(3)(f); and “reasonable time” in subsection (B)(4).

Subsection (B)(4) is unclear because it is written in the passive voice.

Subsection (A) uses a negative subject with the affirmative “shall.”

R9-21-209. Records

1. Authorization of the rule by existing statute

The rule has specific authority under A.R.S. §§ 36-107, 36-504(B), and 36-509.

2. Objectives

The objectives of the rule are to ensure that a client’s medical records or medical conditions remain confidential and are only disclosed in accordance with state and federal law by:

a. Establishing that a client’s records are private;
b. Identifying authorized individuals and entities that have access to a client’s record;
c. Establishing requirements for mental health agencies for protecting, maintaining, and releasing records;
d. Imposing copying fees for records;
e. Establishing requirements for how records are maintained;
f. Requiring maintenance of a list of individuals who inspect a client’s record;
g. Specifying the parties that are permitted to inspect the client’s records when necessary for the understanding of the client or his attorney;
h. Requiring that the client be informed of a court order or subpoena commanding production of the client’s records; and
i. Establishing a process for a client to challenge whether the client’s records contain inaccurate or misleading information.

3. Analysis of the effectiveness in achieving the objective

Parts of the rule are not effective for the reasons in paragraph 6 and as follows:

Subsection (C)(5) does not allow for disclosure of the client’s records while the administrative and judicial review of a Departmental denial of a client’s request to inspect the client’s records is pending, even though disclosure might be a necessary step of the client’s treatment.

6. Analysis of clarity, conciseness, and understandability

Parts of the rule are not clear, concise, and understandable, as follows:
The rule uses the following undefined words or phrases that have meanings that are dependent on the subjective criteria of the reader: “necessary” in subsection (B)(3); and “timely,” “pertinent,” and “relevant” in subsection (G).

The rule also uses undefined words or phrases that are industry jargon or otherwise attempt to convey ideas that need clarification, such as: “as soon as possible” in subsection (B)(1); “written authorization” in subsection (B)(2); “proper judicial order” in subsection (C)(2); “family members,” “actively participating,” and “proper judicial order” in subsection (C)(5).

It is unclear under subsection (C)(5) whether the client’s records may be disclosed as part of the client’s treatment when there is a pending administrative and judicial review of a Departmental denial of a client’s request to inspect the client’s record.

R9-21-210. Policies and Procedures of Service Providers

2. Objective
The objective of the rule is to encourage mental health agencies to create and implement policies and procedures that are consistent with Arizona statutes and rules by:
   a. Authorizing mental health agencies to establish policies and procedures,
   b. Requiring mental health agencies to inform clients of policies and procedures, and
   c. Requiring mental health agencies to accommodate the needs of disabled clients in the agency’s implementation of policies and procedures.

6. Analysis of clarity, conciseness, and understandability
Parts of the rule are not clear, concise, and understandable, as follows:
The rule contains undefined or indefinite words or phrases including “seriously in disregard” and “reasonable.”

The rule also uses inconsistent terms. The title of the rule is “Policies and Procedures of Service Providers.” The term “service provider” is not used in the text of the rule; instead, “mental health agency” is used.

R9-21-211. Notice of Rights

1. Authorization of the rule by existing statute
The rule has specific authority under A.R.S. §§ 36-504 (A) and 36-506.

2. Objective
The objective of the rule is to ensure that mental health agencies provide a notice of rights to each client by:
a. Establishing the required contents of a notice, and
b. Providing the process by which the mental health agencies must provide that notice.

6. **Analysis of clarity, conciseness, and understandability**

Parts of the rule are not clear, concise, and understandable, as follows:

Subsection (A) uses the undefined ambiguous term “readily visible.” Also, subsection (A) requires agencies to post the exhibit form “in one or more areas” of the agency. This phrase is unclear because the rule does not clearly indicate whether posting the form in one place or multiple places is the minimum action sufficient to fulfill the requirement. Subsection (B) contains passive language that makes it unclear who is required to act under the rule.

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**Exhibit A** Notice of Legal Rights for Persons with Serious Mental Illness

1. **Authorization of the rule by existing statute**
   
   The Exhibit has specific authority under A.R.S. § 36-504(A).

2. **Objective**
   
   The objectives of the Exhibit are to:
   
   a. Provide a condensed list of legal rights for persons with serious mental illness that can be posted at a mental health agency in order to provide the requisite notice of those legal rights to clients, and
   
   b. Provide clients with contact information that clients can use to secure additional information about clients’ rights.

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**Exhibit B** Notice of Legal Rights for Persons with Serious Mental Illness

1. **Authorization of the rule by existing statute**
   
   The Exhibit has specific authority under A.R.S. § 36-506(D).

2. **Objective**
   
   The objective of the Exhibit is to provide a form that mental health agencies can use to inform individuals, in both English and Spanish, that persons undergoing evaluation or treatment under Chapter 21 cannot be denied their civil rights or otherwise discriminated against.

6. **Analysis of clarity, conciseness, and understandability**

Exhibit B is mostly clear, concise, and understandable, except that, as translated into Spanish, it does not include diacritical marks, and as a result is an invalid translation.

1. **Authorization of the rule by existing statute**
   
The rule has specific authority under A.R.S. § 36-3407.

2. **Objectives**
   
The objectives of the rule are to establish:
   a. Responsibilities of the regional authority, clinical team, and case manager in developing and implementing a client’s individual service plan ("ISP");
   b. Requirements for a client’s consent to service planning and services;
   c. Arrangements for a client with special needs;
   d. A process for informing a client and other individuals of information and rights;
   e. Circumstances in which the time to complete an activity may be extended; and
   f. How attendance at meetings may be accomplished.

3. **Analysis of the effectiveness in achieving the objective**
   
   Parts of the rule are not effective for the reasons in paragraphs 4, 5, and 6, and as follows:
   
The rule is not consistent with industry practices. Currently, adult clinical teams are used in the industry for service planning and not the method provided for by the rule.
   
The effectiveness of subsection (B)(2) is diminished when a client is abusing drugs because a treating physician’s medical judgment should dictate which services a client is entitled to receive, not the rule.

4. **Analysis of consistency with state and federal statutes and rules**
   
   Subsection (A)(1)(b) states that “other services may be provided directly by programs operated by the Department or the regional authority . . . .” Under A.R.S. § 36-3410(C) (effective September 1, 2009), RBHAs cannot “deliver behavioral health services directly to clients.” Typically RBHAs contract with providers to deliver services.
   
   However, at the time of the statutory amendment, the RBHA entities also in some cases owned or held equity in provider entities, raising concerns on issues ranging from continuity of services to conflict of interest. The remainder of the rule is consistent with referenced state and federal statutes and rules.

5. **Status of enforcement of the rule**
   
   Subsection (A)(1)(a) is not enforced because the Department does not provide written approval for each contract in this respect. Instead, provider contracts are examined during the Department’s annual administrative review process and each RBHA is required by contract to notify the Department each time it adds or loses a provider.
The Department does not enforce subsections (A)(7)(b) or (e) because it is unclear whether the Department has the power to enforce these provisions against inpatient facilities under this Chapter.

6. **Analysis of clarity, conciseness, and understandability**

Parts of the rule are not clear, concise, and understandable, as follows:

The rule uses undefined words or phrases that have meanings that are dependent on the subjective criteria of the reader or are indefinite, vague, or industry jargon, such as: “work diligently,” “ensure equal access,” and “mainstream of society” in subsection (A)(2); “appropriate” in subsection (A)(4); “reasonable accommodations” and “unreasonably restrict” in subsection (C); “qualified interpreters” in subsection (C)(2); “necessary and relevant information” in subsection (D); “generic providers” and “other services” in subsection (A)(1)(b); “close contact,” “support and assistance,” “promote client involvement,” “problems and disagreements,” and “assist in the exploration of less restrictive alternatives” in subsection (A)(6); “special review” in subsection (C); and “assist,” “individual’s needs,” and “assistance” in subsection (D).

In subsection (A)(3) it is unclear what is meant by the “initial clinical team.” This phrase could be more clear, concise, and understandable if it listed the persons that make up the initial clinical team so as to distinguish it from the “assigned clinical team” referenced in other rules such as subsection (A)(4).

Subsection (A)(6)(g) is overly broad and subsection (A)(6)(k) contains passive language. Subsection (C) is titled “Clients with special needs.” This subsection appears to use this phrase synonymously with “client who needs special assistance.”

Subsection (D)(2) contains passive language. Further, providing titles for each subsection in the rule is not proper rule format.

R9-21-302. **Identification, Application and Referral for Services of Persons with Serious Mental Illness**

1. **Authorization of the rule by existing statute**

The rule has specific authority under A.R.S. §§ 36-550.06 and 36-3408.

2. **Objective**

The objectives of the rule are to ensure that clients receive necessary and supervised behavioral health services by:
a. Requiring a regional authority to develop and implement outreach programs designed
to identify individuals potentially eligible for services for persons with serious mental
illness,
b. Establishing who may make a referral for services,
c. Requires notification of the individual’s rights, and
d. Assigning the client a case manager and clinical team.

3. **Analysis of the effectiveness in achieving the objective**

Parts of the rule are not effective for the reasons in paragraphs 5 and 6.

5. **Status of enforcement of the rule**

The written referral requirement contained in R9-21-302(A)(2) is not done in practice and
not enforced. Although the RBHAs receive referrals, the referrals are not always in
writing.

6. **Analysis of clarity, conciseness, and understandability**

Parts of the rule are not clear, concise, and understandable, as follows:

- The rule uses undefined words or phrases that are industry jargon, ambiguous, or vague.
- Subsection (A) uses “outreach programs;” subsection (B) uses “appropriate individuals.”
- The title of the rule is slightly inaccurate because the individuals referenced in the rule
  have not yet been determined to have a serious mental illness. Once determined, the title
  makes sense retrospectively for those individuals.

R9-21-303. **Eligibility Determination and Initial Assessment**

1. **Authorization of the rule by existing statute**

   The rule has specific authority under A.R.S. §§ 36-550.06 and 36-3408.

2. **Objective**

   The objective of the rule is to ensure that a client who applies for behavioral health
   services receives a thorough assessment by:

   a. Establishing a process for scheduling and conducting an initial interview and
      evaluation of a client; and

   b. Specifying the information that must be assessed during the evaluation, requirements
      for eligibility, and time-frames for determining eligibility.

3. **Analysis of the effectiveness in achieving the objective**

   Parts of the rule are not effective for the reasons in paragraphs 5 and 6 and as follows:
   Subsections (B)(1) and (B)(4)(a) do not indicate what course of action is required where
   the applicant refuses to provide the requisite consent or authorization.
Subsection (F) is inconsistent with industry practice because the qualified clinician does not provide the applicant with the notice required in subsection (G). Rather, the notice is provided by the RBHAs.

Subsection (G)(1)(a) gives the applicant “the right to appeal the SMI eligibility determination . . .” but subsection (G)(1)(b) allows the applicant to reapply for services “at any time.” Under subsection (G)(1)(b), an aggrieved applicant may reapply for services while the applicant has a pending appeal, resulting in wasted resources.

Subsection (G)(2)(b) lists the persons that compose the clinical team. The definition of “clinical team” in R9-21-101(B)(14), however, lists the required clinical team members by job title, even though R9-21-30(G)(2)(b) lists the clinical team members with reference to their credentials. To avoid confusion, R9-21-303(G)(2)(b) should use the same format as the definition.

Further, the rule could be more effective if subsection (D) was presented as the first subsection of the rule.

5. **Status of enforcement of the rule**

Subsection (F) is not followed or enforced because the three day time frame contained in subsection (F) is not enough time for a practitioner to make the SMI eligibility determination. Such is especially difficult in rural Arizona, where there is not the population density of Maricopa County and resources are located much farther apart.

6. **Analysis of clarity, conciseness, and understandability**

The rule is mostly clear, concise, and understandable, but could be improved by defining the following vague or ambiguous words or phrases: subsection (A) uses “qualified clinician” and subsection (F) uses “written notice” and “sufficient information.”

R9-21-304. Interim and Emergency Services

1. **Authorization of the rule by existing statute**

The rule has specific authority under A.R.S. § 36-3408(A).

2. **Objective**

The objective of the rule is to ensure that a client receives interim or emergency services during the interval between determination of eligibility and the development and acceptance of the Individual Service Plan (“ISP”).

R9-21-305. Assessments

2. **Objective**
The objective of the rule is to ensure that a client who applies for behavioral health services receives a thorough assessment that is conducted in a timely manner by:

a. Establishing when an assessment of a client is conducted,
b. Specifying what should be included in a client’s assessment,
c. Establishing timeframes and contents of the assessment report,
d. Establishing requirements for additional evaluation or assessment, and
e. Establishing requirements for a client who requires special assistance.

3. **Analysis of the effectiveness in achieving the objective**

Parts of the rule are not effective for the reasons in paragraphs 5 and 6 and as follows:

Subsection (A)(4) lists the persons who compose the clinical team with reference to their credentials. The definition of “clinical team” in R9-21-101(B)(14), however, lists the required clinical team members by job title. To avoid confusion, subsection (A)(4) should use the same format as the definition.

Subsection (B) is unclear as to what should be done if the information contemplated by the rule is not “available.”

5. **Status of enforcement of the rule**

Subsection (G) is not followed in all cases, because the client is not automatically sent a copy of the client’s assessment report when it would be medically contraindicated to do so. Further, not all service providers are sent a copy of the assessment because not all service providers need the assessment, such as in cases where a client is being treated by one provider for a condition beyond the scope of services of another provider also treating that client, and in other cases, disclosing the assessment could violate privacy laws.

6. **Analysis of clarity, conciseness, and understandability**

Parts of the rule are not clear, concise, and understandable, as follows:

The rule uses the following undefined words or phrases that have meanings that depend on the subjective criteria of the reader: “appropriate” and “necessary” in subsection (A); “relevant” in subsection (C); and “appropriate,” “unreasonably delay,” and “major findings” in subsection (D).

The rule also uses the following undefined words or phrases that are industry jargon or vague: “behavioral health professionals,” “professionals other than behavioral health professionals,” “paraprofessionals,” “participate,” and “comprehensive” in subsection (A); “risk assessment,” “living environment,” and “next steps” in subsection (C); and “resources” in subsection (D).
It is also unclear whether the rule applies to only initial assessments or to each and every assessment conducted throughout a client’s treatment.

The term “DSM” contained in subsection (D)(4) is outdated. The term is likely intended to refer to the current version of the Diagnostic and Statistics Manual for Mental Disorders, which as of May 2013 is the “DSM-5.”

R9-21-306. Identification of Potential Service Providers

2. **Objective**

The objective of the rule is to ensure that clients are matched with service providers that will provide the client with the necessary behavioral health services by establishing:

a. Requirements and time-frames for identifying potential service providers;

b. Procedures for determining which service providers are most appropriate; and

c. Requirements for service providers currently serving the client.

3. **Analysis of the effectiveness in achieving the objective**

The rule is mostly effective, except that subsection (A) does not reflect industry practice. Referrals to specific service providers are completed after the client’s individual service plan (“ISP”) is developed because service providers require the services to be identified in the referrals. Logically, a client’s services must be identified in the client’s ISP before the client chooses the provider of those services. As this is an implementation matter, not an enforcement matter, it detracts slightly from the rule’s effectiveness.

6. **Analysis of clarity, conciseness, and understandability**

The rule is mostly clear, concise and understandable, but could be improved by defining ambiguous or vague phrases such as “promptly contact” and “sufficient information.”

R9-21-307. The Individual Service Plan

1. **Authorization of the rule by existing statute**

The rule has specific authority under A.R.S. § 36-3407(4).

2. **Objective**

The objective of the rule is to ensure that a client’s behavioral health services are provided according to a well-constructed individual service plan (ISP) that focuses on the individual attributes of the client by establishing:

a. Who will be involved in developing an ISP,

b. The process for developing an ISP,

c. Who will attend the ISP meeting,
d. The topics that should be discussed at the ISP meeting,
e. What information will be included in a client’s ISP, and
f. Time-frames for the ISP meeting and the preparation and distribution of the ISP.

3. **Analysis of the effectiveness in achieving the objective**

Parts of the rule are not effective for the reasons in paragraphs 5 and 6 and as follows:
Subsections (B)(3)(c) and (D)(3)(c) are impracticable because they would require the case manager to notify every service provider in Arizona (i.e., every provider is technically a “potential” service provider).

5. **Status of enforcement of the rule**

Parts of the rule are not enforced as written, as follows:
Subsection (A)(2) is not strictly enforced because the rule requires the Department and the RBHAs to plan the client’s service needs without regard for those services that cannot be provided (i.e., “unmet needs”). In practice, the individuals responsible for service planning are aware of the services available to clients and, instead of following the process set up by the rule, they use a more economical approach by considering what services are available and developing the ISP accordingly.
Subsection (B) is not enforced because the time frames in (B)(1) and (B)(3) are arbitrary and unrealistic. When the rules were drafted, the timeframes contained in the rules were achievable. In contemporary practice, inpatient stays are much shorter than when the rules were drafted, making compliance with the rule impracticable.
Subsections (B)(3)(c) and (D)(3)(c) are not enforced for the reasons in paragraph 3.
Subsections (B)(4) and (C) are not followed or enforced because they are overly prescriptive and call for an inflexible approach to conducting the ISP meeting and developing the ISP. Case managers attempt to satisfy the spirit of the rule by using a more economical approach that focuses on the client’s needs and only the topics that affect the client’s care.

For clients who are non-Title XIX, due to funding reductions, assigned case managers and “teams” described in the rule are not always available. To ensure that these clients continue to receive treatment, the Arnold successor agreements allow the Department to coordinate self-directed service plans, peer-support specialist access, and other treatment under the direction of the client’s supervising behavioral health professional.

6. **Analysis of clarity, conciseness, and understandability**

Parts of the rule are not clear, concise, and understandable, as follows:
The rule uses undefined words or phrases that have meanings that depend on the subjective criteria of the reader, or are indefinite, such as: “meaningful,” “most appropriate,” and “easily understood,” in subsection (A); “adequately” in subsection (B); and “the most self-fulfilling” and “adequately” in subsection (C); “actively encourage,” “maximum extent possible,” and “facilitate” in subsection (A); and “long-term view” and “regularly monitored for effectiveness” in subsection (B). Also, subsection (C)(5) uses the phrase “long range goals,” while subsection (C)(6) uses “short-term objectives.” Subsection (B) and (D) provide titles for these subsections, which is not proper rule format.

R9-21-308. Acceptance or Rejection of the Individual Service Plan

2. **Objective**
   The objective of the rule is to ensure that a client receives behavioral health services according to a service plan carefully tailored to the client’s individual circumstances by establishing:
   a. Time-frames for the acceptance, rejection, or modification of an individual service plan (“ISP”);
   b. Procedures for the rejection of an ISP;
   c. Procedures to address a request for other services;
   d. Requirements for the rejection of an ISP or a request of other services;
   e. Procedures for modification of the ISP; and
   f. Requirements for notifying a client of the client’s right to appeal an ISP.

3. **Analysis of the effectiveness in achieving the objective**
   The rule is mostly effective, but could be improved if the issues in paragraph 5 were addressed and as follows: Although R9-21-308(E) and (F) mention a client’s right to appeal the ISP, the rule could be more effective if it more clearly stated those events that trigger a client’s right to appeal issues regarding the ISP.

5. **Status of enforcement of the rule**
   Because of established industry practice, subsection (B) is not enforced as written. Not only do the clients and case managers not wait for 30 days to elapse, but the case manager does not consider the client to have accepted the ISP unless the client or guardian signs it. The rule is otherwise enforced as written.

R9-21-309. Selection of Service Providers
2. **Objective**

The objective of the rule is to ensure that a client is provided behavioral health services by a provider who is capable of meeting the client’s needs that are identified in the individual service plan ("ISP") by:

a. Establishing a process to identify other service providers if previously identified service providers are incapable of meeting the client’s needs, and

b. Requiring service providers to sign and implement the ISP.

3. **Analysis of the effectiveness in achieving the objective**

Parts of the rule are not effective for the reasons in paragraph 6 and as follows: Under subsection (A)(2), it is unclear what a service provider is required to do if the provider does not believe it can effectively treat a patient. Subsection (A) needs to clearly state that the client does not have an absolute right to be treated by a particular provider. Also, the seven-day deadline in subsection (A) and five-day deadline in subsection (A)(2) do not assist in the selection process because it has become customary in the industry for the providers to inform the case manager immediately whether they are unable to satisfy the client’s needs or cannot accept the client because the provider is already at full capacity.

6. **Analysis of clarity, conciseness, and understandability**

Parts of the rule are not clear, concise, and understandable, as follows:

The rule uses the following undefined words or phrases that are ambiguous or vague: "good cause related to the inability of the service provider to safely and professionally meet the client’s needs," "promptly distribute," and "identified services."

R9-21-310. **Implementation of the Individual Service Plan**

2. **Objective**

The objective of the rule is to ensure that a client’s ISP is implemented in the manner contemplated by those persons responsible for creating the ISP by establishing requirements for:

a. When an ISP will be implemented,

b. Assisting a client who is moving into an alternative residential setting, and

c. Contracts with service providers.

6. **Analysis of clarity, conciseness, and understandability**

The rule is mostly clear, concise, and understandable, but could be improved by defining ambiguous or vague words and phrases such as “best efforts,” “appropriate,” “foster the
R9-21-311. Alternative Services

2. **Objective**
The objective of the rule is to ensure that a client receives necessary behavioral health services in the event that the services itemized in the client’s ISP are not immediately available, by establishing:
   a. How and when an alternative service plan is developed,
   b. The persons responsible for developing a plan for alternative services and the procedure for doing so, and
   c. A process for identifying and addressing unmet service needs.

5. **Status of enforcement of the rule**
Not all providers arrange for “alternative services” separate from the ISP. The rule is not enforced because some providers modify the ISP accordingly and the RBHAs each maintain a “Network Plan” that focuses on identifying those services that are needed but otherwise unavailable.

6. **Analysis of clarity, conciseness, and understandability**
The rule is mostly clear, concise, and understandable, but could be improved if it defined ambiguous or vague words and phrases such as “maximum extent possible,” “adequate,” “appropriate,” “least restrictive,” and “client’s freedom.”

R9-21-312. Inpatient Treatment and Discharge Plan

1. **Authorization of the rule by existing statute**
The rule has specific authority under A.R.S. § 36-511(C).

2. **Objective**
The objective of the rule is to ensure that a client receives the necessary behavioral health services for the appropriate amount of time in an inpatient setting by establishing:
   a. A process for the development and review of a client’s inpatient treatment and discharge plan (ITDP);
   b. The persons required to be involved in the development and review of the client’s ITDP;
   c. The information that must be included in the client’s ITDP;
   d. A process for the acceptance, rejection or modification of the ITDP; and
e. A process for the incorporation, approval or modification of the ITDP into the client’s ISP.

3. **Analysis of the effectiveness in achieving the objective**
   Parts of the rule are not effective for the reasons in paragraphs 4, 5, and 6, and as follows:
   Subsection (C)(3)(c) is not effective because non-acute facilities do not admit inpatients.
   Further, although the rule sets forth numerous requirements regarding who must be involved in the development of a client’s discharge plan and the process that must be followed when a client is discharged from inpatient care, the rule does not require that the service providers be included in the ITDP. The rule could be more effective if it required that the service provider be informed of the clients’ medical and psychiatric needs.
   Subsections (B), (C) and (E) contain specific time periods for required actions related to the creation and implementation of the ITDP. At the time the rules were written, patients’ inpatient stays were typically 20 to 30 days and the periods contained in the rule were written with that fact in mind. In the contemporary industry, inpatient stays are typically 5-7 days. The time periods contained in the rule are therefore difficult to comply with in practice.

4. **Analysis of consistency with state and federal statutes and rules**
   Subsection (E)(5), which fixes an appeal window on receipt of the ITDP, is not consistent with R9-21-407(A), which uses receipt of the director’s decision instead. The rule is otherwise consistent with referenced state and federal statutes and rules.

5. **Status of enforcement of the rule**
   Parts of the rule are not enforced as written, as follows:
   Subsection (A)(2) is not always enforced because a patient might require emergency inpatient care. This can occur at a time when it is extremely difficult for a client’s treatment team to be notified of the ITDP before the client is discharged. In this instance, a client’s treatment team will not participate in developing a client’s ITDP.
   Further, under subsection (A)(8), clients are discharged regardless of whether their ITDP is completed. The spirit of subsection (A)(8) is followed and enforced, but the discharge plan for a client is not always a separate document, and is often incorporated into the ISP since the treatment discussed in those documents frequently overlap.

6. **Analysis of clarity, conciseness, and understandability**
   Parts of the rule are not clear, concise, and understandable, as follows:
   The rule uses undefined words or phrases that have meanings that are dependent on the subjective criteria of the reader or that are indistinct, vague, or industry jargon, such as:

Each subsection also includes a title, which is not proper rule format.

**R9-21-313. Periodic Review of Individual Service Plans**

2. **Objective**

   The objective of the rule is to ensure that the client’s ISP remains current by establishing:
   a. A process and time-frames regarding the review of a client’s ISP;
   b. The persons involved in reviewing the ISP and the content of the review; and
   c. Requirements for when the updated ISP will be developed, distributed, approved, and implemented and the process for doing so.

3. **Analysis of the effectiveness in achieving the objective**

   Parts of the rule are not effective for the reasons in paragraphs 5 and 6, and as follows:

   When all of the timeframes in subsection (A) are examined as a whole, the entire process is very confusing, making it difficult for a reader to interpret what the rule requires.

   Subsection (A)(2) requires a periodic review of the client’s ISP. A periodic review is not necessary because clinical best practices dictates that a client’s treatment plan be reviewed (and amended or modified as necessary) each time the treatment team meets.

5. **Status of enforcement of the rule**

   The rule is mostly enforced, except for the following:

   Subsection (B) requires that specific persons be invited in writing to the ISP review. The requisite persons are often invited to the ISP review, but not in writing. Similarly, subsection (B)(2) enumerates various topics to be discussed at the ISP review. Providers do not strictly follow the rule, but instead focus on the needs of the client.

6. **Analysis of clarity, conciseness, and understandability**

   Parts of the rule are not clear, concise, and understandable, as follows:

   The rule uses undefined words or phrases that have meanings that are dependent on the subjective criteria of the reader or are indefinite, such as: “appropriate” and “fullest possible participation” in subsection (A); and “client’s independence,” “to the extent possible given the circumstances of the client and the availability of information” and “necessity or advisability” in subsection (B).

   Each subsection also includes a title, which is not proper rule format.
R9-21-314. Modification or Termination of Plans

2. **Objective**
   The objective of the rule is to ensure that a client’s ISP remains current and is tailored to the client’s need for behavioral health services by:
   a. Allowing for modification or termination of the ISP;
   b. Establishing a process for the modification of a client’s ISP;
   c. Specifying the conditions under which an ISP may be modified; and
   d. Establishing requirements for the approval, incorporation, distribution, and implementation of the ISP.

3. **Analysis of the effectiveness in achieving the objective**
   Parts of the rule are not effective for the reasons in paragraphs 5 and 6, and as follows:
   Subsection (J)(2) is too vague and fails to account for the circumstance where a client desires to be transferred while an appeal is pending or where a client must be transferred to ensure the client’s health or safety. Further, subsection (K) could be more effective if it included a time frame for termination of services under this rule.

5. **Status of enforcement of the rule**
   The rule is mostly enforced, except that subsection (F)(2) is not strictly followed or enforced because service providers do not maintain a copy of the client’s ISP. The case manager, therefore, does not distribute a modified copy of the ISP to all service providers, but only to service providers who need it.

6. **Analysis of clarity, conciseness, and understandability**
   Parts of the rule are not clear, concise, and understandable, as follows:
   The rule uses undefined words or phrases that are ambiguous because they have meanings that are dependent on the subjective criteria of the reader, such as:
   “appropriate” in subsections (C), (F) and (K); “more appropriately” and “suitable” in subsection (D); “promptly” in subsection (E); “serious” and “immediate threat” in subsection (J), “modification” in subsection (C); “needs, goals, and objectives,” and “less restrictive of the client’s freedom” in subsection (D); “notified,” and “as soon as possible” in subsection (E); “deemed” in subsection (G); and “qualified clinician” and “move to terminate” in subsection (K).

R9-21-401. Appeals

2. **Objective**
The objective of the rule is to establish an appeal process for clients wishing to challenge decisions regarding eligibility for behavioral health services, assessments, evaluations, or fees for services, service plans or treatment plans, or implementation of a client’s service plan or treatment plan, by establishing:

a. When a client may file an appeal;

b. The types of situations that may be appealed to the regional authority and the timeframe(s) for doing so;

c. Processes for informing the client of the client’s right to appeal, initiating an appeal, conducting information conferences with the regional authority and the Division of Behavioral Health Services ("DBHS") to attempt to resolve the disputed issue; and

d. Processes for conducting a fair hearing and an expedited appeal and for maintaining a public record of appeals.

3. **Analysis of the effectiveness in achieving the objective**

   Parts of the rule are not effective for the reasons in paragraphs 4, 5 and 6, and as follows:

   Subsection (A)(1) is not effective because the “departmental guidelines” referenced in the rule do not exist in practice.

   Subsection (B) requires a notice to be in English and Spanish, which is unnecessary in cases where the person receiving the notice is not bilingual.

   Subsection (C)(11) is unrealistic because if a client is refusing services, the client will not likely file an appeal, but instead simply stop going for treatment.

   Subsection (C)(14) is unnecessary because the procedure for enforcing the time requirements of the appeal process are already set forth in R9-21-410(C).

   Under subsection (D)(2), oral appeals are a common phenomenon. The rule could be more effective if it clarified a RBHA’s role in accepting a “brief statement of the reasons for the appeal” and set forth the process for documenting an oral appeal.

   Subsection (D)(3) could be more effective if it also stated the process for a party to challenge the RBHA’s or director’s “good cause” determination.

   Subsection (H), regarding an “expedited appeal,” does not explain the procedural process for when an expedited appeal request is denied on procedural grounds, such as when an appeal is dismissed based on lack of jurisdiction or standing. Currently, the rules indicate that an expedited appeal denied on one of these grounds would proceed to the normal appellate process. This is not the most economical approach to resolving these disputes.

   Subsection (G) enumerates various requirements under the heading “The fair hearing.” Many of these provisions are duplicative of the Administrative Procedure Act ("APA").
The rule could be more effective if it contained “fair hearing” provisions that were specific to the Department and not already generally stated in the APA. Subsection (M) (“Appeal log”) could be more effective if it specifically enumerated the portions of the log that constitute a public record. This would allow the Department to more easily comply with public record requests while maintaining the desired confidentiality of the client.

4. **Analysis of consistency with state and federal statutes and rules**
   Subsection (G)(10) requires the Administrative Law Judge (“hearing officer”) to issue a written decision in five days, but A.R.S. § 41-1092.08(A) allows the Administrative Law Judge 20 days to issue a written decision. The rule also references statutes that are no longer used. The rule is otherwise consistent with referenced state and federal statutes and rules.

5. **Status of enforcement of the rule**
   Because of the number of conferences, and the demands on the chief executive officers (CEO) of the RBHAs and the deputy director of DBHS, the CEOs and deputy director do not participate in the informal conferences in R9-21-401(E) and (F).

6. **Analysis of clarity, conciseness, and understandability**
   Parts of the rule are not clear, concise, and understandable, as follows:
   The rule uses the undefined words or phrases that have meanings that are dependent on the subjective criteria of the reader, such as “necessary,” “serious or immediate threat,” “appropriate,” “appropriateness,” “good cause,” “convenient,” “reasonable,” “unwarranted,” “substantial,” “timely,” and “concise.”
   The rule also uses undefined words or phrases that are industry jargon or otherwise attempt to convey ideas that are naturally indistinct and need clarification, such as “assessments and further evaluations,” “fees and waivers,” “categorical ineligibility,” “interfered,” “assist,” “peer support and advocacy services,” “long-term view,” “access,” “assessment or case management services,” “notifying,” “informal conference,” “clarify issues,” “reduced to an agreed statement of facts,” “director of the regional authority or the director’s designee,” “dated written notice to all parties,” “written notice of fair hearing,” “without prejudice to the appeal,” “explained to the client,” “understandable to the client,” and “informal conference.”
   R9-21-401(D) through R9-21-401(M) contain subsection titles, which is not proper rule format, and is inconsistent with the formatting of R9-21-401(A) through R9-21-401(C).
R9-21-402. General

2. **Objective**
   The objectives of the rule are to:
   a. Enumerate the circumstances under which it is the Division’s policy to conduct an investigation, and
   b. Establish the persons who may file or initiate the grievance procedure.

3. **Analysis of the effectiveness in achieving the objective**
   Parts of the rule are not effective for the reasons in paragraph 6 and as follows:
   Subsection (B) is not effective because it needs to be more specific. As written, the rule does not require a grievance to be directed toward a specific individual or incident (“...violation of the client’s rights or of the rights of several clients...”), which allows individuals to file grievances that make only conclusory or generalized allegations. The Department must then blindly investigate generalized complaints.
   Subsection (A) implies that the “Division” is required to conduct investigations in “four circumstances.” R9-21-404 (Persons Responsible for Resolving Grievances and Requests for Investigation), however, specifically itemizes the various persons responsible for resolving grievances and requests for investigation, many of whom are not employed by the Division. Further, in the event of a client death or allegations of abuse, law enforcement personnel that are not part of the Division have the authority to trigger a criminal investigation that is completely beyond the control of the Division.
   Subsection (A) could be clarified to avoid the erroneous impression that the Division is solely responsible to conduct investigations in the “four circumstances” listed in the rule.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is mostly clear, concise, and understandable, but could be improved by defining vague or ambiguous terms or phrases, such as “dangerous,” “inhumane,” “appropriate,” “prompt,” “equitable,” “due regard,” and “dignity” in subsection (A).

R9-21-403. Initiating a Grievance or Investigation

2. **Objective**
   The objective of the rule is to establish the persons that may file a grievance or request for investigation by establishing:
   a. When an investigation is required to be initiated;
   b. When an investigation is within the discretion of the Department; and
c. The procedure for when an employee fails to file, forward, or assist a client in filing a grievance.

3. **Analysis of the effectiveness in achieving the objective**
Parts of the rule are not effective for the reasons in paragraphs 5 and 6 and as follows:
Subsection (F) is an oversimplification of the grievance process and unrealistic in practice. Clients are not generally comfortable with filing a grievance with the same party that the grievance is against. Further, it is equally uncomfortable for the client to seek assistance from the party against whom the grievance was made.
There should be an easier process for clients to initiate grievances. The rules are too complicated for the typical client to discover the appropriate process for filing a grievance. The rule would be more effective if there was a published phone number or e-mail contact point through which a client could file a grievance.

5. **Status of enforcement of the rule**
Parts of the rule are not enforced, as follows:
Subsection (C) cannot be enforced because it is questionable whether the Department has the power to compel employees to file grievances.
Subsection (D) requires the director of a service provider or the director of a regional authority to file a grievance in certain circumstances. This does not happen in practice and is not enforced by the Department.
The Department also does not strictly enforce the requirement in subsection (G) that a written grievance be submitted using a specific form.

6. **Analysis of clarity, conciseness, and understandability**
Parts of the rule are not clear, concise, and understandable, as follows:
The rule uses the following undefined words or phrases that have meanings that are dependent on the subjective criteria of the reader: “non-frivolous” in subsection (D); “best interests” in subsection (E); and “appropriate” in subsection (F).
The rule also uses the following undefined words or phrases that are industry jargon or otherwise vague: “disciplinary action,” “abridged,” and “regional authority” in subsection (C); “director” in subsection (D); and “assist,” “accurately,” “completely,” and “available supervisory or managerial staff” in subsection (F).
Generally, the rule needs to make a clear distinction between a grievance and request for investigation. The rules fail to make this distinction, which confuses those individuals charged with duties under the rules.
Further, the phrase “shall assist” in subsection (F) is too broad. It is unclear what degree of assistance is required. As a result, clients have manipulated this provision to force employees to listen to long diatribes under the pretext of filing an oral grievance.

R9-21-404. Persons Responsible for Resolving Grievances and Requests for Investigations

2. Objective
The objectives of the rule are to establish:
   a. The individuals who will address and initially determine different types of rights violations and conditions requiring investigation, and
   b. The process for notifying the individual who filed a grievance or request for investigation.

6. Analysis of clarity, conciseness, and understandability
The rule is mostly clear, concise and understandable, but could be improved if subsection (B)(1)(b), which contains the provision, “If the mental health agency is operated exclusively by a governmental entity,” simply named the Arizona State Hospital, which is the only such facility in Arizona that meets that description unless or until another such facility is built or opens.

R9-21-405. Preliminary Disposition

2. Objective
The objectives of the rule are to establish:
   a. The circumstances where a grievance or request for investigation must be disposed of without further action or through the individual service planning process,
   b. The circumstances where a grievance or request for investigation may be disposed of without investigation,
   c. The requirements and process for appointing an investigator, and
   d. The procedure for notifying the Office of Human Rights for a client in need of special assistance or actions taken on behalf of a client.

3. Analysis of the effectiveness in achieving the objective
Parts of the rule are not effective for the reasons in paragraphs 4, 5, and 6, and as follows: The rule is unclear with respect to when an individual has the right to file a grievance under the rules (i.e., whether the person has “standing” to file a grievance). It is currently argued in the industry that a person has “standing” to file a grievance or request for
investigation if the person was enrolled in the behavioral health system *when the alleged incident occurred*. Others argue, however, that the person filing a grievance or a request for investigation must be enrolled in the system *at the time of the filing*, regardless of whether the person was enrolled in the system at the time of the incident. The rules should be clarified in this regard.

Subsection (C)(1)(a) allows disposition of a grievance without an investigation if the matter “*involves no dispute as to the facts*.” This rule could be more effective if this language was amended to something like ‘no dispute as to a *material* fact.’ The rule’s effectiveness is compromised where a grievance cannot be summarily disposed of simply because there is a dispute regarding an immaterial fact.

4. **Analysis of consistency with state and federal statutes and rules**

Subsection (C)(2)(b), requiring mandatory dissemination of the decision to a variety of parties, might be inconsistent with state or federal privacy laws. The rule does not require that the decision be “de-identified” of personal information, as is required by A.R.S. § 36-509 and by the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”). See 42 U.S.C. 1320d-1; 45 CFR § 160.103; 45 C.F.R. § 164.502(d)(2); and 45 C.F.R. §§ 164.514(a) and (b). The rule could be clarified to indicate that de-identification should be used to ensure that the rule does not violate HIPAA. A.R.S. § 36-509 was amended in Laws 2011, Ch. 268, § 7 to be consistent with HIPAA.

The rule is otherwise consistent with referenced state and federal statutes and rules.

5. **Status of enforcement of the rule**

Subsection (C)(3) requires a 30 day waiting period before taking action to resolve grievances (i.e., “*after the expiration of the appeal period without appeal by any party . . .*”). This is not always followed in practice or enforced, because immediate action in response to a grievance is required in some cases. The Department also enforces the rule according to the requirements in HIPAA and A.R.S. § 36-509, as described in paragraph 4 above, for any instance when following the rule as written would conflict.

6. **Analysis of clarity, conciseness, and understandability**

Parts of the rule are not clear, concise, and understandable, as follows:

The rule uses the following undefined words or phrases that have meanings that are dependent on the subjective criteria of the reader: “*reasonable*” in subsection (A); “*essential,*” “*promptly,*” and “*appropriately*” in subsection (C);

The rule also uses the following undefined words or phrases that are industry jargon or otherwise attempt to convey ideas that are naturally indefinite and need clarification:
summarily dispose,” “primarily directed,” “fairly and efficiently addressed,” and “directly or indirectly involve” in subsection (B); “prepare” and “anyone else having a direct interest in the matter” in subsection (C); and “a person with direct line of authority over” in subsection (D).

Subsection (C)(1)(b) allows for summary disposition of a grievance or request for investigation where the matter “is patently frivolous.” As discussed in the section of this report regarding R9-21-101, the definition of “frivolous” is not a clear or effective definition. It is also unclear whether the drafters of the rule intended the rule to require a higher standard of frivolity by using the adjective “patently” before the word “frivolous.” Subsections (B) through (D) each have titles, which is not proper rule format and is not consistent with the untitled subsection (A).

R9-21-406. Conduct of Investigation

2. Objective
The objective of the rule is to establish requirements for:
   a. How an investigator will conduct an investigation,
   b. The completion and dissemination of the investigator’s report,
   c. The acceptance or rejection of the investigator’s report, and
   d. Acting upon an accepted report.

3. Analysis of the effectiveness in achieving the objective
Parts of the rule are not effective for the reasons in paragraphs 4, 5, and 6, and as follows:
The time frames contained in the rule are arbitrary, inflexible, and when examined as a whole, are confusing. Including deadlines for major tasks required by the rule is an effective approach, such as requiring that the report be completed within the 30 days. Yet, by also requiring that each task leading up to the completion of the report be done within a specified period of time, the rule is complicating the process and does not allow for the use of a more effective alternative approach to complete the same task. Also, it is questionable whether the Department has the authority to discipline employees under subsection (B)(3).

4. Analysis of consistency with state and federal statutes and rules
Subsections (A)(1)(b) and (B)(1) allow the client to create an audio tape recording of certain conferences that occur during the investigation “provided that the individual must notify all other parties to such meetings or hearings . . .” These rules are inconsistent with A.R.S. § 13-3005 and A.R.S. § 13-3012(9), which allow an individual to record an
oral communication that the individual is a party to, regardless of whether the individual notifies the other parties to the communication.

The rule is otherwise consistent with referenced state and federal statutes and rules.

5. **Status of enforcement of the rule**

Subsection (G) requires a 30-day waiting period before taking action to resolve grievances (i.e., “after the expiration of the appeal period set forth in R9-21-407 . . .”).

This is not always followed or enforced because immediate action in response to an investigation is required in some cases.

6. **Analysis of clarity, conciseness, and understandability**

Parts of the rule are not clear, concise, and understandable, as follows:

The rule uses the following undefined words or phrases that have meanings that are dependent on the subjective criteria of the reader: “promptly” in subsection (A)(2); “relevant” and “appropriate” in subsection (C); and “briefly” in subsection (D).

The rule also uses the following undefined words or phrases that are industry jargon or are otherwise vague: “private, face-to-face conference” in subsection (A); “prepare” in subsection (D); “developing” in subsection (F); and “after the exhaustion of all appeals and subject to the final decision on appeal” in subsection (G).

Subsection (E)(1)(b)(i) contains an incorrect citation (“R9-21-406”) – the citation should be to “R9-21-407.”

R9-21-407. **Administrative Appeal**

2. **Objective**

The objectives of the rule are to establish:

a. A process for filing an appeal to the Department from the findings of a grievance conducted by an agency, and

b. Requirements for the Division’s internal appeal process.

3. **Analysis of the effectiveness in achieving the objective**

Parts of the rule are not effective for the reasons in paragraphs 5 and 6 and as follows:

If an investigation is summarily disposed of under R9-21-405 (“Preliminary Disposition”) before a full investigation is completed and the director rejects the report for insufficiency of facts under subsection (B)(2), then the remaining time to complete the investigation is only 10 days. This is an unrealistic burden where the case has been summarily disposed of because the investigator will have only 10 days to conduct a full investigation.
5. **Status of enforcement of the rule**
Subsection (B)(3) is not enforced because there is not a meeting or conference held during the process described in the rule.
The rule is otherwise consistent with referenced state and federal statutes and rules.

6. **Analysis of clarity, conciseness, and understandability**
The rule is mostly clear, concise, and understandable, but could be improved by defining ambiguous or vague words and phrases, such as “notice of appeal” and “full case record” in subsection (A) and “afforded the opportunity” in subsection (B).

R9-21-408. **Further Appeal to Administrative Hearing**

2. **Objective**
The objective of the rule is to establish processes for:
   a. Requesting and conducting a fair appellate hearing, and
   b. Notifying parties of their right to a hearing and of the disposition of the appeal.

4. **Analysis of consistency with state and federal statutes and rules**
This rule conflicts with the Arizona Administrative Procedure Act (“APA”) and needs to be amended to be consistent with A.R.S. Title 41, Chapter 6, Article 10. A.R.S. § 41-1092.08(A) gives the ALJ 20 days after conclusion of the hearing to issue a written decision, but subsection (B)(7) requires the ALJ to issue the decision within 10 days. A.R.S. § 41-1092.08 requires the Director to issue a written decision within 30 days after the hearing, but subsection (C) requires that it be done in 20 days. Subsection (D) cites A.A.C. R9-1-120, a rule repealed in 2002, regarding rehearing and review. The rule is otherwise consistent with referenced state and federal statutes and rules.

5. **Status of enforcement of the rules**
As discussed in paragraph 4, certain provisions conflict with the APA, and are enforced according to the APA in such instances.

6. **Analysis of clarity, conciseness, and understandability**
Parts of the rule are not clear, concise, and understandable, as follows:
The rule uses the following undefined words or phrases that are ambiguous because they have meanings that depend on the subjective criteria of the reader: “reasonable,” “unwarranted” and “substantial” in subsection (B).
The rule also uses the following undefined industry jargon: “notice requesting a fair hearing” and “notice of further appeal” in subsection (A).
Because of the way subsection (B) is written, it is unclear whether the hearing must be conducted with only those portions of the APA that are consistent with Article 4. Subsection (B) incorrectly cites A.R.S. § 41-1061 et seq. The correct citation for the APA is A.R.S. § 41-1092 et seq.

R9-21-409.  Notice and Records

2.  **Objective**

   The objective of the rule is to establish:
   
   a.  A process for clients to receive information on their grievances and investigation rights;
   b.  The role and responsibilities of the Office of Human Rights ("OHR") and the human rights committees ("HRC") in assisting a client needing special assistance;
   c.  Requirements for notifying, as required by the law, law enforcement, the deputy director or the Division, or another entity of certain actions or events;
   d.  Requirements for the maintenance of case records regarding grievances or requests for investigation; and
   e.  Requirements for maintaining public logs on deaths, grievances, and requests for investigation.

3.  **Analysis of the effectiveness in achieving the objective**

   Parts of the rule are not effective for the reasons in paragraphs 5 and 6 and as follows:
   
   Subsection (A) unnecessarily duplicates the "notice of rights" provisions contained in R9-21-201(A)(12), R9-21-211(A), and Article 2, Exhibit A.
   
   Subsection (B)(2) requires OHR and HRCs to assist clients in filing grievances. The Department does not have enforcement power over HRCs.
   
   Subsection (B)(3) requires an HRC to intervene as a party to a client’s grievance concerning "abuse or a dangerous condition." First, the Department does not have enforcement power over HRCs. Second, there is no apparent benefit to requiring the HRCs to intervene in such cases, other than providing them legislative standing to do so. The HRCs receive a copy the decisions under R9-21-406(E)(1)(a)(v), so they are already required to be informed about what occurs during the process.
   
   Subsection (C)(1) is unnecessary because it requires nothing that is not already required by a different "rule, regulation, statute or other law."
   
   Subsection (C)(2)(a), (b), (c) are unnecessary because they are duplicative of the reporting requirements contained in R9-20-202, "Required Reports."
5. **Status of enforcement of the rule**
Parts of the rule are not enforced as written, as follows:

Subsections (C)(2)(a) through (c) are not enforced because, in practice, the agency director does not know when those events occur.

Subsection (E)(1) is not enforced because public logs are created for every grievance or request investigation at the start of the process. Whether a grievance or investigation request is “frivolous” is not determined until well after the public log is created, and the log already having been published to the public, grievances listed on it are not removed. It makes no sense, therefore, to limit the public log requirement to only “non-frivolous grievances or requests for investigation.”

Subsection (B)(2) requires HRCs to assist clients in filing grievances. The Department does not have enforcement power over HRCs.

6. **Analysis of clarity, conciseness, and understandability**
Parts of the rule are not clear, concise, and understandable, as follows:

The rule uses the following undefined words or phrases that are ambiguous because their meaning depends on the subjective criteria of the reader: “special efforts,” “brief memorandum,” and “prominent place” in subsection (A); “best efforts,” “dangerous condition” and “significant” in subsection (B); and “concise” in subsection (E).

The rule also uses the following undefined words or phrases that are vague because they attempt to convey ideas that are indefinite or indistinct in nature: “informed” in subsection (A); “neglect” in subsection (C); and “public log” and “symbol for the agency” in subsection (E).

Subsection (A) is written in the passive voice.

Each subsection is titled, which is not proper rule format.

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**R9-21-410. Miscellaneous**

2. **Objective**

The objective of the rule is to establish requirements for protecting the health, safety, or security of a client, complaining party, or witness through the grievance process by:

a. Establishing criteria to determine when an official is disqualified from participating in a grievance,

b. Describing the method for requesting an extension of time,

c. Establishing a process for protesting a procedural irregularity, and
3. **Analysis of the effectiveness in achieving the objective**
Parts of the rule are not effective for the reasons in paragraph 6 and as follows:
Subsection (A) could be more effective if it allowed a third party to move to disqualify the officials listed in the rule, instead of relying on the officials to disqualify themselves. 
Subsection (B) essentially permits an unlimited number of requests for extensions of time. An excessive number of extensions could effectively render the timeframes in the rules meaningless. The lack of any language in subsection (C) indicating that decisions regarding procedural irregularities are appealable implies that these decisions are final.
The rule could be more effective if this was clarified.

6. **Analysis of clarity, conciseness, and understandability**
The rule is mostly clear, concise, and understandable, but could be improved if it defined ambiguous words such as “unreasonably,” “threat,” “safety,” “security,” and “necessity” in subsection (B) and “promptly” and “appropriate” in subsection (C), and if it did not contain apparent titles to each subsection, which is not proper rule format.

R9-21-501. **Court-ordered Evaluation**

1. **Authorization of the rule by existing statute**
The rule has specific authority under A.R.S. §§ 36-520.

2. **Objective**
The objectives of the rule are to:
   a. Identify the forms used for applying for a court-ordered evaluation,
   b. Establish responsibilities of a RBHA and mental health agency in initiating a court-ordered evaluation, and
   c. Establish that court-ordered evaluations conducted on an outpatient basis are preferable if consistent with the individual’s medical needs.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable, except that there is a term of jargon used in subsection (B), “pre-petition screening,” that could be further clarified.

Exhibit A **Application for Involuntary Evaluation**

1. **Authorization of the rule by existing statute**
Exhibit A has specific authority under A.R.S. § 36-520.
2. **Objective**
The objective of Exhibit A is to provide a standard form to be used for an application for involuntary evaluation.

**Exhibit B**  Petition for Court-Ordered Evaluation

1. **Authorization of the rule by existing statute**
Exhibit B has specific authority under A.R.S. §§ 36-520 and 36-523.

2. **Objective**
The objective of Exhibit B is to provide a standard form to be used for a petition for court-ordered evaluation.

**R9-21-502.  Emergency Admission for Evaluation**

1. **Authorization of the rule by existing statute**
The rule has specific authority under A.R.S. § 36-524.

2. **Objective**
The objectives of the rule are to:
   a. Identify the form used for initiating an emergency admission for a court-ordered evaluation,
   b. Establish responsibilities of a regional authority and evaluation agency in initiating an emergency admission, and
   c. Establish that a regional authority is not required to pay for an emergency admission unless the evaluation agency provides notification to the regional authority as prescribed by the rule.

6. **Analysis of clarity, conciseness, and understandability**
The rule is mostly clear, concise, and understandable, but could be improved if subsections (B) and (C) did not imply that the RBHAs are financially responsible for emergency evaluations, subsection (D) did not imply that the Department specifically licenses mental health agencies to provide “emergency services,” and somewhere in subsection (B) the petition for court-ordered evaluation was identified as Exhibit B.

**Exhibit C**  Application for Emergency Admission for Evaluation

1. **Authorization of the rule by existing statute**
Exhibit C has specific authority under A.R.S. §§ 36-520 and 36-523.

2. **Objective**
The objective of Exhibit C is to provide a form to be used for an application for emergency admission for evaluation.

R9-21-503. Voluntary Admission for Evaluation

1. **Authorization of the rule by existing statute**
The rule has specific authority under A.R.S. §§ 36-522(C).

2. **Objective**
The objectives of the rule are to:
   a. Identify the form used for initiating a voluntary evaluation, and
   b. Establish responsibilities of a regional authority and evaluation agency in initiating a voluntary evaluation.

6. **Analysis of clarity, conciseness, and understandability**
The rule is mostly clear, concise, and understandable, but could be improved if subsections (B)(2), (D)(2) and (E) did not use industry jargon, “informed consent.”

Exhibit D Application for Voluntary Evaluation

1. **Authorization of the rule by existing statute**
Exhibit D has specific authority under A.R.S. §§ 36-522.

2. **Objective**
The objective of Exhibit D is to provide a standard form to be used for an application for voluntary evaluation.

R9-21-504. Court-ordered Treatment

2. **Objective**
The objectives of the rule are to:
   a. Identify the forms used for initiating court-ordered treatment, and
   b. Establish the responsibilities of a regional authority and the mental health agency in initiating a court-ordered treatment.

3. **Analysis of the effectiveness in achieving the objective**
The rule is mostly effective in achieving the objective, except as discussed in paragraphs 4 and 6.

4. **Analysis of consistency with state and federal statutes and rules**
The rule is mostly consistent with state and federal statutes and rules, except that
R9-21-504(A) permits a RBHA to provide court-ordered treatment services directly, whereas under A.R.S. § 36-3410(C) (effective September 1, 2009), a RBHA cannot “deliver behavioral health services directly to clients.”

Exhibit E  Affidavit
Persistently or Acutely Disabled (Exhibit E, Addendum No. 1)
Gravely Disabled (Exhibit E, Addendum No. 2)

2. **Objective**
The objective of Exhibit E and its addenda is to provide form affidavits that can be used by attesting examining physicians to provide a summary of the facts that support the allegations of the petition, as required in A.R.S. § 36-533.

Exhibit F  Petition for Court-Ordered Evaluation (Gravely Disabled Person)

2. **Objective**
The objective of the Exhibit F is to provide a form that can be used for a petition for court-ordered evaluation for gravely disabled persons that contains the information required by court-ordered treatment process in A.R.S. § 36-533.

6. **Analysis of clarity, conciseness, and understandability**
Exhibit F is mostly clear, concise, and understandable, but could be improved if it identified itself as also being applicable to individuals who are “persistently or acutely disabled,” and if it defined the undefined industry jargon “Title 14 guardian” and “Title 36 guardian.”

R9-21-505.  Coordination of Court-ordered Treatment Plans with ISPs and ITDPs

2. **Objective**
The objective of the rule is to establish a process for coordinating court-ordered treatment plans with ISPs and ITDPs.

R9-21-506.  Review of Court-ordered Individual

2. **Objective**
The objective of the rule is to establish a process for the review and examination of a client and non-client receiving court-ordered treatment.

6. **Analysis of clarity, conciseness, and understandability**
The rule is mostly clear, concise, and understandable, but could be improved if it did not use the following ambiguous words and industry jargon: “effective,” “timely fashion” in subsection (A); “appropriate” and “special record” in subsection (B); and “non-client” in subsection (C). Also, the title uses “individual” in the singular, while R9-21-507 uses “persons” and is plural; the usage should be consistent. The rule’s understandability could also be improved by reorganization; repeatedly in all subsections the rule refers to “review and examination” or “examination and review,” but ultimately the only provisions for “examination” in the rule are buried in subsection (B)(2)(c).

R9-21-507. Transfers of Court-ordered Persons

2. **Objective**
   The objective of the rule is to establish a procedure for transferring clients and individuals who are seriously mentally ill but are not current being treated by a RBHA from one mental health agency to another.

3. **Analysis of the effectiveness in achieving the objective**
   Parts of the rule are not effective for the reasons in paragraph 6 and because subsection (D) states that “all clients shall be transferred according to the procedures in Article 3 of this Chapter,” however, Article 3 does not specifically contain procedures for the transfer of clients, but rather provisions such as R9-21-314(J)’s prohibition of transfer under specified circumstances.

6. **Analysis of clarity, conciseness, and understandability**
   Parts of the rule are not clear, concise, and understandable, as follows:
   The rule uses undefined words or phrases that are ambiguous because they have meanings that are determined by the subjective criteria of the reader: “mental disorder” in subsection (A); “appropriate,” “serious physical harm,” and “serious illness” in subsection (B); and “orderly fashion” in subsection (E).
   Subsection (A) defines the phrase “non-client.” Definitions that are applicable only to a specific article or section should appear at the beginning of that article or section.
   Also, the title uses “persons” in the plural, while R9-21-506 uses “individual” in the singular; the usage should be consistent. The rule is otherwise clear, concise, and understandable.

R9-21-508. Requests for Notification

2. **Objective**
The objective of the rule is to establish a process for the notification of a relative, victim, or other individual when an individual who is determined to be a danger to others is released from court-ordered treatment prior to expiration of the court-order.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is mostly clear, concise, and understandable, but could be improved by minor technical changes such as correcting a grammatical error in subsection (A).

**Exhibit G Demand for Notice by Relative or Victim**

1. **Authorization of the rule by existing statute**
   Exhibit G has specific authority under A.R.S. §§ 36-541.01(D).

2. **Objective**
   The objective of Exhibit G is to provide a form to be used as part of a demand for notice by a relative or victim so that the petitioning relative or victim can request to be informed at a specific mailing address or telephone number when a patient is released prior to the expiration of the period ordered by the court.

**Exhibit H Petition for Notice**

1. **Authorization of the rule by existing statute**
   Exhibit H has specific authority under A.R.S. § 36-541.01.

2. **Objective**
   The objectives of the Exhibit are to:
   a. Provide a form to be used for a petition for notice under A.R.S. § 36-541.01 so that an individual other than a relative or victim can request to be informed when a patient is released prior to the expiration of the period ordered by the court, and
   b. Provide a standard order that can be used by the Superior Court of the State of Arizona to ensure that notice is provided to the petitioning individual.

**R9-21-509. Voluntary Admission for Treatment**

2. **Objective**
   The objectives of the rule are to:
   a. Establish a process and form for voluntarily admitting an individual for treatment,
   b. Specify the responsibilities of the regional authorities of mental health agencies in referring clients,
c. Notify other entities and paying for treatment, and
d. Establish requirements for the development or review of an ISP for an individual receiving voluntary treatment.

6. **Analysis of clarity, conciseness, and understandability**

   The rule is mostly clear, concise, and understandable, but could be improved if subsection (A)(4) did not use the ambiguous phrase “appropriately admitted” and subsection (B) did not use undefined industry jargon, “informed consent.”

**Exhibit I Application for Voluntary Treatment**

1. **Authorization of the rule by existing statute**

   Exhibit I has specific authorization under A.R.S. § 36-518.

2. **Objective**

   The objective of Exhibit I is to provide a form to be used for an application for voluntary treatment to ensure that an individual provides informed consent before receiving treatment.

**R9-21-510. Informed Consent in Voluntary Application for Admission and Treatment**

2. **Objective**

   The objectives of the rule are to:
   
   a. Require informed consent to voluntary treatment,
   
   b. Establish the process and content of an informed consent to voluntary treatment,
   
   c. Establish a process for revoking consent, and
   
   d. Establish requirements for the documentation relative to informed consent to voluntary treatment.

6. **Analysis of clarity, conciseness, and understandability**

   Parts of the rule are not clear, concise, and understandable, as follows:

   The rule uses the following undefined words that are ambiguous because they have meanings that depend on the subjective criteria of the reader: “reasonable” in subsection (B); “reasonably clear,” “necessary,” “harmful,” and “abrupt” in subsection (C); and “fair explanation” and “reasonably” in subsection (D).

   The rule is otherwise clear, concise, and understandable.

**R9-21-511. Use of Psychotropic Medication**

2. **Objective**
The objective of the rule is to establish requirements for:

a. Ordering and administering psychotropic medications for individuals receiving court-ordered evaluation and treatment,

b. Detecting side-effects and toxic reactions to medications, and

c. Policies and procedures for ordering and administering psychotropic medications.

6. Analysis of clarity, conciseness, and understandability

The rule is mostly clear, concise and understandable, but could be improved by defining ambiguous or vague words or phrases such as “toxic reactions” and “deleterious,” and by revising the rule so that subsection (A) does not appear redundant of subsection (B)(4) and to clarify the meaning of subsection (B)(4), which read in tandem with the header for subsection (B) refers to “court-ordered evaluation” “according to R9-21-204 or R9-21-207,” when neither rule specifically addresses “court-ordered evaluation” in its language.

R9-21-512. Seclusion and Restraint

2. Objective

The objective of the rule is to establish when an individual receiving court-ordered evaluation or court-ordered treatment may be placed in seclusion or restraint.
FIVE-YEAR-REVIEW REPORT
(SUPPLEMENTAL)

TITLE 9. HEALTH SERVICES
CHAPTER 21. DEPARTMENT OF HEALTH SERVICES
BEHAVIORAL HEALTH SERVICES FOR PERSONS WITH
SERIOUS MENTAL ILLNESS

Reported
JULY 2013
Supplemented
SEPTEMBER 2014
FIVE-YEAR-REVIEW REPORT
(SUPPLEMENTAL)

TITLE 9. HEALTH SERVICES
CHAPTER 21. DEPARTMENT OF HEALTH SERVICES
BEHAVIORAL HEALTH SERVICES FOR PERSONS WITH
SERIOUS MENTAL ILLNESS

1. FIVE-YEAR-REVIEW SUMMARY (SUPPLEMENTAL) Page 3
2. INFORMATION THAT IS IDENTICAL FOR ALL RULES Page 3
3. JANUARY 2014 AGREEMENT TO TERMINATE LITIGATION Attachment A
FIVE-YEAR-REVIEW SUMMARY (SUPPLEMENTAL)

Arizona Administrative Code (A.A.C.) Title 9, Chapter 21 contains rules governing the provision of services to individuals with serious mental illness. The rules in 9 A.A.C. 21 were originally developed based on a stipulation reached in the lawsuit Arnold v. Sarn, Maricopa County No. C-432355.

In January 2014, the Arizona Department of Health Services (Department) entered into an Agreement in Stipulation for Providing Community Services and for Terminating the Litigation (the "2014 Agreement") with the Arnold plaintiff class, included with this report as Attachment A. The Department agreed to provide certain community services in exchange for termination of the litigation. The 2014 Agreement includes an increase of services in four areas, each of which is within the scope of the rules in 9 A.A.C. 21: Assertive Community Treatment, Supported Employment, Supportive Housing, and Peer and Family Services.

INFORMATION THAT IS IDENTICAL FOR ALL THE RULES

12. Proposed course of action

To address the issues identified in the 2013 Five-Year-Review Report (2013 Report) and integrate changes stipulated in the 2014 Agreement, the Department will substantially revise the rules in 9 A.A.C. 21. In addition to a substantial allocation of staff time and resources, the Department has contracted with outside consultants for assistance in collecting and analyzing data to prepare for the rulemaking. As stated in the 2013 Report, the Department plans to amend the rules in 9 A.A.C. 21 and file a Notice of Final Rulemaking with the Governor's Regulatory Review Council no later than December 31, 2016.
IN THE SUPERIOR COURT OF THE STATE OF ARIZONA
IN AND FOR THE COUNTY OF MARICOPA

CHARLES ARNOLD, MARICOPA COUNTY PUBLIC FIDUCIARY, as
guardian and next friend on behalf of
JOHN GOSS; NANCY E. ELLISTON,
as guardian, conservator and next friend
on behalf of CLIFTON DORSETT and
as next friend on behalf of RICHARD
SCHACHTERLE and SUSAN SITKO;
TERRY BURCH; and on behalf of all
others similarly situated,

Plaintiffs,

vs.

ARIZONA DEPARTMENT OF
HEALTH SERVICES, ARIZONA
STATE HOSPITAL, MARICOPA
COUNTY BOARD OF
SUPERVISORS, and JANICE K.
BREWER, Governor of Arizona,

Defendants.

No. C-432355

STIPULATION FOR PROVIDING
COMMUNITY SERVICES AND
TERMINATING THE LITIGATION

(Assigned to the Honorable Edward W. Bassett)
Plaintiffs¹ and State Defendants Arizona Department of Health Services ("ADHS") and Governor Janice K. Brewer ("Governor") hereby submit this Stipulation for Providing Community Services and Terminating the Litigation ("Stipulation").²

1. This Stipulation is designed to facilitate essential community services, which the Parties agree and acknowledge are best practices for persons with serious mental illness ("SMI"), including Assertive Community Treatment ("ACT"), Supported Housing, Supported Employment, and Consumer Operated Services. This Stipulation further provides a schedule for vacating the Judgment in this case, dismissing the lawsuit, and ensuring that the community mental health system in Maricopa County continues to meet the needs of persons with serious mental illness.

2. The Parties agree that this Stipulation, unless expressly modified by a subsequent Court order, shall be the exclusive means for establishing the specific obligations and requirements of the Defendants and the services and benefits to be provided to Class Members.

3. ADHS has no obligation to take any action or fulfill any requirement of this Stipulation that is solely the responsibility of Maricopa County. Similarly, Maricopa County has no obligation to take any action or fulfill any requirement of this Stipulation that is solely the responsibility of ADHS.

**ARIZONA STATE HOSPITAL**

4. ADHS shall make its best efforts to identify Class Members residing at the Arizona State Hospital ("ASH") who could benefit from community living arrangements.

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¹ For purposes of this Stipulation "Plaintiffs" and/or "Class Members" are defined as adults eighteen (18) years or older that reside in Maricopa County and have a serious mental illness, as set forth in A.R.S. §§ 36-550(4) and 36-550.06.

² Maricopa County will elect its new chairman on January 6, 2014, and it will review this Stipulation at its January 8, 2014 meeting. Maricopa County will file a joinder if it agrees. For purposes of this Stipulation, "Defendants" shall refer collectively to the Governor of the State of Arizona, the Arizona Department of Health Services, and Maricopa County. "Parties" shall refer collectively to Plaintiffs and Defendants.
and take steps to facilitate their discharge from ASH. ADHS will ensure that the census at ASH does not exceed fifty-five Class Members.

5. ADHS will not use ASH for acute admissions, but may continue to use ASH for Class Members who need long-term inpatient treatment, but only to the extent the community living arrangements and services are not appropriate to meet the needs of individual Class Members. Acute inpatient services for Class Members shall be provided in units, programs, or facilities which are cost-effective, federally reimbursable, integrated into the general medical provider system that serves nondisabled citizens as close to the home communities of Class Members as practical, and not associated with ASH.

6. ADHS will ensure that there are no admissions or readmissions of Class Members directly into ASH from community mental health agencies or other entities, programs, or persons. All admissions of Class Members to ASH shall follow attempts to treat in one of the units, programs, or facilities described in ¶ 5.

7. ADHS shall make its best efforts to assure that Class Members are not unnecessarily admitted to ASH and that all admissions to ASH are done in accordance with Chapter 5, Title 36, Arizona Revised Statutes and Title 9 of the Arizona Administrative Code.

SUPERVISORY CARE AND BOARD AND CARE HOMES

8. ADHS will use its best efforts to offer community living arrangements to Class Members who reside in supervisory care homes.

9. ADHS will not encourage or recommend Class Members to reside in a supervisory care home or place them in a supervisory care home.

COUNTY SERVICES

10. Some Class Members at the Maricopa County Jail ("Jail") could benefit from diversion prior to incarceration at the Jail. The County will make its best efforts to develop programs designed to review the appropriateness and necessity for Jail admission of Class Members and to divert Class Members from incarceration when appropriate.
SERVICES

Crisis Services

11. ADHS will make its best efforts to maintain a Crisis System, as described in ¶ 12, which provides timely and accessible services and (i) is available 24 hours per day, 7 days per week, to Class Members experiencing a behavioral health crisis, including a crisis due to substance abuse; (ii) stabilizes individuals as quickly as possible and assists them in returning to their pre-crisis level of functioning; (iii) provides solution-focused and recovery-oriented interventions designed to avoid unnecessary hospitalizations, incarceration, or placement in a more segregated setting; (iv) when safe and clinically appropriate, provides mobile services at the site of the crisis, including the Class Member’s residence; and (v) assesses the individual’s needs, identifies the supports and services that are necessary to meet those needs, and connects the individual to those services.

12. The Crisis System shall include at least the following components:

   i. A Crisis Hotline that provides crisis intervention services over the phone, which includes triage and referral and telephone-based support to persons in crisis and which often serves as the first place of access to the behavioral health system. The service may also include a follow-up call to ensure the person is stabilized.

   ii. Mobile Crisis Teams that provide crisis intervention services by a mobile team or individual who travels to the place where the person is having the crisis (e.g., person’s place of residence, emergency room, jail, or community setting). Crisis intervention services include services aimed at the assessment and immediate stabilization of acute symptoms of mental illness, alcohol and other drug abuse, and emotional distress. The purpose of this service is to stabilize acute psychiatric or behavioral symptoms, evaluate treatment needs, and develop plans to meet the needs of the persons served.
Depending on the situation, the person may be transported to a more appropriate facility for further care (e.g., a crisis services center). Mobile crisis teams shall have the ability to respond, on an average, within one hour to a psychiatric crisis in the community (e.g. homes, schools, or hospital emergency rooms).

iii. Crisis stabilization settings that provide short-term crisis stabilization services (up to 72 hours) in an effort to successfully resolve the crisis, returning the individual to the community instead of transitioning to a higher level of care (i.e. an inpatient setting). Crisis stabilization settings can include licensed Level I sub-acute facilities, Level II facilities, and outpatient clinics offering access 24 hours per day, 7 days per week. Crisis stabilization settings can also include home-like settings such as apartments and single family homes, to the extent covered by Medicaid, where individuals experiencing a psychiatric crisis can stay to receive support and crisis services in the community before returning home.

**Supported Employment**

13. ADHS will make its best efforts to develop supported employment services as more fully described in ¶¶ 32-38. These are services through which Class Members receive assistance in preparing for, identifying, attaining, and maintaining competitive employment. The services provided include job coaching, transportation, assistive technology, specialized job training, and individually tailored supervision.

**Assertive Community Treatment Teams**

14. ADHS will make its best efforts to develop ACT capacity, as more fully described in ¶¶ 32-38. ACT teams will be available 24 hours per day, 7 days per week, and deliver comprehensive, individualized, and flexible support, services, and rehabilitation to individuals in their homes and communities. An ACT team is a multidisciplinary group of professionals including a psychiatrist, a nurse, a social worker,
1 a substance abuse specialist, a vocational rehabilitation specialist, and a peer specialist. Services are customized to an individual’s needs and vary over time as needs change.

**Family and Peer Support**

15. ADHS will make its best efforts to develop a system of peer and family support services, including peer and family-run provider organizations, as set forth in ¶ 32-38.

16. Peer support services are delivered in individual and group settings by individuals who have personal experience with mental illness, substance abuse or dependence, and recovery to help people develop skills to aid in their recovery.

17. Family support services are delivered in individual and group settings and are designed to teach families skills and strategies for better supporting their family member’s treatment and recovery in the community. Supports include training on identifying a crisis and connecting Class Members in crisis to services, as well as education about mental illness and about available ongoing community-based services.

**Supported Housing**

18. ADHS shall make its best efforts to provide supported housing services, consistent with the Substance Abuse and Mental Health Services Administration (“SAMHSA”) definition, as set forth in ¶ 32-38. Supported Housing is permanent housing with tenancy rights and support services that enable people to attain and maintain integrated affordable housing. It enables Class Members to have the choice to live in their own homes and with whom they wish to live. Supported Housing will continue to be integrated, scattered site housing throughout Maricopa County.

19. Support services are flexible and available as needed but not mandated as a condition of maintaining tenancy. Support services are provided by ACT teams for Class Members who receive ACT. For all other Class Members in Supported Housing, support services are provided by the Maricopa County Regional Behavioral Health Authority (“RBHA”) through its Supported Housing provider.
20. Supported Housing also includes rental subsidies or vouchers and bridge funding to cover deposits and other household necessities, although these items alone do not constitute Supported Housing.

**Living Skills Training**

21. ADHS will make its best efforts to develop living skills training services through which Class Members receive assistance and include learning independent living, social, and communication skills in order to maximize their ability to live and participate in the community and to function independently.

**Respite Care**

22. ADHS will make its best efforts to develop respite care services for Class Members to provide rest or relief for family members or other individuals caring for Class Members and may include a range of activities and may be provided in a range of settings, including apartments and single family homes, to the extent covered by Medicaid, to meet social, emotional, and physical needs of the Class Members during the respite period.

**SERVICE STANDARDS**

23. ADHS will ensure that providers of services listed in ¶¶ 11-22 have linguistic and cultural competencies to serve all individuals.

24. ADHS will adopt the SAMHSA models, definitions, and standards for ACT, Supported Housing, Supported Employment, and Consumer Operated Services, by incorporating these SAMHSA standards into the RBHA contract. ADHS will require, through its contract with the RBHA, that all providers of ACT, Supported Housing, Supported Employment, and Consumer Operated Services comply with these standards. ADHS will use, and will require the RBHA to use, SAMHSA assessment tools and/or instruments for evaluating providers’ compliance with SAMHSA standards for each service.

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3 Consumer Operated Services relates to the Family and Peer Support Services set forth in ¶¶ 15-17.
25. In 2014, ADHS will evaluate providers based upon the SAMHSA standards, using SAMHSA and National Association of State Mental Health Program Directors (“NASMHPD”) consultants and the SAMHSA instruments. In 2015, ADHS will evaluate providers based upon the SAMHSA standards using the SAMHSA instruments, through RBHA and ADHS staff who have been trained by the SAMHSA and NASMHPD consultants and who have been determined to be qualified by ADHS. Consistent with a schedule recommended by the consultants, trained ADHS and RBHA staff will evaluate providers based upon the SAMHSA standards using the SAMHSA instruments.

26. The findings and conclusions of the SAMHSA fidelity evaluations will be made available to the public by ADHS. ADHS, through the RBHA, will take all necessary steps, system improvements, and corrective actions to ensure that each provider offers services consistent with the SAMHSA standards for ACT, Supported Housing, Supported Employment, and Consumer Operated Services.

QUALITY SERVICE REVIEWS

27. ADHS will use Quality Service Reviews (“QSR”) to identify strengths, service capacity gaps, and areas for improvement at the system-wide level in Maricopa County. A QSR collects information through the use of a statistically significant sample of total SMI members and includes a medical record review as well as interviews of Class Members.

28. A QSR will objectively evaluate whether the needs of Class Members are being identified, whether Class Members need and are receiving each of the services identified in ¶ 11-22, whether these services are available, whether supports and services that they receive are meeting those needs, and whether supports and services are designed around Class Members’ strengths and goals.

29. ADHS will conduct the QSR process annually to collect and analyze data.
30. ADHS will continue to contract with an independent entity to conduct the QSR. During 2014, the Parties will finalize the QSR content and process, which will include the data elements, collection methodology, the instrument, and the report.

**SERVICE CAPACITY**

31. During the term of this Stipulation, ADHS shall focus on assessing and adjusting the network capacity of a service or services described in ¶¶ 11-22, subject to available funding through legislative appropriation.

32. During Fiscal Years 2015 and 2016, ADHS will develop the following additional service capacity:
   - a. Supported Housing services capable of serving 1200 Class Members,
   - b. Supported Employment services capable of serving 750 Class Members,
   - c. 8 ACT teams, some of which may be specialized teams, and
   - d. Family and Peer Support services capable of serving 1500 Class Members.

   ADHS will make reasonable progress to develop the service capacity described in ¶ 32 over the two year period, and will achieve the full increases in capacity by the completion of Fiscal Year 2016. ADHS will meet with Plaintiffs’ counsel within thirty days of the enactment of the Fiscal Year 2015 budget to discuss ADHS’ funding allocation strategy that will be spent for each of the services set forth in ¶¶ 11-22.

33. For Fiscal Year 2017, unless the service capacity assessment and determination described in ¶¶ 34-36 indicate that additional capacity is not needed in supported housing, supported employment, and/or ACT, ADHS will develop the following additional service capacity:
   - a. Supported Housing services capable of serving 300 Class Members;
   - b. Supported Employment services capable of serving 500 Class Members; and
c. 5 ACT teams, some of which may be specialized teams.

34. For every year after FY 2016, ADHS will implement a reliable process to assess the adequacy of community mental health services in Maricopa County for Class Members, as set forth in ¶ 35-36, with a focus on the adequacy of Supported Employment, Supported Housing, ACT, and Consumer Operated Services.

35. ADHS will use an independent entity like Mercer Government Human Services Consulting or another similarly qualified entity to conduct the service capacity assessment. This service capacity assessment set forth in ¶ 34 will include a need and allocation evaluation of Supported Housing, Supported Employment, Consumer Operated Services and ACT. The assessment shall utilize individual clinical reviews; an analysis of service utilization data; an analysis of outcome data; and interviews with key informants including Class Members, family members, providers and case managers. The assessment may also utilize customer satisfaction surveys; complaint data; geo-access mapping; hospital emergency room utilization; criminal justice records; homeless prevalence; employment data; suicide rates; public forums; and other data as appropriate that may indicate unmet need, utilization or availability of covered services. The independent qualified entity shall provide ADHS with the completed assessment annually.

36. The service capacity assessment, the QSR, and SAMHSA fidelity results will be posted on ADHS’ website. ADHS will collect and analyze data from the QSR, the service capacity assessment, and the findings of the SAMHSA fidelity evaluations to determine the appropriate capacity for each of the services described in ¶¶ 11-22 to meet the needs of Class Members.

37. ADHS shall use the process described in ¶ 36 to develop its budget recommendations to the Governor’s Office of Strategic Planning and Budget (“OSPB”). The Governor shall consider the information in ¶¶ 36-37 to develop the budget request to the Legislature.
38. ADHS agrees to submit to OSPB its anticipated budgetary needs to operate the behavioral health system in Maricopa County in accordance with this Stipulation and to continue to meet the needs of persons with serious mental illness. The Governor agrees to make best efforts to obtain this level of funding each year from the Legislature, based upon the Governor’s assessment of the competing funding needs and priorities of all other state services. ADHS will make its best efforts to provide services, support, and benefits to Class Members as set forth in this Stipulation subject to available funding through legislative appropriation.

ENFORCEMENT AND DISMISSAL

39. Notwithstanding the provisions of this Stipulation that specifically reference best efforts, Defendants agree to make reasonable progress to implement all other terms of the Stipulation.

40. Prior to dismissal, Plaintiffs may bring any action to enforce this Stipulation for failure to substantially comply with its terms, provided, however, the Plaintiffs shall not allege contempt or initiate contempt proceedings prior to February 1, 2015. Prior to initiating any action for noncompliance, the Plaintiffs shall provide written notice to the Defendants detailing their allegations of noncompliance. The Parties agree to meet in person to seek a good faith resolution of these issues without court intervention prior to initiating any action.

41. The common law doctrine of impossibility of performance may be raised as a defense in any action or proceeding to enforce compliance with the terms of this Stipulation. This includes an inability of one or more Defendants to obtain the funds necessary to implement the requirements imposed by this Stipulation.

42. If any of the provisions of this Stipulation are held impossible to perform, the remaining provisions of this Stipulation shall remain binding and in full force and effect.

43. If no enforcement motion has been filed, the Parties shall file, between July 15 and September 1, 2014, a joint motion pursuant to Ariz. R. Civ. P. 41(a) to dismiss the
1 entire case. The motion shall attach and incorporate by reference this Stipulation, and
2 authorize the Court to retain ongoing jurisdiction to enforce the Stipulation. The motion
3 will further make clear that the Court is not vacating its order certifying the class.
4
44. After dismissal, Plaintiffs may bring any action to enforce this Stipulation
5 for failure to substantially comply with its terms. Prior to initiating any action, the
6 Plaintiffs shall provide written notice to the Defendants detailing their allegations of
7 noncompliance. The Parties agree to meet in person to seek a good faith resolution of
8 these issues without court intervention prior to initiating any action. If the Parties are
9 unable to resolve these issues, Plaintiffs may file a motion to restore the matter to the
10 Court’s active docket and enforce the provisions of the Stipulation. In any action or
11 proceeding related to this Stipulation, the Court shall apply a standard of substantial
12 compliance, as defined by the Arizona Courts, to evaluate Defendants’ compliance.
13
45. During the pendency of the Stipulation, no party shall engage in activities
14 which delay, prolong or frustrate performance of the obligations set forth herein.
15
46. This Stipulation and any resulting Order entered by the Court may be
16 amended, modified, or supplemented by a written agreement entered into between all
17 Parties and subsequently approved by the Court. Any party may petition the Court to
18 amend, modify or supplement this Stipulation if the Parties are unable to reach an
19 agreement.
20
47. Other than contempt as set forth in ¶40, nothing herein is intended to alter the
21 inherent authority of the court.
22
ATTORNEYS’ FEES
23
48. The Parties agree that Class Members can recover reasonable and non-
24 duplicative attorneys’ fees and taxable costs incurred in this matter through calendar year
25 2015. Such attorneys’ fees and costs are strictly limited to those incurred through the
26 course of monitoring the implementation by Defendants regarding the obligations set
27 forth in this Stipulation.
49. The Parties agree that reasonable attorneys’ fees and taxable costs incurred by Class Members for monitoring any and all obligations set forth in this Stipulation shall be paid by the Defendants subject to a maximum cap in the amount of $225,000 for all time and expenses incurred during the period July 1, 2013 to December 31, 2015. Time spent on legislative lobbying is not a compensable monitoring activity. After December 31, 2015, there is no further right to fees for monitoring. In any judicial action brought by Plaintiffs to enforce this Stipulation, Plaintiffs may seek to recover reasonable attorneys’ fees and taxable costs related to the enforcement action if they are the prevailing party and such an award is authorized by Arizona law.

50. The Parties agree that Class Members are to submit to Defendants a statement of attorneys’ fees and taxable costs, a form of stipulation, and proposed order to the Court, in order to recover for attorneys’ fees and costs incurred each quarter. Defendants shall be permitted a reasonable time to review each request and attempt to resolve any questions or concerns they may have with Class Members regarding the same. Any request for attorneys’ fees and costs submitted by Class Members to Defendants for their attorneys’ fees and taxable costs shall be submitted no more than three (3) months following the last calendar day for the three (3) month period. If a request is not submitted within this time to Defendants through their respective counsel(s), counsel for the Class Members shall be deemed to have waived any entitlement to recover any fees or costs incurred during the applicable period.

51. Class Members shall have the sole discretion to determine the individual lawyers who should perform work on their behalf and should therefore submit billing statements that provide sufficient detail of the work performed, the lawyer who did the work, and the time spent. The billing rate for Steven Schwartz shall be $400 per hour, Anne Ronan shall be $300 per hour, and Edward Myers (ACDL) shall be $240 per hour. If additional or different lawyers or paralegals than those stated above are to be included in the quarterly billings, Class Members shall notify Defendants in writing of their intent to submit billing statements and their hourly rates for such lawyers/paralegals. The
billing rates in this paragraph shall remain fixed during the term of this Stipulation/Order for all work billed. Class Members do not concede the rates represent fair market rates, because the Parties arrived at the rates through a process of negotiation and compromise.

52. The provisions of the Stipulation regarding attorneys’ fees and taxable costs are applicable to proceedings brought in the Maricopa County Superior Court, the Arizona Court of Appeals, and the Arizona Supreme Court.

53. The Parties agree that Defendants’ obligation to pay Class Members’ attorneys’ fees and taxable costs which are ordered by the Court may be satisfied by making payment to counsel for Plaintiffs who are affiliated with the Arizona Center for Law in the Public Interest, for deposit into that firm’s trust account to be later disbursed to the other attorneys or firms of record who incurred fees and taxable costs through the course of their representation of Plaintiffs.

ADDITIONAL PROVISIONS

54. The Parties agree that Defendants’ obligations under this Stipulation apply only to Class Members.

55. The Court shall hold a fairness hearing and provide reasonable notice to Class Members pursuant to Rule 23(d)(2), Arizona Rules of Civil Procedure, before entering its Order following submission of the Stipulation. The Parties will represent to the Court that this Stipulation is fair and reasonable under Rule 23. The Parties retain the right to appeal from any order which modifies or alters this document.

56. Although Defendants have agreed as part of the negotiation process, which was conducted under Ariz. R. Evid. 408, to undertake certain actions, such agreement and this Stipulation do not constitute an enlargement of the Judgment or an admission of any matter.

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57. Once this Stipulation is approved, and a corresponding Order is entered by the Court, it shall be binding on all Parties.

RESPECTFULLY SUBMITTED this 8th day of January, 2014.

Anne Ronan
Attorney for Plaintiffs

Steven Schwartz
Attorney for Plaintiffs

Joseph Kanefield
Attorney for Governor Janice K. Brewer

Joseph Sciarrotta
Attorney for Governor Janice K. Brewer

Gregory Honig
Attorney for Arizona Department of Health Services
CERTIFICATE OF SERVICE

I certify that on this 8th day of January, 2014, I electronically transmitted a PDF version of this document to the Office of the Clerk of the Superior Court, Maricopa County, for filing using the AZTurboCourt System.

COPY of the foregoing mailed this 8th day of January, 2014 to:

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/s/ Sonya Batten
FIVE-YEAR-REVIEW REPORT

TITLE 9. HEALTH SERVICES
CHAPTER 1. DEPARTMENT OF HEALTH SERVICES ADMINISTRATION
ARTICLE 1. RULES OF PRACTICE AND PROCEDURE
ARTICLE 2. PUBLIC PARTICIPATION IN RULEMAKING
ARTICLE 3. DISCLOSURE OF MEDICAL RECORDS, PAYMENT RECORDS, AND PUBLIC HEALTH RECORDS
ARTICLE 4. CODES AND STANDARDS REFERENCED

JUNE 2014
FIVE-YEAR-REVIEW REPORT

TITLE 9. HEALTH SERVICES
CHAPTER 1. DEPARTMENT OF HEALTH SERVICES
ADMINISTRATION
ARTICLE 1. RULES OF PRACTICE AND PROCEDURE
ARTICLE 2. PUBLIC PARTICIPATION IN RULEMAKING
ARTICLE 3. DISCLOSURE OF MEDICAL RECORDS, PAYMENT RECORDS,
AND PUBLIC HEALTH RECORDS
ARTICLE 4. CODES AND STANDARDS REFERENCED

1. FIVE-YEAR-REVIEW SUMMARY Page 3
2. INFORMATION THAT IS IDENTICAL FOR ALL RULES Page 7
3. INFORMATION THAT IS IDENTICAL FOR GROUPS OF RULES Page 11
4. CURRENT RULES Attachment A
5. GENERAL AND SPECIFIC STATUTES Attachment B
6. ECONOMIC, SMALL BUSINESS, AND CONSUMER IMPACT Attachment C
7. EXAMPLE PETITION Attachment D
FIVE-YEAR-REVIEW SUMMARY

Article 1
Arizona Revised Statutes (A.R.S.) § 41-1003 requires an agency to make rules of practice setting forth the nature and requirements of all formal procedures available to the public. A.R.S. § 41-1002(C) authorizes an agency to grant procedural rights to persons in addition to those conferred by Title 41, Chapter 6, as long as rights conferred on others by any provision of law are not substantially prejudiced. Under A.R.S. § 41-1092.08, an agency head is authorized to review and to accept, reject, or modify an administrative law judge’s written decision issued after an administrative hearing. Under A.R.S. § 41-1092.09, a party to an administrative hearing may file a motion for rehearing or review of the final administrative decision. In Arizona Administrative Code (A.A.C.) Title 9, Chapter 1, Article 1, the Arizona Department of Health Services (“The Department”) provides pertinent definitions and a process for a party to an administrative decision to express an objection to, or obtain a possible rehearing or review of, the administrative decision.

Laws 2010, Ch. 309, § 3 amended A.R.S. § 41-1002, but made no changes to subsection (C), and thus has no implications for the rules in Article 1.

Based on this review, the Department has determined that the rules are effective and clear, concise, and understandable. Accordingly, the Department does not intend to amend the rules until substantive issues arise.

Article 2
A.R.S. § 41-1029 requires an agency to maintain and make available for public inspection an official rulemaking record for each rule proposed and each final rule filed in the Office of the Secretary of State. R9-1-202 specifies where and when the Department’s rulemaking records are available for public inspection.

Under A.R.S. § 41-1033, any person may petition an agency to request a rulemaking or a review of an existing agency practice or substantive policy statement that the petitioner alleges is, in effect, a rule. A.R.S. § 41-1033 authorizes an agency to prescribe the manner and form for such a petition. 9 A.A.C. 1, Article 2 provides pertinent definitions, establishes the requirements to petition the Department for a rulemaking or a review of a practice or substantive policy statement.
that allegedly constitutes a rule, and establishes requirements and a time-frame for the Department to respond.

Laws 2012, Ch. 352, § 11 amended A.R.S. § 41-1033. The amendments have significant implications for the Department beyond the rules in the Article. Specifically, the amendments add a process by which the Governor’s Regulatory Review Council can determine whether an agency practice or substantive policy statement constitutes a rule, place such a matter on its agenda, and require a statement from the Department addressing whether the agency practice or substantive policy statement constitutes a rule. However, R9-1-203(D)'s statutory reference to A.R.S. § 41-1033(B) remains correct and the substantive aspects of the rule did not change as a result of any of the amendments in the session law.

Based on this review, the Department has determined that the rules are effective and clear, concise, and understandable. Accordingly, the Department does not intend to amend the rules until substantive issues arise.

Article 3
A.R.S. § 36-104(9) authorizes the Director to provide information and advice on request by local, state, and federal agencies and by private citizens, business entities, and community organizations on matters within the scope of its duties, subject to the departmental rules and regulations on the confidentiality of information. A.R.S. § 36-105 requires the Department to furnish, subject to confidentiality laws, information to federal health care agencies. A.R.S. § 36-107 authorizes the Director to promulgate rules to protect confidential information, and requires that no names or other information of any applicant, claimant, recipient, or employer be made available for any political, commercial, or other unofficial purpose.

A.R.S. § 36-136(H)(11) requires the Department to take reasonably necessary measures to maintain the confidentiality of information relating to diagnostic findings and treatment of patients and information relating to contacts, suspects, and associates of communicable disease patients, and prohibits making this confidential information available for political or commercial purposes. A.R.S. § 36-351 establishes requirements for the Director to provide safe, secure, and permanent preservation of records, and mandates disclosures of records under specified conditions. The Department creates, obtains, and maintains medical records, payment records,
and public health records in accordance with the above and other statutory requirements, such as A.R.S. §§ 12-2291, 36-133, and 36-202.

Laws 2011, Ch. 18, § 25 amended A.R.S. § 36-351, imposing new requirements on the Department related to document preservation and conveyance to the Arizona State Library. Because R9-1-303(A)(2) exempts the requirements in the Section where the disclosure is of a vital record and occurs pursuant to A.R.S. § 36-351, the Department does not believe the statutory amendment has substantive implications for the rule or Article.

The Department adopted rules in compliance with these statutes in 2006 at 9 A.A.C. 1, Article 3. The rules provide pertinent definitions and specify the conditions under which the Department discloses medical records, payment records, and public health records in accordance with A.R.S. Title 39, Chapter 1, Article 2. The rules in Article 3 are effective, enforced, and clear, concise, and understandable, and the Department does not plan to amend the rules at this time.

Article 4
A.R.S. § 36-405 requires the Department to adopt rules to establish minimum standards and requirements for the construction, modification, and licensing of health care institutions necessary to assure the public health, safety, and welfare. A.R.S. § 36-406 authorizes the Department to review and approve plans and specifications for the construction of or modifications or additions to health care institutions regulated under A.R.S. Title 36, Chapter 4. A.R.S. § 36-421(A) requires an initial license application for a health care institution to include architectural plans and specifications, which are required to meet the minimum standards for licensing within the class or subclass of health care institution for which they are intended.

A.A.C. R9-1-411 establishes rules of construction and provides other information for persons using the codes and standards incorporated by reference in R9-1-412. Based on the Department’s records, the Department believes R9-1-411 may have been enacted June 30, 1977, published with Code Supplement 77-3, and never subsequently amended. The Department last reviewed R9-1-411 in a five-year-review report approved by the Governor’s Regulatory Review Council in January 2010.

A.A.C. R9-1-412 incorporates by reference physical plant health and safety codes and standards that the Department references in its different sets of licensing rules throughout A.A.C. Title 9,
rather than incorporating the same materials separately in each set of licensing rules. The rule was amended by exempt rulemaking on June 30, 2013, to reflect codes and standards published since the rule’s prior amendment in 2007.

A.R.S. § 36-405 was amended twice since the Department’s last five-year-review report on Article 4, via Laws 2009, 3d Special Session, Ch. 10, § 4 and via Laws 2011, Ch. 141, § 2. The 2009 amendment reorganized the Department’s fee framework for health care institution license applications, including architectural reviews that are pertinent to both rules in Article 4 and also the rules in 9 A.A.C. 10. However, the amended statutory language does not appear to make any substantive difference in the function of either R9-1-411 or R9-1-412. The 2011 amendment concerned assisted living facility training programs and is not relevant to the rules in Article 4.

As described in this report, the Department believes that some substantive provisions in R9-1-411 are necessary and effective and should be retained, while other content within the rule can be eliminated. The Department has not yet ascertained whether the most appropriate solution would be amending the rule, or repealing the rule after relocating the necessary and effective provisions of the rule to another rule. Either option has potentially far-reaching economic impact on entities constructing or modifying health care institution facilities, so expected stakeholder involvement would be considerable. The Department recently completed a comprehensive amendment of 9 A.A.C. 10, which is pertinent to the Department’s administration of the necessary and effective provisions of R9-1-411. The Department therefore proposes to continue assessing the implementation of the changes to 9 A.A.C. 10, and determine a course of action for R9-1-411 so as to file a Notice of Final Rulemaking with the Governor’s Regulatory Review Council by June 30, 2016. The Department does not propose to amend R9-1-412 as it is current, effective, enforced, and clear, concise, and understandable.
INFORMATION THAT IS IDENTICAL FOR ALL THE RULES

1. **Authorization of the rule by existing statute**
   All the rules have general authority in A.R.S. §§ 36-104(3) and 36-136(F).

5. **Enforcement of the rule**
   The Department enforces all the rules as written. R9-1-411 contains two provisions that
   are explanatory, not regulatory, but all regulatory provisions are enforced as written.

6. **Analysis of clarity, conciseness, and understandability of the rule**
   All rules may contain minor technical or grammatical issues that do not materially impair
   the clarity, conciseness, or understandability of the rule.

7. **Summary of written criticisms of the rules**
   The Department did not receive any written criticism of the rules in the last five years.

8. **Analysis of estimated economic, small business, and consumer impact**
   The Department submitted economic, small business, and consumer impact statements
   (EISs) in 2002 and 2006 with rulemakings on this Chapter. The Department designates
   costs or benefits as minimal when less than $1,000; moderate when between $1,000 and
   $10,000; substantial when greater than $10,000; and significant when meaningful or
   important but not readily subject to quantification.

   The 2002 EIS estimated the economic impact of Article 1 and R9-1-202. It forecast that
   the Department would bear moderate costs for implementing the rules, and that the
   Department, entities regulated by any Department rules, and the public would experience
   a significant benefit from rules that have been updated to be consistent with other laws
   and to be clear, concise, and understandable. The Department expected no direct impact
   on public or private employment within the state and no additional costs to private
   persons or consumers who are directly affected by the rules. The Department determined
   that the rules were as minimally costly and intrusive as possible. The Department
   believes the actual costs and benefits since 2002 have been as expected for Article 1 and

   The 2006 EIS for Article 2 estimated the economic impact of R9-1-201 and R9-1-203. It
   forecast that the Department would bear moderate costs for implementing the rules, that
   the Department, entities regulated by any Department rules, and the public could incur
   minimal costs under R9-1-203 and would experience a significant benefit from rules that
were updated to be consistent with other laws and to be clear, concise, and understandable. The Department expected no direct impact on public or private employment within the state and no additional costs to private persons or consumers who are directly affected by the rules. The Department receives, on average, less than one rulemaking petition of any kind per year. The Department believes the rules are as minimally costly and intrusive as possible, and that actual costs and benefits since 2006 have been as expected for R9-1-201 and R9-1-203.

The 2006 EIS for Article 3 estimated the economic impact of R9-1-301, R9-1-302, and R9-1-303. It identified stakeholders as the Department and members of the public seeking disclosure, including business entities and individuals. The 2006 EIS forecast that the Department would incur substantial administration and enforcement costs related to rules in the Article. It stated that business entities and individuals seeking records disclosure from the Department, if seeking disclosure for a commercial purpose, could incur significant costs; if seeking disclosure for a purpose other than a commercial purpose, could incur minimal costs; and would benefit from rules that are easier to use, are consistent with state and federal statutes, and are clear, concise, and understandable. The rules in Article 3 were expected to have no direct impact on political subdivisions or public or private employment.

Total public record requests from the Department’s Office of Administrative Counsel and Rules (OACR) were as follows, reflecting the minimal or significant costs to parties seeking disclosure, as forecast in the 2006 EIS:

<table>
<thead>
<tr>
<th>Calendar Year</th>
<th>Total Public Record Requests</th>
<th>Total Charges</th>
<th>Average Charge</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>439</td>
<td>$13,610</td>
<td>$31</td>
</tr>
<tr>
<td>2011</td>
<td>306</td>
<td>$7,374</td>
<td>$24</td>
</tr>
<tr>
<td>2012</td>
<td>327</td>
<td>$7,179</td>
<td>$22</td>
</tr>
<tr>
<td>2013</td>
<td>329</td>
<td>$4,586</td>
<td>$14</td>
</tr>
</tbody>
</table>

The figures have declined year-over-year and are expected to continue to decline for two reasons. First, the Department continues to develop its web infrastructure, so more information is available to the public immediately via online browsing, rather than necessitating a public record request. Of course, some information is not suitable for provision in such a manner, for instance records requiring redaction of confidential information.
content. Public record requests will therefore remain necessary service transactions for the foreseeable future. Second, since 2011, under the guidance of OACR, other offices within the Department now fulfill public record requests from time to time within their areas of expertise. This process is integrated into those offices’ ordinary day-to-day customer service to the public, but it correlates to the reduction in the number of public record requests received at OACR from 2011 to 2013.

The OACR has a Legal Assistant and Legal Secretary that devote a portion of their time to fulfilling public record requests, though this time is not readily separable from their other duties due to the overlap in providing records for other purposes, such as subpoena, and clerical administration of cases to which the Department is the adjudicant or a party. However, as both individuals draw a salary in excess of $10,000 annually, even a portion of their staff time (and some even smaller portion of the staff time of employees in other offices within the Department who provide public records as described in the previous paragraph) would, in aggregate, constitute a substantial cost as forecast in the 2006 EIS.

The Department has determined that the rules are as minimally costly and intrusive as possible. Based on the foregoing, the Department believes the actual costs and benefits since 2006 have been as expected for the rules in Article 3.

The Department has never submitted an EIS for R9-1-411. The Department designates costs or benefits as minimal when less than $1,000; moderate when between $1,000 and $10,000; substantial when greater than $10,000; and significant when meaningful or important but not readily subject to quantification. Subsections (A) and (B) are explanatory, not regulatory, and have no economic impact. Subsection (C) provides a significant benefit to the Department and the public, because having rules of construction to resolve conflicts among or between the codes and standards incorporated in A.A.C. Title 9 saves time for a Department employee or a member of the public who is seeking to understand which standard applies to a given situation. Subsection (D)(1) is redundant with R9-1-412 and has no economic impact, other than a potentially minimal burden to the Department and the public because it might cause confusion. Subsection (D)(2) provides a significant benefit to the Department and the public by providing a substantive framework for administering the correction of deficiencies, but would provide more of a benefit if subsection (D)(2)(c) contained submission guidelines like subsection (D)(2)(b).
The Department did not submit an EIS with the 2013 exempt rulemaking that amended R9-1-412. The Department designates costs or benefits as minimal when less than $5,000 and as significant when meaningful or important but not readily subject to quantification. The Department believes that the 2013 amendments may cause entities that own, operate, or design, construct, or modify health care institutions to incur minimal costs, and that those entities, the Department, and the public should experience significant benefits. Minimal costs to the Department may result from notification of entities that codes and standards have been updated, and minimal costs to entities result from procurement of updated codes and standards from the publishers of the incorporated reference works, which in some instances may have no cost for any referenced codes and standards that are freely available online. The benefits include reduced confusion or redundancy where the Department’s requirements match those of any other overlapping or concurrent jurisdiction that requires adherence to current codes and standards, as well as a public benefit to the health and safety of individuals from having improved health care institution facilities as a result of adherence to current codes and standards.

9. **Summary of business competitiveness analyses of the rules**
The Department has never received a business competitiveness analysis of the rules.

10. **Status of the completion of action indicated in the previous five-year-review report**
In previous five-year-review reports for 9 A.A.C. 1, Articles 1, 2, and 3, the Department proposed not to amend the rules until substantive issues arose. In its previous five-year-review report for R9-1-411 and R9-1-412, the Department proposed to amend the rules “within 18 months after the [Governor’s rulemaking] moratorium is lifted.” As the moratorium was established January 22, 2009 and has continued since then through legislative and executive actions through the present day, the Department’s proposed rulemaking time-frame has never commenced. Nevertheless, the Department did amend R9-1-412 by exempt rulemaking on June 30, 2013.

13. **Analysis of stringency compared to federal laws**
The rules are based on state statutes, in particular the Arizona Administrative Procedure Act (A.R.S. Title 41, Chapter 6), which strongly resembles the federal Administrative Procedure Act, 5 U.S.C. 5, §§ 500 et seq. However, the Department did not rely on authority other than its general or specific statutes in adopting these rules, so there is no applicable stringency comparison.
R9-1-101. Definitions

1. **Authorization of the rule by existing statute**
   Specific authority: A.R.S. §§ 41-1002(C) and 41-1003.

2. **Objective**
   The objective of the rule is to define terms used in the Chapter and Article so that a reader can consistently interpret requirements in the Chapter and Article.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective or mostly effective.

4. **Analysis of consistency with referenced state and federal statutes and rules**
   The rule is consistent with referenced state and federal statutes and other rules.

6. **Analysis of clarity, conciseness, and understandability of the rule**
   The rule is mostly or entirely clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden upon stakeholders necessary to achieve the rule's objective. The costs and benefits of the rule are discussed in paragraph #8.

12. **Proposed course of action**
   As described in the summary of this report, the Department does not intend to amend the rule unless significant substantive issues arise.

14. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**
   Not applicable; the rule was adopted before July 29, 2010.
R9-1-102. Objection to a Recommended Decision

1. **Authorization of the rule by existing statute**
   Specific authority: A.R.S. §§ 41-1002(C), 41-1003, and 41-1092.08.

2. **Objectives**
   The objectives of the rule are to:
   a. Establish a procedure for a party to submit for the Director’s consideration written objections to the recommended decision of an administrative law judge; and
   b. Specify that the Director may consider such a submission in determining whether to accept, reject, or modify the recommended decision.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective or mostly effective.

4. **Analysis of consistency with referenced state and federal statutes and rules**
   The rule is consistent with referenced state and federal statutes and other rules.

6. **Analysis of clarity, conciseness, and understandability of the rule**
   The rule is mostly or entirely clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden upon stakeholders necessary to achieve the rule's objective. The costs and benefits of the rule are discussed in paragraph #8.

12. **Proposed course of action**
   As described in the summary of this report, the Department does not intend to amend the rule unless significant substantive issues arise.

14. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**
   Not applicable; the rule was adopted before July 29, 2010.
R9-1-103.  Rehearing or Review of a Final Administrative Decision

1. **Authorization of the rule by existing statute**
   Specific authority: A.R.S. §§ 41-1002(C), 41-1003, and 41-1092.09.

2. **Objectives**
   The objectives of the rule are to:
   a. Establish requirements for the filing time-frames and content of a motion for rehearing or review of a final administrative decision;
   b. Authorize a party that has filed a motion for rehearing or review to amend the motion at any time before it is decided upon by the Director;
   c. Authorize the Director to require a party to file supplemental memoranda explaining the issues raised in a motion and to allow oral argument;
   d. Establish the grounds on which the Director may grant a motion for rehearing or review; and
   e. Require the Director to specify the grounds for rehearing or review when granted.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective or mostly effective.

4. **Analysis of consistency with referenced state and federal statutes and rules**
   The rule is consistent with referenced state and federal statutes and other rules.

6. **Analysis of clarity, conciseness, and understandability of the rule**
   The rule is mostly or entirely clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden upon stakeholders necessary to achieve the rule's objective. The costs and benefits of the rule are discussed in paragraph #8.

12. **Proposed course of action**
   As described in the summary of this report, the Department does not intend to amend the rule unless significant substantive issues arise.

14. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**
   Not applicable; the rule was adopted before July 29, 2010.
ARTICLE 2. PUBLIC PARTICIPATION IN RULEMAKING

R9-1-201. Definitions

1. **Authorization of the rule by existing statute**
   Specific authority: A.R.S. § 36-136(F)

2. **Objective**
   The objective of the rule is to define terms used in the Article so that a reader can consistently interpret requirements in the Article.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective or mostly effective.

4. **Analysis of consistency with referenced state and federal statutes and rules**
   The rule is consistent with referenced state and federal statutes and other rules.

5. **Analysis of clarity, conciseness, and understandability of the rule**
   The rule is mostly or entirely clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden upon stakeholders necessary to achieve the rule's objective. The costs and benefits of the rule are discussed in paragraph #8.

12. **Proposed course of action**
   As described in the summary of this report, the Department does not intend to amend the rule unless significant substantive issues arise.

14. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**
   Not applicable; the rule was adopted before July 29, 2010.
R9-1-202. Rulemaking Record

1. **Authorization of the rule by existing statute**
   Specific authority: A.R.S. § 41-1029

2. **Objective**
   The objective of the rule is to establish the location and schedule for viewing official rulemaking records.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective, but might be more effective if written with slightly less specificity in favor of greater accuracy. The rule states that an individual may review a rulemaking record “at the Office of the Director.” The actual rulemaking records archive is kept at the OACR. The OACR is organized within the Departmental unit of the “Director’s Office,” but is located in an adjacent building, rather than in the physical Director’s Office. A member of the public who visits the physical Director’s Office to review the records is directed to OACR by Department staff. The rule might therefore be better if it stated that an individual may review a rulemaking record “at the Department’s Phoenix campus” or similar phrasing to that effect. This reflects rare instances, however, as virtually all public inquiries for the Department’s rulemaking records occur online.

4. **Analysis of consistency with referenced state and federal statutes and rules**
   The rule is consistent with referenced state and federal statutes and other rules.

6. **Analysis of clarity, conciseness, and understandability of the rule**
   The rule is mostly or entirely clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden upon stakeholders necessary to achieve the rule's objective. The costs and benefits of the rule are discussed in paragraph #8.

12. **Proposed course of action**
   As described in the summary of this report, the Department does not intend to amend the rule unless significant substantive issues arise.

14. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**
   Not applicable; the rule was adopted before July 29, 2010.
R9-1-203. Petition for Department Rulemaking and Petition for Review of a Department Practice or Substantive Policy Statement

1. **Authorization of the rule by existing statute**
   
   Specific authority: A.R.S. § 41-1033

2. **Objectives**

   The objectives of the rule are to:
   
   a. Establish the contents of a petition for a rulemaking or a petition for review of a Department practice or substantive policy statement;
   
   b. Establish the requirement and time-frame for the Department to notify a petitioner of the Department’s decision on a petition; and
   
   c. Inform a petitioner how the petitioner may proceed following the denial of a petition.

3. **Analysis of effectiveness in achieving the objective**

   The rule is effective, but its effectiveness has been rendered less meaningful by a gradual shift in the Department’s approach to enhancing stakeholder involvement. The Department is in contact with stakeholders on a more regular basis than it was in 2006, when the rule was last amended, due to factors such as ubiquitous electronic communications and a policy shift toward transparency and inclusion. As a result, the Department is “always listening” with regard to stakeholder concerns about the substance and enforcement of rules. On occasion, a stakeholder will submit a written request for the Department to consider a rule change. This written request does not always meet the petition requirements in the rule, but usually includes most or all of the required information, as evidenced by the stakeholder letter included in this report as Attachment D. The Department’s current practice is to evaluate such communications as though they were formal petitions, even if a given communication does not conform perfectly to the rule. The Department then responds to the stakeholder, typically indicating either that a rule change will be considered for current or future rulemaking or that a rule change would be inappropriate for reasons that may be statutory or have some other basis. The Department receives such written petitions, on average, less often than once per year, but receives verbal feedback from stakeholders more frequently.

4. **Analysis of consistency with referenced state and federal statutes and rules**

   The rule is consistent with referenced state and federal statutes and other rules, but not strictly congruent with A.R.S. § 41-1033, the rule instead imposing a more stringent
requirement upon the Department than that imposed in statute. A.R.S. § 41-1033(A) requires an agency to respond to a petition in writing when the agency denies the petition. Subsection (C) requires the Department to respond to each petition in writing, regardless of the Department’s decision regarding the petition. This benefits the Department and the stakeholder alike: the stakeholder is informed of the result of his or her inquiry, while the Department is able to comply with statute without having to file a Notice of Docket Opening immediately or see its response to the petition become de jure a denial.

6. **Analysis of clarity, conciseness, and understandability of the rule**
The rule is mostly or entirely clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The rule imposes the least burden upon stakeholders necessary to achieve the rule's objective. The costs and benefits of the rule are discussed in paragraph #8.

12. **Proposed course of action**
As described in the summary of this report, the Department does not intend to amend the rule unless significant substantive issues arise.

14. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**
Not applicable; the rule was adopted before July 29, 2010.
ARTICLE 3. DISCLOSURE OF MEDICAL RECORDS, PAYMENT RECORDS, AND PUBLIC HEALTH RECORDS

R9-1-301. Definitions

1. Authorization of the rule by existing statute
   Specific authority: A.R.S. §§ 36-104(9), 36-105, 36-107, 36-136(H)(11), and 36-351.

2. Objective
   The objective of the rule is to define terms used in the Article so that a reader can consistently interpret requirements in the Article.

3. Analysis of effectiveness in achieving the objective
   The rule is effective or mostly effective.

4. Analysis of consistency with referenced state and federal statutes and rules
   While the rule is substantively consistent with state statutes, it contains definitions of terms that are references to subsections in A.R.S. § 36-401 that have been renumbered in amendments to A.R.S. § 36-401 since the last time R9-1-301 was promulgated.

6. Analysis of clarity, conciseness, and understandability of the rule
   The rule is mostly or entirely clear, concise, and understandable.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective
   R9-1-301 does not impose the least burden upon stakeholders because it contains outdated statutory cross-references. The burden results from any time or cost incurred by the stakeholder to find the correct statutory subsection referenced.

12. Proposed course of action
   As described in the summary of this report, the Department does not intend to amend the rule unless significant substantive issues arise.

14. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037
   Not applicable; the rule was adopted before July 29, 2010.
R9-1-302. Medical Records or Payment Records Disclosure

1. **Authorization of the rule by existing statute**
   Specific authority: A.R.S. §§ 36-104(9), 36-105, 36-107, and 36-136(H)(11).

2. **Objective**
   The objective of the rule is to specify the conditions under which the Department may disclose medical records and payment records it maintains.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective or mostly effective.

4. **Analysis of consistency with referenced state and federal statutes and rules**
   The rule is consistent with referenced state and federal statutes and other rules.

6. **Analysis of clarity, conciseness, and understandability of the rule**
   The rule is mostly or entirely clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden upon stakeholders necessary to achieve the rule's objective. The costs and benefits of the rule are discussed in paragraph #8.

12. **Proposed course of action**
   As described in the summary of this report, the Department does not intend to amend the rule unless significant substantive issues arise.

14. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**
   Not applicable; the rule was adopted before July 29, 2010.
R9-1-303. Public Health Records Disclosure

1. **Authorization of the rule by existing statute**
   Specific authority: A.R.S. §§ 36-104(9), 36-105, 36-107, and 36-351.

2. **Objective**
   The objective of the rule is to specify the conditions under which the Department may disclose public health records it maintains.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective or mostly effective.

4. **Analysis of consistency with referenced state and federal statutes and rules**
   The rule is consistent with referenced state and federal statutes and other rules.

6. **Analysis of clarity, conciseness, and understandability of the rule**
   The rule is mostly or entirely clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden upon stakeholders necessary to achieve the rule's objective. The costs and benefits of the rule are discussed in paragraph #8.

12. **Proposed course of action**
   As described in the summary of this report, the Department does not intend to amend the rule unless significant substantive issues arise.

14. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**
   Not applicable; the rule was adopted before July 29, 2010.
R9-1-411. Scope and applicability

1. **Authorization of the rule by existing statute**
   Specific authority: A.R.S. §§ 36-405 and 36-406.

2. **Objectives**
   The objectives of the rule are to:
   a. Explain why codes and standards are included in 9 A.A.C. 1;
   b. Inform persons that they need to use the correct edition of the rules;
   c. Inform persons that the requirements of federal, other state, or local jurisdictions may impose additional or more restrictive standards with which they may be required to comply;
   d. Establish rules of construction to resolve conflicts of precedence among the requirements in A.A.C. Title 9;
   e. Exclude from applicability certain provisions in the codes and standards listed in R9-1-412; and
   f. Provide time-frames and administrative requirements related to the correction of deficiencies in physical plants.

3. **Analysis of effectiveness in achieving the objective**
   Subsections (A) and (B) contain language that is explanatory, rather than regulatory. Subsection (D)(1) is redundant with R9-1-412(B). Subsection (D)(2)(c) does not specify submission requirements like subsection (D)(2)(b) does. Because of these issues, by modern rulemaking standards, the rule would not be considered effective. However, despite these issues, the rule has been sufficiently functional to achieve its objectives for almost forty years. For this reason, the Department believes that, regardless that the rule is limited in effectiveness in a technical sense, it is nonetheless effective in practice.

4. **Analysis of consistency with referenced state and federal statutes and rules**
   Subsection (D) states that provisions relating to purpose, scope, enforcement, exceptions, and other administrative matters in the codes and standards incorporated in R9-1-412 are applicable except as specified, but R9-1-412 contains its own exclusions and modifications to the incorporated codes and standards, including some in these subject
areas. While not strictly in conflict, this provision is not fully consistent with the framework of R9-1-412.

6. **Analysis of clarity, conciseness, and understandability of the rule**
The rule predates and does not conform to modern rulemaking format and style requirements, as indicated in paragraph #3 above and in several grammatical and technical deficiencies, such as the use of passive voice and embedded definitions.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
R9-1-411 does not impose the least burden upon stakeholders because of the issues described in the foregoing paragraphs. The burden results from any time or cost incurred by the stakeholder to determine an appropriate course of action, likely to include communication with the Department to ensure that the stakeholder’s conduct will result in compliance.

12. **Proposed course of action**
As described in this report, the Department believes that some substantive provisions in R9-1-411 are necessary and effective and should be retained, while other content within the rule can be eliminated. The Department has not yet ascertained whether the most appropriate solution would be amending the rule, or repealing the rule after relocating the necessary and effective provisions of the rule to another rule. Either option has potentially far-reaching economic impact on entities constructing or modifying health care institution facilities, so expected stakeholder involvement would be considerable. The Department recently completed a comprehensive amendment of 9 A.A.C. 10, which is pertinent to the Department’s administration of the necessary and effective provisions of R9-1-411. The Department therefore proposes to continue assessing the implementation of the changes to 9 A.A.C. 10, and determine a course of action for R9-1-411 so as to file a Notice of Final Rulemaking with the Governor’s Regulatory Review Council by June 30, 2016.

14. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**
Not applicable; the rule was adopted before July 29, 2010.
R9-1-412. Physical Plant Health and Safety Codes and Standards

1. **Authorization of the rule by existing statute**
   Specific authority: A.R.S. §§ 36-405 and 36-406.

2. **Objective**
   The objective of the rule is to incorporate by reference physical plant health and safety codes and standards so that the Department can refer to the rule in its different sets of licensing rules throughout A.A.C. Title 9 rather than including separate incorporations by reference in each set of licensing rules.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective or mostly effective.

4. **Analysis of consistency with referenced state and federal statutes and rules**
   The rule is consistent with referenced state and federal statutes and other rules.

6. **Analysis of clarity, conciseness, and understandability of the rule**
   The rule is mostly or entirely clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden upon stakeholders necessary to achieve the rule's objective. The costs and benefits of the rule are discussed in paragraph #8.

12. **Proposed course of action**
    The Department does not intend to amend the rule.

14. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**
    The rule does not establish licensing, certification, or permit requirements. Accordingly, there is no instance in the rule where a general permit or other permit is administered.
FIVE-YEAR-REVIEW REPORT

TITLE 9.  HEALTH SERVICES

CHAPTER 4.  DEPARTMENT OF HEALTH SERVICES

NONCOMMUNICABLE DISEASES

August 2014
# FIVE-YEAR-REVIEW REPORT

**TITLE 9. HEALTH SERVICES**

**CHAPTER 4. DEPARTMENT OF HEALTH SERVICES**

**NONCOMMUNICABLE DISEASES**

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CHAPTER 4. NONCOMMUNICABLE DISEASES
FIVE-YEAR-REVIEW SUMMARY

Arizona Revised Statutes (A.R.S.) § 36-133 requires the Arizona Department of Health Services (Department) to develop a chronic disease surveillance system for the collection, management, and analysis of information on the incidence of chronic diseases in Arizona. A.R.S. § 36-606 states that the Department “shall develop and implement … a system for reporting and preventing pesticide provoked illnesses.” A.R.S. §§ 36-1673 and 36-1675 require the Department to adopt rules for reporting blood test results showing significant levels of lead and other rules “necessary and feasible to implement the purposes” of A.R.S. Title 36, Chapter 13, Article 6.

The Department has implemented these statutes in Arizona Administrative Code (A.A.C.) Title 9, Chapter 4, Articles 1 through 5. Articles 1 and 4 were amended in a rulemaking that was approved by the Governor’s Regulatory Review Council (GRRC) in January 2006. The rules in Sections R9-4-401, R9-4-403, R9-4-404, and R9-4-405 were further amended in a rulemaking that was approved by GRRC in September 2006. Article 5 was amended in a rulemaking approved by GRRC in May 2007. Articles 2 and 3 have not been amended since 2000.

In preparation for this Five-Year-Review Report, the Department has reviewed the Articles in 9 A.A.C. 4 and identified needed revisions. The Five-Year-Review Report lists Sections requiring revision and describes the revisions that are needed. Before the Governor’s Memorandum, Regulatory Review Plan, dated January 22, 2009, establishing a moratorium on rulemaking, the Department had drafted amended rules to address the areas identified as needing revision. Once the Governor’s current moratorium on rulemaking is lifted, the Department anticipates initiating a new rulemaking to address identified issues and filing a Notice of Final Rulemaking with GRRC by December 2016.
1. **Authorization of the rule by existing statute**
   
   General authority: A.R.S. § 36-136(F)
   
   The rules in Article 2 have A.R.S. § 36-606 as specific authority.
   The rules in Article 3 have A.R.S. §§ 36-1673 and 36-1675 as specific authority.
   The rules in Article 4 have A.R.S. §§ 36-133 and 36-606 as specific authority.
   The rules in Article 5 have A.R.S. § 36-133 as specific authority.

2. **Summary of the written criticisms of the rule received within the last 5 years**
   
   According to staff of the Office of Environmental Health and the Office of Health Registries, the Department has not received any written criticism of the rules in Chapter 4 within the last five years.

3. **Estimated economic, small business, and consumer impact comparison**
   
   The rules in Chapter 4 cover the reporting of pesticide illnesses, blood lead levels, cancer, and birth defects to the Department. During the last five years, the Department received an average of two reported cases of pesticide illness per year. The Department receives approximately 70,000 results of blood lead tests on children annually. An average of 109 children are identified each year with elevated blood lead levels. Over the past five years, the number of new cases ranged from 74 (2011) to 152 (2009). For adults, the Department received approximately 233 blood lead levels results between 10 µg/dL and 24 µg/dL and 39 blood lead results greater than 25µg/dL each year. The Arizona Cancer Registry within the Department collects and maintains data on the incidence and characteristics of cancer in Arizona. For the last five years, the Department has received an average of 38,127 reports per year from hospitals, over 1,660 per year from clinics, over 2,725 per year from physicians, and over 1,360 per year from pathology laboratories. The Arizona Birth Defects Monitoring Program within the Department collects and maintains data on birth defects, including reports from approximately 49 facilities, and reviews an average of 2,222 medical records per year.

   The Department has implemented the requirements of A.R.S. § 36-606 “for reporting and preventing pesticide provoked illnesses” in Article 2 of 9 A.A.C. 4. Article 3 implements A.R.S. §§ 36-1673 and 36-1675 and specifies requirements for reporting the results of blood tests for lead. Article 4 specifies reporting of cancer-related information and implements both A.R.S. § 36-133 and A.R.S. § 36-606. Article 5 also implements A.R.S. § 36-133 and specifies birth defect-related reporting requirements. Article 1 contains definitions common to more than one Article in 9 A.A.C. 4.
Articles 1 and 4 were amended in a rulemaking that was approved by the Governor’s Regulatory Review Council (GRRC) in January 2006. The rules in Sections R9-4-401, R9-4-403, R9-4-404, and R9-4-405 were further amended in a rulemaking that was approved by GRRC in September 2006. Article 5 was amended in a rulemaking approved by GRRC in May 2007. Articles 2 and 3 were last amended in 2000. A Five-Year-Review Report for all five Articles in 9 A.A.C. 4 was approved by GRRC in 2009.

For each of these rulemakings, an Economic, Small Business, and Consumer Impact Statement (EIS) was submitted to GRRC. The EIS for Article 2 and the EIS for Article 3 designated annual costs/revenues as minimal when less than $1,000, moderate when $1,000 to $9,999, and substantial when $10,000 or greater. The EISs for the 2006 rulemakings for Articles 1 and 4 designated annual costs/revenues changes as minimal when less than $1,000, moderate when between $1,000 and $10,000, and substantial when greater than $10,000 in additional costs or revenues. In the EIS for the 2007 Article 5 rulemaking, annual costs/revenues changes were designated as minimal when less than $1,000, moderate when between $1,000 and $10,000, and substantial when greater than $10,000 in additional costs or revenues. Costs were listed as significant when meaningful or important, but not readily subject to quantification.

The EIS for the 2000 Article 2 rulemaking stated that the Department, the Office of the Secretary of State, and GRRC would incur no economic burden due to the rulemaking, other than expenses associated with the rulemaking process. It further stated that health care providers and poison control centers would receive a minimal benefit from changes that clarified that reports should only be made on working days. In the 2009 Five-Year-Review Report for Article 2, the Department stated that the economic impact of the pesticide illness rules remained unchanged from the 2000 estimates. After a review of 9 A.A.C. 4, Article 2, the Department estimates that, except for impacts described under Information for Individual Rules, the actual economic impact of the rules is consistent with the 2000 EIS.

In the EIS for the Article 3 rulemaking, the Department estimated that the Office of the Secretary of State and GRRC would incur no economic burden due to the rulemaking, other than expenses associated with the rulemaking process. The Department stated that the Department would bear rulemaking costs and moderate-to-substantial costs associated with the management of blood lead level reports. Physician offices and clinical laboratories were believed to incur minimal-to-moderate costs related to completing and submitting reports. The EIS further stated that a minimal increase in medical care fees for individuals patronizing these physician offices and laboratories was possible, and that the Arizona Health Care Cost Containment System (AHCCCS) could bear a minimal increase in costs because physician offices and laboratories that
contract with AHCCCS might increase their fees for providing services to AHCCCS clients. The Department stated in the EIC for the 2009 Five-Year-Review Report for Article 3 that the economic impact of the blood lead reporting rules remained unchanged from the 2000 estimates. The Department estimates that, except for impacts described under Information for Individual Rules, the actual economic impact of the rules is consistent with the 2000 EIS.

For the January 2006 rulemaking for Articles 1 and 4, the EIS stated that the Department would experience minimal costs associated with enforcing and providing education on the rules, and that hospitals with 50 or more licensed beds might experience minimal-to-substantial costs for computer equipment, software and training to enable them to report electronically. The EIS also stated that clinics that report fewer than 100 cases per year, physicians, dentists, registered nurse practitioners, doctors of naturopathic medicine, and pathology laboratories might incur minimal costs associated with reporting or responding to requests for information about their patients. Hospitals with 50 or more licensed beds were estimated to receive a minimal-to-substantial benefit from the rule change relating to reports on analytic patients. Hospitals, clinics, physicians, and dentists were estimated to receive a minimal benefit from clarification of the rules and improvements in definitions. The Department stated in the EIC for the 2009 Five-Year-Review Report that the economic impact of the rules was consistent with the January 2006 EIS. The Department estimates that, except for impacts described under Information for Individual Rules, the actual economic impact of the rules is consistent with the January 2006 EIS.

In the September 2006 rulemaking for Article 4, doctors of naturopathic medicine were required to submit case reports on their patients under specified conditions, rather than just respond to requests for information about their patients with cancer. The rules were also amended to make clear that outpatient radiation treatment centers, in which patients receive cancer-related treatment, are considered to be clinics for cancer reporting purposes. The EIS for this rulemaking stated that the Department would experience minimal costs associated with enforcing and providing education on the rules, and that doctors of naturopathic medicine might experience minimal costs for reporting. Outpatient radiation treatment centers were estimated to incur minimal-to-moderate costs associated with reporting, depending on whether they were already reporting, and to receive minimal benefits from clarification of the rules. The Department stated in the EIC for the 2009 Five-Year-Review Report that the economic impact of the rules was consistent with the September 2006 EIS. The Department estimates that, except for impacts described under Information for Individual Rules, the actual economic impact of the rules is consistent with the September 2006 EIS.
The EIS for the 2007 Article 5 rulemaking stated that the Department would experience minimal-to-moderate costs associated with enforcing and providing education on the rules and receive a moderate benefit from receiving more complete and timely reports. As stated in the EIS, the Department estimated that hospitals may incur minimal-to-moderate costs for developing reports in the Department-specified format and may receive a minimal-to-moderate benefit from reduced costs of retrieving archived records. The EIS also stated that high-risk perinatal practices, genetic testing facilities, and prenatal diagnostic facilities may incur minimal costs for reporting. The EIS further stated that physicians, midwives, registered nurse practitioners, physician assistants, clinics other than high-risk perinatal practices, clinical laboratories other than genetic testing facilities, and medical examiners may incur minimal costs associated with allowing the Department access to patient records. Medical specialists, such as pediatric cardiologists or pediatric surgeons, were believed to receive a minimal benefit from the rules due to more complete hospital reporting. The Department stated in the EIC for the 2009 Five-Year-Review Report that the economic impact of the Article 5 rulemaking was consistent with the 2007 EIS. The Department estimates that, except for impacts described under Information for Individual Rules, the actual economic impact of the rules is consistent with the 2007 EIS.

9. **Summary of business competitiveness analyses of the rules**
The Department did not receive a business competitiveness analysis of the rules in the last five years.

10. **Status of the completion of action indicated in the previous five-year-review report**
In the previous five-year-review report for 9 A.A.C. 4, the Department proposed amending the rules within 20 months after the Governor’s moratorium on rulemaking was lifted. Since the moratorium, established January 22, 2009 and continued through legislative and executive actions to the present day, is still in effect, the Department is complying with the rulemaking action proposed in the previous five-year-review report.

12. **Analysis of stringency compared to federal laws**
The rules are not related to federal laws except to the extent that the programs governed by the rules may report statistical data collected through the rules to federal agencies.

13. **Analysis of whether a general permit could be issued**
The rules do not establish licensing, certification, or permit requirements. Accordingly, there is no instance in the rules where a general permit or other permit is issued.

14. **Proposed course of action**
Once the Governor’s current moratorium on rulemaking is lifted, the Department anticipates initiating a new rulemaking to address identified issues and filing a Notice of Final Rulemaking with GRRC by December 2016.
INFORMATION FOR INDIVIDUAL RULES

ARTICLE 1. DEFINITIONS

R9-4-101. Definitions

1. Authorization of the rule by existing statute
   Specific authority: A.R.S. §§ 36-133, 36-606, 36-1673, and 36-1675

2. Objective
   The objective of the rule is to define terms used in more than one Article in Chapter 4 to enable
   the reader to understand clearly the requirements of the Chapter and allow for consistent
   interpretation.

3. Analysis of effectiveness in achieving the objective
   The rule is mostly effective, although there are terms used in more than one Article of Chapter 4
   that are not included in the rule. For example, both “business day” and “calendar day” are
   defined consistently in R9-4-401 and R9-4-501 but are not included in the rule. In addition,
   hospitals are being required to change from the current ICD-9-CM system to the ICD-10-CM
   system when billing for services. Therefore, the definition of “ICD-9-CM” will be incorrect and
   ineffective.

4. Analysis of consistency with referenced state and federal statutes and rules
   The rule defines “hospital” through a cross-reference to A.A.C. R9-10-201. The definition for
   this term is now contained in A.A.C. R9-10-101.

5. Status of enforcement of the rule
   The rule contains only definitions, so enforcement by the Department is not applicable.

6. Analysis of clarity, conciseness, and understandability
   The rule is clear, concise, and understandable.

11. A determination that the probable benefits of the rule outweigh within this state the
    probable costs of the rule, and the rule imposes the least burden and costs to persons
    regulated by the rule, including paperwork and other compliance costs, necessary to
    achieve the underlying regulatory objective
   The rule does not impose the least burden necessary to achieve the rule’s objective due to
definitions that should be included in the rules, revised to improve clarity, or moved to R9-4-101.
The rule also imposes a burden due to incorrect cross-references to Sections in 9 A.A.C. 10.
ARTICLE 2. PESTICIDE ILLNESS

R9-4-201. Definitions

2. Objective
The objective of the rule is to define terms used only in Article 2 to enable the reader to understand clearly the requirements of the Article and allow for consistent interpretation.

3. Analysis of effectiveness in achieving the objective
The rule is mostly effective, although there are terms used in the rule that need to be defined or better defined to achieve the objective of the rule. In addition, there are terms, such as “physician assistant” and “registered nurse practitioner,” defined in the rule that are also defined in other rules within the Chapter and should be moved to R9-4-101.

4. Analysis of consistency with referenced state and federal statutes and rules
The rule is consistent with applicable state and federal statutes and rules.

5. Status of enforcement of the rule
The rule contains only definitions, so enforcement by the Department is not applicable.

6. Analysis of clarity, conciseness, and understandability
Most of the rule is clear, concise, and understandable. However, the definition of “pest” is unclear and difficult for a reader to understand. Revising the definitions of “cluster illness,” “pesticide,” and “pesticide illness” would also make the terms more understandable. The terms “defoliant,” “desiccant,” and “plant regulator” need to be defined.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective
The rule does not impose the least burden necessary to achieve the rule’s objective due to definitions that should be included in the rules, revised to improve clarity, or moved to R9-4-101.

R9-4-202. Pesticide Illness Reporting Requirements

2. Objective
The objective of the rule is to specify:
   a. The individuals who are required to submit reports,
   b. Under what circumstances reports are required,
   c. Within what time periods reports are required to be submitted,
   d. How reports may be submitted,
   e. The information that is required to be included in the report, and
f. That an individual required to submit a report may designate a representative to make the report.

3. **Analysis of effectiveness in achieving the objective**
   The rule is mostly effective, but it does contain an undefined phrase and is structured in a manner that makes it difficult to understand requirements. The information required in the rule is also inconsistent with the information requested on a reporting form used by the Department.

4. **Analysis of consistency with referenced state and federal statutes and rules**
   The rule is consistent with applicable state and federal statutes and rules.

5. **Status of enforcement of the rule**
   The rule is enforced by the Department as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is mostly clear, concise, and understandable. However, the phrase “working day” is undefined, and the terms “diagnosis or identification” and “diagnosed or identified” are both used to express the same idea.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Because of the issues described in paragraphs 3 and 6 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.
ARTICLE 3. BLOOD LEAD LEVELS

R9-4-301. Definitions

2. Objective
The objective of the rule is to define terms used only in Article 3 to enable the reader to understand clearly the requirements of the Article and allow for consistent interpretation.

3. Analysis of effectiveness in achieving the objective
The rule is effective in achieving its objective.

4. Analysis of consistency with referenced state and federal statutes and rules
The rule is consistent with applicable state and federal statutes and rules.

5. Status of enforcement of the rule
The rule contains only definitions, so enforcement by the Department is not applicable.

6. Analysis of clarity, conciseness, and understandability
The rule is clear, concise, and understandable.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective
The rule imposes the least burden upon stakeholders necessary to achieve the rule’s objective.

R9-4-302. Reporting Significant Blood Lead Levels

2. Objective
The objective of the rule is to specify:
   a. The individuals who are required to submit reports,
   b. Under what circumstances reports are required,
   c. Within what time periods reports are required to be submitted,
   d. How reports may be submitted,
   e. The information that is required to be included in the report, and
   f. That an individual required to submit a report may designate a representative to make the report.

3. Analysis of effectiveness in achieving the objective
The rule is not effective. It has a misleading Section heading and is structured in a manner that makes it difficult to understand requirements. The Section heading does not indicate that test results that are not significant are required to be reported at least once each month. The information required in the rule is also inconsistent with the information requested on a reporting
form used by the Department. Race/ethnicity is requested on the reporting form to enable the Department to better assess the need for and provide education about blood lead levels. The rule does not distinguish between information that a physician is required to submit and information that a clinical laboratory director is required to submit, but to which the clinical laboratory director may not have access. In addition, new in-office blood lead tests are now available and are used with great frequency by physicians. Under the current rules, physicians do not report the results of these tests because only results arising from a laboratory test are reportable. Physicians also do not report blood lead levels in children below 10 micrograms per deciliter. The Centers for Disease Control and Prevention has recently recommended that blood lead levels in children greater than or equal to 5 micrograms per deciliter should be monitored.

4. **Analysis of consistency with referenced state and federal statutes and rules**
The rule is consistent with applicable state and federal statutes and rules.

5. **Status of enforcement of the rule**
The rule is enforced by the Department as written.

6. **Analysis of clarity, conciseness, and understandability**
The rule is mostly clear, concise, and understandable. However, the term “working day” is undefined and is used for the same concept as “business day,” which is defined in both R9-4-401 and R9-4-501.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Because of the issues described in paragraphs 3 and 6 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.
ARTICLE 4. CANCER REGISTRY

R9-4-401. Definitions

2. **Objective**
The objective of the rule is to define terms used only in Article 4 to enable the reader to understand clearly the requirements of the Article and allow for consistent interpretation.

3. **Analysis of effectiveness in achieving the objective**
The rule is mostly effective, except for the issues identified in paragraphs 4 and 6 of the analysis of this rule.

4. **Analysis of consistency with referenced state and federal statutes and rules**
The rule defines “admitted,” “discharge,” and “special hospital” through cross-references to A.A.C. R9-10-201. The definitions for these terms are now contained in A.A.C. R9-10-101. The definition of “health care institution” is no longer defined in A.A.C. R9-10-101, since the term is defined in A.R.S. § 36-401, which is referenced in the lead-in to the Section. The term “behavioral health service agency” is no longer defined in A.A.C. R9-20-101. The definition of “pathology laboratory” incorrectly states licensure under 9 A.A.C. 10, Article 1, since a pathology laboratory would instead have a certificate of compliance or a certificate of accreditation issued under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 C.F.R. 493, Laboratory Requirements.

5. **Status of enforcement of the rule**
The rule contains only definitions, so enforcement by the Department is not applicable.

6. **Analysis of clarity, conciseness, and understandability**
The rule is mostly clear, concise, and understandable. However, terms, such as “admitted,” “business day,” “calendar day,” and “registered nurse practitioner,” are defined in both R9-4-401 and R9-4-501 and should be moved to R9-4-101.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The rule does not impose the least burden necessary to achieve the rule’s objective due to definitions that should be included in the rules, revised to improve clarity, or moved to R9-4-101. The rule also imposes a burden due to incorrect cross-references to Sections in 9 A.A.C. 10.

R9-4-402. Exceptions

2. **Objective**
The objective of the rule is to establish the types of hospitals to which the rules in Article 4 do not apply.

3. **Analysis of effectiveness in achieving the objective**
   The rule is not effective since a hospital is no longer licensed as both a special hospital and a behavioral health service agency. Instead, the exception should be for a special hospital licensed to provide psychiatric services.

4. **Analysis of consistency with referenced state and federal statutes and rules**
   The rule is consistent with applicable state and federal statutes and rules.

5. **Status of enforcement of the rule**
   The rule is enforced by the Department as written, consistent with the intent of the rule to not require a special hospital providing only organized psychiatric services to report.

6. **Analysis of clarity, conciseness, and understandability**
   Except as described in paragraph 3, the rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Because of the issue described in paragraph 3 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

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R9-4-403. **Case Reports**

2. **Objective**
   The objective of the rule is to specify:
   a. The persons who are required to submit case reports,
   b. The information that is required to be included in a case report, and
   c. The source of any codes required in a case report.

3. **Analysis of effectiveness in achieving the objective**
   The rule is mostly effective, but the rule’s effectiveness is limited because some of the required information is no longer appropriate and should be removed or replaced. For example, religious preference and surgical approach are no longer required, and factors that indicate the presence of a specific type of tumor, other than Tumor Marker 1 and Tumor Marker 2, are now detected through genomic and other types of laboratory testing and should be reported.

4. **Analysis of consistency with referenced state and federal statutes and rules**
   The rule is consistent with applicable state and federal statutes and rules.
5. **Status of enforcement of the rule**

The rule is enforced as written, except that the Department no longer requires a submitter to provide religious preference and surgical approach and requires the reporting of tumor-specific factors besides Tumor Marker 1 and Tumor Marker 2.

6. **Analysis of clarity, conciseness, and understandability**

The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

The rule imposes the least burden upon stakeholders necessary to achieve the rule’s objective.

### R9-4-404. Requirements for Submitting Case Reports and Allowing Review of Hospital Records

2. **Objective**

The objective of the rule is to specify:

a. Under what circumstances specific persons are required to report to the Department;

b. Under what circumstances and with what frequency specific persons are required to allow the Department to review patient records or pathology reports to obtain specified information;

c. The time period during which a report is required to be submitted to the Department, if applicable;

d. Under what circumstances specific persons are required to provide requested information to the Department or a hospital requesting the information;

e. The time period during which a specific person is required to provide the requested information to the Department or hospital; and

f. In what format specific persons are required to provide information or, if applicable, copies of documents to the Department.

3. **Analysis of effectiveness in achieving the objective**

The rule is mostly effective, but it does have a misleading Section heading. The Section heading does not mention follow-up reports or providing information to the Department or hospital in response to a letter requesting information. The Department has also answered questions from physicians, doctors of naturopathic medicine, dentists, and registered nurse practitioners about reporting requirements and when they are required to make a report, and believes the rule would
be more effective if reporting requirements for these individuals in subsection (E) were clarified. The Department has received similar questions from clinics submitting fewer than 100 case reports per year and believes that subsection (D) should also be clarified. The rule would also be more effective if subsection (H) were amended to specify that pathology reports be provided in a Department-provided format. In addition, the rule specifies ICD-9-CM codes, which are being replaced by ICD-10-CM codes for billing.

4. **Analysis of consistency with referenced state and federal statutes and rules**
   The rule is consistent with applicable state and federal statutes and rules.

5. **Status of enforcement of the rule**
   The rule is enforced by the Department as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is mostly clear, concise, and understandable. However, the rule could be improved if reporting requirements for physicians, doctors of naturopathic medicine, dentists, and registered nurse practitioners were clarified.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Because of the issues described in paragraphs 3 and 6 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-4-405. **Data Quality Assurance**

2. **Objective**
   The objective of the rule is to specify:
   a. The methods the Department may use to help ensure the accuracy of reported information,
   b. The time period associated with each quality assurance method, and
   c. The circumstances under which the Department shall consider a specified person as having complied with the requirements of Article 4.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

4. **Analysis of consistency with referenced state and federal statutes and rules**
   The rule uses cross-references to A.A.C. R9-10-214 and A.A.C. R9-10-1709 for logs of surgical procedures, both of which are incorrect since the exempt rulemaking of 9 A.A.C. 10, effective
October 1, 2013. The requirements for logs of surgical procedures are now in A.A.C. R9-10-215 for hospitals and in A.A.C. R9-10-911 for outpatient surgical centers.

5. **Status of enforcement of the rule**
   The rule is enforced by the Department as written, consistent with the correct cross-references.

6. **Analysis of clarity, conciseness, and understandability**
   Except as described in paragraph 4, the rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule does not impose the least burden necessary to achieve the rule’s objective due to incorrect cross-references to Sections in 9 A.A.C. 10.
ARTICLE 5. BIRTH DEFECTS MONITORING PROGRAM

R9-4-501. Definitions

2. **Objective**
   The objective of the rule is to define terms used only in Article 5 to enable the reader to understand clearly the requirements of the Article and allow for consistent interpretation.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective, except for the issues identified in paragraphs 4 and 6 of the analysis of this rule.

4. **Analysis of consistency with referenced state and federal statutes and rules**
   The rule defines “admitted” and “discharge” through a cross-reference to A.A.C. R9-10-201. The definition for this term is now contained in A.A.C. R9-10-101. The definition of “pathology laboratory” incorrectly states licensure under 9 A.A.C. 10, Article 1, since a pathology laboratory would instead have a certificate of compliance or a certificate of accreditation issued under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 C.F.R. 493, Laboratory Requirements. In addition, Laws 2011, Ch. 31, moved Children’s Rehabilitative Services from the Department to the Arizona Health Care Cost Containment System, so the definition of the term “CRS” is no longer correct.

5. **Status of enforcement of the rule**
   The rule contains only definitions, so enforcement by the Department is not applicable.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is mostly clear, concise, and understandable. However, terms, such as “admitted,” “business day,” “calendar day,” “discharge,” “discharge date,” “pathology laboratory,” and “registered nurse practitioner,” are defined in both R9-4-401 and R9-4-501 and should be moved to R9-4-101.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule does not impose the least burden necessary to achieve the rule’s objective due to definitions that should be included in the rules, revised to improve clarity, or moved to R9-4-101.

R9-4-502. Reporting Sources; Information Submitted to the Department

2. **Objective**
   The objective of the rule is to specify:
a. The individuals who are required to submit reports,
b. Under what circumstances reports are required,
c. Within what time periods reports are required to be submitted,
d. How reports are to be submitted, and
e. The information that is required to be included in the report.

3. **Analysis of effectiveness in achieving the objective**
The rule is mostly effective but specifies ICD-9-CM codes, which are being replaced by ICD-10-CM codes for billing.

4. **Analysis of consistency with referenced state and federal statutes and rules**
The rule is consistent with applicable state and federal statutes and rules.

5. **Status of enforcement of the rule**
The Department enforces the rule, except requirements for high-risk perinatal practices. While some high-risk perinatal practices submit reports as required, some do not. Although the information provided by high-risk perinatal practices is important to identify children with birth defects, the Department did not have sufficient staff to work with high-risk perinatal practices to ensure compliance. However, the Department has begun working with high-risk perinatal to improve compliance.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

Because of the issue described in paragraph 3 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-4-503. **Review of Records; Information Collected**

2. **Objective**
The objective of the rule is to specify:
   a. Under what circumstances and with what frequency specific persons or facilities are required to allow the Department access to the facility and specific records,
   b. The types of records that the Department may review at the facility, and
   c. The types of information the Department may collect.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective.

4. **Analysis of consistency with referenced state and federal statutes and rules**
   The rule uses cross-references to A.A.C. R9-10-214 and A.A.C. R9-10-1709 for logs of surgical procedures, both of which are incorrect since the exempt rulemaking of 9 A.A.C. 10, effective October 1, 2013. The requirements for logs of surgical procedures are now in A.A.C. R9-10-215 for hospitals and in A.A.C. R9-10-911 for outpatient surgical centers.

5. **Status of enforcement of the rule**
   The rule is enforced by the Department as written, consistent with the correct cross-references.

6. **Analysis of clarity, conciseness, and understandability**
   Except as described in paragraph 4, the rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule does not impose the least burden necessary to achieve the rule’s objective due to incorrect cross-references to Sections in 9 A.A.C. 10.

R9-4-504. **Data Quality Assurance**

2. **Objective**
   The objective of the rule is to specify:
   a. That the Department may request revision of a report submitted to the Department,
   b. The time period during which a person who receives a request from the Department for revision of a report is required to submit a revised report, and
   c. That the Department may discuss the information the Department obtains under this Article with another person specified in the Article to obtain additional information about a patient’s diagnosis or treatment.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

4. **Analysis of consistency with state and federal statutes and rules**
   The rule is mostly consistent with applicable state and federal statutes and rules. However, in 2008, A.R.S. § 36-133 was revised to allow the Department and the Arizona Early Intervention Program (AZEIP) to use information collected according to this Article to notify families of children with birth defects about programs and services available to assist them. The rule specifies that the Department may discuss the information with entities specified in the rule, but
does not provide notice that the information may also be used to notify families, as allowed in A.R.S. § 36-133.

5. **Status of enforcement of the rule**
The Department enforces the rule consistent with statute. However, since AZEIP is covered under the Family Educational Rights and Privacy Act, the Department has difficulty in learning whether the families of children referred to AZEIP were contacted and whether the children are receiving services.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The benefit of the rule would be increased if the rule specified that information collected according to this Article could be shared with AZEIP to notify families of children with birth defects about programs and services that are available to assist them.
FIVE-YEAR-REVIEW REPORT

TITLE 9. HEALTH SERVICES
CHAPTER 6. DEPARTMENT OF HEALTH SERVICES
COMMUNICABLE DISEASES AND INFESTATIONS
ARTICLE 4. AIDS DRUG ASSISTANCE PROGRAM (ADAP)

AUGUST 2014
FIVE-YEAR-REVIEW REPORT

TITLE 9. HEALTH SERVICES
CHAPTER 6. DEPARTMENT OF HEALTH SERVICES
COMMUNICABLE DISEASES AND INFESTATIONS
ARTICLE 4. AIDS DRUG ASSISTANCE PROGRAM (ADAP)

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FIVE-YEAR-REVIEW SUMMARY

Arizona Revised Statutes (A.R.S.) § 36-136(H)(1) requires the Arizona Department of Health Services (Department) to make rules defining and prescribing “reasonably necessary measures for detecting, reporting, and controlling communicable and preventable diseases” and prescribing measures “reasonably required to prevent the occurrence of, or to seek early detection and alleviation of, disability, insofar as possible, from communicable or preventable diseases.” Although A.R.S § 36-136 was amended in Laws 2011, Ch. 84, § 1 and Laws 2013, Ch. 6, § 1, neither amendment modified subsection (H)(1).

Arizona Administrative Code (A.A.C.) Title 9, Chapter 6, Article 4 implements A.R.S. § 36-136(H)(1) by establishing rules for the AIDS Drug Assistance Program (ADAP), a primarily federally funded program, through which the Department provides prescription drugs to HIV-infected residents of Arizona to prevent the occurrence of, or to seek alleviation of, disability from HIV-related diseases, including AIDS. For the purposes of this report, "participant" and "enrolled individual" are used synonymously to refer to HIV-infected residents of Arizona who receive benefits under this program.

The rules in 9 A.A.C. 6, Article 4 were last revised in 2007, except one Section, R9-6-402, which is explanatory and not regulatory. Based on this review, the Department has determined that most of the rules are effective, consistent with listed state and federal statutes and rules, enforced as written, and clear, concise, and understandable. The Department believes that at least two rules should be amended, and may amend rules throughout the Article to ensure continuity and consistency. The Department therefore proposes to file a Notice of Final Rulemaking with the Governor’s Regulatory Review Council by December 31, 2016.
1. **Authorization of the rule by existing statute**
   All the rules have general authority in A.R.S. §§ 36-104(3), 36-132(A)(1), and 36-136(F).
   All the rules have specific authority in A.R.S. § 36-136(H)(1).

4. **Analysis of consistency with referenced state and federal statutes and rules**
   All the rules are consistent with referenced state and federal statutes and other rules except R9-6-401. As described in this report, there is a substantive difference between R9-6-407 and applicable federal reporting requirements, as discussed in the entry for R9-6-407 in the information for individual rules, but the rule is not in conflict (it does not prevent the Department from fulfilling the federal reporting requirements).

6. **Analysis of clarity, conciseness, and understandability of the rule**
   All the rules except R9-6-401 are mostly or entirely clear, concise, and understandable. In some cases, the rules contain minor technical or grammatical issues, but none that materially impair the clarity, conciseness, or understandability of the rules.

7. **Summary of written criticisms of the rules**
   The Department did not receive any written criticism of the rules in the last five years.

8. **Analysis of estimated economic, small business, and consumer impact**
   The Department submitted an economic, small business, and consumer impact statement (EIS) in 2007 with its rulemaking revising all Sections except R9-6-402. The 2007 rulemaking included changes to address the ability of eligible elderly and disabled individuals to obtain prescription drugs under Medicare Part D through prescription drug plans under contract to Medicare. At the time of the 2007 rulemaking, those who qualified for a full income-based subsidy through Medicare did not pay for Medicare Part D drug coverage and were excluded from ADAP participation. However, the mechanism for benefit distribution through Medicare Part D changed to TROOP, or "True Out of Pocket" premium payment structuring, allowing individuals with full-income subsidies to enroll in ADAP but not to receive the same benefit twice (through ADAP and through direct Medicare benefits). Changes were also made to address the Department’s using a vendor pharmacy for drug distribution and to allow individuals eligible for, but choosing not to use, Veterans Health Administration or Indian Health Service benefits for prescription drugs to enroll in ADAP. Lastly, the rulemaking added, amended, and clarified definitions, application and notification requirements, and drug distribution requirements.
The Department received $18,329,158 in federal funds for ADAP in federal fiscal year 2013 and $14,818,929 for 2014. The State matched these funds with a total of $1 million in funding: $750,000 for ADAP disbursements and $250,000 for HIV Surveillance, a component of the Department's ADAP administration framework. With these funds, the Department provided HIV-related prescription drugs for a monthly average of 1,817 individuals during 2013 and 1,204 individuals during 2014, as of May 30th.

In the 2007 EIS, the Department designated costs or benefits as minimal when less than $1,000; moderate when between $1,000 and $10,000; substantial when greater than $10,000; and significant when meaningful or important but not readily subject to quantification. The economic impact of R9-6-402 is either none or some small value of "significant," because the Section’s entire objective and substance is to notify the public that ADAP ceases to provide drugs when ADAP funding is exhausted or terminated, information a member of the public could readily discover from annual legislative appropriations records.

The 2007 EIS stated that the rules may impose a minimal burden on primary care providers when requesting a restricted drug for an individual enrolled in ADAP and for notifying the vendor pharmacy when discontinuing a drug for an individual enrolled in ADAP. The 2007 EIS also stated that the rules may impose a minimal cost on community service organizations and case managers for providing documentation for individuals applying for or enrolled in ADAP, for assisting individuals to apply for ADAP or to continue enrollment, and for notifying the Department of a change that may affect the eligibility of an individual enrolled in ADAP. The 2007 EIS stated that the Department could incur a minimal cost for providing education about and enforcing the rules and that an HIV-infected individual applying for participation in ADAP may incur minimal costs from the requirement that the applicant submit residency information and information about eligibility for the Medicare income-based subsidy. The 2007 EIS stated that the rules may provide minimal benefits to the Department, primary care providers, community service organizations and case managers, HIV-infected individuals applying for participating in ADAP, and society in general. The Department has determined that, except for the issues discussed in paragraph #11 in appropriate entries in the information for individual rules, the rules are as minimally costly and intrusive as
possible. Upon review, the Department believes the economic impact of the rules in Article 4 has been consistent with the impact predicted in the 2007 EIS.

The Department has never received a business competitiveness analysis of the rules.

10. Status of the completion of action indicated in the previous five-year-review report
In previous five-year-review report for 9 A.A.C. 6, Article 4, approved February 2, 2010, the Department proposed to amend the rules by June 2012. Because of other rulemaking priorities, such as legislatively mandated rulemakings, and due to limited Departmental resources, this proposed course of action was not completed. The issues discussed in this report are substantially the same as those discussed in the report approved in 2010.

12. Proposed course of action
As described in the summary of this report, based on this review, the Department has determined that most of the rules are effective, consistent with listed state and federal statutes and rules, enforced as written, and clear, concise, and understandable. The Department believes that at least two rules, R9-6-401 and R9-6-404, should be amended, and may amend rules throughout the Article to ensure continuity and consistency. The Department therefore proposes to file a Notice of Final Rulemaking with the Governor’s Regulatory Review Council by December 31, 2016.

13. Analysis of stringency compared to federal laws
The rules implement a federally funded program, the Ryan White Comprehensive AIDS Resources Emergency Act (Ryan White CARE Act), Pub.L. 101-381, 104 Stat. 576, enacted August 18, 1990. The rules impose the same requirements on participants as the applicable provisions of Medicare Part D (e.g. 20 CFR Part 418, Subpart D) for acquiring prescription drugs through plans under contract to Medicare.

14. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037
Not applicable, as the rules were adopted before July 29, 2010.
INFORMATION FOR INDIVIDUAL RULES

R9-6-401. Definitions

2. Objective
The objective of the rule is to define terms used in the Article so that a reader can consistently interpret requirements in the Chapter and Article.

3. Analysis of effectiveness in achieving the objective
The rule is effective or mostly effective.

4. Analysis of consistency with referenced state and federal statutes and rules
The rule is consistent with referenced state and federal statutes and other rules except that the definition of “physician” in A.A.C. R9-6-101 includes allopathic, naturopathic, osteopathic, and homeopathic physicians, while the definition of “physician” in the rule includes only allopathic and osteopathic physicians, who are authorized to provide all the drugs provided through ADAP. However, naturopaths and homeopaths don't prescribe the drugs in the ADAP formulary, so this inconsistency may only be technical.

5. Enforcement of the rule
The Department enforces the rules as written except in one respect. The terms “physician,” “physician assistant,” and “registered nurse practitioner” specify that the individual be licensed under Arizona statutes. However, some ADAP applicants or participants live in remote areas of the State where it is more reasonable to obtain HIV-related care from a health professional licensed in a state bordering Arizona. Allowing those participants to receive services, for example, in Las Vegas, San Diego, or Gallup, from a health professional licensed in Nevada, California, or New Mexico, as applicable, is consistent with ADAP's federal funding requirements and represents a reduced burden on participants who are Arizona residents. The California, Nevada, or New Mexico physicians, physician assistants, and registered nurse practitioners providing HIV-related care to these ADAP participants do not meet the definition of the terms specified in rule, but ADAP accepts their prescription orders for drugs for their patients as long as those individuals are licensed to practice by the equivalent professional boards of their states.

6. Analysis of clarity, conciseness, and understandability of the rule
The rule is mostly clear, concise, and understandable, but could be improved in several respects. First, several terms, including “diagnosis,” “guardian,” and “treatment,” are defined in A.A.C. R9-6-101 and need not be defined again in this Section. Conversely, the terms “HIV infection” and “AHCCCS” are used in more than one Article in the
Chapter and should appear in A.A.C. R9-6-101 instead of here. Also, the definition of “physician” could be removed from this rule and the term “primary care provider” could be amended to specify that it includes physicians, physician assistants, and registered nurse practitioners licensed according to their applicable Arizona statutory authority, and the equivalents in bordering states as discussed in paragraph #5 above. In the definition of “support services,” subsection (60)(d) could be changed to remove use of the defined term. In the definition of “unearned income,” subsection (65)(n) could clarify that the term includes interest or dividends from savings or investments.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

The rule does not provide the least burden and costs to persons regulated by the rule, for the reasons described in the foregoing paragraphs. The burden results from any time or cost incurred by the stakeholder to discover, through communication with the Department or other means, the correct course of action to ensure that the stakeholder’s conduct will result in compliance with the rule. If the rule was amended to address the issues described in paragraphs #4, #5, and #6 above, it would impose the least burden and costs necessary. The costs and benefits of the rule are discussed in paragraph #8.

R9-6-402. Limitations and Termination of Program

2. **Objective**

The objective of the rule is to inform the public that ADAP is not an entitlement program and that ADAP ceases to provide drugs when ADAP funding is exhausted or terminated.

3. **Analysis of effectiveness in achieving the objective**

The rule is effective or mostly effective.

5. **Enforcement of the rule**

The Department enforces the rule as written.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

The rule imposes the least burden upon stakeholders necessary to achieve the rule's objective. The costs and benefits of the rule are discussed in paragraph #8.
R9-6-403. Eligibility Requirements

2. **Objective**
The objective of the rule is to establish eligibility requirements for ADAP participation.

3. **Analysis of effectiveness in achieving the objective**
The rule is mostly effective in achieving its objective. However, increasing numbers of applicants, combined with limited funding, have created a scenario in which the Department has had to reduce the number of drugs on the ADAP formulary in order to continue to enroll eligible individuals and not be forced to establish a waiting list or a hypothetical rationing scheme. Ultimately, the Department believes a rule change could become necessary to ensure that ADAP funds are used for individuals who have the most need and no other mechanism for obtaining HIV-related drugs.

5. **Enforcement of the rule**
The Department enforces the rule as written.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The rule imposes the least burden upon stakeholders necessary to achieve the rule's objective. The costs and benefits of the rule are discussed in paragraph #8.

R9-6-404. Initial Application Process

2. **Objective**
The objective of the rule is to establish the information that:
   a. An individual is required to submit to the Department when applying for participation in ADAP; and
   b. The primary care provider of an applicant is required to provide.

3. **Analysis of effectiveness in achieving the objective**
The rule is mostly effective in achieving its objective, but could be improved if it required an additional category of information. The rule requires an ADAP applicant to disclose whether the applicant has health insurance other than Medicare that would pay for drugs on the ADAP formulary, but the rule should instead simply require the applicant to disclose whether the applicant is eligible for any type of health insurance, such as through the federal Affordable Care Act. Although the rule is transparent with
regard to the specific ADAP funding instruments used to disburse payments for participant benefits, the Department could use information collected under this rule to determine which ADAP funding instrument, such as the ADAP Assist insurance subsidy, would be most appropriate to ensure that the applicant obtains drug coverage, while ensuring that ADAP remains the payor of last resort for HIV-related prescription drugs for eligible Arizona residents.

5. **Enforcement of the rule**
   The Department enforces the rules as written except in one respect. Instead of requiring an applicant to report an estimate of family income as specified in subsection (C), the Department derives the needed information from the documentation submitted in subsection (A)(7)(b). This reduces the burden upon the applicant.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule does not provide the least burden and costs to persons regulated by the rule, for the reasons described in the foregoing paragraphs. The burden results from any time or cost incurred by the stakeholder to discover, through communication with the Department or other means, the correct course of action to ensure that the stakeholder’s conduct will result in compliance with the rule. If the rule was amended to address the issues described in paragraph #5 above, it would impose the least burden and costs necessary. The costs and benefits of the rule are discussed in paragraph #8.

R9-6-405. **Enrollment Process; Provisional Enrollment**

2. **Objective**
   The objective of the rule is to establish:
   a. The process by which the Department will approve or deny ADAP participation to an applicant; and
   b. Under what circumstances an applicant may be granted provisional enrollment.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective or mostly effective.

5. **Enforcement of the rule**
   The Department enforces the rule as written.
11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

   The rule imposes the least burden upon stakeholders necessary to achieve the rule's objective. The costs and benefits of the rule are discussed in paragraph #8.

R9-6-406. **Notification Requirements**

2. **Objective**

   The objective of the rule is to establish requirements for notifying:
   
   a. The Department of a change in an enrolled individual’s primary care provider or of circumstances that may affect the enrolled individual’s eligibility to continue participation in ADAP; and
   
   b. The pharmacy dispensing a drug regarding a change in a prescribed drug.

3. **Analysis of effectiveness in achieving the objective**

   The rule is effective or mostly effective.

5. **Enforcement of the rule**

   The Department enforces the rule as written.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

   The rule imposes the least burden upon stakeholders necessary to achieve the rule's objective. The costs and benefits of the rule are discussed in paragraph #8.

R9-6-407. **Continuing Enrollment**

2. **Objectives**

   The objectives of the rule are to establish:
   
   a. Requirements for an enrolled individual to continue participation in ADAP; and
   
   b. The Department’s processes for determining eligibility for continuing enrollment in ADAP and for notifying an individual of the Department’s decision.

3. **Analysis of effectiveness in achieving the objective**

   The rule is mostly effective in achieving its objective, but could be improved if it required an enrolled individual to include documentation of CD4-T-lymphocytes levels
when applying for continuing enrollment, both as a means of effectively assessing the enrolled individual's circumstances and in order to fulfill federal reporting requirements described in paragraph #4. This information is part of the medical documentation submitted by a new applicant, but can change over the course of treatment. In order to simplify continued enrollment and reduce the burden on participants, the Department typically synchronizes continuing enrollment with a participant's birthday and the halfway point in the year between birthdays. It is typical for the Department to acquire the necessary information anyway in the course of receiving and validating prescription orders. Regardless, the rule would be more effective if this process were spelled out in text, rather than being followed simply as a result of administrative accommodation or common practice. The Department reports to federal funding sources this information, in aggregate, as a condition of continued funding.

4. **Analysis of consistency with referenced state and federal statutes and rules**

The rule is consistent with referenced state and federal statutes and other rules except for a reporting requirement that differs from what the U.S. Department of Health and Human Services mandates in *Guidelines for the Use of Antiretroviral Agents in HIV-1 Infected Adults and Adolescents*. This information regarding measurement of an enrolled individual's CD4-T-lymphocytes levels ("ART"), as described in paragraph #3, is part of the medical documentation submitted by a new applicant, but usually is only updated as a result of administrative accommodation, and not because it is explicitly required in the rule. In effect, a participant could refuse to provide this information and could not be refused continuing enrollment solely on that ground. However, as there is no cure for AIDS, the only likely consequence might be prioritization due to changing severity of a participant's condition, if prioritization became necessary and were implemented in rule as indicated in the information for individual rules entry for R9-6-403.

5. **Enforcement of the rule**

The Department enforces the rule as written.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

The rule does not provide the least burden and costs to persons regulated by the rule, for the reasons described in the foregoing paragraphs. However, the additional burden this rule imposes is confined solely to the Department, which must gather information beyond
what the rule indicates in order to meet federal reporting requirements. If the rule was amended to address the issues described in paragraphs #3 and #4 above, it would impose the least burden and costs necessary. The costs and benefits of the rule are discussed in paragraph #8.

R9-6-408. Termination from ADAP Services

2. **Objectives**
The objectives of the rule are to establish:
   a. The circumstances under which the Department may terminate an individual’s participation in ADAP or approval of a restricted drug for the individual; and
   b. The process by which the Department will notify the individual of termination.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective or mostly effective.

5. **Enforcement of the rule**
The Department enforces the rule as written.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The rule imposes the least burden upon stakeholders necessary to achieve the rule's objective. The costs and benefits of the rule are discussed in paragraph #8.

R9-6-409. Drug Prescription and Distribution Requirements

2. **Objective**
The objective of the rule is to establish the process by which an individual enrolled in ADAP may receive drugs, including restricted drugs, through ADAP.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective or mostly effective.

5. **Enforcement of the rule**
The Department enforces the rule as written.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to**
persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

The rule imposes the least burden upon stakeholders necessary to achieve the rule's objective. The costs and benefits of the rule are discussed in paragraph #8.

R9-6-410. Confidentiality

2. Objective

The objective of the rule is to provide notice that the Department will comply with all applicable federal and state laws relating to protecting confidential information obtained by the Department while administering ADAP.

3. Analysis of effectiveness in achieving the objective

The rule is effective or mostly effective.

5. Enforcement of the rule

The Department enforces the rule as written.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

The rule imposes the least burden upon stakeholders necessary to achieve the rule's objective. The costs and benefits of the rule are discussed in paragraph #8.
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August 2014
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CHAPTER 19. VITAL RECORDS AND STATISTICS
FIVE-YEAR-REVIEW SUMMARY

Arizona Revised Statutes (A.R.S.) § 36-136(H)(3) requires the Department to define and prescribe reasonably necessary procedures for the registration, issuance, use and accessibility of vital records; delayed birth registration; and the completion, change, and amendment of vital records. A.R.S. Title 36, Chapter 3, Vital Records and Public Health Statistics, was added by Laws 2004, Ch. 117, § 8 effective August 25, 2004, to replace A.R.S. Title 36, Chapter 3, Vital Statistics, which was repealed at the same time. A.R.S. § 36-302 establishes the Director of the Department of Health Services as the state registrar of vital records and requires the state registrar to implement, organize, operate, and maintain a statewide system of vital records. A.R.S. 36-325 was amended by Laws 2010, Ch. 205, § 1 to specify the time within which a death certificate is signed or registered, and A.R.S. §§ 36-301 and 36-325 were amended by Laws 2012, Ch. 60, §§ 3 and 4 to establish definitions and requirements related to death certificates. A.R.S. § 36-341 was amended by Laws 2011, Ch. 31, § 7 to change the funding mechanism for vital records activities.

Arizona Administrative Code (A.A.C.) R9-19-101 through R9-19-415 implement these statutes by providing a defined administrative process for the creation, retention, and issuance of vital records for the State of Arizona. Article 1 establishes a local-based (county) mechanism for the initial collection and recording of birth and death information, describes the roles and responsibilities of various health personnel within the county-based system, defines the types of acceptable forms for the collection of birth and death data, and provides specific instructions for amending or correcting information on vital records. Article 2 establishes the maximum time limitations for the collection of birth data, provides alternative birth registration processes if the maximum time limitation has expired, and establishes documentation requirements for the alternative birth registration processes. Article 3 establishes requirements for a human remains release form, establishes timelines and requirements for the collection and submission of the data on a death record including the individuals responsible for submitting specific data, establishes requirements for disposition-transit permits, and details the role of the medical examiner in specific causes of death and cremation of human remains. Article 4 specifies who is eligible to receive a certified copy of a birth or death record, defines the type of vital statistics information that can be released to specific organizations, and establishes fees for vital records services and documents provided to the public.

In preparation for this Five-Year-Review Report, the Department has reviewed the Articles in 9 A.A.C. 19 and identified needed revisions. The Department anticipates submitting a Notice of Final Rulemaking for the rules in 9 A.A.C. 19 by December 2016. This proposed course of action is subject to change based on the Department’s priorities, legislative action, and resource availability.
INFORMATION THAT IS IDENTICAL FOR ALL RULES

1. Authorization of rule by existing statute
   General authority: A.R.S. §§ 36-132(A)(3) and 36-136(F)
   Specific authority: A.R.S. §§ 36-302 and 36-136(H)(3)

2. Objective
   The purpose of the rules in Article 1 is to promote the effectiveness of the registration process.
   The purpose of the rules in Article 2 is to specify the processes related to registering a birth.
   The purpose of the rules in Article 3 is to specify the processes related to registering a death.
   The purpose of the rules in Article 4 is to specify who may apply for access to a birth or death certificate and how application is made.

4. Analysis of consistency with state and federal statutes and rules
   The rules in Article 4, except R9-19-402, are consistent with applicable state and federal statutes and rules.

5. Status of enforcement of the rule
   The rules in Article 3 are enforced as written.
   The rules in Article 4, except R9-19-402 and R9-19-403, are enforced as written.

6. Analysis of clarity, conciseness, and understandability
   The rules in Article 2 contain minor grammatical errors that do not substantially affect clarity, conciseness, and understandability.

7. Summary of the written criticisms of the rule received within the last 5 years
   According to staff of the Office of Vital Records, the Department has not received any written criticism of the rules in Chapter 19 within the last five years.

8. Economic, small business, and consumer impact comparison
   In calendar year 2013, the Department’s Office of Vital Records registered 90,394 births and 50,895 deaths. For fiscal year 2014, there were 141,454 certified birth certificate copies and 255,423 certified death/fetal death certificate copies issued through the local registrars in the counties under the statewide system of vital records. Figures for certificates issued by the Department are provided under Information for Individual Rules for R9-19-413. From funds collected through surcharges from the counties and from certificates issued by the Department, the Department, in compliance with A.R.S. § 36-341, deposited $2,896,096 into the vital records electronic systems fund, established by A.R. S. § 36-341.01, and $494,565 into the general fund.
The Department was appropriated $3,634,700 in FY 2014 and also in FY 2015 from the vital records electronic systems fund. Expenses for the Office of Vital Records from the vital records electronic systems fund were $2,455,953 in FY 2014.


The rules in 9 A.A.C. 19, Article 2, specify the requirements for registering live births and were promulgated effective July 31, 1989. The rules contained in 9 A.A.C. 19, Article 3, specify the duties and requirements for registering death records and prescribe post-mortem procedures and were most recently amended effective January 6, 2007. The rules contained in 9 A.A.C. 19, Article 4, specify the eligibility and procedures for obtaining copies of vital records. Except for R9-19-412 and R9-19-413, the rules in Article 4 were most recently amended effective July 31, 1989. R9-19-412 was most recently amended effective October 4, 2003, and R9-19-413 was last amended by exempt rulemaking effective July 1, 2011, under Laws 2011, Ch. 31, § 7. The economic impacts of these two rules are described under the individual rules.

An Economic, Small Business, and Consumer Impact Statement (EIS) was prepared when R9-19-101 was amended and R9-19-301 through R9-19-314 were adopted, effective January 6, 2007. Annual costs/revenue changes were designated as minimal when less than $10,000, moderate when between $10,000 and $50,000, and substantial when greater than $50,000. In the EIS, the Department indicated the following increased costs:

- Minimal increased costs for the State Registrar, local registrars, and deputy local registrars to revise forms and processes;
- Minimal increased costs for hospitals, nursing care institutions, and hospice inpatient facilities to develop and implement the use of a human remains release form;
- Minimal increased costs for a funeral establishment or responsible person for the submission of human remains release forms; and
- Minimal-to-moderate decreased revenue for a funeral establishment that is no longer needed to store human remains until a disposition-transit permit is obtained.

The EIS indicated the following benefits or decreased costs:

- Minimal benefit for medical certifiers who are allowed to amend a medical certification of death without obtaining the signature of the medical examiner;
- Minimal-to-moderate benefit for hospitals, nursing care institutions, and hospice inpatient facilities from being able to remove human remains before obtaining a disposition-transit permit;
- Minimal benefit for medical examiners by requiring the list of circumstances in A.R.S. § 11-593(A) and whether notification required in A.R.S. § 11-593 was made on the human remains release form to ensure applicable cases are referred to the medical examiner;
- Minimal-to-substantial benefit to county health departments and the public at large from requiring human remains release forms with pertinent health information to be submitted to county health departments within 24 hours after removing human remains;
- Minimal benefit to funeral establishments and responsible persons by requiring the list of circumstances in A.R.S. § 11-593(A) and whether notification required in A.R.S. § 11-593 was made on the human remains release form to ensure applicable cases are referred to the medical examiner and not inadvertently released to a funeral establishment or responsible person;
- Minimal-to-moderate benefit to funeral establishments and responsible persons by no longer requiring a disposition-transit permit before removing human remains from a registration district;
- Minimal decrease in costs for persons in charge of a place of final disposition by no longer requiring a copy of a disposition-transit permit or disinterment-reinterment permit to be sent to the State Registrar;
- Minimal benefit for persons in charge of a place of final disposition by clarification of record retention requirements;
- Minimal decrease in costs for families of deceased individuals by not having to obtain a disposition-transit permit or pay to store the deceased individual’s human remains before removing the deceased individual’s human remains from a registration district;
- Minimal-to-substantial benefit to the general public by requiring the list of circumstances in A.R.S. § 11-593(A) and whether notification required in A.R.S. § 11-593 was made on the human remains release form to ensure that any follow-up such as further investigation or referral to the local law enforcement agency is necessary to protect public health and safety; and
- Minimal-to-substantial benefit to the general public by requiring a timely submission of a human remains release form with specific health information to the local health department to ensure that any necessary follow-up, such as further investigation or quarantine, is initiated in a more timely manner, which provides better public health protection.
The Department believes that the assessment was, and continues to be, accurate.

For the remainder of the rules, the Department estimates the following cost/benefit to the affected groups:

**Cost bearers**

- The Department bears the cost of administration and enforcement of the rules, as well as the cost of development and maintenance of electronic systems that register the births and deaths.
- Local registrars, including those local registrars that are part of a county health department, bear the costs of completing the duties prescribed in the rules.
- Individuals who request copies of vital records, statistical information, or amendments to birth or death certificates bear the cost of making that request, including any fees that may be involved.
- Hospitals, clinics, funeral establishments, physicians, midwives, pathologists, medical examiners, funeral directors, or any other institutions or individuals required to provide information for vital records bear the cost of providing that information.

**Beneficiaries**

- The Department benefits from the fees collected from requests for copies of vital records.
- Local registrars, including those local registrars that are part of a county health department, benefit from the fees they receive for completing the duties prescribed in the rules.
- Individuals may benefit from a receipt of a certified copy of a vital record, if the record is required to obtain a benefit from other entities, such as the Social Security Administration. Additionally, individuals that receive statistical information from the Office of Vital Records may receive financial benefit from the resulting product generated with the assistance of that statistical information. For instance, statistical information regarding deaths due to cholera may result in a report that supports changes in public health functions that ultimately reduce the number of individuals dying of cholera.

As used in the following table, minimal means less than $1,000, moderate means between $1,000 and $10,000, and substantial means more than $10,000.

<table>
<thead>
<tr>
<th>Groups Affected</th>
<th>Description of Effect</th>
<th>Increased Costs/ Decreased Revenues</th>
<th>Decreased Costs/ Increased Revenues</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Department</td>
<td>Staff time is required for administration and enforcement</td>
<td>Substantial</td>
<td>Substantial</td>
</tr>
<tr>
<td>Local registrars</td>
<td>Staff time is required for administration</td>
<td>Substantial</td>
<td>Substantial</td>
</tr>
<tr>
<td>Individuals who</td>
<td>Individuals pay minimal fees</td>
<td>Minimal</td>
<td>Minimal-to-substantial</td>
</tr>
<tr>
<td>Groups Affected</td>
<td>Description of Effect</td>
<td>Increased Costs/ Decreased Revenues</td>
<td>Decreased Costs/ Increased Revenues</td>
</tr>
<tr>
<td>----------------------------------------------------------</td>
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<td>------------------------------------------------------------</td>
<td>------------------------------------------------------------</td>
</tr>
<tr>
<td>request copies of vital records</td>
<td>for copies of the records. Additionally, there may be travel, postage, or telephone costs incurred.</td>
<td>depending on the purpose for requesting the document (i.e., IRS, Social Security or VA benefits, will probate, school admission, etc.)</td>
<td></td>
</tr>
<tr>
<td>Individuals who request statistical information</td>
<td>Individuals pay fees for the statistical information.</td>
<td>Minimal-to-moderate depending on the number of certificates or files requested</td>
<td>Not quantifiable, could be significant in terms of public health</td>
</tr>
<tr>
<td>Individuals who request amendment of vital records</td>
<td>Minor administrative changes: An individual may expend time and additional costs in order to provide the information needed to make a minor administrative change to a vital record</td>
<td>Minimal</td>
<td>Minimal-to-substantial, depending on the purpose for requesting the amendment</td>
</tr>
<tr>
<td></td>
<td>Major administrative changes: An individual may expend time and additional costs in order to provide the information needed to make a major administrative change to a vital record</td>
<td>Minimal-to-moderate</td>
<td>Minimal-to-substantial, depending on the purpose for requesting the amendment</td>
</tr>
<tr>
<td></td>
<td>Court-ordered changes: An individual may expend time and additional costs in order to obtain the court order needed to make a change to a vital record</td>
<td>Minimal-to-substantial</td>
<td>Minimal-to-substantial, depending on the purpose for obtaining the court order for the amendment</td>
</tr>
<tr>
<td>Hospitals, clinics, and other health care institutions required to provide information for vital records</td>
<td>Staff time is required to register births as required by rule</td>
<td>Minimal-to-substantial, depending on the number of births that take place in the hospital, clinic, or other health care institutions</td>
<td>Minimal-to- substantial, depending on the fees charged for birth-related services</td>
</tr>
<tr>
<td>Doctors, registered nurse practitioners, midwives, and other health care personnel required to provide information for birth records</td>
<td>The amount of time expended in complying with the rules will vary, depending on the number of births the individual attends</td>
<td>Minimal-to-moderate, depending on the number of births the individual attends</td>
<td>Minimal-to-moderate, depending on the fees charged for birth related services</td>
</tr>
</tbody>
</table>

The Department did not receive a business competitiveness analysis of the rules in the last five years.

10. **Status of the completion of action indicated in the previous five-year-review report**
    In the previous five-year-review report for 9 A.A.C. 19 approved by the Governor’s Regulatory Review Council in February 2010, the Department proposed amending R9-19-101 and Article 2 within two years after the Governor’s moratorium on rulemaking was lifted, amending Article 1 and Article 4 within three years after the rulemaking moratorium was lifted, and not amending Article 3. Since the moratorium, established January 22, 2009 and continued through legislative and executive actions to the present day, is still in effect and a rulemaking for 9 A.A.C. 19 would likely not meet the criteria for an exception from the moratorium, the Department is complying with the rulemaking action proposed in the previous five-year-review report.

12. **Analysis of stringency compared to federal laws**
    The rules are not related to federal laws except to the extent that the programs governed by the rules may report statistical data collected through the rules to federal agencies under a contract with the National Center for Health Statistics, part of the Centers for Disease Control and Prevention.

13. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**
    The rules were adopted before July 29, 2010 and do not establish licensing, certification, or permit requirements.

14. **Proposed course of action**
    The Department intends to amend the rules in 9 A.A.C. 19 to address issues identified in this report. The Department anticipates submitting a Notice of Final Rulemaking for the rules in 9 A.A.C. 19 by December 2016. This proposed course of action is subject to change based on the Department’s priorities, legislative action, and resource availability.
ARTICLE 1. ADMINISTRATIVE ORGANIZATION, DUTIES AND PROCEDURES

R9-19-101. Definitions

2. Objective
   The objective of the rule is to define terms and phrases used in the Chapter to enable a reader to have a better understanding of the requirements contained in the Chapter.

3. Analysis of effectiveness in achieving the objective
   The rule is effective in achieving its objective.

4. Analysis of consistency with state and federal statutes and rules
   The rule defines “hospital” through a cross-reference to A.A.C. R9-10-201. The rule defines “inpatient hospice facility” as having the same meaning as “hospice inpatient facility” as defined in A.A.C. R9-10-801. The definitions for these terms are now contained in A.A.C. R9-10-101. The term “medical certifier” may be inconsistent with A.R.S. § 36-301(19), as amended by Laws 2012, Ch. 60, §3, since a health care provider also includes midwives, nurse midwives, and physician assistants, and A.R.S. § 36-325 specifies when a health care provider is required to complete and sign a medical certification of death. The term “registered nurse practitioner” is now defined as having the same meaning as “nurse practitioner” A.R.S. §36-301. The term “nurse practitioner” is not defined in A.R.S. §36-301, but “registered nurse practitioner” is defined in A.R.S. § 32-1601. The rule is otherwise consistent with applicable state and federal statutes and rules.

5. Status of enforcement of the rule
   The rule is enforced consistent with statute and rule, as described in paragraph 3.

6. Analysis of clarity, conciseness, and understandability
   With the exception of the issues described in paragraph 4, the rule is clear, concise, and understandable.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective
   Because of the issues described in paragraph 4 of the analysis of this rule, which could result in a need for a stakeholder to clarify the rule, the rule does not impose the least burden and costs on persons regulated by the rule.
R9-19-104. Duties of local registrars

1. **Authorization of rule by existing statute**
   Additional specific authority: A.R.S. §§ 36-311 and 36-312

2. **Objective**
   The objective of the rule is to specify the duties of a local registrar to allow for effective conduct of registration duties.

3. **Analysis of effectiveness in achieving the objective**
   Although the rule is mostly effective, subsections (1), (4), and (5) only restate statutory requirements in A.R.S. § 36-312, without additional clarification. In addition, the rule cites a repealed statute and contains ambiguous or undefined terms, as stated in paragraph 6.

4. **Analysis of consistency with state and federal statutes and rules**
   The rule lists a local registrar’s duties “[i]n addition to the duties outlined in A.R.S. § 36-308,” which was repealed in 2004. The statutory list of a local registrar’s duties is now in A.R.S. § 36-312. Subsection (5) is inconsistent with other state rules because it refers to R9-19-112, which expired effective December 31, 2004. The rule is otherwise consistent with applicable state and federal statutes and rules.

5. **Status of enforcement of the rule**
   The rule is enforced consistent with statute and rule.

6. **Analysis of clarity, conciseness, and understandability**
   The rule’s clarity, conciseness, and understandability are limited by the use of ambiguous terms, such as “properly” and “timely and accurate”; undefined terms, such as “normal working hours” and “normal working day,” which may have different meanings depending on the type of work; and incorrect terms, such as “disposal-transit permits” rather than “disposition-transit permits.” In addition, subsection (2) does not conform to current rulemaking format and style requirements, and subsection (5) uses outdated language.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

Because of the issues described in paragraphs 3, 4, and 6 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-19-105. Removal of local registrars

1. **Authorization of the rule by existing statute**
Additional specific authority: A.R.S. §§ 36-302(B)(6) and 36-311

2. **Objective**
The objective of the rule is to establish criteria for the removal of a local registrar to provide notice and avoid arbitrary action.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective.

4. **Analysis of consistency with state and federal statutes and rules**
The rule requires a local registrar to be removed according to A.R.S. § 36-307(B). The rule is inconsistent with state statutes because A.R.S. § 36-307 was repealed in 2004. Requirements for the removal of a local registrar are included in A.R.S. § 36-311(C). The rule is otherwise consistent with applicable state and federal statutes and rules.

5. **Status of enforcement of the rule**
The Department is enforcing the substance of the rule consistent with current statutory authority in A.R.S. § 36-311(C).

6. **Analysis of clarity, conciseness, and understandability**
The rule is mostly clear, concise, and understandable, but could be improved by removing outdated language, such as the use of “pursuant,” and revising the statutory citations in subsections (1) and (2) to conform to current rulemaking format and style requirements.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Because of the issues described in paragraphs 4 and 6 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-19-106. **Vital record forms**

1. **Authorization of the rule by existing statute**
   Additional specific authority: A.R.S. § 36-302(B)(7)

2. **Objective**
The objective of the rule is to permit only forms provided by the State Registrar when preparing, printing, and registering birth and death records and reports to provide notice and avoid the use of unacceptable forms.

3. **Analysis of effectiveness in achieving the objective**
The rule is mostly effective but could be improved by more clearly allowing forms and worksheets to be supplied electronically.

4. **Analysis of consistency with state and federal statutes and rules**
   The rule is consistent with applicable state and federal statutes and rules.

5. **Status of enforcement of the rule**
   The rule is enforced as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule’s clarity, conciseness, and understandability are limited by passive language and by an inconsistent use of terms. Subsection (A) uses the term “vital statistics records and reports” and subsection (B) uses the term “recording vital events,” and it is unclear whether the terms refer to the same records and to what “vital events” refers. In addition, the title of the Section refers to “vital record,” and the correct term is “vital records.”

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Because of the issues described in paragraphs 3 and 6 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-19-108. **Unacceptable forms**

1. **Authorization of rule by existing statute**
   Additional specific authority: A.R.S. §§ 36-302(B)(1) and 36-302(B)(11)

2. **Objective**
   The objective of the rule is to specify the circumstances under which the State Registrar will reject a form submitted for registration or other purposes to provide notice to persons submitting forms.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

4. **Analysis of consistency with state and federal statutes and rules**
   The rule is consistent with applicable state and federal statutes and rules.

5. **Status of enforcement of the rule**
   When this rule was adopted, the form for registration became a birth or death certificate, but now information on worksheets is entered into an electronic system. Subsection (3) is obsolete and is not enforced as written.
6. **Analysis of clarity, conciseness, and understandability**

The rule’s clarity, conciseness, and understandability are limited by the use of passive language and ambiguous or undefined terms. It is not clear whether the term “necessary” in subsection (1) is supposed to have the same meaning as “required” or if it applies to a different set of information than the required information. Similarly, it is not clear to what the term “other purposes” refers. The terms “soiled” and “untidy” are subjective and have no clear meaning in rule. In addition, the rule contains minor grammatical errors that do not substantially affect clarity, conciseness, and understandability.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

Because of the issues described in paragraphs 5 and 6 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-19-109. **Review and transmittal procedures for forms**

1. **Authorization of rule by existing statute**

Additional specific authority: A.R.S. §§ 36-312(4), 36-312(5), and 36-312(6)

2. **Objective**

The objectives of the rule are:

a. To specify the steps a local registrar is required to follow in processing or rejecting forms that are submitted;

b. To specify the time limitation for the transmittal procedure; and

c. To require a local registrar to maintain a list of all births, deaths, and fetal deaths in a register designated for that purpose.

3. **Analysis of effectiveness in achieving the objective**

The rule is only partially effective because the rule contains an inconsistency with current statutes, as stated in paragraph 4, and ambiguous or undefined terms, as stated in paragraph 6. The requirements in subsections (2) and (3) are also outdated, since subsection (2) appears to imply the use of paper registers, and information gathered on worksheets is now entered into an electronic system, rather than forms being transmitted to the State Registrar, as specified in subsection (3).

4. **Analysis of consistency with state and federal statutes and rules**
The rule is inconsistent with current statutes that no longer reference Class A and Class B registration districts. The rule is otherwise consistent with applicable state and federal statutes and rules.

5. **Status of enforcement of the rule**
   Although the rule is inconsistent with current statutes, as stated in paragraph 4, and contains outdated requirements in subsections (2) and (3) and ambiguous or undefined terms, as stated in paragraph 6, the Department is enforcing the substance of the rule to the extent possible.

6. **Analysis of clarity, conciseness, and understandability**
   The rule’s clarity, conciseness, and understandability are limited by the use of passive language and ambiguous or undefined terms. The terms “promptly” and “timeliness” are used, and it is unclear how promptness and timeliness affect eligibility for payment. The term “general appearance” is not defined, and it is not clear what the criteria are for rejecting a form because of the form’s general appearance. In addition, the rule contains minor grammatical errors that do not substantially affect clarity, conciseness, and understandability.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Because of the issues described in paragraphs 3, 4, and 6 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-19-111. Local registrar’s responsibility to review death certificates for medical examiner referral

1. **Authorization of rule by existing statute**
   Additional specific authority: A.R.S. §§ 36-321 and 36-325

2. **Objective**
   The objective of the rule is to specify the procedure that a local registrar is required to follow when a certificate is received for a death or a fetal death that occurred under any of the circumstances listed in A.R.S. § 11-593 or when a certificate is received indicating that the human remains are to be cremated. Both instances require the county medical examiner’s signature.

3. **Analysis of effectiveness in achieving the objective**
   Although the rule contains passive or outdated language and ambiguous, undefined, or incorrect terms, as stated in paragraph 6, subsections (A), (B), and (C) are mostly effective. Subsection (D) of the rule is not effective because there are no disciplinary actions that the Department is
authorized to impose except removal of a local registrar, and the criteria for the removal of a local registrar are contained in R9-19-105.

4. **Analysis of consistency with state and federal statutes and rules**
The rule is consistent with applicable state and federal statutes and rules.

5. **Status of enforcement of the rule**
The Department is not enforcing subsection (D) because there is no statutory authority for disciplinary action other than removal, which is covered under R9-19-105. Although the rule contains passive language and ambiguous, undefined, and incorrect terms, as stated in paragraph 6, the Department is enforcing the substance of subsections (A), (B), and (C).

6. **Analysis of clarity, conciseness, and understandability**
The rule’s clarity, conciseness, and understandability are limited by the use of passive or outdated language and ambiguous, undefined, or incorrect terms. The term “nearest peace officer” is ambiguous because it seems to denote that the location of the peace officer is the important factor, rather than the peace officer’s jurisdiction. The term “improperly” is not defined, and it is not clear what constitutes an improperly completed certificate. The term “disposal-transit permit” is incorrect and should be “disposition-transit permit.”

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Because of the issues described in paragraphs 3 and 6 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-19-112.01. **Amendments to Birth or Death Certificates by County Registrars**

1. **Authorization of rule by existing statute**

2. **Objective**
The objective of the rule is to specify when and how a county registrar may correct, amend, or make additions to birth and death certificates.

3. **Analysis of effectiveness in achieving the objective**
The rule is only partially effective because the rule contains inconsistencies with statutory definitions, as stated in paragraph 4, and passive language and ambiguous or undefined terms, as stated in paragraph 6. In addition, a “county registrar” may enter notations, but not at the locations specified in subsection (C).
4. **Analysis of consistency with state and federal statutes and rules**

The use of “amend” and “correct” in subsections (A), (B), and (E) is not consistent with the statutory definitions of “amend” and “correction” in A.R.S. § 36-301. The statutory definitions of “amend” and “correction” provide that amend and correct apply to making a change to a registered certificate. The rule contains requirements for “amending” and “correcting” a certificate before the certificate is registered. In addition, the rule refers to “county registrar,” and the statutory term is “local registrar”. In addition, subsection (B) refers to documentation requirements in R9-19-119, which is expired. Requirements related to changes in a death certificate are now in R9-19-310 and R9-19-311. The remainder of the rule is consistent with applicable state and federal statutes and rules.

5. **Status of enforcement of the rule**

The Department is not enforcing the requirement for drawing a single line through an incorrect entry and correcting the information “immediately above or as near the initial entry as practicable” in subsection (C) or for “typing missing or omitted information in the appropriate spaces on the certificate” in subsection (D) because many of the certificates are electronic and not typed. The Department is enforcing the substance of the remainder of the rule, although the rule is inconsistent with statutory definitions, as stated in paragraph 4, and contains ambiguous terms or undefined terms, as stated in paragraph 6.

6. **Analysis of clarity, conciseness, and understandability**

The rule’s clarity, conciseness, and understandability are limited by inconsistencies with statutory definitions and ambiguous or undefined terms. In addition, subsections (A) and (B) include the phrase “prior to submitting a birth (death) certificate to the State Registrar,” and it is unclear whether subsections (C), (D), and (E) are also “prior to submitting to the State Registrar.” It is unclear to what the phrase “make additions” refers. The terms “medical cause of death” and “manner of death” are not defined, and it is unclear to what the two terms refer. Passive language is also used in subsections (C) and (D). In addition, the rule contains minor grammatical errors that do not substantially affect clarity, conciseness, and understandability.

8. **Economic, small business, and consumer impact comparison**

An EIS was prepared for R9-19-112.01 when the rule was adopted in 1992 and another when the rule was amended in 1993. In 1992, the rule was adopted to specify standards for a county registrar to add or correct death certificates. The 1993 rulemaking added standards for a county registrar to add or correct birth certificates. In both EISs, the Department indicated that the impact of the rule changes on the Department, other public agencies, private entities, and consumers would be minimal. The Department believes that the assessment was, and continues to be, accurate.
11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

Because of the issues described in paragraphs 3, 4, and 6 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-19-114. **Correction and amendment of vital records after official acceptance of certificate**

1. **Authorization of rule by existing statute**
   Additional specific authority: A.R.S. §§ 36-136(H)(3), 36-323, and 36-337

2. **Objective**
   The objective of the rule is to establish the criteria and procedure for correcting and amending vital records after a certificate has been assigned a state file number.

3. **Analysis of effectiveness in achieving the objective**
   The first sentence of the rule is partially effective because of the issues described in paragraphs 5 and 6. The remainder of the rule is not effective, because it does not provide complete information on the types of changes and the documents required in order to make the changes. Although the specific requirements are contained in subsequent rules in the Article, those specific rules are not referenced in this rule.

4. **Analysis of consistency with state and federal statutes and rules**
   The rule is consistent with applicable state and federal statutes and rules.

5. **Status of enforcement of the rule**
   The Department is enforcing the spirit of the first sentence. Old paper certificates had previously been marked as “amended” when the information on the certificate was changed, but no notations are made to these certificates when new changes are made. Instead, information from the paper certificate is used to create a new, corrected certificate, with notations of the changes and supporting documents stored electronically. For all others, the information in the electronic record is updated appropriately and, if the change is other than a minor administrative change, the record is noted as being amended. The Department does not mark a certificate record as “amended” if the changes were made due to typographical errors or if there is inaccurate information on a birth certificate due to a hospital error. In these instances, the Department makes the changes to the birth certificate as a correction and does not mark the certificate “amended,” regardless of the length of time following the date of birth.

6. **Analysis of clarity, conciseness, and understandability**
The rule’s clarity, conciseness, and understandability are limited by the use of passive language and ambiguous or undefined terms. It is unclear what constitutes “fully.” Although the terms “alterations,” “changes,” “corrections,” “additions,” “deletions,” and “substitutions” are all used in the rule, only “correction” is defined, and it is unclear what the rest of the terms mean. In addition, the rule contains minor grammatical errors that do not substantially affect clarity, conciseness, and understandability.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

Because of the issues described in paragraphs 3 and 6 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-19-115. **Classification of changes to correct or amend vital records**

1. **Authorization of rule by existing statute**
   Additional specific authority: A.R.S. §§ 36-323 and 36-337

2. **Objective**
   The objective of the rule is to establish the classification of changes to vital records to include judicial, major administrative, or minor administrative changes.

3. **Analysis of effectiveness in achieving the objective**
   The rule is only partially effective because the rule contains inconsistencies with statute, as stated in paragraph 4, and passive language and ambiguous or undefined terms, as stated in paragraph 6.

4. **Analysis of consistency with state and federal statutes and rules**
   Current statutes provide authority for amending a vital record and establish the circumstances for amending a vital record. A.R.S. § 36-301(2) defines “amend” as making a change, other than a correction, to a registered certificate by adding, deleting, or substituting information on that certificate. A.R.S. § 36-323 also grants authority to the State Registrar to adopt rules for making corrections. “Correction” is defined in A.R.S. § 36-301(6) as a change made to a registered certificate because of a typographical error, including misspelling and missing or transposed letters or numbers. The rule is not consistent with current statutory definitions because the rule does not address the differences between a change that meets the definition of “amend” and a change that meets the definition of “correction.” The rule is otherwise consistent with applicable state and federal statutes and rules.

5. **Status of enforcement of the rule**
The rule is enforced consistent with statute.

6. **Analysis of clarity, conciseness, and understandability**
The rule’s clarity, conciseness, and understandability are limited by the use of passive language and ambiguous or undefined terms, such as the following. Although the term “materially affect” is used to distinguish between a major administrative change and a minor administrative change, there is no criteria to determine when an alteration, addition, deletion, or substitution would “materially affect” the validity or integrity of a certificate. The term “integrity” is used, but it is unclear what it means. Similarly, it is unclear what constitutes a “fundamental relationship” or a “court of competent jurisdiction.” In addition, the terms “alterations,” “additions,” “deletions,” and “substitutions” are used but not defined. In addition, the rule contains minor grammatical errors that do not substantially affect clarity, conciseness, and understandability.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Because of the issues described in paragraphs 4 and 6 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-19-116. **Authority to request changes on certificate**

1. **Authorization of rule by existing statute**
   Additional specific authority: A.R.S. § 36-323

2. **Objective**
The objective of the rule is to identify the individuals who are allowed to request changes to a vital record.

3. **Analysis of effectiveness in achieving the objective**
The rule is partially effective. The rule's effectiveness is limited by inconsistencies with statute and rule, as stated in paragraph 4, and the use of passive language and ambiguous or undefined terms, as stated in paragraph 6. Requirements for correcting a death certificate or a fetal death certificate are now contained in R9-19-310, while R9-19-311 now contains all the requirements for amending a death certificate or a fetal death certificate.

4. **Analysis of consistency with state and federal statutes and rules**
Subsections (B)(2) and (B)(3) refer to requirements for a physician or pathologist and a medical examiner in R9-19-310. R9-19-310 has been amended and does not contain requirements specific to physicians, pathologists, which are now in R9-19-311, or medical examiners, which
are now in R9-19-303. Subsection (B)(4) refers to requirements for a funeral director or a “person acting in such capacity” in A.R.S. § 36-327(B), which no longer contains requirements specific to funeral directors or persons acting in such a capacity. The rule is otherwise consistent with applicable state and federal statutes and rules.

5. **Status of enforcement of the rule**
   The rule is enforced consistent with statute and rule.

6. **Analysis of clarity, conciseness, and understandability**
   The rule’s clarity, conciseness, and understandability are limited by the use of passive language and ambiguous or undefined terms. In addition to the term “identifying information,” the term “personal particulars” is used, and it is unclear what the distinction is between “identifying information” and “personal particulars.” The term “other close relative” is not defined, and it is unclear which relatives are considered “close.” It is also unclear to whom the term “attendant” refers or who is a “guardian.” In addition, the rule contains minor grammatical errors that do not substantially affect clarity, conciseness, and understandability. Finally, the rule would be clearer if requirements for fetal death certificates were separate from requirements for birth certificates.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Because of the issues described in paragraphs 3, 4, and 6 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-19-117. **Documentary evidence requirements**

1. **Authorization of rule by existing statute**
   Additional specific authority: A.R.S. §§ 36-323 and 36-337

2. **Objective**
   The objective of the rule is to specify what documentary evidence is necessary to make a judicial, major administrative, or minor administrative change to a vital record.

3. **Analysis of effectiveness in achieving the objective**
   The rule is only partially effective because the rule contains inconsistencies with other rules in the Chapter, as stated in paragraph 4, and passive language and ambiguous terms or undefined terms, as stated in paragraph 6. The rule also does not appear to allow the Department to make and retain an electronic copy of a document submitted to support a change.

4. **Analysis of consistency with state and federal statutes and rules**
The requirements for changing a birth certificate in subsections (A)(1) and (A)(2) are not consistent with A.R.S. § 36-337, which contains statutory requirements for amending a birth certificate. The rule also uses the term “independent factual document” and is inconsistent with current statutes that use the term “evidentiary document.” The requirements for changing a death certificate or a fetal death certificate in subsections (A)(2) and (A)(3) are not consistent with R9-19-310, which contains the requirements for correcting a death certificate or a fetal death certificate, and R9-19-311, which contains the requirements for amending a death certificate or a fetal death certificate. The rule is otherwise consistent with applicable state and federal statutes and rules.

5. **Status of enforcement of the rule**
The Department is only enforcing the rule for amending or correcting birth certificates, since updated requirements for death certificates are now in Article 3.

6. **Analysis of clarity, conciseness, and understandability**
The rule’s clarity, conciseness, and understandability are limited by the use of passive language and ambiguous or undefined terms. The term “desired” is used, and it is unclear if the term refers to changes that are being requested. The term “authenticated abstracts” is used, but it is not clear to what the term refers. The term “existing vital record form” is not defined, and it is unclear whether the term refers to a birth, death, or fetal death certificate. The term “personal knowledge” is also used but not defined. In addition, the rule is hard to understand with multiple requirements within the same subsection and contains minor grammatical errors that do not substantially affect clarity, conciseness, and understandability.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Because of the issues described in paragraphs 3, 4, and 6 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-19-118. **Changes on birth and fetal death certificates**

1. **Authorization of rule by existing statute**
   Additional specific authority: A.R.S. §§ 36-323 and 36-337

2. **Objective**
The objective of the rule is to establish the criteria for determining whether a change on a birth or fetal death certificate is considered a judicial, major administrative, or minor administrative change.

3. **Analysis of effectiveness in achieving the objective**
   Although the current rule establishes categories of changes to a birth or fetal death certificate, the rule is only partially effective because the rule does not contain criteria and procedures for changing a birth or fetal death certificate. In addition, the rule’s effectiveness is limited by inconsistencies with statute and rule, as stated in paragraph 4, and passive language and ambiguous or undefined terms, as stated in paragraph 6.

4. **Analysis of consistency with state and federal statutes and rules**
   As mentioned under paragraph 4 for the analysis of R9-19-112.01, A.R.S. § 36-301 defines the terms “amend” and “correction.” The rule is not consistent with current statutory definitions. In addition, subsection (B)(10) is not consistent with the requirements for voluntary acknowledgment of paternity in A.R.S. § 25-812. The rule is otherwise consistent with applicable state and federal statutes and rules.

5. **Status of enforcement of the rule**
   The rule is enforced consistent with statute and rule.

6. **Analysis of clarity, conciseness, and understandability**
   The rule’s clarity, conciseness, and understandability are limited by the use of passive language and ambiguous or undefined terms, such as the following. The term “substantial alteration” is used, and, although the rule states that it does not apply to those changes covered by judicial authorization, there are no other standards as to when an alteration is substantial. The term “minor errors of spelling” is used, but it is unclear what constitutes a minor error of spelling. The term “surgical alterations of chromosomal counts” is used, and it is unclear whether the term refers to surgery to the registrant’s genitalia to conform to a determination of gender based on chromosomal counts or to alter the apparent gender regardless of chromosomal counts. The term “both parents” is used when adding a father’s name, and it is unclear whether it applies to the mother and the man who is being added as the father. The term “new birth certificate” in not currently used in statute or practice and is not defined. In addition, the rule contains minor grammatical errors that do not substantially affect clarity, conciseness, and understandability.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Because of the issues described in paragraphs 3, 4, and 6 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-19-120. Changes on a delayed birth certificate

1. Authorization of rule by existing statute
   Additional specific authority: A.R.S. §§ 36-323 and 36-337

2. Objective
   The objective of the rule is to specify the circumstances under which a delayed birth certificate may be changed.

3. Analysis of effective in achieving the objective
   The rule is only partially effective because the rule is inconsistent with statute, as stated in paragraph 4, and contains passive language and ambiguous terms, as stated in paragraph 6.

4. Analysis of consistency with state and federal statutes and rules
   Subsection (2) allows an individual’s delayed birth certificate after the adoption of the individual to remain the same with only a notation of the adoption on the delayed birth certificate. This is inconsistent with the requirement in A.R.S. § 36-337(D) for written statements from the mother and father listed on the birth certificate or certified copies of death certificates for the mother or father to retain information on the birth certificate after the adoption. The rule is otherwise consistent with applicable state and federal statutes and rules.

5. Status of enforcement of the rule
   The rule is enforced consistent with statute.

6. Analysis of clarity, conciseness, and understandability
   The rule’s clarity, conciseness, and understandability are limited by the use of passive language and ambiguous terms. The phrase “may be shown” is used to refer to a new name or a notation referencing an adoption on the birth certificate, and it is unclear whether the new name is written directly on the birth certificate or if a new certificate is issued with the new name printed on it. The term “administrative” is used referring to an error, and it is unclear what constitutes an “administrative” error. The term “person” rather than “individual” is used when referring to the adoptee.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective
Because of the issues described in paragraphs 4 and 6 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.
ARTICLE 2. DUTIES REGARDING LIVE BIRTHS

R9-19-201. Registration of live births

1. **Authorization of rule by existing statute**
   Additional specific authority: A.R.S. §§ 36-329 and 36-333

2. **Objective**
   The objectives of the rule are to:
   a. Explain the procedure for and list the information required when providing monthly reports of live births and fetal deaths to the State Registrar, and
   b. Specify the time-frame and procedure for notifying a local registrar that there will be a delay in filing a birth certificate or fetal death certificate.

3. **Analysis of effectiveness in achieving the objective**
   The rule is only partially effective because the rule contains inconsistencies with statute, as stated in paragraph 4, and ambiguous or undefined terms, as stated in paragraph 6. The rule’s effectiveness is also limited because the heading does not reflect the requirements contained in the rule for monthly reports of fetal deaths.

4. **Analysis of consistency with state and federal statutes and rules**
   Subsection (A) refers to birth registration requirements in A.R.S. § 36-322. Birth certificate registration requirements are in A.R.S. § 36-333. In addition, A.R.S. § 36-333 requires that a birth certificate for registration be submitted within seven days after a child’s birth in this state. A.R.S. § 36-333.01 states that a birth certificate for registration submitted later than seven days after the child’s birth but less than one year after the child’s birth is considered a late birth certificate and is required to meet the requirements in rule for a late birth certificate. There is no statutory authority for allowing a delay in submitting the birth certificate for registration for up to 20 days after the child’s birth as stated in subsection (B) without considering the birth certificate a late birth certificate. Nor is there statutory authority for allowing a hospital, clinic, or other institution providing maternity services to wait a month or more before furnishing details of a live birth or fetal death. The rule is otherwise consistent with applicable state and federal statutes and rules.

5. **Status of enforcement of the rule**
   The Department is not allowing an extension of time for the filing of a birth certificate for registration and, although the remainder of the rule contains ambiguous or undefined terms, the Department is enforcing the substance of the remainder of the rule. Since the submission information for births and “registrable fetal deaths” is done electronically, hospitals, clinics, and
other institutions providing maternity services are not being required to submit a “monthly report.”

6. **Analysis of clarity, conciseness, and understandability**
   
   In addition to the issues identified under Information that is Identical for all Rules, the rule’s clarity, conciseness, and understandability are limited by the use of passive language and ambiguous or undefined terms. The term “because of circumstances beyond its control” is used without any criteria for determining when this would apply. It is also unclear to what the terms “clinic” and “regular maternity services” refer.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

   Because of the issues described in paragraphs 3, 4, and 6 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-19-202. **General requirements regarding late birth certificates**

1. **Authorization of rule by existing statute**
   
   Additional specific authority: A.R.S. § 36-333.01

2. **Objective**
   
   The objectives of the rule are to specify the:
   
   a. Requirements for late birth certificates registered within one year from the date of birth, and
   
   b. Information needed to register a late birth certificate.

3. **Analysis of effectiveness in achieving the objective**
   
   The rule’s effectiveness in achieving its objective is limited by an inconsistency with statute, as stated in paragraph 4, and passive language and ambiguous or undefined terms, as stated in paragraph 6.

4. **Analysis of consistency with state and federal statutes and rules**
   
   Subsection (4) states that a late birth certificate shall be registered by the local registrar of the district in which the birth occurred and is inconsistent with the requirements in A.R.S. § 36-333.01, which states that a local registrar, deputy local registrar, or the state registrar shall register a late birth certificate if the late birth certificate meets the requirements in rules and statutes. The rule also uses the term “independent factual document” and is inconsistent with current statutes.
that use the term “evidentiary document.” The rule is otherwise consistent with applicable state and federal statutes and rules.

5. **Status of enforcement of the rule**
   The requirements in subsection (2) for a signature on the certificate is not enforced when a late birth certificate is filed electronically and the required signature is on the worksheet used to file the late birth certificate. In addition, subsection (4) is not being enforced as written. The substance of the remainder of the rule is being enforced.

6. **Analysis of clarity, conciseness, and understandability**
   In addition to the issues identified under *Information that is Identical for All Rules*, the rule’s clarity and conciseness, and understandability are limited by the use of passive language and ambiguous or undefined terms. From the rule, it is unclear that a late birth certificate is one registered more than seven days and less than one year after birth. A birth certificate registered within seven days after birth, even though it is “within one year from the date of the birth,” is not a late birth certificate. The phrase “unless exempted by law” is used, and it is unclear who or what might possibly be exempted by law, the local registrar or the act of registering the birth certificate. It is also unclear to whom the terms “relative” and “other attendant” refer. The term “personal knowledge” is also used but not defined. In addition, subsection (3) does not conform to current rulemaking format and style requirements.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Because of the issues described in paragraphs 4 and 6 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.

**R9-19-205. Application for delayed birth registration**

1. **Authorization of rule by existing statute**
   Additional specific authority: A.R.S. § 36-333.02

2. **Objective**
   The objectives of the rule are to specify:
   a. Who may apply for delayed birth registration;
   b. What the procedure is for applying for delayed birth registration;
   c. The time-frame before a pending application lapses; and
d. That, if an individual voluntarily withdraws the request for delayed birth registration before the lapsed date, the individual is entitled to a fee refund.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective.

4. **Analysis of consistency with state and federal statutes and rules**
Subsection (A) refers to R9-19-203, which expired effective December 31, 2004. The rule is otherwise consistent with applicable state and federal statutes and rules.

5. **Status of enforcement of the rule**
Except as described in paragraph 4, the rule is enforced as written.

6. **Analysis of clarity, conciseness, and understandability**
In addition to the issues identified under *Information that is Identical for All Rules*, the rule’s clarity, conciseness, and understandability are limited by the use of passive language, outdated language such as “his,” and ambiguous terms. The terms “formal application” and “application” are used, and it is not clear what each term means in each instance. The phrase “withdraws his request” is used, and it is unclear if the word “request” means “application” or something different. The term “person” rather than “individual” is used when referring to the adoptee.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Because of the issues described in paragraphs 4 and 6 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-19-206. **General requirements for delayed birth registration**

1. **Authorization of rule by existing statute**
Additional specific authority: A.R.S. § 36-333.02

2. **Objective**
The objective of the rule is to specify the requirements for registering a delayed birth, including the facts and signatures that must be provided when submitting a delayed birth certificate for registration.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective.

4. **Analysis of consistency with state and federal statutes and rules**
The term “name” is defined in A.R.S. § 36-301 and appears to have the same meaning as the term “full name” used in subsection (B)(1). The remainder of the rule is consistent with state and federal statutes and rules.

5. **Status of enforcement of the rule**

The Department does not allow the “next of kin of the person whose birth is to be registered” in subsection (C)(3) to sign the statement required in subsection (C). Although the remainder of the rule contains passive language, outdated language, and ambiguous terms, as stated in paragraph 6, the Department is enforcing the substance of the remainder of the rule.

6. **Analysis of clarity, conciseness, and understandability**

In addition to the issues identified under *Information that is Identical for All Rules*, the rule’s clarity, conciseness, and understandability are limited by the use of passive language, outdated language such as “prior to” and “therein,” and ambiguous or undefined language. The terms “delayed birth registration,” “delayed birth certificate,” “delayed registration,” and “delayed certificate of birth” are used, and it is unclear what each of the terms means and the relationship of each term to the other terms. The term “next of kin” is used and is not defined, and it unclear what family members are considered “next of kin.” The term “guardian” is also used but not defined. In addition, the rules do not conform to current rulemaking format and style requirements and use the term “person” rather than “individual” when referring to the pending registrant.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

Because of the issues described in paragraphs 4, 5, and 6 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-19-207. **Documentary requirements for delayed birth registration**

1. **Authorization of rule by existing statute**

Additional specific authority: A.R.S. § 36-333.02

2. **Objective**

The objectives of the rule are to:

a. Specify the documentary evidence to accompany an application for the registration of a delayed birth certificate, and
b. Provide notice that the State Registrar makes the determination of whether or not a submitted document is acceptable or complete.

3. Analysis of effectiveness in achieving the objective
The statement in subsection (C) that a document established before an individual’s fourth birthday shall be preferred over a document established after the individual’s fourth birthday is not effective because it does not establish a requirement or provide criteria for complying with the rule. The rule also does not appear to allow the Department to make and retain an electronic copy of the documentary evidence. In addition, the rule’s effectiveness is limited by grammatical errors and the use of passive language, outdated language, and ambiguous or undefined terms, as stated in paragraph 6.

4. Analysis of consistency with state and federal statutes and rules
The rule does not contain an exception in subsection (B) for individuals whose birthdate was before 1970, as allowed in A.R.S. § 36-333.02(B). The rule also uses the term “independent factual document” and is inconsistent with current statutes that use the term “evidentiary document.” The rule is otherwise consistent with applicable state and federal statutes and rules.

5. Status of enforcement of the rule
The rule is enforced consistent with statute.

6. Analysis of clarity, conciseness, and understandability
In addition to the issues identified under Information that is Identical for All Rules, the rule’s clarity, conciseness, and understandability are limited by the use of passive language, outdated language, such as “prior to” and “therefor,” and ambiguous or undefined terms. The terms “fact of birth” or “birth facts” are not defined and refer to the information in R9-19-206(B). The term “clearly” and the phrase “shall be preferred” are used in subsection (C), and it is unclear what they mean. Although the term “family member” is defined in A.R.S. § 36-301, the term is used in the rule but not defined by reference to the statute or otherwise. The terms “inadequate,” “unsatisfactory,” and “conflicting” in subsection (E) are used to refer to documents, but there are not specific standards as to how the Department determines if a document is inadequate, unsatisfactory, or conflicting. The term “personal knowledge” is also used but not defined.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective
Because of the issues described in paragraphs 3, 4, and 6 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.
R9-19-208. Cancellation of a delayed birth certificate; duties of State Registrar

2. **Objective**
   The objectives of the rule are to specify:
   a. Under which circumstances the State Register can cancel the registration of a delayed birth certificate,
   b. How the registrant is notified when the registration of a delayed birth certificate is cancelled, and
   c. That the registrant may appeal the cancellation of the registration of a delayed birth certificate.

3. **Analysis of effectiveness in achieving the objective**
   Subsection (B) is not effective because the subsection references statute but does not provide a citation to the specific statute, A.R.S. § 41-1092.02, applicable for an appealable agency action. Subsection (A) is mostly effective.

4. **Analysis of consistency with state and federal statutes and rules**
   The rule is consistent with applicable state and federal statutes and rules.

5. **Status of enforcement of the rule**
   The rule is enforced as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable but does not define “administrative remedies.”

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Because of the issue described in paragraph 3 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.
ARTICLE 3. VITAL RECORDS FOR DEATH

R9-19-301. Human Remains Release Form

1. Authorization of rule by existing statute
   Additional specific authority: A.R.S. § 36-326(B)

2. Objective
   The objective of the rule is to establish information, signature, and submission requirements for a human remains release form.

3. Analysis of effectiveness in achieving the objective
   The rule is mostly effective but could be improved by clarifying what happens to the form specified in subsection (B).

4. Analysis of consistency with state and federal statutes and rules
   Subsections (A) and (B) refer to the “form required by A.R.S. § 36-326(C) to accompany a deceased individual's human remains.” A.R.S. § 36-326 was amended by Laws 2006, Ch. 139, and the correct citation is now A.R.S. § 36-326(B). Subsection (A)(4) provides for the signature of the medical certification of death by a physician or registered nurse practitioner. According to A.R.S. § 36-325(G), as amended by Laws 2012, Ch. 60, §4, a health care provider may sign the medical certification of death, and, according to the definition of “health care provider” in A.R.S. § 36-301(19), as amended by Laws 2012, Ch. 60, §3, a health care provider also includes midwives, nurse midwives, and physician assistants. The rule is otherwise consistent with applicable state and federal statutes and rules.

6. Analysis of clarity, conciseness, and understandability
   The rule contains minor grammatical errors that do not substantially affect clarity, conciseness, and understandability.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective
   Because of the issues described in paragraphs 3 and 4 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-19-302. Disposition-transit Permits

1. Authorization of rule by existing statute
   Additional specific authority: A.R.S. § 36-326
2. **Objective**  
The objective of the rule is to establish requirements for disposition-transit permits for human remains, including requirements for:

a. When a disposition-transit permit is necessary;
b. How to obtain a disposition-transit permit, including what information needs to be submitted;
c. When a disposition-transit permit is valid; and
d. How a disposition-transit permit affects the disposition of human remains.

3. **Analysis of effectiveness in achieving the objective**  
The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**  
The rule is mostly clear, concise, and understandable, but could be improved by clarifying in subsection (D)(4) that there are dispositions possible other than hospital or abortion clinic. The rule would also be improved by clarifying the meaning(s) and differences between the terms “anatomical gift of the human remains except for donation of a part” and “anatomical gift except for donation of a part.” In addition, the rule contains minor grammatical errors that do not substantially affect clarity, conciseness, and understandability.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**  
Because of the issues described in paragraph 6 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.

**R9-19-303. Medical Certification for a Death Certificate**

1. **Authorization of rule by existing statute**  
Additional specific authority: A.R.S. § 36-325

2. **Objective**  
The objective of the rule is to establish requirements for the medical certification on a death certificate, including:

a. When a medical certification is required to be submitted,
b. The information required on a medical certification, and
c. Signature requirements for the medical certification.
3. **Analysis of effectiveness in achieving the objective**
   The rule is mostly effective but could be improved by clarifying whether only a physician or registered nurse practitioner or a medical examiner can sign a medical certification of death or whether other types of health care providers, as defined in A.R.S. § 36-301, can sign under A.R.S. § 36-325(G).

4. **Analysis of consistency with state and federal statutes and rules**
   The rule may be inconsistent with A.R.S. §§ 36-301 and 36-325 because only physicians, registered nurse practitioners, and medical examiners are mentioned in the rule, but A.R.S. § 36-325(G) requires a health care provider, which also includes midwives, nurse midwives, and physician assistants, to complete and sign the medical certification of death. The rule is otherwise consistent with applicable state and federal statutes and rules.

6. **Analysis of clarity, conciseness, and understandability**
   The rule contains minor grammatical errors that do not substantially affect clarity, conciseness, and understandability.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Because of the issue described in paragraphs 3 and 4 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-19-304. **Information for a Death Certificate**

1. **Authorization of rule by existing statute**
   Additional specific authority: A.R.S. § 36-325

2. **Objective**
   The objectives of the rule are to establish:
   a. Requirements for information on a death certificate including the specific information required;
   b. When and to whom the information is required to be submitted; and
   c. Requirements for the duplication, retention, and production of the information submitted.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
The rule is mostly clear, concise, and understandable but could be improved by clarifying the meaning(s) and differences between the terms “anatomical gift of the human remains except for donation of a part” and “anatomical gift except for donation of a part.” In addition, the rule contains minor grammatical errors that do not substantially affect clarity, conciseness, and understandability.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

Because of the issue described in paragraph 6 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.

**R9-19-305. Delayed Death Certificate**

1. **Authorization of rule by existing statute**
   Additional specific authority: A.R.S. § 36-325.01

2. **Objective**
   The objective of the rule is to establish requirements for registering an individual’s death more than one year after the individual’s death, including the specific information required depending on who is submitting the information.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

   The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

**R9-19-306. Information for a Fetal Death Certificate**

1. **Authorization of rule by existing statute**
   Additional specific authority: A.R.S. § 36-329
2. **Objective**
   The objective of the rule is to establish requirements for information on a fetal death certificate, including:
   a. The specific information required;
   b. Who is required to submit the information;
   c. When and to whom the information is required to be submitted; and
   d. Requirements for the duplication, retention, and production of the information submitted.

3. **Analysis of effectiveness in achieving the objective**
   The rule is mostly effective but could be improved by clarifying how the rule would address the situations of a midwife delivering a baby in a location other than the mother’s home and of a mother being transferred to a hospital from the mother’s home while attempting a home birth.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is mostly clear, concise, and understandable but could be improved by clarifying the differences between the terms “prenatal care visit” and “prenatal visit” and defining the single term that is to be used. The rule could also be improved by clarifying the meaning(s) and differences between the terms “anatomical gift of the human remains except for donation of a part” and “anatomical gift except for donation of a part.” In addition, the rule contains minor grammatical errors that do not substantially affect clarity, conciseness, and understandability.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Because of the issues described in paragraphs 3 and 6 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-19-307. **Delayed Fetal Death Certificate**

1. **Authorization of rule by existing statute**
   Additional specific authority: A.R.S. § 36-329.01

2. **Objective**
   The objective of the rule is to establish requirements for registering a fetal death more than one year after the fetal death, including the specific information required depending on who is submitting the information.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.
6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-19-308. **Certificate of Birth Resulting in Stillbirth**

1. **Authorization of rule by existing statute**
   Additional specific authority: A.R.S. § 36-330

2. **Objective**
The objective of the rule is to provide the circumstances under which a certificate of birth resulting in stillbirth is provided to a parent or parents.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-19-309. **Validation of Information**

1. **Authorization of rule by existing statute**
   Additional specific authority: A.R.S. § 36-302(B)

2. **Objective**
The objectives of the rule are to:
   a. Establish a process for requiring additional documents to validate submitted information for the registration or amendment of a vital record that a local registrar, deputy local registrar, or the state registrar determines may not be valid or accurate; and
b. Specify that the local registrar, deputy local registrar, or state registrar shall not register or amend the certificate if the additional documents are not submitted.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-19-310. **Correcting Information on a Death Certificate or a Fetal Death Certificate**

1. **Authorization of rule by existing statute**
Additional specific authority: A.R.S. § 36-323(C)

2. **Objective**
The objective of the rule is to establish requirements for correcting information on a death certificate or fetal death certificate including information, attestation, and evidentiary document requirements.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-19-311. **Amending Information on a Death Certificate or a Fetal Death Certificate**

1. **Authorization of rule by existing statute**
Additional specific authority: A.R.S. § 36-323
2. **Objective**
   The objective of the rule is to establish requirements for amending information on a death certificate or a fetal death certificate, including who can request an amendment for specific information on the death certificate or fetal death certificate, who is required to sign a request for an amendment for specific information, submission requirements, and notification requirements.

3. **Analysis of effectiveness in achieving the objective**
   The rule is mostly effective, but the effectiveness could be improved by addressing the issues described in paragraphs 4 and 6.

4. **Analysis of consistency with state and federal statutes and rules**
   Subsection (C)(3)(b) is inconsistent with the lead-in to subsection (C) because the information on a fetal death certificate is specified in R9-19-306, not R9-19-303. The rule is otherwise consistent with applicable state and federal statutes and rules.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is mostly clear, concise, and understandable, but it could be improved by revising the phrase in subsection (C) “the information on the death certificate in R9-19-303” to clarify that the information is specified in R9-19-303, not the death certificate. In addition, the rule contains minor grammatical errors that do not substantially affect clarity, conciseness, and understandability.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Because of the issues described in paragraphs 4 and 6 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-19-312. Transporting Human Remains into the State for Final Disposition

1. **Authorization of rule by existing statute**
   Additional specific authority: A.R.S. § 36-326

2. **Objective**
   The objective of the rule is to establish requirements for transporting human remains into Arizona for final disposition including document submission requirements and disposition-transit permit issuance requirements.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-19-313. **Disinterment-reinterment Permit**

1. **Authorization of rule by existing statute**
   Additional specific authority: A.R.S. § 36-327

2. **Objective**
The objective of the rule is to establish requirements for obtaining a disinterment-reinterment permit before disinterring a deceased individual’s human remains, including requirements for authorization; information submission; and document reproduction, retention, and production.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
   Although the term “family member” is defined in A.R.S. § 36-301, the term is used in the rule but not defined by reference to the statute or otherwise. The rule also contains minor grammatical errors that do not substantially affect clarity, conciseness, and understandability.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Despite the minor issues described in paragraph 6, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-19-314. **Duties of Persons in Charge of Place of Final Disposition**

1. **Authorization of rule by existing statute**
   Additional specific authority: A.R.S. § 36-331

2. **Objective**
The objective of the rule is to establish document retention and production requirements for persons in charge of a place of final disposition.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.
ARTICLE 4. ACCESS TO RECORDS; COPIES; FEES


1. **Authorization of rule by existing statute**
   Additional specific authority: A.R.S. §§ 36-136(H)(3) and 36-324

2. **Objective**
   The objective of the rule is to specify the information required when applying for a certified copy of a vital record and to specify that all applications are required to be in writing unless authorized by the State Registrar.

3. **Analysis of effectiveness in achieving the objective**
   The rule’s effectiveness in achieving its objective is limited by the issue described in paragraph 4 and the passive language, outdated language, and ambiguous or undefined terms, as stated in paragraph 6.

4. **Analysis of consistency with state and federal statutes and rules**
   Subsections (A) and (C) are inconsistent, since subsection (A) requires a request for a certified copy of a vital record to be in writing, but subsection (C) allows for telephone orders or verbal requests “in extraordinary circumstances.” The rule is otherwise consistent with applicable state and federal statutes and rules.

5. **Status of enforcement of the rule**
   The portion of subsection (A) stating that the register may require sworn statements is not enforced because a sworn statement does not establish eligibility to receive a copy of a certificate. The remainder of the rule is enforced consistent with current statutory authority.

6. **Analysis of clarity, conciseness, and understandability**
   The rule’s clarity, conciseness, and understandability are limited by passive language, outdated language, such as “such” and “therein”, and ambiguous or undefined terms. The term “filing” is used in subsection (A), and the appropriate term is “submit.” The terms “sufficiently” and “sufficient” are used in subsections (A) and (B), respectively, but there are no standards for what is considered sufficient. It is unclear what constitutes a “reasonable search” in subsection (B) or “extraordinary circumstances” in subsection (C). In addition, the term “valid” is used and is not defined and the rule contains minor grammatical errors that do not substantially affect clarity, conciseness, and understandability.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Because of the issues described in paragraphs 4 and 6 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-19-403. Eligibility for Certified Copy of Birth Certificate

1. **Authorization of rule by existing statute**
   Additional specific authority: A.R.S. § 36-136(H)(3) and 36-324

2. **Objective**
   The objective of the rule is to specify who is eligible to receive a certified copy of a birth certificate based on the relationship of the person to the registrant on the birth certificate.

3. **Analysis of effectiveness in achieving the objective**
   The rule’s effectiveness in achieving its objective is limited by the issues described in paragraph 6.

5. **Status of enforcement of the rule**
   The portion of the rule allowing a certified copy of a birth certificate to be issued to an “unemancipated registrant” under 18 years of age with the permission of a parent is not enforced as written. The Department does not issue certified copies of birth certificates to “unemancipated registrant[s]” under 18 years of age. The remainder of the rule is enforced consistent with current statutory authority.

6. **Analysis of clarity, conciseness, and understandability**
   The rule’s clarity, conciseness, and understandability are limited by passive language and ambiguous or undefined terms. The term “control of” is used in reference to a minor, and it is unclear what the term means. The terms “registrant” and “unemancipated registrant” are also used, and it is unclear what the terms mean. Although the term “family member” is defined in A.R.S. § 36-301, the term is used in the rule but not defined by reference to the statute or otherwise. The term “guardian” is also used but not defined, and the outdated term “out-of-wedlock” is also used. In addition, the rule seems to imply that there are two types of birth certificates, a regular birth certificate and another for a birth out of wedlock. There is only one type of birth certificate issued. The rule also contains minor grammatical errors that do not substantially affect clarity, conciseness, and understandability.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Because of the issues described in paragraph 6 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-19-404. Eligibility for Certified Copy of Birth Certificate for Adoption Agencies and Private Attorneys

1. **Authorization of rule by existing statute**
   Additional specific authority: A.R.S. §§ 36-136(H)(3) and 36-324

2. **Objective**
   The objective of the rule is to specify under what circumstances an adoption agency or private attorney may receive a certified copy of a birth certificate.

3. **Analysis of effectiveness in achieving the objective**
   The rule’s effectiveness in achieving its objective is limited by passive language and ambiguous or undefined terms, as stated in paragraph 6.

6. **Analysis of clarity, conciseness, and understandability**
   The rule’s clarity, conciseness, and understandability are limited by passive language and ambiguous or undefined terms. The term “pending” is used, and it is unclear at what point an adoption is considered “pending.” The terms “adoption agency” and “adoptive parents” are used and not defined, and the outdated term “out-of-wedlock” is also used.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Because of the issues described in paragraph 6 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-19-405. Eligibility for Certified Copy of Death Certificate

1. **Authorization of rule by existing statute**
   Additional specific authority: A.R.S. §§ 36-36-136(H)(3) and 36-324

2. **Objective**
   The objective of the rule is to specify who is eligible to receive a certified copy of a death certificate.
3. **Analysis of effectiveness in achieving the objective**

The rule is only partially effective because the rule contains passive language and ambiguous or undefined terms, as stated in paragraph 6.

6. **Analysis of clarity, conciseness, and understandability**

The rule’s clarity, conciseness, and understandability are limited by passive language and ambiguous or undefined terms. The phrases “legal or other vital interest” and “proof of interest” are used, and it is unclear what the phrases mean. The terms “business purposes,” “business relations,” and “business matters” are used, and it is unclear what each term means and what is the relationship between the terms. Although the term “family member” is defined in A.R.S. § 36-301, the term is used in the rule but not defined by reference to the statute or otherwise. In addition, the terms “immediate family” and “relative” are used and are not defined, and the rule contains minor grammatical errors that do not substantially affect clarity, conciseness, and understandability.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

Because of the issues described in paragraph 6 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-19-406. **Eligibility for Certified Copy of Fetal Death Certificate**

1. **Authorization of rule by existing statute**

Additional specific authority: A.R.S. §§ 36-136(H)(3) and 36-324

2. **Objective**

The objective of the rule is to specify who is eligible to receive a certified copy of a fetal death certificate.

3. **Analysis of effectiveness in achieving the objective**

The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**

The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-19-408. Standards for Copies

1. **Authorization of rule by existing statute**
   Additional specific authority: A.R.S. § 36-324

2. **Objective**
   The objective of the rule is to specify standards for certified copies of birth and death certificates.

3. **Analysis of effectiveness in achieving the objective**
   The rule is only partially effective because it contains passive language and ambiguous or undefined terms, as stated in paragraph 6.

6. **Analysis of clarity, conciseness, and understandability**
   The rule’s clarity, conciseness, and understandability are limited by passive language and ambiguous or undefined terms. The term “reproduction” is used, and it is unclear whether it refers to something different than a “copy.” The term “vital record form” is used, and it is unclear if it refers to a birth or death certificate or some other form. In addition, the term “custody of the record” is used and is not defined, and the rule contains minor grammatical errors that do not substantially affect clarity, conciseness, and understandability.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Because of the issues described in paragraph 6 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-19-412. Payment of Fees

1. **Authorization of rule by existing statute**
   Additional specific authority: A.R.S. § 36-341

2. **Objective**
   The objective of the rule is to establish acceptable methods of paying the fees required in this Chapter.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

8. **Economic, small business, and consumer impact comparison**
   An EIS was prepared when R9-19-412 was amended effective October 4, 2003. In the EIS, the Department indicated that the impact on the general public of no longer being allowed to use personal checks was expected to be minimal and the impact on the Department of establishing a system to accept credit cards for the payment of fees to the Office of Vital Records was expected to be substantial. The Department believes that the assessment was, and continues to be, accurate.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-19-413. **Fee Schedule**

1. **Authorization of rule by existing statute**
   Additional specific authority:  A.R.S. § 36-341

2. **Objective**
   The objective of the rule is to establish fees for vital records services and documents.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

8. **Economic, small business, and consumer impact comparison**
   Prior to 2002, the Department was appropriated monies from the general fund to support all the functions established within the Department according to A.R.S. Title 36, Chapter 3, Vital Records and Public Health Statistics. Laws 2002, Ch. 160 established a Vital Records Electronic Systems Fund, into which 40% of the fees collected by the Department according to R9-19-413 were deposited. The remaining monies were to be deposited into the general fund. The Department amended the fees, effective August 2002, to comply with Laws 2002, Ch. 160 to ensure that the monies deposited into the general fund were not reduced. The Department was appropriated funding from the general fund and the Vital Records Electronic Systems Fund for the operation of the Office of Vital Records. The rule was further amended, effective January 2007, to ensure that the monies deposited into the Vital Records Electronic Systems Fund did not
exceed $500,000, but the Department continued to receive appropriated funds for the operation of
the Office of Vital Records. Laws 2011, Ch. 31 made the Office of Vital Records self-funded,
and Laws 2011, Ch. 31 § 7 allowed the Department to establish new fees charged by the Office of
Vital Records for searches, copies of registered certificates, certified copies of registered
certificates, amending registered certificates, and correcting certificates that are processed by the
Department. Laws 2011, Ch. 31, § 7 also allowed the Department to establish a surcharge fee to
be assessed on local registrars for access to the Department's vital records automation system.
Because R9-19-413 was amended by exempt rulemaking in 2011, an EIS was not prepared. Non-
certified copies of a certificate or searches to verify birth or death data increased from three to
five dollars. Certified copies increased from $9 to $19, as did submissions of a request for
certificate registration. Submissions of a request to amend or correct information increased from
$22 to $29. A one dollar surcharge was assessed for the Department to issue certified copies of
registered birth or death certificates, for local registrars to issue certified copies of registered birth
or death certificates, and for local registrars to access the vital records automation system for a
noncertified copy of a certificate. A four dollar surcharge was assessed for local registrars to
access the vital records automation system for a certified copy of a certificate. A summary of
certificates issued/searches performed is shown in the Table below. The numbers of birth
certificates and death certificates issued by the counties are shown in aggregate, derived from the
number of surcharges assessed for certified copies of a certificate.

Table - Summary of Certificates Issued and Searches Performed, with
Revenue Generated for FY 2014

<table>
<thead>
<tr>
<th>Type of Certificate/Search</th>
<th>Number Issued</th>
<th>Revenue to the Department</th>
<th>Increase Due to Change in Fees</th>
</tr>
</thead>
<tbody>
<tr>
<td>County-issued</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Birth certificates ($4 surcharge)</td>
<td>141,454</td>
<td>$565,816</td>
<td>$565,816</td>
</tr>
<tr>
<td>Death certificates ($4 surcharge)</td>
<td>255,423</td>
<td>$1,021,692</td>
<td>$1,021,692</td>
</tr>
<tr>
<td>County-issued Totals</td>
<td>396,877</td>
<td>$1,587,508</td>
<td>$1,587,508</td>
</tr>
<tr>
<td>Department-issued</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Birth certificates</td>
<td>68,455</td>
<td>$1,369,100</td>
<td>$753,005</td>
</tr>
<tr>
<td>Birth certificate corrections/amendments</td>
<td>7,023</td>
<td>$210,690</td>
<td>$56,184</td>
</tr>
<tr>
<td>Foreign-born birth certificates</td>
<td>191</td>
<td>$3,820</td>
<td>$2,101</td>
</tr>
<tr>
<td>Delayed birth certificates</td>
<td>222</td>
<td>$4,440</td>
<td>$2,442</td>
</tr>
<tr>
<td>No-fee birth certificates</td>
<td>3,832</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Service</td>
<td>Quantity</td>
<td>Fee</td>
<td>Refunds</td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>----------</td>
<td>------</td>
<td>---------</td>
</tr>
<tr>
<td>Putative Father Search</td>
<td>1,064</td>
<td>$5,320</td>
<td>$0</td>
</tr>
<tr>
<td>Death certificates</td>
<td>11,355</td>
<td>$227,100</td>
<td>$124,905</td>
</tr>
<tr>
<td>Death certificates issued according to a court order</td>
<td>6</td>
<td>$120</td>
<td>$66</td>
</tr>
<tr>
<td>Fetal death certificates</td>
<td>18</td>
<td>$360</td>
<td>$198</td>
</tr>
<tr>
<td>Stillbirth death certificates</td>
<td>15</td>
<td>$300</td>
<td>$165</td>
</tr>
<tr>
<td>Death certificate corrections</td>
<td>121</td>
<td>$3,630</td>
<td>$968</td>
</tr>
<tr>
<td>Delayed death certificates</td>
<td>4</td>
<td>$80</td>
<td>$44</td>
</tr>
<tr>
<td>No-fee death certificates</td>
<td>1,020</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-certified birth certificates</td>
<td>327</td>
<td>$1,635</td>
<td>$654</td>
</tr>
<tr>
<td>Non-certified death certificates</td>
<td>872</td>
<td>$4,360</td>
<td>$1,744</td>
</tr>
<tr>
<td><strong>Department-issued Totals</strong></td>
<td><strong>94,525</strong></td>
<td><strong>$1,830,955</strong></td>
<td><strong>$942,476</strong></td>
</tr>
</tbody>
</table>

According to these figures, the Department received $565,816 in surcharges from counties for certified copies of birth certificates issued by the counties and $1,021,692 in surcharges from counties for certified death certificates. This represents a total of $1,587,508 more than the Department received before the 2011 rulemaking. In addition, as of July 31, 2014, the Department received from the counties and deposited $134,834, according to A.R.S. § 36-341(B), into the confidential intermediary and fiduciary fund established by A.R.S. § 8-135 and $244,978, according to A.R.S. § 36-341(E), into the child fatality review fund established by A.R.S. § 36-3504.

During FY 2014, the Department issued a total of 94,525 certificates, including 4,852 birth or death certificates for no charge under A.R.S. § 39-122(A) and R9-19-414, and received a total of $1,377,360 for certified copies of birth certificates, $227,960 for certified death certificates, and $225,635 from corrected/amended certificates, non-certified certificates, and other functions. This represents a total of $942,476 more than the Department received before the 2011 rulemaking. As of July 31, 2014, the Department deposited $199,916, according to A.R.S. § 36-341(B), into the confidential intermediary and fiduciary fund established by A.R.S. § 8-135 and $240,739, according to A.R.S. § 36-341(E), into the child fatality review fund established by A.R.S. § 36-3504 from funds received by the Department for certificates issued by the Department and the counties and for other functions provided by the Department. No searches to verify birth or death data for statistical, medical, research, or administrative purposes were conducted during fiscal year 2014.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons**
regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-19-414. Services Without Charge

1. Authorization of rule by existing statute
   Additional specific authority: A.R.S. §§ 36-341 and 39-122(A)

2. Objective
   The objective of the rule is to establish when the Department does not charge for a records search or a certified copy of a vital record.

3. Analysis of effectiveness in achieving the objective
   The rule’s effectiveness in achieving its objective is limited by passive language and ambiguous or undefined terms, as stated in paragraph 6.

6. Analysis of clarity, conciseness, and understandability
   The rule’s clarity, conciseness, and understandability are limited by passive language and ambiguous or undefined terms. The term “similar retirement benefits” is used, and it is unclear what it refers to. The phrase “a search of the files” is used, and it is unclear whether that means a “record search” or if it means something different. The phrase “in the opinion of the State Registrar” is used, and it is unclear what the phrase means. In addition, the term “NSLI life insurance” is used and is not defined.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective
   Because of the issues described in paragraph 6 of the analysis of this rule, which could result in a need for a stakeholder to clarify the requirements of the rule, the rule does not impose the least burden and costs on persons regulated by the rule.
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6. 2013 EXEMPT RULEMAKING  
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Arizona Revised Statutes ("A.R.S.") §§ 36-897 et seq. require the Arizona Department of Health Services ("Department") to certify residential facilities that regularly provide child care for compensation for periods of less than 24 hours per day for between five and ten children through the age of 12 ("child care group homes"). The Department is required under A.R.S. § 36-897.01(I) to adopt rules necessary for the proper administration and enforcement of the duties prescribed in Title 36, Chapter 7.1, Article 4 for child care group homes. Through its administrative rules, the Department establishes operational and administrative requirements for child care group homes, including minimum programmatic, personnel, supervision, training, physical environment and other standards, and the criteria for granting, denying, suspending and revoking a certificate.

Arizona Administrative Code ("A.A.C.") Title 9, Chapter 3 establishes the certification and operating requirements for child care group homes. Since 2010, the previous year in which a Five-year-review Report was submitted, the Department has conducted four rulemakings on these rules. Pursuant to Laws 2010, Ch. 248, §§ 3 and 5, the majority of the rules were amended by exempt rulemaking at 17 A.A.R. 1530, effective September 30, 2011. In that rulemaking, the Department streamlined the rules by eliminating obsolete, inefficient, or ineffective requirements; amending and updating the remaining certification requirements consistent with statutory authority, industry standards, and Department policies; and reorganized the rules to make them more clear, concise, and understandable. During exempt rulemaking at 19 A.A.R. 2607, effective August 1, 2013, the Department amended portions of R9-3-202 and R9-3-301 to ensure that child care group home certificate holders comply with A.R.S. §§ 8-804 and 8-804.01 for central registry background checks. Two other exempt rulemakings became effective in 2010, amending fee requirements in R9-3-203.

Upon review of the rules in 9 A.A.C. 3, the Department determined that the only rule needing a substantive amendment at this time is R9-3-408, as described in this report. The Department proposes to submit a Notice of Final Rulemaking by December 31, 2017 to amend R9-3-408 and address other substantive issues that may arise.
INFORMATION THAT IS IDENTICAL FOR ALL RULES

1. **Authorization of the rule by existing statute**
   All the rules have general authority in A.R.S. §§ 36-132(A)(1) and 36-136(F).
   All the rules have specific authority in A.R.S. §§ 36-897 through 36-897.12.

4. **Analysis of consistency with referenced state and federal statutes and rules**
   With the exception of R9-3-408, all rules are consistent with referenced state and federal statutes.

5. **Status of enforcement of the rule**
   With the exception of R9-3-408, the Department enforces all rules as written.

7. **Summary of the written criticisms of the rule received within the last 5 years**
   The Department did not receive any written criticism of the rules in the last five years.

8. **Analysis of estimated economic, small business, and consumer impact**
   The Child Care Group Home rules, except R9-3-203, were most recently amended by exempt rulemakings in 2011 and 2013, and the Department did not file an economic, small business, and consumer impact statement (EIS) for either rulemaking. This analysis of estimated economic impact designates annual costs and benefits as minimal when less than $1,000; moderate when $1,000 to $10,000; and substantial when greater than $10,000. Costs and benefits are designated as significant when meaningful or important but not readily subject to quantification. Only costs resulting from the rulemaking are considered, rather than costs imposed by legislation.

   For fiscal year 2014, the Department certified 163 new facilities, with 200 certification applications received. A total of 924 applications were approved, counting initial licenses, renewals, and amended licenses. The Department did not deny any applications, and 25 initial applications were withdrawn. At the end of the fiscal year, 88 applications, of which 12 were initial applications, were in pending status. During the fiscal year, 195 facilities elected to close.

   In fiscal year 2014, the Department performed 2,638 regular compliance inspections and 530 complaint-based inspections. These figures are in addition to the inspection that accompanies each application for initial certification listed above. The Department
performed 40 enforcement actions, some of them consolidating multiple complaints. This is lower than the enforcement totals reported in the 2010 Five-year review Report.

The Department currently has 27 surveyors who are responsible for regulating approximately 312 child care group homes. The Department currently has 15 surveyor positions vacant and 6 staff positions vacant. Each surveyor currently has a survey caseload of approximately 12 homes, including for each a portion of the pending applications. This is a slight reduction in caseload since 2010.

The economic, small business, and consumer impact for 2010 rulemaking that increased fees for certificates holders is discussed in the analysis of R9-3-203.

In general, the rulemakings imposed some new costs upon certificate holders while conferring benefits upon all stakeholders, as discussed in the following summary of economic impact. Generalized changes are addressed first, followed by categorical changes and finally specific changes.

Virtually all Sections were amended to streamline and simplify requirements, remove cumbersome phrasing or requirement structures, update references, clarify definitions and requirements, and/or require fewer submittals. The Department believes that these changes imposed none-to-minimal costs on stakeholders, depending whether the change was a clarification of current practice or a change requiring staff retraining, and provided a significant benefit. The Department, child care group homes, and consumers benefit significantly from rules that are easier to use, less expensive to enforce, and more efficiently and effectively protect the health and safety of enrolled children.

The 2011 rulemaking made amendments throughout the Chapter in changing certificate renewal into a pro forma process in which all certifications in good standing remain in effect upon payment of a certification fee every three years, sharply reducing the administrative burden on the Department and child care group homes. The Department expects to experience a substantial benefit due to reduced costs from staff time saved. While the Department does not collect data sufficient to determine administrative savings for a child care group home, it is by definition a non-zero reduction in costs and thus represents a minimal or greater benefit.
In 2011, Article 1 was simplified by eliminating unneeded definitions and making R9-3-102 conform to the changes made through 16 A.A.R. 1561 to R9-3-203 and R9-3-207. This resulted in a significant benefit to stakeholders.

Article 2 modernized the application process by adding requirements such as for an applicant to provide an e-mail address, designating individuals to act on behalf of a business entity, and disclosing instances of prior denial or revocation of a license or certificate for health or safety reasons. While these changes do not affect the vast majority of applicants for certification, the Department expects that there may be some portion of potential applicants for whom these requirements represent a greater burden than the previous requirements. Because an individual sufficiently burdened by the changed requirements may never apply for certification, the Department cannot quantify the degree of burden, and therefore classifies the expected potential burden as significant. In other respects, the streamlining of the application process created a significant benefit for the Department and applicants for certification for a child care group home.

Multiple Articles amended several procedural requirements consistent with expected performance levels in the industry, and therefore would only cause a certificate holder deficient in meeting those criteria to incur costs to meet those requirements, including:

- Notification to the Department and to the parents of enrolled children of pertinent information;
- Maintenance of specified documentation and staff records;
- Updates to requirements related to tuberculosis, immunizations, and exclusion during outbreaks to be consistent with Department policy;
- Requiring staff with current training in first aid and CPR to be present during hours of operation when an enrolled child is on a field trip;
- Administration and storage of prescription medications;
- Requirements for infants and toddlers for sleeping, waking, and eating;
- Discipline and child separation procedures;
- Food preparation requirements, including hand-washing provisions, serving requirements based on an enrolled child's age or needs, and food storage;
- Requirements regarding telephones and air-circulating fans; and
• Requirements related to wood-burning stoves, fireplaces, chimineas, electric portable heaters, smoking, and a fire/emergency plan.

Multiple Articles removed or reduced bookkeeping or procedural requirements for a certificate holder, resulting in none to minimal benefits, including:

• Removing a requirement for a provider to check the status of immunizations every three months;

• Removing prohibitions against feeding cereal by bottle to an infant or toddler and against serving high-sugar cereal more than twice weekly;

• Reducing the capacity requirements for fire extinguishers from 2A-10-BC to 1A-10-BC;

• Removing a requirement to document evacuation time; and

• Removing a requirement for poisonous plants to be inaccessible.

In some cases, the Department added new requirements that may impose minimal or moderate cost upon certificate holders, depending on the certificate holder's circumstances, and that are expected to cause enrolled children to benefit from improved health and safety, including:

• Updated health-related equipment and supervision requirements, such as the contents of first-aid kits, heat exposure monitoring procedures, and physical plant requirements involving diaper-changing surfaces, windows, mirrors, window blinds, climate-control fixtures and appliances, and outdoor activity areas;

• Changes in when and how a provider may apply diapering products, sunscreen, or other substances to an enrolled child's skin;

• Updated requirements regarding the use of wheelchairs in motor vehicles; and

• Added a requirement for staff to teach "habits of good nutrition" to enrolled children.

Child care group homes effectively always meet the definition of "small business" in A.R.S. § 41-1001. Even where multiple child care group homes are owned by a single business entity, each child care group home is certified and regulated as an autonomous unit by the rules in this Chapter, and, due to the limited enrollment permitted in statute, a child care group home will by definition operate in the manner of a small business.
Accordingly, it is not feasible for the Department to promulgate separate rules imposing a
different degree of compliance on small businesses.

9. **Summary of business competitiveness analyses of the rules**
The Department has never received a business competitiveness analysis of the rules.

10. **Status of the completion of action indicated in the previous five-year-review report**
In the Department's previous Five-year-review Report on this Chapter, approved April 6, 2010, the Department proposed to submit a Notice of Final Rulemaking to GRRC 24 months after the Governor’s moratorium on rulemaking ended, subject to the Department’s priorities and staffing. The Department completed a comprehensive amendment of the rules in 2011, accomplishing the proposed course of action from 2010.

12. **Analysis of stringency compared to federal laws**
The rules govern operation of a state program of certification of child care group homes and are not related to federal laws.

13. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**
The rules establish certification requirements for specific entities under specific circumstances as required in A.R.S. §§ 36-897 et seq. Accordingly, under A.R.S. § 41-1037(A)(3), the issuance of a general permit is not technically feasible and would not meet statutory requirements such as e.g. A.R.S. § 36-897.01(F).

14. **Proposed course of action**
The only rule that needs a substantive amendment is R9-3-408, as described in this report. The Department anticipates submitting a Notice of Final Rulemaking for the Child Care Group Home rules by December 31, 2017 to amend R9-3-408 and address other substantive issues that may arise in the interim.
R9-3-101. Definitions

2. **Objective**
   The objective of the rule is to define terms used in the Chapter so that a reader can consistently interpret requirements in the Chapter.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.
R9-3-102. Time-frames

2. **Objective**
   The objective of the rule is to establish how the Department will apply the licensing time-frames in A.R.S. § 41-1072 and the notice requirements in A.R.S. § 41-1076 when issuing certificates to applicants for the operation of a Child Care Group Home.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.

---

Table 1.1. Time-frames (in days)

2. **Objective**
   The objective of the rule is to establish the time-frames described in A.R.S. § 41-1072 for each type of approval granted by the Department under this Chapter.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.
R9-3-103. **Individuals to Act for Applicant or Certificate Holder**

2. **Objective**
   The objective of the rule is to establish which individuals may act on behalf of an applicant or certificate holder based on whether the applicant or certificate holder is an individual or business organization.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.
ARTICLE 2. CERTIFICATION

R9-3-201. Application for a Certificate

2. Objectives
   The objectives of the rule are to inform an applicant for a Child Care Group Home of:
   a. The age requirement to submit an application; and
   b. The types of information and documents that must be included in an application packet.

3. Analysis of effectiveness in achieving the objective
   The rule is effective as written.

6. Analysis of clarity, conciseness, and understandability
   The rule is clear, concise, and understandable.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective
   The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.
R9-3-202. Fingerprinting Requirements

1. **Authorization of rule by existing statute**
   Additional specific authority:  A.R.S. § 8-804(C).

2. **Objectives**
   The objectives of the rule are to:
   a. Establish requirements for fingerprinting documentation and verification for a certificate holder, each adult staff member, and each adult resident at a Child Care Group Home; and
   b. Inform the certificate holder, adult staff member, and adult resident about the effect of a fingerprint clearance card denial.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.
R9-3-203. Certification Fees

2. Objectives
   The objectives of the rule are to:
   a. Establish the certification fees for a certificate holder; and
   b. Inform a certificate holder when such fees are due.

3. Analysis of effectiveness in achieving the objective
   The rule is effective as written.

6. Analysis of clarity, conciseness, and understandability
   The rule is clear, concise, and understandable.

8. Analysis of estimated economic, small business, and consumer impact
   The rule was amended by exempt rulemaking twice in the past five years. Prior to 2010, the Department was appropriated monies from the general fund to support the functions of the certification and administration of child care group homes. Pursuant to Laws 2009, 3d Special Session, Ch. 10, §§ 8 and 37, and Ch. 7, § 28, the rule was amended effective January 1, 2010. Pursuant to Laws 2010, Ch. 248, §§ 2 and 5, the rule was amended again by exempt rulemaking July 29, 2010. In both cases the session laws authorized the Department to increase fees so that the functions of certification and administration of child care group homes could be funded primarily by fees. At the time of the Department's previous Five-year-review Report on this Chapter, the first amendment had not been in effect long enough to determine economic impact, and the second amendment had not yet been completed. Accordingly, the Department estimates economic impact for this Section here.

   This analysis of estimated economic impact designates annual costs and benefits as minimal when less than $1,000; moderate when $1,000 to $10,000; and substantial when greater than $10,000. Costs and benefits are designated as significant when meaningful or important but not readily subject to quantification. The characteristics of stakeholders and Departmental administration and enforcement actions are described in this report on the economic impact analysis on pages 4 through 7.

   Through the rulemakings, the certification fee for a child care group home increased from $50 to $1,000. Half the fee, or $500, was discounted for any child care group home that implemented a program of health and safety best practices known as the Empower Pack.
The increase in certification fee from $50 to $1,000 per child care group home increased the economic impact of certification on those stakeholders from minimal to moderate.

The increase in certification fee from $50 to $1,000 per child care group home increased revenue for the Department. The fees did not suffice to pay for the operation of the certification program for child care group homes, and the difference was made up in general appropriations and applicable funds, as indicated on the following table.

<table>
<thead>
<tr>
<th>CHILD CARE LICENSING</th>
<th>FY 2012</th>
<th>FY 2013</th>
<th>FY 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Revenue</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child care revenue from fees</td>
<td>A</td>
<td>$2,162,331</td>
<td>$2,044,493</td>
</tr>
<tr>
<td><strong>Expenditures</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expenditures (all direct sources)</td>
<td>B</td>
<td>$3,522,903</td>
<td>$3,334,365</td>
</tr>
<tr>
<td>Applicable indirect charges</td>
<td>C</td>
<td>$583,358</td>
<td>$578,169</td>
</tr>
<tr>
<td>Total child care expenditures</td>
<td>B+C=D</td>
<td>$4,106,260</td>
<td>$3,912,535</td>
</tr>
<tr>
<td>Development Fund (CCDF)</td>
<td>E</td>
<td>$854,100</td>
<td>$830,900</td>
</tr>
<tr>
<td>Expenditures less CCDF</td>
<td>D-E=F</td>
<td>$3,252,160</td>
<td>$3,081,635</td>
</tr>
<tr>
<td><strong>Shortfall</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shortfall (revenue – expenditures)</td>
<td>A-F=G</td>
<td>($1,089,829)</td>
<td>($1,037,141)</td>
</tr>
<tr>
<td><strong>First Things First</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>FTF Funding</td>
<td>H</td>
<td>$312,700</td>
<td>$576,185</td>
</tr>
<tr>
<td>Final shortfall (gap)</td>
<td>G+H=I</td>
<td>($777,129)</td>
<td>($460,956)</td>
</tr>
</tbody>
</table>

*In the above table, C is calculated as of September 2, 2014.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective, in that a fee change of any kind would reduce costs to some stakeholders while increasing costs by the same amount for other stakeholders, resulting in no net change.

For example, if the rule imposed a greater fee on child care group homes, it could reduce
the burden on the Department, and through that, the state. To achieve a further reduction in costs to any stakeholder without increasing costs on any other may not be possible given current statutory requirements in A.R.S. §§ 36-897 et seq.

R9-3-204. Invalid Certificate

2. Objective

The objective of the rule is to inform a certificate holder that a certificate to operate a Child Care Group Home is not valid if the certificate holder fails to submit the certification fee pursuant to R9-3-203.

3. Analysis of effectiveness in achieving the objective

The rule is effective as written.

6. Analysis of clarity, conciseness, and understandability

The rule is clear, concise, and understandable.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.
R9-3-205. Changes Affecting a Certificate

2. **Objectives**

The objectives of the rule are to:

a. Inform a certificate holder that it must notify the Department when it plans to change the name, space utilization or capacity, ownership, location, or business organization of a Child Care Group Home;

b. Inform a certificate holder what information it must submit to the Department to document the change;

c. Require the Department to review and approve certain changes and/or issue an amended certificate; and

d. Inform persons and certificate holders when new certificates, rather than amended certificates, are necessary.

3. **Analysis of effectiveness in achieving the objective**

The rule is effective as written.

6. **Analysis of clarity, conciseness, and understandability**

The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.
R9-3-206. Inspections; Investigations

2. Objectives
   The objectives of the rule are to inform an applicant, certificate holder, or provider that during an inspection or investigation, the Department must be allowed:
   a. Access to the physical premises of the child care group home, and
   b. Interviews with staff members or enrolled children outside the presence of others.

3. Analysis of effectiveness in achieving the objective
   The rule is effective as written.

6. Analysis of clarity, conciseness, and understandability
   The rule is clear, concise, and understandable.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective
   The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.

R9-3-207. Denial, Revocation, or Suspension of a Certificate

2. Objectives
   The objectives of the rule are to establish:
   a. The circumstances under which the Department may deny, revoke, or suspend a certificate to operate a child care group home; and
   b. That the Department will consider the threat to the health and safety of enrolled children in determining whether to deny, suspend, or revoke a certificate.

3. Analysis of effectiveness in achieving the objective
   The rule is effective as written.

6. Analysis of clarity, conciseness, and understandability
   The rule is clear, concise, and understandable.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective
   The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.
ARTICLE 3. OPERATING A CHILD CARE GROUP HOME

R9-3-301. Certificate Holder and Provider Responsibilities

2. Objectives

The objectives of the rule are to educate certificate holders about their responsibilities to:

a. Ensure providers and staff members meet age requirements, have necessary experience, and are properly supervised;

b. Ensure that residents and staff members document immunizations/evidence of immunity, and freedom from infectious diseases;

c. Ensure that certain documents are maintained and/or displayed on site in the child care group home;

d. Ensure access to the premises to certain individuals, including parents of enrolled children;

e. Ensure that specified information is shared with parents of enrolled children;

f. Secure and maintain property insurance of a specified level;

g. Ensure sufficient adult staffing ratios; and

h. Notify the Department when providers and hours of operation change, and when the child care group home is left unoccupied during hours of operation.

3. Analysis of effectiveness in achieving the objective

The rule is effective as written.

6. Analysis of clarity, conciseness, and understandability

The rule is clear, concise, and understandable.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.

R9-3-302. Staff Training

2. Objectives

The objectives of the rule are to require the certificate holder to:

a. Provide specific training to staff within certain time-frames; and
b. Document and monitor training completion.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.

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**R9-3-303. Enrollment of Children**

2. **Objectives**
   The objectives of the rule are to require a certificate holder to:
   a. Ensure that children are enrolled only by qualified persons;
   b. Collect certain demographic, emergency, and health information about enrolled children; and
   c. Maintain enrollment and disenrollment records.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.

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**R9-3-304. Enrolled Child Immunization Requirements**

2. **Objectives**
   The objectives of the rule are to ensure that enrolled children are safe from exposure to disease at a child care group home by requiring a certificate holder to:
a. Refuse admission to an enrolled child who has not received current, age-appropriate immunizations pursuant to A.A.C. R9-6-702 or provided an exemption affidavit;
b. Ensure that each enrolled child’s immunizations or exemption affidavit are documented;
c. Ensure that parents are notified when immunizations are not current; and
d. Prohibit an enrolled child from attending the child care group home during an outbreak of disease listed in A.A.C. R9-6-702(A) if the enrolled child lacks documentation of immunization or evidence of immunity to the disease.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective as written.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.
2. **Objectives**

The objectives of the rule are to ensure safety of enrolled children by requiring a certificate holder to:

a. Ensure that the arrival and departure of enrolled children from the child care group home is documented; and

b. Ensure that enrolled children are admitted or released only to authorized individuals.

3. **Analysis of effectiveness in achieving the objective**

The rule is effective as written.

6. **Analysis of clarity, conciseness, and understandability**

The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.
2. **Objectives**

The objective of the rule is to alert certificate holders of their responsibility to make certain pesticide information available to parents of enrolled children before pesticide application occurs in a child care group home.

3. **Analysis of effectiveness in achieving the objective**

The rule is effective as it relates to parental notification.

6. **Analysis of clarity, conciseness, and understandability**

The rule is clear and concise as it relates to the mechanics of the parental notification. However, subsection (4), requiring the notification to include the “name and telephone number of the **pesticide business licensee** and the name of the **licensed applicator**” (emphasis added), may be confusing because it is unclear whether pesticides may only be applied by such individuals.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.
R9-3-307. Illness and Infestation

2. Objective
The objective of the rule is to prevent the spread of illness or infestation in a child care group home by requiring certificate holders to:
   a. Ensure that enrolled children, staff members, or residents who exhibit signs or symptoms of illness, communicable disease, or infestation are excluded from child care group homes;
   b. Provide written notice to parents of enrolled children and staff members when a potential exposure of a communicable disease or infestation occurs;
   c. Document incidents of illness, communicable disease, or infestation in child care group home files; and
   d. Notify local health agencies as required pursuant to 9 A.A.C. 6, Article 2, when an enrolled child, staff member, or resident has a reportable infestation or communicable disease.

3. Analysis of effectiveness in achieving the objective
The rule is effective as written.

6. Analysis of clarity, conciseness, and understandability
The rule is clear, concise, and understandable.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective
The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.
R9-3-308. Suspected Abuse or Neglect of an Enrolled Child

2. **Objective**

   The objective of the rule is to protect enrolled children from abuse or neglect by requiring:

   a. Certificate holders and staff members to report suspected abuse or neglect of an enrolled child to Child Protective Services or local law enforcement; and

   b. Document those reports in Child Care Group Home files.

3. **Analysis of effectiveness in achieving the objective**

   The rule is effective as written.

6. **Analysis of clarity, conciseness, and understandability**

   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

   The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.
R9-3-309. Medications

2. **Objective**
   The objective of the rule is to ensure proper administration of prescription and non-prescription medications to enrolled children by requiring certificate holders to:
   a. Ensure that medications for enrolled children are authorized in writing by a parent and/or medical professional;
   b. Ensure that medications are administered consistent with written instructions and documented on Department-approved forms; and
   c. Ensure the proper storage and disposal of medications.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.
R9-3-310. Accident and Emergency Procedures

2. **Objective**
   The objective of the rule is to ensure the safety of enrolled children in the Child Care Group Home by informing the certificate holder of the responsibility to:
   a. Ensure that a stocked first-aid kit is available on site in the Child Care Group Home;
   b. Ensure that first aid or medical attention is provided to enrolled children in cases of accident, injury, or emergency; parents notified; and the event documented in Child Care Group Home files; and
   c. Notify the Department if an enrolled child’s death at the Child Care Group Home during hours of operation.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule as written is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.
ARTICLE 4. PROGRAM AND EQUIPMENT STANDARDS

R9-3-401. General Program, Equipment, and Health and Safety Standards

2. Objective

The objective of the rule is to require a certificate holder to protect the health, safety, and welfare of enrolled children by requiring the certificate holder to:

a. Ensure the facility and equipment are free of hazards and in good repair;

b. Ensure that toys, materials, and equipment for children are age-appropriate, of a sufficient number, and accessible to enrolled children, and that age-appropriate activities are offered on a weekly schedule;

c. Ensure that staff members monitor the well-being of enrolled children by changing soiled or wet clothing, observing for overheating or overexposure to the sun, making drinking water available, and applying sunscreen, diapering products, or other substances to a child’s skin upon parent request.

3. Analysis of effectiveness in achieving the objective

The rule is effective as written.

6. Analysis of clarity, conciseness, and understandability

The rule is clear, concise, and understandable.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.
2. **Objective**
   The objective of the rule is to require a certificate holder to provide for the sleeping and napping needs of enrolled children by:
   a. Ensuring that each sleeping or napping child has a clean bed, mat, cot, or crib suitable to the child’s height and weight;
   b. Ensuring that cribs meet certain safety standards; and
   c. Allowing a staff member to sleep during specified hours and only if the staff member can hear and respond to waking children.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.
R9-3-403. **Supplemental Standards for Care of an Enrolled Infant or One- or Two-Year-Old Child**

2. **Objective**
   The objective of the rule is to inform certificate holders of their responsibility to respond to the unique needs of 1- and 2-year-old enrolled children by:
   a. Limiting awake time spent in a crib, playpen, swing, feeding chair, infant seat, or other equipment;
   b. Providing age-specific eating and drinking utensils, toys, foods, and feeding chairs;
   c. Storing and preparing formula, breast milk, or other food according to parent instructions;
   d. Utilizing safe sleeping positions, bedding, and positioning devices; and
   e. Immediately changing wet or soiled diapers and developing a toilet training program in consultation with parents.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.
R9-3-404. Supplemental Standards for Care of an Enrolled Child with Special Needs

2. **Objective**
   The objective of the rule is to inform certificate holders of their responsibility to respond to the unique needs of enrolled children with special needs, including:
   a. Obtaining written instructions from parents of enrolled children regarding medications; medical equipment; personal care; nutrition, including feeding tubes; and emergency response;
   b. Ensuring that at least one staff member understands the unique needs of an enrolled child and can interact with, feed, and care for the enrolled child; and
   c. Ensuring staff comply with Department-imposed standards related to feeding tubes and transportation of enrolled children who use wheelchairs.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.
2. **Objective**

   The objectives of the rule are to require certificate holders to:
   
   a. Impose and consistently apply reasonable guidelines and limits for enrolled children;
   
   b. Prohibit methods of discipline that could cause harm to the health, safety, or welfare of enrolled children; and
   
   c. Require a staff member to impose similar forms of discipline with the staff member’s own child on site during hours of operation.

3. **Analysis of effectiveness in achieving the objective**

   The rule is effective as written.

6. **Analysis of clarity, conciseness, and understandability**

   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

   The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.
**R9-3-406. General Nutrition and Menu Standards**

2. **Objective**
   The objective of the rule is to ensure that child care group homes comply with the Department’s meal pattern requirements by requiring the certificate holder to:
   a. Prepare and serve meals and snacks according to Table 4.1;
   b. Develop and post a weekly, and varied, menu; and
   c. Maintain a sufficient food supply.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.

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**Table 4.1. Meals and Snacks Required to Be Served to Enrolled Children**

2. **Objective**
   The objective of the rule is to provide requirements for the times each type of meal is to be served to an enrolled child at a child care group home.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.
Table 4.2. Meal Pattern Requirements for Children

2. **Objective**
   The objective of the rule is to provide requirements the contents, quantities, and permitted and non-permitted combinations of each component of a meal required to be served to an enrolled child at a child care group home.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.

R9-3-407. General Food Service and Food Handling Standards

2. **Objective**
   The objective of the rule are to insure that food is stored, served, and consumed in a safe and sanitary manner by requiring a certificate holder to ensure that:
   a. Staff members and enrolled children employ proper hand-washing techniques;
   b. Staff members assist enrolled children with meals;
   c. Utensils and equipment are properly cleansed, stored, and/or disposed of; and
   d. Food is properly prepared, stored, and/or disposed of.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.
R9-3-408. Field Trips and Other Trips Away from the Child Care Group Home

2. **Objective**
   The objective of the rule is to ensure that enrolled children are safely transported during hours of operation by requiring a certificate holder to:
   
   a. Obtain written permission from a parent before taking an enrolled child away from the child care group home during hours of operation and that the written authorization is maintained within child care group home files;
   
   b. Ensure that motor vehicles utilized by the child care group home are safe and operational, registered with the Arizona Department of Transportation, and insured, and that staff who transport enrolled children are 18 years or older and have a valid driver’s license; and
   
   c. Ensure enrolled children are transported safely.

3. **Analysis of effectiveness in achieving the objective**
   The rule is mostly effective as written, except as indicated in paragraphs #4 and #5.

4. **Analysis of consistency with referenced state and federal statutes and rules**
   Subsection (E) is not fully consistent with Arizona statute. Subsection (E) requires enrolled children under age five to be secured in a passenger restraint system pursuant to A.R.S. § 28-907, and children ages five and older to be secured with a lap belt or integrated lap and shoulder belt pursuant to A.R.S. § 28-909. A.R.S. § 28-907(B) was amended by Laws 2012, Ch. 314, § 1 and now requires children ages 5 through 8 who are not at least 4’10” tall be “restrained in a child restraint system.” As the statutory requirements are more stringent, an individual in compliance with the statute will also be in compliance with the rule. However, an individual relying solely on the rule's guidance could be in violation of the statute.

5. **Status of enforcement of the rule**
   The Department enforces subsection (E) consistent with A.R.S. § 28-907. In all other respects, the Department enforces the rule as written.

6. **Analysis of clarity, conciseness, and understandability**
   Although the rule is not consistent with Arizona statute as it relates to child restraint systems, the rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to**
persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective, despite the issues identified in paragraphs #4 and #5. Because the statute imposes the rule's requirements plus additional requirements beyond what the rule requires, any stakeholder in compliance with the statute will already be in compliance with the rule without having to discover any additional information.
ARTICLE 5. PHYSICAL ENVIRONMENT STANDARDS

R9-3-501. General Physical Environment Standards

2. **Objective**
   The objective of the rule is to ensure that the child care group home has sufficient square footage, toileting facilities, climate control, and lighting.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.

R9-3-502. Outdoor Activity Area Standards

2. **Objective**
   The objective of the rule is to ensure that a child care group home has sufficient outdoor activity area, shading, play equipment, landscaping, and fencing.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.
R9-3-503. Swimming Pool Standards

2. **Objective**
The objective of the rule is to establish a safe swim environment by requiring a certificate holder to:

a. Monitor the pool’s chemical disinfection and deny use by an enrolled child on any day when the pool’s water quality does not meet Department standards;
b. Enclose the swimming pool with a fence that meets Department standards;
c. Provide an individual with lifeguard certification, an accessible ring buoy, and a shepherd’s crook whenever an enrolled child uses the pool;
d. Safely store pool equipment, machinery, and chemicals so they are not accessible by enrolled children; and
e. Obtain written permission from parents before an enrolled child swims in the pool.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective as written.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.
2. **Objective**

The objective of the rule is to establish fire emergency standards in child care group homes by requiring the certificate holder to:

a. Clearly mark the house number and maintain working smoke detectors and portable fire extinguishers;

b. Ensure that electrical cords, outlets, and wiring are safely maintained;

c. Ensure that electric portable heaters are safely used; wood burning stoves are inaccessible to enrolled children; and unvented space heaters, open-flame space heaters, candles or incense, and smoking are not permitted during hours of operation;

d. Prepare a fire and emergency plan, and conduct and document unannounced evacuation drills; and

e. Obtain a gas inspection if gas pipes connect from a gas meter to an appliance or location on the premises.

3. **Analysis of effectiveness in achieving the objective**

The rule is effective as written.

6. **Analysis of clarity, conciseness, and understandability**

The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.
R9-3-505. General Safety Standards

2. **Objective**
   The objective of the rule is to set general safety standards at a child care group home by requiring a certificate holder to:
   a. Limit the provision of care to enrolled infants, children younger than age 5, and children who use a wheelchair to the ground floor of the child care group home absent unique circumstances;
   b. Secure toxic substances, substances that contain a warning label noting they are hazardous to children, and flammable liquids; window blind or curtain cords; fans; stairways; mobile home/manufactured home skirting; and glass surfaces located lower than 36 inches above the floor;
   c. Store firearms unloaded, out of view of children, and in locked areas/cabinets/containers, and kept separate from locked areas/cabinets/containers storing ammunition;
   d. Provide one operable telephone for staff members' use; and
   e. Ensure that enrolled children do not have access to certain equipment and machinery, pools of water, or trampolines.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.
R9-3-506. General Cleaning and Sanitation Standards

2. **Objective**
   The objective of the rule is to ensure that a child care group home and its furnishings, equipment, supplies, materials, utensils, and toys are kept clean and free of insects and vermin, by requiring a certificate holder to:
   a. Ensure that bathrooms, equipment, materials, and toys used by or accessible to enrolled children are maintained in a clean and disinfected condition;
   b. Ensure that plumbing fixtures are maintained in operating condition and that sufficient water pressure exists to meet toileting and cleaning needs;
   c. Ensure that each bathroom used by an enrolled child is sufficiently stocked with paper products and soap;
   d. Ensure that proper hand washing techniques are employed after toileting; and
   e. Ensure proper food waste storage and disposal.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.
R9-3-507. Diaper-Changing Standards

2. **Objective**

The objective of the rule is to establish requirements for maintaining clean and sanitary conditions when changing and disposing of diapers of enrolled children at a child care group home by requiring a certificate holder to:

a. Provide a nonabsorbent, sanitizable diaper changing surface in the child care group home;

b. Ensure that diaper-changing surfaces are cleaned and hands are washed after each diaper change;

c. Ensure that diaper changes are documented in child care group home files; and

d. Ensure that soiled clothing and diapers are properly stored.

3. **Analysis of effectiveness in achieving the objective**

The rule is effective as written.

6. **Analysis of clarity, conciseness, and understandability**

The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.
2. **Objective**

   The objective of the rule is to establish requirements for maintaining clean and sanitary conditions when animals are kept on the premises of a child care group home by requiring a certificate holder to:

   a. Ensure that animals are vaccinated and documents maintained in child care group home files;

   b. Ensure that pets and animals are controlled and that pet and animal habitats are maintained so that the child care group home is kept clean and no individual at the child care group home is endangered;

   c. Ensure that all animals except dogs and cats are kept in enclosures that are inaccessible to enrolled children, except as an activity, during hours of operation; and

   d. Ensure that reptiles are never used as part of an activity.

3. **Analysis of effectiveness in achieving the objective**

   The rule is effective as written.

6. **Analysis of clarity, conciseness, and understandability**

   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

   The rule imposes the least burden on stakeholders necessary to achieve the rule’s objective.
FIVE-YEAR-REVIEW REPORT
TITLE 9. HEALTH SERVICES
CHAPTER 6. DEPARTMENT OF HEALTH SERVICES
COMMUNICABLE DISEASES AND INFESTATIONS
ARTICLE 2. COMMUNICABLE DISEASE AND INFESTATION REPORTING

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Arizona revised Statutes (A.R.S.) § 36-136(H)(1) requires the Arizona Department of Health Services (Department) to make rules defining and prescribing “reasonably necessary measures for detecting, reporting, preventing, and controlling communicable and preventable diseases.” The Department has adopted rules to implement this statute in Arizona Administrative Code (A.A.C.) Title 9, Chapter 6. The rules specifying reporting requirements for communicable diseases are in 9 A.A.C. 6, Article 2.

The rules in 9 A.A.C. 6, Article 2 cover the reporting of specific communicable diseases by health care providers; the administrators of health care institutions or correctional facilities; the administrators of schools, child care establishments, or shelters; clinical laboratory directors; and pharmacists or administrators of pharmacies. The rules also cover reporting requirements for local health agencies. The rules covering reporting by the administrators of schools, child care establishments, or shelters and by pharmacists or administrators of pharmacies were last revised in 2004, while the other rules in the Article were further revised in 2008.

Through an analysis of the rules in Article 2, the Department has determined that, with the exceptions noted, the rules are effective, enforced as written, consistent with state and federal statutes and rules, and clear, concise, and understandable. The Department has received one written criticism of the rules in the past five years. The Department plans to amend R9-6-202, Table 1, Table 3, R9-6-206, and Table 4 of Article 2, which will be revised as described under the individual rules and to improve their effectiveness. The Department anticipates submitting a Notice of Final Rulemaking to the Governor’s Regulatory Review Council by December 2017. This timetable is subject to change based on the Department’s priorities, the length of the moratorium, and staffing.
INFORMATION THAT IS IDENTICAL FOR ALL THE RULES

1. Authorization of rule by existing statute
   General authority: A.R.S. §§ 36-132(A)(1) and 36-136(F)
   Specific authority: A.R.S. § 36-136(H)(1)

7. Summary of the written criticisms of the rule received within the last 5 years
   According to staff of the Office of Infectious Disease Services and the Office of Integration and Services, the Department has received one written criticism of the rules in Article 2 within the last five years.
   Comment: An individual from the Maricopa County Department of Public Health suggested that reporting requirements for several conditions be removed from the rules.
   Response: While the Department agrees that reporting requirements for aseptic meningitis, Kawasaki syndrome, and Reye syndrome should be removed from the rules, the Department believes that the current requirements for reporting of the other conditions mentioned by the commenter should remain in the rules. The Department believes that vaccinia-related adverse events and outbreaks of conjunctivitis, although rare, are still public health concerns and should remain reportable conditions. Both coccidioidomycosis and campylobacteriosis are nationally reportable conditions and public health concerns. Coccidioidomycosis is primarily a regional disease in the Southwest and the second most commonly reported infectious disease in Arizona. Campylobacteriosis is the leading cause of diarrheal illness in the US and can lead to other debilitating conditions. Both are underreported, so further limiting reporting to only laboratories would be counterproductive. Hepatitis C is a growing public health problem, with increasing occurrences of exposures and outbreaks from improper injection practices and drug diversions in our state. Although curative drugs are available, individuals and outbreaks need to be identified through reporting from both providers and laboratories and infected individuals referred for treatment to lessen the impact of this disease on the healthcare system.

8. Economic, small business, and consumer impact comparison
   The rules in Article 2 require reporting of specific communicable diseases. Attachment D shows the number of cases of selected reportable communicable diseases for calendar year 2013 and through August in 2014. The rules in Article 2 were completely amended in a rulemaking effective in October 2004. The 2004 rulemaking added the requirement for the administrators of correctional facilities, registered nurse practitioners, physician assistants, dentists, and shelter administrators to report communicable diseases. An Economic, Small Business, and Consumer Impact Statement (EIS) was submitted with this rulemaking and designated annual costs/revenues as minimal when less than $1,000, moderate from $1,000 to $10,000, and substantial when $10,000 or greater. The 2004 EIS stated that reporting communicable diseases would result in no burden to minimal burden
for these individuals, depending on whether any reports needed to be made. The rulemaking also required additional information to be provided in each report, estimated to cause a minimal burden on persons who report a communicable disease. The list of reportable communicable diseases and the time periods within which reports were required to be made were also amended in the 2004 rulemaking, and these changes were estimated in the 2004 EIS to cause a minimal burden on persons who report a communicable disease.

The requirement that clinical laboratory directors submit isolates weekly for certain communicable diseases was also added in the 2004 rulemaking and was estimated to cause a minimal-to-moderate burden on a clinical laboratory director, depending on the number of isolates submitted. The rulemaking also added a requirement for pharmacists and administrators of pharmacies to report when two or more anti-tuberculosis drugs are initially prescribed, which was estimated to cause a minimal burden on a pharmacist or administrator of a pharmacy. The added requirement for local health agencies to distribute communicable disease forms was estimated in the 2004 EIS to cause no burden to minimal burden on local health agencies, while the requirement for reporting information concerning an unexplained death with a history of fever was estimated to cause a local health agency to incur a minimal-to-moderate burden. The rulemaking clarified and added information local health agencies were required to report and the time period for reporting, with these changes being estimated to result in no burden to a minimal burden on local health agencies. The rulemaking also added a requirement related to a federal or tribal entity reporting communicable disease-related information, which was estimated to cause no burden to a minimal burden on a federal or tribal entity. The 2004 EIS estimated that these changes would result in a significant benefit to the Department, local health agencies, and the public, while changes that clarified the rules, removed reporting requirements, or increased the times to report certain communicable diseases would also provide minimal benefits to health care providers, health care institutions, schools, child care establishments, and clinical laboratory directors.

The rules in Sections R9-6-201, R9-6-202, Table 1, R9-6-204, Table 3, and R9-6-206 were further amended, and Table 4 was newly made, in a rulemaking that was effective April 1, 2008. An EIS was also submitted with this rulemaking and designated annual costs/revenues as minimal when less than $1,000, moderate when between $1,000 and $10,000, and substantial when greater than $10,000. The 2008 rulemaking defined the term “health care provider required to report” and clarified and amended the information that health care providers required to report, administrators of health care institutions or correctional facilities, and clinical laboratory directors are required to submit, which were estimated in the 2008 EIS to result in no burden to a minimal burden on persons who submit a report. The rulemaking also changed the time period within which local health agencies are required to submit information to the Department; this requirement was estimated in the 2008 EIS to result in a minimal-to-substantial cost to a local health agency. A minimal-to-
substantial cost was also estimated to result from adding requirements for certain diseases to be reported to the Department within 24 hours, and others within one working day, and adding requirements for local health agencies to ensure that an isolate or specimen is submitted to the Arizona State Laboratory. The repeal of incorporated reporting forms in this rulemaking was estimated in the 2008 EIS to result in at most a minimal cost to local health agencies. The 2008 EIS estimated that the Department and the public would receive significant benefit from clarification of the rules and amending the information required to be submitted, while local health agencies and persons required to submit a report would receive minimal-to-substantial benefit from clarification of the rules and amending the information required to be submitted. The repeal of incorporated reporting forms was estimated to result in a minimal benefit to the Department and local health agencies, and local health agencies were estimated to receive at least minimal benefits from the addition of Table 4 and changes in reporting time periods.

The Department is unaware of any local health agency that incurred a substantial cost due to the 2008 rulemaking. Otherwise, the economic impact of the rules in Article 2 remains unchanged from the 2004 and 2008 estimates.

9. **Summary of business competitiveness analyses of the rules**
The Department did not receive a business competitiveness analysis of the rules in the last five years.

10. **Status of the completion of action indicated in the previous five-year-review report**
In the previous five-year-review report for 9 A.A.C. 6, Article 2, the Department stated that, with the exception of Table 1 and Table 3, no rulemaking was planned for the rules in 9 A.A.C. 6, Article 2. For Table 1 and Table 3, the Department proposed amending these rules to address identified issues, approximately 20 months after the Governor’s moratorium on rulemaking was lifted. Since the moratorium, established January 22, 2009 and continued through legislative and executive actions to the present day, is still in effect, the Department is complying with the rulemaking action proposed in the previous five-year-review report.

12. **Analysis of stringency compared to federal laws**
The rules are not related to federal laws except to the extent that the programs governed by the rules may report statistical data collected through the rules to federal agencies.

13. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**
The rules were adopted before July 29, 2010 and do not establish licensing, certification, or permit requirements.

14. **Proposed course of action**
The Department plans to amend R9-6-202, Table 1, Table 3, R9-6-206, and Table 4 of Article 2 as described in this report and to improve effectiveness. The Department anticipates submitting a Notice of Final Rulemaking to the Governor’s Regulatory Review Council by December 2017. This
proposed course of action is subject to change based on the Department’s priorities, legislative action, and resource availability.
R9-6-201. Definitions

2. Objective

The objective of the rule is to define terms used only in Article 2 to enable the reader to understand clearly the requirements of the Article and allow for consistent interpretation.

3. Analysis of effectiveness in achieving the objective

The rule is effective in achieving its objective.

4. Analysis of consistency with state and federal statutes and rules

The rule is consistent with state and federal statutes and rules.

5. Status of enforcement of the rule

The rule contains only definitions, so enforcement by the Department is not applicable.

6. Analysis of clarity, conciseness, and understandability

The rule is clear, concise, and understandable.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-6-202. Reporting Requirements for a Health Care Provider Required to Report or an Administrator of a Health Care Institution or Correctional Facility

2. Objective

The objective of the rule is to notify health care providers required to report and administrators of health care institutions or correctional facilities:

a. Under what circumstances the health care providers required to report and administrators of health care institutions or correctional facilities are required to report communicable diseases,

b. To whom they are required to report,

c. What information they are required to provide, and

d. How they may make a report.

3. Analysis of effectiveness in achieving the objective

The rule in 9 A.A.C. 6, Article 3 that had established control measures for instances of unexplained death with a history of fever, R9-6-384, was allowed to expire under A.R.S. § 41-1056(J) in 2013.
Therefore, subsection (D) is no longer needed or effective. The balance of the rule is effective in achieving its objective.

4. **Analysis of consistency with state and federal statutes and rules**

Except as described in paragraph 3, the rule is consistent with state and federal statutes and rules.

5. **Status of enforcement of the rule**

The Department is not enforcing subsection (D) but is enforcing the balance of the rule as written.

6. **Analysis of clarity, conciseness, and understandability**

The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

Because of the issue described in paragraph 3 and 5 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

Table 1. Reporting Requirements for a Health Care Provider Required to Report or an Administrator of a Health Care Institution or Correctional Facility

2. **Objective**

The objective of the rule is to specify:

a. The communicable diseases for which reports are required;

b. Within what time period reports are required to be submitted; and

c. If applicable, under what circumstances reports are required, for example, only for outbreaks of the communicable disease.

3. **Analysis of effectiveness in achieving the objective**

The rule is mostly effective, although there are conditions listed in Table 1, Reye syndrome and Kawasaki syndrome, which are not technically communicable diseases. Control measures for these conditions are no longer contained in 9 A.A.C. 6, Article 3. Reye syndrome may develop in a child who is given aspirin to treat the symptoms of a viral infection. There is no known infectious agent that causes Kawasaki syndrome, which is diagnosed in an individual based on the symptoms displayed by the individual. In the last five years, the Department has received no reports of Reye syndrome and 103 reports of Kawasaki syndrome. In addition, the condition, unexplained death with a history of fever, is nebulous, cases reported under this condition are often not a significant health risk, and control measures for the condition are no longer contained in 9 A.A.C. 6, Article 3. Those that are significant could be reported under another reportable condition, such as emerging or exotic diseases. Only 20 rare or imported conditions were reported in the last five years. Other conditions required to be reported, enterotoxigenic *Escherichia coli*, aseptic (viral) meningitis, and herpes
genitalis, are also not public health issues, and the reporting of these conditions pose a burden on health care providers and administrators of health care institutions or correctional facilities. The Department believes the rule would be just as effective and less burdensome if these conditions were removed from the list of reportable conditions. On the other hand, arboviral diseases not already included in Table 1, such as Chikungunya, are becoming more of a public health concern. Although some of these diseases could be reported under the category of emerging or exotic diseases, unless or until the disease becomes endemic to Arizona, the Department believes that calling out this group of diseases in Table 1 would improve the reporting of arboviral diseases and make the Table more effective.

4. **Analysis of consistency with state and federal statutes and rules**
   Except as described in paragraph 3, the rule is consistent with state and federal statutes and rules.

5. **Status of enforcement of the rule**
   The Department is not enforcing the reporting of Reye syndrome, Kawasaki syndrome, unexplained death with a history of fever, enterotoxigenic *Escherichia coli*, aseptic (viral) meningitis, or herpes genitalis, but is enforcing the balance of the rule as written.

6. **Analysis of clarity, conciseness, and understandability**
   Most of the rule is clear, concise, and understandable. However, Table 1 lists “Ehrlichiosis and Anaplasmosis” together, which may cause confusion if an individual looks for and does not find “Anaplasmosis” listed alphabetically. Revising Table 1 to separate “Anaplasmosis” from “Ehrlichiosis” would make Table 1 more understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Because of the issues described in paragraphs 3, 5, and 6 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-6-203. **Reporting Requirements for an Administrator of a School, Child Care Establishment, or Shelter**

2. **Objective**
   The objective of the rule is to notify administrators of schools, child care establishments, or shelters:
   a. Under what circumstances the administrators of schools, child care establishments, or shelters are required to report communicable diseases;
   b. To whom they are required to report;
   c. What information they are required to submit; and
   d. How they may make a report.
3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective.

4. **Analysis of consistency with state and federal statutes and rules**
The rule is consistent with state and federal statutes and rules.

5. **Status of enforcement of the rule**
The rule is enforced by the Department as written.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

Table 2. **Reporting Requirements for an Administrator of a School, Child Care Establishment, or Shelter**

2. **Objective**
The objective of the rule is to specify:
   a. The communicable diseases for which reports are required;
   b. Within what time period reports are required to be submitted; and
   c. If applicable, under what circumstances reports are required, for example, only for outbreaks of the communicable disease.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective.

4. **Analysis of consistency with state and federal statutes and rules**
The rule is consistent with state and federal statutes and rules.

5. **Status of enforcement of the rule**
The rule is enforced by the Department as written.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-6-204. Clinical Laboratory Director Reporting Requirements

2. Objective
The objective of the rule is to notify clinical laboratory directors:
   a. Under what circumstances the clinical laboratory directors are required to report tests for the agents causing communicable diseases,
   b. Under what circumstances they are required to report the receipt of specimens for testing for the agents causing communicable diseases,
   c. To whom they are required to report,
   d. What information they are required to submit, and
   e. How they may make a report.

3. Analysis of effectiveness in achieving the objective
The rule is effective in achieving its objective.

4. Analysis of consistency with state and federal statutes and rules
The rule is consistent with state and federal statutes and rules.

5. Status of enforcement of the rule
The rule is enforced by the Department as written.

6. Analysis of clarity, conciseness, and understandability
The rule is clear, concise, and understandable.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective
The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

Table 3. Clinical Laboratory Director Reporting Requirements

2. Objective
The objective of the rule is to specify:
   a. The agents causing communicable diseases for which reports are required, and, if applicable:
      i. The type of test,
      ii. The age of the subject for which a report is required,
      iii. The type of test result, and
iv. Whether the test results for other related agents are to be included in the report;
b. Within what time period reports are required to be submitted;
c. The agents for which an isolate or a specimen is required to be submitted to the Arizona State Laboratory; and
d. If applicable, under what circumstances reports or isolates are required, for example, only for an initial positive test result for a communicable disease.

3. **Analysis of effectiveness in achieving the objective**
The rule is mostly effective but could be more effective. Since more and more clinical laboratories rely on nucleic acid testing to determine information about an infectious agent, the effectiveness of Table 3 would be improved by clarifying that a clinical laboratory is required to report the detection of the infectious agent causing tuberculosis, regardless of whether testing was performed by culturing the agent or through nucleic acid testing. In addition, a clinical laboratory may not culture a specimen of *Escherichia coli* prior to determining that the bacteria are Shiga-toxin producing and, therefore, may not have an isolate to submit to the Department as specified in Table 3. Similarly, a clinical laboratory may not test a specimen containing *Escherichia coli* O157:H7, a particularly dangerous strain of enterohemorrhagic bacteria, to determine if the bacteria are Shiga-toxin producing. The Department needs to ensure that the Department receives a sample of bacteria that may be Shiga-toxin producing so that further analyses may be performed. Therefore, the effectiveness of Table 3 would be improved by requiring a clinical laboratory to submit to the Department an isolate, if available, or a specimen for all Shiga-toxin producing *Escherichia coli* and all *Escherichia coli* O157:H7 specimens. Conversely, the Department believes that receiving an isolate for each specimen testing positive for *Streptococcus pneumonia* is no longer needed and that the rule would be just as effective and less burdensome if this requirement were removed from the rule.

4. **Analysis of consistency with state and federal statutes and rules**
The rule is consistent with state and federal statutes and rules.

5. **Status of enforcement of the rule**
Except as described in paragraph 3, the rule is being enforced by the Department as written.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Because of the issues described in paragraph 3 and 5 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.
R9-6-205. Reporting Requirements for a Pharmacist or an Administrator of a Pharmacy

2. **Objective**
The objective of the rule is to notify pharmacists and administrators of pharmacies:
   a. Under what circumstances the pharmacists and administrators of pharmacies are required to report to the Department,
   b. What information they are required to submit, and
   c. How they may make a report.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective.

4. **Analysis of consistency with state and federal statutes and rules**
The rule is consistent with state and federal statutes and rules.

5. **Status of enforcement of the rule**
The rule is enforced by the Department as written.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-6-206. Local Health Agency Responsibilities Regarding Communicable Disease Reports

2. **Objective**
The objective of the rule is to specify:
   a. From whom local health agencies obtain reporting forms;
   b. To whom local health agencies distribute copies of the reporting forms;
   c. Under what circumstances, how, and within what time period local health agencies are required to submit information to the Department; and
   d. The information to be submitted to the Department in each circumstance for which a report is required.

3. **Analysis of effectiveness in achieving the objective**
Since R9-6-384, which had established control measures for instances of unexplained death with a history of fever, was allowed to expire under A.R.S. § 41-1056(J) in 2013, subsection (E) is no longer needed or effective. The balance of the rule is effective in achieving its objective.
4. **Analysis of consistency with state and federal statutes and rules**
   Except as described in paragraph 3, the rule is consistent with state and federal statutes and rules.

5. **Status of enforcement of the rule**
   The Department is not enforcing subsection (E) but is enforcing the balance of the rule as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Because of the issue described in paragraph 3 and 5 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

**Table 4. Local Health Agency Reporting Requirements**

2. **Objective**
   The objective of the rule is to specify:
   a. The communicable diseases for which reports are required;
   b. Within what time period reports are required to be submitted;
   c. For which communicable diseases local health agencies are required to ensure that an isolate or specimen is submitted to the Arizona State Laboratory; and
   d. If applicable, under what circumstances reports are required, for example, for outbreaks of the communicable disease.

3. **Analysis of effectiveness in achieving the objective**
   The rule is mostly effective, although the conditions specified in the analysis of the effectiveness of Table 1, Reye syndrome, Kawasaki syndrome, unexplained death with a history of fever, enterotoxigenic Escherichia coli, aseptic (viral) meningitis, and herpes genitalis, are also listed in Table 4 and should be removed. Local health agencies had been responsible for control measures for the first three of these conditions, as required in 9 A.A.C. 6, Article 3, until the Sections corresponding to these conditions were allowed to expire in 2013. Local health agencies only investigate outbreaks for aseptic (viral) meningitis under R9-6-307, and do not investigate cases of herpes genitalis.

4. **Analysis of consistency with state and federal statutes and rules**
   Except as provided in paragraph 3, the rule is consistent with state and federal statutes and rules.

5. **Status of enforcement of the rule**
   Except as described in paragraph 3, the rule is being enforced by the Department as written.

6. **Analysis of clarity, conciseness, and understandability**
Most of the rule is clear, concise, and understandable. However, Table 4 lists “Ehrlichiosis and Anaplasmosis” together, which may cause confusion if an individual looks for and does not find “Anaplasmosis” listed alphabetically. Revising Table 4 to separate “Anaplasmosis” from “Ehrlichiosis” would make Table 4 more understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

Because of the issues described in paragraphs 3, 5, and 6 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-6-207. **Federal or Tribal Entity Reporting**

2. **Objective**

   The objective of the rule is to specify how, to the extent permitted by law, a federal or tribal entity is required to report communicable disease-related information.

3. **Analysis of effectiveness in achieving the objective**

   The rule is effective in achieving its objective.

4. **Analysis of consistency with state and federal statutes and rules**

   The rule is consistent with state and federal statutes and rules.

5. **Status of enforcement of the rule**

   The rule is enforced by the Department as written.

6. **Analysis of clarity, conciseness, and understandability**

   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

   The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.
FIVE-YEAR-REVIEW REPORT

TITLE 9. HEALTH SERVICES
CHAPTER 6. DEPARTMENT OF HEALTH SERVICES
COMMUNICABLE DISEASES AND INFESTATIONS
ARTICLE 5. RABIES CONTROL

October 2014
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FIVE-YEAR-REVIEW SUMMARY

Arizona Revised Statutes (A.R.S.) § 11-1003 requires the Department to regulate “the handling and disposition of animals other than livestock that have been bitten by a rabid or suspected rabid animal or are showing symptoms suggestive of rabies.” In addition, A.R.S. § 36-136(H)(1) requires the Department to “define and prescribe reasonably necessary measures for detecting, reporting, preventing and controlling communicable and preventable diseases.” The Department has adopted rules to implement A.R.S. §§ 11-1003 and 36-136(H)(1) in Arizona Administrative Code (A.A.C.) Title 9, Chapter 6. The rules specifying rabies control are found in 9 A.A.C. 6, Article 5, which was last amended in 2004.

The rules in 9 A.A.C. 6, Article 5 cover definitions applicable to the Article, requirements for the management of exposed animals and suspect cases, and requirements for reporting to the Department the number of animal bites to humans during the preceding year. In the last five-year-review report in 2009, the Department stated that the Department had no plans to amend or repeal any of the rules.

Through an analysis of the rules in Article 5, the Department has determined that the rules are effective; enforced as written; consistent with listed state and federal statutes and rules; and clear, concise, and understandable. The Department has received no written criticism of the rules in the past five years. The Department does not plan to amend the rules in Article 5, unless subsequent substantive issues arise.
INFORMATION THAT IS IDENTICAL FOR ALL THE RULES

1. **Authorization of rule by existing statute**
   General authority: A.R.S. §§ 36-132(A)(1) and 36-136(F)
   Specific authority: A.R.S. §§ 11-1003 and 36-136(H)(1)

2. **Objective**
   The purpose of the rules in Article 5 is to specify the handling, disposition, and reporting of animals, other than livestock, that have been bitten by a rabid or suspected rabid animal or are showing symptoms suggestive of rabies.

3. **Analysis of effectiveness in achieving the objective**
   All of the rules in 9 A.A.C. 6, Article 5 are effective.

4. **Analysis of consistency with listed state and federal statutes and rules**
   All of the rules in 9 A.A.C. 6, Article 5 are consistent with listed state and federal statutes and rules.

5. **Status of enforcement of the rule**
   All of the rules are enforced as written.

6. **Analysis of clarity, conciseness, and understandability**
   Although R9-6-502 uses passive language in subsection (D), all of the rules in 9 A.A.C. 6, Article 5 are clear, concise, and understandable.

7. **Summary of the written criticisms of the rule received within the last 5 years**
   The Department has not received any written criticism of the rules within the last five years.

8. **Economic, small business, and consumer impact comparison**
   The Department serves as a repository for information about rabies control activities and provides assistance and guidance to animal control agencies. The Department also performs tests for rabies on animals submitted for testing and monitors human exposure to laboratory-confirmed rabid animals. The following table provides the number of laboratory-confirmed rabies-positive animals and the number of humans exposed to laboratory-confirmed rabid animals:

<table>
<thead>
<tr>
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<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Lab-confirmed Rabies Positive Animals</td>
<td>280</td>
<td>114</td>
<td>70</td>
<td>60</td>
<td>70</td>
<td>97</td>
</tr>
<tr>
<td>Humans Exposed to Lab-confirmed Rabid Animals</td>
<td>47</td>
<td>14</td>
<td>15</td>
<td>7</td>
<td>19</td>
<td>13</td>
</tr>
</tbody>
</table>

Animal control agencies have a major responsibility for rabies control through immunization and licensure programs and through impounding and, if appropriate, euthanizing suspect rabies cases or exposed animals.
As stated in the 2009 five-year-review report, the rules in Article 5 were amended effective October 2004. The 2004 rulemaking added definitions, added ferrets to the animals treated as pets, revised the format of the rules to improve clarity, and removed some reporting requirements. An Economic, Small Business, and Consumer Impact Statement (EIS) was submitted with the 2004 rulemaking and designated annual costs/revenues as minimal when less than $1,000, moderate from $1,000 to $10,000, and substantial when $10,000 or greater. The 2004 EIS stated that the Department, animal control agencies, and the public would receive a minimal benefit from adding definitions and clarifying the rules. Adding ferrets to R9-6-502 was estimated in the 2004 EIS to impose a minimal-to-moderate burden on animal control agencies that would have to treat ferrets in the same manner as cats and dogs, rather than just euthanizing exposed ferrets, and to provide a significant benefit to ferret owners whose pets were exposed to rabid animals or suspect cases. Removing some reporting requirements was estimated to provide animal control agencies with a minimal-to-moderate benefit. Upon review, the Department believes the economic impact of the rules in Article 5 has been consistent with the impact predicted in 2004.

9. **Summary of business competitiveness analyses of the rules**
The Department has not received a business competitiveness analysis of the rules.

10. **Status of the completion of action indicated in the previous five-year-review report**
In the previous five-year-review report for 9 A.A.C. 6, Article 5, the Department did not plan to amend the rules. Accordingly, no rulemaking actions have occurred.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Notwithstanding any costs imposed by statutes or caused by the rules of other agencies, the rules impose the least burden and costs to persons regulated by the rules, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

12. **Analysis of stringency compared to federal laws**
The rules are not related to federal laws.

13. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037.**
Not applicable, as the rules were adopted before July 29, 2010 and do not require the issuance of a regulatory permit, license, or agency authorization.

14. **Proposed course of action**
The Department does not plan to amend the rules in Article 5.
INFORMATION FOR INDIVIDUAL RULES

R9-6-501. Definitions
2. **Objective**
The objective of the rule is to define terms used only in Article 5 to enable the reader to understand clearly the requirements of the Article and allow for consistent interpretation.

R9-6-502. Management of Exposed Animals
The objectives of the rule are to specify:
  a. How an animal control agency shall handle animals other than livestock that are exposed to a rabid animal or an animal suspected of being rabid, and
  b. How livestock shall be handled.

R9-6-503. Suspect Cases
2. **Objective**
The objectives of the rule are to specify:
  a. The term of confinement for an animal suspected of being rabid, and
  b. The treatment of the brain of an animal suspected of being rabid that has been euthanized by an animal control agency.

R9-6-504. Animal Control Agency Reporting Requirements
2. **Objective**
The objective of the rule is to specify the content of a report that is required to be submitted by animal control agencies to the Department by April 30 of each year.
FIVE-YEAR-REVIEW REPORT

TITLE 9. HEALTH SERVICES
CHAPTER 6. DEPARTMENT OF HEALTH SERVICES
COMMUNICABLE DISEASES AND INFESTATIONS
ARTICLE 13. IMMUNIZATIONS OR VACCINES REQUIRING
PRESCRIPTIONS FOR PHARMACIST ADMINISTRATION

October 2014
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4. GENERAL AND SPECIFIC STATUTES .......... Attachment B
FIVE-YEAR-REVIEW SUMMARY

Arizona Revised Statutes (A.R.S.) § 32-1974(I), created by Laws 2009, Ch. 41, requires the Arizona Department of Health Services (Department) to make rules that “establish and maintain a list of immunizations or vaccines that may be administered to adults by a pharmacist only pursuant to a prescription order.” The Department adopted one rule to implement this statute in Arizona Administrative Code (A.A.C.) Title 9, Chapter 6 through exempt rulemaking effective October 5, 2009. The rule in 9 A.A.C. 6, Article 13 covers definitions applicable to the Section and identifies the immunizations or vaccines that require a prescription order before being administered under R4-23-411. A.R.S. § 32-1974(I) was amended by Laws 2011, Ch. 103, § 2, to clarify that the immunizations or vaccines required under A.R.S. § 32-1974(I) may only be administered to adults.

This report is an initial review of the rule in 9 A.A.C. 6, Article 13. Based on its review, the Department has determined that the rule is effective, enforced as written, consistent with state and federal statutes, and clear, concise, and understandable. The Department has received no written criticism of the rule in the past five years. The Department has identified an outdated reference to 21 CFR 600.3, adopted by the U.S. Food and Drug Administration and discusses the matter in paragraph 6. The Department believes that the outdated reference is not substantive and does not create a purpose for the Department to revise the rule. The Department plans to revise R9-13-1301 when a substantive matter occurs and will address the outdated reference at that time.
R9-6-1301. Immunizations or Vaccines Requiring a Prescription Order for Pharmacist Administration

1. Authorization of rule by existing statute
   General authority: A.R.S. §§ 36-132(A)(1) and 36-136(F)
   Specific authority: A.R.S. § 32-1974(I)

2. Objective
   The objectives of the rule are to:
   a. Define terms used in the rule to enable the reader to understand clearly the requirements of the Section and allow for consistent interpretation, and
   b. Identify the specific immunizations or vaccines that require a prescription order before a certified pharmacist may administer the immunization or vaccine.

3. Analysis of effectiveness in achieving the objective
   The rule is effective.

4. Analysis of consistency with and list of state and federal statutes and rules used to determine
   Laws 2011, Ch. 103, § 2, effective July 20, 2011, amended A.R.S. § 32-1974(I) adding the language “to adults.” Also, subsection (B) of the rule cites A.A.C. R4-23-411. A.A.C. R4-23-411 prescribes the requirement regarding “pharmacist-administered adult immunizations that require a prescription order” and was last amended in Notice of Final Rulemaking published at 17 A.A.R. 2596, effective February 4, 2012. The Department believes after reviewing both Laws 2011, Ch. 103, § 2 and A.A.C. R4-23-411 that the rule is consistent with state and federal statutes and other rules.

5. Status of enforcement of the rule
   The rule is enforced as written.

6. Analysis of clarity, conciseness, and understandability
   The rule is clear, concise, and understandable. The Department identified that the definition “vaccine” in subsection (A) of the rule should reference the revised 21 CFR 600.3, dated April 1, 2013. However, the Department does not believe that referencing 21 CFR 600.3 dated April 1, 2008 causes the rule to be unclear since 21 CFR 600.3 dated April 1, 2008 is available and the revised 21 CFR 600.3 did not change the definition “biological product” included in the definition of “vaccine.”

7. Summary of the written criticisms of the rule received within the last 5 years
   The Department has not received any written criticism of the rule within the last five years.

8. Economic, small business, and consumer impact comparison
   Because the rule was adopted under exempt rulemaking, the Department was not required to complete an economic, small business, and consumer impact statement for R9-6-1301. Subsection (A) is explanatory, not regulatory, and has no economic impact. Subsection (B) contains a list of
vaccines that require a prescription order before being administered by a pharmacist authorized under A.A.C. R4-23-411. The vaccinations on the list may have severe side effects, have different forms of the vaccine, or have restriction/consideration that should be discussed with a medical practitioner before administration. As required by statute, the immunizations or vaccines identified in subsection (B) are either listed in the U.S. Centers for Disease Control and Prevention (CDC) recommended adult immunization schedule or the CDC’s health information for international travel. From November 2009 through December 2012, pharmacists have administered 29 doses of the Japanese Encephalitis vaccine; 94 doses of the Rabies vaccine; 2179 doses of the Typhoid vaccine; and 300 doses of the Yellow Fever vaccine. Since it is not possible to determine who will request one of these vaccines or what health risks they may have, subsection (B) provides a significant benefit to the public, in that the benefit is meaningful and important, but not readily subject to quantification.

9. **Summary of business competitiveness analyses of the rules**
The Department did not receive a business competitiveness analysis of the rule.

10. **Status of the completion of action indicated in the previous five-year-review report**
This is an initial review of the rule in 9 A.A.C. 6, Article 13.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Although an additional, and very minimal, burden may occur as a result of a person seeking either the 2013 version or the 2008 version of 21 CFR 600.3 to verify the definition of “vaccine,” the Department believes that the rule provides the least burden and cost to persons regulated by the rule.

12. **Analysis of stringency compared to federal laws**
The rules are not related to federal laws.

13. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037.**
Not applicable, as the rule was adopted before July 29, 2010.

14. **Proposed course of action**
The Department will revise the rule when a substantive matter occurs and will address the outdated reference in subsection (A) at that time.
FIVE-YEAR-REVIEW REPORT

TITLE 9. HEALTH SERVICES

CHAPTER 24. DEPARTMENT OF HEALTH SERVICES

ARIZONA MEDICALLY UNDERSERVED AREA HEALTH SERVICES

OCTOBER 2014
FIVE-YEAR-REVIEW REPORT

TITLE 9. HEALTH SERVICES
CHAPTER 24. DEPARTMENT OF HEALTH SERVICES
ARIZONA MEDICALLY UNDERSERVED AREA HEALTH SERVICES

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5. GENERAL AND RELATED STATUTES Attachment 2
Arizona Revised Statutes (A.R.S.) § 36-2352 requires the Arizona Department of Health Services (Department) to designate areas of medical need in Arizona as medically underserved if an area is designated in 42 Code of Federal Regulations as a health professional shortage area or if an area meets specific indicators identified in A.R.S. § 36-2352(A)(2)(a) – (e).

Arizona Administrative Code (A.A.C.) Title 9, Chapter 24, Article 2, adopted September 30, 2006, consists of five rules. In R9-24-201, the Department establishes definitions pertaining to the five rules and the rules in Article 3. In R9-24-202, the criteria for designating primary care areas and Arizona medically underserved areas are established. In R9-24-203, the Primary Care Index, the Department identifies each criterion and its scoring measures used to determine whether a designated primary care area may be designated as an Arizona medically underserved area. In R9-24-204, the Department establishes requirements to determine the boundaries of all primary care areas for the state, and R9-24-205 establishes the time-frames for approving a primary care area boundary change request.

A.R.S. § 36-2354 requires the Department to establish the functions to be performed by a coordinating medical provider for an Arizona medically underserved area who has entered into an agreement with a county, incorporated city of town, health service district or the Department. A.A.C. Title 9, Chapter 24, Article 3, adopted September 30, 2006, consists of two rules. In R9-24-301, the Department establishes definitions that pertain to the rules in Article 3 and R9-24-302 establishes a coordinating medical provider’s role and functions.

During the review of 9 A.A.C. 24, Article 2 and Article 3, the Department discovered some minor, non-substantive issues with the rules concerning clarity, conciseness, and understandability. At this time, the Department does not intend to amend these rules. The Department will revise the rules when a matter arises necessitating a substantive change to the rules; and at that time, the Department will address the non-substantive issues mentioned and discussed in this 2014 Five-year-review Report.
1. **Authorization of rule by existing statute**
   General authority: A.R.S. § 36-136(F)
   The rules in Article 2 have A.R.S. § 36-2352 as specific authority.
   The rules in Article 3 have A.R.S. § 36-2354 as specific authority.

3. **Analysis of effectiveness in achieving the objective**
   The rules in Article 2 and Article 3 are effective.

4. **Analysis of consistency with referenced state and federal statutes and rules**
   A.R.S. § 36-2352 requires the Department to designate an area of medical need in this state as medically-underserved if the area is designated as a primary care health professional shortage area (HPSA) defined in 42 Code of Federal Regulation part 5. In R9-24-201(31), the Department defines a primary care HPSA and in R9-24-202(1), the Department states that a “primary care HPSA” shall be designated as an Arizona medically underserved area. The rules in Article 2 and Article 3 are consistent with state and federal statutes and rules.

5. **Status of enforcement of the rule**
   The rules in Article 2 and Article 3 are enforced as written without difficulties.

7. **Summary of the written criticisms of the rule received within the last 5 years**
   The Department has not received any written criticism of the rules in Article 2 and Article 3 in the past five years.

8. **Analysis of estimated economic, small business, and consumer impact comparison**
   In the 2006 Economic, Small Business, and Consumer Impact Statement (EIS), the Department stated that the rules would not have an additional impact on the Department and would not impose any direct costs to individuals or entities. The Department stated that from the adjustment made in the Article 2 rules, the effect on Arizona medically underserved area (AzMUAs) designation would increase the number of primary care providers as the number of AzMUAs’ designations increase. The Department also stated that these increases would indirectly benefit medical facilities located, and individuals residing, in areas designated as an AzMUA.

   In this estimated economic, small business, and consumer impact comparison (EIC), the Department reports numbers consist with the EIS estimate that an increase in primary care
providers would occur as the numbers of AzMUAs increased. In 2010 a total of 91 AzMUAs existed. The number of AzMUAs increased in 2012 to 94 and in 2014 to 98 AzMUAs. Likewise, in 2011 a total of 324 primary care providers were providing services to individuals living in an AzMUAs. In 2012, the number of primary care providers increased to 337; in 2013, increased to 340 primary care providers; and in 2014, increased to 497 primary care providers.

The significant increase in the number of primary care providers in 2014 occurred as a result of the National Health Services Corps in 2013 increasing the number of eligible sites or health care facilities located in Health Professional Shortage Areas from 500 eligible sites to over a 1000 eligible sites. In 2013, the newly eligible sites applied and received approval for certification. The 2013 increase in the number of certified sites allowed for more primary care providers, those employed by the newly certified sites, in 2014. The Department believes that the increase number of AzMUAs and primary care providers increased the indirect benefit to health care facilities and individuals receiving ambulatory medical care.

The Department also indicated in the EIS that rules R9-24-204, Primary Care Area Boundaries Determination, and R9-24-205, Time-frames, “will not have additional economic impact on the Department and will not impose any direct costs on any other individual or entity.” To date, the Department has not received a (any) primary care area boundary change requests. Hence, the Department agrees that the rules in R9-24-204 and R9-24-205 have no economic impact to the Department or other individuals or entities.

The EIS summary also stated that Article 3 had no economic impact to the Department or other individual or entity because a coordinating medical provider has never been designated. The Department believes since it is still true that a coordinating medical provider has never been designated, the rules continue to have no economic impact to the Department or other individuals or entities. The Department believes the rules have not had any additional impact on the Department and have not imposed any direct costs on other individuals or entities. The Department believes that the costs and benefits of the rules are consistent with the 2006 EIS.

9. **Summary of business competitiveness analyses of the rules**
The Department did not receive a business competitiveness analysis of the rules during the past five years.

10. **Status of the completion of action indicated in the previous five-year-review report**
In the Department’s 2009 Five-year-review Report, the Department stated that the Department would revise the rules at a time when the Department determined that a substantive change to the rules is needed. To date, the Department has not identified any substantive change necessitating a need to revise the rules.

12. **Analysis of stringency compared to federal laws**

The rules in Article 2 govern the method for identifying areas in Arizona having medical need and designating those areas as medically-underserved if either (1) the area is designated as a health professional shortage area [HPSA] or (2) the area is designated as medically underserved by the Department based on certain indicators required by A.R.S. § 36-2352. R9-24-201(31) makes reference to 42 U.S.C. 254e, 42 CFR 5.1 through 5.4, and 42 CFR Part 5, Appendix A, and in R9-24-202, the rule mentions “primary care HPSAs.” These federal codes and regulations establish the criteria and procedures for the designation of geographic areas, population groups, medical facilities, and other public facilities, in the States, as health professional shortage areas. The reference made in R9-24-201(1) provides the location of information provided to assist the Department in determining Arizona medically underserved areas. The rules in Article 2 and Article 3 govern the designation of Arizona medically underserved areas and coordinating medical providers and are not related to matters of stringency regarding federal laws.

13. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with Section 41-1037**

The rules were adopted before July 29, 2010, and do not require the issuance of a regulatory permit, license, or agency authorization.

14. **Proposed course of action**

The Department continues to hold the same course of action as in the 2009 Five-year-review Report. The Department will revise the rules when a substantive change necessitates.
INFORMATION FOR INDIVIDUAL RULES
ARTICLE 2. ARIZONA MEDICALLY UNDERSERVED AREAS

R9-24-201. Definitions

2. Objective
The objective of the rule is to define terms and phrases used in Chapter 24, Article 2 to enable readers to understand clearly the requirements of the Article and to allow for consistent interpretation.

6. Analysis of clarity, conciseness, and understandability
The rule is mostly clear, concise, and understandable. The rule, in the definition of “ambulatory care sensitive conditions,” “birth life expectancy,” “legal holiday,” and “poverty threshold,” contains webpage addresses that are outdated. While these webpage addresses are outdated, the information the reader is seeking is still accessible to the reader at the website. For example: the webpage address http://www.cdc.gov/nchs/fastats/lifexpec.htm is referenced in the definition of “birth life expectancy.” When a reader attempts to access the webpage, the reader is redirected to http://www.cdc.gov/nchs/fastats/life-expectancy.htm. The reader is able to obtain the information and their understanding is not hindered.

11. A determination that the probable benefits for the rule outweigh within this state the probable costs of the rules, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective
The rule imposes the least burden on stakeholders necessary to achieve the rule’s objectives.

R9-24-202. Arizona Medically Underserved Area Designation

2. Objective
The objective of the rule is to provide a statement of how the Department will designate Arizona medically underserved areas.

6. Analysis of clarity, conciseness, and understandability
The rule is clear, concise, and understandable.

11. A determination that the probable benefits for the rule outweigh within this state the probable costs of the rules, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective
The rule imposes the least burden on stakeholders necessary to achieve the rule's objectives.
R9-24-203. Primary Care Index

2. **Objective**
   The objective of the rule is to establish the criterion and criterion values and scoring measures used to determine whether a primary care area determined under R9-22-204 qualifies as an Arizona medically underserved areas. The rule also establishes annual review and reporting requirements of the Arizona medically underserved areas.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable. However, the rule could be improved upon if the rule were revised to use of the term “percent” in subsections (B)(4) and (B)(5) rather than using the percent symbol (%). The rule may also be clearer in subsection (B)(12) if the reference to data location remained and the report titles were removed.

11. **A determination that the probable benefits for the rule outweigh within this state the probable costs of the rules, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Even though the rule could be improved upon as stated above, the rule imposes the least burden on stakeholders necessary to achieve the rules’ objectives.

Table 1. Primary Care Index Scoring

2. **Objective**
   The objective of the table is to present a matrix showing each criterion used by the Department in designating primary care areas as Arizona medically underserved areas, the value ranges within each criterion, and the points attached to each value within a criterion.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits for the rule outweigh within this state the probable costs of the rules, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden on stakeholders necessary to achieve the rule’s objectives.

R9-24-204. Primary Care Area Boundaries Determination

2. **Objective**
The objective of the rule is to establish the Department’s requirements for determining the boundaries of primary care areas in the state and for processing a primary care boundary change request.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits for the rule outweigh within this state the probable costs of the rules, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The rule imposes the least burden on stakeholders necessary to achieve the rule’s objectives.

R9-24-205. **Time-frames**

1. **Authorization of rules by existing statute**
   Specific authority: A.R.S. §§ 41-1072 through 41-1076

2. **Objective**
The objective of the rule is to establish the Department’s time-frames for a primary care area boundary change request.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits for the rule outweigh within this state the probable costs of the rules, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The rule imposes the least burden on stakeholders necessary to achieve the rule’s objectives.

ARTICLE 3. COORDINATING MEDICAL PROVIDERS

R9-24-301. **Definitions**

2. **Objective**
The objective of the rule is to define terms and phrases used in Chapter 24, Article 3 to enable readers to have a better understanding of the requirements of the Article.

4. **Analysis of consistency with referenced state and federal statute and rules**
   R9-24-301(2) states that continuing medical education means instruction that meets the requirements in “A.R.S. § 32-1825 and A.A.C. R4-22-109 for a physician licensed under A.R.S.
Title 32, Chapter 17.” A.A.C. R4-22-109 has been revised and renumbered to A.A.C. R4-22-207 in Notice of Final Rulemaking at 12 A.A.R. 2765, effective September 9, 2006. The Department believes that even though A.A.C. R4-22-109 has been revised and renumbered, the information provided at A.A.C. R4-22-109 effectively redirects a reader to the correct location where the current requirements reside, A.A.C. R4-22-207.

6. Analysis of clarity, conciseness, and understandability
The rule is clear, concise, and understandable. Even though, the definition of “continuing medical education” contains a cross-reference that needs to be updated as previously mentioned, the Department does not believe that the rule is any less clear, concise, and understandable.

11. A determination that the probable benefits for the rule outweigh within this state the probable costs of the rules, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective
As mentioned above, even though the rule contains an outdated cross-reference; the Department does not believe that the rule is any less clear, concise, and understandable. Likewise, the Department believes that although the rule contains an outdated cross-reference, the rule still imposes the least burden on stakeholders necessary to achieve the rule’s objectives.

R9-24-302. CMP Functions

2. Objective
The objective of the rule is to establish the functions of a coordinating medical provider.

6. Analysis of clarity, conciseness, and understandability
The rule is clear, concise, and understandable.

11. A determination that the probable benefits for the rule outweigh within this state the probable costs of the rules, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective
The rule imposes the least burden on stakeholders necessary to achieve the rule’s objectives.
FIVE-YEAR-REVIEW REPORT

TITLE 9. HEALTH SERVICES

CHAPTER 11. DEPARTMENT OF HEALTH SERVICES

HEALTH CARE INSTITUTION FACILITY DATA

September 2015
FIVE-YEAR-REVIEW REPORT
TITLE 9. HEALTH SERVICES
CHAPTER 11. DEPARTMENT OF HEALTH SERVICES
HEALTH CARE INSTITUTION FACILITY DATA
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5. GENERAL AND SPECIFIC STATUTES Attachment B
6. PREVIOUS ECONOMIC IMPACT STATEMENT FOR 9 A.A.C. 11 Attachment C
Arizona Revised Statutes (A.R.S.) § 36-125.04 requires hospitals to submit annual financial statements to the Arizona Department of Health Services (Department). A.R.S. § 36-2901.08, added by Laws 2013, Ch. 10, § 5, requires an “assessment on hospital revenues, discharges or bed days for the purpose of funding the nonfederal share of the costs” for persons eligible for medical assistance under 42 U.S.C. § 1396a (a)(10)(A)(i)(viii). A.R.S. § 36-2901.08(G) requires a hospital to submit to the Department “an attestation that it has not passed on the cost of the assessment to patients” as part of its financial statement. A.R.S. § 36-125.04 also requires hospitals, nursing care institutions, and hospices to submit uniform accounting reports (UARs) to the Department. The rules in Arizona Administrative Code (A.A.C.) Title 9, Chapter 11, Article 2, implement A.R.S. §§ 36-125.04 and 36-2901.08 by providing requirements for hospitals, nursing care institutions, and hospices to follow when submitting annual financial statements or UARs to the Department. The Department receives annual financial statements and UARs from 113 hospitals and UARs from 147 nursing care institutions and 157 hospices. No civil money penalties have been imposed for failure to comply with this statute and rules.

A.R.S. §§ 36-436 through 36-436.03 require hospitals, nursing care institutions, home health agencies, and outpatient treatment centers to submit to the Department a schedule of rates and charges and changes made to the schedule. The rules in 9 A.A.C. 11, Article 3, implement A.R.S. §§ 36-436 through 36-436.03 by providing requirements for submitting schedules of rates and charges or changes to the schedules. The Department receives rates and charges schedules and changes to the schedules from 113 hospitals, 147 nursing care institutions, 221 home health agencies, and 1,844 outpatient treatment centers. No civil money penalties have been imposed for failure to comply with these statutes and rules.

A.R.S. § 36-125.05 requires hospitals to submit inpatient and emergency department discharge data to the Department. The rules in 9 A.A.C. 11, Articles 4 and 5, implement A.R.S. § 36-125.05 by providing requirements for submitting the discharge data. As of December 2014, the Department receives inpatient discharge data from 113 hospitals and emergency department discharge data from 74 hospitals. During the five-year period of calendar 2010-2014, the Department has fined 12 hospitals and collected a total of $65,845 in civil money penalties for late submissions or failures to correct errors.

The Department completed a revision of the rules in 9 A.A.C. 11 in a rulemaking approved by GRRC on October 2, 2007 and effective December 1, 2007. The Department subsequently revised R9-11-202, effective January 1, 2014, by exempt rulemaking to comply with the requirements in A.R.S. § 36-2901.08. Through an analysis of the rules in 9 A.A.C. 11, the Department has determined that, except for
R9-11-101, the rules are effective; except for R9-11-101, R9-11-201, R9-11-205, and R9-11-301, the rules are consistent with state and federal statutes and rules; except for R9-11-101, the rules are enforced; and except for R9-11-101, the rules are clear, concise, and understandable. The Department has received no written criticism of the rules. The Department estimates that the actual economic impact of the rules is consistent with the 2007 EIS for the 9 A.A.C. 11 rulemaking. The Department does not plan to amend the rules in 9 A.A.C. 11 until substantive issues with the rules arise.
1. **Authorization of the rule by existing statute**
The rules in 9 A.A.C. 11 have A.R.S. § 36-136(F) as general statutory authority.
The rules in Article 2 have specific statutory authority in A.R.S. § 36-125.04.
The rules in Article 3 have specific statutory authority in A.R.S. §§ 36-436, 36-436.01, and 36-436.02.
The rules in Articles 4 and 5 have specific statutory authority in A.R.S. § 36-125.05.

2. **The purpose of the rule**
The purpose of the rules in Article 2 is to provide requirements for hospitals, nursing care institutions, and hospices to follow when submitting annual financial statements or UARs to the Department.
The purpose of the rules in Article 3 is to provide requirements for submitting schedules of rates and charges or changes to the schedules.
The purpose of the rules in Article 4 is to provide requirements for submitting inpatient discharge data to the Department.
The purpose of the rules in Article 5 is to provide requirements for submitting emergency department discharge data to the Department.

3. **Analysis of effectiveness in achieving the objective**
All of the rules in Articles 2, 3, 4, and 5 are effective in achieving their respective objectives.

4. **Analysis of consistency with state and federal statutes and rules**
Except for R9-11-201, R9-11-205, and R9-11-301, the rules in Article 2, Article 3, Article 4, and Article 5 are consistent with state and federal statutes and rules.

5. **Status of enforcement of the rule**
Except as described in the analysis for R9-11-101 for the definition of “inpatient,” the Department is enforcing the rules as written.

6. **Analysis of clarity, conciseness, and understandability**
All of the rules in Articles 2, 3, 4, and 5 are clear, concise, and understandable.

7. **Summary of the written criticisms of the rule received within the last five years**
The Department has not received any written criticisms of the rules in 9 A.A.C. 11 in the past five years.

8. **Economic, small business, and consumer impact comparison**
The rules in 9 A.A.C. 11 were completely amended in a rulemaking effective December 1, 2007. The 2007 rulemaking repealed the requirement for nursing care institutions to submit UAR data using the obsolete Arizona Reporting System for Nursing Institutional Costs.
ARSNIC; amended and clarified reporting requirements for hospital, nursing care institution, and hospice UARs and hospital, nursing care institution, and home health agency rates and charges schedules; adopted new reporting requirements for outpatient treatment center rates and charges schedules; repealed obsolete forms and data format specifications; repealed the requirement for outpatient surgical centers to submit discharge data to the Department according to changes in statute; and amended and clarified hospital inpatient and emergency department discharge data reporting requirements according to the UB-04 National Billing Data Element Specifications. An Economic, Small Business, and Consumer Impact Statement (EIS) was submitted with this rulemaking and designated annual costs/revenues as minimal when less than $1,000, moderate when between $1,000 and $10,000, and substantial when greater than $10,000 in additional costs or revenues. Costs were listed as significant when meaningful or important, but not readily subject to quantification.

The 2007 EIS stated that the Department might experience a minimal-to-moderate benefit from the clarification of reporting requirements, a minimal-to-moderate cost for educating affected health care institutions of the new requirements, a minimal-to-moderate benefit from the submission of updated reporting requirements in a uniform format, and a substantial cost for updating data systems to accept the data in the specified uniform format. AHCCCS was expected to receive a minimal-to-moderate benefit and the U.S. Department of Health and Human Services a minimal-to-substantial benefit from the improved accuracy of data submitted due to updated reporting requirements in a uniform format. The Department anticipated that counties, cities, tribes, and other governmental entities in Arizona would receive a minimal-to-substantial benefit from the more complete and accurate data that will result from the amended and clarified requirements for the submission of inpatient and emergency department discharge data.

The Department anticipated that hospitals might receive a minimal benefit from the ability to submit a combined annual financial statement and to request an extension for submitting an annual financial statement. Hospitals and nursing care institutions were expected to bear a minimal-to-moderate cost to change computer reports that generate UAR or rates and charges data and receive a significant benefit from the requirement to submit data in a uniform format, and a minimal-to-substantial benefit from the opportunity to use more accurate data from themselves and other hospitals/nursing care institutions to make better business decisions. Hospitals were also expected to incur minimal-to-moderate costs and receive minimal-to-moderate benefits from the clarification and adoption of new UAR requirements with fewer data elements and requirements for establishing and amending rates and changes schedules, the lengthening of time for UAR submission from 120 days to 150 days after the end of the hospital’s
fiscal year, and the adoption of a rates and charges overview form. Nursing care institutions were expected to incur minimal costs and receive minimal benefits from the clarification and adoption of new UAR requirements and the lengthening of time for UAR submission from 120 days to 150 days after the end of the nursing care institution’s fiscal year, and to incur minimal-to-moderate costs and receive minimal-to-moderate benefits from the clarification and adoption of requirements for establishing and amending rates and changes schedules. In addition, hospitals were expected to experience a minimal-to-moderate cost for computer-related changes and minimal-to-substantial benefit from the clarification and adoption of requirements, such as the ability to correct errors without the assessment of civil penalties, for the submission of inpatient and emergency department discharge data.

Hospices, home health agencies, and outpatient treatment centers were expected to bear a minimal-to-moderate cost from the requirements for submitting UAR or rates and charges data and receive a minimal benefit from the clarity of the rules. The Department anticipated that hospices would experience a minimal-to-moderate cost and minimal-to-substantial benefit from the opportunity to correct errors in submitted data, and to incur minimal costs and receive minimal-to-moderate benefits from the clarification and adoption of new UAR requirements and the lengthening of time for UAR submission from 120 days to 150 days after the end of the hospice’s fiscal year. Home health agencies and outpatient treatment centers were expected to incur minimal costs from amended or new requirements for rates and charges schedules and receive minimal-to-moderate benefits from being able to submit a report already prepared for other purposes to satisfy rule requirements.

The Department anticipated that business users of data, such as health care consultants, developers, attorneys, banks, and insurance companies, as well as universities and research organizations might incur minimal costs related to requesting more reports, but could receive a minimal-to-substantial benefit from more complete and accurate reports and from requirements that reports be submitted in a uniform format. The public was also expected to receive a significant benefit from the submission of updated reporting requirements in a uniform format.

The Department further amended R9-11-202 in a rulemaking effective January 1, 2014, in compliance with A.R.S. § 36-2901.08(G), as added by Laws 2013, Ch. 10, § 5, to require a hospital to submit to the Department an attestation as part of its financial statement that it has not passed on to patients the cost of the assessment funding the nonfederal share of the medical assistance costs under 42 U.S.C. § 1396a (a)(10)(A)(i)(viii). Since the attestation is specifically required by statute and the rulemaking just added the specific statutory requirement to the rule, any costs incurred by a hospital, associated with the addition of the attestation to the financial
statement, are directly attributable to the statute, rather than to the rulemaking. Therefore, the Department believes there are no economic effects directly attributable to this rulemaking. The Department believes the actual economic impact of the rules in 9 A.A.C. 11 remains as estimated in the 2007 Economic, Small Business, and Consumer Impact Statement.

9. **Summary of business competitiveness analyses of the rules**
The Department did not receive a business competitiveness analysis of the rules in the last five years.

10. **Status of the completion of action indicated in the previous five-year-review report**
As stated in the previous five-year-review report, the Department did not plan to amend the rules in 9 A.A.C. 11 until substantive issues with the rules arose. When Laws 2013, Ch. 10, § 5, required a change be made to the rules, the Department revised R9-11-202, effective January 1, 2014, by exempt rulemaking to comply with the requirements in A.R.S. § 36-2901.08. Therefore, the Department has completed the action indicated in the previous five-year-review report.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
All of the rules in Article 3, Article 4, and Article 5, except R9-11-301, impose the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

12. **Analysis of stringency compared to federal laws**
The rules are not related to federal laws.

13. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**
The rules were adopted before July 29, 2010 and do not establish licensing, certification, or permit requirements.

14. **Proposed course of action**
The Department does not plan to amend the rules in 9 A.A.C. 11 until substantive issues with the rules arise.
INFORMATION FOR INDIVIDUAL RULES
ARTICLE 1. GENERAL

R9-11-101. Definitions

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. § 36-136(F) as specific statutory authority.

2. **Objective**
   The objective of the rule is to define terms and phrases used in more than one Article in the Chapter to enable the reader to clearly understand the requirements of the Articles in the Chapter and allow for consistent interpretation.

3. **Analysis of effectiveness in achieving the objective**
   The rule is mostly effective in achieving its objective but could be improved by revising the definition of “inpatient” in subsection (46). The current definition references the definition in A.A.C. R9-10-201, which defines an inpatient as an individual who either is admitted to a hospital or receives hospital services for 24 consecutive hours or more. Because a patient may receive hospital services in an emergency department for more than 24 hours but not be admitted to the hospital as an inpatient, the definition in R9-11-101 needs to be changed to better ensure that only information about individuals admitted to a hospital is reported as inpatient data.

4. **Analysis of consistency with state and federal statutes and rules**
   The rule is mostly consistent with state and federal statutes and rules, but some of the citations to definitions in 9 A.A.C. 10 are incorrect due to the recent rulemakings for 9 A.A.C. 10. For example, the definitions of “hospital” and “resident” are now in A.A.C. R9-10-101, and the definition of “emergency” was removed from rule.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable but could be improved by reformatting the definition of “discharge status” in subsection (27).

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Because of the issues described in paragraphs 3, 4, and 6 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.
ARTICLE 2. ANNUAL FINANCIAL STATEMENTS AND UNIFORM ACCOUNTING REPORTS

R9-11-201. Definitions

2. Objective
   The objective of the rule is to define terms used only in Article 2 to enable the reader to understand clearly the requirements of the Article and allow for consistent interpretation.

4. Analysis of consistency with state and federal statutes and rules
   The rule is mostly consistent with state and federal statutes and rules, but some of the citations to definitions in 9 A.A.C. 10 are incorrect due to the recent rulemakings for 9 A.A.C. 10. For example, the definitions of “hospice inpatient facility” and “volunteer” are now in A.A.C. R9-10-101, and the terms of “hospice service” and “inpatient services” are no longer defined or used in 9 A.A.C. 10.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective
   Because of the issues described in paragraph 4 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-11-202. Hospital Annual Financial Statement

1. Authorization of the rule by existing statute
   The rule has A.R.S. § 36-2901.08 as additional specific statutory authority.

2. Objective
   The objectives of the rule are to specify:
   a. Requirements for a hospital to submit an annual financial statement or a combined annual financial statement, along with a report of an audit of the annual financial statement and an attestation that the hospital has not passed on the cost of the assessment established in A.R.S. § 36-2901.08 to patients;
   b. Under what circumstances the Department will grant extensions for submitting an annual financial statement and report of the audit of the annual financial statement;
   c. What recourse a hospital has if the Department denies a request for an extension for submitting an annual financial statement and report of the audit of the annual financial statement; and
d. That the Department may assess civil penalties for failure to submit an annual financial statement and report of the audit of the annual financial statement according to this Section.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable but could be improved by adding the phrase “report of the” to subsections (C), (C)(4), (C)(5), (F), (F)(2), (F)(3), (G), and (H) before the phrase “audit of the annual financial statement.”

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Despite the minor improvement that could be made to the rule, as described in paragraph 6, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-11-203. Hospital Uniform Accounting Report

2. **Objective**
The objectives of the rule are to specify:
   a. The submission dates and content of the hospital uniform accounting report,
   b. The time period within which a hospital is required to submit a requested revised uniform accounting report, and
   c. That the Department may assess civil penalties for failure to submit a uniform accounting report according to this Section.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-11-204. Nursing Care Institution Uniform Accounting Report

2. **Objective**
The objectives of the rule are to specify:
a. The submission dates and content of the nursing care institution uniform accounting report,
b. The time period within which a nursing care institution is required to submit a requested revised uniform accounting report, and
c. That the Department may assess civil penalties for failure to submit a uniform accounting report according to this Section.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-11-205. Hospice Uniform Accounting Report

2. **Objective**

The objectives of the rule are to specify:

a. The submission dates and content of the hospice uniform accounting report,
b. The time period within which a hospice is required to submit a requested revised uniform accounting report, and
c. That the Department may assess civil penalties for failure to submit a uniform accounting report according to this Section.

4. **Analysis of consistency with state and federal statutes and rules**

The rule is mostly consistent with state and federal statutes and rules, but the information requested in subsections (C)(12)(b) through (e) and (13)(b)(i) through (iii) is not consistent with the rules in 9 A.A.C. 10. Under the rules in 9 A.A.C. 10, a hospice may be subclassified as a hospice service agency or hospice inpatient facility. There is no health care institution subclass of “hospital-based hospice,” “nursing care institution-based hospice,” “assisted living-based hospice, or “home health agency-based hospice.” While a hospice service agency may provide hospice services to patients in a hospital, a nursing care institution, or an assisted living facility, a hospice inpatient facility is a separately licensed facility from a hospital, a nursing care institution, or an assisted living facility.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons**
regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

Because of the issues described in paragraph 4 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.
ARTICLE 3. RATES AND CHARGES SCHEDULES

R9-11-301. Definitions

2. **Objective**

   The objective of the rule is to define terms used only in Article 3 to enable the reader to understand clearly the requirements of the Article and allow for consistent interpretation.

4. **Analysis of consistency with state and federal statutes and rules**

   The rule is mostly consistent with state and federal statutes and rules, but the citation to A.A.C. R9-20-101 in the definition of “behavioral health service” is incorrect due to the recent rulemakings for 9 A.A.C. 10 and 9 A.A.C. 20. The definition of “behavioral health services” is now in A.A.C. R9-10-101.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

   Because of the issue described in paragraph 4 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-11-302. Hospital Rates and Charges Schedule

2. **Objective**

   The objectives of the rule are to specify:

   a. The content of a rates and charges package for a hospital,

   b. What a hospital is required to submit when changing current rates and charges information,

   c. When a hospital may implement a rates and charges schedule or changes to rates and charges information,

   d. When the Department will provide written notice to a hospital regarding a submitted rates and charges schedule or changes to current rates and charges information,

   e. The time period within which a hospital is required to submit a requested revision to a rates and charges schedule or changes to rates and charges information, and

   f. That the Department may assess civil penalties for failure to submit a rates and charges schedule or changes to rates and charges information according to this Section.
R9-11-303. Nursing Care Institution Rates and Charges Schedule
2. **Objective**
   The objectives of the rule are to specify:
   a. The content of a rates and charges package for a nursing care institution,
   b. What a nursing care institution is required to submit when changing current rates and charges information,
   c. When a nursing care institution may implement a rates and charges schedule or changes to rates and charges information,
   d. When the Department will provide written notice to a nursing care institution regarding a submitted rates and charges schedule or changes to current rates and charges information,
   e. The time period within which a nursing care institution is required to submit a requested revision to a rates and charges schedule or changes to rates and charges information, and
   f. That the Department may assess civil penalties for failure to submit a rates and charges schedule or changes to rates and charges information according to this Section.

R9-11-304. Home Health Agency Rates and Charges Schedule
2. **Objective**
   The objectives of the rule are to specify:
   a. The content of a rates and charges package for a home health agency,
   b. What a home health agency is required to submit when changing current rates and charges information,
   c. When a home health agency may implement a rates and charges schedule or changes to rates and charges information,
   d. When the Department will provide written notice to a home health agency regarding a submitted rates and charges schedule or changes to current rates and charges information,
   e. The time period within which a home health agency is required to submit a requested revision to a rates and charges schedule or changes to rates and charges information, and
   f. That the Department may assess civil penalties for failure to submit a rates and charges schedule or changes to rates and charges information according to this Section.

R9-11-305. Outpatient Treatment Center Rates and Charges Schedule
2. **Objective**
   The objectives of the rule are to specify:
   a. The content of a rates and charges package for an outpatient treatment center,
b. What an outpatient treatment center is required to submit when changing current rates and charges information,

c. When an outpatient treatment center may implement a rates and charges schedule or changes to rates and charges information,

d. When the Department will provide written notice to an outpatient treatment center regarding a submitted rates and charges schedule or changes to current rates and charges information,

e. The time period within which an outpatient treatment center is required to submit a requested revision to a rates and charges schedule or changes to rates and charges information, and

f. That the Department may assess civil penalties for failure to submit a rates and charges schedule or changes to rates and charges information according to this Section.
ARTICLE 4.  HOSPITAL INPATIENT DISCHARGE REPORTING

R9-11-401. Definitions

2. Objective
   The objective of the rule is to define terms used only in Article 4 to enable the reader to understand clearly the requirements of the Article and allow for consistent interpretation.

R9-11-402. Reporting Requirements

2. Objective
   The objectives of the rule are to specify:
   a. The content of an inpatient discharge report,
   b. The information required to be submitted with the inpatient discharge report,
   c. When a hospital is required to submit an inpatient discharge report,
   d. The time period within which a hospital is required to submit a requested revision to an inpatient discharge report, and
   e. That the Department may assess civil penalties for failure to submit an inpatient discharge report according to this Section.
ARTICLE 5. EMERGENCY DEPARTMENT DISCHARGE REPORTING

R9-11-501. Definitions
2. Objective
   The objective of the rule is to define terms used only in Article 5 to enable the reader to understand clearly the requirements of the Article and allow for consistent interpretation.

R9-11-502. Reporting Requirements
2. Objective
   The objectives of the rule are to specify:
   a. The content of an emergency department discharge report,
   b. The information required to be submitted with the emergency department discharge report,
   c. When a hospital is required to submit an emergency department discharge report,
   d. The time period within which a hospital is required to submit a requested revision to an emergency department discharge report, and
   e. That the Department may assess civil penalties for failure to submit an inpatient discharge report according to this Section.
FIVE-YEAR-REVIEW REPORT
TITLE 9. HEALTH SERVICES
CHAPTER 18. DEPARTMENT OF HEALTH SERVICES
LOCAL HEALTH DEPARTMENT SERVICES
ARTICLE 1. PER CAPITA MATCHING FUNDS
October 2015
FIVE-YEAR-REVIEW REPORT  
TITLE 9. HEALTH SERVICES  
CHAPTER 18. DEPARTMENT OF HEALTH SERVICES  
LOCAL HEALTH DEPARTMENT SERVICES  
ARTICLE 1. PER CAPITA MATCHING FUNDS  

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FIVE-YEAR-REVIEW SUMMARY
LOCAL HEALTH DEPARTMENT SERVICES
ARTICLE 1. PER CAPITA MATCHING FUNDS

Arizona Revised Statutes (A.R.S.) § 36-132(A)(1) requires the Arizona Department of Health Services (Department) to protect the health of the people of the state of Arizona. A.R.S. § 36-136(F) requires the Department to promulgate rules necessary for the proper administration and enforcement of the laws relating to the public health.

A.R.S. § 36-189 authorizes the Department to use funds "not otherwise appropriated to match funds provided by cities and counties to establish and maintain local health department services" and authorizes the Department to establish by rule reasonable terms that local health departments are required to meet in order to receive matching funds. A.R.S. § 36-132(A)(2) requires the Department to "provide financial assistance to local health departments or districts and services that meet minimum standards of personnel and performance and [submit] a plan and budget ... to the Department for approval." If a local health department meets the minimum standards of personnel and performance established by the Department, the Department is required in A.R.S. § 36-189(A) to reimburse the local health department from funds appropriated for this purpose an amount up to 50% of the local health department's submitted budget, but not in excess of $1.25 per capita (or a prorated portion if sufficient funds are not available to meet the approved requests).

Arizona Administrative Code (A.A.C.) Title 9, Chapter 18, Article 1 contains rules that implement A.R.S. §§ 36-132 and 36-189 by providing the standards, terms, and procedures under which the matching funds are distributed to local health departments. Since FY 2010, there have been no funds allocated, so the Department did not distribute any funds. Accordingly, the rules are not currently enforced.

These rules were last amended at 12 A.A.R. 3715, effective November 11, 2006. The rules contained in this five-year-review report are effective in their current state and will be enforced when funding is appropriated by the Legislature for this purpose. The Department does not plan to amend 9 A.A.C. 18, Article 1 until further substantive issues are identified.
INFORMATION THAT IS IDENTICAL FOR ALL THE RULES

1. **Authorization of the rule by existing statute**
   General authority:  A.R.S. §§ 36-132(A) and 36-136(F)
   Specific authority:  A.R.S. §§ 36-132(A) and 36-189(A)

2. **The purpose of the rule**
   The purpose of the rule is to establish minimum standards of personnel and performance for a local health department in order for the Department to disburse matching funds to the local health department.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective or mostly effective.

4. **Analysis of consistency with state and federal statutes and rules**
   The rule is consistent with state and federal statutes and rules.

5. **Status of enforcement of the rule**
   Since FY 2010, there have been no funds allocated, so the Department has not distributed any funds. Accordingly, the rules in this Article are not currently enforced. If funding is allocated for PCMF grants in the future, the Department would anticipate resuming enforcement of the rules in this Article.

6. **Analysis of clarity, conciseness, and understandability**
   Except for the issue identified in the analysis of R9-18-106, the rules are clear, concise, and understandable.

7. **Summary of the written criticism of the rule received within the last five years**
   The Department has not received any written criticisms of the rules in 9 A.A.C. 18, Article 1 in the past five years.

8. **Economic, small business, and consumer impact comparison**
   The Department submitted an economic, small business, and consumer impact statement (EIS) with the rulemaking effective November 11, 2006, included in this report in Attachment A. The 2006 EIS identified cost bearers and beneficiaries as the Department, local health departments, and "society in general" (the public). The 2006 EIS designated costs as minimal when less than $1,000, moderate when between $1,000 and $10,000, and substantial when greater than $10,000. The 2006 EIS expected the Department to bear moderate costs to complete the rulemaking process. The Department believes this benefit has occurred as expected.
The 2006 EIS expected the Department and local health departments to experience a minimal-to-moderate benefit from the reduced staff time necessary to administer clearer rules with simplified requirements. Based on verbal feedback from stakeholders and stakeholder involvement in the rulemaking process in 2006, the Department believes this benefit has occurred as expected.

The 2006 EIS noted that local health departments might incur minimal costs associated with credentialing a registered nurse to fulfill waiver requirements as specified in R9-18-104. No waivers have been requested since the previous five-year-review report, and no waivers are currently expected for as long as the PCMF grant has no funding, so the actual economic impact has been no cost.

The 2006 EIS expected local health departments to incur minimal costs to retain records for five years rather than three years. The Department believes this is probably occurring, based on other requirements for record retention and the likelihood that local health departments are following the rule in anticipation of the PCMF grant being funded again in the future, but the Department has not verified whether this is occurring because the rules are not currently being enforced.

The 2006 EIS expected the public to experience a minimal-to-moderate benefit from local health department services made more abundant by the PCMF grant defraying some local health department costs and a minimal benefit from improved services as a result of additional training of registered nurses who do not meet certain criteria. The Department believes local health departments experienced the minimal-to-moderate benefit during the years that PCMF grant funding was in place, but that they are not currently experiencing that benefit. The Department believes there was no benefit from the additional training of registered nurses because there were no waiver requests indicating that a local health department had a registered nurse that needed to meet the requirements in R9-18-104(C).

The 2006 EIS expected there to be no direct impact on public or private employment in Arizona or on state revenues. No small businesses are subject to the rules, and there are no less intrusive or less costly alternatives for achieving the purpose of the rules.

9. **Summary of business competitiveness analyses of the rule**
   The Department did not receive a business competitiveness analysis of the rules in the last five years.

10. **Status of the completion of action in the previous five-year-review report**
    In the previous five-year-review report, the Department did not plan to amend 9 A.A.C. 18, Article 1 until further substantive issues were identified. No further substantive issues
were identified and no amendments were made. Accordingly, the course of action the Department described in the previous five-year-review report was completed.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

The rules establish requirements for local health departments to be eligible for reimbursement for costs to maintain local health services from funds appropriated to the Department for this purpose. No funds have been appropriated since the previous five-year-review report. No small businesses are subject to the rules, and there are no less intrusive or less costly alternatives for achieving the purpose of the rules.

12. **Analysis of stringency compared to federal laws**

The rules are not related to federal laws.

13. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**

The rules were adopted before July 29, 2010 and do not establish licensing, certification, or permit requirements.

14. **Proposed course of action**

The rules contained in this five-year-review report are effective in their current state and will be enforced when funding is appropriated by the Legislature for this purpose. The Department does not plan to amend 9 A.A.C. 18, Article 1 until further substantive issues are identified.
INFORMATION FOR INDIVIDUAL RULES

R9-18-101. Definitions
2. The objective of the rule
   The objective of the rule is to define terms used in 9 A.A.C. 18, Article 1 so that a reader can understand requirements in the Article.

R9-18-102. Grant Application
2. The objective of the rule
   The objective of the rule is to establish requirements for an application for a Per Capita Matching Grant that include:
   a. The information and documentation required; and
   b. The submission deadline.

R9-18-103. Review of Application and Awarding of Grant
2. The objective of the rule
   The objective of the rule is to establish:
   a. Procedures for approval or denial of an application;
   b. Deadlines and notification requirements for the review, approval, and denial of applications; and
   c. Deadlines and notification requirements for authorization of payment of Per Capita Matching Grant funds.

R9-18-104. Minimum Standard of Personnel; Waiver
2. The objective of the rule
   The objective of the rule is to:
   a. Specify the personnel that are required for the delivery of clinical services by a local health department,
   b. Establish the credentials required for a registered nurse to provide direction for public health nursing services,
   c. Provide a procedure for an individual to obtain a waiver of the requirements specified in (b),
   d. Provide a procedure for the Department to approve or deny a waiver request specified in (b),
e. Provide an exception for any "registered nurse providing direction for public health nursing services" in Arizona on the date the Article became effective, and
f. Require a sanitarian providing environmental health services in the designated service area to be currently registered in Arizona.

R9-18-105. Record Retention and Review

2. The objective of the rule

The objective of the rule is to:

a. Establish records retention and accessibility requirements, and
b. Describe the circumstances under which the Department may require a refund of funds paid under a Per Capita Matching Grant.

R9-18-106. Notice to Department

2. The objective of the rule

The objective of the rule is to require local health departments to notify the Department:

a. Within 30 days of any change in the physician, registered nurse, or sanitarian specified in R9-18-104; or
b. Upon any modification to a plan for which Per Capita Matching Funds were allocated.

7. Analysis of clarity, conciseness, and understandability

The rule is clear, concise, and understandable, but could be improved by rephrasing to clarify that 30-day timeframe applies only to changes in personnel, not to modification of the local health department's PCMF allocation plan.
FIVE-YEAR-REVIEW REPORT

TITLE 9. HEALTH SERVICES

CHAPTER 14. DEPARTMENT OF HEALTH SERVICES

LABORATORIES

ARTICLE 6. LICENSING OF ENVIRONMENTAL LABORATORIES

November 2015
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Arizona Revised Statutes (A.R.S.) § 36-495.01 requires the Arizona Department of Health Services (Department) to license environmental laboratories engaged in compliance testing and to adopt rules establishing minimum standards of proficiency, methodology, quality assurance, operation, and safety for environmental laboratories. A.R.S. § 36-495.01 also authorizes the Department to adopt rules prescribing standards for personnel education, training, and experience to meet federal environmental statutes or regulations; enabling reciprocity with other states; and prescribing the manner and form in which compliance testing results are reported. A.R.S. § 36-495.01 requires that the rules be developed in cooperation with the Arizona Department of Environmental Quality (ADEQ) and that the rules be consistent with A.R.S. Title 49 and the rules administered or enforced by ADEQ. A.R.S. § 36-495.13 allows the Department to adopt other rules necessary for the administration and enforcement of the Chapter.

The remaining statutes in A.R.S. Title 36, Chapter 4.3 establish exemptions from A.R.S. Title 36, Chapter 4.3; provide authority for further exemptions; establish provisions for environmental laboratory licensure, laboratory director duties, provisional licenses, fees, inspections and investigations, and laboratory reports; provide enforcement authority; establish the powers of the director; establish provisions for out-of-state laboratories; and establish the environmental laboratory licensure revolving fund and the environmental laboratory advisory committee.

The rules in Arizona Administrative Code (A.A.C.) Title 9, Chapter 14, Article 6, implement the statutes in A.R.S. Title 36, Chapter 4.3 by establishing application and fee requirements and the process for licensing environmental laboratories; minimum standards of proficiency, methodology, quality assurance, operation, and safety for environmental laboratories; minimum standards for laboratory records and reports; specific requirements for mobile laboratories and out-of-state laboratories; and time-frames.

The rules in 9 A.A.C. 14, Article 6, were last amended in a rulemaking, effective in December 2006, that addressed issues identified in the previous five-year-review report. Although some of these rules are effective; consistent with state and federal statutes and rules; enforced; and clear, concise, and understandable, this five-year-review report lists Sections requiring revision and describes the revisions that are needed. The Department plans to request an exception from the rulemaking moratorium and to submit a Notice of Final Rulemaking to the Governor’s Regulatory Review Council within 18 months after receiving the exception. This timetable is subject to change based on the Department’s priorities and staffing.
1. **Authorization of the rule by existing statute**

   The rules in 9 A.A.C. 14, Article 6, have A.R.S. §§ 36-132(A)(1) and 36-136(F) as general statutory authority.

   The rules in 9 A.A.C. 14, Article 6, have specific statutory authority in A.R.S. §§ 36-495.01 and 36-495.13.

2. **The purpose of the rule**

   The purpose of the rules in 9 A.A.C. 14, Article 6, is to implement the requirements in A.R.S. Title 36, Chapter 4.3 to ensure the health and safety of the public, as well as of employees of environmental laboratories.

4. **Analysis of consistency with state and federal statutes and rules**

   Except as described for R9-14-611, the rules in 9 A.A.C. 14, Article 6, are consistent with cited state and federal statutes and rules.

7. **Summary of the written criticisms of the rule received within the last five years**

   Except for comments about obsolete methods in R9-14-610, the Department has not received any written criticisms of the rules in 9 A.A.C. 14, Article 6, in the past five years.

8. **Economic, small business, and consumer impact comparison**

   The rules in Chapter 14, Article 6, establish application and fee requirements and the process for licensing environmental laboratories that perform compliance testing. The rules include minimum standards of proficiency, methodology, quality assurance, operation, and safety for environmental laboratories; minimum standards for laboratory records and reports; specific requirements for mobile laboratories and out-of-state laboratories; and time-frames. Under these rules, the Department licenses approximately 141 environmental laboratories, including 62 environmental laboratories that are located out-of-state. From these environmental laboratories, the Department annually collects over $700,000 in licensing fees, with approximately half of the funds submitted in March through June. These funds are deposited into the environmental laboratory licensure revolving fund established under A.R.S. § 36-495.15, from which the Department receives a legislative appropriation to run the Environmental Laboratory Licensure Program (Program) within the Department. Because of the inconsistent cash flow, the Department had relied on monies kept in the fund to run the Program during times with lower cash flows. During the FY 2009 budget crisis, the Legislature swept the monies remaining in the fund, leaving the Department with only the monies coming in from licensure fees to run the Program. In FY 2015, the Department imposed no civil penalties and denied no licenses.

   With the 2006 rulemaking, the Department submitted an Economic, Small Business, and Consumer Impact Statement (EIS) to GRRC. While the actual economic impact of most of the rules is as estimated in the 2006 EIS, for two of the rules the actual economic impact differs from
that estimated in the 2006 EIS. R9-14-607 specifies the fees an applicant is required to submit to the Department with an application for an initial or renewal license, and Exhibit I specifies method and instrumentation fees. In the 2006 EIS, the Department estimated that the Department would receive a moderate benefit from requiring out-of-state laboratories to pay an annual update fee and a substantial benefit from increased application fees, including cumulative method and instrumentation fees determined according to Tables 1 and 2 in Exhibit I.

While these estimates of moderate and substantial benefits are correct, the dollar amount estimated to be received from increased application fees, including cumulative method and instrumentation fees, was more than was actually received. The Department estimated receiving $858,654 in revenue for FY2007 with the fee increases in the rulemaking. However, the revenue since the rules fee increase has fallen short each fiscal year, with the fee collection for FY 2015 being only $758,623. While the Department continued to license approximately the same number of environmental laboratories as before the 2006 rulemaking, many of the environmental laboratories reduced the number of methods and instruments for which licensing was requested, thereby reducing the cumulative method and instrumentation fees and consequently the Department’s revenue. The Department adjusted to the reduced revenue through salary cost savings from the furloughs and temporarily shifting personnel to other duties and by delaying expenditures for laboratory software and supplies.

Otherwise, the actual economic impact of the rule is as estimated in the 2006 Economic, Small Business, and Consumer Impact Statement.

9. **Summary of business competitiveness analyses of the rules**
The Department did not receive a business competitiveness analysis of the rules in the last five years.

10. **Status of the completion of action indicated in the previous five-year-review report**
As stated in the previous five-year-review report, the Department planned to amend the rules in 9 A.A.C. 14, Article 6, by March 2013, which is 21 months after the rulemaking moratorium was scheduled to be lifted on June 30, 2011. Since the moratorium, established January 22, 2009 and continued through legislative and executive actions to the present day, is still in effect, the Department is complying with the rulemaking action proposed in the previous five-year-review report.

12. **Analysis of stringency compared to federal laws**
The rules are not more stringent than federal laws.

13. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**
Although the rules do establish licensing, certification, or permit requirements, the rules were adopted before July 29, 2010.
14. **Proposed course of action**

The Department intends to request an exception from the rulemaking moratorium established by Executive Order 2015-01 to amend the following rules as described in the information for individual rules: R9-14-601 through R9-14-603, R9-14-606, R9-14-607, R9-14-609 through R9-14-615, and Exhibits I and II. Changes may also be made to other rules, as necessary, to correct cross-references or otherwise clarify the rules. Assuming that the Department obtains the exception by February 2016, the Department anticipates submitting a Notice of Final Rulemaking to the Governor’s Regulatory Review Council (GRRC) by August 2017. This timetable is subject to change based on when an exception/approval to conduct rulemaking is received and the Department’s priorities and staffing.
INFORMATION FOR INDIVIDUAL RULES

R9-14-601. Definitions

2. **Objective**
The objective of the rule is to define terms used in Article 6 to enable the reader to understand clearly the requirements of the Article and allow for consistent interpretation.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective but could be improved if the issues described in paragraph 6 were addressed.

5. **Status of enforcement of the rule**
The Department is enforcing the rule to the extent that definitions can be enforced.

6. **Analysis of clarity, conciseness, and understandability**
The rule is mostly clear, concise, and understandable. However, the definitions of several terms need to be amended. For example, the definition of “approved method” uses the defined term in the definition. The term “Initial Demonstration of Capability” does not need to be capitalized and can be combined with the definition of “IDOC,” which is the abbreviation for the term. The definition of “laboratory inspection” needs to be amended to clarify that the term also refers to the assessment of an applicant’s compliance with A.R.S. Title 36, Chapter 4.3 and 9 A.A.C. Chapter 14, Article 6. The definition of “limit of detection” needs to be amended to remove from the definition the requirement that the estimate be developed according to R9-14-615(C)(7). The definition of “statistical outlier” also needs to be amended to insert the word “been” after the phrase “determined through statistical analysis to have” to make the definition understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Because of the issues described in paragraph 6 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-14-602. Exemptions from Applicability

1. **Authorization of the rule by existing statute**
The rule has A.R.S. § 36-495.02 as additional specific statutory authority.

2. **Objective**
The objective of the rule is to establish exemptions from the Article’s applicability.

3. **Analysis of effectiveness in achieving the objective**
The rule is mostly effective in achieving its objective in achieving its objective but should be amended to add two new categories of exemptions, as allowed under A.R.S. § 36-495.02(B). The first category is a hospital that adds chlorine dioxide to its water supply to reduce cross-infection
rates and increase patient safety and monitors these chlorine levels. The second category consists of municipal wastewater laboratories that perform ultra-low chlorine testing of the water supply at specific satellite sites away from the licensed environmental laboratory. Currently, a licensee would have to pay almost $1,900 for the licensure of each of these locations as satellite laboratories.

5. **Status of enforcement of the rule**

While the Department provides training and technical assistance to the personnel of hospitals that add chlorine dioxide to their water supplies and municipal wastewater laboratories that perform ultra-low chlorine testing at satellite sites, the Department does not license these entities. Otherwise, the rule is enforced as written.

6. **Analysis of clarity, conciseness, and understandability**

The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

Because of the issues described in paragraphs 3 and 5 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

**R9-14-603. License Application and Process**

1. **Authorization of the rule by existing statute**

The rule has A.R.S. §§ 36-495.03 and 36-495.06 as additional specific statutory authority.

2. **Objective**

The objectives of the rule are to specify:

a. The content of an initial or renewal license application;

b. The time period for submission of a license application;

c. The criteria for the Department’s issuance of a single laboratory license;

d. The conditions under which a license is valid;

e. That non-payment of applicable fees constitutes a violation of the requirements for licensure; and

f. That no fee is charged for a new license issued in response to a change in laboratory name, laboratory director, or ownership reported to the Department within 20 days after the change.

3. **Analysis of effectiveness in achieving the objective**

The rule is effective but would be just as effective and less burdensome if subsection (A)(14) were removed since the laboratory director and licensee are responsible for a final report
submitted to the U.S. Environmental Protection Agency (EPA) or ADEQ for compliance monitoring, regardless of who signs the final report.

5. **Status of enforcement of the rule**
   The Department is enforcing the rule as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable. However, the rule could be improved if the semicolons in subsection (A)(5) were replaced with commas.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Because of the issue described in paragraph 3 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

**R9-14-604. Third Party Accreditation**

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. § 36-495.07 as additional specific statutory authority.

2. **Objective**
   The objective of the rule is to specify the conditions under which accreditation of a laboratory by a third party is acceptable in lieu of licensure.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

5. **Status of enforcement of the rule**
   The Department is enforcing the rule as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

**R9-14-605. Compliance Monitoring**

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. §§ 36-495.07 and 36-495.09 as additional specific statutory authority.
2. **Objective**
   The objective of the rule is to establish requirements for compliance monitoring to help ensure the health of members of the public, including specifying:
   a. Requirements for mandatory and permissive inspections, investigations, and proficiency testing;
   b. The actions the Department may take in response to deficiencies found during compliance monitoring; and
   c. Requirements related to corrective action plans.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

5. **Status of enforcement of the rule**
   The Department is enforcing the rule as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

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**R9-14-606. Provisional Licensing**

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. § 36-495.05 as additional specific statutory authority.

2. **Objective**
   The objectives of the rule are to specify:
   a. The conditions under which the Department may issue a provisional license to a licensee,
   b. The elements the Department will consider in deciding whether to issue a provisional license,
   d. The period of time during which a provisional license is valid, and
   e. How a licensee with a provisional license may request and obtain a regular license.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective but could be improved if the issues described in paragraph 6 were addressed.

5. **Status of enforcement of the rule**
   The Department is enforcing the rule as written.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable. However, the rule could be improved by clarifying that the “plan” specified in subsection (A) is a “corrective action plan” and that this “plan” is “the corrective action plan” specified in subsection (G). Subsection (D) also seems to be out of place and, to improve the understandability of the rule, should either be moved into a different Section or be more closely associated with another subsection, such as subsection (A).

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

Because of the issues described in paragraph 6 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

**R9-14-607. Fees**

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. §§ 36-495.06, 36-495.14, and 36-495.15 as additional specific statutory authority.

2. **Objective**
   The objective of the rule is to specify the fees an applicant is required to submit to the Department with an application for an initial or renewal license to sustain the environmental laboratory licensure program.

3. **Analysis of effectiveness in achieving the objective**
   The rule is partly effective in achieving its objective. The Department needs to add a credit card fee for those applicants who want to pay their licensure fees by credit card to offset the cost credit card providers charge the Department for this service. In addition, the fees specified in rule are no longer high enough to cover the costs of the licensure program, as required by A.R.S. § 36-495.15.

5. **Status of enforcement of the rule**
   The Department is enforcing the rule as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Because of the issues described in paragraph 3 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule necessary to achieve the regulatory objective.

R9-14-608. Installment Payment of Fees by Small Businesses

1. Authorization of the rule by existing statute
   The rule has A.R.S. § 36-495.06 as additional specific statutory authority.

2. Objective
   The objective of the rule is to specify the conditions of and requirements for fee installment payments by a small business.

3. Analysis of effectiveness in achieving the objective
   The rule is effective in achieving its objective.

5. Status of enforcement of the rule
   The Department is enforcing the rule as written.

6. Analysis of clarity, conciseness, and understandability
   The rule is clear, concise, and understandable.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective
   The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-14-609. Proficiency Testing

1. Authorization of the rule by existing statute
   The rule has A.R.S. § 36-495.07 as additional specific statutory authority.

2. Objective
   The objective of the rule is to specify the frequency of proficiency testing and the mechanism by which an applicant or licensee may demonstrate proficiency in the type of compliance testing performed by the laboratory to help ensure the health of members of the public.

3. Analysis of effectiveness in achieving the objective
   The rule is mostly effective in achieving its objective but could be improved by addressing the issue in paragraph 6.

5. Status of enforcement of the rule
   The Department is enforcing the rule as written.

6. Analysis of clarity, conciseness, and understandability
The rule is mostly clear, concise, and understandable. However, the Food and Drug Administration (FDA) recommends that bottled water, which is regulated by the FDA as a food, should be tested under drinking water standards. Therefore, the rule could be improved by clarifying that an applicant or licensee of a laboratory performing compliance testing of bottled water is required to comply with the proficiency testing requirements for an applicant or licensee of a laboratory performing compliance testing of drinking water.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

Because of the issue described in paragraph 6 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

**R9-14-610. Approved Methods and References**

2. **Objective**

The objectives of the rule are to:

a. Require that compliance testing be performed by an approved method or a method alteration approved by the Department,

b. Incorporate by reference the publications containing the approved methods,

c. Specify the mechanism by which a person may request approval of a different method or method alteration, and

d. Establish the criteria the Department will use in making the decision of whether or not to approve a different method or method alteration.

3. **Analysis of effectiveness in achieving the objective**

The rule is mostly effective in achieving its objectives. Some of the references incorporated in the rule are obsolete and need to be updated or removed. In addition, other newer methods have been approved by the Environmental Protection Agency (EPA), the Department, or another regulatory body, and references to these methods need to be incorporated into the rule. The rule would also be more effective if an applicant or person exempt from licensure under A.R.S. § 36-495.02(A)(3), as well as a licensee, were able to request an alternate method. The rule’s effectiveness would also be improved by addressing the issues in paragraph 6.

5. **Status of enforcement of the rule**

Because of the Department’s ability to add newer methods under subsection (C), the Department is able to enforce the rule as written.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable. However, the rule could be improved by replacing the comma after “editions or amendments” in subsection (B) with a semicolon. In subsection (C)(3), the words “at a” should be removed from the phrase “performed by a laboratory at a designated by the Department.”

7. **Summary of the written criticisms of the rule received within the last five years**

   Criticism 1: An employee of an environmental lab in 2013 commented about the methods for analysis of Hexavalent Chromium and Total Chromium in the Standard Methods for the Examination of Water and Wastewater (19th ed. 1995), incorporated by reference in subsection (B) as Key Reference C, being obsolete.
   
   Response 1: The Department agrees that the methods incorporated by reference as Key Reference C are obsolete since the current version is the 22nd edition, 2012. The Department plans to update the reference when the rules are revised.

   
   Response 2: The Department agrees that the methods incorporated by reference as Key Reference C2 are obsolete since the current version is the 22nd edition, 2012. The Department plans to update the reference when the rules are revised.

   Criticism 3: An employee of an environmental lab in 2014 commented about the methods for analysis of Polychlorinated biphenyls (PCBs) in the EPA Pub. No. SW-846, incorporated by reference in subsection (B) as Key Reference F, being obsolete.
   
   Response 3: The Department agrees that the methods incorporated by reference as Key Reference F are obsolete since the rules include updates to the 3rd edition only up to July 2005, and many updates have been added since then. The Department plans to update the reference when the rules are revised.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

Because of the issues described in paragraphs 3 and 6 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-14-611. Drinking Water Compliance Testing

2. **Objective**
The objective of the rule is to specify requirements for laboratories performing compliance testing of drinking water to help ensure the health of members of the public.

3. Analysis of effectiveness in achieving the objective
The rule is mostly effective in achieving its objective. However, the effectiveness of the rule is compromised because an approved method by which drinking water samples are required to be analyzed may be obsolete, such as Key Reference C2 as described in the response to a criticism of R9-14-610. Although the Department can add new methods under R9-14-610(C), methods previously approved by this route may also become obsolete, leading to a situation where licensees may be confused about which method is required to be used. Since bottled water should be tested under drinking water standards, the rule could also be improved by clarifying that a licensee of a laboratory performing compliance testing of bottled water is required to comply with the requirements for a licensee of a laboratory performing compliance testing of drinking water. The rule would also be more effective if the rule clarified that a licensee is required to ensure that compliance testing is performed not only using an approved method but also following quality assurance guidelines associated with the approved method.

4. Analysis of consistency with state and federal statutes and rules
The rule is consistent with cited state and federal statutes and rules. However, the rule is not consistent with EPA standards and guidelines for drinking water, since the cited Key Reference D4 is obsolete.

5. Status of enforcement of the rule
Because of the Department’s ability to add newer methods under R9-14-610(C), the Department is able to enforce the rule as written.

6. Analysis of clarity, conciseness, and understandability
The rule is clear, concise, and understandable.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective
Because of the issues described in paragraph 3 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule or achieve the regulatory objective.

R9-14-612. Wastewater Compliance Testing
2. Objective
The objective of the rule is to specify requirements for laboratories performing compliance testing of wastewater to help ensure the health of members of the public.
3. **Analysis of effectiveness in achieving the objective**
   The rule is mostly effective in achieving its objective. However, the effectiveness of the rule is compromised because an approved method by which wastewater samples are required to be analyzed may be obsolete, such as Key Reference C2 as described in the response to a criticism of R9-14-610. Although the Department can add new methods under R9-14-610(C), as mentioned earlier, methods previously approved by this route may also become obsolete, leading to a situation where licensees may be confused about which method is required to be used. The rule would also be more effective if the rule clarified that a licensee is required to ensure that compliance testing is performed not only using an approved method but also following quality assurance guidelines associated with the approved method.

5. **Status of enforcement of the rule**
   Because of the Department’s ability to add newer methods under R9-14-610(C), the Department is able to enforce the rule as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Because of the issues described in paragraph 3 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule or achieve the regulatory objective.

R9-14-613. **Solid Waste Compliance Testing**

2. **Objective**
   The objective of the rule is to specify requirements for laboratories performing solid waste compliance testing to help ensure the health of members of the public.

3. **Analysis of effectiveness in achieving the objective**
   The rule is mostly effective in achieving its objective. However, the effectiveness of the rule is compromised because an approved method by which solid waste samples are required to be analyzed may be obsolete, such as Key Reference F as described in the response to a criticism of R9-14-610. Although the Department can add new methods under R9-14-610(C), as mentioned earlier, methods previously approved by this route may also become obsolete, leading to a situation where licensees may be confused about which method is required to be used. The rule would also be more effective if the rule clarified that a licensee is required to ensure that solid waste compliance testing is performed not only using an approved method but also following
quality assurance guidelines associated with the approved method. The rule’s effectiveness would also be improved if the issues described in paragraph 6 were addressed.

5. **Status of enforcement of the rule**
   Because of the Department’s ability to add newer methods under R9-14-610(C), the Department is able to enforce the rule as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is mostly clear, concise, and understandable. However, the rule could be improved by clarifying that a licensee of a laboratory performing solid waste compliance testing using an 8000 series method from Key Reference F is not required to follow the applicable procedures in all three of the references specified in subsection (B)(3) but may choose an applicable procedure from any of the three. Similarly, the rule should clarify that a licensee of a laboratory performing solid waste compliance testing using a non-8000 series method from Key Reference F is not required to follow the applicable procedures in both of the references specified in subsection (C) but may choose an applicable procedure from either.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Because of the issues described in paragraphs 3 and 6 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule or achieve the regulatory objective.

**R9-14-614. Air and Stack Compliance Testing**

2. **Objective**
   The objective of the rule is to specify requirements for laboratories performing air or stack compliance testing to help ensure the health of members of the public.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective. However, the rule would be more effective if the rule clarified that a licensee is required to ensure that air or stack compliance testing is performed not only using an approved method but also following quality assurance guidelines associated with the approved method. Although the Department can add new methods under R9-14-610(C), as mentioned earlier, methods previously approved by this route may become obsolete, leading to a situation where licensees may be confused about which method is required to be used.

5. **Status of enforcement of the rule**
   Because of the Department’s ability to add newer methods under R9-14-610(C), the Department is able to enforce the rule as written.
6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Because the issue described in paragraph 3 may affect the health of members of the public, while the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, the underlying regulatory objective cannot be achieved with these rules.

R9-14-615. **Quality Assurance**

2. **Objective**
The objectives of the rule are to establish:
   a. Minimum standards for quality assurance, including the development and implementation of a quality assurance plan and standard operation procedures, to help ensure the health of members of the public; and
   b. Requirements and processes for obtaining an exemption from the requirement for a licensee or applicant to have available at the laboratory all methods, equipment, reagents, and glassware necessary for compliance testing of all licensed parameters.

3. **Analysis of effectiveness in achieving the objective**
The rule is mostly effective in achieving its objectives. The rule would be more effective if the rule required in the quality assurance plan specifications for appropriate manual integration of chromatography results, including descriptions of inappropriate manual integration. The rule should also require in subsection (C)(11) that the licensee or applicant maintain a record showing the traceability of standards and other laboratories supplies or equipment that may affect the accuracy or validity of test results. The rule’s effectiveness would also be improved if the issues described in paragraph 6 were addressed.

5. **Status of enforcement of the rule**
The Department is enforcing the rule as written.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable. However, the rule could be improved by replacing the term “line of authority” in subsection (B)(3) with the term “lines of authority” and adding the word “of” after the phrase “limit of quantitation” in subsection (B)(14). Subsection (C)(3)(f) would also be more understandable if the rule required a statement of the quantitative methods...
used to calculate the final concentration of analyte in the sample, including any factors used in the calculations, rather than “calculations for the quantitation … and the calibration algorithm.”

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

Because of the issues described in paragraph 3 and 6 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule or achieve the underlying regulatory objective.

**R9-14-616. Operation**

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. § 36-495.04 as additional specific statutory authority.

2. **Objective**
   The objective of the rule is to establish the minimum standards for environmental laboratory operations.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

5. **Status of enforcement of the rule**
   The Department is enforcing the rule as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable. However, the rule could be improved if the redundant citation to A.R.S. §36-495.02(A) were removed from subsection (1)(c) since the statute is included as a subsection in R9-14-602. Subsection (5)(e) would be clearer if the word “by” in the phrase “as required by each” were replaced by the word “for.”

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

   Despite the rule’s minor clarity issue, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

**R9-14-617. Laboratory Records and Reports**

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. § 36-495.08 as additional specific statutory authority.
2. **Objective**
The objective of the rule is to establish the minimum standards for compliance testing records and reports and for the maintenance and accessibility of records and reports.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective.

5. **Status of enforcement of the rule**
The Department is enforcing the rule as written.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable. However, the rule could be improved if the word “a” in the phrase “a longer period of time agreed upon” in subsection (5) were replaced with the word “the.” The term “critical step” in subsection (7)(f) should also be defined or explained.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Despite the rule’s minor clarity issues, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-14-618. **Mobile Laboratories**

1. **Authorization of the rule by existing statute**
The rule has A.R.S. §§ 36-495.03 and 36-495.08 as additional specific statutory authority.

2. **Objective**
The objectives of the rule are to require that:
   a. A mobile laboratory be licensed and comply with the Article; and
   b. The licensee for a mobile laboratory provide to the Department, upon request, the mobile laboratory’s location and a list of the parameters for which testing is performed at the mobile laboratory.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective.

5. **Status of enforcement of the rule**
The Department is enforcing the rule as written.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**


regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective
The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-14-619. Out-of-State Environmental Laboratory Licensing

1. Authorization of the rule by existing statute
The rule has A.R.S. § 36-495.14 as additional specific statutory authority.

2. Objective
The objective of the rule is to require an out-of-state environmental laboratory to comply with the statutes and rules applicable to an out-of-state environmental laboratory and to pay the Department’s expenses incurred as a result of the laboratory’s out-of-state location.

3. Analysis of effectiveness in achieving the objective
The rule is effective in achieving its objective.

5. Status of enforcement of the rule
The Department is enforcing the rule as written.

6. Analysis of clarity, conciseness, and understandability
The rule is clear, concise, and understandable.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective
The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-14-620. Changes to a License

2. Objective
The objective of the rule is to specify the mechanism by which a licensee may request a change to the parameters for which the laboratory is licensed and the Department will process the request.

3. Analysis of effectiveness in achieving the objective
The rule is effective in achieving its objective.

5. Status of enforcement of the rule
The Department is enforcing the rule as written.

6. Analysis of clarity, conciseness, and understandability
The rule is clear, concise, and understandable. However, the rule could be improved if subsections (A) and (B) were combined and subsection (E) were clarified to read “for the fourth request and each subsequent request for deletion during a license period.”

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

Despite the rule’s minor clarity issue, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

### R9-14-621. Time-frames

1. **Authorization of the rule by existing statute**
   
The rule has A.R.S. §§ 36-495.07, 36-495.09, and 41-1073 through 41-1076 as additional specific statutory authority.

2. **Objective**
   
The objective of the rule is to specify the administrative processes the Department will perform during the time-frames in Table 1.

3. **Analysis of effectiveness in achieving the objective**
   
The rule is effective in achieving its objective.

5. **Status of enforcement of the rule**
   
The Department is enforcing the rule as written.

6. **Analysis of clarity, conciseness, and understandability**
   
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

   The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

### Table 1. Time-frames (in days)

1. **Authorization of the rule by existing statute**
   
The table has A.R.S. §§ 36-495.07, 36-495.09, and 41-1073 through 41-1076 as additional specific statutory authority.

2. **Objective**
The objective of the table is to establish the time-frames for the Department’s administrative processes for the approvals issued under this Article.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

5. **Status of enforcement of the rule**
   The Department is enforcing the rule as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable. However, having three Tables 1 in the Article may be confusing.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

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**Exhibit I. Approved Methods; Method Fees; Instrument Fees**

**Table 1. Approved Methods; Method Fees**

**Table 2. Instrumentation Fees**

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. § 36-495.06 as additional specific statutory authority.

2. **Objective**
   The objectives of the tables in the exhibit are to:
   a. Provide a list of drinking water parameters, wastewater parameters, solid waste parameters, air and stack parameters, and director-approved methods;
   b. Specify the methods by which each analyte under the different types of parameters may be tested, the licensing fee for each method, and a reference for the method; and
   c. Specify the licensing fee associated with each type of instrument used in compliance testing.

3. **Analysis of effectiveness in achieving the objective**
   The rule is partly effective in achieving its objectives. The listed methods, references, and instrumentation need to be updated to reflect changes in the field, some of which may also require other Sections to be amended and this rule to be amended to be consistent with the other Sections of the rules.

5. **Status of enforcement of the rule**
   The Department is enforcing the rule as written.
6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable. However, having three Tables 1 in the Article may be confusing.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Because of the issue described in paragraph 3 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

**Exhibit II. Alternate Default Limits**

**Table 1. Default Limits**

2. **Objective**
The objective of the table is to specify the default limits for quality control parameters without acceptance criteria specified in the method.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective but could be improved by adding more default limits to benefit the regulated community.

5. **Status of enforcement of the rule**
The Department is enforcing the rule as written.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable. However, having three Tables 1 in the Article may be confusing.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Because of the issue described in paragraph 3 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.
FIVE-YEAR-REVIEW REPORT

TITLE 9. HEALTH SERVICES
CHAPTER 8. DEPARTMENT OF HEALTH SERVICES
FOOD, RECREATIONAL, AND INSTITUTIONAL SANITIATION
ARTICLE 7. PUBLIC SCHOOLS

January 2016
FIVE-YEAR-REVIEW REPORT
TITLE 9. HEALTH SERVICES
CHAPTER 8. DEPARTMENT OF HEALTH SERVICES
FOOD, RECREATIONAL, AND INSTITUTIONAL SANITIATION
ARTICLE 7. PUBLIC SCHOOLS

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Arizona Revised Statutes (A.R.S.) § 36-136(H)(9) requires the Arizona Department of Health Services (Department) to “Define and prescribe reasonably necessary measures concerning the sewage and excreta disposal, garbage and trash collection, storage and disposal, water supply and food preparation of all public schools.” In addition to prescribing minimum standards for sanitary conditions that shall be maintained in all public schools, A.R.S. § 36-136(H)(9) requires the Department to provide minimum standards for inspection of public schools and for abatement of a public nuisance identified on the premises of a public school.

The Department has adopted in Arizona Administrative Code (A.A.C.) Title 9, Chapter 8, Article 7 rules to implement A.R.S. § 36-136(H)(9). These rules provide standards pertaining to public schools' water supply, sewage disposal, refuse management, pest control, animals in schools, inspections, cafeterias and food service, indoor areas, and restrooms, bathrooms and shower rooms. The rules are used by county sanitarians, who perform sanitary inspections in public schools under delegation agreements with the Department, and by Department sanitarians, who perform sanitary inspections in public schools in Graham County. In FY 2015, 1,832 inspections were conducted at the 1,722 public schools in Arizona, and 33 enforcement actions were taken.

The current rules in 9 A.A.C. 8, Article 7 were made in response to the 2001 Five-year-review Report, approved by the Governor's Regulatory Review Council on August 6, 2002, and were adopted effective March 11, 2006. Through an analysis of the rules in 9 A.A.C. 8, Article 7, the Department has determined that all rules are effective; are consistent with state and federal statutes and rules; are enforced; and are mostly clear, concise, and understandable. The Department has received no written criticism of the rules. The Department estimates that the actual economic impact of the rules is consistent with the 2006 EIS for the rulemaking. The Department does not plan to amend the rules in 9 A.A.C. 8, Article 7 as indicated in this report.
1. **Authorization of the rule by existing statutes**
   The general statutory authority for the rules in 9 A.A.C. 8 Article 7 is A.R.S. § 36-136(F).
   The specific statutory authority for the rules in 9 A.A.C. 8 Article 7 is A.R.S. § 36-136(H)(9).

2. **The purpose of the rule**
   The purpose of the rules in Article 7 is to provide minimum standards for maintaining reasonable sanitary conditions for sewage and excreta disposal, garbage and trash collection, storage and disposal, water supply and food preparation at public schools. The rules also provide minimum standards for inspection of public schools premises.

3. **Analysis of effectiveness in achieving the objective**
   All of the rules in Articles 7 are effective in achieving their respective objectives.

4. **Analysis of consistency with state and federal statutes and rules**
   The rules in Article 7 are consistent with state and federal statutes and rules.

5. **Status of enforcement of the rule**
   The rules in Article 7 are enforced as written without difficulty by Department sanitarians or by county sanitarians according to delegation agreements.

6. **Analysis of clarity, conciseness, and understandability**
   Despite for minor issues identified in R9-8-701 and R9-8-703, the rules in Article 7 are clear, concise, and understandable.

7. **Summary of the written criticisms of the rule received within the last five years**
   The Department did not receive any written criticisms of the rules in 9 A.A.C. 8, Article 7 in the past five years.

8. **Economic, small business, and consumer impact comparison**
   The actual economic impact of the rules is as estimated in the 2006 Economic, Small Business, and Consumer Impact Statement (EIS). The Department determined that the probable impacts and effects to state and local government agencies, school districts, privately owned business, and consumers are as reported is the 2006 EIS.
9. **Summary of business competitiveness analyses of the rules**

The Department did not receive a business competitiveness analysis of the rules in the last five years.

10. **Status of the completion of action indicated in the previous five-year-review report**

In the previous five-year-review report, the Department planned to amend the rule in R9-8-710 to add requirements to prevent bats from roosting on school buildings. During 2009 and 2010, the Department had received four incident reports of public school children's exposure to a rabid bat. At that time, the Department, county sanitarians, and county health officials provided technical assistance to public schools concerning roosting bats. The Department anticipated submitting a Notice of Final Rulemaking by March 2014. The Department also stated that the submission date could change based on the Department's priorities, the length of the moratorium, and staffing. Since the Department, county sanitarians, and county health officials provided technical assistance to public schools concerning roosting bats, the Department has not received any incident reports involving public school children's exposure to a rabid bat. The Department has determined that amending R9-15-710 to add requirements to prevent bats from roosting on school buildings would impose an undue burden on persons regulated by the rule and is no longer required. Therefore, the Department did not amend the rules.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

Except for minor issues identified in R9-8-701 and R9-8-703, the rules in Article 7 impose the least burden and costs to persons regulated by the rule while achieving the regulatory objective consistent with statutory requirements.

12. **Analysis of stringency compared to federal laws**

The rules are not related to federal laws.

13. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**

The rules were adopted before July 29, 2010 and do not establish licensing, certification, or permit requirements.
14. **Proposed course of action**

With the Department having almost 60 five-year-review reports due in 2017, 2018, and 2019, the Department does not plan to amend the rules to address format and clarity issues in R9-8-701 and R9-8-703 until after the next five-year-review report is due in 2021 unless a substantive matter with the rules arises before the next five-year-review report.
R9-8-701. Definitions
2. **Objective of the rule**
   The objective of the rule is to define terms used in the Article to help members of the general public read and understand the rules, as well as allow for consistent interpretation of the rules.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable, however, could be improved. For example, the terms “calendar year” and “complaint” is used only in R9-8-711 and the term “hydration” is used only in R9-8-706(F)(2). The rule would be clearer if these terms were described in the rule were the terms are located rather than defining the terms in this Section. Similarly, other terms are used only in other definitions and could be described in those definitions. For example, the terms “aquifer,” “constructed underground storage facility,” and “managed underground storage facility” all cite statutory references and are used only in subsection (50) “underground water source.”

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Although the rule contains minor formatting issues as described in paragraph 6, the rule provides the least burden and costs to persons regulated by the rule and achieves the regulatory objective consistent with statutory requirements.

R9-8-702. General Provisions
2. **Objective of the rule**
   The objective of the rule is to specify responsible persons, defined in R9-8-701, who shall ensure that a school complies with the requirements of this Article and with federal and state statutes and rules and local ordinances governing subjects included in A.R.S. § 36-136(H)(9). The rule also identifies that a violation of this Article is a public nuisance under A.R.S. § 36-601. A.R.S. § 36-601 specifies the conditions that constitute public nuisances and authority for abatement.

R9-8-703. Restroom, Bathroom, and Shower Room Requirements
2. **Objective of the rule**
The objective of the rule is to specify requirements related to restrooms, bathrooms, and shower rooms in a public school.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable, however, could be improved by clarifying that a lavatory is not required to have multiple hand dryers and that if a school provides cloth towels, the cloth towels are machine washed with detergent and machine dried after each use.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
In the past five years, the Department has not received any reports from a county health department that this rule, specifically the matters discussed in paragraph 6, has created a burden to regulated persons. Therefore, even though the rule could be improved as described in paragraph 6, the Department has determined that the rule continues to provide the least burden and costs to persons regulated by the rule and achieves the regulatory objective consistent with statutory requirements.

R9-8-704. **Cafeterias and Food Service**
2. **Objective of the rule**
The objective of the rule is to specify requirements related to cafeterias and food service in a public school.

R9-8-705. **Indoor Areas**
2. **Objective of the rule**
The objective of the rule is to specify requirements related to indoor areas of a public school.

R9-8-706. **Water Supply**
2. **Objective of the rule**
The objective of the rule is to specify requirements related to the water supply in a public school.

R9-8-707. **Sewage Disposal**
2. **Objective of the rule**
The objective of the rule is to specify requirements related to the disposal of sewage in a public school.
R9-8-708. Refuse Management

2. **Objective of the rule**
   The objective of the rule is to specify requirements related to the management of refuse at a public school.

R9-8-709. Animal Standards

2. **Objective of the rule**
   The objective of the rule is to specify requirements related to keeping an animal at a public school.

R9-8-710. Pest Control

2. **Objective of the rule**
   The objective of the rule is to specify requirements related to the control of pests in a public school.

R9-8-711. Inspections

2. **Objective of the rule**
   The objective of the rule is to specify requirements for inspections of public schools by the Department.
FIVE-YEAR-REVIEW REPORT

TITLE 9. HEALTH SERVICES

CHAPTER 8. DEPARTMENT OF HEALTH SERVICES

FOOD, RECREATIONAL, AND INSTITUTIONAL SANITATION

ARTICLE 1. FOOD AND DRINK

April 2016
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   2012 RULEMAKING
7. WRITTEN COMMENTS .............................................................. Attachment D
Arizona Revised Statutes (A.R.S.) § 36-136(H)(4) requires the Department to “prescribe reasonably necessary measures to assure that all food or drink, including meat and meat products and milk and milk products sold at the retail level, provided for human consumption is free from unwholesome, poisonous or other foreign substances and filth, insects or disease-causing organisms.” It further requires the rules adopted by the Department to “prescribe reasonably necessary measures governing the production, processing, labeling, storing, handling, serving and transportation” of food and drink and include minimum standards for the sanitary facilities and conditions that are to be “maintained in any warehouse, restaurant or other premises, except a meat packing plant, slaughterhouse, wholesale meat processing plant, dairy product manufacturing plant or trade product manufacturing plant.” The rules are to “prescribe minimum standards for any truck or other vehicle in which food or drink is produced, processed, stored, handled, served or transported.” The Department is responsible “for the inspection and licensing of premises and vehicles so used and for abatement as public nuisances of any premises or vehicles that do not comply with the rules and minimum standards.”

Additional statutes that address specific areas of food and drink include A.R.S. § 36-132(A)(13), A.R.S. § 36-136(H)(5), and A.R.S. § 36-136(H)(7). A.R.S. § 36-132(A)(13) requires the Department to take “all actions necessary or appropriate to ensure that bottled water sold to the public and water used to process, store, handle, serve and transport food and drink are free from filth, disease-causing substances and organisms and unwholesome, poisonous, deleterious or other foreign substances.” A.R.S. § 36-136(H)(5) requires the Director to prescribe “reasonably necessary measures to assure that all meat and meat products for human consumption handled at the retail level are delivered in a manner and from sources” approved by the Arizona Department of Agriculture and “are free from unwholesome, poisonous or other foreign substances and filth, insects or disease-causing organisms.” The rules are to “prescribe standards for sanitary facilities to be used in identity, storage, handling and sale of all meat and meat products sold at the retail level.” A.R.S. § 36-136(H)(7) requires the Department to “define and prescribe reasonably necessary measures governing ice production, handling, storing and distribution to assure that all ice sold or distributed for human consumption or for the preservation or storage of food for human consumption is free from unwholesome, poisonous, deleterious or other foreign substances and filth or disease-causing organisms.” The rules are to contain “minimum standards for the sanitary facilities and conditions and the quality of ice” that is to be “maintained at any ice plant, storage and truck or vehicle in which ice is produced, stored,
handled or transported” and “provide for inspection and licensing of the premises and vehicles, and for abatement as public nuisances of ice, premises, equipment, processes or vehicles that do not comply with the minimum standards.”

The Department has adopted in Arizona Administrative Code (A.A.C.) Title 9, Chapter 8, Article 1, rules to implement A.R.S. § 36-136(H)(4) by providing standards that ensure that food and drink in Arizona are fit for human consumption. The rules were initially adopted in October 2001 and incorporated the United States Food and Drug Administration (FDA) publication, *Food Code: 1999 Recommendations of the United States Public Health Service, Food and Drug Administration* (FC) as modified. Only three of the rules have been amended since they were adopted. R9-8-102 was amended in 2003 to exempt hospice inpatient facilities from the requirements of the Article. R9-8-102 was again amended, along with R9-8-107, in 2006 to include milk and milk products sold at the retail level under this Article, to implement Laws 2004, Ch. 51. R9-8-101 was amended and R9-8-102 was further amended in 2012 to clarify requirements and exempt certain categories of foods, in compliance with Laws 2006, Ch. 272, § 1; Laws 2008, Ch. 149 § 1; and Laws 2011, Ch. 84, § 1.

The sanitarians in the Department and in the health departments or environmental health departments of Arizona’s counties use these rules in conjunction with county codes while conducting inspections of licensed food establishments. In FY2015, there were 33,217 regulated food establishments in Arizona, at which state and county sanitarians conducted 80,484 food safety-related inspections (routine or re-inspection). The frequency of inspections depends on the complexity of the food service operations, with those facilities conducting more complex operations being inspected more frequently. In addition, the individuals in 168 sanitarian FTEs and 15.5 sanitarian aide FTEs conducted 7,237 pre-operational inspections of new facilities, 8,971 complaint investigations, and 8,499 inspections of temporary food operations. These inspections resulted in 1,001 compliance proceedings.

The Department had begun a rulemaking to amend the rules in 9 A.A.C. 8, Article 1, in January 2007 and was in the process of revising the rules to incorporate the 2005 FC when the rulemaking moratorium was established in January 2009 and rulemaking was halted. In the 2011 five-year-review report, the Department stated that the Department would amend R9-8-102 to be consistent with statutory changes, but would wait until the 2013 version of the FC was released before deciding what further rulemaking should be done. The Department did not anticipate completing other rulemaking until after the 2016 five-year-review report was due. Since then, two counties have adopted the 2009 FC, and four have adopted the 2013 FC, with two more working towards the adoption of the 2013 FC. Because of the issues identified in this five-year-review report, the Department plans to amend the rules in 9 A.A.C. 8, Article 1, by April 2019 to improve the effectiveness of the rule.
1. **Authorization of the rule by existing statute**
   The rules in 9 A.A.C. 8, Article 1, have A.R.S. §§ 36-136(A)(7) and 36-136(F) as general statutory authority.
   The rules in 9 A.A.C. 8, Article 1, have specific statutory authority in A.R.S. §§ 36-104(1)(b)(i), 36-132(A)(13), 36-136(H)(4), 36-136(H)(5), and 36-136(H)(7).

2. **The purpose of the rule**
   The purpose of the rules in 9 A.A.C. 8, Article 1, is to prescribe reasonably necessary measures to assure that all food or drink sold at the retail level are fit for human consumption.

7. **Summary of the written criticisms of the rule received within the last five years**
   Except for criticisms of R9-8-102 and R9-8-107 provided as Attachment D, the Department has not received written criticisms of the rules in 9 A.A.C. 8, Article 1, during the past five years.

8. **Economic, small business, and consumer impact comparison**
   The food and drink rules were adopted by final rulemakings published in the *Arizona Administrative Register* (A.A.R.) at 7 A.A.R. 1719, effective October 3, 2001. The rules were amended by rulemaking at 9.A.A.R. 317, effective March 14, 2003; 12.A.A.R. 2768, effective September 9, 2006; and 17 A.A.R. 2608, effective February 4, 2012. The 2001 rulemaking incorporated by reference the 1999 FC publication by the FDA, as modified. The 1999 FC uses a “science-based food evaluation system known as Hazard Analysis and Critical Control Point” (HACCP) to ensure food safety. An economic, small business, and consumer impact statement (EIS) was submitted to the Governor’s Regulatory Review Council (GRRC) as part of the Notice of Final Rulemaking package for the rulemaking effective October 3, 2001. The EIS stated the anticipation of a substantial economic benefit to employers and the general public from the reduced risk of foodborne illnesses resulting from food establishments implementing the practices required in the 1999 FC. Each food establishment was expected to incur minimal costs for training employees, especially the person in charge, on the new requirements; counties might also incur short-term substantial costs to train inspectors on the new standards, which could be offset by “a more efficient regulatory process” once inspectors and the regulated community became familiar with the rules. Food establishments in general could incur substantial costs from the time to “modify and monitor food processes” and employee personal hygiene practices to meet the 1999 FC requirements. Both food establishments and regulatory authorities could receive a benefit from the added flexibility and allowances for variances if an approved HACCP plan were used to prepare food. Allowing a 10-year period, rather than the five-year period projected in the
1999 FC, for a food establishment to come into compliance with a reduction in cold storage temperatures from 45° to 41° F and allowing the hot holding temperature to be 130°, rather than 140° F in the 1999 FC, were thought to help mitigate the potentially substantial costs for implementing time and temperature controls associated with adopting the 1999 FC. The 2003 rulemaking added an exemption for hospice inpatient facilities with 20 or fewer patients to the list of exemptions from the food and drink rules in R9-8-102, and provided a significant benefit to these health care institutions and their patients. An EIS was not submitted because the rulemaking was exempt from the requirement under A.R.S. § 41-1055(D)(3), as stated in the Notice of Final Rulemaking. The 2006 rulemaking amended R9-8-102 and R9-8-107 to make these rules consistent with A.R.S. § 36-136(H)(4), as amended by Laws 2004, Ch. 51, effective August 25, 2004. The 2006 rulemaking removed milk and milk products from the list of exemptions from the food and drink rules in R9-8-102 and incorporated portions of the FC that apply to milk and milk products into R9-8-107. An EIS was submitted to GRRC with the 2006 rulemaking, stating that a person selling milk or milk products at the retail level might incur minimal-to-substantial costs to become licensed as a food establishment, if not already licensed, and to comply with the 1999 FC requirements for milk or milk products. The Department was unaware of any persons selling milk or milk products at the retail level that were not already licensed as food establishments. County health departments, which perform the bulk of food establishment license inspections, were expected to incur minimal additional costs to inspect currently licensed food establishments and moderate additional costs to inspect a new food establishment requesting licensing for adherence to requirements for milk and milk products. The 2012 rulemaking amended R9-8-101 and R9-8-102 to make these rules consistent with A.R.S. § 36-136(H)(4), as amended by Laws 2006, Ch. 272; Laws 2008, Ch. 149; and Laws 2011, Ch. 84 by exempting certain categories of food and drink from requirements of the Article. An EIS was submitted to GRRC with the 2006 rulemaking and specified that only the economic impacts directly attributable to the rulemaking would be considered in the EIS. The EIS stated that regulated food establishments were expected to receive a significant benefit from the rule’s clarification of the applicability of the rules in 9 A.A.C. 8, Article 1; persons providing food or drink that is statutorily exempt were expected to receive a significant benefit from being better able to determine whether they are required to apply for a license as a food establishment and, for those exempt, a minimal-to-substantial benefit from saving the costs of becoming a licensed food establishment and complying with requirements in 9 A.A.C. 8, Article 1. The Department believes the costs and benefits identified in the 2001, 2006, and 2012 EISs are generally consistent with the actual costs and benefits of the rules.
9. **Summary of business competitiveness analyses of the rules**
The Department did not receive a business competitiveness analysis of the rules in the last five years.

10. **Status of the completion of action indicated in the previous five-year-review report**
As stated in the 2011 five-year-review report, the Department planned to amend R9-8-102 to be consistent with statutory changes but did not plan to amend the rest of the rules in 9 A.A.C. 8, Article 1, until after the 2016 five-year-review report was due. The Department completed the rulemaking action proposed in the previous five-year-review report through the rulemaking effective February 4, 2012.

12. **Analysis of stringency compared to federal laws**
The rules are not more stringent than federal laws.

13. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**
Since neither R9-8-101 nor R9-8-102 establish licensing, certification, or permit requirements, the rules establishing licensing, certification, or permit requirements were adopted before July 29, 2010.

14. **Proposed course of action**
The Department intends to amend the rules in 9 A.A.C. 8, Article 1, to incorporate a more recent version of the FC and make other changes to address issues described in this report and improve the effectiveness of the rules. To allow time for adequate stakeholder input into revised rules and the review of the next version of the FC, the Department anticipates submitting a Notice of Final Rulemaking to the Governor’s Regulatory Review Council (GRRC) by April 2019. This timetable is subject to change based on the Department’s priorities and staffing.
INFORMATION FOR INDIVIDUAL RULES

R9-8-101. Definitions
2. **Objective of the rule**
The objective of the rule is to define terms and phrases used in the Article to enable the reader to clearly understand the requirements of the Article and allow for consistent interpretation.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective but could be improved if the issues described in paragraph 6 were addressed.

4. **Analysis of consistency with state and federal statutes and rules**
The rule is consistent with cited state and federal statutes and rules.

5. **Status of enforcement of the rule**
The Department is enforcing the rule to the extent that definitions can be enforced.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable but could be improved by adding definitions of undefined terms used in R9-8-103, as specified in paragraph 6 for the Section. The rule could also be improved by replacing the period after subsection (2)(g) with a semicolon.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Because of the issues described in paragraph 6 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-8-102. Applicability
2. **Objective of the rule**
The objective of the rule is to specify the categories of facilities and foods to which the rules apply and those that are exempt from the Article.

3. **Analysis of effectiveness in achieving the objective**
The rule is mostly effective in achieving its objective. The effectiveness of the rule is decreased by the issues described in paragraphs 4 and 6.

4. **Analysis of consistency with state and federal statutes and rules**
Subsection (B)(9)(f) of the rule is inconsistent with A.R.S. § 36-136(H)(4)(f), as amended by Laws 2013, Ch.6, which removed the limitation on the display area for food that is not potentially hazardous. In addition, many of the cross references in subsection (B) are not specific or are incorrect. “Group home” is defined in A.R.S. § 36-551, within A.R.S. Title 36, Chapter 5.1,
Article 1; “child care group home” is defined in A.R.S. § 36-897, within A.R.S. Title 36, Chapter 7.1, Article 4; and “residential group care facility” is defined in A.A.C. R6-5-7401, within 6 A.A.C. 5, Article 74. The definition of “assisted living home” is in A.R.S. § 36-401. The term “adult day health care services” is not defined, but “adult day health care facility” and “adult day health services” are both defined in A.R.S. § 36-401. Due to the recent rulemakings for 9 A.A.C. 10 and 9 A.A.C. 20, the cross references for “behavioral health service agencies” and “hospice inpatient facilities” are also incorrect.

5. **Status of enforcement of the rule**
The rule is enforced as written, except that the correct definitions of the terms in subsection (B) are used when determining if the Article applies to a facility.

6. **Analysis of clarity, conciseness, and understandability**
The rule is mostly clear, concise, and understandable. The clarity of the rule could be improved by separating out the types of facilities to which the Article does not apply from the types of foods to which the Article does not apply. It is also unclear what the term “partial care services” in subsection (B)(7) means.

7. **Summary of the written criticisms of the rule received within the last five years**
**Crisisim:** The Department has received a written criticism of the rule from a county representative, questioning whether interstate food processing facilities should be regulated under the Article and asking for “appropriate code or statute references relevant to” such regulation.

The Department has received other comments about whether breweries are regulated under the Article. The Department has received several comments expressing confusion about whether activities, such as honey production, amaranth processing, dove or crayfish preparation, or nut, seed, trail mix, and candy re-packaging, are regulated under the Article.

**Response:** As stated in paragraph 14 under Information That Is Identical for All of the Rules, the Department plans to amend the rules in 9 A.A.C. 8, Article 1, by April 2019. As part of the rulemaking, the applicability of the Article will be clarified to improve the effectiveness of the rule.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Because of the issues described in paragraphs 4 and 6 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.
R9-8-103. Food Establishment License Application

2. **Objective of the rule**
   The objective of the rule is to explain the process an applicant must follow to apply for a food establishment license.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective but could be improved if the issues described in paragraph 6 were addressed.

4. **Analysis of consistency with state and federal statutes and rules**
   The rule is consistent with cited state and federal statutes and rules, but the inclusion of subsection (A)(7)(g) may be confusing as described in paragraph 6.

5. **Status of enforcement of the rule**
   The rule is enforced as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is mostly clear, concise, and understandable but could be improved. The terms “mobile,” “stationary,” “temporary,” and “permanent” are open to interpretation and should be defined or described. The rule states in subsection (A)(5)(a) that a food establishment may be under construction when an application is submitted. However, subsection (A)(2) requires the telephone number of the food establishment, which may not be available for a food establishment under construction. In addition, the inclusion of subsection (A)(7)(g) in an application for a food establishment license is confusing because, under A.R.S. § 36-136(H)(4)(f), as amended by Laws 2013, Ch.6, the rules in 9 A.A.C. 8, Article 1 do not apply to prepackaged food that is not potentially hazardous.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Because of the issues described in paragraph 6 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-8-104. Time-frames

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. §§ 41-1073 through 41-1076 as additional specific statutory authority.

2. **Objective of the rule**
   The objective of the rule is to specify the administrative procedures the regulatory authority will perform during the time-frames in Table 1.
3. **Analysis of effectiveness in achieving the objective**
The rule is mostly effective in achieving its objective but could be improved. The rule contains administrative procedures related to the licensing process, including the issuance of a license itself, approval of a variance, approval of plans and specifications, and approval of a “HACCP PLAN.” These administrative procedures may be performed by any regulatory authority. However, the administrative procedures associated with a “requestor” may only be performed by the Department since the “requestor” of approval of an inspection form or quality assurance program is another regulatory authority. In addition, these latter approvals are not subject to the provisions of A.R.S. Title 41Chapter 6, Article 7.1, since they are only tangentially related to licensing and more associated with the delegation of authority. Therefore, the effectiveness of the rule would be improved by removing administrative procedures associated with requests for approval by a “requestor” from this rule or moving them into a separate Section.

4. **Analysis of consistency with state and federal statutes and rules**
The rule is consistent with cited state and federal statutes and rules.

5. **Status of enforcement of the rule**
The rule is enforced as written.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Because of the issues described in paragraph 3 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

### Table 1. Time-frames (in days)

1. **Authorization of the rule by existing statute**
The table has A.R.S. §§ 41-1073 through 41-1076 as additional specific statutory authority.

2. **Objective of the rule**
The objective of the table is to establish the time-frames for the regulatory authority’s administrative processes for the approvals issued under this Article.

3. **Analysis of effectiveness in achieving the objective**
The table is effective in achieving its objective but could be improved if the time-frames for approval of an inspection form or quality assurance program were removed from the table.
4. **Analysis of consistency with state and federal statutes and rules**  
The rule is consistent with cited state and federal statutes and rules.

5. **Status of enforcement of the rule**  
The rule is enforced as written.

6. **Analysis of clarity, conciseness, and understandability**  
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**  
Despite the minor issue described in paragraph 3, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-8-105. **Issuance of License**

2. **Objective of the rule**  
The objective of the rule is to specify the information that a regulatory authority is required to put on a food establishment license to identify a licensed food establishment.

3. **Analysis of effectiveness in achieving the objective**  
The rule is effective, but it could be improved by requiring the name, address, and telephone number of the regulatory authority issuing the license to be on the license.

4. **Analysis of consistency with state and federal statutes and rules**  
The rule is consistent with cited state and federal statutes and rules.

5. **Status of enforcement of the rule**  
The rule is enforced as written.

6. **Analysis of clarity, conciseness, and understandability**  
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**  
Despite the minor issue described in paragraph 3, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.
R9-8-106. License Suspension or Revocation

2. **Objective of the rule**
   The objectives of the rule are to:
   a. Explain the regulatory authority’s power to suspend or revoke a food establishment license if the food establishment is in violation of the rules in this Article, and
   b. Provide information about revocation or suspension hearings.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective, but it could be improved by removing subsection (B)(3). The citation in subsection (B)(3) to A.R.S. § 36-183.04(E) in the rule adopted in 2001 is incorrect because it refers to text in A.R.S. § 36-183.04 that was repealed by Laws 2002, Ch. 313, § 3. The current text in A.R.S. § 36-183.04 was added by Laws 2002, Ch. 313, § 4, and is not relevant.

4. **Analysis of consistency with state and federal statutes and rules**
   The rule is consistent with A.R.S. § 36-136(H)(4) and the other cited statutory authorities, but the citation in subsection (B)(3) to A.R.S. § 36-183.04 is incorrect, as described in paragraph 3.

5. **Status of enforcement of the rule**
   The rule is enforced as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Because of the issues described in paragraphs 3 and 4 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-8-107. Food Safety Requirements

2. **Objective of the rule**
   The objective of the rule is to explain the food safety requirements a licensed food establishment must follow in order to maintain food safety and be licensed to operate in Arizona.

3. **Analysis of effectiveness in achieving the objective**
   The rule is partly effective in achieving its objectives. The rule incorporates the 1999 FC as modified. Since this rule was made, three revisions of the FC have been released by the FDA. The rule would be more effective in protecting health and safety if the rule were amended to
incorporate a newer version of the FC. As part of the rulemaking planned for 9 A.A.C. 8, Article 1, the Department plans to compare the requirements in the FCs and obtain input from licensed food establishments and sanitarians who use the rules before deciding what requirements will be incorporated into revised rules.

4. **Analysis of consistency with state and federal statutes and rules**
The rule is consistent with cited state and federal statutes and rules.

5. **Status of enforcement of the rule**
The rule is enforced as written.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable but could be improved by revising subsection (A) to meet current style and format standards.

7. **Summary of the written criticisms of the rule received within the last five years**
**Criticism:** The Department has received a written criticism of the rule from a representative of a restaurant chain, expressing concern that the rule still incorporates by reference the 1999 FC, rather than the most recent version of the FC.

**Response:** As stated in paragraph 14 under *Information That Is Identical for All of the Rules*, the Department plans to amend the rules in 9 A.A.C. 8, Article 1, by April 2019 to incorporate a more recent version of the FC and to improve the effectiveness of the rule.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Because of the issues described in paragraph 3 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-8-108. **Inspections Standardization and Documentation**

2. **Objective of the rule**
The objective of the rule is to specify the process a regulatory authority must follow when inspecting a food establishment.

3. **Analysis of effectiveness in achieving the objective**
The rule is somewhat effective in achieving its objective but could be improved in several ways. The inspection report specified in subsection (B) would be improved if the name, address, and telephone number of the regulatory authority conducting the inspection were included on the report. The rule would also be more effective if the issue described in paragraph 5 were
addressed. The rule would also be improved if information about creating separate inspection
forms and requesting approval of a quality assurance program, as specified in subsections (D) and
(E), were removed from the rules or placed in a separate Section.

4. **Analysis of consistency with state and federal statutes and rules**
The rule is consistent with cited state and federal statutes and rules.

5. **Status of enforcement of the rule**
The rule is not enforced as written. Some counties, which have adopted more recent versions of
the FC, are not using the term “critical items” in inspection reports. Instead they categorize a
violation as “priority” (is likely to cause a food-borne illness), “priority foundation” (may lead to
a food-borne illness if other conditions are present), and “core” (is not according to basic to good
food-handling practices). In addition, in counties that have adopted a newer version of the FC,
violations may not be cited with the FC sections listed in the rule.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable but could be improved as described in paragraphs 3
and 5.

11. **A determination that the probable benefits of the rule outweigh within this state the
probable costs of the rule, and the rule imposes the least burden and costs to persons
regulated by the rule, including paperwork and other compliance costs, necessary to
achieve the underlying regulatory objective**
Because of the issues described in paragraphs 3 and 5 of the analysis of this rule, the rule does not
impose the least burden and costs on persons regulated by the rule.

R9-8-109. **Cease and Desist and Abatement**

2. **Objective of the rule**
The objectives of the rule are to:
   a. Notify the reader that a violation of this Article constitutes a public nuisance, and
   b. Explain the process a regulatory authority initiates if the regulatory authority has
      reasonable cause to believe that a food establishment is creating or maintaining a public
      nuisance.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective but could be improved by addressing the issues
identified in paragraphs 4 and 6.

4. **Analysis of consistency with state and federal statutes and rules**
The rule is consistent with A.R.S. § 36-136(H)(4) and the other cited statutory authorities, but the citation in subsection (B)(4)(b) to A.R.S. § 36-183.04(E) is incorrect, because the text in A.R.S. § 36-183.04 to which the rule refers was repealed by Laws 2002, Ch. 313, § 3.

5. **Status of enforcement of the rule**
   The rule is enforced as written.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is mostly clear, concise, and understandable but could be improved by clarifying that information about the alleged nuisance should be included in the order.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Because of the issues described in paragraphs 4 and 6 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.
FIVE-YEAR-REVIEW REPORT

TITLE 9. HEALTH SERVICES

CHAPTER 14. DEPARTMENT OF HEALTH SERVICES LABORATORIES

ARTICLE 7. HEALTH SCREENING SERVICES

February 2016
FIVE-YEAR-REVIEW REPORT

TITLE 9. HEALTH SERVICES

CHAPTER 14. DEPARTMENT OF HEALTH SERVICES LABORATORIES

ARTICLE 7. HEALTH SCREENING SERVICES

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Arizona Revised Statutes (A.R.S.) § 36-405.01 specifies the manner in which health screening services are required to be conducted and authorizes the Arizona Department of Health Services (Department) to “adopt such ... regulations necessary or appropriate to carry out the purposes of this section.” “Health screening services” is defined in A.R.S. § 36-401 as “the acquisition, analysis and delivery of health-related data of individuals to aid in the determination of the need for medical services.”

In the 2006, effective February 2007, the Department allowed all Sections of Article 7 to expire except Arizona Administrative Code R9-14-701. The Department revised R9-14-701 to include necessary definitions and requirements for health screening laboratory services to accomplish the purpose of A.R.S. § 36-405.01.

The Department adopted in R9-14-701 all definitions and requirements for health screening laboratory services consistent with Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 C.F.R. 493, Laboratory Requirements. After an analysis of R9-14-701, the Department has determined that the rule is effective; is consistent with state and federal statutes and rules; is enforced; and is clear, concise, and understandable. The Department has received no written criticism of the rule. The Department estimates that the actual economic impact of the rules is consistent with the 2006 Economic Impact Statement for the rulemaking. The Department does not plan to amend the rule as indicated in the report.
INFORMATION FOR INDIVIDUAL RULES

R9-14-701. Health Screening Laboratory Services

1. **Authorization of the rule by existing statute**
   The general statutory authority for the rule is A.R.S. §§ 36-132(A)(1) and 36-136(F).
   The specific statutory authority for the rule is A.R.S. § 36-405.01.

2. **The purpose of the rule**
   The purpose of the rule is to provide definitions and requirements for persons conducting health screening laboratory services and specifies situations in which the rules does not apply.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

4. **Analysis of consistency with state and federal statutes and rules**
   The rule is consistent with state and federal statutes and rules.

5. **Status of enforcement of the rule**
   The rule is enforced as written without difficulty.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

7. **Summary of the written criticisms of the rule received within the last five years**
   The Department has not received any written criticisms of the rule in the past five years.

8. **Economic, small business, and consumer impact comparison**
   The Department conducts surveys of clinical laboratories, under a federal contract, to ensure compliance with CLIA. The 2006 Economic, Small Business, and Consumer Impact Statement (EIS) stated that the Department might incur minimal-to-moderate costs if more persons applied for and received a CLIA certificate due to the rule. Since 2006, the Department has received no requests for CLIA applications in conjunction with individuals inquiring about health screenings. All of the facilities that inquire about health screenings were already CLIA-certified facilities. The Department has determined that the actual economic impact of the rule is as stated in the 2006 EIS.
9. **Summary of business competitiveness analyses of the rules**
   The Department did not receive a business competitiveness analysis of the rule in the last five years.

10. **Status of the completion of action indicated in the previous five-year-review report**
    As stated in the 2011 Five-year-review Report, the Department did not amend the rules.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
    The rule imposes the least burden and costs to persons regulated by the rule while achieving the regulatory objective consistent with statutory requirements.

12. **Analysis of stringency compared to federal laws**
    The rule is not more stringent than federal laws.

13. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**
    The rule was adopted in 2006 and has not been changed.

14. **Proposed course of action**
    The Department does not plan to amend the rule in 9 A.A.C. 14 Article 7 until a substantive issue with the rule arises.
FIVE-YEAR-REVIEW REPORT  
TITLE 9. HEALTH SERVICES  
CHAPTER 17. DEPARTMENT OF HEALTH SERVICES  
MEDICAL MARIJUANA PROGRAM  
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On November 2, 2010, Arizona voters passed I-04-2010, the Arizona Medical Marijuana Act (Act), which became Arizona Revised Statutes (A.R.S.) Title 36, Chapter 28.1. The Act allows a "qualifying patient" who has a "debilitating medical condition" to obtain an "allowable amount of marijuana" from a "nonprofit medical marijuana dispensary" and to possess and use the marijuana to treat or alleviate the debilitating medical condition or symptoms associated with the medical condition. The Act also requires the Arizona Department of Health Services (Department) to adopt and enforce a regulatory system for the distribution of marijuana for medical use, including a system for approving, renewing, and revoking the registration of qualifying patients, designated caregivers, dispensaries, and dispensary agents. The Department implemented A.R.S. Title 36, Chapter 28.1 in Arizona Administrative Code (A.A.C.) Title 9, Chapter 17.

The rules in 9 A.A.C. 17 were originally adopted by exempt rulemaking, effective April 14, 2011. The rules in Article 1 contain requirements that affect qualifying patients, designated caregivers, dispensaries, and dispensary agents. Article 1 provides definitions, time-frames, and expiration information; specifies fees, general requirements for submitting applications, and procedures for changing information on a registry identification card or requesting a replacement registry identification card; and identifies requirements related to adding a debilitating medical condition. Article 2 contains requirements associated with qualifying patients and designated caregivers. Article 3 contains the requirements associated with dispensaries and dispensary agents. Subsequently, a court order (CV 2011-011290) invalidated several rules in 9 A.A.C. 17 related to dispensary eligibility and application requirements and caused the Department to amend the rules. Several rules were amended by emergency rulemaking, effective April 11, 2012, with a subsequent regular rulemaking, effective December 5, 2012.

On July 29, 2013, the Arizona Superior Court issued an order (CV 2013-005901) directing the Department to establish by rule a process by which the Department may consider the reasons why a dispensary had not obtained an approval to operate within a year after being allocated a dispensary registration certificate and criteria by which to decide whether a dispensary registration certificate should be renewed despite the dispensary not receiving an approval to operate. Under an exception to the rulemaking moratorium established by Executive Order 2012-03, the Department began amending the rules in 9 A.A.C. 17 to comply with the court order and to make other changes that may reduce the regulatory burden, improve processes, increase security, or enhance clarity and consistency. When Executive Order 2015-01 established
a new rulemaking moratorium, the Department discontinued rulemaking activity and requested an exception to the moratorium to continue the rulemaking. An exception was received on February 1, 2016.

Through an analysis of the rules in 9 A.A.C. 17, the Department has determined that a number of rules could be revised to improve their effectiveness or to clarify their content, as described in this report, in addition to changes required by the court order. The Department plans to resume rulemaking and to submit a Notice of Final Rulemaking to the Governor’s Regulatory Review Council (Council) by December 2017.
INFORMATION THAT IS IDENTICAL FOR ALL THE RULES

1. **Authorization of the rule by existing statute**
The rules in 9 A.A.C. 17 have A.R.S. § 36-136(F) as general statutory authority and A.R.S. § 36-2803 as specific rulemaking authority.
The rules in Article 2 have additional specific statutory authority in A.R.S. §§ 36-2804.02 through 36-2804.05.
The rules in Article 3 have additional specific statutory authority in A.R.S. §§ 36-2804, 36-2804.03 through 36-2804.06, and 36-2806.

2. **The purpose of the rule**
Except for R9-17-106, the purpose of the rules in Article 1 is to specify requirements that affect qualifying patients, designated caregivers, and dispensaries and dispensary agents.
The purpose of the rules in Article 2 is to specify requirements for qualifying patients and designated caregivers.
The purpose of the rules in Article 3 is to specify requirements for dispensaries and dispensary agents.

4. **Analysis of consistency with state and federal statutes and rules**
The rules are consistent with state statutes and rules and, to the extent that federal statutes and regulations are consistent with state statutes, with federal statutes and regulations.

5. **Status of enforcement of the rule**
Except for R9-17-308, which is enforced as required by court order, CV 2013-005901, the Department enforces the rules as written.

7. **Summary of the written criticisms of the rule received within the last five years**
The Department has received many comments on the Department’s implementation of the current rules and on the possible rule changes to the rules during the rulemaking that had been discontinued by the moratorium established by Executive Order 2015-01. Except for the written criticism of R9-17-202, the Department does not have a record of receiving any written criticisms of the rules that are not related to the discontinued rulemaking.

8. **Economic, small business, and consumer impact comparison**
For the purpose of this economic impact comparison, annual costs/revenues are designated as minimal when $5,000 or less, moderate when between $5,000 and $50,000, and substantial when $50,000 or greater in additional costs or revenues. A cost is listed as significant when meaningful or important, but not readily subject to quantification.

   The rules in 9 A.A.C. 17 were originally adopted by exempt rulemaking, effective April 14, 2011. Several rules were amended by emergency rulemaking, effective April 11, 2012, to
comply with a court order (CV 2011-011290) alleging that the Department did not have authority for some provisions in the rules. The Department conducted a subsequent regular rulemaking, effective December 5, 2012. Although minor changes were made to rules in Articles 1 and 2 through the regular rulemaking, the bulk of the changes were made to the rules in Article 3. An Economic, Small Business, and Consumer Impact Statement (EIS) was submitted with the regular rulemaking, which made changes to requirements for applicants for dispensary registration certificates, the allocation process, and time-frames for completion of the review of an application for a dispensary registration certificate; repealed R9-17-302; and made minor changes to other Sections in Article 3.

The rules in Article 1 contain requirements that affect qualifying patients, designated caregivers, dispensaries, and dispensary agents. Article 1 provides definitions, time-frames, and expiration information; specifies fees, general requirements for submitting applications, and procedures for requesting changes to information on a registry identification card or requesting a replacement registry identification card; and identifies requirements related to adding a debilitating medical condition. The Department uses an electronic system for all applications and registry identification card-related requests, including obtaining information for a new registry identification card. The rules contain requirements to ensure that the individual using the electronic system to request a replacement or change to a registry identification card is the individual for whom the registry identification card was initially issued. The Department believes that the information required in rule to obtain a replacement registry identification card or a registry identification card on which the cardholder’s name or address has been changed is the minimum necessary to achieve these purposes. If a cardholder has the required information/documents available, it may take the cardholder less than five minutes to make the request, thereby imposing at most a minimal burden on cardholders. The requirements to help ensure the correct individual receives the replacement or changed registry identification card provide a significant benefit to the cardholder to whom the registry identification card was initially issued and to the general public.

Over the past four years, approximately four requests to add debilitating medical conditions were received per review cycle or approximately eight per year. In January 2012, the Department received requests according to R9-17-106 to add Post-Traumatic Stress Disorder (PTSD), Depression, Migraines, and Generalized Anxiety Disorder to the list of debilitating medical conditions. After holding a public meeting on May 25, 2012, to collect public comments about the addition of these medical conditions, and reviewing medical and scientific literature about use of medical marijuana for the debilitating medical conditions, the Department denied the
requests. In July 2012 and January 2013, additional requests were received to add debilitating medical conditions, but the requests were denied without a public hearing. In July 2013, the Department received nine requests to add debilitating medical conditions, and a public hearing was held on October 29, 2013, to collect comments about PTSD, Depression, and Migraines. On January 15, 2014, the Department issued a decision denying the request for adding these medical conditions. Subsequent to an appeal of that decision and the receipt of more evidence for the benefit of palliative use of medical marijuana for PTSD, the Department issued a decision to add the palliative use of medical marijuana for PTSD beginning January 1, 2015.

The Department estimates that it costs the Department approximately $13,000 in staff time to process a request. This amount covers the costs of a review of the request; a review of medical, scientific, or other evidence submitted to or obtained by the Department related to the request; setting up and holding a public hearing; making a determination about the request; and notifying the requester of the Department’s decisions. For a request for which a public hearing is not scheduled, the cost would be less. The rules do not require a person to submit a request to add a debilitating medical condition or incur the cost of preparing a submission. Therefore, the rules impose a burden only on the Department, which may incur a moderate-to-substantial cost due to the rule. The public may receive a significant benefit from being able to have a debilitating medical condition added based on a request made according to the rule.

Article 2 contains requirements for qualifying patients and designated caregivers, including requirements for applying for, amending, or renewing a registry identification card and conditions under which a qualifying patient’s or designated caregiver’s registry identification card may be denied or revoked. The Department has issued more than 278,000 registry identification cards since April 14, 2011, over 94% of which were for qualifying patients. As of December 31, 2015, there were 87,733 qualifying patients with active registry identification cards. Of these, 11,093 qualifying patients (approximately 12%), who provided documentation of participation in the U.S. Department of Agriculture, Food and Nutrition Services, Supplemental Nutrition Assistance Program, paid a reduced fee for a registry identification card. As of December 31, 2015, 149 qualifying patients with active registry identification cards are minors. As of December 31, 2015, 789 designated caregivers (approximately 0.87% of cardholders) had active registry identification cards, including a custodial parent or legal guardian of a qualifying patient who is a minor.

The Department also uses the electronic system for individuals applying for, amending, or renewing a qualifying patient or designated caregiver registry identification card, and made the application process as simple as possible. If an applicant or cardholder has the required
information/documents available and submits the fee required in R9-17-102, it may take the applicant or cardholder only a few minutes, depending on the applicant’s computer skills and access to a computer, to complete the request for initial issuance of a qualifying patient or designated caregiver registry identification card or to amend or renew a qualifying patient or designated caregiver registry identification card. By using the electronic system for these actions, the Department attempted to impose the minimal burden on applicants or cardholders who are qualifying patients or designated caregivers, consistent with obtaining required information.

Before a qualifying patient can apply for a registry identification card, the Arizona Medical Marijuana Act (Act) requires the qualifying patient to obtain a certification from a physician stating that the qualifying patient has at least one of the debilitating medical conditions and that the physician is recommending the medical use of marijuana for the qualifying patient. The rules in Article 2 specify the information required for a physician’s certification, and the Department provides a form containing that information for a physician to use. From July 1, 2013 to December 31, 2015, a total of 934 physicians provided certifications to qualifying patients. Since much of the form contains check boxes, with a place for the physician’s initials, the Department estimates that it may take a physician only a few minutes to complete the form. Thus, a physician completing a certification for a qualifying patient may incur a minimal burden from the time it takes to complete the form, which would be offset by the fee paid by the qualifying patient for the examination and certification.

From July 1, 2014 to June 30, 2015, the Department voided a total of 2,898 cards for qualifying patients and designated caregivers. For the same period, the Department revoked the cards for seven designated caregivers and no qualifying patients. The Act specifies the conditions under which a registry identification card may be denied or revoked, which are reflected in rule. The Department estimates that the Department may incur costs from actions necessary to deny or revoke a registry identification card, but these costs are a result of the Act, not the rules.

Article 3 contains requirements for dispensaries and dispensary agents. In 2012, the Department conducted an allocation of dispensary registration certificates according to the rules adopted through the emergency rulemaking, which are no longer in effect. During May 2012, the Department accepted 486 dispensary registration certificate applications. Dispensary registration certificates were allocated based on one dispensary per Community Health Analysis Area (CHAA). For CHAAs for which more than one application was received that was complete and in compliance, the Department held a lottery on August 7, 2012. In total, 100 dispensary registration certificates have been allocated. The entities holding these dispensary registration certificates...
certificates are estimated to have received a substantial benefit from the rules in effect during the allocation process.

In the 2012 regular rulemaking, the time for completion of administrative and substantive reviews of applications for dispensary registration certificate was reduced to ensure compliance with the Act’s time-frames. The EIS stated that the Department might experience a moderate increase in cost due to the reduced time-frames allowed for the Department to complete the administrative and substantive reviews for dispensary registration certificate applications. Conversely, the Department estimated that the Department might receive a moderate benefit from clarifying language and cross-references and reducing the amount of time it would take the Department to review applications, since fewer documents were required to be submitted as part of an application. The Department anticipated that applicants for dispensary registration certificates might also receive a moderate benefit from clarifying language and cross-references and a moderate-to-substantial benefit from the reduction in the documents required to be submitted to the Department as part of an application for a dispensary registration certificate.

Since no dispensary registration certificates have been allocated under the current rules, the Department cannot determine whether the actual economic impact would be as estimated in the 2012 EIS.

The rules in Article 3 also specify requirements for an entity with a dispensary registration certificate to apply for an approval to operate a dispensary, to make changes to a dispensary registration certificate or the location of a dispensary or cultivation site, and to apply to renew a dispensary registration certificate. The Department believes that any requirements in rule not specifically required in statute may impose a minimal burden on entities applying for or holding a dispensary registration certificate. Similarly, administrative requirements in rule for operating a dispensary that are not specifically required in statute may impose a minimal burden on entities holding a dispensary registration certificate. As of December 31, 2015, 91 dispensaries have received an approval to operate, and all these dispensaries are currently available to dispense medical marijuana. During calendar year 2015, five entities holding a dispensary registration certificate submitted an application to change the location of a dispensary and three to change the location of a cultivation site, of which four of the five dispensary applications and all three cultivation site applications were approved.

Article 3 also contains requirements for operating a dispensary, including requirements for qualifying patient records, a medical director, inventory control, product labeling and analysis, security, edible food products, cleaning and sanitation, and physical plant. These requirements are based on what is specified in statute and were developed to help prevent diversion and ensure
that a dispensary meets minimum requirements for recordkeeping, security, and health and safety. The Department believes that these requirements may impose a substantial burden on entities applying for or holding a dispensary registration certificate, but would be offset by the substantial benefit of operating a dispensary.

Requirements for submitting a request for a dispensary agent registry identification card for an individual serving as a principal officer or board member for the dispensary, employed by the dispensary, or providing volunteer services at or on behalf of the dispensary, or to renew a dispensary registry identification card for such an individual are also contained in Article 3. Statutes specify application requirements, which are included in the rules. A dispensary may incur a minimal burden due to the rules for each dispensary agent registry identification card, which may be offset by the benefit of having an additional dispensary agent to assist in operating the dispensary. As of December 31, 2015, there were 2,250 dispensary agents (approximately 2.5% of cardholders) with active registry identification cards. From July 1, 2014 to June 30, 2015, the Department voided the cards for 537 dispensary agents and revoked the cards for 3 dispensary agents.

9. **Summary of business competitiveness analyses of the rules**
The Department did not receive a business competitiveness analysis of the rules in the last five years.

10. **Status of the completion of action indicated in the previous five-year-review report**
Not applicable. This is the first five-year-review report on these rules.

12. **Analysis of stringency compared to federal laws**
The rules are governed by Arizona statutes and are less stringent than federal laws.

13. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**
The rules establish licensing, certification, or permit requirements that comply with A.R.S. § 41-1037(A)(2). Dispensary registration certificates are issued under A.R.S. § 36-2804 for dispensaries, and registry identification card are issued under A.R.S. § 36-2804.01 for dispensary agents and under A.R.S. § 36-2804.02 for qualifying patients and designated caregivers.

14. **Proposed course of action**
The Department plans to continue the rulemaking to amend the rules in 9 A.A.C. 17 in response to the court order and to address issues identified in this report, now that the Department has received an exception from the rulemaking moratorium established by Executive Order 2015-01, and to submit a Notice of Final Rulemaking to the Council by December 2017.
INFORMATION FOR INDIVIDUAL RULES

ARTICLE 1. GENERAL

R9-17-101. Definitions

2. Objective
The objective of the rule is to define terms and phrases used in the Chapter to enable the reader to clearly understand the requirements of the Chapter and allow for consistent interpretation.

3. Analysis of effectiveness in achieving the objective
The rule’s effectiveness in achieving its objective could be enhanced by including “public transportation vehicles,” as well as “public transportation facilities,” in the definition of “public place.”

6. Analysis of clarity, conciseness, and understandability
The rule is clear, concise, and understandable, but the definitions of “batch” and “batch number” could be clearer. Since the term “enclosed area” is not used in the rules, the descriptions of the term expressed in the definition could be moved into the appropriate Sections. The definition of “residence address,” which is now in R9-17-202, could also be moved into the rule, since the term is also used in Sections in Articles 1 and 3.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective
Despite the minor clarifications needed, as described in paragraphs 3 and 6, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-17-102. Fees

2. Objective
The objectives of the rule are to specify the:

a. Fees required for applying for, renewing, or amending or changing a registry identification card or dispensary registration certificate; and

b. Reduced fee for a qualifying patient enrolled in the U.S. Department of Agriculture, Food and Nutrition Services, Supplemental Nutrition Assistance Program who submits documentation of enrollment.

3. Analysis of effectiveness in achieving the objective
The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-17-103. Application Submission

2. **Objective**
The objective of the rule is to specify general requirements for submitting a dispensary registration certificate application or an application to the Department for a registry identification card or to amend, change, or replace a registry identification card for a qualifying patient, designated caregiver, or dispensary agent.

3. **Analysis of effectiveness in achieving the objective**
The rule is mostly effective in achieving its objective but appears to be missing Arizona residential address requirements for a dispensary agent, other than a principal officer or board member, which are implied by the identification requirements in R9-17-311(5) and R9-17-312(2) for obtaining a dispensary agent registry identification card.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-17-104. Changing Information on a Registry Identification Card

1. **Authorization of the rule by existing statute**
The rule has A.R.S. § 36-2808 as additional specific authority.

2. **Objective**
The objective of the rule is to specify the requirements for a request to change a cardholder's name or address on the cardholder's registry identification card.

3. **Analysis of effectiveness in achieving the objective**
   The electronic system, which the Department uses for all registry identification card-related requests, requires a cardholder to provide documentation supporting the cardholder's identity before allowing the cardholder to undertake any action. The rule requires such documentation when requesting a name change on a registry identification card, but the rule could be more effective in achieving its objective if it also stated that the documentation is required when requesting a change in address.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Because of the issue described in paragraph 3 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.
regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective
Because of the issue described in paragraph 3 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-17-106. Adding a Debilitating Medical Condition

1. Authorization of the rule by existing statute
   The rule has A.R.S. § 36-2801.01 as additional specific authority.

2. Purpose/Objective
   The purpose of the rule is to specify a mechanism for adding a debilitating medical condition.
   The objectives of the rule are to:
   a. Identify requirements related to adding a debilitating medical condition, and
   b. Specify the review process.

3. Analysis of effectiveness in achieving the objective
   The rule is effective in achieving its objective.

6. Analysis of clarity, conciseness, and understandability
   The rule is clear, concise, and understandable.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective
   The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-17-107. Time-frames

1. Authorization of the rule by existing statute
   The rule has A.R.S. §§ 36-2804.01, 36-2819, 41-1073 through 41-1076, and 41-1079 as additional specific statutory authority.

2. Objective
   The objective of the rule is to specify the review-time-frame process for each type of approval in Table 1.1.

3. Analysis of effectiveness in achieving the objective
   The rule is effective in achieving its objective.

6. Analysis of clarity, conciseness, and understandability
The rule is mostly clear, concise, and understandable. The language in subsection (F)(2)(b) that states that the “Department shall deny the dispensary agent registry identification card application and provide notice…” could be revised to state that the Department shall issue a notice of an intent to deny the dispensary agent registry identification card application that complies with A.R.S. § 41-1092.03 to ensure that the affected individual knows that the denial can be appealed.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

Despite the minor clarification needed, as described in paragraph 6, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

**TABLE 1.1 Time-frames**

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. §§ 41-1073 through 41-1076, and 41-1079 as additional specific statutory authority.

2. **Objective**
   The objective of the rule is to specify time-frames for the Department to approve or deny an action specified in the Table.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

   The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

**R9-17-108. Expiration of a Registry Identification Card or a Dispensary Registration Certificate**

1. **Authorization of the rule by existing statute**
The rule has A.R.S. § 36-2804.06 as additional specific authority.

2. **Objective**
The objective of the rule is to specify when registry identification cards and dispensary registration certificates expire.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-17-109. **Notifications and Void Registry Identification Cards**

1. **Authorization of the rule by existing statute**
The rule has A.R.S. §§ 36-2804.06 and 36-2808 as additional specific authority.

2. **Objective**
The objective of the rule is to specify when and to whom notification is provided when the Department voids a registry identification card.

3. **Analysis of effectiveness in achieving the objective**
The rule is partially effective in achieving its objective, but does not first specify the conditions under which a registry identification card is void, before specifying the notification the Department provides when a registry identification card is void.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Because of the issue described in paragraph 3 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.
ARTICLE 2. QUALIFYING PATIENTS AND DESIGNATED CAREGIVERS

R9-17-201. Debilitating Medical Conditions
1. **Authorization of the rule by existing statute**
   The rule has A.R.S. § 36-2801 as additional specific authority.
2. **Objective**
   The objective of the rule is to specify the debilitating medical conditions, a diagnosis with which makes an individual eligible for a qualifying patient registry identification card.
3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.
6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.
11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-17-202. Applying for a Registry Identification Card for a Qualifying Patient or a Designated Caregiver
1. **Authorization of the rule by existing statute**
   The rule has A.R.S. § 36-2819 as additional specific authority.
2. **Objective**
   The objective of the rule is to specify requirements for a qualifying patient or, for a qualifying patient who is under 18 year of age, the qualifying patient’s custodial parent or legal guardian to apply for:
   a. A registry identification card for the qualifying patient; and
   b. If applicable, a registry identification card for a designated caregiver for the qualifying patient.
3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective. Although not affecting the effectiveness of this rule, the rules in 9 A.A.C. 17 would be more effective if the definition of “residence address” were moved from subsection (I) into R9-17-101.
6. **Analysis of clarity, conciseness, and understandability**
The rule is mostly clear, concise, and understandable, but it is not clear in subsection (F)(5) that a physician’s written certification that is submitted in support of an application must be from the physician identified in the application in subsection (F)(1).

7. **Summary of the written criticisms of the rule received within the last five years**
**Criticism:** The Department has received a written criticism of the rule from an individual who was concerned that the 25 miles “includes the area contained within a circle that extends for 25 miles in all directions from a specific location,” stating that the distance should be calculated based on the driving distance between a qualifying patient’s residence and the nearest operating dispensary, rather than “as the crow flies.”

**Response:** As stated in paragraph 14 under *Information That Is Identical for All of the Rules*, the Department plans to amend the rules in 9 A.A.C. 17 by December 2017. As part of the rulemaking, the Department may consider mechanisms to take into consideration the terrain or other circumstances that may affect road placement, which may make the driving distance in Arizona considerably farther than that distance on a map.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Because of the issue described in paragraph 6 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-17-203. **Amending a Qualifying Patient's or Designated Caregiver's Registry Identification Card**

1. **Authorization of the rule by existing statute**
The rule has A.R.S. § 36-2819 as additional specific authority.

2. **Objective**
The objective of the rule is to specify requirements for a qualifying patient to amend:
   a. A registry identification card to add a designated caregiver or to request a change of the qualifying patient's designated caregiver,
   b. The qualifying patient’s address on a registry identification card when the qualifying patient or the qualifying patient's designated caregiver is authorized to cultivate marijuana, or
   c. A registry identification card to add authorization to cultivate marijuana.
3. **Analysis of effectiveness in achieving the objective**
   The rule is mostly effective in achieving its objective but does not specify that a qualifying patient must submit a copy of an Arizona driver’s license, an Arizona identification card, or the photograph page in the qualifying patient’s U.S. passport when accessing the electronic system to request the amendment. The rule also does not allow a qualifying patient to remove a designated caregiver without replacement.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is mostly clear, concise, and understandable. The conciseness of the rule would be improved by removing the redundant wording in subsection (C)(4), “Whether the qualifying patient is requesting,” and (C)(5) “If the qualifying patient is requesting authorization for cultivating marijuana plants,” since the lead-in for the subsection already contains this information about the purpose of the subsection.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Despite the minor clarifications needed, as described in paragraphs 3 and 6, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-17-204. **Renewing a Qualifying Patient's or Designated Caregiver's Registry Identification Card**

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. § 36-2819 as additional specific authority.

2. **Objective**
   The objective of the rule is to specify requirements for a qualifying patient or, for a qualifying patient who is under 18 year of age, the qualifying patient’s custodial parent or legal guardian to apply for renewal of:
   a. A registry identification card for the qualifying patient; and
   b. If applicable, a registry identification card for a designated caregiver for the qualifying patient.

3. **Analysis of effectiveness in achieving the objective**
   The rule is mostly effective in achieving its objective but does not specify that a qualifying patient or, if the qualifying patient is under 18 year of age, the qualifying patient’s custodial
parent or legal guardian must submit a copy of an Arizona driver’s license, an Arizona identification card, or the photograph page in the qualifying patient’s or, if applicable, custodial parent’s or legal guardian’s U.S. passport when accessing the electronic system to request renewal of the registry identification card.

6. **Analysis of clarity, conciseness, and understandability**
The rule is mostly clear, concise, and understandable, but it is not clear in subsection (A)(5) that a physician’s written certification that is submitted in support of an application must be from the physician identified in the application in subsection (A)(1).

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Despite the minor clarifications needed, as described in paragraphs 3 and 6, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

**R9-17-205. Denial or Revocation of a Qualifying Patient's or Designated Caregiver's Registry Identification Card**

1. **Authorization of the rule by existing statute**
The rule has A.R.S. § 36-2815 as additional specific authority.

2. **Objective**
The objective of the rule is to specify:
   a. The circumstances under which the Department will deny an application for a qualifying patient registry identification card or a designated caregiver registry identification card or revoke a qualifying patient's or designated caregiver's registry identification card, and
   b. How the Department will provide notice of the denial or revocation.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
The rule is mostly clear, concise, and understandable. The language in subsections (G) and (H) that state that “If the Department denies or revokes . . . , the Department shall provide written notice…” could be revised to state that the Department shall issue a notice of an intent to deny or revoke the qualifying patient or designated caregiver registry identification card application that
complies with A.R.S. § 41-1092.03 to ensure that the affected individual knows that the denial or revocation can be appealed.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

Despite the minor clarification needed, as described in paragraph 6, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.
ARTICLE 3. DISPENSARIES AND DISPENSARY AGENTS

R9-17-301. Principal Officers and Board Members

2. **Objective**
The objective of the rule is to specify who the Department considers to be a principal officer or board member of an entity applying for or holding a dispensary registration certificate.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-17-303. Dispensary Registration Certificate Allocation Process

2. **Objective**
The objective of the rule is to specify the process the Department will use to allocate dispensary registration certificates.

3. **Analysis of effectiveness in achieving the objective**
The Department believes the rule would be effective in achieving its objective but has not conducted an allocation of dispensary registration certificates under this rule. The Department plans to conduct an allocation later in 2016.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.
R9-17-304. Applying for a Dispensary Registration Certificate

2. **Objective**
   The objectives of the rule are to specify:
   a. Limitations on the number of dispensary registration certificate applications for which an individual may be an applicant, principal officer, or board member;
   b. How the Department will handle situations when the limitation is exceeded;
   c. Requirements for applying for a dispensary registration certificate; and
   d. The requirement that an entity with a dispensary registration certificate applies for and obtains an approval to operate a dispensary before the entity begins operating a dispensary.

3. **Analysis of effectiveness in achieving the objective**
   The rule is mostly effective in achieving its objective but does not include a requirement for how current the documentation required in subsections (C)(6) and (7) must be.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Despite the minor clarification needed, as described in paragraph 6, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-17-305. Applying for Approval to Operate a Dispensary

2. **Objective**
   The objective of the rule is to specify the requirements for an entity with a dispensary registration certificate to apply for an approval to operate a dispensary.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons**
regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-17-306. Changes to a Dispensary Registration Certificate

2. Objective

The objective of the rule is to specify limitations on:

a. The transfer or assign the dispensary registration certificate;

b. A change in the location of a dispensary or cultivation site; and

c. A dispensary’s or cultivation site’s ability to cultivate, manufacture, distribute, dispense, or sell medical marijuana at a new location.

3. Analysis of effectiveness in achieving the objective

The rule is effective in achieving its objective.

6. Analysis of clarity, conciseness, and understandability

The rule is clear, concise, and understandable.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-17-307. Applying to Change a Dispensary's Location or Change or Add a Dispensary's Cultivation Site

2. Objective

The objectives of the rule are to:

a. Specify the mechanism by which a dispensary that is operating in a CHAA may change the location of the dispensary or the dispensary’s cultivation site or add a cultivation site, and

b. Provide notice that an application for a change in location may not be combined with an application for renewing a dispensary registration certificate.

3. Analysis of effectiveness in achieving the objective

The rule is effective in achieving its objective.
6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-17-308. **Renewing a Dispensary Registration Certificate**

2. **Objective**
The objective of the rule is to specify the requirements for an entity to renew a dispensary registration certificate.

3. **Analysis of effectiveness in achieving the objective**
The rule is mostly effective in achieving its objective, but the requirement in subsection (B)(3) for an applicant to include as part of the application a copy of an annual financial statement for the previous year may not be appropriate. Since a renewal of a dispensary registration certificate must, according to A.R.S. § 36-2804.03(A)(1), approve or deny an application for renewal within 10 days, it may be more effective for the Department to review the annual financial statement as part of an on-site inspection.

5. **Status of enforcement of the rule**
The rule requires an entity with a dispensary registration certificate to have an approval to operate before submitting an application for renewal of the dispensary certificate. Due to the court order (CV 2013-005901), the Department is not denying timely filed applications for a renewal of a dispensary registration certificate on the ground that the applicant has not obtained an approval to operate. Otherwise, the Department enforces the rule as written.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable but could be clearer by specifying in subsection (B) that it is the entity with a dispensary registration certificate that would submit a request to renew the dispensary registration certificate.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Because of the issues described in paragraphs 3 and 6 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-17-309. Inspections

2. **Objective**
The objectives of the rule are to:

a. Provide notice of the Department’s right to enter and inspect a dispensary and, if applicable, the dispensary's cultivation site;

b. Provide notice that the Department does not accept anonymous reports alleging a dispensary's noncompliance with medical marijuana statutes and rules;

c. Specify the conditions under which the Department may conduct an inspection; and

d. Specify the process to be followed if the Department identifies a violation.

3. **Analysis of effectiveness in achieving the objective**
The rule is mostly effective in achieving its objective but does not specifically state that a Department inspection may include an inspection of dispensary records or that the Department may periodically review the information in the medical marijuana electronic verification system to monitor a dispensary’s compliance with statutes and rules.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

Despite the minor clarifications needed, as described in paragraph 3, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-17-310. Administration

2. **Objective**
The objective of the rule is to specify the administrative actions a dispensary is required to take and the documents the dispensary is required to develop and maintain.

3. **Analysis of effectiveness in achieving the objective**
The rule is mostly effective in achieving its objective but does not include requirements for a dispensary to send to the Department a copy of amended by-laws and to notify the Department
when there is a change in the designated individual listed on an initial application, in R9-17-304(C)(1)(d), or renewal application, in R9-17-308(B)(1)(e).

6. **Analysis of clarity, conciseness, and understandability**
The rule is mostly clear, concise, and understandable but does not establish a period of time after the dispensary receives an approval to operate to allow the dispensary to grow, stock, or otherwise obtain a supply of marijuana before the dispensary is able to dispense medical marijuana.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Because of the issues described in paragraphs 3 and 6 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-17-311. Submitting an Application for a Dispensary Agent Registry Identification Card

1. **Authorization of the rule by existing statute**
The rule has A.R.S. § 36-2819 as additional specific authority.

2. **Objective**
The objective of the rule is to specify requirements for a dispensary when submitting a request for a dispensary agent registry identification card for an individual serving as a principal officer or board member for the dispensary, employed by the dispensary, or providing volunteer services at or on behalf of the dispensary.

3. **Analysis of effectiveness in achieving the objective**
The rule is mostly effective in achieving its objective but does not contain identification documentation requirements for obtaining a dispensary agent registry identification card specific to a principal officer or board member, since principal officers and board members are not required to be Arizona residents.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Because of the issue described in paragraph 3 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-17-312. Submitting an Application to Renew a Dispensary Agent's Registry Identification Card

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. § 36-2819 as additional specific authority.

2. **Objective**
   The objective of the rule is to specify requirements for a dispensary when submitting a request for renewing a dispensary agent registry identification card for an individual serving as a principal officer or board member for the dispensary, employed by the dispensary, or providing volunteer services at or on behalf of the dispensary.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

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R9-17-313. Medical Director

2. **Objective**
   The objective of the rule is to specify the qualifications and responsibilities of a medical director for a dispensary.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is mostly clear, concise, and understandable but does not state that it is a dispensary agent, not a qualifying patient, who must be able to contact the medical director.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons**
regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

Despite the minor clarification needed, as described in paragraph 6, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-17-314. Dispensing Medical Marijuana

1. **Authorization of the rule by existing statute**
The rule has A.R.S. §§ 36-2806.02, 36-2807, and 36-2816 as additional specific authority.

2. **Objective**
The objective of the rule is to specify the responsibilities of a dispensary agent when dispensing medical marijuana.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-17-315. Qualifying Patient Records

1. **Authorization of the rule by existing statute**
The rule has A.R.S. § 36-2801 as additional specific authority.

2. **Objective**
The objective of the rule is to establish requirements:
   a. For a dispensary to establish and maintain a qualifying patient record for each qualifying patient who obtains medical marijuana from the dispensary, including the content of the qualifying patient record; and
   b. Regarding access to and security of a qualifying patient record.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

**R9-17-316. Inventory Control System**

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. § 36-2816 as additional specific authority.

2. **Objective**
   The objectives of the rule are to specify requirements for:
   a. A dispensary’s inventory control system to document information about the marijuana acquired by the dispensary, cultivated by the dispensary, or provided by the dispensary to another dispensary;
   b. Oversight of the dispensary’s inventory control system and from whom the dispensary may acquire marijuana;
   c. Conducting an audit of the dispensary’s inventory; and
   d. Maintaining documentation related to the dispensary’s inventory control system.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is mostly clear, concise, and understandable but requires “an audit of the dispensary’s inventory,” which may be confused with an audit of financial records, rather than a review and reconciliation of a dispensary’s inventory with acquisition and disbursement (provision to another dispensary or dispensing for a qualifying patient) records.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Because of the issue described in paragraph 6 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-17-317. Product Labeling and Analysis

2. **Objective**
   The objectives of the rule are to:
   a. Specify how medical marijuana is required to be labeled, and
   b. Provide notice that a dispensary is required to provide to the Department upon request a sample of the dispensary's medical marijuana for analysis.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-17-318. Security

2. **Objective**
   The objective of the rule is to specify security requirements for a dispensary or the dispensary’s cultivation site or when a dispensary is transporting marijuana.

3. **Analysis of effectiveness in achieving the objective**
   The rule is mostly effective in achieving its objective but does not require in subsection (C)(1)(c) a list by qualifying patient or dispensary and the products being transported to each.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is mostly clear, concise, and understandable but could be improved by clarifying in subsection (C)(1) that a trip plan is “developed and documented.”

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Despite the minor clarifications needed, as described in paragraphs 3 and 6, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-17-319. Edible Food Products

2. Objective
The objective of the rule is to specify requirements related to the preparation, sale, or dispensing of edible food products containing marijuana.

3. Analysis of effectiveness in achieving the objective
The rule is effective in achieving its objective.

6. Analysis of clarity, conciseness, and understandability
The rule is mostly clear, concise, and understandable but does not specifically state in subsection (A)(2) that marijuana-infused food products are required to be prepared at a dispensary or the dispensary’s cultivation site.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective
Despite the minor issue described in paragraph 6, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-17-320. Cleaning and Sanitation

2. Objective
The objective of the rule is to specify requirements:

a. For a dispensary to ensure that buildings or equipment used by a dispensary for the cultivation, harvest, preparation, packaging, storage, infusion, or sale of medical marijuana are maintained in a clean and sanitary condition; and

b. To reduce the possibility of contamination of marijuana by a dispensary agent.

3. Analysis of effectiveness in achieving the objective
The rule is effective in achieving its objective.

6. Analysis of clarity, conciseness, and understandability
The rule is clear, concise, and understandable.
11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

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**R9-17-321. Physical Plant**

2. **Objective**

The objective of the rule is to specify requirements related to the physical plant of a dispensary and, if applicable, the dispensary’s cultivation site.

3. **Analysis of effectiveness in achieving the objective**

The rule is partially effective in achieving its objective but should be revised because of an issue with subsection (A). Subsection (A) specifies that a “dispensary or a dispensary's cultivation site shall be located at least 500 feet from a private school or a public school that existed before the date the dispensary submitted the initial dispensary registration certificate application,” but states nothing about where a dispensary may move or establish a new cultivation site.

6. **Analysis of clarity, conciseness, and understandability**

The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

Because of the issue described in paragraph 3 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

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**R9-17-322. Denial or Revocation of a Dispensary Registration Certificate**

1. **Authorization of the rule by existing statute**

The rule has A.R.S. § 36-2815 as additional specific authority.

2. **Objective**

The objective of the rule is to specify:

a. The circumstances under which the Department will deny an application for a dispensary registration certificate or revoke a dispensary’s registration certificate, and

b. How the Department will provide notice of the denial or revocation.
3. **Analysis of effectiveness in achieving the objective**
   The rule is partially effective in achieving its objective but should be revised. Subsection (A)(1) should be revised because of the issue described in paragraph 3 of the analysis for R9-17-321, and subsection (A)(2)(b)(ii) should be revised to comply with the court order.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Because of the issues described in paragraph 3 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-17-323. **Denial or Revocation of a Dispensary Agent's Registry Identification Card**

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. §§ 36-2804.01 and 36-2815 as additional specific authority.

2. **Objective**
   The objective of the rule is to specify:
   a. The circumstances under which the Department will deny an application for a dispensary agent registry identification card or revoke a dispensary agent's registry identification card, and
   b. How the Department will provide notice of the denial or revocation.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.
FIVE-YEAR-REVIEW REPORT

TITLE 9. HEALTH SERVICES

CHAPTER 16. DEPARTMENT OF HEALTH SERVICES

OCCUPATIONAL LICENSING

ARTICLE 4. REGISTRATION OF SANITARIANS

May 2016
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7. WRITTEN CRITICISM  
   Attachment D
Arizona Revised Statutes (A.R.S.) § 36-132(A)(1) requires the Arizona Department of Health Services (Department) to protect the health of the people of the state of Arizona. A.R.S. § 36-136(F) authorizes the Department to make and amend rules necessary for the proper administration and enforcement of the laws relating to the public health. A.R.S. § 36-136.01 authorizes the Department to establish a sanitarians council (Council) and establish rules for the registration of sanitarians in the state of Arizona.

The Department adopted at Arizona Administrative Code (A.A.C.) Title 9, Chapter 16, Article 4 rules to implement A.R.S. § 36-136.01. A.A.C. R9-16-401, R9-16-402, and R9-16-405 through R9-16-414 were originally promulgated in September 1976. The rules were substantially amended effective May 16, 2002 and last amended effective September 11, 2004, following the amendment of A.R.S. § 36-136.01 by Laws 2003, Ch. 21.

The current rules in 9 A.A.C. 16, Article 4 contain definitions; examination, registration, and renewal registration requirements; continuing education requirements; time-frames; registered sanitarian's authority; and criteria for the denial, suspension, or revocation of a sanitarian registration. The rules are used by the Council, who approves applicants to take the sanitarian examination, approves applicants for sanitarian registration, and approves registered sanitarians registration renewal, including registered sanitarians' continued education. In 2015, the Council approved 51 sanitarian registration applications, administered the sanitarian examination to 55 applicants, of which 31 applicants passed, approved 35 new registered sanitarians including registered sanitarians from other jurisdictions, and approved 493 registered sanitarian registration renewals.

The rules in 9 A.A.C.16, Article 4 are effective; clear, concise, and understandable; and consistent with state and federal statutes. The rules are enforced without difficulty. The Department received a written criticism regarding R9-16-403 from a county health department, but, due to existing statutes, the Department is not able to resolve the criticism to the county health department's satisfaction. The Department does not plan to amend the rules in 9 A.A.C. 16, Article 4 as indicated in this report.
INFORMATION THAT IS IDENTICAL FOR ALL THE RULES

1. Authorization of the rule by existing statutes
   The general statutory authority for the rules in 9 A.A.C. 16, Article 4, is A.R.S. §§ 36-132(A)(1) and 36-136(F).
   The specific statutory authority for the rules in 9 A.A.C. 16, Article 4, is A.R.S. § 36-136.01.

2. The purpose of the rule
   The purpose of the rules in 9 A.A.C. 16, Article 4, is to prescribe standards and limits for the registration of sanitarians in Arizona.

3. Analysis of effectiveness in achieving the objective
   Except for the use of an antiquated term identified in R9-16-401, the rules in Articles 4 are effective in achieving their respective objectives.

4. Analysis of consistency with state and federal statutes and rules
   Except for the outdated reference described in R9-16-408, the rules in Article 4 are consistent with state and federal statutes and rules.

5. Status of enforcement of the rule
   The rules in Article 4 are enforced as written without difficulty to the Department, the Council, registered sanitarians, and county health departments.

6. Analysis of clarity, conciseness, and understandability
   Despite the outdated language in R9-16-402 and the use of the term "address" in R9-16-404, the rules in Article 4 are clear, concise, and understandable.

7. Summary of the written criticisms of the rule received within the last five years
   In the past five years, the Department received one written criticism for the rules in Article 4. The written criticism received is discussed in R9-16-403 Information for Individual Rules.

8. Economic, small business, and consumer impact comparison
   The 2004 Economic, Small Business, and Consumer Impact Statement (EIS) included an analysis for all the rules in Article 4 except for rules in R9-16-401, Definitions; R9-16-402, Sanitarian Examination; R9-16-406, Change of Name or Address; and R9-16-408, Authority of a Registered Sanitarian.
In the Department's review of the rules in the 2004 EIS, the Department determined that the actual economic impact and probable effects to the persons directly affected by the rules are as estimated in the 2004 EIS. The persons directly affected by the rules are: the Department, county health departments, registered sanitarians, applicants for sanitarian registration that hold an equivalent accreditation from another jurisdiction, sanitarians who are ill or on active military duty, and the general public.

The Department determined in its analysis of rules R9-16-401, R9-16-402, R9-16-406, and R9-16-408 that the persons directly affected by bearing the costs of or by benefiting from the rules are the same as stated in the 2004 EIS. The Department concludes from its review of R9-16-401, R9-16-406, and R9-16-408 that the Department incurred a minimal cost to add to the rules the definitions, the notification for reporting a name or address change, and the standard for registered sanitarian authority. Additionally, the Department and others affected receive a minimal benefit from using the definitions to consistently interpret the rules, using the request process to notify the Department of a name or address change, and using the registered sanitarian authority standard to determine registered sanitarian's compliance.

The Department's review of R9-16-402 identified that there is a considerable difference between the fees paid by the applicants to take the sanitarian examination and the actual cost to the Department to administer the sanitarian examination. The cost to the Department to review sanitarian examination applications has increased due to increased salaries and time to review longer applications with additional forms, such as verifying proof of U.S. citizenship or legal residency required by A.R.S. § 1-501. The Department has had an increase of inquiries from individuals due to a change to the sanitarian examination administered. The Department now estimates that it takes four hours, compared to the previous one to two hours, of staff time at an average of $25 per hour to review a sanitarian examination. The fees collected cover only 52% of the actual costs to administer the sanitarian examination. The fees do not directly fund the Department, but they indirectly fund the Department through general fund appropriations. The Department expects that the cost to the Department is greater than originally estimated and the cost to others affected is likely none-to-minimal. And the benefit to the Department is less than expected, and the benefit to others affected greater than expected. The Department anticipates that there are no less intrusive or less costly alternatives for achieving the purpose of rules in 9 A.A.C. 16, Article 4.

9. **Summary of business competitiveness analyses of the rules**
The Department did not receive a business competitiveness analysis of the rules in the last five years.

10. **Status of the completion of action indicated in the previous five-year-review report**

In the 2011 Five-year-review Report, the Department stated that the Department did not plan to amend the rules within the next five years unless a substantive issue arises. The Department carried out this plan, and during the last five years, the Department did not amend the rules in Article 4.

12. **Analysis of stringency compared to federal laws**

The rules are not related to federal laws.

13. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**

The rules were adopted before July 29, 2010.

14. **Proposed course of action**

The Department has determined that the rules are effective and achieve the regulatory objectives required by A.R.S. §§ 36-132(A), 36-136(F), and 36-136.01. With the rules sufficient to protect public health safety, the Department does not plan to amend the rules. Should an issue occur that prevents the Department from meeting its regulatory objectives, the Department will amend the rules in 9 A.A.C. 16, Article 4. The Department establishes its rulemaking priorities based on: emergency matter to protect public health safety, legislative mandates, court orders, voter's approved propositions, and available resources.
R9-16-401. Definitions

2. **Objective**

   The objective of the rule is to define terms used in 9 A.A.C. 16, Article 4, so that a reader may consistently interpret the requirements in the Article.

3. **Analysis of effectiveness in achieving the objective**

   The rule is effective but could be more effective if the term "natural science" were revised to list the specialized fields of the two branches of natural science: life science and physical science.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

   Despite the antiquated term identified in paragraph 3, the rule imposes the least burden and costs to persons regulated by the rule while achieving the regulatory objective consistent with statutory requirements.

R9-16-402. Sanitarian Examination

2. **Objective**

   The objective of the rule is to establish standards for the sanitarian examination, including:
   a. The frequency at which the sanitarian examination is offered,
   b. Qualification requirements,
   c. Examination application requirements,
   d. Applicable fees, and
   e. Passing criteria.

6. **Analysis of clarity, conciseness, and understandability**

   The rule is clear, concise, and understandable; however, there is language in the rule that reflects an outdated practice and use of term. The rule could be clearer if in subsection (C)(2) and (3), the rule do not require that a letter verifying an applicant's employment or military duty in environmental health be provided "from the individual who supervised the applicant," since it is unlikely that that individual is still in a position to provide a letter verifying the applicant's employment or military duty. The rule could also be improved if the term "current address" used
in subsection (C)(1)(b) were replaced with the term "mailing address" requested in R9-16-406(B). The Department in R9-16-406 instructs a registered sanitarian to send a written notice to the Council if the registered sanitarian's mailing address changes.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

The Department understands that requesting an applicant to provide a letter verifying the applicant's employment or military duty in environmental health "from the individual who supervised the applicant," could be burdensome to the applicant. To eliminate a potential increase in burden to an applicant, the Department accepts letters verifying employment from the employer were the applicant completed years of employment as a sanitarian aide and accepts letters verifying environmental health experience from the military unit were the applicant completed years of full-time military duty in environmental health. Because the Department's acceptance of the other verification letters eliminates any increase in burden to the applicant, the rules continue to impose the least burden and cost to persons regulated while achieving the regulatory objective consistent with statutory requirements.

**R9-16-403. Sanitarian Registration**

2. **Objective**

The objective of the rule is to establish the application requirements for an applicant who is registered as a sanitarian in another jurisdiction and an applicant who is not registered as a sanitarian in another jurisdiction.

7. **Summary of the written criticism of the rule received within the last five years**

**Criticism:** In May 2015, one written criticism from Pima County Health Department (CHD) regarding R9-16-403, Sanitarian Registration, was received. CHD stated, "It would be nice is [if] some common sense was used and reciprocity for individuals registered by NEHA [National Environmental Health Association] having taken NEHA exam and having a score of 70% or greater be able to get reciprocity."

**Response:** The Department is required by A.R.S. § 36-136.01(C) to register an applicant as a sanitarian without an examination if the applicant is an individual who is registered as a sanitarian in another jurisdiction, meets at least one of the requirements in subsection (I) and the examination requirements in the applicants' jurisdiction are substantially equivalent to this state's
examination. Although NEHA's examination is substantially equivalent to this state's examination, NEHA is not "another jurisdiction" (state) and therefore does not meet the statutory requirements under which the Department can register an applicant without an examination.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

Despite the written criticism described in paragraph 7, the rule imposes the least burden and costs to persons regulated by the rule while achieving the regulatory objective consistent with statutory requirements.

**R9-16-404. Annual Registration Renewal**

2. **Objective**

The objective of the rule is to establish the requirements for renewal of registration as a sanitarian.

6. **Analysis of clarity, conciseness, and understandability**

The rule is mostly clear, concise, and understandable, but could be improved if the term "current address" used in subsection (A)(1) were replaced with the term "mailing address" used in R9-16-406(B). The Department in R9-16-406 instructs a registered sanitarian to send a written notice to the Council if the registered sanitarian's mailing address changes.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

The use of the term "address" identified in paragraph 6 does not affect the rule; and the rule continues to impose the least burden and cost to persons regulated by the rule while achieving the regulatory objective consistent with statutory requirements.

**R9-16-405. Continuing Education**

2. **Objective**

The objective of the rule is to establish requirements for continuing education for a registered sanitarian, including procedures for deferring continuing education.
11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

The rule imposes the least burden and costs to persons regulated by the rule while achieving the regulatory objective consistent with statutory requirements.

R9-16-406. Change of Name or Address

2. **Objective**

   The objective of the rule is to establish requirements for providing notice to the Department when there is a change in the registered sanitarian's name or address.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

The rule imposes the least burden and costs to persons regulated by the rule while achieving the regulatory objective consistent with statutory requirements.

R9-16-407. Time-frames

2. **Objectives**

   The objectives of the rule are to establish time-frames for:

   a. Departmental approval or denial to take the sanitarian examination;
   b. Registration upon completion of the sanitarian examination;
   c. Registration of an individual who is registered, certified, or licensed as a sanitarian in another jurisdiction; and
   d. Annual renewal of registration.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

The rule imposes the least burden and costs to persons regulated by the rule while achieving the regulatory objective consistent with statutory requirements.
R9-16-408. Authority of a Registered Sanitarian

2. **Objectives**
The objectives of the rule are to:
   a. Establish registered sanitarians as the regulatory authority in A.A.C. R9-8-107(B)(11),
   b. Prohibit an individual who is not a registered sanitaryan from functioning as a registered sanitaryan, and
   c. Require an individual who is not a registered sanitaryan and who prepares an inspection report under 9 A.A.C. 8 to submit the report to a registered sanitaryan.

4. **Analysis of consistency with state statutes and rules**
The rule is substantively consistent with state statutes and rules. There is an outdated reference in subsections (A)(2) and (C) to an inspection report "under 9 A.A.C. 8 or 9 A.A.C. 17." The Pure Food Control rules were originally promulgated in 9 A.A.C. 17. The regulations for Pure Food Control have since been incorporated into 9 A.A.C. 8, Article 1, so the inspection reports referenced in subsections (A)(2) and (C) "under 9 A.A.C. 8 or 9 A.A.C. 17" are now regulated only under 9 A.A.C. 8. The outdated reference to 9 A.A.C. 17, Medical Marijuana Program, has no substantive effect on the rule.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Despite the outdated reference identified in paragraph 4, the rule imposes the least burden and costs to persons regulated by the rule while achieving the regulatory objective consistent with statutory requirements.

R9-16-409. Denial, Suspension, or Revocation

2. **Objective**
The objective of the rule is to establish the criteria and procedures the Department follows to deny an applicant's request for sanitaryan registration or suspend or revoke a registered sanitaryan's registration.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons**
regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

The rule imposes the least burden and costs to persons regulated by the rule while achieving the regulatory objective consistent with statutory requirements.
FIVE-YEAR-REVIEW-REPORT

TITLE 9. HEALTH SERVICES

CHAPTER 16. DEPARTMENT OF HEALTH SERVICES

OCCUPATIONAL LICENSING

ARTICLE 1. LICENSING OF MIDWIFERY

August 2016
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Arizona Revised Statutes (A.R.S.) § 36-132(A)(1) requires the Arizona Department of Health Services (Department) to protect the health of the people of the state of Arizona. A.R.S. § 36-136(F) requires the Department to promulgate rules necessary for the proper administration and enforcement of the laws relating to the public health.

A.R.S. Title 36, Chapter 6, Article 7 contains the statutes for the licensing of midwives. A.R.S. § 36-751(3) defines a midwife as "a person who delivers a baby or provides health care related to pregnancy, labor, delivery, and postpartum care of the mother and her infant." A.R.S. § 36-752(A) prohibits, in most cases, an individual from performing the duties of a midwife without being licensed by the Department. A.R.S. § 36-754(A) requires the Department to issue a license to qualified individuals who pay applicable fees. A.R.S. § 36-755 allows the Director to adopt rules necessary for the proper administration and enforcement of the A.R.S. Title 36, Chapter 6, Article 7 and requires the Director to, by rule, adopt standards with respect to the practice of midwifery designed to safeguard the health and safety of the mother and infant.

When the Department promulgates licensing rules required in law for various individuals, agencies, or facilities, hereinafter referred to as entity or entities, the Department works with affected stakeholders to establish, consistent with the specific statutory authority, requirements that protect the health and safety of an individual receiving services from the licensed entity and the public. In addition to information provided by affected stakeholders, the Department considers evolving industry standards, economic burden, statistical information, historical data, and rulemaking standards and requirements when promulgating health and safety licensing rules.

Once established, licensing rules become the minimum standard for a licensed entity if the entity wants to continue to operate and provide services. Other governmental agencies establish minimum licensing standards in rule for providing services based on what is necessary to protect health and safety. An entity licensed by the Department or another governmental agency is required to comply with the requirements established in rule if the licensed entity wants to continue to operate and provide services that are reserved for licensed entities.

An entity cannot provide services at a level lower than the established minimum to a member of the public based on the member's request. For example: if a parent who enrolls the parent's infant in a licensed child care facility states that the ratio of one caregiver to five infants is not necessary for the parent's infant because the infant sleeps most of the time and requests that the infant be placed in a setting...
of one to six or one to seven, the licensed child care facility is not allowed to place the infant in a setting of one to six or one to seven; if a resident in a licensed nursing care institution or the resident's family requests that the resident not be served the minimum required amounts of food or have a room that does not have the minimum required square footage, the licensed nursing care institution is still required to serve at least the minimum required amounts of food and provide a room that has at least the minimum required square footage; and if an individual requests that a licensed hearing aid dispenser diagnosis the underlying cause of the individual's hearing loss, the licensed hearing aid is not allowed to provide a diagnosis to the individual.

When an individual receives a license from a governmental agency to provide services, there is a scope of practice that governs the type and the level of services the licensed individual is authorized to provide. For example, a licensed practical nurse (LPN) has a limited scope and is required to be under the supervision of a registered nurse (RN). The RN can provide nursing services independently but usually provides nursing services under the direction of a physician or registered nurse practitioner (NP). The NP can provide nursing services and certain medical services independently and be authorized by the governmental agency, based on the NP's education, skills, knowledge, and credentials at the time of licensing, to have an extended scope of practice. A LPN with 20 years of experience is not allowed to practice independently based on the LPN's experience. In order to operate independently, the LPN must obtain a license to practice as a RN by acquiring the required education, skills, knowledge, and credentials and complying with the RN licensing rules. Experience does not qualify a LPN to provide services as a RN or a RN to provide services as a NP. A licensed midwife is required to have specific education, skills, knowledge, and credentials in order to be authorized by the Department to provide midwifery services. Even though a licensed midwife obtains skills and knowledge about women's health, pregnancy, childbirth, and postpartum care through experience, the licensed midwife is not allowed to provide obstetrical or gynecological services that are not delineated as midwifery services or are prohibited by midwifery rules unless the licensed midwife demonstrates to the appropriate governing agency that the licensed midwife has the education, skills, knowledge, and credentials required by the governing agency to obtain a license that would allow an expanded scope of practice.

There are currently four types of midwives who provide midwifery services: certified nurse-midwives (CNM), certified midwives (CM), certified professional midwives (CPM), and direct-entry midwives (DM). Formal midwifery education programs that lead to the CNM and CM credential involve graduate education. Most programs require a bachelor's degree in nursing for entry, but some will accept a registered nurse (RN) without a bachelor's degree, providing a bridge program to a Bachelor of Science in Nursing (BSN) before the registered nurse begins the midwifery portion of the program. Certified
nurse-midwives and certified midwives are licensed and regulated, usually under a state's Board of Nursing, and are allowed to provide midwifery services in all 50 states.

In order to provide midwifery services in Arizona, independent midwives, those individuals who do not have a CNM or CM license, are required to obtain a midwifery license from the Department. Midwives licensed by the Department include CPMs and DMs. The CPM is the newest credential that was first issued in 1994 to independent midwives who provide out-of-hospital midwifery services. The credential is issued by the North American Registry of Midwives (NARM) to individuals who may or may not have formal education, but who provide verification of the required experience and skills and pass the NARM Skills Assessment. According to the Midwives Alliance-North America website, certified professional midwives are allowed to provide midwifery services in 28 states. The NARM website identifies 26 states that have some kind of legal recognition for CPMS. DMs include those individuals who obtained, through demonstrated experience, skills, and knowledge, and have continuously held, a midwifery license in this state since 1999.

Current rules in 9 A.A.C. 16, Article, 1, require an individual applying for an initial midwifery license to have obtained a CPM credential. Before the current rules were effective, an individual could submit to the Department verification of the individual's experience, knowledge, and skills, take and pass a knowledge test, practical test, and jurisprudence test (based on state laws for midwifery) and receive a midwifery license and would be considered a DM. A midwife currently licensed under A.R.S. Title 36, Chapter 6, Article 7 and rules in 9 Arizona Administrative Code (A.A.C.) 16, Article 1 is a CPM or DM depending on when the midwife obtained the midwifery license or if the midwife chose to become a CPM after the midwife obtained a midwifery license. Currently, of the 78 licensed midwives, there are 54 CPMs and 24 DMs.

A.A.C. Title 9, Chapter 16, Article 1 contains the rules for the licensing of midwifery. The rules in 9 A.A.C. 16, Article 1 were adopted effective July 1, 2013. Laws 2012, Chapter 93 required the Department to consider adopting rules regarding midwifery that would reduce the regulatory burden on licensed midwives, revise the midwifery scope of practice, and if available, adopt national licensure testing standards. In addition to the rulemaking authority in Laws 2012, Ch. 93, the Department is required by, A.R.S. § 36-755(B) to "adopt standards with respect to the practice of midwifery designed to safeguard the health and safety of the mother and child."

Laws 2012, Ch. 93 included exempt rulemaking authority until July 1, 2013 and provisions for reports to be submitted to the Department supporting an increase in a midwife's scope of practice. In addition, a midwifery scope of practice advisory committee to assist the Department in adopting and amending the rules related to midwifery scope of practice was established and was required to be comprised of two licensed midwives, two public members who have used midwifery services, one
physician licensed under A.R.S. Title 32, Chapter 13 experienced in obstetrics, one physician licensed under A.R.S. Title 32, Chapter 17 experienced in obstetrics, one physician licensed under A.R.S. Title 32, Chapter 13 or 17 who specializes in family medicine, and one nurse midwife or nurse practitioner.

Laws 2012, Ch. 93, also required the Department to provide public notice and an opportunity for public comments on recommendations from the midwifery scope of practice advisory committee and draft proposed rules on the Department's website. The Department posted draft midwifery licensing rules on the Department's website on December 12, 2012; January 8, 2013; February 10, 2013; March 9, 2013; May 8, 2013; and May 24, 2013 with an opportunity for the public to comment each time draft rules were posted. The Department held public meetings with the midwifery scope of practice advisory committee on November 27, 2012; December 17, 2012; January 14, 2013; February 11, 2013; April 3, 2013; May 5, 2013; and June 3, 2013 that provided opportunities for public comment. The Department's website at http://azdhs.gov/director/administrative-counsel-rules/rules/index.php#rulemakings-completed-2013 for the completed midwifery licensing rulemaking contains documents related to the rulemaking including every draft posted, every meeting agenda, every comment received, and every report submitted to the Department supporting an increase in the midwifery scope of practice.

The midwifery licensing rules, effective July 1, 2013, established a midwifery advisory committee (MAC) which is required to examine aggregate data from midwife reports, notifications of client and client's newborn fatalities received by the Department, and evidence-based research pertaining to the practice of midwifery. Based on the review, the MAC is required to develop an annual report on midwifery and home births, including an analysis and summary of the above information and any recommendations for changes to the midwifery licensing rules.

In addition to the data from the midwife reports, recommendations for changes to rules, and a listing of evidence-based research, the MAC Report 2014-2015 included sections on complaints and enforcement actions and consumer voice. The report stated that written proposals for rule changes had been submitted to the MAC by the Arizona Association of Midwives and that the MAC had reviewed, and, in consensus, presented three of the proposals in the Report as recommendations to the Department.

RECOMMENDATION: Request that a rule be added that would allow a midwife to "continue care for a midwifery client with the current pregnancy as stated in subsection R9-16-111(B)(25) if all of the following criteria are met in the postpartum period: 1) the hemorrhage responds to treatments available in the out of hospital setting and is well controlled, (a) the client is alert and oriented, (b) the client's blood pressure remains within normal limits of between 90/60 and 140/90, or 2) the client has been discharged from physician care following a transfer of care for hemorrhage."
RECOMMENDATION: Request that the language in R9-16-111(B) be changed to read "(A) midwife shall not knowingly accept for midwifery services or continue midwifery services without documentation of condition treated and resolved, following which midwifery services may resume; for a client who has or develops any of the following..." The report states that the Department does not allow a midwife to resume care once the condition is treated by other health care professionals and resolved.

RECOMMENDATION: Request that the language in R9-16-111(B)(25) be changed to allow a midwife to continue care for a midwifery client with a postpartum hemorrhage if the hemorrhage responds to treatments available in the out-of-hospital setting and is well controlled as evidenced by the client being alert and the client's blood pressure remaining within normal limits of between 90/60 and 140/90 and the client has been discharged from physician care following a transfer of care for hemorrhage.

A.A.C. Title 9, Chapter 16, Article 1 rule sections include:

- R9-16-102 that currently contains requirements for an individual applying for an initial application. References to documents verifying experience obtained during an apprenticeship were repealed during the last rulemaking.
- R9-16-103 that currently contains requirements for a midwife applying to renew the midwife's license. During the last rulemaking, the requirements for a midwife apprenticeship including documentation requirements and a preceptor rating guide were repealed. In addition, written and oral examination requirements were repealed.
- R9-16-104 that currently contains requirements for Department notifications and recordkeeping. The last rulemaking repealed references to examinations administered by the Department that were previously addressed in the Section.
- R9-16-105 that currently contains requirements for continuing education. The last rulemaking repealed renewal requirements including an exhibit that was the "Application for Biennial Renewal of Midwife License" form and the "Affidavit of Continuing Education" form
- R9-16-106 that currently contains requirements for changing a midwife's name on the midwife's midwifery license and for requesting a duplicate license.
- R9-16-107 that contains time-frames for the administrative completeness and substantive review of submitted midwifery applications.
- R9-16-108 that delineates the responsibilities and scope of practice for a licensed midwife.
• R9-16-109 that contains requirements for informed consent for midwifery services.
• R9-16-110 that contains provisions documenting when a client declines a required test.
• R9-16-111 that delineates prohibited practices and transfer of care requirements.
• R9-16-112 that delineates client conditions and conditions that a client's newborn may have that would require a midwife to obtain a consultation.
• R9-16-113 that contains requirements for emergency measures that a midwife may take including ensuring that an emergency medical services provider is called.
• R9-16-114 that contains requirements for a report for each client from the midwife after the midwife terminates the client's midwifery services.
• R9-16-115 that contains requirements for a client's record and the client's newborn's record.
• R9-16-116 that delineates circumstances under which the Department may deny, suspend or revoke a midwifery license.
• R9-16-117 that establishes requirements for the composition and functions of a midwifery advisory committee. Although the Department plans to solicit input from licensed midwives regarding the licensing process, and may ask the current committee to function in that role, the Department does not believe that there is specific statutory authority requiring the Department to establish a midwife advisory committee in rule. The Department is not reviewing the Section and allowing the Section to expire.

The Department plans to complete the review of midwifery services outcomes information and the reports submitted by the MAC and start the rule amendment process by July, 2019. At that time the Department will amend the rules to address any changes determined to be necessary to the scope of practice for licensed midwives and the midwifery licensing rules as a result of the review and to address any issues identified in this report.
INFORMATION IDENTICAL FOR ALL THE RULES

1. Authorization of the rule by existing statutes
   General: A.R.S. §§ 36-132(A)(1) and 36-136(F).
   Implementing (specific): A.R.S. §§ 36-752 and 36-755 (statutory authority for the entire article)

2. The purpose of the rule
   The purpose of the rules is to specify requirements for obtaining a license and operating as a licensed midwife.

4. Analysis of consistency with state and federal statutes and rules
   The rules are consistent with state statutes and rules and, to the extent that federal statutes and regulations are consistent with state statutes, with federal statutes and regulations.

5. Status of enforcement of the rule
   The Department enforces the rules as written.

7. Summary of the written criticisms of the rule received within the last five years
   Since the current rules became effective July 1, 2013, the Department has received nine written criticisms, eight from the Arizona Association of Midwives and one from a consumer of midwifery services. One criticism received from the Arizona Association of Midwives was a request for a review of an agency practice. The remainder of the criticisms received from the Arizona Association of Midwives are related to subsections in R9-16-111, Prohibited Practice; Transfer of Care and R9-16-101, Definitions, and although the criticism from the consumer did not contain a reference to a specific rule, it also is a criticism of R9-16-111. The criticisms are addressed in the analyses of R9-16-101 and R9-16-111.

8. Economic, small business, and consumer impact comparison
   For the purpose of this economic impact comparison, annual costs/revenues are designated as minimal when $5,000 or less, moderate when between $5,000 and $50,000, and substantial when $50,000 or greater in additional costs or revenues. A cost is listed as significant when meaningful or important, but not readily subject to quantification. The rules in 9 A.A.C. 16, Article 1, were adopted by exempt rulemaking, effective July 1, 2013 and there is not an economic, small business, and consumer impact statement available for a comparison. Unless otherwise stated, the numbers provided in the following analysis are for calendar year 2015.
   There are, as of July 1, 2016, 78 midwives licensed by the Department. Of these 78 licensed midwives, 54 are recognized as CPMs by NARM.
A.R.S. § 36-758 provides the authority for the Department to establish in rule and collect nonrefundable fees that do not exceed $25 for an initial application, $50 for an initial license, $250 for testing, $50 for license renewal, and $10 for a duplicate license.

**INITIAL MIDWIFERY LICENSE**

The Department estimates that it cost the Department $10 to issue an initial midwifery license based on an average of .5 hours for review X $20/hour for salary. The Department issued 4 initial midwifery licenses in calendar year 2015, so the Department estimates the total cost was $40. The midwifery licensing rules that were in effect before July 1, 2013 had established a fee of $25 for filing an initial midwifery application, $100 for testing and an additional $25 for a licensing fee. An applicant was required to submit a filing fee of $25 with the initial application. The initial application included documentation showing that the applicant completed a midwifery apprenticeship with an assessment of above average or excellent and documentation showing that the applicant obtained knowledge specific to the provision of midwifery services with an assessment of above average or excellent. If the Department determined that the application complied with the requirements, the applicant was approved to take the written examination from NARM. The applicant submitted the notice of the Department's approval and a written examination fee ($700-$900, the cost of the written examination increased during the time the rules were in effect) to NARM to qualify to take the written examination. After the applicant passed the NARM written examination, the Department informed the applicant that a $100 testing fee was required before the applicant could take the Department's practical examination and jurisprudence examination. If the applicant passed the practical and jurisprudence examinations, the applicant was required to submit a $25 licensing fee before the Department issued an initial midwifery license to the applicant. The total cost for licensing fees and examination fees to an applicant when obtaining an initial midwifery license under the rules that were in effect before July 1, 2013 was $850 - $1050 depending on the cost of the NARM written examination.

The midwifery licensing rules that became effective July 1, 2013 maintained the established fees of $25 for filing an initial midwifery application, $100 for testing, and an additional $25 for licensing. An applicant submitting an initial application is now required to submit documentation of NARM certification. According to the NARM Candidate Information Book, an individual applying for certification as a professional midwife is required to submit an application fee of $950 to $1100 and an examination fee of up to $900 to NARM. There is a fee of $115 paid directly to the testing company that is in addition to the NARM fees. Licensing fees and examination fees for an initial midwifery license under the current rules are $2115 to $2265.
which reflects a minimal increase in costs for obtaining an initial midwifery license, since the increase is less than $5000.

RENEWAL LICENSE

The Department estimates that it cost the Department $30 to renew a midwifery license based on an average of 1.5 hours for review X $20/hour salary. The Department renewed 22 midwifery licenses in calendar year 2015, so the Department estimates that the total cost was $660.

The midwifery licensing rules that were in effect before July 1, 2013 had established a fee of $25 for renewing a midwifery license. Although the licensing renewal fee in the current rules remains $25, a midwife who has not been continuously licensed by the Department since 1999 is required to maintain certification as a professional midwife by NARM. This includes a recertification fee of $150 every three years, imposing a minimal increase in costs on the 54 licensed midwives/CPMs.

RECORD SUBMISSION

The midwifery rules that were in effect before July 1, 2013 included Exhibit E. Individual Quarterly Report, a three-page form that a licensed midwife was required to complete and submit for each client for whom the midwife provided midwifery services on a quarterly basis. Current midwifery rules require a licensed midwife to submit a report on midwifery services provided to each client no more than 30 days after the termination of midwifery services. The Department has established an on-line report streamlining the reporting process and providing a significant benefit to licensed midwives and the Department.

ENFORCEMENT ACTIVITIES

The Department investigated 5 complaints that the Department estimates it cost the Department between $3,600 to $5,400 to investigate.

The Department received 73 midwifery services reports after the required submission date. The Department estimates this cost the Department $1,460 based on an average of 1 hour review and document drafting time X $20/hour salary.

Enforcement actions requiring the preparation of a hearing notice average 15 hours program staff time with salaries ranging from $18 to $40 with an estimated cost of $435 per enforcement action. The Department estimates a total cost of approximately $10,000 for preparing hearing notice for enforcement actions.

The Department assessed 21 civil penalties with the amount assessed ranging from $50 to $1,200 with an average amount of $200 assessed against a specific licensed midwife.
9. **Summary of business competitiveness analyses of the rules**
The Department did not receive a business competitiveness analysis of the rules in the last five years.

10. **Status of the completion of action indicated in the previous five-year-review report**
In the previous five-year-review report, the Department stated that, if the moratorium ended on July 1, 2011, (Laws 2010, Ch. 287, § 18 had continued the moratorium until July 1, 2011), the Department planned to submit a Notice of Final Rulemaking no later than July 1, 2013. Although the moratorium continued, the Department completed an exempt rulemaking according to Laws 2012, Ch. 93, effective July 1, 2013.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The rules impose the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

12. **Analysis of stringency compared to federal laws**
There are no specific federal laws regulating certified professional midwives or direct entry midwives.

13. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**
The rules establish midwifery licensing requirements that comply with A.R.S. § 41-1037(A)(2).

14. **Proposed course of action**
Laws 2012, Ch. 93, § 1 established a "midwifery scope of practice advisory committee" to assist the Director in adopting and amending rules related to midwifery scope of practice. Laws 2012, Ch. 93, § 1 included the process for the established committee to provide recommendations concerning proposed rules relating to a change in the scope of practice. The composition and functions of the committee established in R9-16-117 are not the same as the committee's composition and functions in Laws 2012, Ch. 93, § 1. Although the Department plans to solicit input from licensed midwives regarding the licensing process, and may ask the current comment to function in that role, the Department does not believe that there is specific statutory authority requiring the Department to establish a midwife advisory committee in rule. The Department is not reviewing R9-16-117 and allowing R9-16-117 to expire.
The Department plans to amend the remainder of the rules which were completed effective July 1, 2013 and revised the scope of practice for licensed midwives effective July 1, 2014. Current rules allow:

- A midwife to provide midwifery services to a healthy woman, determined through a physical assessment and review of the woman's obstetrical history, whose expected outcome of pregnancy is most likely to be the delivery of a health newborn and intact placenta;
- A midwife's client to refuse a test:
  - For blood type including ABO and Rh, with antibody screen;
  - Urinalysis;
  - HIV;
  - Hepatitis B;
  - Hepatitis C;
  - Rubella titer;
  - Blood glucose screening for diabetes;
  - Hematocrit, Hemoglobin, or a complete blood count;
  - Gonorrhea;
  - Chlamydia; and
  - Group B Strep Streptococcus; and
- A midwife's client to refuse an ultrasound to determine placental location, fetal presentation, and fetal weight; and
- A midwife under specific circumstances to provide midwifery services to a woman who has had a prior Cesarean section or whose fetus is in a complete breech or a frank presentation.

The Department is reviewing midwifery services outcomes from women receiving midwifery services as reported by licensed midwives to ensure that the changes in the rules related to midwifery services and the midwife's scope of practice do not increase negative health and safety outcomes for a mother or the mother's child. Based on the number of births typically attended by licensed midwives annually, the Department believes that five years of midwifery services outcomes are necessary to have information that is statistically significant.

The Department plans to complete the review of the reports submitted by licensed midwives including the information about health and safety outcomes and any reports submitted by the MAC before the expiration of R9-16-117, and start the rulemaking process to amend the rules by
July, 2019. At that time, the Department will also amend the rules to address any changes determined to be necessary to the scope of practice for licensed midwives or the midwifery licensing rules as a result of the review. The Department also plans to address issues identified in this report at that time. The Department expects to submit a Notice of Final Rulemaking to the Governor's Regulatory Review Council by July 2021. This timetable is subject to change based on statutory priorities, legislative mandates, Department priorities including rulemakings required to prevent imminent harm, and available resources.
R9-16-101. Definitions

2. Objective
The objective of the rule is to define terms and phrases used in the Article to enable the reader to clearly understand the requirements of the Article and allow for consistent interpretation.

3. Analysis of effectiveness in achieving the objective
The rule is effective in achieving the stated objective but could be more effective if the issues in paragraph 6 were addressed.

6. Analysis of clarity, conciseness, and understandability
The rule is clear, concise, and understandable but could be clearer if the definition of "addiction" is repealed because it is not used in the Article, the term "client" is defined, and the definitions are put in alphabetic order, "calendar day" is paragraph #9 and "complete breech" is paragraph #8. In addition, the following terms are only used once in the Article and may be moved to and defined in the rule where the term is used: "abnormal presentation," "aseptic," "current photograph," "infant," "intrapartum," "local registrar," "para," "parity," "prenatal care," "primigravida," "primipara," "serious mental illness," and "substance abuse."

7. Summary of the written criticisms of the rule received within the last 5 years
Criticism: AzAM 5/26/15 letter requests that the definition of "midwifery services" be amended to read "health care, provided by a midwife, related to pregnancy, labor, delivery, and postpartum care. This care includes preconception counseling, well-woman care, preventative care, the promotion of normal birth, the detection of complications in pregnancy and the newborn, the accessing of medical care or other appropriate assistance and the carrying out of emergency measures."

Response: The term "midwife" is defined in A.R.S. § 36-751, as "a person who delivers a baby or provides health care related to pregnancy, labor, delivery and postpartum care of the mother and her infant." The Department believes that the statutory definition of "midwife" establishes the care a midwife is authorized to provide and the definition of midwifery services is consistent with the statutory definition.

Criticism: AzAM 6/2/15 letter requests that the definition of "serious mental illness" in R9-16-101 and requirements in R9-16-111(B)(15) that a midwife not accept for midwifery services a client who has or develops a serious mental illness (SMI) be repealed. The letter states that pregnant patients with SMI, as long as they demonstrate decision making capacity, have the right to be provided with the same treatment options as the general population and the presence of a possible or diagnosed SMI does not remove this right. The written criticism references a
definition of severe mental illness attributed to the National Alliance on Mental Illness (NAMI) which states that severe mental illness includes "major depression, schizophrenia, bipolar disorder, obsessive compulsive disorder, panic disorder, post traumatic stress disorder, and borderline personality disorder." The written criticism also states that one out of every six women will experience unstable mental health during their childbearing years.

Response: The term "serious mental illness" is defined in R9-16-101(44) and includes a reference to the statutory definition of "mental disorder" in A.R.S. § 36-501, which is the equivalent definition to the NAMI definition provided in the written criticism. In order for an individual to have a designation of SMI, the individual's mental disorder needs to be severe and persistent, resulting in a long-term limitation of the individual's functional capacities for primary activities of daily living and the individual's mental disorder impairs or substantially interferes with the capacity of the individual to remain in the community without supportive treatment or services of a long-term or indefinite duration. The Department does not believe that one out of every six women of childbearing years, as stated in the written criticism, could be considered to have a serious mental illness as defined in these rules and the source of this information in the written criticism is not specified. The Department's decision to require a licensed midwife to decline to provide or to transfer the care of a pregnant woman with a "serious mental illness" as defined in this section, is based on the fact that the training, skills, and knowledge required to obtain a midwifery license does not qualify a licensed midwife to be able to identify and address issues related to the pregnant woman's SMI including the effects of prescribed psychotropic drugs on the pregnancy and recognizing signs and symptoms of decompensation, that may impact the woman's pregnancy or to identify and address how the woman's pregnancy may impact the woman's SMI. The limitation in rule is not based on a limitation of the rights of a SMI patient but on the lack of training, skills, and knowledge of a licensed midwife to ensure the health and safety of a pregnant woman with a SMI.

Criticism: AzAM 5/26/15 letter states that "midwives are not mental health professionals and therefore are not trained in the identification and diagnosis of mental disorders, serious mental illness, or severe psychiatric illness."

Response: In R9-16-111(B), there is a list of medical conditions that require the licensed midwife to not accept a pregnant woman for care or to transfer care of the pregnant woman to a qualified health care professional. In R9-16-112, there is a list of medical conditions that a pregnant woman may have that require the licensed midwife to obtain a consultation. Some of the information pertaining to the medical conditions would be obtained by the licensed midwife by asking the pregnant woman if the pregnant woman had or has the medical condition. Some
examples include information about previous uterine surgeries; a history of severe postpartum bleeding, of unknown cause, which required transfusion; a serious mental illness; evidence of substance abuse, including six months prior to pregnancy; history of seizure disorder, history of stillbirth, premature labor, or parity greater than 5; heart disease; kidney disease; and blood disease. The licensed midwife is not required to diagnose all of the medical conditions but is expected to obtain information from the pregnant woman to determine whether the pregnant woman has one of the medical conditions in R9-16-111 or R9-16-112 in order to comply with the requirements.
R9-16-102. Application for Initial Licensure

1. **Authorization of the rule by existing statutes**
   
   Additional implementing (specific) statute: A.R.S. § 36-753

2. **Objective**
   
   The objective of the rule is to establish application requirements for obtaining an initial midwifery license.

3. **Analysis of effectiveness in achieving the objective**
   
   The rule is effective in achieving the stated objective but could be more effective if the issues in paragraph 6 were addressed.

6. **Analysis of clarity, conciseness, and understandability**
   
   The rule includes the requirements for an application for initial licensure. If an individual submits an application for initial licensure and is approved, the individual does not receive an initial license but receives notification of eligibility to take the midwifery jurisprudence test. Subsection (C)(3) states that an applicant may take the jurisprudence test as many times as desired without paying an additional testing fee but subsection (F) states that the Department shall provide a written notice of denial to an applicant who does not score 80% or higher within 180 calendar days after the applicant receives the notice of eligibility to take the jurisprudence test. Upon notification from the Department that the individual has scored 80% or higher on the jurisprudence test, the individual is required to submit a licensing fee of $25 and current CPR/first aid documentation. Only after the applicant receives notification of eligibility to take the midwifery jurisprudence test, scores at least 80% within 180 calendar days of notification, and submits a licensing fee and current CPR/first aid documentation does the Department issue an initial license to the applicant. There is no licensing time-frame identified for processing an initial licensure application. Because the terms "licensure" and "licensing" are both used in the rule it is unclear whether the terms have the same meaning or not.
R9-16-103. Renewal

1. **Authorization of the rule by existing statutes**
   Additional implementing (specific) statute: A.R.S. § 36-754

2. **Objective**
   The objective of the rule is to establish the application requirements for renewing a midwifery license.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving the stated objective.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.
R9-16-104. Administration

2. **Objective**
   The objective of the rule is to establish administrative requirements pertaining to licensed midwives including the process for requesting being listed or not being listed on the Department's public list of licensed midwives, reporting requirements for the death of a client or the client's newborn, and documentation maintenance requirements.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving the stated objective.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.
2. **Objective**
   The objective of the rule is to establish requirements for continuing education for licensed midwives to ensure that a licensed midwife's ability to provide midwifery services is continually improved.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving the stated objective but could be more effective if the issue identified in paragraph 6 was addressed.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is concise and understandable but could be clearer if the terms "continuing education unit" and "health professional organization" were defined.
R9-16-106. Name Change; Duplicate License

2. **Objective**
   The objective of the rule is to establish the process for changing a midwife's name on a midwifery license or request a duplicate midwifery license.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving the stated objective.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.
R9-16-107. Time-frames

1. **Authorization of the rule by existing statutes**
   Authorizing statutes (specific): A.R.S. §§ 41-1073 through 41-1076

2. **Objective**
   The objective of the rule is to establish licensing time frames for midwifery licenses required in A.R.S. Title 41, Chapter 6, Article 7.1.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving the stated objective but could be more effective if the rule more clearly delineated the initial license application process.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, conciseness, and understandable.
R9-16-108. Responsibilities of a Midwife; Scope of Practice

2. **Objective**
   The objective of the rule is to establish standards for the provision of midwifery services that ensure the health and safety of a client and the client's newborn.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving the stated objective but would be more effective if the issues identified in paragraph 6 were addressed.

6. **Analysis of clarity, conciseness, and understandability**
   The clarity, conciseness, and understandability of the rule are affected by ambiguous or undefined terms such as: "healthy," "client," "credentials," "delivery," "child," "weekly visits," "adequate," "emergency management," "appropriate baby care," and an incorrect use of a sentence in a listing in subsection (K)(2)(c). In addition, the term "document" is used in subsection (I)(5)(d) when the appropriate term is "documentation" and the terms "woman," "mother," and "client" are all used in the rule without any indication if and how the terms are related.

7. **Summary of the written criticisms of the rule received within the last 5 years**
   Criticism: AzAM 8/10/15 letter is a Petition for a Review of an Agency Practice related to the interpretation of R9-16-108(I)(1) and the phrase that requires a licensed midwife to "schedule or arrange" a test for "syphilis as required in A.R.S. § 36-693."
   Response: The Department does not believe that the rule provides authority for a licensed midwife to "take the blood sample," that is to actually draw blood from a pregnant client but requires the licensed midwife to "cause a sample of blood of each pregnant woman…..to be taken under the direction of a duly licensed physician" as required in A.R.S. § 36-693.
2. **Objective**
   The objective of the rule is to establish requirements for a licensed midwife to obtain and document informed consent from a woman before the woman becomes the licensed midwife's client and begins receiving midwifery services from the licensed midwife to ensure that the woman has information including the licensed midwife's scope of practice and potential risks, adverse outcomes, complications, and alternatives associated with an at-home delivery specific to the woman's condition, necessary for the woman to make an informed decision.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving the stated objective but would be more effective if the issue identified in paragraph 6 were addressed.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable but the term "client file" is ambiguous because R9-16-115 establishes requirements for "client records."
R9-16-110. Assertion to Decline Required Tests

2. **Objective**
The objective of the rule is to establish the process and requirements for when a client declines a required test to ensure that the client has received information pertaining to the potential risks for declining a test.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving the stated objective but could be more clear if the issue in paragraph 6 was addressed.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable but would be more clear if the undefined and ambiguous term "client file" was addressed. R9-16-115 establishes requirements for "client records."
R9-16-111. Prohibited Practice; Transfer of Care

2. **Objective**

   The objective of the rule is to establish the medical conditions that would require a licensed midwife to not accept for care a pregnant woman or to transfer care of a client or the client's newborn to ensure that the pregnant woman, client, or newborn receives care from a health care professional who has the skills, knowledge, training, and credentials to provide the level of care necessary to ensure the pregnant woman's, client's or newborn's health and safety.

3. **Analysis of effectiveness in achieving the objective**

   The Department is reviewing midwifery services outcomes from clients and clients' newborns receiving midwifery services as reported by licensed midwives to ensure that the changes in the rules related to midwifery services and the licensed midwife's expanded scope of practice do not increase negative health and safety outcomes for a pregnant mother, client, or the client's newborn. Based on the number of births typically attended by licensed midwives annually, the Department believes that five years of midwifery services outcomes are necessary to have information that is statistical significant to determine the effectiveness of the rule in achieving the stated objective.

6. **Analysis of clarity, conciseness, and understandability**

   The rule is clear, concise, and understandable but could be more clear if the ambiguous and undefined terms "baby," "evidence," and "excessive" were clarified.

7. **Summary of the written criticisms of the rule received within the last 5 years**

   **Criticism:** AzAM 5/5/15 letter requests that the language in subsection (B) be changed to read "(A) midwife shall not knowingly accept for midwifery services or continue midwifery services without documentation of condition treated and resolved, following which midwifery services may resume; for a client who has or develops any of the following…"

   **Response:** The Department completed a rulemaking effective July 1, 2013 with extensive opportunities for input from the public and the regulated community. The regulated community did not identify an issue with the language at that time. The Department plans to complete the review of midwifery services outcomes information, the reports submitted by the MAC, and any changes to the industry standards and start the rule amendment process by July 2019. At that time the Department will amend the rules to address any changes determined to be necessary to the scope of practice for licensed midwives or the midwifery licensing rules and to improve the clarity, conciseness, and understandability, as a result of the review.

   **Criticism:** AzAm 5/19/15 letter requests that subsection (B)(12) which prohibits a licensed midwife from accepting a client for midwifery services or continuing midwifery services if the...
client develops a blood pressure of 140/90 or an increase of 30 millimeters of Mercury systolic or 15 millimeters of Mercury diastolic over the client's lowest baseline blood pressure for two consecutive readings taken at least six hours apart be moved from the R9-16-111. Prohibited Practice; Transfer of Care to R9-16-112. Required Consultation and be amended as follows: Diastolic blood pressure (dBP) of 90-109 millimeters of mercury or systolic blood pressure greater than or equal to 160 millimeters of mercury taken in two consecutive readings taken at least six hours apart or dBP greater than or equal to 110 millimeters of mercury in one single reading warrants medical consultation.

Criticism: Lacey Smith-Herron 4/30/16 e-mail, submitted to the Governor's Regulatory Review Council and forwarded to the Department, requests that an individual can choose to receive midwifery services from her midwife of choice even if the individual has or had a medical condition that would require a transfer to another health care professional.

Response for the 5/19/15 letter and the 4/30/16 e-mail: The Department is reviewing midwifery services outcomes from women receiving midwifery services as reported by licensed midwives to ensure that the changes in the rules related to midwifery services and the licensed midwife's scope of practice do not increase negative health and safety outcomes for a mother or the mother's child. Based on the number of births typically attended by licensed midwives annually, the Department believes that five years of midwifery services outcomes are necessary to have information that is statistical significant. The Department plans to complete the review of midwifery services outcomes information, the reports submitted by the MAC, and any changes to the industry standards and start the rule amendment process by July 2019. At that time the Department will amend the rules to address any changes determined to be necessary to the scope of practice for licensed midwives or the midwifery licensing rules as a result of the review.

Criticism: AzAM 6/2/15 letter requests that the definition of "serious mental illness" and requirements in R9-16-111(B)(15) that a midwife not accept for midwifery services a client who has or develops a serious mental illness be repealed.

Response: The term "serious mental illness" is defined in the section and includes a reference to the statutory definition of "mental disorder" in A.R.S. § 36-501 which is the equivalent definition to the NAMI definition provided in the written criticism. In order for an individual to have a designation of SMI, the individual's mental disorder needs to be severe and persistent, resulting in a long-term limitation of the individual's functional capacities for primary activities of daily living and the individual's mental disorder impairs or substantially interferes with the capacity of the individual to remain in the community without supportive treatment or services of a long-term or indefinite duration. The Department does not believe that one out of every six women of
childbearing years, as stated in the written criticism, could be considered to have a serious mental illness and the source of this information in the written criticism is not specified. The Department's decision to require a licensed midwife to decline to provide or to transfer the care of a pregnant woman with a "serious mental illness" as defined in this section, is based on the fact that the training, skills, and knowledge required to obtain a midwifery license does not qualify a licensed midwife to be able to identify and address issues related to the pregnant woman's SMI including the effects of prescribed psychotropic drugs on the pregnancy and recognizing signs and symptoms of decompensation, that may impact the woman's pregnancy or to identify and address how the woman's pregnancy may impact the woman's SMI. The limitation in rule is not based on a limitation of the rights of a SMI patient but on the lack of training, skills, and knowledge of a licensed midwife to ensure the health and safety of a pregnant woman with a SMI.

Criticism: AzAM 6/30/15 letter requests that the requirement in R9-16-111(B)(10)(b) that a midwife not accept for midwifery services a client or continue midwifery services for a client who has active syphilis be repealed.

Response: R9-16-108(A) requires that a midwife provides midwifery services only to a healthy woman whose expected outcome of pregnancy is most likely to be the delivery of a healthy newborn. A pregnant woman with active syphilis is not a healthy woman and the fact that the pregnant woman has active syphilis jeopardizes the delivery of a healthy newborn. The Department believes that, in order to provide the best possible outcome for a pregnant woman who has syphilis and the pregnant woman's newborn, a health care professional with knowledge, skills, training, and credentials, provides medical services to the pregnant woman.

Criticism: AzAM 7/10/15 letter requests that the requirement for a licensed midwife to transfer care of a client who experiences "a postpartum hemorrhage of greater than 500 milliliters in the current pregnancy" in R9-16-111(B)(25) be moved to R9-16-112, Required Consultation and the following criteria added to be met in the postpartum period:

a. The hemorrhage responds to treatments available in the out of hospital setting and is well controlled
   i. The client is alert and oriented
   ii. The client is not experiencing syncope greater than one occurrence
   iii. The client's blood pressure remains within normal limits of between 90/60 and 140/90; or
b. The client has been discharged from physician care following a transfer of care for hemorrhage
Response: The Department believes that, in order to provide the best possible outcome for a pregnant woman who has a postpartum hemorrhage of greater than 500 milliliters in the current pregnancy, a health care professional with knowledge, skills, training, and credentials, provides medical services to the pregnant woman.

Criticism: AzAM 7/21/15 letter requests that the requirement for a licensed midwife to transfer care of a client who experiences "a gestation beyond 42 weeks" in R9-16-111(B)(21) be moved to R9-16-112, Required Consultation.

Response: R9-16-108(A) requires that a midwife provides midwifery services only to a healthy woman whose expected outcome of pregnancy is most likely to be the delivery of a healthy newborn. When a woman's pregnancy extends beyond 42 weeks gestation, there is a risk that the outcome of the pregnancy will not be the delivery of a healthy newborn. The Department believes that, in order to provide the best possible outcome for a pregnant woman who experiences a gestation beyond 42 weeks and the pregnant newborn's unborn fetus, a health care professional with knowledge, skills, training, and credentials, provides medical services to the pregnant woman.
R9-16-112. Required Consultation

2. Objective
The objective of the rule is to establish the medical conditions that would require a licensed midwife to consult with a health care professional pertaining to the care of a client or the client's newborn to ensure that the client or the client's newborn receives care based on the consultation with the health care professional who has the appropriate skills, knowledge, training, and credentials to recommend the care necessary to ensure the client or the client's newborn's health and safety.

3. Analysis of effectiveness in achieving the objective
The rule is effective in achieving the stated objective.

6. Analysis of clarity, conciseness, and understandability
The rule is clear concise, and understandable.
2. **Objective**

   The objective of the rule is to require a licensed midwife to notify an emergency medical services provider when the licensed midwife determines that the health or safety of a client or the client's newborn is at risk and to establish the specific emergency measures that a licensed midwife is authorized and allowed to provide.

3. **Analysis of effectiveness in achieving the objective**

   The rule is effective in achieving the stated objective.

6. **Analysis of clarity, conciseness, and understandability**

   The rule is clear, concise, and understandable.
R9-16-114. Midwife Report after Termination of Midwifery Services

2. **Objective**
   The objective of the rule is to establish the specific information pertaining to a client or a client's newborn that a licensed midwife is required to submit to the Department that will assist with monitoring whether the licensed midwife is complying with applicable health and safety standards in rules and statutes when providing midwifery services to the client and the client's newborn.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving the stated objective because the Department reviews the client or the client's newborn's information in the report submitted by a licensed midwife to determine if there is reason to believe that the licensed midwife may not have complied with applicable health and safety rules and statutes. If the Department determines that more information is necessary, the Department may require the licensed midwife to provide the client record or the client's newborn's record according to A.R.S. § 36-756.01.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.
R9-16-115. Client and Newborn Records

2. **Objective**
   The objective of the rule is to establish recordkeeping requirements for the midwifery services provided to a client or the client's newborn.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving the stated objective.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.
R9-16-116. Denial, Suspension, or Revocation of License; Civil Penalties; Procedures

1. **Authorization of the rule by existing statutes**
   
   Implementing statute (specific): A.R.S. § 36-756

2. **Objective**
   
   The objective of the rule is to establish the conditions or circumstances under which the Department may deny, suspend, or revoke a midwife's license to practice midwifery or assess a midwife a civil penalty.

3. **Analysis of effectiveness in achieving the objective**
   
   The rule is effective in achieving the stated objective but may be more clear if the Department clarified the phrase "deny, suspend, or revoke a license permanently or for a definite period of time." It is unclear whether the phrase "permanently or for a definite period of time" is supposed to modify "deny, suspend, or revoke" or just "revoke." Typically, when the Department revokes a license, the revocation is permanent. A license that is suspended can be reinstated, usually after the licensee demonstrates compliance or an ability to comply.

6. **Analysis of clarity, conciseness, and understandability**
   
   The rule is clear, concise, and understandable but adding the phrase "required by A.R.S. Title 36, Chapter 6, Article 7.1 or these rules" to the language "Falsification of records" in subsection (3) would make the requirement clearer.

8. **Estimated economic, small business, and consumer impact comparison**
   
   Although the previous rule established a civil penalty of $50 for the first offense and $100 for each subsequent offense, the current rule does not establish a specific amount or a method to determine a specific amount. The current rules may have increased costs for civil penalties but it is difficult to determine because A.R.S. § 36-756(D) states that "the director may assess a civil penalty of not more than $100 for each violation" but there is no stated criteria in rule as to how the Department determines if a civil penalty will be $10 or $100.
FIVE-YEAR-REVIEW REPORT

TITLE 9. HEALTH SERVICES

CHAPTER 1. DEPARTMENT OF HEALTH SERVICES – ADMINISTRATION

ARTICLE 5. SLIDING FEE SCHEDULES

October 2016
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6. 2006 ECONOMIC IMPACT STATEMENT ......................... Attachment C
Arizona Revised Statutes (A.R.S.) § 36-136(A)(7) requires the Arizona Department of Health Services (Department) to prepare sanitary and public health rules. A.R.S. § 36-136(F) requires the Department to promulgate rules necessary for the proper administration and enforcement of the laws relating to public health. A.R.S. § 36-2907.06 authorizes the Department to implement a primary care program to establish contracts with community health centers to provide uninsured individuals medical services at discounted fees based on a Department-approved sliding fee schedule required in A.R.S. § 36-2907.06(E).

The Department implemented the primary care program and promulgated sliding fee schedule rules at Arizona Administrative Code (A.A.C.) Title 9, Chapter 2, Article 1, Tobacco Tax-funded Programs effective December 1995. In 2006, the Department repealed 9 A.A.C. 2, Article 1, amended the sliding fee schedule rules, and adopted amended sliding fee schedule rules in 9 A.A.C. 1, Administration, as new Article 5, Sliding Fee Schedules. Due to budget restrictions, the primary care program was unfunded in 2010, and the Department no longer contracts with community health centers. Currently, the Department's Primary Care Provider Loan Repayment Program under A.R.S. § 36-2172, the Rural Private Primary Care Provider Loan Repayment Program under A.R.S. § 36-2174, and the J-1 Visa Waiver Program and National Interest Waiver Program under A.R.S. § 36-104(16) utilize the sliding fee schedule rules.

The rules in 9 A.A.C. 1, Article 5 provide the criteria for determining family members and family income of an uninsured individual, requirements for submission and content of a sliding fee schedule, sliding fee schedule approval time-frames, and discounted fee requirements and limitations. Family members and family income are used to determine whether an uninsured individual is eligible to receive a provider's sliding fee schedule discounted fee for medical services provided to the uninsured individual by the provider defined in R9-1-501. As of June 2016, the Department has 43 providers participating in the Primary Care Provider Loan Repayment Program, four providers participating in the Rural Private Primary Care Provider Loan Repayment Program, 99 providers participating in the J-1 Visa Waiver Program, and three letters of support for providers in the National Interest Waiver Program. In addition to the Department approving a sliding fee schedule for a provider, when approving the provider's initial or
renewal application, the Department approves the sliding fee schedule for the provider's service site where the provider will provide or provides medical services to uninsured individuals.

The Department has determined that the rules in 9 A.A.C. 1, Article 5 are effective, clear, concise, and understandable. The rules are consistent with state statutes and federal laws, enforced as written, and provide the least burden on and cost to uninsured individuals, providers, the public, and the Department. The Department has not received any written criticism in the past five years.

The Department has determined that the rules are necessary and the matters identified in this report do not create an issue that would make rulemaking a priority for the Department. The Department's rulemaking priorities take into account emergency conditions to protect public health and safety, legislative mandates, court orders, voter approved propositions, and available resources. With the rules sufficient to protect public health and safety, the Department does not plan to amend the rules in 9 A.A.C. 1, Article 5 before the next five-year-review report is due. However, the Department will amend the rules, including the matters identified, should an issue occur that affects public health or safety or prevents the Department from meeting its regulatory objectives.
1. **Authorization of the rule by existing statutes**

The general statutory authority for the rules in Article 5 are A.R.S. §§ 36-136(A)(7) and 36-136(F).

The specific statutory authority for the rules in Article 5 are A.R.S. §§ 36-104(16), 36-2172(B), 36-2174(A) and 36-2907.06.

2. **The purpose of the rule**

The purpose of the rules in Article 5 is to increase access to medical services for uninsured individuals by establishing standards for providers to adhere to when determining and applying discounted fees for medical services provided to uninsured individuals. The rules establish sliding fee schedule content and approval, and criteria for determining an uninsured individual's eligibility based on family members and family income.

3. **Analysis of effectiveness in achieving the objective**

Except for R9-1-502, the rules in Article 5 are effective in achieving their respective objectives.

4. **Analysis of consistency with state and federal statutes and rules**

Except for R9-1-505, the rules in Article 5 are consistent with state and federal statutes and rules.

5. **Status of enforcement of the rule**

The rules in Article 5 are enforced without difficulty to the Department, providers, and uninsured individuals.

7. **Summary of the written criticisms of the rule received within the last five years**

The Department did not receive any written criticisms of the rules in Article 5 in the past five years.

8. **Economic, small business, and consumer impact comparison**

The 2006 Economic, Small Business, and Consumer Impact Statement (EIS) states that under the new rules, the Department will approve sliding fee schedules used by providers under other Department programs. The Department anticipated the cost to the Department as minimal-to-moderate based on the new rules being clearer and easier to use. For providers participating in the Department's programs, the Department anticipated providers would incur a minimal cost for preparing and submitting a sliding fee schedule for approval and for assessing discounted fees.
according to the sliding fee schedule. A substantial benefit to providers was anticipated because
the new rules added a single administrative fee up to $25 that a provider may assess for medical
services provided to uninsured individuals with an income at or below 100 percent of the federal
poverty guidelines.

The Department anticipated that uninsured individuals with a family income more than
100 percent of the federal poverty guidelines would see a minimal increase in fees for medical
services received from providers. The Department expected that the improved access to care
uninsured individuals would experience would offset any single administrative fee or increased
discounted fee paid for medical services. The Department also determined that the new rules had
no measureable impact to the public, stating, "Non-quantifiable [costs and] benefits from
controlling the total bill for health care in the state."

In the Department's 2011 Five-Year-Review Report, the Department stated that in 2010-
2011: 15 providers participated in the Primary Care Provider Loan Repayment Program; five
providers participated in the Rural Primary Care Provider Loan Repayment Program; 26
providers participated in the J-1 Visa Waiver Program; and two letters of support were issued for
providers in the National Interest Waiver Program. In addition, the Department indicated that in
2009-2010 the primary care program had 19 contractors operating 138 community health centers.
As of June 2016, the Department has 43 providers participating in the Primary Care Provider
Loan Repayment Program; four providers participating in the Rural Primary Care Provider Loan
Repayment Program; 99 providers participating in the J-1 Visa Waiver Program; and three letters
of support were issued for providers in the National Interest Waiver Program.

In its economic impact comparison analysis of the rules, the Department has determined
that the increase in the number of providers in the Department's other programs and the closure of
the primary care program has had a minimal effect both in cost and benefit for providers and
uninsured individuals affected by the rules. The Department anticipates that the economic impact
of the rules is consistent with the 2006 EIS for providers, uninsured individuals, and the public.
The Department also expects that the Department has received a moderate increase in the benefit
of the rules has occurred since the Department's other programs utilize the sliding fee schedule
rules.


The Department did not receive a business competitiveness analysis of the rules in the last five
years.
10. **Status of the completion of action indicated in the previous five-year-review report**

In the 2011 Five-Year-Review Report, the Department intended to amend and submit a Notice of Final Rulemaking to the Governor's Regulatory Review Council by November 2014, subject to the Department's priorities, the length of the rules moratorium, and the availability of resources. The Department did not amend the rules as intended.

12. **Analysis of stringency compared to federal laws**

Except for R9-1-506, the rules in Article 5 are consistent with federal laws.

13. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**

The rules were adopted before July 29, 2010.

14. **Proposed course of action**

The Department has determined that the rules are necessary and the matters identified in this report do not create an issue or priority for the Department. The Department's rulemaking priorities take into account emergency conditions to protect public health and safety, legislative mandates, court orders, voter-approved propositions, and available resources. With the rules sufficient to protect public health and safety, the Department does not plan to amend the rules in Article 5 before the next five-year-review report. However, the Department will amend the rules, including the matters identified in this report, should an issue occur that affects public health and safety or prevents the Department from meeting its regulatory objectives.
R9-1-501. Definitions

2. **Objective of the rule**
   The objective of the rule is to define terms used in the Article to help members of the public read and understand the rules, as well as allow for consistent interpretation of the rules.

6. **Analysis of clarity, conciseness, and understandability in achieving the objective**
   The rule is clear, concise, and understandable in achieving its objective; however, it could be improved. For example, the term "business day" is only used once in R9-1-505(D). The rule could be clearer if the term were described in the rule where the term is used rather than defining the term in this Section. The term "OASDI" is an antiquated term for a social insurance program that today is commonly recognized as the Social Security Act, 42 U.S.C. 1395. The term "OASDI" is used in definitions (11) and (37). Since "Social Security tax" is already used in definitions (11) and (37), deleting the term "OASDI" from those definitions could improve the understandability of the rules. Additionally, the term "fetus" means "the same as in A.R.S. § 36-2152." However, Laws 2009, Ch. 172 deleted the term "fetus" from A.R.S. § 36-2152. The term "viable fetus" in A.R.S § 36-2301.01 could be used in place of the term "fetus."

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to regulated persons by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Even though the rule contains antiquated and outdated terms described in paragraph 6, the Department and providers continue to use the rules without increase in cost or burden. The Department has determined that the economic impact of the rule is consistent with the 2006 EIS and provides the least burden and cost to the Department and regulated persons.

R9-1-502. Family Member Determination

2. **Objective of the rule**
   The objective of the rule is to establish criteria for a provider to use to determine the number of an uninsured individual’s family members.

3. **Analysis of effectiveness in achieving the objective**
   Although the rule is effective, the rule could be improved if the criteria determining if an individual is an uninsured individual's family member were clarified. A.R.S. § 36-2172 requires
the Department in its Primary Care Provider Loan Repayment Program to "prescribe application and eligibility requirements that are consistent with the requirements" of the National Health Service Corps (NHSC) Loan Repayment Program. The NHSC in its NHSC Sliding Fee Discount Program Information Package\(^1\) states that eligibility is based on income and family size only. Family is defined as: a group of two people or more (one of whom is the householder) related by birth, marriage, or adoption and residing together; all such people (including related subfamily members) are considered as members of one family. If the criteria used for determining the number of an uninsured individual's family members were less prescriptive, the effectiveness of the rule would increase by allowing more uninsured individuals access to medical services.

6. **Analysis of clarity, conciseness, and understandability in achieving the objective**
The rule is clear, concise, and understandable in achieving its objective.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to regulated persons by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Although paragraph 3 contains a matter that could improve the rules, the Department and providers continue to use the rules without increase in cost or burden. The Department has determined that the economic impact of the rule is consistent with the 2006 EIS and provides the least burden and cost to the Department and regulated persons.

R9-1-503. **Family Income Determination**

2. **Objective of the rule**
The objective of the rule is to establish criteria for a provider to use to determine an uninsured individual's family income, which allows the provider to determine the sliding fee schedule discounted fee an uninsured individual will pay for medical service received from the provider.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to regulated persons by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

\(^1\) NHSC Sliding Fee Discount Program Information Package: [https://nhsc.hrsa.gov/downloads/discountfeeschedule.pdf](https://nhsc.hrsa.gov/downloads/discountfeeschedule.pdf)
The Department has determined that the economic impact of the rule is consistent with the 2006 EIS and provides the least burden and cost to the Department and regulated persons.

R9-1-504. Sliding Fee Schedule Submission and Contents

2. **Objective of the rule**
The objectives of the rule is to establish the contents of a fee-percentage or flat-fee sliding fee schedule used by a provider who provides medical services to uninsured individuals and the submission date a sliding fee schedule is required to be submitted to the Department for approval.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable, but the rule would be clearer if the rule did not specify that "By April 1 of each year, a provider shall submit to the Department the provider's sliding fee schedule..." For the primary care program, the Department specified an April 1 submission date with the intent that the Department would begin reviewing all sliding fee schedules received on April 1. Additionally, the rule in R9-1-505 requires the Department to approve or deny a sliding fee schedule within 32 days from the day the sliding fee schedule is received by the Department. Also, the other Department programs require a provider to submit their sliding fee schedule with the provider's initial or renewal application. A provider, requesting to participate or requesting to continue participation in the Primary Care Provider Loan Repayment Program or the Rural Primary Care Provider Loan Repayment Program under 9 A.A.C. 15, Article 1, is required to submit their application in June, April, or October of each year. In the J-1 Visa Waiver program, a provider is required to submit their application in October of each year, and, in the National Interest Waiver Program, a provider is not required to submit their application at any specific time but as needed. Since the rule does not specify how many days before April 1 a provider may submit a sliding fee schedule and with the other Department programs accepting initial and renewal applications based on a program's established needs, the rule would be clear if the rule specified that "A sliding fee schedule submitted to the Department each year required by the applicable Department's program's initial or renewal application submission date."

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to regulated persons by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Even though the rule contains an outdated submission date described in paragraph 6, the Department and providers continue to use the rules without increase in cost or burden. The
Department has determined that the economic impact of the rule is consistent with the 2006 EIS and provides the least burden and cost to the Department and regulated persons.

R9-1-505. Sliding Fee Schedule Approval Time-frames

2. **Objective of the rule**
The objective of the rule is to establish the requirements for administrative and substantive review of a sliding fee schedule submitted to the Department and written notice granting or denying approval of a provider's sliding fee schedule.

4. **Analysis of consistency with state and federal statutes and rules**
The rule is clear, concise, and understandable in achieving its objective. However, the rule in R9-1-505 (D) contains a citation to A.A.C. R2-5-402 that has been repealed. The correct citation is A.A.C. R2-5A-101.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to regulated persons by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Even though the rule contains an outdated rule citation described in paragraph 4, the Department and providers continue to use the rules without increase in cost or burden. The Department has determined that the economic impact of the rule is consistent with the 2006 EIS and provides the least burden and cost to the Department and regulated persons.

R9-1-506. Fees Payable by Uninsured Individuals Under a Sliding Fee Schedule

2. **Objective of the rule**
The objective of the rule is to establish limitations for discounted fees a provider may charge an uninsured individual based on current federal poverty guidelines and to establish requirements regarding a single administrative fee a provider may charge for medical services to an uninsured individual.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to regulated persons by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Even though the rule allows for a single administrative fee described in paragraph 12, the Department and providers continue to use the rules without increase in cost or burden. The Department has determined that the economic impact of the rule is consistent with the 2006 EIS and provides the least burden and cost to the Department and regulated persons.

12. **Analysis of stringency compared to federal laws**

A.R.S. § 36-2172 requires the Department in its Primary Care Provider Loan Repayment Program to "prescribe application and eligibility requirements that are consistent with the requirements" of the National Health Service Corps (NHSC) Loan Repayment Program according to 42 Code of Federal Regulations part 62. In R9-1-506(E), a provider may charge an uninsured individual a single administrative fee for medical services, not to exceed $25, in lieu of a sliding fee schedule discounted fee. The Department determined that even though 42 CFR 62 does not include a single administrative fee; NHSC does, in its Sliding Fee Discount Program Information Package, permit adopt of a nominal charge for medical services. The Department determined that a single administrative fee is equivalent to a nominal charge; and the Department considers the rule consistent with federal law, since the single administrative fee is by definition a discounted fee for an uninsured individual and the amount of the single administrative fee is nominal and reasonable.
FIVE-YEAR-REVIEW REPORT

TITLE 9. HEALTH SERVICES

CHAPTER 2. DEPARTMENT OF HEALTH SERVICES

TOBACCO-RELATED PROGRAMS

ARTICLE 1. SMOKE-FREE ARIZONA

December 2016
FIVE-YEAR-REVIEW REPORT
TITLE 9. HEALTH SERVICES
CHAPTER 2. DEPARTMENT OF HEALTH SERVICES
TOBACCO-RELATED PROGRAMS
ARTICLE 1. SMOKE-FREE ARIZONA

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FIVE-YEAR-REVIEW SUMMARY

Arizona Revised Statutes (A.R.S.) § 36-601.01(G)(11) requires the Arizona Department of Health Services (Department) to implement and enforce A.R.S. § 36-601.01, which was enacted as part of the Smoke-Free Arizona Act, and authorizes the Department to make rules for that purpose. A.R.S. § 36-601.01(G)(11) gave the Department exempt rulemaking authority until May 1, 2007 to adopt rules to implement and enforce a statewide smoking ban in most public places and places of employment under A.R.S. § 36-601.01. The Department has adopted these rules in Arizona Administrative Code (A.A.C.) Title 9, Chapter 2, Article 1, which became effective on May 1, 2007. The rules establish a “reasonable distance” around entrances, windows, and ventilation systems where smoking is prohibited to prevent smoke from entering a public place or non-vehicle place of employment. The rules also specify individual and proprietor responsibilities, signage requirements, conditions under which smoking is prohibited in private residences, requirements for retail tobacco stores and outdoor patios where smoking is permitted, and rules related to enforcement.

The Department delegates the authority to respond to a complaint regarding compliance with A.R.S. § 36-601.01 or 9 A.A.C. 2, Article 1 to the health departments or environmental health departments of all but one of Arizona’s counties. After an analysis of the rules in 9 A.A.C. 2, Article 1, the Department has determined that the rules are effective; consistent with state and federal statutes and rules; enforced; and clear, concise, and understandable. Although the Department has received several written concerns about smoking in areas that are not covered under A.R.S. § 36-601.01, the Department has received no written criticism of the rules. The Department does not plan to amend the rules in 9 A.A.C. 2, Article 1 until substantive issues arise.
1. **Authorization of the rule by existing statutes**
The general statutory authority for the rules in 9 A.A.C. 2, Article 1 are A.R.S. §§ 36-136(A)(7) and 36-136(F).
The specific statutory authority for the rules in 9 A.A.C. 2, Article 1 is A.R.S. § 36-601.01.

2. **The purpose of the rule**
The purpose of the rules in 9 A.A.C. 2, Article 1 is to specify requirements necessary to implement and enforce a statewide smoking ban in most public places and places of employment.

3. **Analysis of effectiveness in achieving the objective**
The rules in 9 A.A.C. 2, Article 1 are effective in achieving their respective objectives, although R9-2-108 and R9-2-110 could be improved as described under Information for Individual Rules.

4. **Analysis of consistency with state and federal statutes and rules**
The rules in 9 A.A.C. 2, Article 1 are consistent with state and federal statutes and rules.

5. **Status of enforcement of the rule**
The rules in 9 A.A.C. 2, Article 1 are enforced without difficulty by the Department and county health departments or environmental health departments.

6. **Analysis of clarity, conciseness, and understandability**
The rules in 9 A.A.C. 2, Article 1 are clear, concise, and understandable, although R9-2-101 could be improved as described under Information for Individual Rules.

7. **Summary of the written criticisms of the rule received within the last five years**
The Department has received several written concerns about smoke infiltrating apartments from other apartments in multi-family dwellings, as shown in Attachment D. However, private residences are exempt from requirements in A.R.S. § 36-601.01, according to A.R.S. § 36-601.01(B)(1), and are not covered under the rules in 9 A.A.C. 2, Article 1. The Department did not receive any written criticisms of the rules in the past five years.

8. **Economic, small business, and consumer impact comparison**
The rules in 9 A.A.C. 2, Article 1 were made by exempt rulemaking and published in the *Arizona Administrative Register* (A.A.R.) at 13 A.A.R. 1512, effective May 1, 2007. Although an economic, small business, and consumer impact statement was not prepared as part of the rulemaking package, the W. P. Carey School of Business in the Arizona State University conducted a study of the economic effect of the Smoke-Free Arizona Act in December 2006 at the Department’s request. This report (Attachment C) was submitted to the Department in August 2008 and compared the economic effect of the smoking ban on the restaurant and bar
industry in Arizona. The report stated that the smoking ban “did not result in any distinguishable large-scale economic effect on the restaurant or bar industry in the state.” This conclusion was based on an analysis of aggregate sales data from the beginning of 1986 through the second quarter of 2008. Two surveys of businesses in Arizona at which food or drinks are served (restaurants, bars, microbreweries, veterans and fraternal clubs, and government facilities) were also conducted, the first just prior to the implementation of the Smoke-Free Arizona Act (in February through April 2007) and a second in July and early August 2008. On the basis of these surveys, the report stated that “the ban appears to have had a negative effect on some businesses and a positive effect on others.” In communities that had a comprehensive smoking ban before the implementation of the Smoke-Free Arizona Act, A.R.S. § 36-601.01 had little to no effect. According to the report, some businesses with only indoor seating lost income to businesses with both indoor seating, in which smoking was prohibited, and outdoor patio seating, in which smoking was permitted.

Since A.R.S. § 36-601.01 became effective in May 2007, the Department has prepared and published nine annual reports describing the implementation of the program. The 2016 Smoke-Free Arizona Annual Report is available at http://azdhs.gov/documents/preparedness/epidemiology-disease-control/smoke-free-arizona/reports/sfa-annual-report-2016.pdf.

Each report shows greater acceptance of the smoking ban and more compliance. In the 2016 Annual Report, the Department reported that a total of 25,833 educational visits, consultations, and on-site visits were conducted between May 1, 2015 and April 30, 2016. A total of 1,425 complaints were received during that period, most related to people smoking outside within 20 feet of an entrance or ashtrays located within 20 feet of an entrance. After the first year of implementation, the number of complaints received has remained fairly level. The number of notices of violation has decreased since the 2012 Annual Report. A total of 18 were issued statewide between May 1, 2010 and April 30, 2011, while only two were issued between May 1, 2015 and April 30, 2016. Most of these notices of violation were issued to proprietors who allowed employees, customers, or visitors to smoke inside public places or places of employment. According to the 2016 Annual Report, the proprietors that were issued these notices of violation corrected violations observed and did not face any civil money penalties.

Persons affected by the rules in 9 A.A.C. 2, Article 1, include state and local government entities, businesses of all types, the owners or proprietors of those businesses, and the public. According to the Preamble of the Notice of Exempt Rulemaking, the costs associated with the rulemaking resulted from the Smoke-Free Arizona Act, which was approved by the majority of
those voting in November 2006, implying that these voters believed that the benefits to the health and safety welfare of Arizonans resulting from Smoke-Free Arizona Act outweighed the costs.

The Department solicited and received more than 2,200 written comments while developing these rules and used these comments in making the rules that were adopted. On the basis of the studies described above, the Department estimates that the actual costs and benefits experienced by persons affected by the rules are generally consistent with the costs and benefits considered in developing the rules.

9. **Summary of business competitiveness analyses of the rules**

The Department did not receive a business competitiveness analysis of the rules in the last five years.

10. **Status of the completion of action indicated in the previous five-year-review report**

In the 2012 Five-Year-Review Report, the Department stated that the Department did not plan to amend the rules in 9 A.A.C. 2, Article 1 until substantive issues arise. No substantive issue has arisen, so the Department has adhered to the plan.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to regulated persons by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

The Department has determined that the rules in 9 A.A.C. 2, Article 1 impose the least burden and costs to persons regulated by the rules, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective, despite the minor improvements that may be made to the rules.

12. **Analysis of stringency compared to federal laws**

The rules in 9 A.A.C. 2, Article 1 are consistent with federal laws.

13. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**

The rules were adopted before July 29, 2010.

14. **Proposed course of action**

The Department does not plan to amend the rules in 9 A.A.C. 2, Article 1 until substantive issues arise.
R9-2-101. Definitions

2. Objective of the rule
The objective of the rule is to define terms and phrases used in the Article to enable the reader to clearly understand the requirements of the Article and allow for consistent interpretation.

6. Analysis of clarity, conciseness, and understandability
The rule is clear, concise, and understandable but could be improved by revising the definition of “private residence.” The definition of “private residence” could clarify that a hotel or motel room is not a private residence even though, like a health care institution, an individual may live and sleep in a hotel or motel room for a time. Specific requirements for hotel and motel rooms are contained in A.R.S. § 36-601.01(B)(2).

R9-2-102. Reasonable Distance

2. Objective of the rule
The objective of the rule is to provide the specific distance from an entrance, window, or ventilation system where smoking is not permitted and into which a proprietor shall not allow smoke to drift.

R9-2-103. Individual Responsibilities

2. Objective of the rule
The objective of the rule is to establish an individual’s responsibility not to smoke in an area where smoking is not permitted under A.R.S. § 36-601.01 or R9-2-102 and to stop smoking immediately when requested to do so by a proprietor.

R9-2-104. Proprietor Responsibilities

2. Objective of the rule
The objective of the rule is to establish a proprietor’s responsibilities under A.R.S. § 36-601.01 and this Article, including how responsibility is allocated when a building or facility is under the control of multiple proprietors, and to specify that a proprietor may declare that smoking is prohibited in an entire establishment, facility, or outdoor area.

R9-2-105. Sign Requirements

2. Objective of the rule
The objective of the rule is to specify the size, content, and posting requirements for signs to comply with A.R.S. § 36-601.01(E).

R9-2-106. Private Residence
2. **Objective of the rule**
The objective of the rule is to specify that, although A.R.S. § 36-601.01 does not apply to the private residence of an individual receiving services from a health care professional in the individual’s private residence, smoking is not permitted in:

   a. A health care professional’s private residence, in an area where the health care professional provides services to an individual, while the health care professional is providing services; or
   
   b. A private residence or parts thereof licensed or certified by the Department as an adult day care, a child care facility, or a child care group home.

R9-2-107. Retail Tobacco Store
2. **Objective of the rule**
The objective of the rule is to establish the responsibilities of a proprietor of a retail tobacco store under A.R.S. § 36-601.01 and this Article, including preparing an affidavit stating the proprietor’s contention that the business is a retail tobacco store, maintaining the affidavit on the premises, and providing to the Department or the Department’s designee upon request documents supporting the proprietor’s contention that the business is a retail tobacco store.

R9-2-108. Outdoor Patio
2. **Objective of the rule**
The objective of the rule is to establish the conditions under which a proprietor may designate an area as an outdoor patio where smoking is permitted.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective, but the rule may be improved by clarifying how the limits of an outdoor patio should be delineated to distinguish the outdoor patio area from outdoor space that is not an outdoor patio and not subject to this rule.

R9-2-109. Complaint; Observation; Notification; Inspection
2. **Objective of the rule**
The objective of the rule is to specify:
a. The information a complaint must contain,
b. The circumstances under which a complaint is required to be filed, and
c. The actions the Department or the Department’s designee is required to take in response to a complaint.

R9-2-110. Determination of Violation
2. Objective of the rule
The objective of the rule is to specify the factors the Department or the Department’s designee is required to consider in determining whether a violation of A.R.S. § 36-601.01 has occurred.

3. Analysis of effectiveness in achieving the objective
The rule is effective in achieving its objective but could be improved by making the wording of subsection (3) consistent with the wording in subsections (1) and (4).

R9-2-111. Notice of Violation; Notice of Assessment
2. Objective of the rule
The objective of the rule is to specify:
   a. That the Department or the Department’s designee may issue a notice of violation to a proprietor after determining that a violation of A.R.S. § 36-601.01 has occurred;
   b. The information a notice of violation must contain, including a notice of assessment if a civil penalty is being assessed; and
   c. How the person to whom the notice of violation or notice of assessment has been issued may appeal the determination that a violation occurred or the assessment.

R9-2-112. Criteria for Issuing a Notice of Violation or Notice of Assessment
2. Objective of the rule
The objective of the rule is to specify the factors the Department or the Department’s designee is required to consider in determining whether to issue a notice of violation, whether to issue a notice of assessment, or the amount of a civil penalty to be assessed.
FIVE-YEAR-REVIEW-REPORT
TITLE 9. HEALTH SERVICES
CHAPTER 33. DEPARTMENT OF HEALTH SERVICES
GROUP HOMES FOR INDIVIDUALS WITH
A DEVELOPMENTAL DISABILITY
December 2016
FIVE-YEAR-REVIEW REPORT
TITLE 9. HEALTH SERVICES
CHAPTER 33. DEPARTMENT OF HEALTH SERVICES
GROUP HOMES FOR INDIVIDUALS WITH A DEVELOPMENTAL DISABILITY

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6. PREVIOUS ECONOMIC, SMALL BUSINESS, AND CONSUMER IMPACT STATEMENT Attachment C
Arizona Revised Statutes (A.R.S.) §§ 36-132(A)(21) and 36-591 require the Arizona Department of Health Services (Department) to license and regulate the health and safety of group homes for the developmentally disabled (group homes). The programmatic oversight of group homes is vested in the Arizona Department of Economic Security, Division of Developmental Disabilities (Division) in A.R.S. §§ 36-591 through 36-595.03. Put simply, the Department licenses group home facilities, while the Division licenses group home services.

Arizona Administrative Code (A.A.C.) Title 9, Chapter 33 contains the 16 rules for the licensing of group home facilities. The rules include definitions; a requirement for licensure; application for, issuance of, renewal of, and changes to a license; investigation and enforcement; and health and safety requirements for group home facilities. The rules were adopted December 31, 2012.

During calendar year 2015, the Department licensed 1,110 group homes, of which 1,080 held a two-year license and 30 held a three-year license. During 2015, the Department received 293 new applications, of which 45 were initial licenses and 248 of which were renewal licenses. During 2015, the Department revoked one group home license.

Overall, the rules in Chapter 33 are effective, enforced as written, and clear, concise, and understandable. The Department does not plan to amend the rules at this time, but will continue to track items that could be improved for future rulemakings.
INFORMATION IDENTICAL FOR ALL THE RULES

1. **Authorization of the rule by existing statutes**
   General: A.R.S. §§ 36-104, 36-132(A) and 36-136(F)
   Implementing (specific): A.R.S. §§ 36-132(A)(21), 36-591(B), and 36-595(C) and (D)

2. **The purpose of the rule**
   The purpose of the rules is to specify the requirements for obtaining a license from the Department to operate a facility as a group home as defined in A.R.S. § 36-551.

3. **Analysis of effectiveness in achieving the objective**
   The rules are effective in achieving their objectives.

4. **Analysis of consistency with state and federal statutes and rules**
   The rules are consistent with state statutes and any applicable federal statutes and rules.

5. **Status of enforcement of the rule**
   The Department enforces the rules as written.

6. **Analysis of clarity, conciseness, and understandability**
   Except for R9-33-101 and R9-33-206, the rules are clear, concise, and understandable.

7. **Summary of the written criticisms of the rule received within the last five years**
   No written criticisms have been received.

8. **Economic, small business, and consumer impact comparison**
   The economic impact of the rule is consistent with the economic, small business, and consumer impact statement submitted in 2012 with the previous rulemaking.

10. **Status of the completion of action indicated in the previous five-year-review report**
    In the 2012 five-year review report, the Department indicated that the rules could be amended to reduce the cost of compliance for many stakeholders and that it was in the process of amending Chapter 33 accordingly. The Department completed that rulemaking in 2012, with the amended rules taking effect December 31, 2012.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
    The rules impose the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

12. **Analysis of stringency compared to federal laws**
    There are no specific federal laws related to the rules.
13. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**

The rules establish group home facility licensing requirements that comply with A.R.S. § 41-1037(A)(2).

14. **Proposed course of action**

Because the rules are effective as written, recently underwent a rulemaking process with stakeholder input, and pose no threat to health and safety, the Department plans to take no action at this time.
INFORMATION FOR INDIVIDUAL RULES

R9-33-101. Definitions

2. Objectives

The objective in this rule is to define terms used in 9 A.A.C. 33 so that a reader can consistently interpret requirements in the Chapter.

6. Analysis of clarity, conciseness, and understandability

The rule is clear, concise, and understandable, but could be improved by removing redundancies in the definitions of “Administrative completeness review time-frame,” “Overall time-frame,” and “Substantive review time-frame.” These definitions all refer to A.R.S. § 41-1072, but A.R.S. § 41-1072 is referred to again in R9-33-108.

R9-33-102. Requirement for Licensure

2. Objectives

The objectives of the rule are to:

a. Require an entity operating a group home to be licensed by the Department; and
b. Indicate that the license is restricted to the place, person, and time listed on the license.

R9-33-103. Individuals to Act for Applicant or Licensee

2. Objectives

The objective of this rule is to establish who may act for an applicant or licensee.

R9-33-104. Application and Inspection

2. Objectives

The objectives of the rule are to:

a. Require an applicant to submit an application to the Department in order to be licensed to operate a group home;

b. Describe the application;

c. Establish the process by which the Department issues a license to an applicant who meets the requirements in this Chapter, including applicable time-frames; and

d. Establish that an applicant or licensee shall allow the Department immediate access to inspect the premises.
R9-33-105. License Renewal

2. Objectives

The objectives of the rule are to:

a. Require a licensee to submit an application to the Department in order to renew the licensee's license to operate a group home; and

b. Establish the process by which the Department issues a renewal to a licensee who meets the requirements in this Chapter.

R9-33-106. Changes Affecting a License

2. Objective

The objective of the rule is to establish requirements for a licensee to notify the Department if the licensee's operation of a group home or service provider contract with the Division is going to be terminated.

R9-33-107. Investigation of Complaints

2. Objectives

The objectives of the rule are to:

a. Establish the process by which the Department investigates complaints at group homes or information suggesting that a group home may not be in compliance with applicable laws and rules; and

b. Require a licensee to correct deficiencies listed on a plan of correction within 30 days from the date of the plan of correction.

R9-33-108. Time-frames

2. Objectives

The objective of the rule is to establish time-frames for processing applications.

R9-33-109. Denial, Revocation, or Suspension of a License

2. Objectives

The objectives of the rule are to:

a. Establish the conditions under which the Department may deny, revoke, or suspend a license to operate a group home;

b. Notify applicants and licensees of their statutory right of appeal; and
c. Require the Department to notify the Division of a denial, revocation, or suspension under this Chapter.

**R9-33-201. Emergency Procedures and Evacuation Drills**

2. **Objectives**
   
The objectives of the rule are to establish requirements for:
   
a. Developing and implementing of a group home's emergency plan;
   b. Maintaining proper address signage at the group home;
   c. Ensuring safety measures related to ingress and egress from the group home; and
   d. Conducting evacuation drills.

**R9-33-202. Fire Safety Requirements**

2. **Objectives**
   
The objectives of the rule are to:
   
a. Establish which fire safety requirements apply to a group home at each of the two fire risk prevention levels;
   b. Require licensees to obtain fire inspections; and
   c. Require licensees to have and maintain fire extinguishers, smoke detectors, and other appropriate fire safety fixtures, procedures, and equipment.

**R9-33-203. Physical Plant Requirements**

2. **Objectives**
   
The objectives of the rule are to require licensees to:
   
a. Ensure that a group home is in compliance with applicable disability laws;
   b. Maintain a safe air and water temperature range;
   c. Maintain adequate ventilation and appliances for cooking and cooling food; and
   d. Maintain safe and working electrical and plumbing systems.

**R9-33-204. Environmental Requirements**

2. **Objectives**
   
The objectives of the rule are to require licensees to:
   
a. Maintain a facility free from garbage, refuse, insects, and vermin;
   b. Keep the facility free of hazards; and
   c. Not use unsafe space heaters.
**R9-33-205. Vehicle Safety**

2. **Objectives**

The objectives of the rule are to:

a. Require licensees to ensure that a vehicle used to transport a resident is properly equipped and maintained to be safe and in good repair; and

b. Establish documentation requirements for a vehicle used to transport a resident.

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**R9-33-206. Swimming Pool Requirements**

2. **Objectives**

The objective of the rule is to establish requirements for a private residential swimming pool and a spa at a group home.

6. **Analysis of clarity, conciseness, and understandability**

The rule is clear, concise, and understandable, but could be further improved by removing a possible inconsistency between the requirement of a “rigid” fence and the allowance of a “wire mesh fence.”
Attachment A
TITLE 9. HEALTH SERVICES

CHAPTER 33. DEPARTMENT OF HEALTH SERVICES
GROUP HOMES FOR INDIVIDUALS WITH A DEVELOPMENTAL DISABILITY

Editor's Note: 9 A.A.C. 33, consisting of Articles 1 and 2, made by final rulemaking at 8 A.A.R. 910, effective February 11, 2002 (Supp. 02-1).

ARTICLE 1. LICENSURE REQUIREMENTS

Article 1, consisting of Sections R9-33-101 through R9-33-107, made by final rulemaking at 8 A.A.R. 910, effective February 11, 2002 (Supp. 02-1).

Section
R9-33-101. Definitions
R9-33-102. Requirement for Licensure
R9-33-103. Individuals to Act for Applicant or Licensure
R9-33-104. Application and Inspection
R9-33-105. License Renewal
R9-33-106. Changes Affecting a License
R9-33-107. Investigation of Complaints
R9-33-108. Time-frames
R9-33-109. Denial, Revocation, or Suspension of a License
Table 1.1 Time-frames (in days)

ARTICLE 2. GROUP HOME REQUIREMENTS

Article 2, consisting of Sections R9-33-201 through R9-33-207, made by final rulemaking at 8 A.A.R. 910, effective February 11, 2002 (Supp. 02-1).

Section
R9-33-201. Emergency Procedures and Evacuation Drills
R9-33-202. Fire Safety Requirements
R9-33-203. Physical Plant Requirements
R9-33-204. Environmental Requirements
R9-33-205. Vehicle Safety Requirements
R9-33-206. Swimming Pool Requirements
R9-33-207. Repealed

ARTICLE 1. LICENSURE REQUIREMENTS

R9-33-101. Definitions

In addition to the definitions in A.R.S. § 36-551, the following definitions apply in this Chapter unless otherwise specified:

1. "Accreditation" means recognition as having met the operating standards and criteria of a nationally recognized accreditation organization.
2. "Administrative completeness review time-frame" means the same as in A.R.S. § 41-1072.
3. "Applicant" means an individual or business organization requesting a license under R9-33-104 to open a group home.
4. "Application packet" means the forms, documents, and additional information the Department requires to be submitted by an applicant.
5. "Business organization" means the same as "entity" in A.R.S. § 10-140.
6. "Controlling person" means a person who, with respect to a business organization:
   a. Through ownership, has the power to vote at least 10% of the outstanding voting securities of the business organization;
   b. If the business organization is a partnership, is a general partner or is a limited partner who holds at least 10% of the voting rights of the partnership;
   c. If the business organization is a corporation, association, or limited liability company, is the president, the chief executive officer, the incorporator, an agent, or any person who owns or controls at least 10% of the voting securities; or
   d. Holds a beneficial interest in 10% or more of the liabilities of the business organization.
7. "Day" means a calendar day, not including the day of the act, event, or default: from which a designated period of time begins to run, but including the last day of the period unless it is a Saturday, Sunday, or state holiday, in which case the period runs until the end of the next day that is not a Saturday, Sunday, or state holiday.
8. "Department" means the Arizona Department of Health Services.
9. "Documentation" means information in written, photographic, electronic, or other permanent form.
10. "Facility" means the building or buildings used for operating a group home.
11. "Fire risk prevention level" means a designation applied to a group home by the Division based on a formula aggregating safety factors existing at the group home.
12. "Hazard" means an object, equipment, situation, or condition that may result in physical injury or illness to an individual.
13. "Licensure" means the individual or business organization to which the Department has issued a license to operate a group home.
14. "Modification" means the substantial improvement, enlargement, reduction, alteration, or other substantial change in the facility or another structure on the premises at a group home.
15. "Overall time-frame" means the same as in A.R.S. § 41-1072.
16. "Plumbing system" means fixtures, pipes, and related parts, including a septic apparatus, assembled to carry clean water into a structure and to carry sewage out of a structure.
17. "Premises" means:
   a. A facility, and
   b. The grounds surrounding the facility that are owned, leased, or controlled by the licensee, including other structures.
18. "Private residential swimming pool" means the same as in A.A.C. R18-5-201.
19. "Resident" means an individual who is accepted by a licensee under the terms of a contract with the Division to live at the licensee's group home.
20. "Safety-approved" means tested and designated as meeting applicable safety standards by one or more of the following organizations:
   a. Underwriters Laboratories,
   b. Canadian Standards Association, or
   c. Factory Mutual Insurance Company Global.
21. "Service provider contract" means the entirety of an applicant's or licensee's qualified vendor agreement with the Division.
22. "Spa" means the same as in A.A.C. R18-5-201.
23. "Staff" means the employees or volunteers who provide habilitation to residents at a group home.
24. "Substantive review time-frame" means the same as in A.R.S. § 41-1072.
Historical Note
New Section made by final rulemaking at 8 A.A.R. 910, effective February 11, 2002 (Supp. 02-1). Amended by final rulemaking at 18 A.A.R. 3295, effective February 3, 2013 (Supp. 12-4).

R9-33-102. Requirement for Licensure
A. An applicant shall obtain a license to operate a group home from the Department before providing supervision or habilitation to an individual with a developmental disability in a group home.
B. A license to operate a group home is valid for the following, as indicated on the license:
   1. Address of the group home;
   2. Name of the licensee;
   3. Name of the group home, if applicable;
   4. Fire risk prevention level; and
   5. Licensing period for the group home.

Historical Note
New Section made by final rulemaking at 8 A.A.R. 910, effective February 11, 2002 (Supp. 02-1). Amended by final rulemaking at 18 A.A.R. 3295, effective February 3, 2013 (Supp. 12-4).

R9-33-103. Individuals to Act for Applicant or Licensee
When an applicant or licensee is required by this Chapter to provide information or sign an application form or other document, the following shall satisfy the requirement on behalf of the applicant or licensee:
   1. If the applicant or licensee is an individual, the individual; and
   2. If the applicant or licensee is a business organization, the individual who the business organization has designated to act on the business organization’s behalf for purposes of this Chapter and who:
      a. Is a controlling person of the business organization,
      b. Is a U.S. citizen or legal resident, and
      c. Has an Arizona address.

Historical Note
New Section made by final rulemaking at 8 A.A.R. 910, effective February 11, 2002 (Supp. 02-1). R9-33-103 renumbered to R9-33-104; new R9-33-103 made by final rulemaking at 18 A.A.R. 3295, effective February 3, 2013 (Supp. 12-4).

R9-33-104. Application and Inspection
A. For a license to operate a group home, an applicant shall submit to the Department a completed application packet that contains:
   1. An application form provided by the Department that includes:
      a. The applicant’s name;
      b. The proposed group home’s name, if any;
      c. The address and telephone number of the proposed group home;
      d. The applicant’s address and telephone number, if different from the address or telephone number of the proposed group home;
      e. The applicant’s e-mail address;
      f. The name and contact information of an individual acting on behalf of the applicant according to R9-33-103, if applicable;
      g. Whether the applicant agrees to allow the Department to submit supplemental requests for information under R9-33-108(C)(2);
      h. Whether the applicant is a current service provider or intends to become a service provider;
      i. The fire risk prevention level at which the applicant anticipates operating the group home; and
      j. The applicant’s signature and the date signed;
   2. A copy of the applicant’s:
      a. U.S. passport, current or expired;
      b. Birth certificate;
      c. Naturalization documents; or
      d. Documentation of legal resident alien status;
   3. A copy of the applicant’s:
      a. Current service provider contract with the Division indicating that services are to be provided at the address of the proposed group home; or
      b. Documentation from the Division demonstrating that the applicant has a service provider contract pending for providing services at the address of the proposed group home; and
   4. A copy of the applicant’s accreditation report issued by a nationally recognized accreditation organization, if applicable.
B. An applicant or licensee shall allow the Department immediate access to all areas of the premises, a resident, record, or vehicle used to transport a resident, according to A.R.S. § 41-1009.
C. Upon receipt of the application packet in subsection (A), the Department shall issue or deny a license to an applicant as provided in R9-33-108.

Historical Note

R9-33-105. License Renewal
A. At least 60 days before the expiration date indicated on a license to operate a group home, for renewal of the license to operate a group home, a licensee shall submit to the Department an application packet that contains the information and documents in R9-33-104(A)(1), R9-33-104(A)(3)(a), and R9-33-104(A)(4).
B. The Department shall renew a license to operate a group home:
   1. If, after conducting an on-site inspection, the Department determines that the license is in compliance with the applicable requirements in this Chapter; and
   2. According to the time-frames in R9-33-108.

Historical Note

R9-33-106. Changes Affecting a License
A. A licensee shall notify the Department in writing at least 30 days before the effective date of:
   1. Termination of operation of a group home;
   2. Termination of a service provider contract with the Division;
   3. A change in the ownership of the group home;
   4. A change in the name of the group home;
   5. If the licensee is an individual, a legal change of the licensee’s name;
   6. Construction or modification of the facility or another structure on the premises other than construction or modification undertaken in accordance with R9-33-203(A); or
7. If approved by the Division, a change in the group home’s fire risk prevention level.

B. If the Department receives the notification in subsection (A)(1), the Department shall void the licensee’s license to operate a group home as of the termination date specified by the licensee.

C. If the Department receives the notification in subsection (A)(2), the Department shall take the applicable action in R9-33-109.

D. If the Department receives the notification in subsection (A)(3), the Department shall void the licensee’s license to operate a group home upon issuance of a new license to operate a group home to the entity assuming ownership of the group home.

E. If the Department receives the notification in subsection (A)(4) or (5), the Department shall issue to the licensee an amended license that incorporates the change but retains the expiration date of the existing license.

F. If the Department receives the notification in subsection (A)(6) or (7), the Department shall conduct an inspection of the premises as indicated in R9-33-104(3) and, if the group home is in compliance with A.R.S. Title 36, Chapter 5.1 and this Chapter, if applicable, issue to the licensee an amended license that incorporates the change but retains the expiration date of the existing license.

G. An individual or business organization planning to assume operation of an existing group home shall obtain a new license as required in R9-33-102(A) before beginning operation of the group home.

Historical Note

R9-33-107. Investigation of Complaints

A. Upon receipt of a complaint or information indicating that a group home may not be in compliance with A.R.S. Title 36, Chapter 5.1 or this Chapter, the Department shall:

1. Investigate the complaint or information about noncompliance within 30 days after receipt of the complaint or information about noncompliance;

2. Develop a written report documenting the investigation;

3. Provide the licensee with the written report in subsection (A)(2); and

4. If the complaint or information about noncompliance was substantiated, notify the Division of the outcome of the investigation.

B. If the Department substantiates a complaint or information about noncompliance at a group home, the licensee of the group home shall:

1. Establish a plan of correction, if applicable, for correction of a deficiency;

2. Agree to carry out the plan of correction by signing the written report in subsection (A)(2); and

3. Ensure that a deficiency listed on the plan of correction is corrected within 30 days after the date of the plan of correction or within a time period the Department and the licensee agree upon in writing.

Historical Note

R9-33-108. Time-frames

A. The overall time-frame described in A.R.S. § 41-1072 for a license granted by the Department under this Chapter is set forth in Table 1.1 and begins on the date that the Department receives an application packet.

1. The Department shall send a notice of administrative completeness or deficiencies to the applicant or licensee within the administrative completeness review timeframe.

a. A notice of deficiencies shall list each deficiency and the information or items needed to complete the application.

b. The administrative completeness review time-frame and the overall time-frame are suspended from the date that the notice of deficiencies is sent until the date that the Department receives all of the missing information or items from the applicant or licensee.

c. If an applicant or licensee fails to submit to the Department all of the information or items listed in the notice of deficiencies within 120 days after the date that the Department sent the notice of deficiencies or within a time period the applicant or licensee and the Department agree upon in writing, the Department shall consider the application withdrawn.

2. If the Department issues a license during the administrative completeness review timeframe, 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 set forth in Table 1.1 and begins on the date of the notice of administrative completeness.

1. As part of the substantive review of an application for a license, the Department shall conduct an inspection that may require more than one visit to the group home.

2. The Department shall send a license or a written notice of denial of a license within the substantive review timeframe.

3. During the substantive review timeframe, the Department may make one comprehensive written request for additional information, unless the applicant or licensee has agreed in writing to allow the Department to submit supplemental requests for information.

a. If the Department determines that an applicant or licensee, a group home, or the premises are not in substantial compliance with A.R.S. Title 36, Chapter 5.1 and this Chapter, the Department shall send a comprehensive written request for additional information that includes a written statement of deficiencies stating each statute and rule upon which noncompliance is based.

b. An applicant or licensee shall submit to the Department all of the information requested in a comprehensive written request for additional information or a supplemental request for information, including, if applicable, documentation of the corrections required in a statement of deficiencies, within 30 days after the date of the comprehensive written request for additional information or the supplemen-
Department of Health Services - Group Homes for Individuals Who are Developmentally Disabled

Historical Note
New Section made by final rulemaking at 18 A.A.R. 3295, effective February 3, 2013 (Supp. 12-4).

R9-33-109. Denial, Revocation, or Suspension of a License
A. The Department may deny an application or suspend or revoke a license to operate a group home if:
1. An applicant or licensee does not meet the application requirements contained in R9-33-104 or R9-33-105(A);
2. A licensee is not a service provider for the duration of one licensure period;
3. A licensee does not correct the deficiencies according to the plan of correction contained in R9-33-107 by the time stated in the plan of correction; or
4. The nature or number of violations revealed by any type of inspection or investigation of a group home poses a direct risk to the life, health, or safety of a resident.
B. An applicant or licensee may appeal the Department’s determination in subsection (A) according to A.R.S. Title 41, Chapter 6, Article 10.
C. The Department shall immediately notify the Division when an application is denied and when a license to operate a group home is suspended or revoked.

Historical Note
New Section renumbered from R9-33-107 and amended by final rulemaking at 18 A.A.R. 3295, effective February 3, 2013 (Supp. 12-4).

ARTICLE 2. GROUP HOME REQUIREMENTS

R9-33-201. Emergency Procedures and Evacuation Drills
A. A licensee shall ensure that a written plan for emergencies:
1. Is developed and implemented;
2. Is available and accessible to staff and each resident at the facility;
3. Contains procedures for responding to fire, emergency, severe weather conditions, and other disasters, including:
   a. Routes of evacuation, location of firefighting equipment, and evacuation devices identified on a floor plan of the facility;
   b. Instructions on the use of fire alarm systems, firefighting equipment, and evacuation devices;
   c. Procedures for evacuating each resident, including a resident who is not capable of self-preservation or who has a mobility, sensory, or other physical impairment;
   d. Procedures for notifying an emergency response team, law enforcement, and the licensee or the licensee’s designee; and
4. Includes procedures for when a resident is missing from the premises.
B. A licensee shall ensure that:

Table 1.1 Time-frames (in days)

<table>
<thead>
<tr>
<th>Type of approval</th>
<th>Statutory authority</th>
<th>Overall time-frame</th>
<th>Administrative completeness review time-frame</th>
<th>Substantive review time-frame</th>
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</thead>
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<tr>
<td>Application for a license under R9-33-104</td>
<td>A.R.S. § 36-132(A)(21)</td>
<td>120</td>
<td>50</td>
<td>60</td>
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<tr>
<td>Renewal of a license under R9-33-105</td>
<td>A.R.S. § 36-132(A)(21)</td>
<td>60</td>
<td>30</td>
<td>30</td>
</tr>
</tbody>
</table>

Historical Note
Table 1.1 made by final rulemaking at 18 A.A.R. 3295, effective February 3, 2013 (Supp. 12-4).

1. The facility’s street address is painted or posted against a contrasting background so that the group home’s street address is visible from the street; or
2. The local emergency response team, such as the local fire department, is notified of the location of the facility in writing at least once every 12 months. The licensee shall make the written notification available for review at the facility for at least two years from the date of the notification.
C. A licensee shall ensure that:
1. Except as described in subsection (D), an evacuation drill that includes all residents, except any residents otherwise specifically excluded from evacuation drills as indicated on documentation provided by the Division for the resident, is conducted at least once every six months on each shift; and
2. Documentation of an evacuation drill is available for review at the facility for at least two years after the date of the evacuation drill that includes:
   a. The date and time of the evacuation drill;
   b. The length of time to evacuate or simulate the evacuation of all residents from the facility;
   c. A summary of the evacuation drill, including a list of the residents and staff who were present at the time of the drill, how the drill was performed, how
long the drill took to complete, and, if applicable, a list of residents for whom evacuation was simulated; and

d. Except as provided in subsection (D)(2), if the length of time to evacuate all residents from the facility exceeds three minutes, a plan of correction to bring the evacuation time to three minutes or less in case of an actual emergency requiring evacuation.

D. If a group home provides services to a resident whom the Division has identified, through the assessment process used to determine the group home’s fire risk prevention level, as having a condition that could cause a resident to be harmed if the resident participated in an evacuation drill, a licensee shall ensure that:

1. An evacuation drill:
   a. Does not include the resident, and
   b. Simulates the evacuation of the resident according to the plan required in subsection (A)(3)(c), and

2. The documentation of an evacuation drill required in subsection (C)(2) also includes, if the length of time to evacuate or simulate the evacuation of all residents exceeds five minutes, a plan of correction to bring the evacuation time to five minutes or less in case of an actual emergency requiring evacuation.

E. A licensee shall ensure that:

1. A first aid kit is available in the facility that has the following items in a quantity sufficient to meet the needs of residents and staff:
   a. Adhesive sterile bandages of assorted sizes,
   b. Sterile gauze pads,
   c. Sterile gauze rolls,
   d. Adhesive or self-adhering tape,
   e. Antiseptic solution or sealed antiseptic wipes,
   f. Re-closable plastic bags of at least one-gallon size,
   g. Single-use non-porous gloves,
   h. Scissors,
   i. Tweezers, and
   j. A cardiopulmonary resuscitation mouth guard or mouth shield;

2. All stairways, hallways, walkways, and other routes of evacuation are free of any obstacle that may prevent evacuation of a resident in an emergency;

3. If a window or door contains locks, bars, grills, or other devices that obstruct evacuation, each device contains a release mechanism that is operable from the inside of a facility and that does not require the use of a key, special knowledge, or special effort;

4. Each facility contains a working non-cellular telephone that is available and accessible to staff and each resident at all times; and

5. The following are posted at the location of a facility’s telephone:
   a. Instructions to dial 911 or the telephone number of another local emergency response team, and
   b. The address and telephone number of the group home.

Historical Note
New Section made by final rulemaking at 8 A.A.R. 910, effective February 11, 2002 (Supp. 02-1). Amended by final rulemaking at 18 A.A.R. 3295, effective February 3, 2013 (Supp. 12-4).

R9-33-202. Fire Safety Requirements
A. The Department shall issue to an applicant or licensee:

1. A fire risk prevention level 1 group home license if the group home meets the requirements in subsections (B) through (G); and

2. A fire risk prevention level 2 group home license if the group home meets the requirements in subsections (B) through (H).

B. A licensee shall ensure that the premises are in compliance with all applicable state and local fire safety regulations and that:

1. Before a license is issued or renewed, a fire inspection is conducted by the local fire department, the Department, or an entity authorized by the Department;

2. Any repair or correction stated in a fire inspection report is made or corrected according to the requirements and time in the fire inspection report; and

3. A current fire inspection report is available for review at the group home.

C. A licensee shall ensure that the facility has at least one working, portable, all-purpose fire extinguisher labeled as rated at least 2A-10-Bc by Underwriters Laboratories, or two located working, portable, all-purpose fire extinguishers labeled as rated at least 1A-10-Bc by Underwriters Laboratories, installed and maintained in the facility as prescribed by the manufacturer or the fire authority having jurisdiction.

D. A licensee shall ensure that a fire extinguisher:

1. Is either:
   a. Disposable and has a charge indicator showing green or "ready" status; or
   b. Serviced at least once every 12 months by a fire extinguisher technician certified by the National Fire Protection Agency, the International Code Council, or Compliance Services and Assessments; and

2. If serviced, is tagged specifying:
   a. The date of purchase or the date of recharging, whichever is more recent; and
   b. The name of the organization performing the service, if applicable.

E. A licensee shall ensure that smoke detectors are:

1. Working and audible at a level of 75 decibels at the location of each bed used by a resident in the facility;

2. Capable of alerting all residents in the facility, including a resident with a mobility or sensory impairment;

3. Installed according to the manufacturer’s instructions;

4. Located in at least the following areas:
   a. Each bedroom;
   b. Each room or hallway adjacent to a bedroom, except a bathroom or a laundry room; and
   c. Each room or hallway adjacent to the kitchen, except a bathroom, a pantry, or a laundry room; and

5. If the licensee has been cited more than once in the previous four years under subsections (E)(1) through (4), either:
   a. Hard-wired to the electrical system of the group home with a battery backup; or
   b. Connected to an early-warning fire detection system required in subsection (D)(2), if applicable.

F. A licensee shall ensure that each bedroom has at least one openable window or door to the outside for use as an emergency exit.

G. A licensee shall ensure that:

1. A usable fireplace is covered by a protective screen or covering at all times; and

2. Combustible or flammable materials are not stored within three feet of a furnace, heater, water heater, or usable fireplace.
II. A licensee of a fire risk prevention level 2 group home shall ensure that:
   1. The facility contains an emergency lighting system that:
      a. Works without in-house electrical power,
      b. Illuminates the path of evacuation, and
      c. Is inspected at least once every 12 months by the manufacturer or an entity that installs and repairs emergency lighting systems;
   2. The facility has an early-warning fire detection system that:
      a. Is safety-approved;
      b. Is hard-wired or connected wirelessly, with battery back-up;
      c. Sounds every alarm in the facility when smoke is detected;
      d. Is installed in each bedroom, each room or each hallway adjacent to a bedroom, and each room or each hallway adjacent to a kitchen; and
      e. Is inspected at least once every 12 months by the manufacturer or by an entity that installs and repairs early-warning fire detection systems;
   3. The facility has one of the following:
      a. Sufficient staff on duty to evacuate all residents present at the facility within three minutes or, if applicable under R9-33-201(D), within five minutes; or
      b. An automatic sprinkler system installed according to the applicable standard incorporated by reference in A.A.C. R9-1-412 and installed according to NFPA 13, NFPA 13R, or NFPA 13D, as applicable, that:
         i. Covers every room in the facility; and
         ii. Is inspected at least once every 12 months by the manufacturer or by an entity that installs and repairs automatic sprinkler systems; and
   4. Documentation is available at the facility for two years after the date of an inspection:
      a. For:
         i. The emergency lighting system inspection required in subsection (I)(1)(c);
         ii. The early-warning fire detection system inspection required in subsection (I)(2)(c); and
         iii. If applicable, the automatic sprinkler system inspection required in subsection (I)(3)(b)(ii); and
      b. That includes:
         i. The date of the inspection,
         ii. The name of the entity performing the inspection,
         iii. A tag on the system or a written report of the results of the inspection, and
         iv. A description of any repairs made to the system as a result of the inspection.

Historical Note
New Section made by final rulemaking at 8 A.A.R. 910, effective February 11, 2002 (Supp. 02-1). Amended by final rulemaking at 18 A.A.R. 3295, effective February 3, 2013 (Supp. 12-4).

R9-33-203. Physical Plant Requirements
A. A licensee shall ensure that:
   1. A group home is in compliance with applicable federal and state disability laws;
   2. If a group home has a resident with a mobility, sensory, or other physical impairment, documentation is available for review at the group home that:
      a. Is provided by the Division; and
      b. Identifies modifications, if any, needed to the premises to ensure that the premises are accessible to and usable by the resident;
   3. The premises have been modified as identified by the Division in subsection (A)(2)(b);
   4. Ramps, stairs, or steps on the premises are secured firmly to the ground or a permanent structure and have slip-resistant surfaces; and
   5. If handrails and grab bars are installed in a facility, handrails and grab bars are securely attached and stationary.

B. A licensee shall ensure that:
   1. A method of heating and cooling maintains the facility between 65°F and 85°F in areas of the facility occupied by residents;
   2. Ventilation is provided by an operable window, air conditioning, or other mechanical device;
   3. Working, safe appliances for cooking and cooling food are provided in the facility that:
      a. Are safety-approved;
      b. If used to refrigerate food, maintain the food at a temperature of 40°F or below at all times; and
      c. If used to freeze food, maintain the food at a temperature of 0°F or below at all times;
   4. Hot water temperatures in the facility are maintained between 95°F and 120°F; and
   5. Bathtubs and showers contain slip-resistant strips, rubber bath mats, or slip-resistant surfaces.

C. A licensee shall ensure that:
   1. Electrical lighting is contained in each room in the facility;
   2. Electrical devices and equipment on the premises are safety-approved, safe, and in working order;
   3. Electrical outlets on the premises are safe, covered with a faceplate, and installed in accordance with the requirements of the local jurisdiction;
   4. If the facility was built or modified on or after the effective date of this Chapter, any electrical outlet located within 3 feet of a water source includes a ground fault circuit interrupt (GFCI);
   5. An appliance, light, or other device with a frayed or spliced electrical cord is not used on the premises; and
   6. An electrical cord, including an extension cord, on the premises is:
      a. Used as a substitute for permanent wiring,
      b. Run under a rug or carpeting,
      c. Run over a nail, or
      d. Run from one room to another.

D. A licensee shall ensure that:
   1. A facility contains a safe, working plumbing system;
   2. If a facility's plumbing system is connected to a non-municipal sewage disposal system, the plumbing system and connective piping are free of visible leakage; and
   3. The premises do not contain unfenced or uncovered wells, ditches, or holes into which an individual may step or fall.

Historical Note
New Section made by final rulemaking at 8 A.A.R. 910, effective February 11, 2002 (Supp. 02-1). Amended by final rulemaking at 18 A.A.R. 3295, effective February 3, 2013 (Supp. 12-4).

R9-33-204. Environmental Requirements
A. A licensee shall ensure that:
   1. The premises are free of accumulations of garbage or refuse;
   2. Garbage and refuse in the facility are:
a. Stored in cleanable containers or in scalable plastic bags; and
b. Removed from the facility at least once every seven days;
3. Cleaning compounds and toxic substances are maintained in labeled containers that:
a. Are stored to prevent a hazard;
b. Are appropriate to the contents of each container;
c. If appropriate based on a resident's disability, are locked; and
d. Are stored in a separate location from food or medicine;
4. Unused furniture, equipment, fabrics, or devices are removed from the facility or maintained in a covered area on the premises that is designated by the licensee for storage in a manner that does not create a hazard; and
5. There are no firearms or ammunition on the premises;
B. A licensee shall ensure that:
   1. The facility is maintained free of insects and vermin;
   2. The premises and its structures and furnishings are:
      a. In a clean condition,
      b. Free of odors, such as urine or rotting food; and
      c. In sufficiently good repair that no object, equipment, or condition present constitutes a hazard; and
   3. Standing water is not allowed to accumulate on the premises, except in an area or vessel the purpose of which is to hold standing water.
C. A licensee shall ensure that:
   1. An unvented space heater or open-flame space heater is not used on the premises;
   2. An electric portable heater or electric radiant heater is not used on the premises unless the electric portable heater or electric radiant heater:
      a. Has:
         i. Either a non-porous casing, or a grill with a mesh small enough to prevent cloth or a child's finger from entering the casing,
         ii. A tilt switch that shuts off power to the electric portable heater if the electric portable heater tips over;
         iii. An automatic shutoff control to prevent overheating, and
         iv. A thermostat control; and
      b. Is plugged directly into a wall outlet; and
   3. A vented space heater used on the premises is:
      a. Safety-approved;
      b. Professionally installed in accordance with the requirements of the local jurisdiction; and
      c. Mounted as a permanent fixture in a wall, floor, or ceiling.

Historical Note
New Section made by final rulemaking at 8 A.A.R. 910, effective February 11, 2002 (Supp. 02-1). Section renumbered to R9-33-204; new Section renumbered from R-33-206 and amended by final rulemaking at 18 A.A.R. 3295, effective February 3, 2013 (Supp. 12-4).

R9-33-205. Vehicle Safety Requirements
A. A licensee shall ensure that a vehicle used to transport a resident:
   1. Is maintained in safe and working order; and
   2. Is equipped with:
      a. A working heating and air conditioning system;
      b. A first aid kit that meets the requirements in R9-33-201(E)(1);
      c. Working seat belts for the driver and each passenger; and
      d. Floor mounted seat belts and wheel chair lock-down devices for each wheel chair passenger transported, if the vehicle is used to transport a passenger in a wheelchair.
B. A licensee shall ensure that documentation of each maintenance or repair of a vehicle used to transport a resident is available for review at the facility for at least two years after the date of the maintenance or repair.

Historical Note
New Section made by final rulemaking at 8 A.A.R. 910, effective February 11, 2002 (Supp. 02-1). Section renumbered to R9-33-204; new Section renumbered from R-33-206 and amended by final rulemaking at 18 A.A.R. 3295, effective February 3, 2013 (Supp. 12-4).

R9-33-206. Swimming Pool Requirements
A. Except as provided in subsection (B), a licensee shall ensure that a private residential swimming pool on the premises:
   1. If filled with water, is surrounded by a fence or enclosure constructed of rigid material that:
      a. Is at least 5 feet high;
      b. Is free of an opening that exceeds 4 inches or, if a wire mesh fence, is free of an opening that exceeds 1 3/4 inches;
      c. Is free of openings for handholds or footholds on the exterior of the fence or enclosure;
      d. Is at least 20 inches from the edge of the private residential swimming pool;
      e. Is clear of objects out to a distance of 30 inches on either side of the fence or enclosure from the level of the ground to a height of 5 feet above the fence or enclosure;
      f. Has at least one gate that:
         i. Opens outward from the private residential swimming pool;
         ii. Has a self-closing latch attached no less than 54 inches above ground level as measured from the exterior side of the fence or enclosure, and
         iii. Is locked when the private residential swimming pool is not in use;
      g. Is secured perpendicular to level ground; and
      h. Is located at least 54 inches from the exterior wall of the facility to allow evacuation without entering the private residential swimming pool area;
   2. Is not located in the path of an emergency exit;
   3. If filled with water, is equipped with the following:
      a. An operational water circulation system that clarifies the swimming pool water;
      b. An operational vacuum cleaning system that maintains the sides and bottom of the pool free of dirt and debris,
      c. A shepherd's crook that is attached to its own pole, and
      d. A ring buoy with an attached rope that is at least 10 feet long plus two distance from the edge to the middle of the private residential swimming pool, and
   4. If not filled with water, is covered completely by a covering that:
      a. Is permitted by the local jurisdiction;
      b. Is free of an opening that exceeds 1 inch,
      c. Withstands weight of at least 495 pounds per square foot on all parts of the covering without any distortion or compression, and
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2. If a resident is under 6 years of age, is enclosed by a fence specified in subsection (A)(1).

B. The requirements in subsection (A) do not apply to a group home if the Division provides to the Department written documentation indicating that the Division has determined that the private residential swimming pool is safe, based upon the functional level of the residents:
1. At the time of initial licensure,
2. At the time of license renewal, and
3. Upon the placement of a resident at the group home.

C. A licensee shall ensure that a spa:
1. Except as specified in subsection (C)(2), is covered and locked when not in use, with a mechanism that a resident cannot open, and

Historical Note
New Section made by final rulemaking at 8 A.A.R. 910, effective February 11, 2002 (Supp. 02-1). Section renumbered to R9-33-205; new Section made by final rulemaking at 18 A.A.R. 3295, effective February 3, 2013 (Supp. 12-4).

R9-33-207. Repealed

Historical Note
New Section made by final rulemaking at 8 A.A.R. 910, effective February 11, 2002 (Supp. 02-1). Repealed by final rulemaking at 18 A.A.R. 3295, effective February 3, 2013 (Supp. 12-4).
Attachment B
36-104. Powers and duties

This section is not to be construed as a statement of the department's organization. This section is intended to be a statement of powers and duties in addition to the powers and duties granted by section 36-103. The director shall:

1. Administer the following services:

(a) Administrative services, which shall include at a minimum the functions of accounting, personnel, standards certification, electronic data processing, vital statistics and the development, operation and maintenance of buildings and grounds utilized by the department.

(b) Public health support services, which shall include at a minimum:

(i) Consumer health protection programs that include at least the functions of community water supplies, general sanitation, vector control and food and drugs.

(ii) Epidemiology and disease control programs that include at least the functions of chronic disease, accident and injury control, communicable diseases, tuberculosis, venereal disease and others.

(iii) Laboratory services programs.

(iv) Health education and training programs.

(v) Disposition of human bodies programs.

(c) Community health services, which shall include at a minimum:

(i) Medical services programs that include at least the functions of maternal and child health, preschool health screening, family planning, public health nursing, premature and newborn program, immunizations, nutrition, dental care prevention and migrant health.

(ii) Dependency health care services programs that include at least the functions of need determination, availability of health resources to medically dependent individuals, quality control, utilization control and industry monitoring.

(iii) Children with physical disabilities services programs.

(iv) Programs for the prevention and early detection of an intellectual disability.

(d) Program planning, which shall include at least the following:

(i) An organizational unit for comprehensive health planning programs.

(ii) Program coordination, evaluation and development.

(iii) Need determination programs.
(iv) Health information programs.

2. Include and administer, within the office of the director, staff services, which shall include at a minimum budget preparation, public information, appeals, hearings, legislative and federal government liaison, grant development and management and departmental and interagency coordination.

3. Make rules and regulations for the organization and proper and efficient operation of the department.

4. Determine when a health care emergency or medical emergency situation exists or occurs within the state that cannot be satisfactorily controlled, corrected or treated by the health care delivery systems and facilities available. When such a situation is determined to exist, the director shall immediately report that situation to the legislature and the governor. The report shall include information on the scope of the emergency, recommendations for solution of the emergency and estimates of costs involved.

5. Provide a system of unified and coordinated health services and programs between the state and county governmental health units at all levels of government.

6. Formulate policies, plans and programs to effectuate the missions and purposes of the department.

7. Make contracts and incur obligations within the general scope of the department's activities and operations subject to the availability of funds.

8. Be designated as the single state agency for the purposes of administering and in furtherance of each federally supported state plan.

9. Provide information and advice on request by local, state and federal agencies and by private citizens, business enterprises and community organizations on matters within the scope of the department's duties subject to the departmental rules and regulations on the confidentiality of information.

10. Establish and maintain separate financial accounts as required by federal law or regulations.

11. Advise with and make recommendations to the governor and the legislature on all matters concerning the department's objectives.

12. Take appropriate steps to reduce or contain costs in the field of health services.

13. Encourage and assist in the adoption of practical methods of improving systems of comprehensive planning, of program planning, of priority setting and of allocating resources.

14. Encourage an effective use of available federal resources in this state.

15. Research, recommend, advise and assist in the establishment of community or area health facilities, both public and private, and encourage the integration of planning, services and programs for the development of the state's health delivery capability.

16. Promote the effective utilization of health manpower and health facilities that provide health care for the citizens of this state.
17. Take appropriate steps to provide health care services to the medically dependent citizens of this state.

18. Certify training on the nature of sudden infant death syndrome, which shall include information on the investigation and handling of cases involving sudden and unexplained infant death for use by law enforcement officers as part of their basic training requirement.

19. Adopt protocols on the manner in which an autopsy shall be conducted under section 11-597, subsection D in cases of sudden and unexplained infant death.

20. Cooperate with the Arizona-Mexico commission in the governor's office and with researchers at universities in this state to collect data and conduct projects in the United States and Mexico on issues that are within the scope of the department's duties and that relate to quality of life, trade and economic development in this state in a manner that will help the Arizona-Mexico commission to assess and enhance the economic competitiveness of this state and of the Arizona-Mexico region.

21. Administer the federal family violence prevention and services act grants, and the department is designated as this state's recipient of federal family violence prevention and services act grants.

22. Accept and spend private grants of monies, gifts and devises for the purposes of methamphetamine education. The department shall disburse these monies to local prosecutorial or law enforcement agencies with existing programs, faith based organizations and nonprofit entities that are qualified under section 501(c)(3) of the United States internal revenue code, including nonprofit entities providing services to women with a history of dual diagnosis disorders, and that provide educational programs on the repercussions of methamphetamine use. State general fund monies shall not be spent for the purposes of this paragraph. If the director does not receive sufficient monies from private sources to carry out the purposes of this paragraph, the director shall not provide the educational programs prescribed in this paragraph. Grant monies received pursuant to this paragraph are no lapsing and do not revert to the state general fund at the close of the fiscal year.

23. Identify successful methamphetamine prevention programs in other states that may be implemented in this state.

24. Pursuant to chapter 13, article 8 of this title, coordinate all public health and risk assessment issues associated with a chemical or other toxic fire event if a request for the event is received from the incident commander, the emergency response commission or the department of public safety and if funding is available. Coordination of public health issues shall include general environmental health consultation and risk assessment services consistent with chapter 13, article 8 of this title and, in consultation with the Arizona poison control system, informing the public as to potential public health risks from the environmental exposure. Pursuant to chapter 13, article 8 of this title, the department of health services shall also prepare a report, in consultation with appropriate state, federal and local governmental agencies, that evaluates the public health risks from the environmental exposure. The department of health services' report shall include any department of environmental quality report and map of smoke dispersion from the fire, the results of any environmental samples taken by the department of environmental quality and the toxicological implications and public health risks of the environmental exposure. The department of health services shall consult with the Arizona poison control system regarding toxicology issues and shall prepare and produce its report for the public as soon as practicable after the event. The department of health services shall not use any monies pursuant to section 49-282, subsection E to implement this paragraph.
36-132. Department of health services; functions; contracts

A. The department shall, in addition to other powers and duties vested in it by law:

1. Protect the health of the people of the state.

2. Promote the development, maintenance, efficiency and effectiveness of local health departments or districts of sufficient population and area that they can be sustained with reasonable economy and efficient administration, provide technical consultation and assistance to local health departments or districts, provide financial assistance to local health departments or districts and services that meet minimum standards of personnel and performance and in accordance with a plan and budget submitted by the local health department or districts to the department for approval, and recommend the qualifications of all personnel.

3. Collect, preserve, tabulate and interpret all information required by law in reference to births, deaths and all vital facts, and obtain, collect and preserve information relating to the health of the people of the state and the prevention of diseases as may be useful in the discharge of functions of the department not in conflict with the provisions of chapter 3 of this title, and sections 36-693, 36-694 and 39-122.

4. Operate such sanitariums, hospitals or other facilities assigned to the department by law or by the governor.

5. Conduct a statewide program of health education relevant to the powers and duties of the department, prepare educational materials and disseminate information as to conditions affecting health, including basic information for the promotion of good health on the part of individuals and communities, and prepare and disseminate technical information concerning public health to the health professions, local health officials and hospitals. In cooperation with the department of education, the department of health services shall prepare and disseminate materials and give technical assistance for the purpose of education of children in hygiene, sanitation and personal and public health, and provide consultation and assistance in community organization to counties, communities and groups of people.

6. Administer or supervise a program of public health nursing, prescribe the minimum qualifications of all public health nurses engaged in official public health work, and encourage and aid in coordinating local public health nursing services.

7. Encourage and aid in coordinating local programs concerning control of preventable diseases in accordance with statewide plans that shall be formulated by the department.

8. Encourage and aid in coordinating local programs concerning maternal and child health, including midwifery, antepartum and postpartum care, infant and preschool health and the health of school children, including special fields such as the prevention of blindness and conservation of sight and hearing.

9. Encourage and aid in the coordination of local programs concerning nutrition of the people of the state.

10. Encourage, administer and provide dental health care services and aid in coordinating local programs concerning dental public health, in cooperation with the Arizona dental association. The department may bill and receive payment for costs associated with providing dental health care services and shall deposit the monies in the oral health fund established by section 36-138.
11. Establish and maintain adequate serological, bacteriological, parasitological, entomological and chemical laboratories with qualified assistants and facilities necessary for routine examinations and analyses and for investigations and research in matters affecting public health.

12. Supervise, inspect and enforce the rules concerning the operation of public bathing places and public and semipublic swimming pools adopted pursuant to section 36-136, subsection H, paragraph 10.

13. Take all actions necessary or appropriate to ensure that bottled water sold to the public and water used to process, store, handle, serve and transport food and drink are free from filth, disease-causing substances and organisms and unwholesome, poisonous, deleterious or other foreign substances. All state agencies and local health agencies involved with water quality shall provide to the department any assistance requested by the director to ensure that this paragraph is effectuated.

14. Enforce the state food, caustic alkali and acid laws in accordance with chapter 2, article 2 of this title, chapter 8, article 1 of this title and chapter 9, article 4 of this title, and collaborate in the enforcement of the federal food, drug and cosmetic act of 1938 (52 Stat. 1040; 21 United States Code sections 1 through 905).

15. Recruit and train personnel for state, local and district health departments.

16. Conduct continuing evaluations of state, local and district public health programs, study and appraise state health problems and develop broad plans for use by the department and for recommendation to other agencies, professions and local health departments for the best solution of these problems.

17. License and regulate health care institutions according to chapter 4 of this title.

18. Issue or direct the issuance of licenses and permits required by law.

19. Participate in the state civil defense program and develop the necessary organization and facilities to meet wartime or other disasters.

20. Subject to the availability of monies, develop and administer programs in perinatal health care, including:

(a) Screening in early pregnancy for detecting high risk conditions.

(b) Comprehensive prenatal health care.

(c) Maternity, delivery and postpartum care.

(d) Perinatal consultation, including transportation of the pregnant woman to a perinatal care center when medically indicated.

(e) Perinatal education oriented toward professionals and consumers, focusing on early detection and adequate intervention to avert premature labor and delivery.

21. License and regulate the health and safety of group homes for persons with developmental disabilities. The department shall issue a license to an accredited facility for a period of the accreditation, except that
no licensing period shall be longer than three years. The department is authorized to conduct an inspection of an accredited facility to ensure that the facility meets health and safety licensure standards. The results of the accreditation survey shall be public information. A copy of the final accreditation report shall be filed with the department of health services. For the purposes of this paragraph, "accredited" means accredited by a nationally recognized accreditation organization.

B. The department may accept from the state or federal government, or any agency of the state or federal government, and from private donors, trusts, foundations or eleemosynary corporations or organizations grants or donations for or in aid of the construction or maintenance of any program, project, research or facility authorized by this title, or in aid of the extension or enforcement of any program, project or facility authorized, regulated or prohibited by this title, and enter into contracts with the federal government, or an agency of the federal government, and with private donors, trusts, foundations or eleemosynary corporations or organizations, to carry out such purposes. All monies made available under this section are special project grants. The department may also expend these monies to further applicable scientific research within this state.

C. The department, in establishing fees authorized by this section, shall comply with title 41, chapter 6. The department shall not set a fee at more than the department's cost of providing the service for which the fee is charged. State agencies are exempt from all fees imposed pursuant to this section.

D. The department may enter into contracts with organizations that perform nonrenal organ transplant operations and organizations that primarily assist in the management of end stage renal disease and related problems to provide, as payors of last resort, prescription medications necessary to supplement treatment and transportation to and from treatment facilities. The contracts may provide for department payment of administrative costs it specifically authorizes.
36-591. Adult developmental homes; child developmental homes; licensing; applicability

A. An adult developmental home or child developmental home shall be licensed pursuant to this article.

B. Group homes, except for those described in subsection E of this section, shall be licensed for health and safety by the department of health services pursuant to section 36-132.

C. The division shall notify the department of health services of:

1. Service providers who enter into contracts with the division for group homes.

2. Any violation of health and safety standards observed during monitoring visits.

D. The department of health services shall immediately notify the division:

1. When a group home license has been denied, suspended or revoked.

2. Of any other licensing action taken on a group home by the department of health services.

3. Of substantiated complaints regarding health and safety.

E. The division shall ensure that state-operated residential settings that are owned or leased facilities operated by the division meet the same standards as group homes unless they are certified as intermediate care facilities for persons with an intellectual disability pursuant to 42 Code of Federal Regulations section 483.400. An intermediate care facility for persons with an intellectual disability that is operated by the division or a private entity is not required to be licensed under this section if the facility is certified pursuant to 42 Code of Federal Regulations section 483.400.

F. The department shall visit each adult developmental home and child developmental home and inspect the premises used for the care of children or vulnerable adults for sanitation, fire and other actual and potential hazards. The department shall take any action it deems necessary to carry out the duties imposed by this section, including the denial of the application for licensure and the suspension or revocation of the home's license.
36-595. Programmatic and contractual monitoring: deemed status

A. The department of economic security shall perform programmatic and contractual monitoring of the services it provides or for which it contracts.

B. The department shall promulgate rules that provide for deemed status. The department shall grant deemed status to a service provider that presents evidence that it maintains a current accreditation from a nationally recognized agency that the department determines maintains accreditation standards that meet the standards established by the department. On determination by the department that there is reasonable cause to believe a service provider is not adhering to the programmatic or contractual requirements of the department, the department and any duly designated employee or agent of the department may enter on and into the premises at any reasonable time for the purpose of determining the state of compliance with the programmatic or contractual requirements of the department. The department may revoke deemed status based on the findings of programmatic and contractual monitoring.

C. The department of health services may deny, suspend or revoke a license for a violation of this article or department rules. At least thirty days before the department denies, revokes or suspends a license it shall mail the applicant or licensee a notice of that person's right to a hearing. The department shall issue this notice by certified mail, return receipt requested. The notice shall state the hearing date and the facts constituting the reasons for the department's action and shall cite the specific statute or rule violated.

D. If the person does not respond to the written notice, the department of health services, at the expiration of the time fixed in the notice, shall take the action prescribed in the notice. If the person, within the period fixed in the notice, conforms the application or the operation of the facility to the applicable statute or rule, the department may grant the license or withdraw the notice of suspension or revocation.
TITLE 9. HEALTH SERVICES
CHAPTER 33. DEPARTMENT OF HEALTH SERVICES
GROUP HOMES FOR INDIVIDUALS
WITH A DEVELOPMENTAL DISABILITY
2012 FINAL RULEMAKING

ECONOMIC, SMALL BUSINESS, AND CONSUMER IMPACT STATEMENT
ECONOMIC, SMALL BUSINESS, AND CONSUMER IMPACT STATEMENT
TITLE 9. HEALTH SERVICES
CHAPTER 33. DEPARTMENT OF HEALTH SERVICES
GROUP HOMES FOR INDIVIDUALS
WITH A DEVELOPMENTAL DISABILITY

1. An identification of the rulemaking

Since the rules in Arizona Administrative Code (A.A.C.) Title 9, Chapter 33 were last revised in 2002, several changes within the industry have occurred that have made unnecessary some of the costs that stakeholders currently incur to achieve compliance. Additionally, the Department’s Five-year-review Report approved by the Governor’s Regulatory Review Council on April 3, 2012 identified several substantive and technical issues with the rules. The Department received an exception from the Governor’s rulemaking moratorium, established by Executive Order 2011-05, and is proposing to amend the rules in 9 A.A.C. 33 to allow stakeholders to achieve cost savings in applicable cases and to address the issues identified in the Five-year-review Report.

In calendar year 2011, the Department licensed 975 group homes, of which 951 held a two-year license and 24 held a three-year license. During 2011, the Department received 67 new applications, of which all were approved and issued licenses. During 2011, the Department renewed 402 licenses, denied no license renewals, and has a further 18 license renewals still pending. During 2011, the Department received 32 complaints, of which 17 were substantiated. Enforcement typically results in citation and a plan of correction under R9-33-106, which occurred for each substantiated complaint. In one instance, a settlement agreement in lieu of revocation was necessary as a further enforcement action. There were no other suspensions, revocations, or denials of group home licenses in 2011.

a. The conduct and its frequency of occurrence that the rule is designed to change:

The rules establish minimum health and safety standards for the licensing of group homes. Licensees are required by the rules to meet prescribed minimum health and safety standards at all times. The Department believes that some degree of non-compliance by licensees may result from aspects of the rules that could be clarified, streamlined, or simplified. With this rulemaking, the Department hopes to minimize or eliminate non-compliance, if there is any, resulting from these factors.
b. The harm resulting from the conduct the rule is designed to change and the likelihood it will continue to occur if the rule is not changed:

Any failure of a licensee to meet the minimum health and safety standards prescribed by rule poses a threat to the welfare of a resident, and residents of group homes are members of a vulnerable population of individuals with developmental disabilities. To the extent that any licensee non-compliance with minimum health and safety standards results from an aspect of the rules that could be clarified, streamlined, or simplified, the Department believes that forgoing rulemaking will result in such non-compliance continuing to occur.

c. The estimated change in frequency of the targeted conduct expected from the rule change:

To the extent that any licensee non-compliance with minimum health and safety standards results from an aspect of the rules that could be clarified, streamlined, or simplified, the Department believes that so amending the rules will make such non-compliance less frequent and thus better protect the health and safety of the vulnerable population of residents of group homes.

2. A brief summary of the information contained in the economic, small business, and consumer impact statement:

This rulemaking amends all the rules for format, structure, clarity, conciseness, and understandability, and among the amendments are several substantive changes that have potential economic implications. None of the amendments are expected to impose new costs or increase existing costs for licensees in compliance with the rules or for other stakeholders. In general, the amendments are expected to cause monetary or other benefits to stakeholders.

3. The agency's contact person who can answer questions about or provide data from the economic, small business, and consumer impact statement:

Name: Rohno Geppert, Office Chief
Address: Arizona Department of Health Services
Office of Special Licensing
150 N. 18th Avenue, Suite 460
Phoenix, AZ 85007
Telephone: (602) 364-3048
Fax: (602) 364-4769
E-mail: Rohno.Geppert@azdhs.gov
4. **Persons who will incur direct costs or experience direct benefits from the rulemaking:**

This economic, small business, and consumer impact statement identifies as stakeholders:

- The Department,
- The Division,
- Individuals and entities that operate group homes, and
- Individuals with a developmental disability who are residents of group homes.

None of the amendments are expected to impose new costs or increase existing costs for licensees in compliance with the rules or for other stakeholders. In general, the amendments are expected to cause monetary or other benefits to stakeholders. See cost/benefit analysis in paragraph (5).

5. **Cost/benefit analysis:**

As used in this summary, annual costs/revenues are designated as minimal when less than $1,000, moderate when between $1,000 and $10,000, and substantial when greater than $10,000. Costs are listed as significant when meaningful or important, but not readily subject to quantification.

Only the economic, small business, and consumer impact directly attributable to this rulemaking, rather than the impact imposed by the statute, is considered. For example, A.R.S. § 41-1080, effective May 1, 2008 and most recently updated in 2011, requires an applicant or licensee to demonstrate citizenship by submitting appropriate documents to the Department at the time of initial licensing or renewal. The Department is amending R9-33-104 to conform to A.R.S. § 41-1080. The updated requirements impose costs on applicants and licensees, but the increased costs are solely attributable to statutory requirements.
<table>
<thead>
<tr>
<th>Description of affected groups</th>
<th>Description of effect</th>
<th>Increased cost/ decreased revenue</th>
<th>Decreased cost/ increased revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A. State and local government agencies</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The Department</td>
<td>Streamlining, reorganization, and clarification of requirements in all Sections. Includes corrections to cross-references and other technical changes with no additional economic implications other than the benefit of making the rules clearer and easier to use and thus reducing the difficulty of compliance.</td>
<td>None</td>
<td>Significant</td>
</tr>
<tr>
<td></td>
<td>Expanding R9-33-106 to include more scenarios in which a licensee can make changes to its license without requiring issuance of a new license.</td>
<td>None</td>
<td>Minimal-to-moderate -- The cost and time required to change an existing license is less than the cost and time required for issuance of a new license.</td>
</tr>
<tr>
<td></td>
<td>Adding to R9-33-201 new subsection (D) providing instructions on how licensees simulate the evacuation of bedridden residents instead of moving them, which would often be medically inadvisable.</td>
<td>None</td>
<td>Significant -- Due to medical necessity, the Department had already been implementing this workaround with licensees, and having it in the rule gives licensees all the information needed for compliance without requiring them to turn to the Department for technical assistance or to attempt to move bedridden residents.</td>
</tr>
<tr>
<td></td>
<td>In accordance with A.R.S. § 41-1055, the Department estimates that no additional employees are expected to be needed as a result of this rulemaking.</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>The Division</td>
<td>Streamlining, reorganization, and clarification of requirements in all Sections. Includes corrections to cross-references and other technical changes with no additional economic implications other than the benefit of making the rules clearer and easier to use and thus reducing the difficulty of compliance.</td>
<td>None</td>
<td>Significant</td>
</tr>
</tbody>
</table>
### B. Privately owned businesses

<table>
<thead>
<tr>
<th>Change Description</th>
<th>Impact</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Streamlining, reorganization, and clarification of requirements in all Sections. Includes corrections to cross-references and other technical changes with no additional economic implications other than the benefit of making the rules clearer and easier to use and thus reducing the difficulty of compliance.</td>
<td>None</td>
<td>Significant – There are multiple instances in which explicit requirements have been added to clarify the meaning of a previous requirement under which they were encompassed. For example, R9-33-203 contains new language in subsections (C)(3) through (C)(6). However, these are not new requirements. In the previous rules, R9-33-205(B)(1) required that a group home facility be in good repair and not contain a hazard. All of the conditions listed in the new R9-33-203(C)(3) through (C)(6) constitute hazards. A licensee failing to meet those requirements would have been cited under the previous rules under R9-33-205(B)(1). In an effort to improve compliance and reduce hazards that threaten the health and safety of residents, the Department has added clarifying language in this rulemaking throughout Article 2 that more explicitly identifies many common hazards that licensees must abate. This clarification also helps licensees feel that they are treated fairly and equally, and that a Department inspector citing a hazard is acting according to rule and not making a subjective judgment.</td>
</tr>
<tr>
<td>Expanding R9-33-106 to include more scenarios in which a licensee can make changes to its license without requiring relicensure.</td>
<td>None</td>
<td>Minimal-to-moderate – The cost and time to change an existing license is less than the cost and time to apply for and be issued a new license.</td>
</tr>
<tr>
<td>Amending R9-33-107(A)(2) to reflect that the Department may revoke or suspend a license if a licensee is not a service provider for the duration of one licensure period.</td>
<td>None</td>
<td>Significant – The previous wording allowed the Department discretion to revoke or suspend a license immediately upon the licensee not meeting the statutory definition of “service provider,” but the new wording reduces the burden on licensees that may only temporarily be without a resident placement: from the Division by preconditioning the Department’s discretion to revoke or suspend a license under subsection (A)(2) on one full licensure period having elapsed without the licensee being a service provider.</td>
</tr>
<tr>
<td>Adding to R9-33-201 new subsection (D) providing instructions on how licensees simulate the evacuation of bedridden residents instead of moving them, which would often be medically inadvisable.</td>
<td>None</td>
<td>Significant – Due to medical necessity, the Department had already been implementing this workaround with licensees, and having it in the rule gives licensees all the information needed for compliance without requiring them to turn to the Department for technical assistance or to attempt to move bedridden residents.</td>
</tr>
<tr>
<td>Removing from the first-aid kit requirements in R9-33-201(E) (formerly R9-33-207(A)) the requirement for a triangle bandage for use as a sling in a group home’s first aid kit and modernizing other first aid kit requirements.</td>
<td>None</td>
<td>Minimal -- the new requirements reflect the typical contents of first aid kits sold at retail in 2012. Licensees may experience savings as a result of needing no additional purchases to stock a first aid kit appropriately to protect the health and safety of residents.</td>
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<tr>
<td>---</td>
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</tr>
<tr>
<td>Amending R9-33-202(C) to allow licensees to use two co-located 1A-10-BC fire extinguishers instead of a 2A-10-BC fire extinguisher.</td>
<td>None</td>
<td>Minimal -- The 2A-10-BC fire extinguisher is more common in commercial use than in residential use and costs $40-$180, depending on manufacturer and whether the extinguisher is disposable or rechargeable. The 1A-10-BC fire extinguisher is common and available for as little as $15 from retail stores.</td>
</tr>
<tr>
<td>Amending R9-33-202(D) to allow the use of disposable fire extinguishers instead of requiring rechargeable fire extinguishers.</td>
<td>None</td>
<td>Minimal -- A 2A-10-BC disposable fire extinguisher can cost as much as $100 less than a rechargeable model. Additionally, the cheaper 1A-10-BC fire extinguishers are almost always disposable, so this change was necessary to allow licensees to realize the cost savings intended by the amendment to R9-33-202(C).</td>
</tr>
<tr>
<td>Amending R9-33-202(E)(5) so that a licensee who is cited more than once for having an inoperable smoke detector under subsection (E) must either hardwire the smoke detector to the facility’s electrical system with battery backup or connect it to the facility’s alarm system in subsection (H), if applicable.</td>
<td>None or minimal -- A licensee in compliance with R9-33-202 incurs no cost from this change. A licensee not in compliance with R9-33-202 jeopardizes the health and safety of residents, and could experience minimal costs if the licensee does not already have an alarm system in the facility.</td>
<td>None or significant -- Licensees can help to ensure the health and safety of residents by maintaining working smoke detectors.</td>
</tr>
<tr>
<td>Amending R9-33-202(F) to allow the use of an alarm system that utilizes a wireless connection to its monitoring apparatus.</td>
<td>None</td>
<td>None or minimal-to-moderate -- Since the previous rules were adopted in 2002, wireless alarm systems have attained industry ubiquity. A wireless alarm system can cost up to $1000 less than a wired alarm system depending on the facility, avoiding $50-$150 in labor costs per technician-hour to install wiring throughout a residential building and a variable cost of materials for wire and fixtures. Licensees who already have wired alarm systems are unaffected.</td>
</tr>
</tbody>
</table>
## C. Private persons and consumers

<table>
<thead>
<tr>
<th>Individuals with a developmental disability who are residents of group homes</th>
<th>Streamlining, reorganization, and clarification of requirements in all Sections. Includes corrections to cross-references and other technical changes with no additional economic implications other than the benefit of making the rules clearer and easier to use and thus reducing the difficulty of compliance.</th>
<th>None</th>
<th>Significant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adding to R9-33-201 new subsection (D) providing instructions on how licensees simulate the evacuation of bedridden residents instead of moving them, which would often be medically inadvisable.</td>
<td>None</td>
<td>Significant – Due to medical necessity, the Department had already been implementing this workaround with licensees, and having it in the rule is added assurance for bedridden residents that they will not incur health risks by being moved unnecessarily due to an evacuation drill.</td>
<td></td>
</tr>
<tr>
<td>Amending R9-33-202(E)(5) so that a licensee who is cited more than once for having an inoperable smoke detector under subsection (E) must either hard-wire the smoke detector to the facility’s electrical system with battery backup or connect it to the facility’s alarm system in subsection (H), if applicable.</td>
<td>None</td>
<td>Significant – Residents of group homes benefit from not being in jeopardy of their health and safety from inoperable smoke detectors in case of a fire.</td>
<td></td>
</tr>
</tbody>
</table>

6. **A general description of the probable impact on public and private employment:**

   There is no direct effect on public or private employment from the rulemaking. Indirectly, if reduced costs help licensees to realize greater revenue, licensees may be able to expand their businesses and thus employ more individuals to serve the needs of group home residents.

7. **The probable impact of the rulemaking on small businesses:**

   **a. An identification of small businesses subject to the rulemaking:**

   The Department believes that all, or nearly all, licensees are either individual proprietors or small businesses as defined in A.R.S. § 41-1001. Because of local zoning ordinances and the requirements of insurers, even licensees who are individual proprietors will often be organized as charitable trusts or limited liability companies.

   **b. The administrative and other costs required for compliance with the rulemaking:**

   The rulemaking imposes no additional administrative or other costs on stakeholders.

   **c. A description of the methods that the agency may use to reduce the impact on small businesses:**
i. **Establish less costly or less stringent compliance or reporting requirements:**
Group homes are expected to maintain minimum standards for the health and safety of residents at all times. The compliance and reporting requirements in rule are established accordingly, and apply to all licensees, the majority of which are believed to be small businesses, equally. The Department does not believe that any further reduction in the cost or stringency of compliance or reporting is possible at this time.

ii. **Establish less costly schedules or less stringent deadlines for compliance:**
Group homes are expected to maintain minimum standards for the health and safety of residents at all times. There are no schedules or deadlines for compliance in this respect as this is an ongoing requirement.

iii. **Consolidate or simplify compliance or reporting requirements:**
This rulemaking does consolidate and simplify compliance and reporting requirements throughout the amendments proposed, and these consolidated and simplified compliance and reporting requirements apply to all licensees, the majority of which are believed to be small businesses, equally. The Department does not believe that any further consolidation or simplification beyond what is presented in this rulemaking is possible at this time.

iv. **Establish separate performance standards:**
As described in paragraph (7)(a), virtually all licensees are either small businesses or other entities organized in an effectively equivalent form. Accordingly, the rules and the Department's administration and enforcement of the rules are oriented primarily toward small businesses, and the Department does not believe that establishing separate performance standards for small businesses would be appropriate to ensure the health and safety of residents of group homes.

v. **Exempt small businesses from any or all requirements:**
As described in paragraph (7)(a), virtually all licensees are either small businesses or other entities organized in an effectively equivalent form. Accordingly, the rules and the Department's administration and enforcement of the rules are oriented primarily toward small businesses, and the Department does not believe that exempting small businesses from any or all requirements would be appropriate to ensure the health and safety of residents of group homes.
8. The probable cost and benefit to private persons and consumers who are directly affected by the rulemaking:

The probable benefit to private persons and consumers is given in the cost/benefit analysis in paragraph (5). This rulemaking is expected to impose no costs on private persons or consumers.

9. The probable effect on state revenues:

The rulemaking does not impose any fees or charges that would be deposited to, or establish any payments that would be disbursed from, the general fund or any other state account, and so has no direct effect on state revenues.

10. A description of any less intrusive or less costly alternative methods of achieving the purpose of the rulemaking:

Under A.R.S. § 36-132(A)(21), the Department licenses group homes and performs administrative and enforcement actions related to facility health and safety. However, as of 1997, A.R.S. Title 36, Chapter 5.1 authorizes the Division to administer the placement of individuals with a developmental disability at group homes and perform contract monitoring for those placements. The Division maintains programmatic rules for group homes at 6 A.A.C. 6, Article 8, Programmatic Standards and Contract Monitoring for Community Residential Settings. A licensee, therefore, must maintain compliance with two regulatory authorities: the Division for programmatic elements, and the Department for facility health and safety elements. The Department already licenses or certifies both programmatic and facility health and safety elements of other residential care settings, such as assisted living homes, child care group homes, and behavioral health homes, and the Department believes it could do the same for group homes for individuals with a developmental disability. However, for this to happen, legislation to that effect would have to be enacted.

a. Monetizing of the costs and benefits for each option:

The Department does not collect data sufficient to articulate a monetary cost for having group homes subject to regulatory oversight by two separate agencies, but believes that such cost, by definition, must be more than if group homes were subject to regulatory oversight by a single agency.

b. Rationale for not using non-selected alternatives:

The Department is limited by its current statutory authority over group homes of licensing and performing administrative and enforcement actions related to facility health and safety. For the Department to promulgate rules on programmatic matters related to group homes, legislation to that effect would have to be enacted.
ARIZONA DEPARTMENT OF HEALTH SERVICES

FIVE-YEAR-REVIEW REPORT
TITLE 9. HEALTH SERVICES
CHAPTER 25. DEPARTMENT OF HEALTH SERVICES
EMERGENCY MEDICAL SERVICES
ARTICLE 1. DEFINITIONS
ARTICLE 12. TIME-FRAMES FOR DEPARTMENT APPROVALS

February 2017
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FIVE-YEAR-REVIEW REPORT
TITLE 9. HEALTH SERVICES
CHAPTER 25. DEPARTMENT OF HEALTH SERVICES
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ARTICLE 12. TIME-FRAMES FOR DEPARTMENT APPROVALS

FIVE-YEAR-REVIEW SUMMARY

Arizona Revised Statutes (A.R.S.) §§ 36-2202(A)(3) and (4) and 36-2209(A)(2) require the Arizona Department of Health Services (Department) to adopt standards and criteria pertaining to the quality of emergency care, rules necessary for the operation of emergency medical services, and rules for carrying out the purposes of A.R.S. Title 36, Chapter 21.1. The Department has implemented these statutes in Arizona Administrative Code (A.A.C.) Title 9, Chapter 25; both Article 1 and Article 12 were last revised effective December 2013. The rules in 9 A.A.C. 25, Article 1 establish definitions used in the Chapter and who may provide information on or sign an application or other document required by the Chapter, and the rules in 9 A.A.C. 25, Article 12 establish requirements for review of applications or requests for approval and the time-frames for these actions.

After an analysis of the rules in 9 A.A.C. 25, Articles 1 and 12, the Department has determined that the rules are effective, enforced as written, and clear, concise, and understandable. No written criticism or analysis of competitiveness for the rules has been received by the Department. Except for the reference to a statutory authority for some of the applications listed in Table 12.1, the rules are consistent with statutes and rules. To the extent that the rules have an economic cost or benefit in themselves, separate from the cost imposed or benefit derived from a rule using a rule in Article 1 or 12 to provide clarity or describe a time-frame action, the Department believes that the probable benefits of the rules outweigh within this state the probable costs of the rules, and the rules impose the least burden and costs to regulated persons necessary to achieve the underlying regulatory objective. The Department does not plan to revise the rules unless a substantive issue arises.
INFORMATION THAT IS IDENTICAL FOR ALL OF THE RULES

1. Authorization of the rule by existing statute
The general statutory authority for the rules in 9 A.A.C. 25, Articles 1 and 12 are A.R.S. §§ 36-136(A)(7), 36-136(F), 36-2202, and 36-2209(A)(2).
The specific statutory authority for the rules in 9 A.A.C. 25, Article 1 is A.R.S. § 36-2202.
The specific statutory authority for the rules in 9 A.A.C. 25, Article 12 are A.R.S. §§ 41-1072 through 41-1079.

2. The purpose of the rule
The purpose of the rules in 9 A.A.C. 25, Article 1 is to provide clarity for other rules within the Chapter.
The purpose of the rules in 9 A.A.C. 25, Article 12 is to provide information about the review of applications or requests for approval and the time-frames related to the review.

3. Analysis of effectiveness in achieving the objective
The rules in 9 A.A.C. 25, Articles 1 and 12 are effective in achieving their respective objectives.

4. Analysis of consistency with state and federal statutes and rules
The rules in 9 A.A.C. 25, Article 1 are consistent with state and federal statutes and rules,
Except for a reference in Table 12.1 to a statutory authority that was changed by Laws 2012, Ch. 94, as described under Information for Individual Rules, the rules in Article 12 are consistent with state and federal statutes and rules.

5. Status of enforcement of the rule
To the extent that the rules are enforceable, the rules in 9 A.A.C. 25, Articles 1 and 12 are enforced without difficulty by the Department.

6. Analysis of clarity, conciseness, and understandability
The rules in 9 A.A.C. 25, Articles 1 and 12 are clear, concise, and understandable.

7. Summary of the written criticisms of the rule received within the last five years
The Department has not received any written criticisms of the rules in the past five years.

8. Economic, small business, and consumer impact comparison
The rules in 9 A.A.C. 25, Articles 1 and 12 were last revised by exempt rulemaking, to comply with Laws 2012, Ch. 94, and published in the Arizona Administrative Register (A.A.R.) at 19 A.A.R. 4032, effective December 1, 2013. In this economic, small business, and consumer impact comparison, annual cost/revenues are designated as “minimal” when less than $1,000.00; “moderate” when between $1,000.00 and $10,000.00; “substantial” when $10,000.00 or more; and “significant” when meaningful or important, but not readily subject to quantification.
As part of the 2013 rulemaking, the Department removed from R9-25-101 seven terms defined in A.R.S. § 36-2201 by referring to the statute in the lead-in to definitions, 17 terms no longer used in the current rules, and 14 terms that were described in the rules rather than being defined. The rulemaking also added definitions for 17 terms and revised 13 terms to improve clarity. The rulemaking also consolidated in R9-25-102 duplicated requirements in several Articles, describing who can act for a regulated person. In Article 12, the Department renamed the Table from “Table 1” to “Table 12.1” to clarify which of the three Tables 1 in the Chapter was meant, corrected cross-references and references to the classifications of EMCTs, removed three unnecessary time-frames, and clarified that the addition of a training course, not the amendment of a training program certificate, requires approval. The Department believes that these changes provided a significant benefit to anyone reading or using the rules.

9. **Summary of business competitiveness analyses of the rules**

The Department did not receive a business competitiveness analysis of the rules in the last five years.

10. **Status of the completion of action indicated in the previous five-year-review report**

In the 2012 Five-Year-Review Report, the Department stated that the Department planned to amend the rules in 9 A.A.C. 25 to comply with statutory changes made in Laws 2012, Ch. 94 and to file a Notice of Exempt Rulemaking by December 31, 2013. The rules in Articles 1 and 12 were revised as part of that rulemaking. The Department complied with this plan.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to regulated persons by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

The Department has determined that the rules in 9 A.A.C. 25, Articles 1 and 12 impose the least burden and costs to persons regulated by the rules, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective, despite the minor change that may be made to Table 12.1.

12. **Analysis of stringency compared to federal laws**

Federal laws do not apply to the rules in 9 A.A.C. 25, Articles 1 and 12.

13. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**

The rules in Article 1 do not require the issuance of a regulatory permit. The rules in Article 12 explain the process and timeframes for the review of applications for certifications, licenses, registrations, and requests for approval, all of which require the issuance of a specific agency authorization, which is authorized by A.R.S. § 36-2204(5) for ALS base hospitals, A.R.S. § 36-
2204(3) for training programs, A.R.S. § 36-2202 (A)(2) and (H) for EMCT certification, A.R.S. §§ 36-2213 and 36-2214 for air ambulances and air ambulance services, and A.R.S. Title 36, Chapter 21.1, Article 2 for ground ambulances and ambulance services. Therefore, a general permit is not applicable.

14. Proposed course of action

The Department does not plan to amend the rules in 9 A.A.C. 25, Articles 1 and 12 until substantive issues arise.
ARTICLE 1. DEFINITIONS

1. Authorization of the rule by existing statute
The rule has A.R.S. §§ 36-2201, 36-2204, and 36-2205 as additional specific authority.
2. Objective
The objective of the rule is to define terms used in more than one Article in Chapter 25 to enable the reader to understand clearly the requirements of the Chapter and allow for consistent interpretation.

R9-25-102. Individuals to Act for a Person Regulated Under This Chapter (Authorized by A.R.S. § 36-2202)
2. Objective
The objective of the rule is to establish who may provide information on or sign an application or other document required by the Chapter.

ARTICLE 12. TIME-FRAMES FOR DEPARTMENT APPROVAL

R9-25-1201. Time-frames (Authorized by A.R.S. §§ 41-1072 through 41-1079))
2. Objective
The objective of the rule is to establish requirements for the process by which applications or requests for approval are reviewed, consistent with A.R.S. §§ 41-1072 through 41-1079.

Table 12.1. Time-frames (in days)
2. Objective
The objective of the rule is to establish the time-frames for review of applications or requests for approval, consistent with A.R.S. §§ 41-1072 through 41-1079.

4. Analysis of consistency with state and federal statutes and rules
The “Statutory Authority” citation to A.R.S. § 36-2202(G) for EMCT Certification (R9-25-403), EMCT Recertification (R9-25-404), Extension to File for EMCT Recertification (R9-25-405), Downgrading of Certification (R9-25-406) should be to A.R.S. § 36-2202(H), which was changed by Laws 2012, Ch. 94. Otherwise, the rule is consistent with state and federal statutes and rules.
ARIZONA DEPARTMENT OF HEALTH SERVICES

FIVE-YEAR-REVIEW REPORT
TITLE 9. HEALTH SERVICES
CHAPTER 25. DEPARTMENT OF HEALTH SERVICES
EMERGENCY MEDICAL SERVICES
ARTICLE 3. TRAINING PROGRAMS
ARTICLE 4. EMCT CERTIFICATION

March 2017
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Arizona Revised Statutes (A.R.S.) §§ 36-2202(A)(3) and (4) and 36-2209(A)(2) require the Arizona Department of Health Services (Department) to adopt standards and criteria pertaining to the quality of emergency care, rules necessary for the operation of emergency medical services, and rules for carrying out the purposes of A.R.S. Title 36, Chapter 21.1. A.R.S. § 36-2204(1) and (3) requires the Department to adopt statewide standardized training, certification and recertification standards, and standardized continuing education criteria for all classifications of emergency medical care technicians (EMCTs). A.R.S. §§ 36-2202(H) and 36-2204(6) require EMCTs to apply for certification and recertification and require standards and mechanisms for monitoring and ongoing evaluation of performance levels of all classifications of EMCTs.

The Department has implemented these statutes in Arizona Administrative Code (A.A.C.) Title 9, Chapter 25, Articles 3 and 4, which were last revised effective December 2013. The rules in 9 A.A.C. 25, Article 3 establish the application, administrative, and course and examination requirements and possible enforcement actions for training programs providing instruction leading to a student testing for EMCT certification. The rules in 9 A.A.C. 25, Article 4 establish requirements for certification and recertification, methods to apply for an extension or for downgrading an EMCT’s classification, and standards of conduct, and specify types of and considerations for enforcement actions.

After an analysis of the rules in 9 A.A.C. 25, Articles 3 and 4, the Department has determined that the rules are effective, enforced as written, and clear, concise, and understandable. No written criticism or analysis of competitiveness for the rules has been received by the Department. Although the rules, themselves, are consistent with statutes and rules, several of the rules in Article 4 have an incorrect statutory reference in the titles of the rules. The Department believes that the probable benefits of the rules outweigh within this state the probable costs of the rules, and the rules impose the least burden and costs to regulated persons necessary to achieve the underlying regulatory objective. The Department does not plan to revise the rules unless a substantive issue arises.
INFORMATION THAT IS IDENTICAL FOR ALL OF THE RULES

1. **Authorization of the rule by existing statute**
The general statutory authority for the rules in 9 A.A.C. 25, Articles 3 and 4 are A.R.S. §§ 36-136(A)(7), 36-136(F), 36-2202(A)(3) and (4), and 36-2209(A)(2).
The specific statutory authority for the rules in 9 A.A.C. 25, Article 3 are A.R.S. § 36-2204(1) and (3).
The specific statutory authority for the rules in 9 A.A.C. 25, Article 4 are A.R.S. §§ 36-2202(A)(2) and 36-2204(1) and (6).

2. **The purpose of the rule**
The purpose of the rules in 9 A.A.C. 25, Article 3 is to specify statewide standards for certification of training programs for all classifications of EMCTs.
The purpose of the rules in 9 A.A.C. 25, Article 4 is to specify statewide standardized training, certification, and recertification standards, and standardized continuing education criteria for all classifications of EMCTs.

3. **Analysis of effectiveness in achieving the objective**
The rules in 9 A.A.C. 25, Articles 3 and 4 are effective in achieving their respective objectives, although the effectiveness of R9-25-301, R9-25-302, and R9-25-407 could be improved as described under Information for Individual Rules.

4. **Analysis of consistency with state and federal statutes and rules**
Except for R9-25-305 and R9-25-306 as described under Information for Individual Rules, the rules in 9 A.A.C. 25, Article 3 consistent with state and federal statutes and rules.
Except for R9-25-404, which is correct, and R9-25-407, which does not reference the citation, the titles of the rules in Article 4 contain an incorrect statutory citation. The citation should be to A.R.S. § 36-2202(H), rather than to A.R.S. § 36-2202(G), which was changed by Laws 2012, Ch. 94.
Otherwise, the rules in Article 4 are consistent with state and federal statutes and rules.

5. **Status of enforcement of the rule**
The rules in 9 A.A.C. 25, Articles 3 and 4 are enforced without difficulty by the Department.

6. **Analysis of clarity, conciseness, and understandability**
The rules in 9 A.A.C. 25, Articles 3 and 4 are clear, concise, and understandable, although the clarity of R9-25-301 and the conciseness of R9-25-305 could be improved as described under Information for Individual Rules.

7. **Summary of the written criticisms of the rule received within the last five years**
The Department has not received any written criticisms of the rules in the past five years.
8. **Economic, small business, and consumer impact comparison**

The rules in 9 A.A.C. 25, Articles 3 and 4 were last revised by exempt rulemaking, to comply with Laws 2012, Ch. 94, and published in the *Arizona Administrative Register* (A.A.R.) at 19 A.A.R. 4032, effective December 1, 2013. In this economic, small business, and consumer impact comparison, annual cost/revenues are designated as “minimal” when less than $1,000.00; “moderate” when between $1,000.00 and $10,000.00; “substantial” when $10,000.00 or more; and “significant” when meaningful or important, but not readily subject to quantification.

Currently, 76 training programs are regulated under Article 3. Of these, 31 provide Basic Life Support (BLS) training, 7 provide only Advanced Life Support (ALS) training, and 38 provide both BLS and ALS training. Of these, 24 are associated with community colleges, 34 are governmental, 3 are associated with hospitals, and 15 are private businesses. During calendar year 2016, a total of 631 courses/refresher challenge examinations were provided, 232 courses leading to EMT certification, 39 for Paramedic certification, 196 EMT refresher courses, 86 ALS refresher courses, and 78 refresher challenge examinations. In the 22 months between April 15, 2015 and February 14, 2017, the number of students in training courses included: 5,085 in EMT certification courses, 4,221 in EMT refresher courses, 786 in Paramedic certification courses, and 1,432 in ALS refresher courses. Some training programs, especially those associated with smaller fire departments or with fire districts, provide courses to 10 or fewer students per year, while others, especially those associated with community colleges, may provide training to 100 or more students per year and offer multiple courses running concurrently. The Department receives an average of four new applications per year and expects to provide reviews of 27 existing training programs in 2017 and of 47 existing training programs in 2018. In the past five years, the Department has received four complaints about compliance that have been investigated. One is still pending, and for the others, the training programs were found to have violations, which were identified and corrected, and brought back into compliance.

Approximately 18,450 EMCTs are regulated under Article 4. Of these, approximately 11,640 are EMTs, approximately 70 are AEMTs, 19 are EMT-I(99)s, and approximately 6,725 are Paramedics. Certification is for a two-year period. During 2015 and 2016, the Department received a total of 4,388 initial applications, of which 4,250 were approved; 14,148 applications for recertification, of which 13,931 were approved; 25 requests for extensions, 23 of which were approved; and 34 requests for downgrading, of which 33 were approved. In addition, 853 applications were received from EMCTs requesting certification at a higher classification of EMCT, 736 of which were approved. During the same time period, the Department conducted 121
investigations involving EMCTs, resulting in 18 EMCTs on probation, 33 decrees of censure, and 6 revocations.

As part of the 2013 rulemaking, the Department added requirements in Article 3 for a training program director to have training related to instructional methodology; to notify students of eligibility requirements and prerequisite knowledge, skill, and abilities for a course; and to document and maintain documentation that a student meets eligibility requirements and prerequisites for a course or refresher challenge examination. The Department estimates that these changes may have caused a minimal cost to a training program. The rulemaking also removed unnecessary definitions, corrected cross-references, allowed an applicant to submit an accreditation certificate from a national accrediting organization in lieu of routine inspections; replaced a requirement for a lead instructor to be “present” with a requirement for the lead instructor to be available for student-instructor interaction to allow for on-line instruction; removed the requirement for a written test for an initial certification course to have 150 multiple choice questions to allow for computer-generated smart exams based on student responses; and removed the prohibition of a training program director or an instructor from proctoring a written test. The Department estimates that these changes may have provided a minimal benefit to a training program. The revised rules also updated qualifications for a training program medical director to be consistent with new wording for administrative medical directors in R9-25-202, providing a significant benefit to the three base hospitals that also conduct a certified a training program. Because Laws 2012, Ch. 94, adopted a new classification scheme for EMCTs, with different knowledge and skill requirements, additional training was required for EMCTs who were certified at the previous EMCT classification levels (EMT-Bs and EMT-Ps) and not registered by a national certification organization. For these EMCTs, the rulemaking had included training courses to enable the EMCTs to obtain the new knowledge and skills to transition them to the requirements of the new EMCT classifications. The Department believes that adding the transition training courses and a time-frame for transition training to the rules provided a significant, if not substantial, benefit to an EMCT who needed to obtain the new knowledge and skills to retain employment at the same pay level. As of February 2017, 71 EMT-Bs still need to transition to the EMT classification level and 269 EMT-Ps need to transition to the Paramedic level.

In Article 4, the 2013 rulemaking updated cross-references and the new EMCT classification scheme, removed duplicative/informational requirements, and reorganized the rules to improve clarity. The rulemaking also clarified confidentiality requirements, the two-year certification/recertification period, when an individual may apply for initial certification, when an application for recertification may be made, when probation is a condition of recertification, the information/documentation required when applying for an extension to file an application for
recertification, the conditions of the extension, and what happens if an individual who received an extension is not recertified. The rulemaking also clarified and consolidated downgrading requirements, improved the understandability of conditions that could lead to enforcement actions, and clarified what those enforcement actions could be. The Department estimates that these changes may have provided a significant benefit to an applicant or EMCT.

9. **Summary of business competitiveness analyses of the rules**
The Department did not receive a business competitiveness analysis of the rules in the last five years.

10. **Status of the completion of action indicated in the previous five-year-review report**
In the 2012 Five-Year-Review Report, the Department stated that the Department planned to amend the rules in 9 A.A.C. 25 to comply with statutory changes made in Laws 2012, Ch. 94 and to file a Notice of Exempt Rulemaking by December 31, 2013. The Department complied with this plan. The Department also planned to amend applicable rules in Articles 3 and 4 and submit a Notice of Final Rulemaking to the Governor’s Regulatory Review Council (Council) by December 2015 if any issues identified for Articles 3 or 4 were not addressed in the exempt rulemaking. No such issues were identified, so the Department complied with this plan.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to regulated persons by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The Department has determined that the rules in 9 A.A.C. 25, Articles 3 and 4 impose the least burden and costs to persons regulated by the rules, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective, despite the minor improvements that may be made to the rules.

12. **Analysis of stringency compared to federal laws**
Federal laws do not apply to the rules in 9 A.A.C. 25, Articles 3 and 4.

13. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**
The rules require the issuance of a specific agency authorization, which is authorized by A.R.S. § 36-2204(3) for training programs and A.R.S. § 36-2202 (A)(2) and (H) for EMCT certification, so a general permit is not applicable.

14. **Proposed course of action**
The Department does not plan to amend the rules in 9 A.A.C. 25, Articles 3 and 4 until substantive issues arise.
R9-25-301. Definitions; Application for Certification (Authorized by A.R.S. §§ 36-2202(A)(3) and (4) and 36-2204(1) and (3))

2. **Objective**
   The objectives of the rule are to establish application and review requirements for training program certification.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective but could be improved by moving “according to A.R.S. § 41-1009” from subsection (D) to subsection (D)(2).

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable but could be improved by removing the word “definition” from the title of the rule since no definitions are included in the rule.

R9-25-302. Administration (Authorized by A.R.S. §§ 36-2202(A)(3) and (4) and 36-2204(1) and (3))

2. **Objective**
   The objective of the rule is to establish administrative requirements for training program certificate holders.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective but might be improved by increasing the required reading proficiency level in subsection (D)(1)(a) to higher than “the 9th grade level.”

R9-25-303. Changes Affecting a Training Program Certificate (Authorized by A.R.S. §§ 36-2202(A)(3) and (4) and 36-2204(1) and (3))

2. **Objective**
   The objectives of the rule are to specify requirements when:
   a. There is a change in the name, address, or e-mail address of the training program certificate holder;
   b. There is a change in the training program medical director or training program director; or
   c. A training program certificate holder intends to add a course.
R9-25-304. Course and Examination Requirements (Authorized by A.R.S. §§ 36-2202(A)(3) and (4) and 36-2204(1), (2), and (3))

1. **Authorization of the rule by existing statute**
The rule has A.R.S. § 36-2204(2) as additional specific authority.

2. **Objective**
The objective of the rule is to establish general course and examination requirements for a course taught by a training program.

R9-25-305. Supplemental Requirements for Specific Courses (Authorized by A.R.S. §§ 36-2202(A)(3) and (4) and 36-2204(1) and (3))

2. **Objective**
The objective of the rule is to establish requirements that are specific to a course and the process for renewal of air ambulance licensure.

4. **Analysis of consistency with state and federal statutes and rules**
The cross-reference in subsection (A) should be to subsection (C) rather than to subsection (B). Otherwise, the rule is consistent with state and federal statutes and rules.

6. **Analysis of clarity, conciseness, and understandability**
The rule is mostly clear, concise, and understandable but could be improved by removing subsections (D)(3)(b)(i) and (ii) and (F)(3)(d)(i) through (iii), because the time period for the subsection’s applicability has passed, and subsection (C)(3), because it is duplicative of subsection (A)(3).

R9-25-306. Training Program Notification and Recordkeeping (Authorized by A.R.S. §§ 36-2202(A)(3) and (4) and 36-2204(1) and (3))

2. **Objective**
The objectives of the rule are to establish requirements for a training program certificate holder to:
   a. Submit certain documentation to the Department within specified time periods, and
   b. Maintain records required under the Article.

4. **Analysis of consistency with state and federal statutes and rules**
The cross-reference in subsection (D)(1)(f) should be to R9-25-304(A)(2)(d)(i), rather than to R9-25-304(A)(2)(c)(i). Otherwise, the rule is consistent with state and federal statutes and rules.

R9-25-307. Training Program Enforcement Actions (Authorized by A.R.S. §§ 36-2202(A)(3) and (4) and 36-2204(1) and (3))
2. **Objective**

The objectives of the rule are to establish:

a. The grounds for enforcement, and

b. The potential enforcement actions that may be taken against a training program certificate holder.
ARTICLE 4. EMCT CERTIFICATION

R9-25-401. EMCT General Requirements (Authorized by A.R.S. §§ 36-2202(A)(2), (A)(3), (A)(4), (A)(6), and (G) and 36-2204(1), (6), and (7))

1. **Authorization of the rule by existing statute**
The rule has A.R.S. §§ 36-2202(A)(6) and (H) and 36-2204(7) as additional specific authority.

2. **Objective**
The objective of the rule is to establish general requirements relating to EMCT certification.

R9-25-402. EMCT Certification and Recertification Requirements (Authorized by A.R.S. §§ 36-2202(A)(2), (A)(3), (A)(4), (A)(6), and (G) and 36-2204(1), (6), and (7))

1. **Authorization of the rule by existing statute**
The rule has A.R.S. §§ 36-2202(A)(6) and (H) and 36-2204(7) as additional specific authority.

2. **Objective**
The objective of the rule is to establish eligibility standards for certifying and recertifying EMCTs.

R9-25-403. Application Requirements for EMCT Certification (Authorized by A.R.S. §§ 36-2202(A)(2), (A)(3), (A)(4), and (G) and 36-2204(1) and (6))

1. **Authorization of the rule by existing statute**
The rule has A.R.S. § 36-2202(H) as additional specific authority.

2. **Objective**
The objective of the rule is to establish application requirements for initial EMCT certification.

R9-25-404. Application Requirements for EMCT Recertification (Authorized by A.R.S. §§ 36-2202(A)(2), (3), (4), and (6), (B), and (H) and 36-2204(1), (4), and (6))

1. **Authorization of the rule by existing statute**
The rule has A.R.S. §§ 36-2202(A)(6), (B), and (H) and 36-2204(4) as additional specific authority.

2. **Objective**
The objective of the rule is to establish requirements related to application for EMCT recertification.

R9-25-405. Extension to File an Application for EMCT Recertification (Authorized by A.R.S. §§ 36-2202(A)(2), (A)(3), (A)(4), (A)(6), and (G) and 36-2204(1), (4), (5), and (7))

1. **Authorization of the rule by existing statute**
2. **Objective**

The objective of the rule is to establish standards for requesting and obtaining an extension to file for EMCT recertification.

R9-25-406. **Requirements for Downgrading of Certification (Authorized by A.R.S. §§ 36-2202(A)(2), (A)(3), (A)(4), and (G) and 36-2204(1) and (6))**

1. **Authorization of the rule by existing statute**

   The rule has A.R.S. § 36-2204(H) as additional specific authority.

2. **Objective**

   The objectives of the rule are to:
   
   a. Establish requirements for downgrading to a lower classification of certification during the certification period, and
   
   b. Clarify that downgrading may also be done upon recertification.

R9-25-407. **Notification Requirements (Authorized by A.R.S. §§ 36-2202(A)(2), (A)(3), and (A)(4), 36-2204(1) and (6), and 36-2211)**

1. **Authorization of the rule by existing statute**

   The rule has A.R.S. § 36-2211 as additional specific authority.

2. **Objective**

   The objective of the rule is to establish requirements for EMCTs to notify the Department upon the occurrence of specified events.

3. **Analysis of effectiveness in achieving the objective**

   The rule is effective in achieving its objective but could be improved by adding a requirement for an EMCT to notify the Department of a change in the EMCT’s email address.

R9-25-408. **Unprofessional Conduct; Physical or Mental Incompetence; Gross Incompetence; Gross Negligence (Authorized by A.R.S. §§ 36-2202(A)(2), (A)(3), (A)(4), (A)(6), and (G), 36-2204(1), (6), and (7), and 36-2211)**

1. **Authorization of the rule by existing statute**

   The rule has A.R.S. §§ 36-2202(A)(6) and (H) and 36-2204(7), and 36-2211 as additional specific authority.

2. **Objective**
The objective of the rule is to clarify the meaning of terms used in A.R.S. § 36-2211 that may be grounds for enforcement actions.

R9-25-409. Enforcement Actions (Authorized by A.R.S. §§ 36-2202(A)(2), (A)(3), (A)(4), (A)(6), and (G), 36-2204(1), (6), and (7), and 36-2211))

1. Authorization of the rule by existing statute
   The rule has A.R.S. §§ 36-2202(A)(6) and (H) and 36-2204(7), and 36-2211 as additional specific authority.

2. Objective
   The objectives of the rule are to establish:
   a. The grounds for enforcement, and
   b. The potential enforcement actions that may be taken against an applicant or EMCT.
ARIZONA DEPARTMENT OF HEALTH SERVICES

FIVE-YEAR-REVIEW REPORT
TITLE 9. HEALTH SERVICES
CHAPTER 8. DEPARTMENT OF HEALTH SERVICES
FOOD, RECREATIONAL, AND INSTITUTIONAL SANITATION
ARTICLE 5. TRAILER COACH PARKS

March 2017
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FIVE-YEAR-REVIEW SUMMARY

Arizona Revised Statutes (A.R.S.) § 36-136(H)(8) requires the Arizona Department of Health Services Director (Department) to make rules that define and prescribe reasonably necessary measures concerning sewage and excreta disposal, garbage and trash collection, storage and disposal, and water supply, and to prescribe minimum standards for preparation of food in community kitchens, adequacy of excreta disposal, garbage and trash collection, storage and disposal and water supply for trailer coach parks. A.R.S. § 36-136(H)(8) further requires that the rules provide for inspection of trailer coach parks and for abatement as public nuisances of any premises or facilities that do not comply with these rules.¹

The 11 rules in Arizona Administrative Code (A.A.C.) Title 9, Chapter 8, Article 5 prescribe measures necessary to ensure that trailer coach parks are built, operated, and maintained in a sanitary manner, and specifically provide minimum standards for:

- Plans and specifications;
- Applications for approval;
- Park plan;
- Water supply;
- Sewage disposal system;
- Sanitation facilities;
- Service buildings;
- Community kitchens; recreational facilities; and
- Waste disposal.

For reasons discussed in this Five-Year-Review Report, the Department anticipates submitting a Notice of Final Rulemaking to the Governor’s Regulatory Review Council by June 2019.

¹ A.R.S. § 36-601(A) defines public nuisances that are under the Department’s control as those that are dangerous to public health. A.R.S. § 36-601(B) provides that, based on reasonable cause, the Department may serve a cease and desist order capable of leading to abatement of a public nuisance.
INFORMATION THAT IS IDENTICAL FOR ALL THE RULES

1. **Authorization of the rule by existing statutes**
The general statutory authority for the rules in 9 A.A.C. 8, Article 5 is A.R.S. §§ 36-132(A)(1) and 36-136(A)(4) through (7), and (F). The specific statutory authority for the rules in 9 A.A.C. 8, Article 5 is A.R.S. §§ 36-136(H)(8) and 36-601.

2. **The purpose of the rules**
The purpose of the rules in 9 A.A.C. 8, Article 5 is to ensure that trailer coach parks are built, operated, and maintained in a sanitary manner.

3. **Analysis of effectiveness in achieving the objective**
The rules are effective in achieving their individual objectives.

4. **Analysis of consistency with state and federal statutes and rules**
The rules are mostly consistent with state and federal statutes and rules, except for some incorrect references to Arizona Administrative Code that are discussed in the information for individual rules.

5. **Status of enforcement of the rules**
The Department has delegated its inspection and abatement authority to the local health departments having jurisdiction over their respective trailer coach parks. See A.R.S. § 36-136(D). The rules are enforced without any problems.

6. **Analysis of clarity, conciseness, and understandability**
All the rules are understandable. Some of the rules contain ambiguous language affecting the clarity and conciseness of the rules. Additional specific comments regarding the clarity and conciseness of the rules appear in the information for individual rules.

7. **Summary of the written criticisms of the rule received within the last five years**
The Department has not received any written criticism of the rules in the last five years.

8. **Economic, small business, and consumer impact comparison**
The current trailer coach park rules were adopted by regular rulemaking. The A.A.C. does not include an effective date for these rules and there is no economic impact statement (EIS) on
file. The requirement for an EIS to be included with a regular rulemaking was established after 1980, thus explaining the absence of an EIS on file.

The Department, pursuant to A.R.S. § 36-136(D), has delegated its trailer coach park inspection and abatement authority under A.R.S. § 36-136(H)(8) to the local health departments except for Gila County. Local health departments use the rules while conducting inspections of trailer coach parks. Arizona trailer coach parks are routinely inspected for general sanitation practices including, but not limited to, garbage and trash removal, sewage connections, and water and wastewater. In FY 2016, there were 1,851 trailer coach parks in Arizona. County sanitarians conducted 2,056 regular inspections, 164 complaint-based inspections, and 42 enforcement actions in these facilities. The Department did not conduct any trailer coach inspections in FY 2016.

The rules in 9 A.A.C. 8, Article 5 affect the Department, local health departments, owners and operators of trailer coach parks, and the public. After reviewing the rules the Department determined:

- The Department incurred a minimal cost to write the rules for trailer coach parks.
- The Department incurs a minimal cost to administer the rules for trailer coach parks.
- Local health departments incur a moderate cost to administer and inspect trailer coach parks.
- Owners and operators of trailer coach parks incur at most a minimal cost as a result of the rules.
- The public has incurred at most a minimal cost as a result of the rules. If an owner incurred any expenses as a result of complying with the rules, the owner may have passed that cost on to his customers.
- The public health benefits of having rules for trailer coach parks outweigh the cost of the rules to the Department, the local health departments, owners and operators of trailer coach parks, and the public.

9. **Summary of business competitiveness analyses of the rules**

The Department did not receive a business competitiveness analysis of the rules in the last five years.

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2 A copy of rules published in the Administrative Rules and Regulations in the third quarter of 1980 is attached. The content of the 1980 rules are identical to current rules except for sections R9-8-511 and R9-8-561, which were allowed to expire in June 2002.

3 As used in this estimated economic, small business and consumer impact comparison, cost is minimal when less than $1,000, moderate when between $1,000 and $10,000, and substantial when greater than $10,000.
10. **Status of the completion of action indicated in the previous five-year-review report**

In the 2012 Five-Year-Review Report, the Department noted that the Department did not plan to complete a rulemaking until after the next five-year-review report was due in 2017. Consistent with that intent, the Department did not amend the rules in 9 A.A.C. 8, Article 5 in the past five years.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

Even though the rules contain some ambiguous or undefined language and incorrect references to Arizona Administrative Codes (as described in the sections relevant to individual rules), the Department continues to use the rules without increased cost or burden. For this reason, the Department has determined that the rule provides the least burden and cost to the Department and persons regulated by the rule.

12. **Analysis of stringency compared to federal laws**

The rules are not related to federal laws.

13. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**

The rules were adopted before July 29, 2010.

14. **Proposed course of action**

The Department has determined that the rules are necessary and effective to achieve their regulatory objectives. However, the rules contain some ambiguous or undefined language and incorrect references to Arizona Administrative Codes (as described in the sections relevant to individual rules) that affect their clarity and conciseness. To address issues raised in this report, and to make other changes identified as a result of the Department’s comprehensive review of all rules in 9 A.A.C. 8, the Department anticipates submitting a Notice of Final Rulemaking to the Governor’s Regulatory Review Council by June 2019. This course of action is subject to change based on the Governor’s rulemaking moratorium and the Department’s priorities.
R9-8-512. Definitions

2. Objective of the rule
The objective of the rule is to define terms and phrases used in the Article to enable the reader to have a better understanding of the requirements contained in the Article.

R9-8-521. Plans and specifications

2. Objective of the rule
The objective of the rule is to protect public health by setting forth plan and specification requirements for constructing and maintaining a trailer coach park's public water supply and sewage disposal system.

6. Analysis of clarity, conciseness, and understandability
The rule is understandable, but it could be more clear and concise if ambiguous language such as “public water supply,” “sewage disposal system,” and “park plan” were defined.

R9-8-522. Application

2. Objective of the rule
The objective of the rule is to protect public health by setting forth the application requirements for the operation of a trailer coach park.

6. Analysis of clarity, conciseness, and understandability
The rule is understandable, but it could be more clear and concise if undefined language such as “public water supply main,” “sewer main,” and “municipal or community system” were defined.

R9-8-523. Park Plan

2. Objective of the rule
The objective of the rule is to protect public health by setting forth the requirements necessary to ensure that a trailer coach park is constructed in a manner and at a location conducive to the preservation of public health.

6. Analysis of clarity, conciseness, and understandability
The rule is understandable, but it could be more clear and concise if ambiguous language such as “rapid drainage” and “elimination” were defined.
2. **Objective of the rule**

   The objective of the rule is to protect public health by setting forth requirements necessary to ensure that a trailer coach park has an ample water supply and a sufficient water distribution system.

4. **Analysis of consistency with state and federal statutes and rules**

   The citation to 9 A.A.C. 8, Article 2 in this rule is no longer current. The rule should reference 18 A.A.C. 4, Article 2. In enforcing this rule, the county health departments are aware of the correct location of rules relating to public water supply and distribution systems.

6. **Analysis of clarity, conciseness, and understandability**

   The rule is understandable, but it could be more clear and concise if ambiguous language such as “fixture units,” “residual pressure,” and “trailer site” were defined.

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**R9-8-533. Sewage disposal system**

2. **Objective of the rule**

   The objective of the rule is to protect public health by setting forth the requirements necessary to ensure that a trailer coach park’s sewage disposal system is capable of satisfying the trailer coach park sewage needs.

4. **Analysis of consistency with state and federal statutes and rules**

   The citation to 9 A.A.C. 8, Article 3 in this rule is no longer current. The rule should reference 18 A.A.C. 13, Article 11. In enforcing this rule, the county health departments are aware of the correct location of rules relating to sewage disposal systems.

6. **Analysis of clarity, conciseness, and understandability**

   The rule is understandable, but it could be more clear and concise if ambiguous language such as “treatment facility” and “increased load” were defined.

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**R9-8-541. Sanitation facilities**

2. **Objective of the rule**

   The objective of the rule is to protect public health by setting forth requirements necessary to ensure that inhabitants of a trailer coach park have access to service buildings containing toilets, bathing, laundry, and other sanitation facilities.
6. **Analysis of clarity, conciseness, and understandability**
The rule is understandable, but it could be more clear and concise if ambiguous language such as "other sanitation facilities" and "easy access" were defined.

R9-8-542. **Service buildings**

2. **Objective of the rule**
The objective of the rule is to protect public health by setting forth construction and location requirements necessary to ensure that a service building within a trailer coach park is sanitary, remains sanitary, and fully provides for the sanitation needs of the trailer coach park.

6. **Analysis of clarity, conciseness, and understandability**
The rule is understandable, but it could be more clear and concise if ambiguous language such as "permanent structures," "well lighted," "screened openings," and "impervious material" were defined.

R9-8-543. **Toilet facilities**

2. **Objective of the rule**
The objective of the rule is to protect public health by ensuring that all inhabitants of a trailer coach park have sufficient access to sanitation facilities such as, toilets, urinals, lavatories, and showers.

6. **Analysis of clarity, conciseness, and understandability**
The rule is understandable, but it could be more clear and concise if ambiguous language such as "other sanitation facilities" were defined.

R9-8-544. **Community kitchens; recreational facilities**

2. **Objective of the rule**
The objective of the rule is to protect public health by setting forth the requirements for food handling in a community kitchen or recreational facility located within a trailer coach park.

4. **Analysis of consistency with state and federal statutes and rules**
The citation to 9 A.A.C. 8, Article 2 in this rule is no longer current. The rule should reference 9 A.A.C. 8, Article 1. In enforcing this rule, the county health departments are aware of the correct location of rules relating to food and drink.

6. **Analysis of clarity, conciseness, and understandability**
The rule is understandable, but it could be more clear and concise if ambiguous language such as "community kitchen" and "other recreational facilities" were defined.
Waste disposal

2. **Objective of the rule**
   The objective of the rule is to protect public health by setting forth the requirements for trailer coach park waste storage, collection, transportation, and disposal.

4. **Analysis of consistency with state and federal statutes and rules**
   The citation to 9 A.A.C. 8, Article 4 in this rule is no longer current. The rule should reference 18 A.A.C. 13, Article 3. In enforcing this rule, the county health departments are aware of the correct location of rules relating to waste disposal.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is understandable, but it could be more clear and concise if ambiguous language such as “other objectionable wastes,” “trapped sewer,” and “trap” were defined.
FIVE-YEAR-REVIEW REPORT

TITLE 9. HEALTH SERVICES
CHAPTER 25. DEPARTMENT OF HEALTH SERVICES
EMERGENCY MEDICAL SERVICES
ARTICLE 7. AIR AMBULANCE SERVICE LICENSING
ARTICLE 8. AIR AMBULANCE REGISTRATION

April 2017
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Arizona Revised Statutes (A.R.S.) §§ 36-2202(A)(3) and (4) and 36-2209(A)(2) require the Arizona Department of Health Services (Department) to adopt standards and criteria pertaining to the quality of emergency care, rules necessary for the operation of emergency medical services, and rules for carrying out the purposes of A.R.S. Title 36, Chapter 21.1. A.R.S. § 36-2202(A)(5) requires the Department to adopt “reasonable medical equipment, supply, staffing and safety standards, criteria and procedures for issuance of a certificate of registration to operate an ambulance,” including air ambulances. A.R.S. § 36-2212 prohibits a person from operating an ambulance in Arizona unless the ambulance has a certificate of registration and complies with A.R.S. Title 36, Chapter 21.1, Article 1 and the rules, standards, and criteria adopted pursuant to the Article. A.R.S. §§ 36-2213 through 36-2215 provide specific authority for the regulation of air ambulance services. The Department has implemented these statutes in Arizona Administrative Code (A.A.C.) Title 9, Chapter 25, Articles 7 and 8, which were adopted in April 2006. The rules in R9-25-701, R9-25-704, R9-25-711, R9-25-715, and Table 8.1 were revised by exempt rulemaking in 2013.

The rules in 9 A.A.C. 25, Article 7 establish the standards and processes for air ambulance service (AAS) licensing, including eligibility, initial and renewal applications, terms and transferability of a license, changes affecting a license, inspections, and enforcement actions. The rules also include minimum standards for operations; mission staffing; air ambulance safety, equipment, and supplies; training; communications; medical control; recordkeeping; and interfacility transports. The rules in 9 A.A.C. 25, Article 8 establish the standards and processes for air ambulance registration, including eligibility, initial and renewal applications, terms and transferability of a registration, changes affecting a registration, inspections, enforcement actions, and minimum standards.

After an analysis of the rules in 9 A.A.C. 25, Articles 7 and 8, the Department has determined that the rules are effective or mostly effective and clear, concise, and understandable or mostly clear, concise, and understandable. All but one are consistent with statutes and rules and enforced as written. No
written criticism or analysis of competitiveness for the rules has been received by the Department. Because of the level of stakeholder engagement anticipated during a rulemaking, the Department believes that a rulemaking may take over two years to complete and plans to submit a Notice of Final Rulemaking to the Governor’s Regulatory Review Council (Council) by December 31, 2020.
INFORMATION THAT IS IDENTICAL FOR ALL OF THE RULES

1. **Authorization of the rule by existing statute**
   The general statutory authority for the rules in 9 A.A.C. 25, Articles 7 and 8 are A.R.S. §§ 36-136(A)(7), 36-136(F), 36-2202(A)(3) and (4), and 36-2209(A)(2).
   The specific statutory authority for the rules in 9 A.A.C. 25, Article 7 is A.R.S. § 36-2213.
   The specific statutory authority for the rules in 9 A.A.C. 25, Article 8 is A.R.S. § 36-2212.

2. **The purpose of the rule**
   The purpose of the rules in 9 A.A.C. 25, Article 7 is to specify requirements for the licensing of air ambulance services.
   The purpose of the rules in 9 A.A.C. 25, Article 8 is to specify requirements for the registration of air ambulances.

4. **Analysis of consistency with state and federal statutes and rules**
   Except as described for R9-25-704, the rules in 9 A.A.C. 25, Articles 7 and 8 are consistent with state and federal statutes and rules.

5. **Status of enforcement of the rule**
   Except as described for R9-25-704, the rules in 9 A.A.C. 25, Articles 7 and 8 are enforced as written without difficulty by the Department.

7. **Summary of the written criticisms of the rule received within the last five years**
   The Department has not received any written criticisms of the rules in the past five years.

8. **Economic, small business, and consumer impact comparison**
   The rules in 9 A.A.C. 25, Articles 7 and 8 were adopted by final rulemaking, effective April 8, 2006. The rules in R9-25-701, R9-25-704, R9-25-711, R9-25-715, and Table 8.1 were revised by exempt rulemaking in 2013. At the time of the 2006 rulemaking, there were 13 private AASs operating in Arizona with a total of 91 registered air ambulances, 38 fixed-wing and 53 rotor-wing. Of the 13 private AASs, four operated only fixed-wing air ambulances and three only rotor-wing air ambulances, and seven held CAMTS accreditation. As of March 29, 2017, there are 22 licensed AASs operating in Arizona, all of which are private companies. They operate a total of 117 registered air ambulances, 37 fixed-wing and 80 rotor-wing. Of the 22 private AASs, 13 operate only fixed-wing air ambulances and two only rotor-wing air ambulances, and 12 hold CAMTS accreditation.
   An economic, small business, and consumer impact statement (EIS) was submitted to the Council as part of the Notice of Final Rulemaking package for the 2006 rulemaking. In the EIS, annual cost/revenues were designated as “minimal” when less than $1,000.00; “moderate” when
between $1,000.00 and $10,000.00; “substantial” when $10,000.00 or more; and “significant” when meaningful or important, but not readily subject to quantification. The EIS stated that the Department had incurred moderate-to-substantial costs for promulgating the rules for air ambulance service licensing and air ambulance registration and would incur substantial costs for implementing the rules, including moderate-to-substantial costs for conducting inspections. The Department anticipated that the Department would receive a significant benefit from the rules and that licensure would help to ensure the health and safety of patients and enhance consistency in quality of care of AASs.

The Department estimated that the rules would have a significant impact on AASs, which were used to operating without regulation. The Department believed that AASs might incur a minimal-to-moderate increase in premium costs for increased liability insurance, minimal-to-moderate costs for air ambulance annual regulatory fees, minimal costs for participating in an inspection, minimal-to-moderate costs for equipping and supplying an air ambulance, and substantial costs if not already meeting industry standards for staffing missions, including interfacility neonatal missions and interfacility maternal missions, or medical director qualifications. An AAS might also incur substantial costs if the AAS had been using an unpressurized fixed-wing air ambulance. The Department anticipated that AASs would receive a significant benefit from the clarity of the rules and medical director qualifications. The Department also believed that an AAS would receive a substantial benefit from being able to perform an interfacility critical care mission without supplies and equipment with which an air ambulance is required to be equipped, but unnecessary for the patient being transported, if size or weight considerations made it unsafe or impossible for the air ambulance to carry them.

The Department believed that AAS personnel members would receive substantial benefit from mission staffing standards and medical director qualifications. The Department believed that health care providers, health care institution staff members, and EMS providers would receive a significant benefit from requiring an AAS to publicize hours of operation. Members of the rulemaking Task Force were thought to have incurred minimal-to-moderate costs during the rulemaking process and to have received a significant benefit from having had their recommendations included in the rules. The Department estimated that an AAS medical director might incur substantial costs if the AAS medical director’s qualifications did not already meet the industry standards in the rules. The Department also believed that patients served by air ambulance services (AASs) and their loved ones would receive a significant benefit from AASs complying with the licensing rules and from the Department performing inspections of AASs, and patients served by air ambulance
services (AASs) and their loved ones might receive a substantial benefit from monetary recovery if a patient were harmed by an AAS. The Department anticipated that the general public might receive a substantial benefit from the requirement that liability insurance coverage cover property damage, and that the State of Arizona might receive a substantial benefit from the depositing of air ambulance annual regulatory fees into the general fund. The Department believes the costs and benefits identified in this EIS are generally consistent with the actual costs and benefits of the rules.

As part of the 2013 exempt rulemaking, the Department removed unnecessary definitions from R9-25-701, removed duplicative or unnecessary requirements from and clarified other requirements in R9-25-704, updated the nomenclature for EMCTs, renamed Table 1 in Article 8 to Table 8.1, and corrected cross references. The Department believes these changes caused no additional costs and provided a significant benefit to all stakeholders. As part of the 2013 rulemaking, the Department also added to Table 8.1 a requirement for a blood glucose measuring device and a pulse oximeter to be consistent with the new scope of practice for an EMT. The Department believes that most, if not all, AASs already owned and were using this equipment. For an AAS that did not, the Department estimates that the AAS could have incurred a minimal cost per air ambulance to comply with this requirement. A patient being transported by the AAS and the patient’s family and health insurance carrier, and the general public may receive a significant benefit from increased patient safety.

9. **Summary of business competitiveness analyses of the rules**
The Department did not receive a business competitiveness analysis of the rules in the last five years.

10. **Status of the completion of action indicated in the previous five-year-review report**
In the 2012 Five-Year-Review Report, the Department stated that the Department planned to address concerns described in the report and to simplify and streamline the requirements in the rules for air ambulance services. The Department planned to amend the rules in Articles 7 and 8 and submit a Notice of Final Rulemaking to the Council by December 31, 2016. In 2013, the Department addressed some of the concerns, as described above in paragraph 8, in a rulemaking amending the rules in 9 A.A.C. 25 to comply with statutory changes made in Laws 2012, Ch. 94, filing a Notice of Exempt Rulemaking by December 31, 2013. The Department has not yet addressed other concerns, as described in this report.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to regulated**
persons by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

The Department has determined that the rules in 9 A.A.C. 25, Articles 7 and 8, except for R9-25-704 and R9-25-710, impose the least burden and costs to persons regulated by the rule, despite the minor improvements that may be made to some of the rules.

12. Analysis of stringency compared to federal laws

Federal laws, including 14 CFR 135 and 14 CFR 298, apply to the regulation by the Federal Aviation Administration of aircraft used as air ambulances. In the rules, the Department requires documentation demonstrating compliance with these requirements, but does not exceed federal law except as required by state statutes. The rules impose requirements specific to “medical equipment, supply, staffing, and safety standards,” as required by A.R.S. § 36-2202(A)(5), and establish “minimum standards for the operation of air ambulance services that are necessary to assure public health and safety,” as required by A.R.S. § 36-2213.

13. For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037

The rules require the issuance of a specific agency authorization, which is authorized by A.R.S. §§ 36-2213 and 36-2214, so a general permit is not applicable.

14. Proposed course of action

The Department plans to amend the rules in 9 A.A.C. 25, Articles 7 and 8 to address concerns described in this report and make other changes suggested by stakeholders during a rulemaking. Because of the level of stakeholder engagement anticipated during the rulemaking and to minimize the burden on stakeholders while participating in the rulemaking, the Department believes that a rulemaking may take over two years to complete and plans to submit a Notice of Final Rulemaking to the Governor’s Regulatory Review Council (Council) by December 31, 2020.
INFORMATION FOR INDIVIDUAL RULES

ARTICLE 7. AIR AMBULANCE SERVICE LICENSING

R9-25-701. Definitions (A.R.S. §§ 36-2202(A)(3) and (4), 36-2212, 36-2213, 36-2214, and 36-2215)

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. §§ 36-2212, 36-2214, and 36-2215 as additional specific authority.

2. **Objective**
   The objective of the rule is to define terms used in the Article to assist the reader in understanding the requirements of the Article.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

4. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

R9-25-702. Applicability (A.R.S. §§ 36-2202(A)(4) and 36-2217)

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. § 36-2217 as additional specific authority.

2. **Objective**
   The objective of the rule is to establish to whom the rules in 9 A.A.C. 25, Articles 7 and 8 do not apply.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

4. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

R9-25-703. Requirement and Eligibility for a License (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), 36-2212, 36-2213, 36-2214, and 36-2215)

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. §§ 36-2212, 36-2214, and 36-2215 as additional specific authority.

2. **Objective**
   The objectives of the rule are to:
   a. Prohibit operation of an air ambulance in Arizona without an air ambulance license, and
b. Establish eligibility requirements for air ambulance licensing.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.


1. **Authorization of the rule by existing statute**
   The rule has A.R.S. §§ 36-2214 and 36-2215 as additional specific authority.

2. **Objective**
   The objective of the rule is to establish application requirements and the process for initial air ambulance licensure.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

4. **Analysis of consistency with state and federal statutes and rules**
   The rule is not consistent with A.R.S. § 41-1080 since the rule does not require elements in the application that would allow the Department to ensure adherence with the statute. Otherwise, the rule is consistent with state and federal statutes and rules.

5. **Status of enforcement of the rule**
   The Department enforces R9-25-704 consistent with requirements in A.R.S. § 41-1080. The rule is otherwise enforced as written without difficulty.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to regulated persons by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   The Department has determined that the rule does not impose the least burden and costs to persons regulated by the rule, due to the lack of notice in the rule of requirements related to A.R.S. § 41-1080.

1. **Authorization of the rule by existing statute**
The rule has A.R.S. §§ 36-2214 and 36-2215 as additional specific authority.

2. **Objective**
The objective of the rule is to establish application requirements and the process for renewal of air ambulance licensure.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective but could be improved if subsection (C) were removed as unnecessary and duplicative of the requirement in R9-25-704 (A)(16), referenced in subsection (A)(1).

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable but could be improved by replacing the pronoun “its” in subsection (A) with the noun to which the pronoun refers.


1. **Authorization of the rule by existing statute**
The rule has A.R.S. §§ 36-2214 and 41-1092.11 as additional specific authority.

2. **Objective**
The objectives of the rule are to establish:
a. The term of an air ambulance license, and
b. Requirements related to transfer of an air ambulance license.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable but could be improved by clarifying that the “date of issuance” means the date the initial license was issued and that the “person wanting to transfer an air ambulance service license” refers to the current licensee.


2. **Objective**
The objectives of the rule are to:
a. Establish notification requirements for certain changes affecting a license, and
b. Specify the Department’s actions in response to two of those notifications.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective but could be improved by increasing the number of working days for some of the changes in subsection (D) within which an air ambulance service has to notify the Department. The effectiveness of the rule could also be improved by removing subsection (E), which is unnecessary and duplicates the requirement in R9-25-706(D).

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable but could be improved by replacing the pronoun “its” with the noun to which the pronoun refers in subsections (B), (C)(2), and (D) and clarifying that the “person wanting to transfer an air ambulance service license” in subsection (E) refers to the current licensee. In addition, the rule would be improved if the term “scope of the mission types provided” were clarified to include both level of care and type of transport.


1. **Authorization of the rule by existing statute**
   The rule has A.R.S. § 36-2214 as additional specific authority.

2. **Objective**
   The objectives of the rule are to establish requirements related to the inspection of an air ambulance service and the investigation of an alleged violation of rules or statutes.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective but could be improved by removing subsection (E), which is unnecessary and duplicates the requirements in R9-25-704(A)(16) and R9-25-705(C).

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.


1. **Authorization of the rule by existing statute**
   The rule has A.R.S. §§ 36-2214, 36-2215, 41.1092.03, and 41-1092.11 as additional specific authority.

2. **Objective**
   The objectives of the rule are to establish:
   a. The grounds for the Department to take enforcement action against an air ambulance service,
   b. The types of enforcement action that the Department may take, and
c. The factors the Department will consider in determining whether to take enforcement action.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable but could be improved if the term “summarily” in subsection (B)(3) were replaced with the term “immediately” as in R9-25-806 (B)(2) and if the pronoun “its” in subsection (B)(3) were replaced with the noun to which the pronoun refers.

R9-25-710. **Minimum Standards for Operations (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), and 36-2213)**

2. **Objective**
The objective of the rule is to establish minimum operational standards for an air ambulance service operating in Arizona.

3. **Analysis of effectiveness in achieving the objective**
The rule is mostly effective in achieving its objective but could be improved by including the staffing in the record for each mission required in subsection (A)(8) and requiring that additional information in subsection (A)(8) be submitted to the Department. The rule would also be improved if the requirements currently in R9-25-807(C) were included in the rule since these requirements relate to the operation of a mission under specific circumstances, just as subsections (B) and (D) do, and the report required of a certificate holder under R9-25-807(C)(5) is very similar to the report required in subsection (C) of the rule.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable but could be improved by defining or describing the terms “call number,” “patient reference number,” “publicizes,” and “rescue situation” where the terms are used rather than defining the terms in R9-25-701, and defining the term “run log.” The rule would also be more concise if the reference to A.R.S. § 36-2220 for the definition of “prehospital incident history report” were removed from the rule since the term is now defined in R9-25-101. The rule would also be more understandable if the rule specified in the appropriate subsection of the rule, rather than in R9-25-716, how long and where the records of each mission and a record of a deviation from subsection (A)(5) are kept, and if the pronoun “its” in subsections (A)(2) and (3) were replaced with the noun to which the pronoun refers.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to regulated**
persons by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective
The Department has determined that the rule does not impose the least burden and costs to persons regulated by the rule, because of the items identified in paragraphs 3 and 6.

R9-25-711. Minimum Standards for Mission Staffing (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), and 36-2213)

2. Objective
The objectives of the rule are to establish:
   a. Minimum standards for mission staffing,
   b. Recordkeeping requirements related to use of single-member medical teams, and
   c. Requirements for personnel records.

3. Analysis of effectiveness in achieving the objective
The rule is effective in achieving its objective but could be improved by removing the need to establish a hierarchy of qualifications implied by the term “at least the following qualifications” in subsections (A)(1) and (2).

6. Analysis of clarity, conciseness, and understandability
The rule is clear, concise, and understandable but could be improved by clarifying by whom the “written guidelines” specified in subsection (C) were developed and what the term “no other transport team” means in subsection (C)(5). The rule would also be more understandable if the rule specified in subsections (D) and (E), rather than in R9-25-716, how long and where the applicable information is kept.


2. Objective
The objective of the rule is to establish minimum training requirements for medical team members and minimum recordkeeping requirements for the trainings.

3. Analysis of effectiveness in achieving the objective
The rule is effective in achieving its objective but could be improved by updating the training requirements to reflect current operating norms for air ambulances.

6. Analysis of clarity, conciseness, and understandability
The rule is clear, concise, and understandable but could be improved by specifying in the rule, rather than in R9-25-716, how long and where the training information is kept.
R9-25-714. Minimum Standards for Communications (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), and 36-2213)

2. **Objective**
   The objective of the rule is to establish minimum standards for communication capabilities on a mission.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

R9-25-715. Minimum Standards for Medical Control (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), and 36-2213)

2. **Objective**
   The objective of the rule is to establish minimum standards for medical control and quality management of air ambulance services, including qualifications and responsibilities of a medical director and requirements for an air ambulance service quality management program.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable but could be improved by removing the term “as defined in A.R.S. §36-2201” as unnecessary, since the term “physician” is consistently defined in R9-25-101.


2. **Objective**
   The objective of the rule is to require an air ambulance service to retain required records for a specific period of time and to produce them for review upon the Department’s request.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective, but it would be easier for a reader to understand requirements in the Article if retention requirements were located in the same Section as record creation and maintenance requirements are located.

6. **Analysis of clarity, conciseness, and understandability**
R9-25-717. Minimum Standards for an Interfacility Neonatal Mission (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), and 36-2213)

2. **Objective**
   The objective of the rule is to establish minimum standards for an interfacility neonatal mission, including:
   a. Supplemental medical team member proficiency requirements,
   b. Mission equipment and supply requirements,
   c. Requirements for a physician providing on-line medical direction or on-line medical guidance, and
   d. Requirements for verification and documentation of medical team member proficiencies.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable but could be improved if the term “pediatric emergency care” were defined or described and if the cross-reference to “Table 1 of Article 8 of this Chapter” were corrected to refer to Table 8.1.

R9-25-718. Minimum Standards for an Interfacility Maternal Mission (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), and 36-2213)

2. **Objective**
   The objective of the rule is to establish minimum standards for an interfacility maternal mission, including:
   a. Supplemental medical team member proficiency requirements,
   b. Mission equipment and supply requirements,
   c. Requirements for a physician providing on-line medical direction or on-line medical guidance, and
   d. Requirements for verification and documentation of medical team member proficiencies.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**

The rule is clear, concise, and understandable.
The rule is clear, concise, and understandable but could be improved if the term “advanced emergency cardiac life support” were defined or described and if the cross-reference to “Table 1 of Article 8 of this Chapter” were corrected to refer to Table 8.1.
ARTICLE 8. AIR AMBULANCE REGISTRATION


2. **Objective**
   The objective of the rule is to define terms used in the Article to assist the reader in understanding the requirements of the Article.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable but could be improved by removing the term “drug,” which is already defined in R9-25-101 and not used in the Article.

R9-25-802. Requirement, Eligibility, and Application for an Initial or Renewal Certificate of Registration for an Air Ambulance (A.R.S. §§ 36-2202(A)(4) and (5), 36-2209(A)(2), 36-2212, 36-2213, 36-2214, and 36-2240(4))

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. §§ 36-2202(A)(5), 36-2213, 36-2214, and 36-2240(4) as additional specific authority.

2. **Objective**
   The objectives of the rule are to:
   a. Require an air ambulance to be registered;
   b. Establish eligibility requirements, application requirements, and the application process for air ambulance registration; and
   c. Establish the grounds for denial of an application for registration.

3. **Analysis of effectiveness in achieving the objective**
   The rule is mostly effective in achieving its objective but could be improved if information about the owner/operator of the air ambulance, if different from the applicant, were provided on the application. The effectiveness of the rule would also be improved if subsection (A) were removed as unnecessary and duplicative of the requirement in R9-25-703(A) and if subsection (C)(12) allowed payment by credit card. The rule would also be improved if the applicant was required to include on an application the license number for the applicant’s air ambulance service to better tie an air ambulance to the air ambulance service responsible for ensuring compliance with the requirements in 9 A.A.C. 25, Article 8.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable but could be improved by amending the use of the term “to obtain an initial or renewal certificate of registration” to clarify that submitting an application does not guarantee that an applicant will obtain a certificate of registration. In addition, the rule would be more concise if the information about who is required to sign and attest on an application were removed because the information is now in R9-25-102 and applies to all applications in 9 A.A.C. 25.

R9-25-803. Term and Transferability of Certificate of Registration (A.R.S. §§ 36-2202(A)(4) and (5), 36-2209(A)(2), 36-2212, and 41-1092.11)

1. **Authorization of the rule by existing statute**
The rule has A.R.S. §§ 36-2202(A)(5) and 41-1092.11 as additional specific authority.

2. **Objective**
The objective of the rule is to establish the term and non-transferability of air ambulance registration.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable.

R9-25-804. Changes Affecting Registration (A.R.S. §§ 36-2202(A)(4) and (5), 36-2209(A)(2), and 36-2212)

1. **Authorization of the rule by existing statute**
The rule has A.R.S. § 36-2202(A)(5) as additional specific authority.

2. **Objective**
The objectives of the rule are to:
   a. Establish notification requirements for certain changes affecting registration, and
   b. Specify the Department’s actions in response to two of those notifications.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable but could be improved by amending subsection (B) to make clear that it is the certificate holder who has the “desire to relinquish the certificate of registration” and by replacing the pronoun “its” in subsection (D) with the noun to which the pronoun refers.
R9-25-805. Inspections (A.R.S. §§ 36-2202(A)(4) and (5), 36-2209(A)(2), 36-2212, and 36-2232(A)(11))

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. §§ 36-2202(A)(5) and 36-2232(A)(11) as additional specific authority.

2. **Objective**
   The objective of the rule is to establish requirements related to the inspection of an air ambulance.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

R9-25-806. Enforcement Actions (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), 36-2212, 36-2234(L), 41-1092.03, and 41-1092.11(B))

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. §§ 36-2234(L), 41-1092.03, and 41-1092.11(B) as additional specific authority.

2. **Objective**
   The objectives of the rule are to establish:
   a. The grounds for the Department to take enforcement action against an air ambulance registration,
   b. The types of enforcement action that the Department may take, and
   c. The factors the Department will consider in determining whether to take enforcement action.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective but could be improved by combining elements of the rule into R9-25-709, under which enforcement action may be taken against an air ambulance service for using an air ambulance that does not meet the requirements in 9 A.A.C. 25, Article 8, and repealing the rule.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable but could be improved by replacing the pronoun “its” in subsection (B)(2) with the noun to which the pronoun refers.
R9-25-807. Minimum Standards for an Air Ambulance (A.R.S. §§ 36-2202(A)(3), (4), and (5); 36-2209(A)(2); and 36-2212)

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. § 36-2202(A)(3) and (5) as additional specific authority.

2. **Objective**
   The objective of the rule is to establish minimum physical capability, configuration, and equipment and supply standards for an air ambulance.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective but could be improved if the requirements currently in subsection (C) of the rule were included in R9-25-710, which specifies requirements for the operation of an air ambulance service since this subsection specifies requirements for how an air ambulance is used, rather than requirements for the air ambulance itself.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable but could be improved by clarifying the undefined terms “head strike envelope,” “flight crew,” and “density altitude.” The rule could also be improved by replacing the pronoun “its” in subsection (C)(1) with the noun to which the pronoun refers and replacing the reference to Table 1 with the reference to Table 8.1, the title of which was changed as part of the 2013 exempt rulemaking.

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Table 8.1. Minimum Equipment and Supplies Required on Air Ambulances, by Mission Level and Aircraft Type (A.R.S. §§ 36-2202(A)(3), (4), and (5); 36-2209(A)(2); and 36-2212)

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. § 36-2202(A)(3) and (5) as additional specific authority.

2. **Objective**
   The objective of the rule is to specify the minimum equipment and supplies required on fixed-wing and rotor-wing aircraft and on different mission levels.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.
ARIZONA DEPARTMENT OF HEALTH SERVICES

FIVE-YEAR-REVIEW REPORT
TITLE 9. HEALTH SERVICES
CHAPTER 25. DEPARTMENT OF HEALTH SERVICES
EMERGENCY MEDICAL SERVICES
ARTICLE 2. MEDICAL DIRECTION; ALS BASE HOSPITAL CERTIFICATION
ARTICLE 5. MEDICAL DIRECTION PROTOCOLS FOR EMERGENCY MEDICAL CARE TECHNICIANS

May 2017
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Arizona Revised Statutes (A.R.S.) §§ 36-2202(A)(3) and (4) and 36-2209(A)(2) require the Arizona Department of Health Services (Department) to adopt standards and criteria pertaining to the quality of emergency care, rules necessary for the operation of emergency medical services, and rules for carrying out the purposes of A.R.S. Title 36, Chapter 21.1. The Department has implemented these statutes in Arizona Administrative Code (A.A.C.) Title 9, Chapter 25. The rules in Article 2 establish requirements for medical direction of emergency medical care technicians (EMCTs) and certification of advanced life support (ALS) base hospitals. The rules in Article 5 contain protocols for EMCTs. Both Article 2 and Article 5 were entirely revised in an exempt rulemaking effective December 2013, and Sections in Article 5 have been further revised by exempt rulemaking, authorized by ARS § 36-2205(B), in 2014, 2016, and 2017.

After an analysis of the rules in 9 A.A.C. 25, Articles 2 and 5, the Department has determined that all of the rules are consistent with state and federal statutes and rules; all are clear, concise, and understandable, despite some minor punctuation errors in three of the rules; and all but two of the rules are effective. No analysis of competitiveness for the rules has been received by the Department. Four written criticisms/comments have been received about rules in Article 2, and no written criticism, except for formal requests for rulemaking, were received about the rules in Article 5. Except for the two rules that are the subject of the written criticisms, the Department believes that the probable benefits of the rules outweigh within this state the probable costs of the rules, and the rules impose the least burden and costs to regulated persons necessary to achieve the underlying regulatory objective. Unless a substantive issue arises other than those described in this report, the Department plans to revise the rules in Article 2 to address the concerns raised in the written criticisms, as stated in the report, and to submit a Notice of Final Rulemaking to the Governor’s Regulatory Review Council (Council) by July 1, 2019.
1. **Authorization of the rule by existing statute**
   The general statutory authority for the rules in 9 A.A.C. 25, Articles 2 and 5 are A.R.S. §§ 36-136(A)(7), 36-136(F), 36-2202, and 36-2209(A)(2).
   The specific statutory authority for the rules in 9 A.A.C. 25, Article 2 are A.R.S. §§ 36-2201, 36-2202, and 36-2204.
   The specific statutory authority for the rules in 9 A.A.C. 25, Article 5 are A.R.S. §§ 36-2202, 36-2204, and 36-2205.

2. **The purpose of the rule**
   The purpose of the rules in 9 A.A.C. 25, Article 2, is to establish requirements for medical direction of EMCTs and certification of ALS base hospitals.
   The purpose of the rules in 9 A.A.C. 25, Article 5, is to establish protocols for EMCTs to follow.

3. **Analysis of effectiveness in achieving the objective**
   Except for R9-25-201 and R9-25-202, the rules in 9 A.A.C. 25, Articles 2 and 5 are effective in achieving their respective objectives.

4. **Analysis of consistency with state and federal statutes and rules**
   The rules in 9 A.A.C. 25, Articles 2 and 5 are consistent with state and federal statutes and rules,

5. **Status of enforcement of the rule**
   Except as described in paragraph 3 for R9-25-201 and R9-25-202, the rules in 9 A.A.C. 25, Articles 2 and 5 are enforced without difficulty by the Department.

6. **Analysis of clarity, conciseness, and understandability**
   The rules in 9 A.A.C. 25, Articles 2 and 5 are clear, concise, and understandable despite some minor punctuation errors in R9-25-201, R9-25-206, and R9-25-207.

7. **Summary of the written criticisms of the rule received within the last five years**
   Except for R9-25-201 and R9-25-202, the Department has not received any written criticisms of the rules in the past five years.

8. **Economic, small business, and consumer impact comparison**
   The rules in 9 A.A.C. 25, Articles 2 and 5 were completely revised by exempt rulemaking, to comply with Laws 2012, Ch. 94, and published in the *Arizona Administrative Register* (A.A.R.) at 19 A.A.R. 4032, effective December 1, 2013. Tables 5.1 and 5.2 were further amended in 2014, 2016, and 2017, based on changes recommended by the Emergency Medical Services Council and the Medical Direction Commission, established by A.R.S. §§ 36-2203 and 36-2203.01, respectively; and R9-25-504 was amended in 2014 based on formal requests for rulemaking by stakeholders. In this
economic, small business, and consumer impact comparison, annual costs/revenues changes are
designated as minimal when more than $0 and $1,000 or less, moderate when between $1,000 and
$10,000, and substantial when $10,000 or greater in additional costs or revenues. A cost is listed as
significant when meaningful or important, but not readily subject to quantification.

As part of the 2013 rulemaking, Article 2 was changed to use the new nomenclature for
classifications of EMCTs and to reorganize and consolidate requirements, reducing the number of
Sections from 11 to seven. All requirements for an administrative medical director were included in
R9-25-201, requirements for on-line medical direction were included in R9-25-202, and the
requirements were clarified. The new rules also clarified certification and inspection requirements
for ALS base hospitals, that an ALS base hospital must have the capability of providing both
administrative medical direction and on-line medical direction, that an ALS base hospital must notify
the Department if the administrative medical director specified in the ALS base hospital’s
application changes, and that an emergency medical services provider (EMS provider) or ambulance
service is responsible for ensuring that an EMCT receives administrative medical direction according
to the Chapter. Another method by which a physician could qualify to be an administrative medical
director or provide on-line medical direction was included, as were mechanisms by which an EMS
provider or ambulance provider could provide a qualified administrative medical director. The new
rules also provided an alternate method for documenting the qualifications of an administrative
medical director or a physician providing on-line medical direction and clarified that an EMS
provider or ambulance service that provides only BLS is not required to have an administrative
medical director. In addition, the new rules allowed a special hospital providing surgical and
emergency services only to children to become an ALS base hospital providing administrative
medical direction or on-line medical direction only for patients who are children, and an EMS
provider or ambulance service to use an ALS base hospital that is a special hospital for
administrative medical direction or on-line medical direction for patients who are children. The new
rules removed requirements for notifying the Department upon learning that an EMCT has any of
several specific criminal convictions or has had revoked/suspended certification/registration; that an
administrative medical director or a physician providing on-line medical direction act only on behalf
of specified entities; that an administrative medical director and anyone delegated authority for
administrative medical direction functions must review and document the review of EMS statutes
and rules; and that on-line medical direction be consistent with medical recordkeeping, medical
reporting, and prehospital incident history report requirements approved by the EMCT’s
administrative medical director. Also removed in the new rules were requirements that restate what
is in statute; a requirement to conspicuously post an ALS base hospital certificate and return a
certificate upon decertification; specific requirements for assisting a patient in self-administration of medication; duplicative requirements related to obtaining, providing access to, and monitoring an EMCT’s use of agents by referring to R9-25-202 and specifying exceptions from these requirements; and references to requirements for ALS base hospital administrative medical directors, separate from the general requirements for administrative medical directors. The Department believes that these changes provided at least minimal and in some cases a substantial benefit to EMS providers, ambulance services, EMCTs, and ALS base hospitals or hospitals that might become ALS base hospitals in the future, without affecting the health or safety of a patient.

The new rules in Article 2 added a requirement for a protocol related to the communication of information during transfer of care, as a clarification of requirements for completing and processing prehospital incident history reports. The new rules also clarified chain of custody; mechanisms to control access to agents; and notification of depletion, adulteration, or loss of controlled substances. While these changes may have caused a minimal-to-moderate increase in costs to an EMS provider or ambulance service that were not already implementing these requirements as standard practice, the Department believes that they provided a significant benefit to hospitals receiving the patients brought to the hospitals, the patients and their families, and the general public. Changes to the application for certification as an ALS base hospital included the clarification that the application is in a Department-provided format, the addition of an e-mail address to the application, allowing for a designee of a hospital’s chief administrative officer to be the liaison with the Department, allowing a special hospital meeting specific requirements to be eligible for certification as an ALS base hospital, and requiring the name of each emergency medical services provider or ambulance service with which the facility has a contract to provide medical direction, rather than requiring a copy of the contract. The new rules also clarified that the notification of a name change of an ALS base hospital is provided in a Department-provided format and includes the current name and certificate number, as well as documentation to distinguish a name change from a change in ownership. The new rules removed the Department’s approval or denial of a name change. The Department believes that these changes imposed at most a minimal increased cost and provided a significant benefit to ALS base hospitals or hospitals seeking certification as an ALS base hospital, without affecting the health or safety of a patient.

Article 5 was also extensively changed as part of the 2013 rulemaking. Besides changing to the new nomenclature for classifications of EMCTs, the rules in Article 5 were reorganized and requirements consolidated, reducing the number of Sections from 13 to five, removing definitions now in A.R.S. § 36-2201 or R9-25-101, repealing two Exhibits, adding four Tables, and repealing one Table. The new rules clarified that an administrative medical director authorizes an EMCT to
perform a medical treatment, procedure, or technique or administer a medication; that documentation of training and of competency must be maintained; and that a health care institution to which an EMCT plans to transport a patient needs to be willing to accept the patient before the patient is transported. Also clarified were the requirements for assessment of an EMCT’s competency by reference to relevant policies and procedures in Article 2; requirements related to administration of an immunizing agent to be consistent with requirements for pharmacist administration of immunizing agents in A.A.C. R4-23-411; requirements for infusion pumps; the agents that are required in the drug box used by EMCTs when providing EMS; and the agents that may be administered or monitored during an interfacility transport, which were moved from Table 1 into Table 5.4. The Department believes that these changes imposed at most a minimal increased cost to EMS providers, ambulance services, EMCTs and provided a significant benefit to EMS providers, ambulance services, EMCTs, patients, and the general public.

In the new rules in Article 5, requirements related to administration of a tuberculin skin test were removed, as were requirements that duplicated requirements in R9-25-502, Table 5.1, Table 5.2, or Table 5.3, such as those related to IV access by an EMT-B; to administration, monitoring, or assistance in self-administration of an agent; to endotracheal intubation by an EMT-B; to an EMT-B carrying and administering aspirin; to use of an esophageal tracheal double lumen device by an EMT-B; and for a supplemental skill training instructor. The requirement to provide a written list of alternate locations for transport was also removed, consistent with statutory changes, as was the requirement for notification of the Department before implementing the rule. The Department believes that these changes provided a significant benefit to EMS providers, ambulance services, and EMCTs, without affecting the health or safety of a patient. As part of the rulemaking, definitions used in the Article, a new Table of EMCT scope of practice, and a new Table for agents in a drug box specific to hazardous material incidents were added, and registered nurse practitioners were added to the list of health care providers to whom an EMCT may transfer care. Table 5.2 contained updated eligibility for authorization related to new EMCT classifications. In R9-25-504, the use of the term “emergency medical patient” was replaced with a description of the type of patient for whom the requirements in the rule are applicable to avoid confusion/conflict with the definition in A.R.S. § 41-1831, which is also used by the regulated community. The Department believes that these changes imposed at most a minimal increased cost to EMS providers, ambulance services, EMCTs and provided a significant benefit to EMS providers, ambulance services, EMCTs, patients, and the general public.

In the 2014 rulemaking for Article 5, Table 5.1, Table 5.2 and R9-25-504 were revised. “Assisting patient with his/her own prescribed medications (hydrocortisone sodium succinate)” was
added to Table 5.1, and several optional agents were added to Table 5.2. The rule in R9-25-504 was changed to allow an EMCT transporting a patient to transfer care of the patient to a designee of specified health care providers, rather than just to the specified health care provider. The Department believes that these changes provided a significant benefit to EMS providers, ambulance services, EMCTs, and the specific health care providers, without affecting the health or safety of a patient. In the 2016 rulemaking, requirement related to the administration of naloxone were added to the rules, to comply with Laws 2015, Ch. 313, § 4. The Department believes that these changes provided a significant benefit to EMS providers, ambulance services, EMCTs, patients who may have experienced an overdose of a narcotic and their families, and the general public. In the 2017 rulemaking, the rules were changed to reduce the number of required atropine syringes from three to one, the number of required adult and pediatric epinephrine auto-injectors from two to one each, and the amount of required glucagon from 2 mg to 1 mg; clarify the meaning of “Nitro” and ASA" in Table 5.1 and the concentrations of epinephrine HCl in Table 5.2; add the option for carrying and administering 2% lidocaine for AEMTs, EMT-I(99)s, and Paramedics; and make thiamine an optional agent. The Department believes that these changes provided a significant benefit to EMS providers, ambulance services, EMCTs, and reduced the regulatory burden on regulated entities.

9. **Summary of business competitiveness analyses of the rules**
The Department did not receive a business competitiveness analysis of the rules in the last five years.

10. **Status of the completion of action indicated in the previous five-year-review report**
In the 2012 Five-Year-Review Report, the Department stated that the Department planned to amend the rules in 9 A.A.C. 25 to comply with statutory changes made in Laws 2012, Ch. 94 and to file a Notice of Exempt Rulemaking by December 31, 2013. The rules in Articles 2 and 5 were revised as part of that rulemaking; therefore, the Department complied with this plan.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to regulated persons by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Except for R9-25-201 and R9-25-202, the Department has determined that the rules in 9 A.A.C. 25, Articles 2 and 5 impose the least burden and costs to persons regulated by the rules, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective, despite some minor punctuation errors.

12. **Analysis of stringency compared to federal laws**
Federal laws do not apply to the rules in 9 A.A.C. 25, Articles 2 and 5.
13. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**

The rules require the issuance of a specific agency authorization, which is authorized by A.R.S. § 36-2204(5) and (6), so a general permit is not applicable.

14. **Proposed course of action**

The Department does not plan to conduct a rulemaking for Article 5, except for the regular updates to the protocols. Unless a substantive issue arises other than those described in this report, the Department plans to revise the rules in Article 2 to address the concerns raised in the written criticisms, as stated in the report, and others that may be raised during the rulemaking and to submit a Notice of Final Rulemaking to the Council by July 1, 2019.
ARTICLE 2. MEDICAL DIRECTION; ALS BASE HOSPITAL CERTIFICATION

R9-25-201. Administrative Medical Direction (Authorized by A.R.S. §§ 36-2201, 36-2202(A)(3) and (A)(4), 36-2204(5), (6), and (7), 36-2204.01, and 36-2205(A) and (D))

1. Authorization of the rule by existing statute
The rule has A.R.S. §§ 36-2201.01 and 36-2205 as additional specific authority.

2. Objective
The objectives of the rule are to establish:
   a. Requirements for EMS providers and ambulance services related to administrative medical direction;
   b. General requirements for administrative medical directors;
   c. Requirements for protocols, policies and procedures, recordkeeping, and reporting related an EMCT’s scope of practice; and
   d. To whom an administrative medical director may delegate responsibilities.

3. Analysis of effectiveness in achieving the objective
The rule is effective in achieving its objectives but could be improved by addressing the issues raised in the written criticisms as described in paragraph 7. The effectiveness of the rule could also be improved if subsection (E)(2)(d) were more specific about the time-frame for sharing information with an emergency receiving facility.

7. Summary of the written criticisms of the rule received within the last five years
The Department has received four written criticisms/comments of the rule in the past five years.

Comment: Two comments were received expressing concern that some physicians licensed under A.R.S. Title 32, Chapter 17 do not meet the requirements in subsection (A)(1)(a), (b), or (c), being certified by a different Board than those listed and have to qualify to be an administrative medical director by taking the three courses listed in subsection (A)(1)(d). One commenter thought that these physicians should be grandfathered in as qualified without taking the courses.

Comment: As part of a comment about on-line medical direction described under R9-25-202, a comment was received describing the two pathways by which a physician could become certified in pediatric emergency medicine and expressing the belief that both should satisfy the certification requirements in subsections (A)(1)(a) through (c).

Response: The Department agrees that a physician, Board-certified in emergency medicine by a different Board than one listed or trained through a different pathway, may be qualified to be an
administrative medical director without having to take the three courses listed in subsection (A)(1)(d). The Department plans to address these concerns during the next rulemaking.

Comment: A comment was received stating that subsection (A)(1)(d) requires “current certification” in the courses listed as subsections (A)(1)(d)(i) through (iii), and asking how the Department interprets “when a card is expired for ACLS/CPR” when the card states “recommended renewal date.”

Response: The Department interprets the “recommended renewal date” to be the expiration date for the card, but plans to clarify the Department’s expectations during the next rulemaking.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to regulated persons by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

The Department has determined that the rule does not impose the least burden and costs to persons regulated by the rule, because of the items identified in paragraphs 3 and 7.

R9-25-202. **On-line Medical Direction (Authorized by A.R.S. §§ 36-2201, 36-2202(A)(3) and (A)(4), 36-2204(5), (6), and (7), 36-2204.01, and 36-2205(A) and (D))**

1. **Authorization of the rule by existing statute**

The rule has A.R.S. §§ 36-2201.01 and 36-2205 as additional specific authority.

2. **Objective**

   a. Who may provide on-line medical direction to an EMCT, and
   b. Requirements for providing on-line medical direction, recordkeeping, and equipment and staffing related to the provision of on-line medical direction.

3. **Analysis of effectiveness in achieving the objective**

   The rule is effective in achieving its objectives but could be improved by addressing the issues raised in the written criticisms as described in paragraph 7.

7. **Summary of the written criticisms of the rule received within the last five years**

   The Department has received four written criticisms of the rule in the past five years.

   Comment: Two comments were received expressing concern that some physicians licensed under A.R.S. Title 32, Chapter 17 do not meet the requirements in subsection (A)(1)(a), (b), or (c), being certified by a different Board than those listed and have to qualify to provide on-line medical direction by taking the three courses listed in R9-25-201(A)(1)(d). The commenter thought that the physicians should be grandfathered in as qualified without taking the courses.
Comment: A comment was received expressing concern about two issues. The first issue related to the two pathways by which a physician could become certified in pediatric emergency medicine and expressed the belief that both should satisfy the certification requirements in subsections (A)(1)(a) through (c). The second concern expressed was that physicians providing on-line medical direction only for patients who are children should only be required to take pediatric advanced life support (PALS), not both PALS and advanced cardiac life support “because they will not be providing medical command for adults.”

Response: The Department agrees that a physician, Board-certified in emergency medicine by a different Board than one listed or trained through a different pathway, may be qualified to provide on-line medical direction without having to take the three courses listed in R9-25-201(A)(1)(d). The Department plans to address these concerns during the next rulemaking.

Response: The Department understands that PALS training is specific to children eight years of age and under. Since a child receiving emergency medical services may be older than eight, the Department believes that both PALS and advanced cardiac life support should be required of a physician who does not meet the criteria in subsection (A)(1)(a), (b) or (c) and provides on-line medical direction for children.

Comment: A comment was received stating that subsection (A)(1)(d) requires “current certification” in the courses listed as R9-25-201(A)(1)(d)(i) through (iii), and asking how the Department interprets “when a card is expired for ACLS/CPR” when the card states “recommended renewal date.”

Response: The Department interprets the “recommended renewal date” to be the expiration date for the card, but plans to clarify the Department’s expectations during the next rulemaking.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to regulated persons by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

The Department has determined that the rule does not impose the least burden and costs to persons regulated by the rule, because of the items identified in paragraphs 3 and 7.

R9-25-203. **ALS Base Hospital General Requirements (Authorized by A.R.S. §§ 36-2201, 36-2202(A)(3) and (A)(4), and 36-2204(5), (6), and (7))**

2. **Objective**

The objective of the rule is to establish general requirements for an ALS base hospital.
R9-25-204. Application Requirements for ALS Base Hospital Certification (Authorized by A.R.S. §§ 36-2201, 36-2202(A)(3) and (A)(4), and 36-2204(5))

2. **Objective**
   The objective of the rule is to establish application requirements for ALS base hospital certification.

R9-25-205. Changes Affecting an ALS Base Hospital Certificate (Authorized by A.R.S. §§ 36-2201, 36-2202(A)(3) and (A)(4), and 36-2204(5) and (6))

2. **Objective**
   The objective of the rule is to establish requirements related to a change in the name, address, or ownership of an ALS base hospital.

R9-25-206. ALS Base Hospital Authority and Responsibilities (Authorized by A.R.S. §§ 36-2201, 36-2202(A)(3) and (A)(4), 36-2204(5) and (6), 36-2208(A), and 36-2209(A)(2))

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. §§ 36-2208(A) and 36-2209(A)(2) as additional specific authority.

2. **Objective**
   The objectives of the rule are to establish requirements for an ALS base hospital:
   a. To provide administrative medical direction and on-line medical direction,
   b. To notify the Department of a change in the administrative medical director or the ALS base hospitals qualifications for certification,
   c. When acting as a training program, and
   d. When providing agents to an EMS provider or ambulance service.

R9-25-207. ALS Base Hospital Enforcement Actions (Authorized by A.R.S. §§ 36-2201, 36-2202(A)(3) and (A)(4), and 36-2204(7))

2. **Objective**
   The objectives of the rule are to establish:
   a. The circumstances under which the Department may take action against an ALS base hospital certificate holder, and
   b. The actions the Department may take against an ALS base hospital certificate holder.
ARTICLE 5. MEDICAL DIRECTION PROTOCOLS FOR EMERGENCY MEDICAL CARE TECHNICIANS

R9-25-501. Definitions
2. Objective
The objective of the rule is to provide definitions of terms used in the Article.

R9-25-502. Scope of Practice for EMCTs
2. Objective
The objective of the rule is to establish the scope of practice for EMCTs, including:
   a. What actions an EMCT is allowed to perform, and
   b. The responsibilities of an administrative medical director when authorizing an EMCT to perform an action and for monitoring competency.

Table 5.1. Arizona Scope of Practice Skills
2. Objective
The objective of the rule is to establish the skills that may be performed by each classification of EMCT.

Table 5.2. Eligibility for Authorization to Administer, Monitor, and Assist in Patient Self-administration of Agents by EMCT Classification; Administration Requirements; and Minimum Supply Requirements for Agents
2. Objective
The objectives of the rule are to establish, for each classification of EMCT:
   a. The agents that an EMCT is eligible to administer, monitor, or assist in patient self-administration;
   b. The minimum amounts of agents that an EMCT is required to have available for administration;
   c. If applicable, the route of administration of an agent or other administration requirement; and
   d. The agents that are optional and, if accessible to an EMCT, the minimum amounts of the agents.
Table 5.3. Agents Eligible for Authorization for Administration During a Hazardous Material Incident

2. **Objective**
   The objective of the rule is to establish the agents that a Paramedic may administer during a hazardous material incident.

Table 5.4. Eligibility for Authorization to Administer and Monitor Transport Agents During Interfacility Transports, by EMCT Classification; Administration Requirements

2. **Objective**
   The objective of the rule is to establish, for each classification of EMCT:
   a. The agents that an EMCT is eligible to administer or monitor during an interfacility transport, and
   b. If applicable, the route of administration of the agent or other administration requirement.

R9-25-503. Testing of Medical Treatments, Procedures, Medications, and Techniques that May Be Administered or Performed by an EMCT

2. **Objective**
   The objective of the rule is to establish requirements related to the Department’s authorizing, as allowed by A.R.S. § 36-2205, the testing and evaluation of a medical treatment, procedure, technique, practice, medication, or piece of equipment for possible use by an EMCT or an EMS provider.

R9-25-504. Protocol for Selection of a Health Care Institution for Transport

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. § 36-2232(F) as additional specific authority.

2. **Objective**
   The objectives of the rule are to establish:
   a. Requirements for transport of a patient accessing emergency medical services through a call to 9-1-1 or a similar public emergency dispatch number; and
   b. If the patient is not being transported to an emergency receiving facility, requirements for ensuring the willingness of the health care institution to accept the patient, transferring care of the patient, and recordkeeping.
R9-25-505. Protocol for an EMT-I(99) or a Paramedic to Become Eligible to Administer an Immunizing Agent

2. Objective

The objectives of the rule are to establish:

a. The process by which an EMT-I(99) or Paramedic may be authorized to administer an immunizing agent, and

b. The requirements for an EMT-I(99) or Paramedic administering an immunizing agent.
ARIZONA DEPARTMENT OF HEALTH SERVICES

FIVE-YEAR-REVIEW REPORT

TITLE 9. HEALTH SERVICES
CHAPTER 25. DEPARTMENT OF HEALTH SERVICES
EMERGENCY MEDICAL SERVICES

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RATES AND CHARGES; CONTRACTS

May 2017
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FIVE-YEAR-REVIEW REPORT
TITLE 9. HEALTH SERVICES
CHAPTER 25. DEPARTMENT OF HEALTH SERVICES
EMERGENCY MEDICAL SERVICES

ARTICLE 9. GROUND AMBULANCE CERTIFICATE OF NECESSITY
ARTICLE 10. GROUND AMBULANCE VEHICLE REGISTRATION
ARTICLE 11. GROUND AMBULANCE SERVICE GENERAL PUBLIC RATES AND CHARGES; CONTRACTS

FIVE-YEAR-REVIEW SUMMARY

Arizona Revised Statutes (A.R.S.) §§ 36-2202(A)(3) and (4) and 36-2209(A)(2) require the Arizona Department of Health Services (Department) to adopt standards and criteria pertaining to the quality of emergency care, rules necessary for the operation of emergency medical services, and rules for carrying out the purposes of A.R.S. Title 36, Chapter 21.1. A.R.S. § 36-2202(A)(5) requires the Department to adopt “reasonable medical equipment, supply, staffing and safety standards, criteria and procedures for issuance of a certificate of registration to operate an ambulance,” including ground ambulances. A.R.S. § 36-2212 prohibits a person from operating an ambulance in Arizona unless the ambulance has a certificate of registration and complies with A.R.S. Title 36, Chapter 21.1, Article 1 and the rules, standards, and criteria adopted pursuant to the Article. A.R.S. Title 36, Chapter 21.1, Article 2 provides specific authority for the regulation of ambulances and ambulance services. The Department has implemented these statutes in Arizona Administrative Code (A.A.C.) Title 9, Chapter 25, Articles 9, 10, and 11. Except for the Exhibits in Article 9, the rules in these Articles were adopted in February 2001. In an exempt rulemaking in 2013, the rules in R9-25-901, R9-25-902, R9-25-1002, R9-25-1003, and R9-25-1004 were revised to comply with Laws 2012, Ch. 94. Exhibits 9A and 9B were originally renumbered into Article 9 in June 2006 and renumbered as Exhibits 9A and 9B as part of the 2013 rulemaking.

The rules in 9 A.A.C. 25, Article 9 establish the standards and processes for certificates of necessity, including initial and renewal applications, terms and transferability of a certificate of necessity, determining public necessity, amending a certificate of necessity, insurance requirements, record and reporting requirements, and disciplinary actions. The rules also include considerations for determining response times, response codes, and response-time tolerances for all or part of a service area; financial information required to be reported; and requirements associated with transport and service areas. The rules in 9 A.A.C. 25, Article 10 establish the standards and processes for ground ambulance registration,
including initial and renewal applications; minimum standards for ground ambulance vehicles, equipment
and supplies, and staffing; and inspections. The rules in 9 A.A.C. 25, Article 11 specify the requirements
for establishing or adjusting general public rates; applying for approval of ground ambulance service
contracts, subscription service contracts, and contract rates for interfacility transports or convalescent
transports; considering rate of return on gross revenue and proposed mileage rates; and implementation of
rates and charges.

After an analysis of the rules in 9 A.A.C. 25, Articles 9, 10, and 11, the Department has
determined that all but three of the rules are effective or mostly effective; all but four of the rules are
consistent with statutes and rules; all but one of the rules are enforced as written; and all but three of the
rules are clear, concise, and understandable or mostly clear, concise, and understandable. One written
criticism of the rules has been received by the Department. Because of the level of stakeholder
engagement anticipated during a rulemaking for these rules, the Department believes that the rulemaking
could take over three years to complete. Since the same stakeholders may be participating in another
rulemaking to be begun before this rulemaking, the Department plans to submit a Notice of Final
Rulemaking to the Governor’s Regulatory Review Council (Council) by December 31, 2022.
INFORMATION THAT IS IDENTICAL FOR ALL OF THE RULES

1. **Authorization of the rule by existing statute**
   The general statutory authority for the rules in 9 A.A.C. 25, Articles 9, 10, and 11 are A.R.S. §§ 36-136(A)(7), 36-136(F), and 36-2202(A)(4).
   A specific statutory authority for the rules in 9 A.A.C. 25, Article 9 and Article 11 is A.R.S. § 36-2232.
   A specific statutory authority for the rules in 9 A.A.C. 25, Article 10 is A.R.S. § 36-2202(A)(5).

2. **The purpose of the rule**
   The purpose of the rules in 9 A.A.C. 25, Article 9 is to specify standards and processes for certificates of necessity for ground ambulance services.
   The purpose of the rules in 9 A.A.C. 25, Article 10 is to establish standards and processes for ground ambulance registration.
   The purpose of the rules in 9 A.A.C. 25, Article 11 is to specify requirements related to ground ambulance service rates and charges and for related contracts.

4. **Analysis of consistency with state and federal statutes and rules**
   Federal statutes and rules do not apply to the rules in 9 A.A.C. 25, Articles 9, 10, and 11.
   Except as described in R9-25-902, R9-25-906, R9-25-908, and R9-25-912 in Article 9 and R9-25-1005 in Article 10, the rules are consistent with state statutes and rules.

5. **Status of enforcement of the rule**
   Except as described R9-25-902, the rules in 9 A.A.C. 25, Articles 9, 10, and 11 are enforced as written without difficulty by the Department.

7. **Summary of the written criticisms of the rule received within the last five years**
   Except for one comment about R9-25-1107 and R9-25-1108, the Department has not received any written criticisms of the rules in the past five years.

8. **Economic, small business, and consumer impact comparison**
   The rules in Articles 9, 10, and 11 were adopted by final rulemaking, effective February 13, 2001, to establish rules related to initial and renewal certificates of necessity, ground ambulance registration, and ground ambulance service rates, contracts, subscription service, other charges, and invoicing. At the time of the rulemaking, there were 83 ground ambulance services operating in Arizona. Of these, 20 were private, for-profit businesses, 11 were private, non-profit businesses, and 52 were owned or operated by political subdivisions. As of April 15, 2017, there were 101 ground ambulance services operating in Arizona. Of these, 25 are private, for-profit businesses; five are private, non-profit businesses; 21 are municipal ground ambulance services;
48 are fire districts established under A.R.S. Title 48, Chapter 5; one is operated by a hospital; and one is operated by a county.

An economic, small business, and consumer impact statement (EIS) was submitted to the Governor’s Regulatory Review Council (Council) as part of the Notice of Final Rulemaking package for the 2001 rulemaking. Although not stated in the EIS, the Department assumes that annual cost/revenues were designated as “minimal” when less than $1,000.00; “moderate” when between $1,000.00 and $10,000.00; “substantial” when $10,000.00 or more; and “significant” when meaningful or important, but not readily subject to quantification.

The EIS for the rulemaking stated that the Department would incur minimal costs for the additional time to evaluate an application for a certificate of necessity, provision of ALS services, or transfer of a certificate of necessity; to determine public necessity; and to provide guidelines for determining response times, response codes, response time tolerances, and rate of return on gross revenue. The EIS also stated that the Department would incur minimal-to-moderate costs to take disciplinary action against a certificate holder. The Department was believed to receive a minimal benefit from the new application rules and from providing guidelines for determining response times, response codes, response time tolerances, and rate of return on gross revenue; minimal-to-moderate benefit from taking disciplinary action against a certificate holder; and moderate benefit from a reduction in staff time for receiving, filing, and storing provider records.

The Department anticipated that political subdivisions and private businesses would incur minimal costs for the additional time to submit an application for an initial, renewal, or amended certificate of necessity or for provision of ALS services; minimal-to-moderate costs related to insurance coverage; moderate costs to comply with minimal standards for ground ambulance vehicles; and moderate-to-substantial costs related to minimal standards for medical equipment on ground ambulance vehicles. The EIS also stated that the Department believed that political subdivisions and private businesses would receive a minimal benefit from having consolidated application rules; minimal-to-moderate benefit from eliminating a requirement to submit monthly dispatch logs and other records to the Department; moderate benefit from having disciplinary action guidelines and exceptions to transport requirements; and moderate-to-substantial benefit from eliminating requirements to carry some medical supplies and from allowing the assessment of rates for multiple-patient transport and standby waiting times. Private businesses were also expected to receive a moderate-to-substantial benefit from receiving a minimum 7% rate of return from general public rates.

The Department believes the costs and benefits identified in this EIS are generally consistent with the actual costs and benefits of the rules, but do not include estimates for the costs
incurred by stakeholders to participate in the rulemaking process. At the time of the rulemaking, these costs may have been moderate.

As part of the 2013 exempt rulemaking, the rules in R9-25-901, R9-25-902, Exhibits 9A and 9B, R9-25-1002, R9-25-1003, and R9-25-1004 were revised to comply with Laws 2012, Ch. 94. Although this rulemaking resulted in modest changes to Articles 9 and 10, and none to Article 11, a large group of stakeholders participated in the 2013 rulemaking, lengthening the process and incurring costs for both the Department and the stakeholders. In Article 9, the Department removed unnecessary definitions from R9-25-901; clarified that the application in R9-25-902 was to be submitted in a Department-provided format, added requirements for an e-mail address and for the signature to be dated, and corrected a cross-reference; and in the Exhibits, renamed the Exhibits to include the Article number, corrected the Department’s address, and corrected the terminology for EMCTs. The Department believes the changes in Article 9 caused at most minimal additional costs and provided a significant benefit to all stakeholders. In R9-25-1002, minimum standards for ground ambulance vehicles were updated to require that interior patient compartment wall and floor coverings were in good repair, capable of being disinfected, and maintained in a sanitary manner and that there be at least two means of egress from the patient compartment. In R9-25-1003, minimum standards for equipment and supplies for ground ambulance vehicles were updated to reflect the different scopes of practice of the new EMCT classifications, and a cross-reference was corrected in R9-25-1004. The Department believes that most, if not all, ground ambulance services already complied with the new requirements in R9-25-1002 to protect the health and safety of both the patients served by the ground ambulance service and the EMCTs working for the ground ambulance service. For a ground ambulance service that did not, the Department estimates that the ground ambulance service could have incurred a minimal-to-substantial cost per ground ambulance vehicle to comply with these requirements. The updates of the minimum standards for equipment and supplies for ground ambulance vehicles in R9-25-1003 were caused by the statutory change to EMCT classifications and the resulting changes in scopes of practice. The Department estimates that a ground ambulance service could have incurred a minimal-to-substantial cost per ground ambulance vehicle to comply with these updated equipment requirements. A patient being transported by the ground ambulance service and the patient’s family and health insurance carrier, and the general public may receive a significant benefit from increased patient safety.

9. **Summary of business competitiveness analyses of the rules**

The Department did not receive a business competitiveness analysis of the rules in the last five years.
10. **Status of the completion of action indicated in the previous five-year-review report**

   In the 2012 Five-Year-Review Report, the Department stated that the Department planned to address concerns described in the report and to simplify and streamline the requirements in the rules for ground ambulance services. The Department planned to amend the rules in Articles 9, 10, and 11 and submit a Notice of Final Rulemaking to the Governor’s Regulatory Review Council (Council) by December 31, 2016. In 2013, the Department addressed some of the concerns in a rulemaking amending the rules in 9 A.A.C. 25 to comply with statutory changes made in Laws 2012, Ch. 94, filing a Notice of Exempt Rulemaking by December 31, 2013. The Department has not yet addressed other concerns, as described in this report.

12. **Analysis of stringency compared to federal laws**

   Federal laws do not apply to the regulation of ground ambulance services, which are wholly regulated according to state statutes.

13. **For rules adopted after July 29, 2010 that require the issuance of a regulatory permit, license, or agency authorization, whether the rule complies with section 41-1037**

   The rules require the issuance of a specific agency authorization, which is authorized by A.R.S. § 36-2212 and Title 36, Chapter 21.1, Article 2, so a general permit is not applicable.

14. **Proposed course of action**

   The Department plans to amend the rules in 9 A.A.C. 25, Articles 9, 10, and 11 to address concerns described in this report and make other changes suggested by stakeholders during a rulemaking. Because of the level of stakeholder engagement anticipated during the rulemaking, the Department believes that a rulemaking could take over three years to complete and cannot begin until after the rulemaking for air ambulance services, regulated under 9 A.A.C. 25, Articles 7 and 8, is close to completion since the same staff would be involved in both rulemakings and many of the same stakeholders would participate. Therefore, the Department plans to submit a Notice of Final Rulemaking to the Governor’s Regulatory Review Council (Council) by December 31, 2022.
INFORMATION FOR INDIVIDUAL RULES
ARTICLE 9. GROUND AMBULANCE CERTIFICATE OF NECESSITY

R9-25-901. Definitions (A.R.S. § 36-2202 (A))

1. Authorization of the rule by existing statute
   The rule has A.R.S. § 36-2202(A) as additional specific authority.

2. Objective
   The objective of the rule is to define terms used in Articles 9, 10, and 11 to assist the reader in understanding the requirements of the Articles.

3. Analysis of effectiveness in achieving the objective
   The rule is effective in achieving its objective but could be improved by defining “change in ownership” to account for publicly traded corporations in which the sale or transfer of stock may not influence the controlling persons of the corporation and so the definition is not as subjective as in subsection (9)(c). The definition of “gross revenue” could be amended since it provides an example of how the figure denoted by the term is calculated rather than a definition of what the term means.

6. Analysis of clarity, conciseness, and understandability
   The rule is mostly clear, concise, and understandable but could be improved by clarifying the term “ground ambulance service” because the term is used in the definitions of “ground ambulance service contract,” “indirect costs,” “needs assessment,” and “type of ground ambulance service” and in other rules throughout the Article to mean the actual service provided, which is inconsistent with the definition of “ground ambulance service” in the rule, as meaning a person. In the definition of “level of service,” the term appears to be used both ways. The definition of “minor defect” could be clearer because the condition of being without any problem could be included. In the definition of “suburban area,” the question of whether the population density description is for the “urban area” or the “geographic region” could be clearer. The conciseness of the definition of “substandard performance” could be improved because not meeting the requirements in Article 10 in subsection (46)(c) would be included in noncompliance with 9 A.A.C. 25 in subsection (46)(a). The definitions of “Ambulance Revenue and Cost Report” and “gross revenue” should also be corrected to refer to Exhibits 9A and 9B.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective
Despite the minor changes that could be made, as described in paragraphs 3 and 6, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-25-902. Application for an Initial Certificate of Necessity; Provision of ALS Services; Transfer of a Certificate of Necessity (A.R.S. §§ 36-2204, 36-2232, 36-2233(B), 36-2236(A) and (B), 36-2240)

1. Authorization of the rule by existing statute
The rule has A.R.S. §§ 36-2204, 36-2233, 36-2236, and 36-2240 as additional specific authority.

2. Objective
The objectives of the rule are to establish application requirements and the process for:
   a. Applying for an initial certificate of necessity,
   b. Applying to provide ALS, and
   c. Requesting a transfer of a certificate of necessity.

3. Analysis of effectiveness in achieving the objective
The rule is mostly effective in achieving its objectives but could be improved if the application packet required information about any other name by which the entity “ground ambulance service” was known. The rule could be more effective if the rule required, as part of an application packet for an initial certificate of necessity, the submission of an applicant’s organizational documents, such as articles of incorporation; an application packet for a certificate of registration for each ground ambulance vehicle to be operated by the ground ambulance service under the certificate of necessity; and documentation to comply with A.R.S. § 41-1080. The rule could also be more effective if the rule were amended to include as part of the application packet in subsection (A) the submission of: fees, rather than requiring the fees as a separate submission requirement under subsection (D); the application for establishing initial public rates, specified in R9-25-1101, rather than a “statement of the proposed general public rates”; and the list of items that a certificate holder proposes to charge patients, specified in R9-25-1109, rather than a “statement of the proposed charges.” In addition, the requirement in subsection (A)(4) for the submission of “any other information or documents needed by the Director to clarify incomplete or ambiguous information or documents” could also be replaced with a requirement for stating whether supplementary requests for information can be made by the Department during a substantive review, since these documents are unknown to an applicant at the time of the application and could be requested during the substantive review period specified in Article 12. The rule could also be more effective if subsection (E) included a
reference to R9-25-903, which includes criteria to be used by the Department in deciding whether or not to issue a certificate of necessity.

4. **Analysis of consistency with state and federal statutes and rules**
   The rule is not consistent with A.R.S. § 36-2240(3) because the rule does not require an applicant for an initial certificate of necessity to pay the $200 fee per ambulance required by that statute. Subsection (A)(1)(c) of the rule is inconsistent with R9-25-201 and R9-25-202, which do not require that administrative medical direction and on-line medical direction be provided through affiliation with an ALS base hospital or centralized medical communications center. Otherwise, the rule is consistent with state statutes and rules.

5. **Status of enforcement of the rule**
   The rule is enforced consistent with A.R.S. §§ 36-2240(3) and 41-1080 and R9-25-201 and R9-25-202.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is mostly clear, concise, and understandable but could be improved by clarifying subsection (A)(1)(c) to use the term “ALS base hospital,” which is the term defined in R9-25-101, and subsection (A)(1)(m) to use the term “level of service,” which is the term defined in R9-25-901. The rule could be made clearer by using the term “ground ambulance service” in a manner consistent with the definition in R9-25-901. The clarity of the rule could also be improved if wording similar to that used in R9-25-1101(A)(5) or R9-25-1102(B)(9) replaced the phrase “financial agreement for all capital acquisitions exceeding $5,000” in subsection (A)(3)(c). The rule could also be improved by clarifying that the “person wanting to transfer the certificate of necessity” refers to the current certificate holder and by defining or describing the terms “dispatch center,” “business representative,” and “designated manager.” The rule could also be improved by removing subsection (A)(1)(n)(ii) and correcting several grammatical errors.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Because of the issues described in paragraphs 3, 4, and 6 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-25-903. **Determining Public Necessity (A.R.S. § 36-2233(B)(2))**

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. § 36-2233(B)(2) as additional specific authority.
2. **Objective**
   The objective of the rule is to establish the factors that the Director must consider when determining whether public necessity requires the issuance of an initial or amended certificate of necessity to an applicant.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is mostly clear, concise, and understandable but could be improved by using the term “ground ambulance service” in a manner consistent with the definition in R9-25-901. The rule could also be clearer if the term “population demographics” were defined or described. In addition, the rule could be clearer if subsection (A) referenced A.R.S. § 36-2233 or if standards related to the approval of an initial certificate of necessity were established.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Despite the minor clarifications that could be made, as described in paragraph 6, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.


1. **Authorization of the rule by existing statute**
   The rule has A.R.S. §§ 36-2233, 36-2235, and 36-2240 as additional specific authority.

2. **Objective**
   The objectives of the rule are to establish:
   a. Requirements for applying for renewal of a certificate of necessity, and
   b. Consequences related to failure to file for renewal before the expiration of a certificate of necessity.

3. **Analysis of effectiveness in achieving the objective**
   The rule is mostly effective in achieving its objectives but could be improved by restructuring subsections (B) and (C) to make clear that the Department is not issuing an approval to commence operations but is considering an application for an initial application. The rule could also be more effective if the required insurance coverage included not only the automobile
liability insurance and professional liability insurance required for the ground ambulance service under A.R.S. § 36-2237(A) and R9-25-902(A)(3)(h) but also the professional liability insurance for ALS personnel, for a ground ambulance service providing ALS, as required for an initial application in R9-25-902(B)(2). The rule could also be more effective if the renewal application required the statement specified in R9-25-902(A)(1)(o) and the date of the applicant’s signature. In addition, the rule could be improved by including a standard for approval of a renewal of a certificate of necessity.

6. **Analysis of clarity, conciseness, and understandability**
The rule is mostly clear, concise, and understandable but could be improved by clarifying the meaning of the term “timely” in subsections (B) and (C) and correcting minor grammatical errors.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

Despite the minor changes that could be made, as described in paragraphs 3 and 6, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.


1. **Authorization of the rule by existing statute**
The rule has A.R.S. § 36-2240 as additional specific authority.

2. **Objective**
The objectives of the rule are to establish the requirements and process for applying for an amendment of a certificate of necessity.

3. **Analysis of effectiveness in achieving the objective**
The rule is mostly effective in achieving its objective but could be more effective by amending subsections (A) and (B) to better tailor the documentation submitted by a certificate holder in support of the request to amend a certificate of necessity to the type of change being requested. For example, a change in the legal name of the certificate holder could be supported by documentation of the name change by the Corporation Commission, to distinguish it from a change in ownership, and may require the submission of new documentation of insurance if the required insurance had been issued under the name being changed. Similarly, a change in address may not require a description of the communication equipment being used, the make and year of
each ground ambulance vehicle, or the number of ambulance attendants, currently required as elements of R9-25-902(A)(1). A request to change response times could be supported by not only the proposed response times, response codes, and response-time tolerances currently required, but also by an analysis of actual response times compared with the response times associated with the certificate of necessity. In addition, the rule could be more effective if the requirement in subsection (B)(5) for the submission of “any other information or documents requested by the Director to clarify incomplete or ambiguous information or documents” were replaced with a requirement for stating whether supplementary requests for information can be made by the Department during a substantive review, since these documents are unknown to an applicant at the time of the application and could be requested during the substantive review period specified in Article 12. The rule could also be more effective if subsection (C) included a reference to R9-25-903 and R9-25-906, which includes criteria to be used by the Department in deciding whether or not to amend a certificate of necessity and determine response times, response codes, and response-time tolerances, respectively.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Because some of the issues described in paragraph 3 of the analysis of this rule would decrease the burden while others could increase the burden, the rule does impose the least burden and costs on persons regulated by the rule but could be improved to better achieve the underlying regulatory objective.


1. **Authorization of the rule by existing statute**
   The rule has A.R.S. § 36-2233 as additional specific authority.

2. **Objective**
   The objective of the rule is to establish the factors that the Director may consider in determining response times, response codes, and response-time tolerances.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective but could be improved by referencing or including in the rule the factors listed in A.R.S. § 36-2232(G) to be considered in determining response-time tolerances.

4. **Analysis of consistency with state and federal statutes and rules**
   Although the factors listed in A.R.S. § 36-2232(G) to be considered in determining response-time tolerances are not referenced or included in the rule, the rule is consistent with state statutes and rules.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable but could be improved by clarifying the meaning of the term “medical direction authority” in subsection (4).

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Despite the minor changes that could be made, as described in paragraphs 3 and 6, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

**R9-25-907. Observance of Service Area; Exceptions (A.R.S. § 36-2232)**

2. **Objective**
   The objective of the rule is to establish the general prohibition on a certificate holder’s providing EMS or transport in an area outside of the area covered by the certificate holder’s certificate of necessity, with two listed exceptions.

3. **Analysis of effectiveness in achieving the objective**
   The rule is not effective in achieving its objective because subsection (1) of the rule is confusing and the rule does not capture other conditions where a certificate holder should or may be ethically bound to provide EMS outside the certificate holder’s service area. The Department has issued two substantive policy statements in the past few years to specify the Department’s interpretation of the rule.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is not clear, concise, and understandable because the term “service area’s dispatch” is undefined. Without this term being defined, it is unclear who may authorize EMS or transport in an area other than the service area identified in the certificate holder’s certificate of necessity and may lead to a conflict with the statutory intent in establishing certificates of necessity.
11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

Because of the issues described in paragraphs 3 and 6 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-25-908. Transport Requirements; Exceptions (A.R.S. §§ 36-2224, 36-2232)

1. Authorization of the rule by existing statute

   The rule has A.R.S. § 36-2224 as additional specific authority.

2. Objective

   The objective of the rule is to require a certificate holder to transport a patient unless at least one of the specified circumstances exists.

3. Analysis of effectiveness in achieving the objective

   The rule is not effective in achieving its objective because the rule combines conditions under which a certificate holder shall not transport a patient with conditions under which a certificate holder may, but is not required to, transport a patient. For example, the rule appears to prevent a certificate holder from contracting to provide an interfacility transport of a patient from a hospital in Phoenix to another hospital in Tucson, which may provide the same level of care but is closer to the patient’s family, or to transport a patient who does not qualify for Medicare Part B reimbursement but who can otherwise pay for the transport.

4. Analysis of consistency with state and federal statutes and rules

   The rule is not consistent with A.R.S. § 36-2205(E) and R9-25-504(B), which provide for patient choice. Otherwise, the rule is consistent with state statutes and rules.

6. Analysis of clarity, conciseness, and understandability

   The rule is not clear as to whether the rule refers only to transport related to EMS or to any type of transport. The rule also uses the undefined term “medical direction authority” in subsection (3).

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

   Because of the issues described in paragraphs 3, 4, and 6 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. §§ 36-2233 and 36-2237 as additional specific authority.

2. **Objective**
   The objective of the rule is to establish the minimum standards for the insurance coverage or evidence of financial responsibility required under A.R.S. § 36-2237(A).

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective but could be improved by removing or amending subsection (B), which duplicates requirements in R9-25-902(A)(3)(h) and R9-25-904(A)(2). In addition, the Department could consider whether the minimum insurance coverage levels should be increased. The rule also does not make a distinction between professional liability insurance for the ground ambulance service and the professional liability insurance for ALS personnel that is required of ground ambulance services providing ALS but that is not required for personnel of a ground ambulance service only providing BLS.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Despite the minor changes that could be made, as described in paragraph 3, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-25-910. Record and Reporting Requirements (A.R.S. §§ 36-2232, 36-2241, 36-2246)

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. §§ 36-2241 and 36-2246 as additional specific authority.

2. **Objective**
   The objectives of the rule are to require a certificate holder to:
   a. Submit financial data annually, and
   b. Maintain and give the Department access to specified records.

3. **Analysis of effectiveness in achieving the objective**
The rule is mostly effective in achieving its objectives but could be improved by specifying the length of time, consistent with A.R.S. § 36-2241, a certificate holder is required to maintain records. The rule could also be improved if the rule specified under what circumstances Exhibit 9A or Exhibit 9B is the “appropriate” Ambulance Revenue and Cost Report to be used.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable but could be improved if subsection (B)(6) were amended to specify the maintenance of prehospital incident history reports, required under Article 2, since the documents specified and Sections cited in subsection (B)(6) no longer exist.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Despite the minor changes that could be made, as described in paragraphs 3 and 6, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.


2. **Objective**
The objectives of the rule are to prevent a certificate holder from:
- Providing false or misleading advertising, or
- Circumventing the use by patients of the 9-1-1 or similarly designated emergency telephone number.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable but could be improved by using the defined terms “type of ground ambulance service” and “level of service” rather than “type or level of ground ambulance service.”

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.
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1. **Authorization of the rule by existing statute**
   The rule has A.R.S. §§ 36-2244 and 36-2245 as additional specific authority.

2. **Objective**
   The objectives of the rule are to establish the:
   a. Disciplinary actions that may be taken against the holder of a certificate of necessity,
   b. Circumstances under which disciplinary actions may be taken, and
   c. Criteria that the Department must consider when determining what action to take under A.R.S. § 36-2245.

3. **Analysis of effectiveness in achieving the objective**
   The rule is mostly effective in achieving its objectives but does not provide a regulated person with notice of the immediate suspension allowed under A.R.S. §§ 36-2234(L) and 41-1092.11(B). Nor does the rule address the “other disciplinary action” that may be taken.

4. **Analysis of consistency with state and federal statutes and rules**
   The rule is not consistent with A.R.S. §§ 36-2234(L) and 41-1092.11(B), which allow for the immediate suspension of a certificate of necessity, without notice and a hearing, in case of emergency when there is a potential threat to the public health and safety. Otherwise, the rule is consistent with state statutes and rules.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is mostly clear, concise, and understandable but could be improved by removing passive language and correcting the grammar in subsection (A). The rule could also be clearer if the term “disciplinary action” were replaced with the term “enforcement action,” which is used in R9-25-211, R9-25-317, R9-25-411, R9-25-709, and R9-25-806 in the same context.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Despite the minor changes that could be made, as described in paragraphs 3 and 6, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

Exhibit 9A. Ambulance Revenue and Cost Report, General Information and Certification

2. **Objective**
The objective of the rule is to establish the financial data that must be filed with the Department as part of every application for an initial certificate of necessity and on an annual basis by a certificate holder that is not a fire district or small rural company.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable but could be improved if terms, such as “LIFO,” “FIFO,” “loaded billable miles,” “subsidized patients,” “non-subsidized patients,” “subscription service direct selling,” and “allocation percentage,” were defined. However, since these terms have been used and understood by the regulated community for over 10 years, their meaning is well-understood, and their use without definition is not problematic.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

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**Exhibit 9B. Ambulance Revenue and Cost Report, Fire District and Small Rural Company**

1. **Authorization of the rule by existing statute**
The rule has A.R.S. § 36-2246 as additional specific authority.

2. **Objective**
The objective of the rule is to establish the financial data that must be filed with the Department as part of every application for an initial certificate of necessity and on an annual basis by a certificate holder that is a fire district or small rural company.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable but could be improved if terms, such as “small rural company,” “loaded billable miles,” and “IEMT,” were defined. However, since these terms have been used and understood by the regulated community for over 10 years, their meaning is well-understood, and their use without definition is not problematic.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons**
regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.
ARTICLE 10. GROUND AMBULANCE VEHICLE REGISTRATION

R9-25-1001. Initial and Renewal Application for a Certificate of Registration (A.R.S. §§ 36-2212, 36-2232, 36-2240)

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. §§ 36-2212, 36-2232, and 36-2240 as additional specific authority.

2. **Objective**
   The objectives of the rule are to establish the:
   a. Requirements for applying for an initial or renewal certificate of registration for a ground ambulance vehicle,
   b. Inspection requirements related to obtaining an initial or renewal certificate of registration, and
   c. Process for obtaining a certificate of registration for a ground ambulance vehicle.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objectives but could be improved by requiring other names by which the applicant does business, the title of the individual signing the application, and the date the application was signed. In addition, the rule could be more effective if subsection (E) included either criteria for approving an application or a reference to the criteria to be used by the Department in deciding whether or not to issue a certificate of registration, thus providing notice to a regulated person.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable but could be improved if grammatical errors were corrected and subsection (A)(4) specified that, for a renewal, the identification number of the certificate of necessity is required.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Despite the minor changes that could be made, as described in paragraphs 3 and 6, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.


2. **Objective**
The objective of the rule is to establish minimum physical, mechanical, and equipment standards for a ground ambulance vehicle.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective but could be more effective if subsection (8) included requirements in A.R.S. § 28-955 and subsection (22) clarified who may supply an inspection tag or allowed for a disposable fire extinguisher.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable but could be improved if the word “system” were added to the phrase “power-steering that is” in subsection (14)(b) and if subsection (36) were removed as duplicating the requirement in R9-25-1003(A)(31)(f).

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Despite the minor changes that could be made, as described in paragraphs 3 and 6, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-25-1003. **Minimum Equipment and Supplies for Ground Ambulance Vehicles (A.R.S. § 36-2202(A)(5))**

2. **Objective**
   The objective of the rule is to establish minimum requirements for medical equipment, medical supplies, and communications equipment for a ground ambulance vehicle.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is mostly clear, concise, and understandable but could be improved if the duplication of the requirements in subsection (A)(37)(f) and R9-25-1002(36) were addressed. The terms “crew” in subsection (C) and “medical direction authority” in subsections (D)(2) and (D)(3) could also be clarified. Unless the phrase “in the driver’s compartment” were added in subsection (D)(2), it is unclear how subsections (D)(2) and (D)(3) differ. The rule could also be more understandable if subsection (A)(37)(c) were amended to more clearly specify the weight-carrying capacity of a stretcher.
11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

Despite the minor changes that could be made, as described in paragraph 6, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.


1. **Authorization of the rule by existing statute**
   The rule has A.R.S. § 36-2201 as additional specific authority.

2. **Objective**
   The objective of the rule is to establish minimum staffing requirements for a ground ambulance vehicle.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

The rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.


1. **Authorization of the rule by existing statute**
   The rule has A.R.S. §§ 36-2212, 36-2232, and 36-2234 as additional specific authority.

2. **Objective**
   The objectives of the rule are to:
   a. Establish requirements related to the inspection of ground ambulance vehicles,
   b. Classify defects as major or minor, and
c. Specify what a certificate holder is required to do when an inspection reveals a major defect or minor defect on a ground ambulance vehicle.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objectives but could be improved if subsection (H) also required documentation of the repair being completed.

4. **Analysis of consistency with state and federal statutes and rules**
   Because of changes made to R9-25-1002 in the 2013 rulemaking, some cross-references to that rule are incorrect. For example, the cross-reference to R9-25-1002(6) should be to subsection (7), the cross-reference to R9-25-1002(36) should be to subsection (38), and the cross-reference to R9-25-1002(39) should be to subsection (41). Otherwise, the rule is consistent with state statutes and rules.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable but could be improved if subsection (G) were amended to remove passive language.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Despite the minor changes that could be made, as described in paragraphs 3 and 6, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.


1. **Authorization of the rule by existing statute**
   The rule has A.R.S. §§ 36-2212 and 36-2232 as additional specific authority.

2. **Objective**
   The objective of the rule is to establish requirements related to identification marks on the exterior of ground ambulance vehicles and corresponding staffing.

3. **Analysis of effectiveness in achieving the objective**
   The rule is effective in achieving its objective but the components of the rule could be more effective if the requirement in subsection (A) were included in R9-25-1002, and the requirements in subsection (B) were included in R9-25-1003 and R9-25-1004.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable but could be improved by using the defined term “level of service” rather than “level of ground ambulance service,” replacing the numeral “6” with the word “six,” and removing passive language.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

Despite the minor changes that could be made, as described in paragraphs 3 and 6, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.
ARTICLE 11. GROUND AMBULANCE SERVICE GENERAL PUBLIC RATES AND CHARGES; CONTRACTS

R9-25-1101. Application for Establishment of Initial General Public Rates (A.R.S. §§ 36-2232, 36-2239)

1. Authorization of the rule by existing statute
   The rule has A.R.S. § 36-2239 as additional specific authority.

2. Objective
   The objective of the rule is to establish the requirements for applying for initial general public rates.

3. Analysis of effectiveness in achieving the objective
   The rule is mostly effective in achieving its objective but could be improved by specifying in subsection (A)(3) what period of time an Ambulance Revenue and Cost Report needed to cover, requiring in subsection (A)(4) a projected Ambulance Revenue and Cost Report, and requiring in subsection (A)(9) the date the attestation was signed. The rule could also be more effective if subsection (A)(3) specified under what circumstances financial statements should be submitted and under what circumstances an Ambulance Revenue and Cost Report should be submitted, rather than giving an applicant a choice of submitting either. In addition, the rule could be more effective if the requirement in subsection (A)(10) for the submission of “any other information or documents requested by the Director to clarify or complete the application” were replaced with a requirement for stating whether supplementary requests for information can be made by the Department during a substantive review, since these documents are unknown to an applicant at the time of the application and could be requested during the substantive review period specified in Article 12. The rule could also be more effective if subsection (B) included a reference to R9-25-1106 and R9-25-1107, which include criteria to be used by the Department in deciding whether or not to approve an initial general public rate.

6. Analysis of clarity, conciseness, and understandability
   The rule is mostly clear, concise, and understandable, but could be improved by specifying which Ambulance Revenue and Cost Report must be submitted, clarifying whether the list specified in subsection (A)(5) is the same list as required in R9-25-902(A)(3)(c), and correcting several minor grammatical errors.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons
regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

Despite the minor changes that could be made, as described in paragraphs 3 and 6, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-25-1102. Application for Adjustment of General Public Rates (A.R.S. §§ 36-2234, 36-2239)

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. §§ 36-2234 and 36-2239 as additional specific authority.

2. **Objective**
   The objective of the rule is to establish the requirements for applying for an adjustment of a general public rate.

3. **Analysis of effectiveness in achieving the objective**
   The rule is not effective in achieving its objective. The rule could be more effective if a certificate holder were required to include in the application the certificate of necessity number assigned by the Department to the certificate holder’s certificate of necessity and the date the attestation was signed. The rule could also be more effective if subsection (B)(7) specified what period of time an Ambulance Revenue and Cost Report needed to cover, and subsection (B)(8) required a projected Ambulance Revenue and Cost Report rather than projected income statement and cash-flow statement. In addition, the rule could be more effective if the requirement in subsection (B)(14) for the submission of “any other information or documents requested by the Director to clarify or complete the application” were replaced with a requirement for stating whether supplementary requests for information can be made by the Department during a substantive review, since these documents are unknown to an applicant at the time of the application and could be requested during the substantive review period specified in Article 12. The rule could also be more effective if subsection (C) included a reference to R9-25-1106 and R9-25-1107, which include criteria to be used by the Department in deciding whether or not to approve an adjustment of a general public rate.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is mostly clear, concise, and understandable, but could be improved by correcting several minor grammatical errors and removing subsection (B)(6) from the rule since the elements of a financial statement are included in the Ambulance Revenue and Cost Report, required in subsection (B)(7). Subsection (B)(7) could be clearer if it specified that the
Ambulance Revenue and Cost Report should cover a 24-month period, in compliance with A.R.S. § 36-2234(F).

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

Because of the issues described in paragraphs 3 and 6 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-25-1103. **Application for a Contract Rate or Range of Rates Less than General Public Rates** (A.R.S. §§ 36-2234(G) and (I), 36-2239)

1. **Authorization of the rule by existing statute**

The rule has A.R.S. §§ 36-2234 and 36-2239 as additional specific authority.

2. **Objective**

The objective of the rule is to establish the requirements for applying for a contract rate or range of rates less than the general public rate.

3. **Analysis of effectiveness in achieving the objective**

The rule is mostly effective in achieving its objective but could be more effective if a certificate holder were required to include in the application the certificate of necessity number assigned by the Department to the certificate holder’s certificate of necessity. In addition, the rule could be more effective if subsection (B) included a reference to R9-25-1106 and R9-25-1107, which include criteria to be used by the Department in deciding whether or not to approve an application for a contract rate or range of rates less than the general public rate.

6. **Analysis of clarity, conciseness, and understandability**

The rule is not clear, concise, and understandable since the rule does not specify how “providing interfacility transports or convalescent transports” relates to applying for approval of a contract rate or range of rates. A certificate holder could charge the general public rate for these transports without receiving approval from the Department for a contract rate. The rule could also make clearer that submitting an application does not guarantee that an applicant will obtain the requested contract rate or range of rates. The rule is also not clear as to how the information required in subsection (A)(1)(d) differs from the documents required in R9-25-1102(B)(6) through (B)(9), included in subsection (A)(2).

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons**
regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

Because of the issues described in paragraphs 3 and 6 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-25-1104. Ground Ambulance Service Contracts (A.R.S. §§ 36-2232, 36-2234(K))

1. Authorization of the rule by existing statute
   The rule has A.R.S. § 36-2234 as additional specific authority.

2. Objective
   The objective of the rule is to establish the requirements for applying for approval of a ground ambulance service contract.

3. Analysis of effectiveness in achieving the objective
   The rule is mostly effective in achieving its objective but could be more effective if a certificate holder were required to include in the cover letter the certificate of necessity number assigned by the Department to the certificate holder’s certificate of necessity and the name of the other party to the contract. The rule could also be more effective if subsection (B) included a reference to R9-25-1106, R9-25-1107, and, if applicable, A.R.S. § 36-2234(K), which include criteria to be used by the Department in deciding whether or not to approve a ground ambulance service contract and review requirements. The rule could also be more effective if the rule specified that a contract may not be implemented until approved by the Department.

6. Analysis of clarity, conciseness, and understandability
   The rule is mostly clear, concise, and understandable but could be clearer if the rule specified whether a ground ambulance service contract may only be used for interfacility transports or convalescent transports, as implied by R9-25-1103, or whether EMS may also be provided under a service contract, and, if so, requirements for service contracts with health care institutions or other companies for interfacility transports or convalescent transports were separated from requirements for service contracts with political subdivisions for the provision of EMS services. The rule could also be clearer as to whether a proposed contract or a signed and executed contract must be submitted for approval. This lack of clarity resulted in the Department’s issuance of a guidance document related to political subdivision contracts for ambulance service. The rule could also be improved if subsection (A) were restructured to conform to current rulemaking format and style requirements.

11. A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons
regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective

Because of the issues described in paragraphs 3 and 6 of the analysis of this rule, the rule does not impose the least burden and costs on persons regulated by the rule.

R9-25-1105. Application for Provision of Subscription Service or Establish a Subscription Service Rate (A.R.S. § 36-2232(A)(1))

2. **Objective**
   The objectives of the rule are to establish the requirements for applying to:
   a. Provide subscription service,
   b. Establish a subscription service rate, or
   c. Obtain approval of a subscription service contract.

3. **Analysis of effectiveness in achieving the objective**
   The rule is mostly effective in achieving its objectives, but the rule could be more effective if there were separate subsections to specify the requirements for the three objectives of the rule or if the objectives of the rule were amended. Subsection (A)(1) requires the submission of some information that is useful in determining a subscription service rate, but the rule does not require the name of the certificate holder or number assigned by the Department to the certificate of necessity.

6. **Analysis of clarity, conciseness, and understandability**
   The rule is clear, concise, and understandable, but subsection (A)(2) could be clearer by specifying that the proposed subscription service contract is a template to be used with a multitude of subscribers.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
   Despite the minor changes that could be made, as described in paragraphs 3 and 6, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-25-1106. Rate of Return Setting Considerations (A.R.S. §§ 36-2232, 36-2239)

1. **Authorization of the rule by existing statute**
   The rule has A.R.S. § 36-2239 as additional specific authority.
2. **Objective**
The objectives of the rule are to establish:

a. The factors the Department will consider when determining the rate of return on gross revenue,

b. How the Director will determine just, reasonable, and sufficient rates, and

c. How the rate of return is calculated by the Department.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objectives but could be more effective if the factors listed in subsection (A) were linked to the information required in the Ambulance Revenue and Cost Report in Exhibits 9A and 9B. The rule could also be more effective if subsection (C) provided a cap on the rate of return.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable, but could be improved if terms used in the rule, such as “balance sheet,” “income statement,” “cash flow statement,” “variable and fixed costs,” “method of indirect cost allocation,” “reimbursable and non-reimbursable charges,” and “accrual method” were defined. However, since these terms have been used and understood by the regulated community for over 10 years, their meaning is well-understood, and their use without definition is not problematic. The references in subsection (D) should also be corrected to refer to Exhibits 9A and 9B.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

Despite the minor changes that could be made, as described in paragraphs 3 and 6, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-25-1107.  **Rate Calculation Factors (A.R.S. § 36-2232)**

2. **Objective**
The objectives of the rule are to:

a. Establish the factors the Department will consider when evaluating a proposed mileage rate, BLS rate, and ALS rate;

b. Require the Department to adjust rates to maximize Medicare reimbursement; and

c. Establish how the standby waiting rate is calculated by the Department.
3. **Analysis of effectiveness in achieving the objective**

The rule is effective in achieving its objectives but could be more effective if subsection (C) provided for the costs of additional professional insurance for ALS personnel, required in R9-25-902(B)(2), and if the method of determining the standing waiting rate in subsection (E) were assessed to determine if it was still appropriate.

6. **Analysis of clarity, conciseness, and understandability**

The rule is clear, concise, and understandable but could be improved if the factors listed in subsection (A) were linked to the information required in the Ambulance Revenue and Cost Report in Exhibits 9A and 9B.

7. **Summary of the written criticisms of the rule received within the last five years**

The Department has received one written criticism/comment of the rule in the past five years.

**Comment:** A comment was received expressing confusion about billing for standby waiting as the requirement in rule seems in conflict with how AHCCCS and other third party payers reimburse for services. The rules require the rate (in dollars per hour) to be calculated by dividing the BLS rate (the rate that an ambulance service is approved to charge for Basic Life Support services) by four and require a certificate holder to assess the rate in quarter-hour increments (R9-25-1108), but CMS (used by AHCCCS, Medicare, and other insurance companies) reimburses in half-hour increments.

**Response:** The Department has no authority for determining how AHCCCS reimburses for services or how CMS requires billing to be done. No other certificate holders appear to have an issue with the apparent inconsistency. However, the Department plans to address these concerns during the next rulemaking.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**

Despite the minor changes that could be made, as described in paragraphs 3 and 6, and the confusion expressed by one stakeholder, as described in paragraph 7, the probable benefits of the rule outweigh the probable costs of the rule and rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

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1. **Authorization of the rule by existing statute**
The rule has A.R.S. § 36-2239 as additional specific authority.

2. **Objective**
The objectives of the rule are to establish the requirements for:
   a. Assessing rates and charges, and
   b. Refunding a rate or charge.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objectives but could be more effective if the rule specified that under A.R.S. § 36-2239(D) a rate or charge is not effective and cannot be charged until approved by the Department. The rule could also be more effective if subsection (A)(2) allowed a ground ambulance service to calculate mileage using software designed for that purpose.

6. **Analysis of clarity, conciseness, and understandability**
The rule is mostly clear, concise, and understandable, but could be improved by replacing the pronoun “its” in subsection (D) with the noun to which the pronoun refers.

7. **Summary of the written criticisms of the rule received within the last five years**
The Department has received one written criticism/comment of the rule in the past five years, which is described in paragraph 7 of the analysis for R9-25-1107, along with the Department’s response.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Despite the minor changes that could be made, as described in paragraphs 3 and 6, and the confusion expressed by one stakeholder, as described in paragraph 7, the probable benefits of the rule outweigh the probable costs of the rule and rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-25-1109. **Charges (A.R.S. §§ 36-2232, 36-2239(D))**

1. **Authorization of the rule by existing statute**
The rule has A.R.S. § 36-2239 as additional specific authority.

2. **Objective**
The objective of the rule is to require a certificate holder to submit a list of disposable supplies, medical supplies, medications, and oxygen-related costs for which a ground ambulance service
charges a patient, the proposed charges, and the effective date of the proposed charges before implementing the charge and whenever a charge is changed.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable, but could be improved by clarifying that the Department does not approve the charges for disposable supplies, medical supplies, medications, and oxygen-related costs. The rule could also be improved if the rule were restructured to enhance clarity.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Despite the minor changes that could be made, as described in paragraphs 3 and 6, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.

R9-25-1110. **Invoices (A.R.S. §§ 36-2234, 36-2239)**

1. **Authorization of the rule by existing statute**
The rule has A.R.S. §§ 36-2234 and 36-2239 as additional specific authority.

2. **Objective**
The objective of the rule is to establish requirements related to invoices submitted to patients for services rendered.

3. **Analysis of effectiveness in achieving the objective**
The rule is effective in achieving its objective but could be more effective if subsections (C) and (D) were combined since they both address combined rates and charges.

6. **Analysis of clarity, conciseness, and understandability**
The rule is clear, concise, and understandable, but could be improved by restructuring the rule to remove passive language.

11. **A determination that the probable benefits of the rule outweigh within this state the probable costs of the rule, and the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective**
Despite the minor changes that could be made, as described in paragraphs 3 and 6, the rule imposes the least burden and costs to persons regulated by the rule, including paperwork and other compliance costs, necessary to achieve the underlying regulatory objective.