NOTICE OF FINAL RULEMAKING TITLE 9. HEALTH SERVICES

2022 APR -6 PM 4: 17

CHAPTER 25. DEPARTMENT OF HEALTH SERVICES

FILED

EMERGENCY MEDICAL SERVICES

PREAMBLE

<u>1.</u>	Article, Part or Sections Affected (as applicable)	Rulemaking Action
	R9-25-701	Amend
	R9-25-703	Amend
	R9-25-704	Amend
	R9-25-705	Repeal
	R9-25-705	Renumber
	R9-25-705	Amend
	R9-25-706	Renumber
	R9-25-706	Amend
	R9-25-707	Renumber
	R9-25-707	Amend
	R9-25-708	Renumber
	R9-25-708	Amend
	R9-25-709	Renumber
	R9-25-709	Amend
	R9-25-710	Renumber
	R9-25-710	Amend
	R9-25-711	Renumber
	R9-25-711	Amend
	R9-25-712	Renumber
	R9-25-712	Amend
	R9-25-713	Renumber
	R9-25-714	Repeal
	R9-25-715	Renumber
	R9-25-716	Repeal
	R9-25-717	Repeal
	R9-25-718	Repeal

R9-25-801	Repeal
R9-25-801	Renumber
R9-25-801	Amend
R9-25-802	Renumber
R9-25-802	Amend
R9-25-803	Renumber
R9-25-803	Amend
R9-25-804	Renumber
R9-25-804	Amend
R9-25-805	Amend
R9-25-806	Repeal
R9-25-807	Renumber
Table 8.1	Repeal
R9-25-1201	Amend
Table 12.1	Amend

Citations to the agency's statutory rulemaking authority to include the authorizing statute (general) and the implementing statute (specific):

Authorizing statutes: A.R.S. §§ 36-132(A)(1), 36-136(G), 36-2202(A)(4), and 36-2209(A)(2)

Implementing statutes: A.R.S. §§ 36-2201, 36-2202(A)(3) and (5), 36-2204, 36-2212, 36-2213,

36-2214, 36-2215, 36-2240(4)

3. The effective date of the rules:

The Arizona Department of Health Services (Department) requests the normal 60-day delayed effective date for this rulemaking.

<u>4.</u> Citations to all related notices published in the *Register* as specified in R1-1-409(A) that pertain to the record of the proposed rule:

Notice of Rulemaking Docket Opening: 25 A.A.R. 1271, May 17, 2019

Notice of Rulemaking Docket Opening: 26 A.A.R. 1946, September 2020

Notice of Proposed Rulemaking: 27 A.A.R. 1297, August 27, 2021

5. The agency's contact person who can answer questions about the rulemaking:

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6. An agency's justification and reason why a rule should be made, amended, repealed or renumbered, to include an explanation about the rulemaking:

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 adopted rules to implement these statutes in 9 A.A.C. 25. The rules in 9 A.A.C. 25, Articles 7 and 8 establish requirements for licensing air ambulance services and for registration of air ambulances, respectively, to ensure the health and safety of patients being transported. In a fiveyear-review report approved by the Governor's Regulatory Review Council on July 6, 2017, the Department identified several issues with the rules and proposed a rulemaking to address these issues. These issues include non-compliance with A.R.S. § 41-1080, unnecessary or duplicative requirements, unclear requirements, obsolete requirements, and poor organization of the rules. All of these issues may affect the effectiveness of the rules and, thus, threaten the health and safety of patients being transported. The Department also requested input from stakeholders to identify additional issues. After receiving an exception from the Governor's rulemaking moratorium established by Executive Order 2019-01, the Department began revising the rules in 9 A.A.C. 25, Articles 7 and 8, to address these issues and other issues identified by stakeholders as part of the rulemaking process and to restructure the rules to improve clarity, remove duplication, and increase effectiveness. The Department also identified changes needed in Article 12 of the Chapter to address issuing an approval of a license with a corrective action plan to an air

ambulance service and to correct cross-references to renumbered Sections. The new amendments conform to rulemaking format and style requirements of the Governor's Regulatory Review Council and the Office of the Secretary of State.

A reference to any study relevant to the rule that the agency reviewed and proposes either to rely on or not to rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

The Department did not review or rely on any study for this rulemaking.

8. A showing of good cause why the rulemaking is necessary to promote a statewide interest if the rulemaking will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

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

The Department anticipates that the rulemaking may affect the Department; air ambulance services, ground ambulance services, and other EMS providers; hospitals and other health care institutions licensed under 9 A.A.C. 10 and hospitals operating under federal or tribal law; emergency medical care technicians (EMCTs); patients and their families; and the general public. Annual costs/revenues changes are designated as minimal when more than \$0 and \$2,000 or less, moderate when between \$2,000 and \$20,000, and substantial when \$20,000 or greater in additional costs or revenues. A cost is listed as significant when meaningful or important, but not readily subject to quantification. As of July 2021, the Department licenses 19 entities as air ambulance services under the rules in 9 A.A.C. 25, Article 7, and 131 air ambulances, operated by these licensees, are registered under Article 8.

Having rules that are clearer, easier to understand, and better organized may provide a significant benefit to all affected persons. If an air ambulance service has not been complying with these current requirements due to misunderstanding the requirement, the Department believes their clarification could cause an air ambulance service to incur as much as moderate costs to come into compliance. Changes to applications may provide a significant benefit to the Department and may cause an air ambulance service to incur as much as a minimal cost to comply with the changes. The proposed rules include provisions for an aircraft leased by an air ambulance services to be registered as an air ambulance. This change may prove as much as a substantial benefit to an air ambulance service or applicant.

Additional requirements for documentation are included in the proposed rules, as are requirements for reporting information to the Department and exceptions to some requirements.

The Department estimates that these changes may cause the Department to incur a minimal increase in costs and to receive a significant benefit from having the reported data. The Department anticipates that changes related to an air ambulance service terminating operations at a specific location may provide a significant benefit to the Department and hospitals/health care institutions relying on the air ambulance service, while causing the Department at most a minimal increase in costs to work with such an air ambulance service and hospital. The Department believes that some of these changes may provide up to a moderate benefit to an air ambulance service, while others may cause an air ambulance service to incur as much as moderate costs to implement the requirement or come into compliance, if not already performing these activities as routine operations or as a standard of care. EMCTs may also incur a significant burden from documentation requirements, but may receive a significant benefit from changes to required equipment and supplies and from being able to provide better patient care.

The changes related to allowing corrective action plans may cause the Department to incur as much as a minimal increase in costs to review submitted corrective action plans, but may also cause a minimal-to-moderate decrease in costs related to enforcement. While the preparation and implementation of a corrective action plan may cause an air ambulance service to incur up to substantial costs, the Department believes that the inclusion of provisions for submission of a corrective action plan in lieu of enforcement actions may provide as much as a substantial benefit to an air ambulance service.

Requirements for supplies and equipment are also being changed to reflect the current standards of care. The Department believes that these changes may provide as much as a moderate benefit to an air ambulance service, depending on the number of aircraft used by the air ambulance service, the number of missions performed, and list of agents the administrative medical director has authorized for use, while potentially causing the air ambulance service to incur as much as moderate costs. Changing requirements for supplies and equipment to current standards may also provide an EMCT with a significant benefit.

There are many instances in which an air ambulance service either receives a patient for transport from or transfers care of a patient to a hospital/other health care institution or a ground ambulance service or other EMS provider. The proposed rules specify the content of the protocol for communicating information during a transfer of care required in R9-25-201(E)(2)(d)(i). The Department anticipates that adding these requirements to the rules to clarify an existing requirement in Article 2 of the Chapter may cause an air ambulance service to incur as much as moderate costs to come into compliance, and to provide a significant benefit to a hospital/other health care institution, another ambulance service, or an EMS provider. By improving patient

care, this requirement is also expected to provide a significant benefit to patients and their families and the general public.

10. A description of any changes between the proposed rulemaking, to include supplemental notices, and the final rulemaking:

Between the proposed rulemaking and final rulemaking, the Department further reorganized Sections in both Articles of the rulemaking to improve the flow of the rules and enhance their effectiveness. Corresponding changes were made to correct cross-references to the reorganized Sections. No other changes were made to the rules between the proposed rulemaking and the final rulemaking.

11. An agency's summary of the public stakeholder comments made about the rulemaking and the agency response to the comments:

During the formal public comment period, the Department received no written comments about the rules and no regulated entities or members of the public attended the oral proceeding held on September 28, 2021.

- 12. All agencies shall list other matters prescribed by statute applicable to the specific agency or to any specific rule or class of rules. Additionally, an agency subject to Council review under A.R.S. §§ 41-1052 and 41-1055 shall respond to the following questions:
 - a. Whether the rule requires a permit, whether a general permit is used and if not, the reasons why a general permit is not used:

A.R.S. § 36-2214 authorizes the Department to issue a license to an air ambulance service that meets criteria established by statute and rule. Although the activities that an air ambulance service is authorized to undertake are specified on the license, based on criteria in rule, the Department considers the license to be a general permit. A.R.S. § 36-2212 authorizes the Department to issue a certificate of registration for operation of an aircraft as an air ambulance. The Department considers the certificate of registration to be a general permit.

Whether a federal law is applicable to the subject of the rule, whether the rule is more stringent than federal law and if so, citation to the statutory authority to exceed the requirements of federal law:

Not applicable

<u>whether a person submitted an analysis to the agency that compares the rule's impact of the competitiveness of business in this state to the impact on business in other states:</u>

No business competitiveness analysis was received by the Department.

13. A list of any incorporated by reference material as specified in A.R.S. § 41-1028 and its location in the rules:

Not applicable

14. Whether the rule was previously made, amended or repealed as an emergency rule. If so, cite the notice published in the *Register* as specified in R1-1-409(A). Also, the agency shall state where the text was changed between the emergency and the final rulemaking packages:

Not applicable

<u>15.</u> <u>The full text of the rules follows:</u>

TITLE 9. HEALTH SERVICES

CHAPTER 25. DEPARTMENT OF HEALTH SERVICES EMERGENCY MEDICAL SERVICES

ARTICLE 7. AIR AMBULANCE SERVICE LICENSING

Section

- R9-25-701. Definitions (Authorized by A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), 36-2212, 36-2213, 36-2214, and 36-2215)
- R9-25-703. Requirement and Eligibility for a License (<u>Authorized by A.R.S. §§ 36-2202(A)(3)</u> and (4), 36-2209(A)(2), 36-2212, 36-2213, 36-2214, and 36-2215)
- R9-25-704. Initial Application and Licensing Process (Authorized by A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), 36-2213, 36-2214, and 36-2215)
- R9 25 705. Renewal Application and Licensing Process (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), 36-2213, 36-2214, and 36-2215)
- R9-25-710.R9-25-705. Minimum Standards for Operations (<u>Authorized by A.R.S. §§ 36-2202(A)(3)</u> and (4), 36-2209(A)(2), and 36-2213)
- R9-25-711.R9-25-706. Minimum Standards for Mission Staffing (Authorized by A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), and 36-2213)
- R9-25-713.R9-25-707. Minimum Standards for Training (<u>Authorized by A.R.S. §§ 36-2202(A)(4)</u>, 36-2209(A)(2), and 36-2213)
- R9-25-715.R9-25-708. Minimum Standards for Medical Control (Authorized by A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), and 36-2213)
- R9-25-707.R9-25-709. Changes Affecting a License (Authorized by A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2213)
- R9-25-706.R9-25-710. Term and Transferability of License (<u>Authorized by A.R.S.</u> §§ 36-2202(A)(4), 36-2209(A)(2), 36-2213, 36-2214, and 41-1092.11)
- R9-25-708.R9-25-711. Inspections and Investigations (Authorized by A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), 36-2213, and 36-2214)
- R9-25-712. Expired
- R9-25-709.R9-25-712. Enforcement Actions (<u>Authorized by A.R.S. §§ 36-2202(A)(4)</u>, 36-2209(A)(2), 36-2213, 36-2214, 36-2215, 41-1092.03, and 41-1092.11(B))
- R9-25-713. Renumbered
- R9-25-714. Minimum Standards for Communications (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), and 36-2213) Repealed

- R9-25-715. Renumbered
- R9-25-716. Minimum Standards for Recordkeeping (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2213) Repealed
- 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) Repealed
- 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) Repealed

ARTICLE 8. AIR AMBULANCE REGISTRATION

Section

- R9 25 801. Definitions (A.R.S. §§ 36 2202(A)(4), 36 2209(A)(2), and 36 2212)
- R9-25-802.R9-25-801. Requirement, Eligibility, and Application for an Initial or Renewal Certificate of Registration for an Air Ambulance (<u>Authorized by A.R.S. §§ 36-2202(A)(4)</u> and (5), 36-2209(A)(2), 36-2212, 36-2213, 36-2214, and 36-2240(4))
- R9-25-807.R9-26-802. Minimum Standards for an Air Ambulance (<u>Authorized by A.R.S. §§ 36-2202(A)(3)</u>, (4), and (5); 36-2209(A)(2); and 36-2212)
- R9-25-804.R9-25-803. Changes Affecting Registration (<u>Authorized by A.R.S. §§ 36-2202(A)(4)</u> and (5), 36-2209(A)(2), and 36-2212)
- R9 25-803.R9-25-804. Term and Transferability of Certificate of Registration (Authorized by A.R.S. §§ 36-2202(A)(4) and (5), 36-2209(A)(2), 36-2212, and 41-1092.11)
- R9-25-805. Inspections (<u>Authorized by A.R.S.</u> §§ 36-2202(A)(4) and (5), 36-2209(A)(2), 36-2212, and 36-2232(A)(11))
- 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)) Repealed
- R9-25-807. Renumbered
- Table 8.1. Minimum Equipment and Supplies Required on Air Ambulances, By Mission Level and Aircraft Type (Authorized by A.R.S. §§ 36-2202(A)(3), (4), and (5); 36-2209(A)(2); and 36-2212) Repealed

ARTICLE 12. TIME-FRAMES FOR DEPARTMENT APPROVALS

Section

- R9-25-1201. Time-frames (Authorized by A.R.S. §§ 41-1072 through 41-1079)
- Table 12.1. Time-frames (in days)

ARTICLE 7. AIR AMBULANCE SERVICE LICENSING

R9-25-701. Definitions (Authorized by A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), 36-2212, 36-2213, 36-2214, and 36-2215)

In addition to the definitions in A.R.S. § 36-2201 and R9-25-101, the following definitions apply in this Article and in Article 8 of this Chapter, unless otherwise specified:

- 1. "Air ambulance" means an aircraft that is an "ambulance" as defined in A.R.S. § 36-2201.
- 2. "Air ambulance service" means an ambulance service that operates an air ambulance.
- 3. "Application packet" means the information, applicable fees, and documents required by the Department when making a decision for:
 - a. Licensing an air ambulance service, or
 - b. <u>Issuing a certificate of registration for an air ambulance.</u>
- 3.4. "Base location" means a physical location at which a person houses an air ambulance or equipment and supplies used for the operation of an air ambulance service or provides administrative or other support for the operation of an air ambulance service.
- 4. "Business organization" means an entity such as an association, cooperative, corporation, limited liability company, or partnership.
- 5. "Call number" means a unique identifier used by an air ambulance service to identify a specific mission.
- 6.5. "CAMTS" means the Commission on Accreditation of Medical Transport Systems, formerly known as the Commission on Accreditation of Air Medical Services.
- "Certificate holder" means a person who holds a current and valid certificate of registration for an air ambulance.
- 7. "Change of ownership" means a transfer of controlling legal or controlling equitable interest and authority in an air ambulance service.
- 8. "Critical care" means pertaining to a patient whose condition requires care commensurate with the scope of practice of a physician or registered nurse who has an illness or injury acutely impairing one or more organ systems, such that the conditions are life-threatening and require constant monitoring to avoid deterioration of the patient's condition.
- 9. "Estimated time of arrival" means the number of minutes from the time that an air ambulance service agrees to perform a mission to the time that an air ambulance arrives at the scene.
- 10. "Holds itself out" means advertises through print media, broadcast media, the Internet, or

other means.

- 41-10. "Interfacility" means between two health care institutions.
- 11. "Interfacility maternal transport" means an interfacility transport of a woman:
 - a. Whose pregnancy is considered by a physician to be high risk,
 - b. Who is in need of critical care services related to the pregnancy, and
 - who is being transferred to a medical facility that has the specialized perinatal and neonatal resources and capabilities necessary to provide an appropriate level of care.
- 12. "Interfacility neonatal transport" means an interfacility transport of an infant who is 28 days of age or younger and who is in need of critical care services.
- 12.13. "Licensed respiratory care practitioner" has the same meaning as in A.R.S. § 32-3501.
- 14. "Licensee" means a person who holds a current and valid license from the Department to operate an air ambulance service.
- "Maternal" means pertaining to a woman whose pregnancy is considered by a physician to be high risk, who is in need of critical care services related to the pregnancy, and who is being transferred to a medical facility that has the specialized perinatal and neonatal resources and capabilities necessary to provide an appropriate level of care.
- 14.15. "Medical team" means personnel whose main function on a mission is the medical care of the patient being transported.
- 15.16. "Mission" means a transport job event that involves an air ambulance service's sending an air ambulance to a patient's location to provide transport of the patient from one location to another, whether or not transport of the patient is actually provided.
- 17. "Mission level" means critical care services or ALS services, based on the staffing and the services provided by the air ambulance service.
- 18. "Mission type" means an emergency medical services transport, interfacility transport, interfacility maternal transport, or interfacility neonatal transport provided by an air ambulance service.
- 16. "Neonatal" means pertaining to an infant who is 28 days of age or younger and who is in need of critical care services.
- 17.19. "On-line medical guidance" means emergency medical services direction or information provided to a non-EMCT medical team member by a physician through two-way voice communication.
- 18.20. "Operate an air ambulance in this state" means:
 - a. Transporting a patient via air ambulance from a location in this state to another

- location in this state,
- b. Operating an air ambulance from a base location in this state, or
- c. Transporting a patient via air ambulance from a location in this state to a location outside of this state more than once per month.
- 19.21. "Owner" means a person that holds a controlling legal or equitable interest and authority in a business enterprise organization.
- 20. "Patient reference number" means a unique identifier used by an air ambulance service to identify an individual patient.
- 21.22. "Personnel" means individuals who work for an air ambulance service, with or without compensation, whether as employees, contractors, or volunteers.
- 22.23. "Premises" means each physical location of air ambulance service operations and includes all equipment and records at each location.
- 23.24. "Proficiency in neonatal resuscitation" means current and valid certification in neonatal resuscitation obtained through completing a nationally recognized training program such as the American Academy of Pediatrics and American Heart Association NRP: Neonatal Resuscitation Program.
- 24. "Publicizes" means makes a good faith effort to communicate information to the general public through print media, broadcast media, the Internet, or other means.
- 25. "Regularly" means at recurring, fixed, or uniform intervals.
- 26. "Rescue situation" means an incident in which:
 - a. An individual's life, limb, or health is imminently threatened; and
 - b. The threat may be reduced or eliminated by removing the individual from the situation and providing medical services.
- 27.26. "Subspecialization" means:
 - a. For a physician board certified by a specialty board approved by the American
 Board of Medical Specialties, subspecialty certification;
 - b. For a physician board certified by a specialty board approved by the American Osteopathic Association, attainment of either a certification of special qualifications or a certification of added qualifications; and
 - c. For a physician who has completed an accredited residency program, completion of at least one year of training pertaining to the specified area of medicine.
- 28.27. "Two-way voice communication" means that two individuals are able to convey information back and forth to each other orally, either directly or through a third-party relay.

- 29.28. "Valid" means that a license, certification, or other form of authorization is in full force and effect and not suspended.
- 30.29. "Working day" means the period between 8:00 a.m. and 5:00 p.m. on a Monday, Tuesday, Wednesday, Thursday, or Friday that is not a state holiday.

R9-25-703. Requirement and Eligibility for a License (<u>Authorized by A.R.S. §§ 36-2202(A)(3)</u> and (4), 36-2209(A)(2), 36-2212, 36-2213, 36-2214, and 36-2215)

- A. A person shall not operate an air ambulance in this state unless the person has a current and valid air ambulance service license and, except as provided in A.R.S. § 36-2212(C), a current and valid certificate of registration for the air ambulance as required under Article 8 of this Chapter.
- **B.** To be eligible to obtain an air ambulance service license, an applicant shall:
 - Hold current and valid Registration registration and Exemption exemption issued by the
 Federal Aviation Administration under 14 CFR 298, as evidenced by a current and valid
 <u>U.S. Department of Transportation</u> OST Form 4507 showing the effective date of
 registration;
 - 2. Hold the following issued by the Federal Aviation Administration:
 - A current and valid Air Carrier Certificate authorizing common carriage under 14
 CFR 135;
 - If operating a rotor-wing air ambulance, current and valid Operations
 Specifications authorizing aeromedical helicopter operations;
 - c. If operating a fixed-wing air ambulance, current and valid Operations

 Specifications authorizing airplane air ambulance operations;
 - d. A current and valid Certificate of Registration for each air ambulance to be operated; and
 - e. A current and valid Airworthiness Certificate for each air ambulance to be operated;
 - 3. Have applied for a certificate of registration, issued by the Department under Article 8 of this Chapter, for each air ambulance to be operated by the air ambulance service;
 - 4. Hold Possess a copy of a current and valid registration, issued by the Arizona Department of Transportation under A.R.S. Title 28, Chapter 25, Article 4, to the owner of the aircraft for each air ambulance to be operated by the air ambulance service;
 - 5. Have current and valid liability insurance coverage for the air ambulance service that complies with A.R.S. § 36-2215 and that has at least the following maximum liability limits:
 - a. \$1 million for injuries to or death of any one person arising out of any one

- incident or accident;
- b. \$3 million for injuries to or death of more than one person in any one incident or accident; and
- c. \$500,000 for damage to property arising from any one incident or accident;
- 6. Have current and valid malpractice insurance coverage for the air ambulance service that complies with A.R.S. § 36-2215 and that has a maximum liability limit of at least \$1 million per occurrence; and
- 7. Comply with all applicable requirements of this Article, Articles 2 and 8 of this Chapter, and A.R.S. Title 36, Chapter 21.1.
- C. To maintain eligibility for an air ambulance service license, an air ambulance service a licensee shall meet the requirements of subsections (B)(1)-(2) and (4)-(7) (B)(1), (2), and (4) through (7) and hold a current and valid certificate of registration, issued by the Department under Article 8 of this Chapter, for each air ambulance operated in Arizona by the air ambulance service.

R9-25-704. Initial Application and Licensing Process (Authorized by A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), 36-2213, 36-2214, and 36-2215)

- A. An applicant for an initial license shall submit an application <u>packet</u> to the Department, in a Department provided format, including:
 - 1. The following information in a Department-provided format:
 - <u>a.</u> <u>The applicant's name; mailing address; e-mail address; fax number, if any; and telephone number;</u>
 - 2.b. Each business name to be used for The names of all other business organizations operated by the applicant related to the air ambulance service;
 - 3.c. The physical and mailing addresses to be used for the air ambulance service, if different from the applicant's mailing address;
 - 4.d. The name, title, address, e-mail address, and telephone number of the applicant's statutory agent or the individual designated by the applicant to accept service of process and subpoenas for the air ambulance service;
 - e. The name, title, address, e-mail address, and telephone number of the individual acting on behalf of the applicant according to R9-25-102;
 - 5.<u>f.</u> If the applicant is a business organization:
 - a.i. The type of business organization; and
 - b.ii. The following information about name; address; e-mail address; telephone number; and fax number, if any, of the individual who is to serve as the primary contact for information regarding the application;

- i. Name:
- ii. Address;
- iii. E-mail address;
- iv. Telephone number; and
- v. Fax number, if any;
- c. The name, title, and address of each officer and board member or trustee;
- d. A copy of the business organization's articles of incorporation, articles of organization, or partnership or joint venture documents, if applicable;
- 6.g. The name and Arizona license number for the physician who is to serve as the administrative medical director for the air ambulance service;
- 7.h. The intended hours of operation for the air ambulance service;
- 8.i. The intended schedule of rates for the air ambulance service;
- 9-i. Which of the following mission types is to be provided:
 - a.i. Emergency medical services transports,
 - b.ii. Interfacility transports,
 - e.<u>iii.</u> Interfacility maternal transports, and or
 - d.iv. Interfacility neonatal transports;
- k. Which of the following mission levels is to be provided:
 - i. Critical care, or
 - ii. Advanced life support;
- 1. Whether the applicant plans to use fixed-wing or rotor-wing aircraft for the air ambulance service;
- m. Whether the applicant agrees to allow the Department to submit supplemental requests for information under R9-25-1201(C)(3);
- n. Attestation that the applicant will comply with all applicable requirements in this Article, Articles 2 and 8 of this Chapter, and A.R.S. Title 36, Chapter 21.1;
- Attestation that the information provided in the application packet, including the information in the accompanying documents, is accurate and complete; and
- 10-p. The signature of the applicant and the date signed;
- 2. Documentation for the individual specified according to subsection (A)(1)(e) that complies with A.R.S. § 41-1080;
- 3. A copy of the business organization's articles of incorporation, articles of organization, or partnership documents, if applicable;

- 41.4. A copy of a current and valid <u>U.S. Department of Transportation</u> OST Form 4507, showing the effective date of Federal Aviation Administration registration and exemption under 14 CFR 298;
- 12.5. A copy of the following issued by the Federal Aviation Administration:
 - A current and valid Air Carrier Certificate authorizing common carriage under 14
 CFR 135;
 - b. If intending to operate a rotor-wing air ambulance, the following signed pages of the current and valid Operations Specifications authorizing aeromedical helicopter operations:
 - i. The page showing the certificate number issued by the Federal Aviation Administration and stating the name and contact information for the entity to which the certificate, approving the Operation Specifications authorizing aeromedical helicopter operations, was issued by the Federal Aviation Administration;
 - ii. The page stating the characteristics of the rotor-wing aircraft for which the certificate was issued by the Federal Aviation Administration;
 - <u>iii.</u> Each page stating the name and contact information for the individuals with controlling legal interest or controlling equitable interest in the ownership of the entity specified in subsection (A)(5)(b)(i);
 - iv. Each page stating the name and contact information for the individuals
 designated to act as a point of contact with the Federal Aviation
 Administration about the Operation Specifications for the rotor-wing
 aircraft;
 - v. Each page stating the name and contact information for the individuals with operational control of the rotor-wing aircraft; and
 - vi. Each page listing the tail numbers of the rotor-wing aircraft covered under the Operations Specifications; and
 - If intending to operate a fixed-wing air ambulance, the following signed pages of the current and valid Operations Specifications authorizing airplane air ambulance operations:
 - <u>i.</u> The page showing the certificate number issued by the Federal Aviation Administration and stating the name and contact information for the entity to which the certificate, approving the Operation Specifications authorizing airplane ambulance operations, was issued by the Federal

- Aviation Administration:
- ii. The page stating the characteristics of the fixed-wing aircraft for which the certificate was issued by the Federal Aviation Administration;
- <u>iii.</u> Each page stating the name and contact information for the individuals with controlling legal interest or controlling equitable interest in the ownership of the entity specified in subsection (A)(5)(c)(i);
- iv. Each page stating the name and contact information for the individuals
 designated to act as a point of contact with the Federal Aviation
 Administration about the Operation Specifications for the fixed-wing
 aircraft;
- <u>v.</u> Each page stating the name and contact information for the individuals
 <u>with operational control of the fixed-wing aircraft; and</u>
- <u>vi.</u> Each page listing the tail numbers of the fixed-wing aircraft covered under the Operations Specifications;
- d. A current and valid Certificate of Registration for each air ambulance to be operated; and
- e. A current and valid Airworthiness Certificate for each air ambulance to be operated;
- 13.6. For each air ambulance to be operated for the air ambulance service:
 - a. An application for registration that includes all of the information and items documents required under R9-25-802(C) R9-25-801(B); and
 - b. A copy of a current and valid registration, issued by the Arizona Department of Transportation under A.R.S. Title 28, Chapter 25, Article 4;
- 14.7. A certificate of insurance establishing that the applicant has current and valid liability insurance coverage for the air ambulance service as required under R9-25-703(B)(5);
- 45.8. A certificate of insurance establishing that the applicant has current and valid malpractice insurance coverage for the air ambulance service as required under R9-25-703(B)(6);
- 9. A list of each entity that or physician who is to provide on-line medical direction to EMCTs of the air ambulance service, including:
 - a. For each entity, such as an ALS base hospital, centralized medical direction
 communications center, or physician group practice, the name, mailing address,
 e-mail address, and telephone number of the entity; or
 - <u>b.</u> For each physician who is to provide on-line medical direction, the name,
 professional license number, mailing address, e-mail address, and telephone

number for the physician;

- 16:10. If the applicant holds current CAMTS accreditation for the air ambulance service, a copy of the current CAMTS accreditation report; and
- 17. Attestation that the applicant will comply with all applicable requirements in this Article, Articles 2 and 8 of this Chapter, and A.R.S. Title 36, Chapter 21.1; and
- 18. Attestation that the information provided in the application, including the information in the documents accompanying the application form, is accurate and complete.
- 11. If a document required under subsection (A)(4) or (5) is not issued in the name of the applicant, documentation showing the applicant can legally possess and operate the aircraft covered by the document, signed by the owner of the aircraft.
- No more than 30 days before the expiration date of the current license, a licensee shall submit to
 the Department a renewal application packet including:
 - 1. The information required in subsection (A)(1), in a Department-provided format;
 - 2. The documents required in subsections (A)(4), (5), (7), (8), (9), and, if applicable, (10); and
 - 3. For each air ambulance operated or to be operated by the air ambulance service:
 - a. Either:
 - i. A copy of a current and valid certificate of registration issued by the

 Department under Article 8 of this Chapter, or
 - <u>ii.</u> An application packet for registration that includes all of the information and documents required under R9-25-801(B); and
 - b. A copy of a current and valid registration, issued by the Arizona Department of Transportation under A.R.S. Title 28, Chapter 25, Article 4.
- B.C. Unless an applicant establishes that it holds or licensee documents current CAMTS accreditation, as provided in subsection (A)(16) (A)(10), or is applying for an initial license because of a change of ownership as described in R9-25-706(D) R9-25-710(D), the Department shall conduct an inspection, as required under A.R.S. § 36-2214(B) and R9-25-708 R9-25-711, during the substantive review period for the application for an initial a license.
- C.D. The Department shall review and approve or deny each application packet as described in Article 12 of this Chapter, and:
 - 1. Approve the application;
 - 2. Approve the application with a corrective action plan, as specified in R9-25-711(G)(2); or
 - 3. Deny the application.

- **D.E.** The Department may deny an application if an applicant or licensee:
 - 1. Fails to meet the eligibility requirements of R9-25-703(B);
 - 2. Fails or has failed to comply with any provision in A.R.S. Title 36, Chapter 21.1;
 - 3. Fails or has failed to comply with any provision in this Article or Article 2 or 8 of this Chapter;
 - 4. Knowingly or negligently provides false documentation or false or misleading information to the Department; or
 - 5. Fails to submit to the Department documents or information requested under R9-25-1201(B)(1) or (C)(3), as required under R9-25-1201(D), and requests a denial as permitted under R9-25-1201(E).

R9-25-705. Renewal Application and Licensing Process (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), 36-2213, 36-2214, and 36-2215)

- A. Before the expiration date of its current license, an air ambulance service shall submit to the

 Department a renewal application completed using a Department provided form and including:
 - 1. The information and items listed in R9-25-704(A)(1) (11), (12)(b), and (13) (18); and
 - 2. For each air ambulance operated or to be operated by the air ambulance service:
 - a. A copy of a current and valid certificate of registration issued by the Department under Article 8 of this Chapter; or
 - b. An application for registration that includes all of the information and items required under R9-25-802(C).
- B. Unless an air ambulance service establishes that it holds current CAMTS accreditation as provided in subsection (C), the Department shall conduct an inspection, as required under A.R.S. § 36-2214(B) and R9-25-708, during the substantive review period for the renewal application.
- C. To establish current CAMTS accreditation, an air ambulance service shall submit to the Department, as part of the application submitted under subsection (A), a copy of the air ambulance service's current CAMTS accreditation report.
- The Department shall review and approve or deny each application as described in Article 12 of this Chapter.
- E. The Department may deny an application if an applicant:
 - 1. Fails to meet the eligibility requirements of R9-25-703(C);
 - 2. Fails or has failed to comply with any provision in A.R.S. Title 36, Chapter 21.1;
 - 3. Fails or has failed to comply with any provision in this Article or Article 2 or 8 of this Chapter;
 - 4. Knowingly or negligently provides false documentation or false or misleading

- information to the Department; or
- 5. Fails to submit to the Department documents or information requested under R9-25-1201(B)(1) or (C)(3), as required under R9-25-1201(D), and requests a denial as permitted under R9-25-1201(E).

R9-25-710.R9-25-705. Minimum Standards for Operations (<u>Authorized by A.R.S. §§ 36-2202(A)(3)</u> and (4), 36-2209(A)(2), and 36-2213)

- A. An air ambulance service A licensee shall ensure that the air ambulance service:
 - 1. The air ambulance service maintains Maintains eligibility for licensure as required under R9-25-703(C);
 - The air ambulance service publicizes Makes a good faith effort to communicate
 information about its hours of operation to the general public through print media,
 broadcast media, the Internet, or other means;
 - 3. The air ambulance service makes its Makes the air ambulance service's schedule of rates available to any individual upon request and, if requested, in writing;
 - 4. The air ambulance service provides <u>Provides</u> an accurate estimated time of arrival to the person requesting transport at the time that transport is requested and provides an amended estimated time of arrival to the person requesting transport if the estimated time of arrival changes;
 - 5. The air ambulance service transports Except as provided in subsection (B), only transports patients for whom it the air ambulance service has the resources to provide appropriate medical care; unless subsection (B) or (D) applies;
 - 6. The air ambulance service does <u>Does</u> not perform interfacility transport of a patient unless:
 - a. The transport is requested initiated by the sending health care institutions, and
 - i. A physician; or
 - ii. A qualified medical person, as determined by the sending health care institution's bylaws or policies, after consultation with and approval by a physician; and
 - b. The destination health care institution confirms that a bed is available for the patient;
 - 7. Ensures that the protocol for the transfer of information to be communicated to emergency receiving facility staff concurrent with the transfer of care, required in R9-25-201(E)(2)(d)(i), includes:
 - a. The date and time the call requesting service was received by the air

- ambulance service;
- <u>b.</u> The unique number used by the air ambulance service to identify the mission;
- c. The name of the air ambulance service;
- d. The number or other identifier of the air ambulance used for the mission;
- e. The following information about the patient:
 - <u>i.</u> The patient's name;
 - ii. The patient's date of birth or age, as available;
 - iii. The principal reason for requesting services for the patient;
 - iv. The patient's medical history, including any chronic medical illnesses, known allergies to medications, and medications currently being taken by the patient;
 - <u>v.</u> The patient's level of consciousness at initial contact and when reassessed;
 - vi. The patient's pulse rate, respiratory rate, oxygen saturation, and systolic blood pressure at initial contact and when reassessed;
 - vii. The results of an electrocardiograph, if available;
 - viii. The patient's glucose level at initial contact and when reassessed, if applicable;
 - <u>ix.</u> The patient's level of responsiveness score, as applicable, at initial contact and when reassessed;
 - <u>x.</u> The results of the patient's neurological assessment, if applicable;
 and
 - xi. The patient's pain level at initial contact and when reassessed; and
- <u>f.</u> Any procedures or other treatment provided to the patient at the scene or during transport, including any agents administered to the patient;
- 7.8. The air ambulance service creates <u>Creates</u> a prehospital incident history report, as defined in A.R.S. § 36-2220 in a Department-provided format, for each patient that includes the following information:
 - a. The name and identification number of the air ambulance service;
 - <u>b.</u> <u>Information about the software for the storage and submission of the prehospital incident history report;</u>
 - c. The unique number assigned to the mission;
 - d. The unique number assigned to the patient;

- e. Information about the response to the call requesting service, including:
 - i. The mission level requested;
 - <u>ii.</u> <u>Information obtained by the person providing direction for response to the request:</u>
 - iii. Information about the air ambulance assigned to the mission;
 - <u>iv.</u> <u>Information about the medical team responding to the call requesting service;</u>
 - v. The priority assigned to the response; and
 - vi. Response delays, as applicable;
- <u>Mether patient care was transferred from another EMS provider or ambulance</u> <u>service and, if so, identification of the EMS provider or ambulance service;</u>
- g. The date and time that:
 - i. The call requesting service was received;
 - ii. The request was received by the person coordinating transport;
 - iii. The air ambulance service received the transport request;
 - iv. The air ambulance left for the patient's location;
 - v. The air ambulance arrived at the patient's location;
 - vi. The medical team in the air ambulance arrived at the patient's side;
 - vii. Transfer of the patient's care occurred at a location other than the destination, if applicable;
 - viii. The air ambulance departed the patient's location;
 - ix. The air ambulance arrived at the destination;
 - <u>x.</u> <u>Transfer of the patient's care occurred at the destination;</u>
 - xi. The air ambulance was available to take another mission;
- h. Information about the patient, including:
 - i. The patient's first and last name;
 - ii. The address of the patient's residence;
 - iii. The county of the patient's residence;
 - iv. The country of the patient's residence;
 - v. The patient's gender, race, ethnicity, and age;
 - vi. The patient's estimated weight;
 - vii. The patient's date of birth; and
 - <u>viii.</u> <u>If the patient has an alternate residence, the address of the alternate residence;</u>

- i. The primary method of payment for services and anticipated level of payment;
- j. <u>Information about the scene, including:</u>
 - i. Specific information about the location of the scene;
 - ii. Whether the air ambulance was first on the scene;
 - iii. The number of patients at the scene;
 - iv. Whether the scene was the location of a mass casualty incident; and
 - <u>v.</u> <u>If the scene was the location of a mass casualty incident, triage information;</u>
- <u>k.</u> Information about the reason for requesting service for the patient, including:
 - <u>i.</u> The date and time of onset of symptoms and when the patient was last well;
 - ii. Information about the complaint;
 - iii. The patient's symptoms;
 - iv. The results of the medical team's initial assessment of the patient;
 - v. If the patient was injured, information about the injury and the cause of the injury;
 - vi. If the patient experienced a cardiac arrest, information about the etiology of the cardiac arrest and subsequent treatment provided; and
 - vii. For an interfacility transport, the reason for the transport;
- 1. Information about any specific barriers to providing care to the patient;
- m. Information about the patient's medical history, including:
 - i. Known allergies to medications,
 - ii. Surgical history,
 - iii. Current medications, and
 - iv. Alcohol or drug use;
- n. Information about the patient's current medical condition, including the information in subsections (A)(7)(e)(v) through (xi) and the time and method of assessment;
- Information about agents administered to the patient, including the dose and route of administration, time of administration, and the patient's response to the agent;
- <u>p.</u> <u>If not specifically included under subsection (A)(8)(k), (m)(iv), (n), or (o), the information required in A.A.C. R9-4-602(A);</u>
- q. Information about any procedures performed on the patient and the patient's

- response to the procedure;
- r. Whether the patient was transported and, if so, information about the transport;
- s. <u>Information about the destination of the transport, including the reason for choosing the destination;</u>
- t. Whether patient care was transferred to another EMS provider or ambulance service and, if so, identification of the EMS provider or ambulance service;
- <u>Unless patient care was transferred to another EMS provider or ambulance</u>
 service, information about:
 - Whether the destination facility was notified that the patient being transported has a time-sensitive condition and the time of notification;
 - ii. The disposition of the patient at the destination; and
 - iii. The disposition of the mission;
- v. Any other narrative information about the patient, care receive by the patient, or transport; and
- w. The name and certification level of the medical team member providing the information;
- 8.9. The air ambulance service creates Creates a record for each mission that includes:
 - a. Mission date:
 - b. Mission level—basic life support, advanced life support, or critical care;
 - Mission type—emergency medical services transport, interfacility transport, interfacility maternal transport, interfacility neonatal transport, or convalescent transport;
 - d. Staffing of the mission;
 - d.e. Aircraft type—fixed-wing aircraft or rotor-wing aircraft;
 - e.f. Name of the person requesting the transport;
 - f.g. Time of receipt of the transport request;
 - h. The estimated time of arrival, as provided according to subsection (A)(4);
 - gi. Departure time to the patient's location;
 - h.j. Address of the patient's location;
 - i.k. Arrival time at the patient's location;
 - i.l. Departure time to the destination health care institution;
 - k.m. Name and address of the destination health care institution;
 - 4.n. Arrival time at the destination health care institution;
 - m.o. Patient reference number or call number Either the:

- <u>i.</u> Unique reference number used by the air ambulance service to identify the patient, or
- <u>ii.</u> Unique call number used by the air ambulance service to identify the specific mission; and
- n.p. Aircraft tail number for the air ambulance used on the mission; and
- 9. The air ambulance service submits to the Department by the 15th day of each month, either in an electronic format approved by the Department or in hard copy, a run log of the previous month's missions that includes the information required under subsections (A)(8)(a)-(d), (f), (g), (i), (j), (l), and (m) in a cumulative tabular format.
- 10. Establishes, documents, and, if necessary, implements a plan to address and minimize potential issues of patient health and safety due to the air ambulance service terminating operations at a physical address used for the air ambulance service that:
 - <u>a.</u> Is developed in conjunction with hospitals near the physical address used for the air ambulance service and other persons who may be adversely affected by the air ambulance service terminating operations;
 - b. Includes notification by the air ambulance service of the persons in subsection
 (A)(9)(a) of the intent to terminate operations, at least 30 calendar days before the termination of operations; and
 - c. <u>Includes temporary measures that will be used until alternate methods may be</u> arranged for patient transport that address patient health and safety;
- 11. Establishes, documents, and implements a quality improvement program, as specified in policies and procedures, through which:
 - <u>a.</u> Data related to initial patient assessment, patient care, transport services
 <u>provided, and patient status upon arrival at the destination are:</u>
 - i. Collected continuously;
 - ii. For the information required in subsection (A)(8), submitted to the

 Department, in a Department-provided format and within 48 hours after
 the date of a mission, for quality improvement purposes; and
 - iii. If the air ambulance service is notified that the submission of information to the Department according to subsection (A)(11)(a)(ii) was unsuccessful, corrected and resubmitted within seven days after notification;
 - <u>Continuous quality improvement processes are developed to identify, document,</u>
 <u>and evaluate issues related to the provision of services, including:</u>

- i. Care provided to patients with time-sensitive conditions;
- ii. Transport or documentation, and
- iii. Patient status upon arrival at the destination;
- <u>A committee consisting of the administrative medical director, the individual managing the air ambulance service or designee, and other employees as appropriate:</u>
 - i. Review the data in subsection (A)(11)(a) and any issues identified in subsection (A)(11)(b) on at least a quarterly basis; and
 - <u>ii.</u> <u>Implement activities to improve performance when deviations in patient care, transport, or documentation are identified; and</u>
- d. The activities in subsection (A)(11)(c) are documented, consistent with A.R.S. §§ 36-2401, 36-2402, and 36-2403; and
- 12. Beginning within 12 months after the effective date of this Section, establish and maintain a method to electronically document patient information and treatment that is capable of being transferred.
- B. In a rescue situation, when no other practical means of transport, including another air ambulance service, is available, an air ambulance service may deviate from subsection (A)(5) to the extent necessary to meet the rescue situation.
- B. An air ambulance service may transport a patient for whom the air ambulance does not have the resources to provide appropriate medical care:
 - 1. <u>In a rescue situation in which:</u>
 - a. An individual's life, limb, or health is imminently threatened;
 - b. The threat may be reduced or eliminated by removing the individual from the situation to a location in which medical services may be provided; and
 - <u>c.</u> There is no other practical means of transport, including another air ambulance service, available; or
 - 2. For an interfacility transport of a patient if:
 - a. The sending health care institution provides medically appropriate life support measures, staff, and equipment to sustain the patient during the interfacility transport; and
 - <u>Each staff member provided by the sending health care institution has completed</u>
 <u>training in the subject areas listed in R9-25-707(A) before participating in the interfacility transport.</u>
- C. An If an air ambulance service that completes a mission under subsection (B) for which the air

ambulance service does not have the resources to provide appropriate medical care, the licensee shall ensure that the air ambulance service shall create creates a record within five working days after the mission, including:

- 1. the The information required under subsection (A)(8),
- 2. the The manner in which the air ambulance service deviated from subsection (A)(5), and
- 3. the The justification for operating under subsection (B).
- An air ambulance service may provide interfacility transport of a patient for whom it does not have the resources to provide appropriate medical care if the sending health care institution provides medically appropriate life support measures, staff, and equipment to sustain the patient during the interfacility transport.
- An air ambulance service shall ensure that each staff member provided by a sending health care institution under subsection (D) has completed training in the subject areas listed in R9-25-713(A) before serving on a mission.
- <u>D.</u> If an air ambulance service uses a single-member medical team as authorized under R9-25 706(B) and (C), the licensee shall ensure that the air ambulance service creates a record within five working days after the mission, including:
 - 1. The information required under subsection (A)(9),
 - The name and qualifications of the individual comprising the single-member medical team, and
 - 3. The justification for using a single-member medical team.
- <u>F.</u> <u>If an air ambulance service completes a critical care interfacility transport mission under conditions permitted in R9-25-802(F), the licensee shall ensure that the air ambulance service creates a record within five working days after the mission, including:</u>
 - 1. The information required under subsection (A)(9),
 - 2. A description of the life-support equipment used on the mission,
 - 3. A list of the equipment and supplies required in R9-25-802(C) that were removed from the air ambulance for the mission, and
 - 4. The justification for conducting the mission as permitted under R9-25-802(F).
- F. A licensee shall ensure that an individual does not serve on the medical team for an interfacility maternal transport unless the air ambulance service's medical director has verified and attested in writing to the individual's having the proficiencies described in R9-25-706(A)(2).
- G. A licensee shall ensure that an individual does not serve on the medical team for an interfacility neonatal transport unless the air ambulance service's medical director has verified and attested in writing to the individual's having the proficiencies described in R9-25-706(A)(3).

- H. A licensee shall ensure that the air ambulance service:
 - Retains each document required to be created or maintained under this Article or Article
 2 or 8 of this Chapter for at least three years after the last event recorded in the document,
 and
 - 2. Produces each document for Department review upon request.
- I. A licensee shall ensure that, while on a mission, two-way voice communication is available:
 - 1. Between and among personnel on the air ambulance, including the pilot; and
 - Between personnel on the air ambulance and the following persons on the ground:
 - a. Personnel;
 - <u>b.</u> Physicians providing on-line medical direction or on-line medical guidance to medical team members; and
 - c. For a rotor-wing air ambulance mission:
 - i. Emergency medical services providers, and
 - ii. Law enforcement agencies.

R9-25-711.R9-25-706. Minimum Standards for Mission Staffing (Authorized by A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), and 36-2213)

- A. An air ambulance service A licensee shall ensure that, except as provided in subsection (B):
 - 1. Each critical care mission is staffed by a medical team of at least two individuals with at least the following qualifications:
 - a. For a critical care interfacility transport mission:
 - i. A physician or registered nurse; and
 - b.ii. A physician, registered nurse, Paramedic, or licensed respiratory care practitioner; and
 - b. For a critical care mission that is an emergency medical services transport:
 - i. A physician or registered nurse, and
 - ii. A Paramedic:
 - 2. Each interfacility maternal transport mission is staffed by a medical team that:
 - <u>a.</u> Complies with the requirements for a critical care mission medical team in subsection (A)(1); and
 - b. Has the following additional qualifications:
 - <u>i.</u> Proficiency in advanced emergency cardiac life support that includes
 <u>didactic instruction and a practical skills test, consistent with training recognized by the American Heart Association;</u>
 - ii. Proficiency in neonatal resuscitation; and

- iii. Proficiency in stabilization and transport of the pregnant patient;
- 3. Each interfacility neonatal transport mission is staffed by a medical team that:
 - a. Complies with the requirements for a critical care mission medical team in subsection (A)(1); and
 - b. Has the following additional qualifications:
 - i. Proficiency in pediatric advanced emergency life support that includes
 didactic instruction and a practical skills test, consistent with training
 recognized by the American Heart Association; and
 - ii. Proficiency in neonatal resuscitation and stabilization of the neonatal patient; and
- 2.4. Each advanced life support mission is staffed by a medical team of at least two individuals with at least the following qualifications:
 - a. For an advance life support mission that is an emergency medical services transport:
 - i. A physician, registered nurse, or Paramedic; and
 - ii. Another Paramedic; and
 - <u>b.</u> For an advanced life support interfacility transport mission:
 - i. A physician, registered nurse, or Paramedic, and
 - bii. Another Paramedic or a licensed respiratory care practitioner; and
- 3. Each basic life support mission is staffed by a medical team of at least two individuals, each of whom has at least the qualifications of an EMT.
- B. If the pilot on a mission using a rotor-wing air ambulance determines, in accordance with the air ambulance service's written guidelines required under subsection (C) (C)(1), that the weight of a second medical team member could potentially compromise the performance of the rotor-wing air ambulance and the safety of the mission, and the use of a single-member medical team is consistent with the on-line medical direction or on-line medical guidance received as required under subsection (C) (C)(2), an air ambulance service may use a single-member medical team consisting of an individual with at least the following qualification:
 - 1. For a critical care mission, a physician or registered nurse; and
 - 2. For an advanced life support mission, a physician, registered nurse, or Paramedic; and
 - 3. For a basic life support mission, an EMT.
- C. An air ambulance service A licensee shall ensure that:
 - 1. Each air ambulance service rotor-wing pilot is provided <u>with</u> written guidelines to use in determining when the weight of a second medical team member could potentially

- compromise the performance of a rotor-wing air ambulance and the safety of a mission, including the conditions of density altitude and weight that warrant the use of a single-member medical team;
- 2. The following are done, without delay, after an air ambulance service rotor-wing pilot determines that the weight of a second medical team member could potentially compromise the performance of a rotor-wing air ambulance and the safety of a mission:
 - a. The pilot communicates that information to the medical team,
 - b. The medical team obtains on-line medical direction or on-line medical guidance regarding the use of a single-member medical team, and
 - c. The medical team proceeds in compliance with the on-line medical direction or on-line medical guidance;
- 3. A single-member medical team has the knowledge and medical equipment to perform one-person cardiopulmonary resuscitation;
- 4. The air ambulance service has a quality management process to review regularly the patient care provided by each single-member medical team, including consideration of each patient's status upon arrival at the destination health care institution, is reviewed through the quality improvement processes in R9-25-705(A)(11)(b) and (c); and
- 5. A single-member medical team is used only when no other transport team is available that would be more appropriate for delivering the level of care that a patient requires.
- An air ambulance service that uses a single member medical team as authorized under subsection (B) shall create a record within five working days after the mission, including the information required under R9 25 710(A)(8), the name and qualifications of the individual comprising the single member medical team, and the justification for using a single member medical team.
- E.D. An A licensee shall ensure that the air ambulance service shall ereate creates and maintain maintains for each personnel member a file containing documentation of the personnel member's qualifications, including, as applicable, licenses, certifications, and training records.

R9-25-713.R9-25-707. Minimum Standards for Training (<u>Authorized by A.R.S. §§ 36-2202(A)(4)</u>, 36-2209(A)(2), and 36-2213)

- A. An air ambulance service A licensee shall ensure that each medical team member completes training in the following subjects before serving on a mission:
 - 1. Aviation terminology;
 - 2. Physiological aspects of flight;
 - 3. Patient loading and unloading;
 - 4. Safety in and around the aircraft;

- 5. In-flight communications;
- 6. Use, removal, replacement, and storage of the medical equipment installed on the aircraft;
- 7. In-flight emergency procedures;
- 8. Emergency landing procedures; and
- 9. Emergency evacuation procedures.
- B. An air ambulance service A licensee shall ensure that the air ambulance service document documents each medical team member's completion of the training required under subsection (A), including the name of the medical team member, each training component completed, and the date of completion.

R9-25-715.R9-25-708. Minimum Standards for Medical Control (Authorized by A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), and 36-2213)

- A. An air ambulance service A licensee shall ensure that:
 - 1. The air ambulance service has a <u>an administrative</u> medical director who:
 - a. Meets the qualifications in subsection (B);
 - b. Supervises and evaluates the quality of medical care provided by medical team members;
 - c. Ensures the competency and current qualifications of all medical team members;
 - d. Ensures that each EMCT medical team member receives medical direction as required under Article 2 of this Chapter;
 - e. Ensures that each non-EMCT medical team member receives medical guidance through:
 - i. Written treatment protocols; and
 - ii. On line medical guidance provided by:
 - (1) The medical director;
 - (2) Another physician designated by the medical director; or
 - (3) If the medical guidance needed exceeds the medical director's area of expertise, a consulting specialty physician; and
 - d. Except as provided in subsections (A)(3) and (4), ensures that:
 - <u>i.</u> Each EMCT medical team member receives medical direction as required under Article 2 of this Chapter; and
 - <u>ii.</u> Each non-EMCT medical team member receives medical guidance through written treatment protocols and according to subsection (C); and
 - f.e. Approves, ensures implementation of, and annually reviews treatment protocols

to be followed by medical team members;

- 2. The air ambulance service has a quality management program through which:
 - a. Data related to patient care and transport services provided and patient status upon arrival at destination are:
 - i. Collected continuously; and
 - ii. Examined regularly, on at least a quarterly basis; and
 - b. Appropriate corrective action is taken when concerns are identified; and
- 3. The air ambulance service documents each concern identified through the quality management program and the corrective action taken to resolve each concern and provides this information, along with the supporting data, to the Department upon request.
- 2. The administrative medical director reviews data related to patient care and transport services provided, documentation, and patient status upon arrival at destination that are collected through the quality management program in R9-25-705(A)(11);
- 3. For an interfacility maternal transport mission, on-line medical direction or on-line medical guidance provided to medical team member is provided by a physician who meets the qualifications of subsection (B)(2)(b)(i);
- 4. For an interfacility neonatal transport mission, on-line medical direction or on-line medical guidance provided to medical team member is provided by a physician who meets the qualifications of subsection (B)(2)(b)(ii);
- B. A An administrative medical director shall:
 - 1. Be a physician, as defined in A.R.S. § 36-2201; and
 - 2. Comply with one of the following:
 - a. If the air ambulance service provides emergency medical services transports, meet the qualifications of R9-25-201(A)(1); or
 - b. If the air ambulance service does not provide emergency medical services transports, meet the qualifications of R9-25-201(A)(1) or one of the following:
 - i. If the air ambulance service provides only interfacility maternal <u>transport</u> missions, have board certification or have completed an accredited residency program in one of the following specialty areas:
 - (1) Obstetrics and gynecology, with subspecialization in critical care medicine or maternal and fetal medicine; or
 - (2) Pediatrics, with subspecialization in neonatal-perinatal medicine;
 - ii. If the air ambulance service provides only interfacility neonatal transport

missions, have board certification or have completed an accredited residency program in one of the following specialty areas:

- (1) Obstetrics and gynecology, with subspecialization in maternal and fetal medicine; or
- (2) Pediatrics, with subspecialization in neonatal-perinatal medicine, neonatology, pediatric critical care medicine, or pediatric intensive care; or
- iii. If neither subsection (B)(2)(b)(i) or (ii) applies, have board certification or have completed an accredited residency program in one of the following specialty areas:
 - (1) Anesthesiology, with subspecialization in critical care medicine;
 - (2) Internal medicine, with subspecialization in critical care medicine;
 - (3) If the air ambulance service transports only pediatric patients, pediatrics, with subspecialization in pediatric critical care medicine or pediatric emergency medicine; or
 - (4) If the air ambulance service transports only surgical patients, surgery, with subspecialization in surgical critical care.
- <u>C.</u> An administrative medical director shall ensure that each non-EMCT medical team member receives on-line medical guidance provided by:
 - 1. The administrative medical director;
 - 2. Another physician designated by the administrative medical director; or
 - 3. If the medical guidance needed exceeds the administrative medical director's area of expertise, a consulting specialty physician.

R9-25-707.R9-25-709. Changes Affecting a License (<u>Authorized by A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2)</u>, and 36-2213)

- A. At least 30 days before the date of a change in an air ambulance service's name, the air ambulance service licensee shall send the Department written notice of the name change.
- B. At least 90 days before an air ambulance service ceases to operate, the air ambulance service

 licensee shall send the Department written notice of the intention to cease operating, effective on a specific date, and the desire licensee's intention to relinquish its the air ambulance service's license as of that date.
- C. Within 30 days after the date of receipt of a notice described in subsection (A) or (B), the Department shall:

- 1. For a notice described in subsection (A), issue an amended license that incorporates the name change but retains the expiration date of the current license; and
- 2. For a notice described in subsection (B), send the <u>air ambulance service licensee</u> written confirmation of the voluntary relinquishment of <u>its the air ambulance service</u>'s license, with an effective date consistent with the written notice.
- **D.** A licensee shall notify the Department in writing at least 30 calendar days before:
 - 1. Changing the physical address used for the air ambulance service, as provided according to R9-25-704(A)(1)(c); or
 - 2. Terminating operations at a physical address used for the air ambulance service, as provided according to R9-25-704(A)(1)(c).
- **D.E.** An air ambulance service A licensee shall notify the Department in writing within one working day after:
 - 1. A change in its the air ambulance service's eligibility for licensure under R9-25-703(B) or (C);
 - 2. A change in the business organization information most recently submitted to the Department under R9-25-704(A)(5) or R9-25-705(A) according to R9-25-704(A)(1)(f);
 - 3. A change in its the air ambulance service's CAMTS accreditation status, including a copy of its the air ambulance service's new CAMTS accreditation report, if applicable;
 - 4. A change in its the air ambulance service's hours of operation, as specified according to R9-25-704(A)(1)(h);
 - 5. A change in the air ambulance service's or schedule of rates, as specified according to R9-25-704(A)(1)(i); or
 - 5.6. A change in the scope of the mission types provided, as specified according to R9-25-704(A)(1)(j).
- E. Before the date of an anticipated change of ownership, a person wanting to transfer an air ambulance service license shall submit to the Department the documents required under R9-25-706(D).
- F. If the Department receives a notice specified in subsection (E)(6), the Department:
 - Shall reissue a license for the air ambulance service reflecting the change, but retaining the expiration date on the original license; and
 - 2. May conduct an inspection according to R9-25-711.
- R9-25-706.R9-25-710. Term and Transferability of License (<u>Authorized by A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), 36-2213, 36-2214, and 41-1092.11)</u>
- A. The Department shall issue an initial license:

- When based on current CAMTS accreditation, with a term beginning on the date of issuance of the initial license and ending on the expiration date of the CAMTS accreditation upon which licensure is based; and
- 2. When based on Department inspection, with a term beginning on the date of issuance of the initial license and ending three years later.
- B. The Department shall issue a renewal license with a term beginning on the day after the expiration date shown on the previous license and ending:
 - 1. When based on current CAMTS accreditation, on the expiration date of the CAMTS accreditation upon which licensure is based; and
 - 2. When based on Department inspection, three years after the effective date of the renewal license.
- C. If an applicant a licensee submits an application packet for renewal as described in R9-25-705

 R9-25-704(B) before the expiration date of the current license, the current license does not expire until the Department has made a final determination on the application for renewal, as provided in A.R.S. § 41-1092.11.
- D. A person wanting to transfer an air ambulance service license shall submit to the Department At least 30 days before the an anticipated change of ownership:
 - 1. A <u>licensee wanting to transfer an air ambulance service license shall submit a</u> letter <u>to the</u>

 Department that contains:
 - a. A request that the air ambulance service license be transferred,
 - b. The name and license number of the currently licensed air ambulance service, and
 - The name of the person to whom the air ambulance service license is to be transferred; and
 - 2. An The person to whom the license is to be transferred shall submit to the Department an application packet that complies with R9-25-704(A) completed by the person to whom the license is to be transferred.
- E. A new owner shall not operate an air ambulance in this state until:
 - 1. The new owner complies with requirements in Articles 7 and 8 of this Chapter, and
 - <u>2.</u> the <u>The Department has transferred issued</u> an air ambulance service license to the new owner.
- R9-25-708.R9-25-711. Inspections and Investigations (<u>Authorized by A.R.S. §§ 36-2202(A)(4)</u>, 36-2209(A)(2), 36-2213, and 36-2214)
- A. Except as provided in subsections (D) and (F) (E), the Department shall inspect an air ambulance

- service, as required under A.R.S. § 36-2214(B), before issuing an initial or renewal license, as required under A.R.S. § 36-2214(B), and as often as necessary to determine compliance with this Article, Articles 2 and 8 of this Chapter, and A.R.S. Title 36, Chapter 21.1.
- **B.** A Department inspection may include the <u>air ambulance service's</u> premises, <u>records</u>, <u>and</u> equipment, and each air ambulance operated or to be operated for <u>by</u> the air ambulance service.
- C. If the Department receives written or verbal information alleging a violation of this Article, Article 2 or 8 of this Chapter, or A.R.S. Title 36, Chapter 21.1, the Department shall conduct an investigation.
 - 1. The Department may conduct an inspection as part of an investigation.
 - 2. An air ambulance service A licensee shall allow the Department to inspect the <u>air</u> ambulance service's premises, records, and equipment, and each air ambulance and to interview personnel as part of an investigation.
- As required under A.R.S. § 36-2213(8), the Department shall accept proof of current CAMTS accreditation in lieu of the licensing inspections otherwise required before initial and renewal licensure under subsection (A) and A.R.S. § 36-2214(B).
- E. To establish current CAMTS accreditation, an applicant or air ambulance service shall submit to the Department a copy of its current CAMTS accreditation report as required under R9-25-704(C), R9-25-705(C), or R9-25-707(D).
- <u>D.</u> Except as provided in subsection (C), the Department shall not conduct an inspection of an air ambulance service before issuing an initial or renewal license if an applicant or licensee provides documentation of current CAMTS certification as part of the application packet according to R9-25-704(A)(9).
- **F.E.** When an application for an air ambulance service license is submitted along with a transfer request due to a change of ownership, the Department shall determine whether an inspection is necessary based upon the potential impact to public health, safety, and welfare.
- G.F. The Department shall conduct each inspection in compliance with A.R.S. § 41-1009.
- G. If the Department determines that an air ambulance service is not in compliance with the requirements in this Article, Article 2 or 8 of this Chapter, or A.R.S. Title 36, Chapter 21.1, the Department may:
 - 1. Take an enforcement action as described in R9-25-712; or
 - 2. Require that the air ambulance service submit to the Department, within 15 days after written notice from the Department, a corrective action plan to address issues of compliance that do not directly affect the health or safety of a patient that:
 - a. Describes how each identified instance of non-compliance will be corrected and

reoccurrence prevented, and

<u>b.</u> <u>Includes a date for correcting each instance of non-compliance that is appropriate</u> to the actions necessary to correct the instance of non-compliance.

R9-25-712. Expired

R9-25-709.R9-25-712. Enforcement Actions (<u>Authorized by A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), 36-2213, 36-2214, 36-2215, 41-1092.03, and 41-1092.11(B))</u>

- A. The Department may take an action listed in subsection (B) against an air ambulance service that:
 - 1. Fails to meet the eligibility requirements of R9-25-703(B) or (C);
 - 2. Fails or has failed to comply with any provision in A.R.S. Title 36, Chapter 21.1;
 - 3. Fails or has failed to comply with any provision in this Article or Article 2 or 8 of this Chapter;
 - 4. Does not submit a corrective action plan, as provided in R9-25-711(G)(2), that is acceptable to the Department;
 - 5. Does not complete a corrective action plan submitted according to R9-25-711(G)(2); or
 - 4.6. Knowingly or negligently provides false documentation or false or misleading information to the Department or to a patient, third-party payor, or other person billed for service.
- **B.** The Department may take the following actions against an air ambulance service:
 - 1. Except as provided in subsection (B)(3), after notice and an opportunity to be heard is provided under A.R.S. Title 41, Chapter 6, Article 10, suspend:
 - a. the The air ambulance service license, or
 - b. The certificate of registration of an air ambulance operated by the air ambulance service;
 - 2. After notice and an opportunity to be heard is provided under A.R.S. Title 41, Chapter 6, Article 10, revoke:
 - a. the The air ambulance service license, or
 - <u>b.</u> The certificate of registration of an air ambulance operated by the air ambulance service; and
 - 3. As permitted under A.R.S. § 41-1092.11(B), If if the Department determines that the public health, safety, or welfare imperatively requires emergency action and incorporates a finding to that effect in its the Department's order, summarily immediately suspend:
 - <u>a.</u> the <u>The</u> air ambulance service license pending proceedings for revocation or other action, as permitted under A.R.S. § 41–1092.11(B), or
 - b. The certificate of registration of an air ambulance operated by the air ambulance

service pending proceedings for revocation or other action.

- C. In determining whether to take action under subsection (B), the Department shall consider:
 - 1. The severity of each violation relative to public health and safety;
 - 2. The number of violations relative to the transport volume of the air ambulance service;
 - 3. The nature and circumstances of each violation;
 - 4. Whether each violation was corrected and, if so, the manner of correction; and
 - 5. The duration of each violation.

R9-25-713. Renumbered

R9-25-714. Minimum Standards for Communications (A.R.S. §§ 36-2202(A)(3) and (4), 36-2209(A)(2), and 36-2213) Repealed

An air ambulance service shall ensure that, while on a mission, two-way voice communication is available:

- 1. Between and among personnel on the air ambulance, including the pilot; and
- 2. Between personnel on the air ambulance and the following persons on the ground:
 - a. Personnel;
 - b. Physicians providing on line medical direction or on line medical guidance to medical team members; and
 - e. For a rotor-wing air ambulance mission:
 - i. Emergency medical services providers, and
 - ii. Law enforcement agencies.

R9-25-715. Renumbered

R9-25-716. Minimum Standards for Recordkeeping (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2213) Repealed

An air ambulance service shall retain each document required to be created or maintained under this Article or Article 2 or 8 of this Chapter for at least three years after the last event recorded in the document and shall produce each document for Department review upon request.

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) Repealed

An air ambulance service shall ensure that:

- 1. Each interfacility neonatal mission is staffed by a medical team that complies with the requirements for a critical care mission medical team in R9-25-711(A)(1) and that has the following additional qualifications:
 - a. Proficiency in pediatric emergency care, as defined in R9-25-101; and
 - b. Proficiency in neonatal resuscitation and stabilization of the neonatal patient;

- 2. Each interfacility neonatal mission is conducted using an air ambulance that has the equipment and supplies required for a critical care mission in Table 1 of Article 8 of this Chapter and the following:
 - a. A transport incubator with:
 - i. Battery and inverter capabilities,
 - ii. An infant safety restraint system, and
 - iii. An integrated neonatal-capable pressure ventilator with oxygen-air supply and blender;
 - b. An invasive automatic blood pressure monitor;
 - e. A neonatal monitor or monitors with heart rate, respiratory rate, temperature, non-invasive blood pressure, and pulse oximetry capabilities;
 - d. Neonatal-specific drug concentrations and doses;
 - e. Umbilical catheter insertion equipment and supplies;
 - f. Thoracostomy supplies;
 - g. Neonatal resuscitation equipment and supplies;
 - h. A neonatal size cuff (size 2, 3, or 4) for use with an automatic blood pressure monitor; and
 - i. A neonatal probe for use with a pulse oximeter;
- 3. On line medical direction or on line medical guidance provided to an interfacility neonatal mission medical team member is provided by a physician who meets the qualifications of R9-25-715(B)(2)(b)(ii); and
- 4. An individual does not serve on an interfacility neonatal mission medical team unless the air ambulance service's medical director has verified and attested in writing to the individual's having the proficiencies described in subsections (1)(a) and (b).
- 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) Repealed
- A. This Section applies to an air ambulance service that holds itself out as providing interfacility maternal missions.
- B. An air ambulance service shall ensure that:
 - 1. Each interfacility maternal mission is staffed by a medical team that complies with the requirements for a critical care mission medical team in R9-25-711(A)(1) and that has the following additional qualifications:
 - a. Proficiency in advanced emergency cardiac life support, as defined in R9-25 101;

- b. Proficiency in neonatal resuscitation; and
- e. Proficiency in stabilization and transport of the maternal patient;
- 2. Each interfacility maternal mission is conducted using an air ambulance that has the equipment and supplies required for a critical care mission in Table 1 of Article 8 of this Chapter and the following:
 - a. A Doppler fetal heart monitor;
 - b. Unless use is not indicated for the patient as determined through on-line medical direction or on-line medical guidance provided as described in subsection (B)(3), an external fetal heart and tocographic monitor with printer capability;
 - e. Tocolytic and anti-hypertensive medications;
 - d. Advanced emergency cardiac life support equipment and supplies; and
 - e. Neonatal resuscitation equipment and supplies;
- 3. On-line medical direction or on-line medical guidance provided to an interfacility maternal mission medical team member is provided by a physician who meets the qualifications of R9-25-715(B)(2)(b)(i); and
- 4. An individual does not serve on an interfacility maternal mission medical team unless the air ambulance service's medical director has verified and attested in writing to the individual's having the proficiencies described in subsections (B)(1)(a), (b), and (c).

ARTICLE 8. AIR AMBULANCE REGISTRATION

- R9-25-801. Definitions (A.R.S. §§ 36-2202(A)(4), 36-2209(A)(2), and 36-2212)

 In addition to the definitions in R9-25-701, the following definitions apply in this Article, unless otherwise specified:
 - 1. "Certificate holder" means a person who holds a current and valid certificate of registration for an air ambulance.
 - 2. "Drug" has the same meaning as in A.R.S. § 32-1901.
- R9-25-802, R9-25-801. Requirement, Eligibility, and Application for an Initial or Renewal Certificate of Registration for an Air Ambulance (<u>Authorized by A.R.S.</u> §§ 36-2202(A)(4) and (5), 36-2209(A)(2), 36-2212, 36-2213, 36-2214, <u>36-2232(A)(11)</u>, and 36-2240(4))
- A. A person shall not operate an air ambulance in this state unless the person has a current and valid air ambulance service license as required under Article 7 of this Chapter and, except as provided in A.R.S. § 36-2212(C), a current and valid certificate of registration for the air ambulance as required under this Article.
- **B.A.** To be eligible to obtain a certificate of registration for an air ambulance, an applicant shall:
 - 1. Hold a current and valid air ambulance service license issued under Article 7 of this Chapter;
 - 2. Hold the following issued by the Federal Aviation Administration for the air ambulance:
 - a. A current and valid Certificate of Registration, and
 - b. A current and valid Airworthiness Certificate;
 - 3. Hold Possess a copy of a current and valid registration for the air ambulance, issued by the Arizona Department of Transportation under A.R.S. Title 28, Chapter 25, Article 4, to the owner of the aircraft; and
 - 4. Comply with all applicable requirements of this Article, Articles 2 and 7 of this Chapter, and A.R.S. Title 36, Chapter 21.1.
- C.B. To obtain an initial or renewal certificate of registration for an air ambulance, an An applicant for an initial or renewal certificate of registration for an air ambulance shall submit an application packet to the Department, an application completed using a Department provided form and including:
 - 1. The following information in a Department-provided format:
 - <u>a.</u> <u>The applicant's name; mailing address; e-mail address; fax number, if any; and telephone number;</u>

- 2.b. All other business names used The names of all other business organizations operated by the applicant related to the use of an air ambulance;
- 3.c. The applicant's physical business address of the applicant, if different from the mailing address;
- d. If applicable, the number of the applicant's air ambulance service license;
- e. The name, title, address, e-mail address, and telephone number of the individual acting on behalf of the applicant according to R9-25-102;
- <u>f.</u> The name, address, telephone number, and e-mail address of the owner of the air ambulance, if different from the applicant;
- 4. The following information about the air ambulance for which registration is sought:
 - a. Each mission level for which the air ambulance will be used:
 - i. Basic life support,
 - ii. Advanced life support, or
 - iii. Critical care;
 - b.g. Whether the air ambulance is a fixed-wing or rotor-wing aircraft;
 - e.h. Number The number of engines on the air ambulance;
 - d.i. Manufacturer The manufacturer's name;
 - e.j. Model The model name of the air ambulance;
 - f.k. Year The year the air ambulance was manufactured;
 - g.l. Serial The serial number of the air ambulance;
 - h.m. Aircraft The tail number of the air ambulance;
 - in. Aircraft The aircraft colors, including fuselage, stripe, and lettering; and
 - j.o. A description of any insignia, monogram, or other distinguishing characteristics of the aircraft's appearance;
- 5. A copy of the following issued to the applicant, for the air ambulance, by the Federal Aviation Administration:
 - a. A current and valid Certificate of Registration, and
 - b. A current and valid Airworthiness Certificate;
- 6. A copy of a current and valid registration issued to the applicant, for the air ambulance, by the Arizona Department of Transportation under A.R.S. Title 28, Chapter 25, Article 4;
 - p. The address at which the air ambulance is usually based;
 - 7.q. The location address in Arizona at which the air ambulance will be available for inspection;

- 8-<u>r.</u> The name and telephone number of the individual to contact to arrange for inspection, if the inspection is preannounced;
- Whether the applicant agrees to allow the Department to submit supplemental requests for information under R9-25-1201(C)(3);
- 9. Attestation that the applicant knows all applicable requirements in A.R.S. Title 36, Chapter 21.1; this Article; and Articles 2 and 7 of this Chapter;
- 10.t. Attestation that the information provided in the application <u>packet</u>, including the information in the <u>accompanying</u> documents accompanying the application form, is accurate and complete; and
- 11.u. The dated signature of the applicant:
- a. If the applicant is an individual, the individual;
- b. If the applicant is a corporation, an officer of the corporation;
- e. If the applicant is a partnership, one of the partners;
- d. If the applicant is a limited liability company, a manager or, if the limited liability company does not have a manager, a member of the limited liability company;
- e. If the applicant is an association or cooperative, a member of the governing board of the association or cooperative;
- f. If the applicant is a joint venture, one of the individuals signing the joint venture agreement;
- g. If the applicant is a governmental agency, the individual in the senior leadership position with the agency or an individual designated in writing by that individual; and
- h. If the applicant is a business organization type other than those described in subsections (C)(11)(b) through (f), an individual who is a member of the business organization;
- 2. A copy of the following for the air ambulance, issued by the Federal Aviation Administration:
 - a. A current and valid Certificate of Registration, and
 - b. A current and valid Airworthiness Certificate;
- 3. A copy of a current and valid registration for the air ambulance, issued by the Arizona Department of Transportation under A.R.S. Title 28, Chapter 25, Article 4;
- 4. If a document required under subsection (B)(2) or (3) is not issued in the name of the applicant, documentation showing the applicant can legally possess and operate the

- aircraft covered by the document, signed by the owner of the aircraft; and
- 12.5. Unless the applicant operates or intends to operate the air ambulance only as a volunteer not-for-profit service, a certified cheek, business cheek, or money order made payable to the Arizona Department of Health Services for the following fees:
 - a. A \$50 registration fee, as required under A.R.S. § 36-2212(D); and
 - b. A \$200 annual regulatory fee, as required under A.R.S. § 36-2240(4).
- **D.C.** The Department requires submission of a separate application and the fees in subsection (B)(5) for each air ambulance.
- Except as provided under R9-25-805(C) in A.R.S. § 36-2232(A)(11), the Department shall inspect each air ambulance according to R9-25-805(A) and (B) to determine compliance with the provisions of A.R.S. Title 36, Chapter 21.1 and this Article:
 - 1. before Within 30 calendar days before issuing an initial certificate of registration; and
 - 2. at At least every 12 months thereafter, before issuing a renewal certificate of registration.
- **F.E.** The Department shall review and approve or deny each application as described in Article 12 of this Chapter.
- <u>F.</u> <u>If the Department approves the application and sends the applicant the written notice of approval, specified in R9-25-1201(C)(5), the Department shall issue the certificate of registration to the applicant:</u>
 - For an applicant with a current and valid air ambulance service license issued under
 Article 7 of this Chapter, within five working days after the date on the written notice of approval; and
 - For an applicant that does not have a current and valid air ambulance service license
 issued under Article 7 of this Chapter, when the air ambulance service license is issued.
- G. The Department may deny a certificate of registration for an air ambulance if the applicant:
 - 1. Fails to meet the eligibility requirements of R9-25-802(B) subsection (A);
 - 2. Fails or has failed to comply with any provision in A.R.S. Title 36, Chapter 21.1;
 - 3. Fails or has failed to comply with any provision in this Article or Article 2 or 7 of this Chapter;
 - 4. Knowingly or negligently provides false documentation or false or misleading information to the Department; or
 - 5. Fails to submit to the Department documents or information requested under R9-25-1201(B)(1) or (C)(3), as required under R9-25-1201(D), and requests a denial as permitted under R9-25-1201(E).

R9-25-807. R9-25-802. Minimum Standards for an Air Ambulance (<u>Authorized by A.R.S. §§ 36-2202(A)(3), (4), and (5); 36-2209(A)(2); and 36-2212)</u>

- A. An applicant or certificate holder shall ensure that an air ambulance has:
 - 1. A climate control system to prevent temperature extremes that would adversely affect patient care;
 - 2. If a fixed-wing air ambulance, pressurization capability;
 - 3. Interior lighting that allows for patient care and monitoring without interfering with the pilot's vision;
 - 4. For each place where a patient may be positioned, at least one electrical power outlet or other power source that is capable of operating all electrically powered medical equipment without compromising the operation of any electrical aircraft equipment;
 - 5. A back-up source of electrical power or batteries capable of operating all electrically powered life-support equipment for at least one hour;
 - 6. An entry that allows for patient loading and unloading without rotating a patient and stretcher more than 30 degrees about the longitudinal axis or 45 degrees about the lateral axis and without compromising the operation of monitoring systems, intravenous lines, or manual or mechanical ventilation;
 - 7. A configuration that allows each medical team member sufficient access to each patient to begin and maintain treatment modalities, including complete access to the patient's head and upper body for effective airway management;
 - 8. A configuration that allows for rapid exit of personnel and patients, without obstruction from stretchers and medical equipment;
 - A configuration that protects the aircraft's flight controls, throttles, and communications
 equipment from any intentional or accidental interference from a patient or equipment
 and supplies;
 - 10. A padded interior or an interior that is clear of objects or projections in the head strike envelope;
 - 11. An installed self-activating emergency locator transmitter;
 - 12. A voice communications system that:
 - a. Is capable of air-to-ground communication, and
 - b. Allows the flight crew and medical team members to communicate with each other during flight;
 - 13. Interior patient compartment wall and floor coverings that are:
 - a. Free of cuts or tears,

- b. Made from non-absorbent material,
- b.c. Capable of being disinfected, and
- e.d. Maintained in a sanitary manner; and
- 14. If a rotor-wing air ambulance, the following:
 - a. A searchlight that:
 - i. Has a range of motion of at least 90 degrees vertically and 180 degrees horizontally,
 - ii. Is capable of illuminating a landing site, and
 - iii. Is located so that the pilot can operate the searchlight without removing the pilot's hands from the aircraft's flight controls;
 - b. Restraining devices that can be used to prevent a patient from interfering with the pilot or the aircraft's flight controls; and
 - c. A light to illuminate the tail rotor.
- **B.** An applicant or certificate holder shall ensure that:
 - 1. Except as provided in subsection (C) subsections (D), (E), and (F), each air ambulance has the equipment and supplies required in Table 1 subsection (C) for each mission level for which the air ambulance is used; and
 - 2. The equipment and supplies on an air ambulance are secured, stored, and maintained in a manner that prevents hazards to personnel and patients.
- <u>C.</u> An applicant or certificate holder shall ensure that an air ambulance used for an advanced life support mission or critical care mission has the following equipment and supplies:
 - 1. The following ventilation and airway equipment and supplies:
 - <u>a.</u> <u>Portable and fixed suction apparatus, with wide-bore tubing, rigid pharyngeal</u> curved suction tip, tonsillar and flexible suction catheters, 5F-14F;
 - b. Portable and fixed oxygen equipment, with variable flow regulators;
 - Oxygen administration equipment, including: tubing; non-rebreathing masks
 (adult and pediatric sizes); and nasal cannulas (adult and pediatric sizes);
 - <u>d.</u> Bag-valve mask, with hand-operated, self-reexpanding bag (adult size), with
 oxygen reservoir/accumulator; mask (adult, pediatric, infant, and neonate sizes);
 and valve;
 - e. Airways, oropharyngeal (adult, pediatric, and infant sizes);
 - <u>f.</u> Laryngoscope handle, adult and pediatric, with, if applicable, extra batteries and bulbs;
 - g. Laryngoscope blades, sizes 0, 1, and 2, straight; sizes 3 and 4, straight and

curved;

- <u>h.</u> Endotracheal tube cuff pressure manometer;
- i. Endotracheal tubes, sizes 2.5-5.0 mm cuffed or uncuffed and 6.0-8.0 mm cuffed;
- j. Stylettes for Endotracheal tubes, adult and pediatric;
- k. Airways, nasal (adult, pediatric, and infant sizes), one each in French sizes 16 to 34;
- 1. One type of supraglottic airway device, adult and pediatric;
- m. 10 mL straight-tip syringes;
- <u>Small volume nebulizer(s) and aerosol masks, adult and pediatric;</u>
- o. Magill forceps, adult and pediatric;
- p. Nasogastric tubes, sizes 5F and 8F, Salem sump sizes 14F and 18F;
- <u>q.</u> End-tidal CO2 detectors, quantitative;
- <u>r.</u> Portable automatic ventilator with positive end expiratory pressure; and
- s. <u>In-line viral/bacterial filter;</u>
- 2. The following monitoring and defibrillation equipment and supplies:
 - a. Portable, battery-operated monitor/defibrillator, with:
 - i. Tape write-out/recorder,
 - ii. Defibrillator pads,
 - iii. Adult and pediatric paddles or hands-free patches,
 - iv. ECG leads,
 - v. Adult and pediatric chest attachment electrodes, and
 - vii. Capability to provide electrical discharge below 25 watt-seconds; and
 - b. Transcutaneous cardiac pacemaker, either stand-alone unit or integrated into monitor/defibrillator;
- 3. For rotor wing aircraft only, the following immobilization devices and supplies:
 - a. Cervical collars, rigid, adjustable or in an assortment of adult and pediatric sizes;
 - b. Head immobilization device, either firm padding or another commercial device;
 - <u>Lower extremity (femur) traction device, including lower extremity, limb support</u>
 <u>slings, padded ankle hitch, padded pelvic support, and traction strap; and</u>
 - d. Upper and lower extremity immobilization splints;
- 4. The following bandages:
 - a. Burn pack, including standard package, clean burn sheets;
 - b. Dressings, including:
 - i. Sterile multi-trauma dressings (various large and small sizes);

- ii. Abdominal pads, 10" x 12" or larger; and
- iii. 4" x 4" gauze sponges;
- c. Gauze rolls, sterile (4" or larger);
- d. Elastic bandages, non-sterile (4" or larger);
- e. Occlusive dressing, sterile, 3" x 8" or larger; and
- f. Adhesive or self-adhesive tape, including various sizes (1" or larger)
 hypoallergenic and various sizes (1" or larger) adhesive or self-adhesive;
- 5. The following obstetrical equipment and supplies:
 - a. Separate sterile obstetrical kit, including:
 - i. Towels,
 - ii. 4" x 4" dressing,
 - iii. Umbilical tape,
 - iv. Sterile seissors or other cutting utensil,
 - v. Bulb suction,
 - vi. Clamps for cord,
 - vii. Sterile gloves,
 - viii. Blankets, and
 - ix. A head cover; and
 - b. An alternate portable patient heat source or two heat packs;
- 6. The following infection control equipment and supplies, including the availability of latex-free:
 - a. Eye protection (full peripheral glasses or goggles, face shield);
 - Masks, at least as protective as a National Institute for Occupational Safety and
 Health-approved N-95 respirator, which are fit-tested;
 - c. Gloves, non-sterile;
 - d. Jumpsuits or gowns;
 - e. Shoe covers;
 - f. Disinfectant hand wash, commercial antimicrobial (towelette, spray, or liquid);
 - g. <u>Disinfectant solution for cleaning equipment;</u>
 - h. Standard sharps containers;
 - i. Disposable red trash bags; and
 - j. Protective facemasks or cloth face coverings for patients;
- 7. The following injury prevention equipment:
 - Appropriate restraints, such as seat belts or, if applicable, child safety restraints,

- for patient, personnel, and family members;
- b. For rotor wing aircraft only, safety vest or other garment with reflective material for each personnel member;
- c. Fire extinguisher, either disposable with an indicator of a full charge or with a current inspection tag;
- d. Hazardous material reference guide; and
- e. Hearing protection for patient and personnel;
- 8. The following vascular access equipment and supplies:
 - a. Intravenous administration equipment, with fluid in bags;
 - b. Antiseptic solution (alcohol wipes and povidone-iodine wipes):
 - <u>c.</u> <u>Intravenous pole or roof hook;</u>
 - d. Intravenous catheters 14G-24G;
 - e. Intraosseous needles, adult and pediatric sizes;
 - f. Venous tourniquet;
 - g. One of each of the following types of intravenous solution administration sets:
 - i. A set with blood tubing,
 - ii. A set capable of delivering 60 drops per cc, and
 - iii. A set capable of delivering 10 or 15 drops per cc;
 - h. Intravenous arm boards, adult and pediatric;
 - i. IV pump or pumps (minimum of 3 infusion lines); and
 - i. IV pressure bag;
- 9. The agents, specified in a table of agents established according to A.R.S. § 36-2204 and available through the Department at www.azdhs.gov/ems-regulatory-references, that an administrative medical director has authorized for use, based on the EMCT classification of the medical team; and
- 10. The following miscellaneous equipment and supplies:
 - a. Sphygmomanometer (infant, pediatric, and adult regular and large sizes);
 - b. Stethoscope;
 - c. Pediatric equipment sizing reference guide;
 - d. Thermometer with low temperature capability;
 - e. Heavy bandage or paramedic scissors for cutting clothing, belts, and boots;
 - f. Cold packs;
 - g. Flashlight (1) with extra batteries or recharger, as applicable;
 - h. Blankets;

- i. Sheets;
- <u>Disposable emesis bags or basins;</u>
- k. For fixed wing aircraft only, a disposable bedpan;
- 1. For fixed wing aircraft only, a disposable urinal;
- m. Properly secured patient transport system;
- n. <u>Lubricating jelly (water soluble)</u>;
- o. Glucometer or blood glucose measuring device with reagent strips;
- p. Pulse oximeter with pediatric and adult probes;
- q. Automatic blood pressure monitor; and
- r. A commercially available trauma arterial tourniquet.
- <u>D.</u> An applicant or certificate holder shall ensure that an air ambulance used for an interfacility maternal transport mission has:
 - 1. The equipment and supplies in subsection (C); and
 - 2. The following:
 - a. A Doppler fetal heart monitor;
 - b. Unless use is not indicated for the patient as determined through on-line medical direction or on-line medical guidance provided as described in R9-25-708(A)(3), an external fetal heart and tocographic monitor with printer capability;
 - c. Tocolytic and anti-hypertensive medications;
 - d. Advanced emergency cardiac life support equipment and supplies; and
 - e. Neonatal resuscitation equipment and supplies.
- E. An applicant or certificate holder shall ensure that an air ambulance used for an interfacility neonatal transport mission has:
 - 1. The equipment and supplies in subsection (C); and
 - 2. The following:
 - a. A transport incubator with:
 - <u>i.</u> Battery and inverter capabilities,
 - ii. An infant safety restraint system, and
 - <u>iii.</u> An integrated neonatal-capable pressure ventilator with oxygen-air supply and blender;
 - b. An invasive automatic blood pressure monitor;
 - c. A neonatal monitor or monitors with heart rate, respiratory rate, temperature, non-invasive blood pressure, and pulse oximetry capabilities;
 - d. Neonatal-specific drug concentrations and doses;

- e. Thoracostomy supplies;
- <u>f.</u> Neonatal resuscitation equipment and supplies;
- g. A neonatal size cuff (size 2, 3, or 4) for use with an automatic blood pressure monitor; and
- h. A neonatal probe for use with a pulse oximeter.
- C.F. A certificate holder may conduct an interfacility a critical care interfacility transport mission using an air ambulance that does not have all of the equipment and supplies required in Table 1 for the mission level subsection (C) if:
 - 1. Care of the patient to be transported necessitates use of life-support equipment that, because of its size or weight or both, makes it unsafe or impossible for the air ambulance to carry all of the equipment and supplies required in Table 1 for the mission level subsection (C), as determined by the certificate holder based upon:
 - a. The individual aircraft's capabilities,
 - b. The size and weight of the equipment and supplies required in Table 1 subsection

 (C) and of the additional life-support equipment,
 - c. The composition of the required medical team, and
 - d. Environmental factors such as density altitude;
 - 2. The certificate holder ensures that, during the mission, the air ambulance has the equipment and supplies necessary to provide an appropriate level of medical care for the patient and to protect the health and safety of the personnel on the mission; and
 - 3. The certificate holder ensures that, during the mission, the air ambulance is not directed by the air ambulance service or another person to conduct another mission before returning to a base location;
 - 4.3. The certificate holder ensures that the air ambulance is not used for another mission until the air ambulance has all of the equipment and supplies required in Table 1 for the mission level subsection (C); and
 - 5. Within five working days after each interfacility critical care mission conducted as permitted under subsection (C), the certificate holder creates a record that includes the information required under R9-25-710(A)(8), a description of the life support equipment used on the mission, a list of the equipment and supplies required in Table 1 that were removed from the air ambulance for the mission, and the justification for conducting the mission as permitted under subsection (C).
- R9-25-804.R9-25-803. Changes Affecting Registration (<u>Authorized by A.R.S. §§ 36-2202(A)(4)</u> and (5), 36-2209(A)(2), and 36-2212)

- A. At least 30 days before the date of a change in a certificate holder's name, the certificate holder shall send the Department written notice of the name change.
- B. No later than 10 days after a certificate holder ceases to operate an air ambulance, the certificate holder shall send the Department written notice of the date that the certificate holder ceased to operate the air ambulance and of the desire certificate holder's intention to relinquish the certificate of registration for the air ambulance as of that date.
- C. Within 30 days after the date of receipt of a notice described in subsection (A) or (B), the Department shall:
 - 1. For a notice described in subsection (A), issue an amended certificate of registration that incorporates the name change but retains the expiration date of the current certificate of registration; and
 - 2. For a notice described in subsection (B):
 - a. Void the certificate of registration for the air ambulance; and
 - <u>b.</u> <u>send Send</u> the certificate holder written confirmation of the voluntary relinquishment of the certificate of registration, with an effective date that corresponds to the written notice.
- D. A certificate holder shall notify the Department in writing within one working day after a change in its the certificate holder's eligibility to obtain hold a certificate of registration for an air ambulance under R9-25-802(B) R9-25-801(A).
- E. Upon receiving a notification required in subsection (D), the Department:
 - 1. Shall revoke the certificate for the air ambulance; and
 - 2. If the air ambulance is the only air ambulance operated by an air ambulance service, may revoke the license of the air ambulance service.

R9-25-803, R9-25-804. Term and Transferability of Certificate of Registration (<u>Authorized by</u> A.R.S. §§ 36-2202(A)(4) and (5), 36-2209(A)(2), 36-2212, and 41-1092.11)

- A. The Department shall issue an initial certificate of registration:
 - 1. With a term of one year from date of issuance of the initial certificate of registration; or
 - If requested by the applicant, with a term shorter than one year that allows for the
 Department to conduct annual inspections of all of the applicant's air ambulances at one
 time.
- B. The Department shall issue a renewal certificate of registration with a term of one year <u>from the</u> expiration date on the <u>previous certificate of registration</u>.
- C. If an applicant a certificate holder submits an application for renewal as described in R9 25-802 R9-25-801 before the expiration date of the current certificate of registration, the current

- certificate of registration does not expire until the Department has made a final determination on the application for renewal, as provided in A.R.S. § 41-1092.11.
- **D.** A certificate of registration is not transferable from one person to another.
- E. If there is a change in the ownership of an air ambulance or the person who can legally possess and operate the air ambulance, the new owner or person who can legally possess and operate the air ambulance shall apply for and obtain a new certificate of registration before operating the air ambulance in this state.

R9-25-805. Inspections (<u>Authorized by A.R.S. §§ 36-2202(A)(4)</u> and (5), 36-2209(A)(2), 36-2212, and 36-2232(A)(11))

- A. An Except as provided in R9-25-711(C), an applicant or a certificate holder shall make an air ambulance available for inspection within Arizona at the within 10 working days after a request of by the Department.
- B. The Department shall conduct each inspection in compliance with A.R.S. § 41-1009.
- C. As permitted under A.R.S. § 36-2232(A)(11), upon <u>a</u> certificate <u>holder holder's</u> request and at <u>the</u> certificate <u>holder holder's</u> expense, the annual inspection of an air ambulance required for renewal of a certificate of registration may be conducted by a Department-approved inspection facility.

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)) Repealed

- A. The Department may take an action listed in subsection (B) against a certificate holder's certificate of registration if the certificate holder:
 - 1. Fails or has failed to meet the eligibility requirements of R9-25-802(B);
 - 2. Fails or has failed to comply with any provision in A.R.S. Title 36, Chapter 21.1;
 - 3. Fails or has failed to comply with any provision in this Article or Article 2 or 7 of this Chapter; or
 - 4. Knowingly or negligently provides false documentation or false or misleading information to the Department.
- B. The Department may take the following actions against a certificate holder's certificate of registration:
 - 1. After notice and an opportunity to be heard is provided under A.R.S. Title 41, Chapter 6,

 Article 10, revoke the certificate of registration; and
 - 2. In case of emergency, if the Department determines that a potential threat to the public health and safety exists and incorporates a finding to that effect in its order, immediately suspend the certificate of registration as authorized under A.R.S. § 36-2234(L).

- C. In determining whether to take action under subsection (B), the Department shall consider:
 - 1. The severity of each violation relative to public health and safety;
 - 2. The number of violations relative to the transport volume of the air ambulance service;
 - 3. The nature and circumstances of each violation;
 - 4. Whether each violation was corrected and, if so, the manner of correction; and
 - 5. The duration of each violation.

R9-25-807, Renumbered

Table 8.1. Minimum Equipment and Supplies Required on Air Ambulances, By Mission Level and Aircraft Type (Authorized by A.R.S. §§ 36-2202(A)(3), (4), and (5); 36-2209(A)(2); and 36-2212) Repealed

X = Required

ALS = Advanced Life Support Mission

BLS = Basic Life Support Mission

CC = Critical Care Mission

FW = Fixed Wing Aircraft

RW = Rotor Wing Aircraft

MINIMUM EQUIPMENT AND SUPPLIES	₽₩	RW	BLS	ALS	CC
A. Ventilation and Airway Equipment					
1. Portable and fixed suction apparatus, with wide bore tubing, rigid pharyngeal curved suction tip, tonsillar and flexible suction catheters, 5F-14F	X	X	X	X	X
2. Portable and fixed oxygen equipment, with variable flow regulators	X	X	X	X	X
3. Oxygen administration equipment, including tubing; non- rebreathing masks (adult and pediatric sizes); and nasal cannulas (adult and pediatric sizes)	X	X	X	X	X
4. Bag valve mask, with hand operated, self-reexpanding bag (adult size), with oxygen reservoir/accumulator; mask (adult, pediatric, infant, and neonate sizes); and valve		X	X	X	X
5. Airways, oropharyngeal (adult, pediatric, and infant sizes)	X	X	X	X	X
6. Laryngoscope handle with extra batteries and bulbs, adult and pediatrie	X	X	-	X	X
7. Laryngoscope blades, sizes 0, 1, and 2, straight; sizes 3 and 4, straight and curved		X	-	X	X
8. Endotracheal tubes, sizes 2.5-5.0 mm cuffed or uncuffed and 6.0-8.0 mm cuffed	X	X	-	X	X
9. Meconium aspirator	X	X	-	X	X
10. 10 mL straight tip syringes	X	X	_	X	X
11. Stylettes for Endotracheal tubes, adult and pediatric	X	X	-	X	X
12. Magill forceps, adult and pediatric	X	X	_	X	X
13. Nasogastric tubes, sizes 5F and 8F, Salem sump sizes 14F and 18F	X	X	-	¥	X
14. End-tidal CO ₂ -detectors, colorimetric or quantitative	X	X	-	X	X
15. Portable automatic ventilator with positive end expiratory pressure		X	-	X	X
B. Monitoring and Defibrillation					
1. Automatic external defibrillator	X	X	X	-	_

2. Portable, battery-operated monitor/defibrillator, with tape write-out/recorder, defibrillator pads, adult and pediatric paddles or hands free patches, ECG leads, adult and pediatric chest attachment electrodes, and capability to provide electrical discharge below 25 watt-seconds	X	X		X	X
3. Transcutaneous cardiac pacemaker, either stand-alone unit or integrated into monitor/defibrillator	X	X	-	X	X
C. Immobilization Devices					
1. Cervical collars, rigid, adjustable or in an assortment of adult and pediatric sizes	-	X	X	X	X
2. Head immobilization device, either firm padding or another commercial device	-	X	X	X	X
3. Lower extremity (femur) traction device, including lower extremity, limb support slings, padded ankle hitch, padded pelvic support, and traction strap		X	X	X	X
4. Upper and lower extremity immobilization splints	-	X	X	X	X
D. Bandages					
1. Burn pack, including standard package, clean burn sheets	X	X	X	X	X
2. Dressings, including sterile multi-trauma dressings (various large and small sizes); abdominal pads, 10" x 12" or larger; and 4" x 4" gauze sponges	X	X	X	X	X
3. Gauze rolls, sterile (4" or larger)	X	X	X	X	X
4. Elastic bandages, non-sterile (4" or larger)	X	X	X	X	X
5. Occlusive dressing, sterile, 3" x 8" or larger	X	X	X	X	X
6. Adhesive tape, including various sizes (1" or larger) hypoallergenic and various sizes (1" or larger) adhesive	X	X	X	X	X
E. Obstetrical					
1. Obstetrical kit (separate sterile kit), including towels, 4" x 4" dressing, umbilical tape, sterile scissors or other cutting utensil, bulb suction, clamps for cord, sterile gloves, at least 4 blankets, and a head cover	X	X	X	X	X
2. An alternate portable patient heat source or 2 heat packs	X	X	X	X	X
F.Miscellaneous					
1. Sphygmomanometer (infant, pediatric, and adult regular and large sizes)	X	X	X	X	X
2. Stethoscope	X	X	X	X	X
3. Pediatric equipment sizing reference guide	X	X	X	X	X
4. Thermometer with low temperature capability	X	X	X	X	X
5. Heavy bandage or paramedic scissors for cutting clothing, belts, and boots		X	X	X	X
	X	X	X	X	X

7. Flashlight (1) with extra batteries	X	X	X	X	X
8. Blankets	X	X	X	X	X
9. Sheets	X	X	X	X	X
10. Disposable emesis bags or basins	X	X	X	X	X
11. Disposable bedpan	X	X	X	X	X
12. Disposable urinal	X	X	X	X	X
13. Properly-secured patient transport system	X	X	X	X	X
14. Lubricating jelly (water soluble)	X	X	X	X	X
15. Small volume nebulizer	X	X	-	X	X
16. Glucometer or blood glucose measuring device with reagent strips	X	X	X	X	X
17. Pulse oximeter with pediatric and adult probes	X	X	X	X	X
18. Automatic blood pressure monitor	X	X	X	X	X
G. Infection Control (Latex-free equipment shall be available)					
1. Eye protection (full peripheral glasses or goggles, face shield)	X	X	X	X	X
2. Masks	X	X	X	X	X
3. Gloves, non-sterile	X	X	X	X	X
4. Jumpsuits or gowns	X	X	X	X	X
5. Shoe covers	X	X	X	X	X
6. Disinfectant hand wash, commercial antimicrobial (towelette, spray, or liquid)	X	X	X	X	X
7. Disinfectant solution for eleaning equipment	X	X	X	X	X
8. Standard sharps containers	X	X	X	X	X
9. Disposable red trash bags	X	X	X	X	X
10. High-efficiency particulate air mask	X	X	X	X	X
H. Injury Prevention Equipment					
1. Appropriate restraints (such as seat belts) for patient, personnel, and family members	X	X	¥	X	X
2. Child safety restraints	X	X	X	X	X
3. Safety vest or other garment with reflective material for each personnel member	-	X	¥	X	X
4. Fire extinguisher	X	X	X	X	X
5. Hazardous material reference guide	X	X	X	X	X

6. Hearing protection for patient and personnel	X	X	X	X	X
. Vascular Access					
1. Intravenous administration equipment, with fluid in bags	X	X	<u> </u>	X	X
2. Antiseptic solution (alcohol-wipes and povidone-iodine wipes)	X	X	•	X	X
3. Intravenous pole or roof hook	X	X	-	X	X
4. Intravenous catheters 14G-24G	X	X	-	X	X
5. Intraosseous needles		X	<u></u>	X	X
6. Venous tourniquet		X	_	X	X
7. One of each of the following types of intravenous solution administration sets: a. A set with blood tubing, b. A set capable of delivering 60 drops per cc, and c. A set capable of delivering 10 or 15 drops per ce	X	X		X	X
8. Intravenous arm boards, adult and pediatric	X	X	_	X	X
9. IV pump or pumps (minimum of 3 infusion lines)	X	X	-	X	X
10. IV pressure bag	X	X	-	X	X
. Medications					
1. Agents required in a table of agents, established according to A.R.S. § 36-2204 and available through the Department at www.azdhs.gov/ems-regulatory-references, that an administrative medical director may authorize based on the EMCT classification	X	X	X	X	X

ARTICLE 12. TIME-FRAMES FOR DEPARTMENT APPROVALS

R9-25-1201. Time-frames (Authorized by A.R.S. §§ 41-1072 through 41-1079)

- A. The overall time-frame described in A.R.S. § 41-1072 for each type of approval granted by the Department is listed in Table 12.1. The applicant and the Director may agree in writing to extend the overall time-frame. The substantive review time-frame shall not be extended by more than 25% of the overall time-frame.
- B. The administrative completeness review time-frame described in A.R.S. § 41-1072 for each type of approval granted by the Department is listed in Table 12.1. The administrative completeness review time-frame begins on the date that the Department receives an application form or an application packet.
 - 1. If the application packet is incomplete, the Department shall send to the applicant a written notice specifying the missing document or incomplete information. The administrative completeness review time-frame and the overall time-frame are suspended from the postmark date of the written request until the date the Department receives a complete application packet from the applicant.
 - 2. When an application packet is complete, the Department shall send a written notice of administrative completeness.
 - If the Department grants an approval during the time provided to assess administrative completeness, 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 listed in Table 12.1 and begins on the postmark date of the notice of administrative completeness.
 - 1. As part of the substantive review time-frame for an application for an approval other than renewal of an ambulance registration, the Department shall conduct inspections, conduct investigations, or hold hearings required by law.
 - 2. If required under R9-25-402, the Department shall fix the period and terms of probation as part of the substantive review.
 - 3. During the substantive review time-frame, the Department may make one comprehensive written request for additional documents or information and may make supplemental requests for additional information with the applicant's written consent.
 - 4. The substantive review time-frame and the overall time-frame are suspended from the postmark date of the written request for additional information or documents until the Department receives the additional information or documents.

- 5. The Department shall send a written notice of approval to an applicant who:
 - <u>a.</u> <u>meets Meets</u> the qualifications in A.R.S. Title 36, Chapter 21.1 and this Chapter for the type of application submitted; or
 - <u>b.</u> Is not in compliance with requirements in A.R.S. Title 36, Chapter 21.1 and this
 <u>Chapter</u>, for the type of application submitted, that do not directly affect the
 <u>health or safety of a patient and submits to the Department a corrective action</u>
 <u>plan that is acceptable to the Department to address issues of compliance.</u>
- 6. The Department shall send a written notice of denial to an applicant who fails to meet the qualifications in A.R.S. Title 36, Chapter 21.1, and this Chapter for the type of application submitted.
- D. If an applicant fails to supply the documents or information under subsections (B)(1) and (C)(3) within the number of days specified in Table 12.1 from the postmark date of the written notice or comprehensive written request, the Department shall consider the application withdrawn.
- E. An applicant that does not wish an application to be considered withdrawn may request a denial in writing within the number of days specified in Table 12.1 from the postmark date of the written notice or comprehensive written request for documents or information under subsections (B)(1) and (C)(3).
- **F.** If a time-frame's last day falls on a Saturday, Sunday, or an official state holiday, the Department shall consider the next business day as the time-frame's last day.

Table 12.1. Time-frames (in days)

Type of Application	Statutory Authority	Overall Time- frame	Administrativ e Completeness Time-frame	Time to Respond to Written Notice	Substantiv e Review Time- frame	Time to Respond to Comprehensiv e Written Request
ALS Base Hospital Certification (R9-25-204)	A.R.S. §§ 36- 2201, 36- 2202(A)(3), and 36-2204(5)	45	15	60	30	60
Training Program Certification (R9-25-301)	A.R.S. §§ 36- 2202(A)(3) and 36-2204(1) and (3)	120	30	60	90	60
Addition of a Course (R9-25-303)	A.R.S. §§ 36- 2202(A)(3) and 36-2204(1) and (3)	90	30	60	60	60
EMCT Certification (R9-25-403)	A.R.S. §§ 36-2202(A)(2), (3), and (4), 36- 2202(G), and 36-2204(1)	120	30	90	90	270
EMCT Recertification (R9-25-404)	A.R.S. §§ 36-2202(A)(2), (3), (4), and (6), 36-2202(G), and 36-2204(1) and (4)	120	30	60	90	60
Extension to File for EMCT Recertification (R9-25-405)	A.R.S. §§ 36-2202(A)(2), (3), (4), and (6), 36-2202(G), and 36-2204(1) and (7)	30	15	60	15	60
Downgrading of Certification (R9-25-406)	A.R.S. §§ 36-2202(A)(2), (3), and (4), 36- 2202(G), and 36-2204(1) and (6)	30	15	60	15	60
Initial Air Ambulance Service License (R9-25-704)	A.R.S. §§ 36- 2202(A)(3) and (4), 36- 2209(A)(2), 36- 2213, 36-2214, and 36-2215	150	30	60	120	60

Renewal of an Air	A.R.S. §§ 36- 2202(A)(3) and	90	30	60	60	60
Ambulance Service	(4), 36- 2209(A)(2), 36-					and Addition
License (R9 25-705 <u>R9-25-704</u>)	2213, 36-2214, and 36-2215					
Initial Certificate of Registration for an Air Ambulance (R9-25-802 R9-25-801)	A.R.S. §§ 36- 2202(A)(4) and (5), 36- 2209(A)(2), 36- 2212, 36-2213, 36-2214, and 36- 2240(4)	90	30	60	60	60
Renewal of a Certificate of Registration for an Air Ambulance (R9-25-802 R9-25-801)	A.R.S. §§ 36- 2202(A)(4) and (5), 36- 2209(A)(2), 36- 2212, 36-2213, 36-2214, and 36- 2240(4)	90	30	60	60	60
Initial Certificate of Necessity (R9- 25-902)	A.R.S. §§ 36- 2204, 36-2232, 36- 2233, 36-2240	450	30	60	420	60
Provision of ALS Services (R9-25-902)	A.R.S. §§ 36- 2232, 36-2233, 36-2240	450	30	60	420	60
Transfer of a Certificate of Necessity (R9- 25-902)	A.R.S. §§ 36- 2236(A) and (B), 36-2240	450	30	60	420	60
Renewal of a Certificate of Necessity (R9- 25-904)	A.R.S. §§ 36- 2233, 36-2235, 36-2240	90	30	60	60	60
Amendment of a Certificate of Necessity (R9- 25-905)	A.R.S. §§ 36- 2232(A)(4), 36-2240	450	30	60	420	60
Initial Registration of a Ground Ambulance Vehicle (R9- 25-1001)	A.R.S. §§ 36-2212, 36-2232, 36-2240	90	30	60	60	60

Renewal of a Ground Ambulance Vehicle Registration (R9-25-1001)	A.R.S. §§ 36- 2212, 36-2232, 36-2240	90	30	60	60	60
Establishment of Initial General Public Rates (R9-25-1101)	A.R.S. §§ 36- 2232, 36-2239	450	30	60	420	60
Adjustment of General Public Rates (R9-25- 1102)	A.R.S. §§ 36- 2234, 36-2239	450	30	60	420	60
Contract Rate or Range of Rates Less than General Public Rates (R9-25-1103)	A.R.S. §§ 36- 2234, 36-2239	450	30	60	420	60
Ground Ambulance Service Contracts (R9- 25-1104)	A.R.S. § 36-2232	450	30	60	420	60
Ground Ambulance Service Contracts with Political Subdivisions (R9-25-1104)	A.R.S. §§ 36- 2232, 36-2234(K)	30	15	15	15	Not Applicable
Subscription Service Rate (R9-25-1105)	A.R.S. § 36- 2232(A)(1)	450	30	60	420	60



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TITLE 9. HEALTH SERVICES

CHAPTER 25. EMERGENCY MEDICAL SERVICES

ARTICLE 7. AIR AMBULANCE SERVICE LICENSING ARTICLE 8. AIR AMBULANCE REGISTRATION ARTICLE 12. TIME-FRAMES FOR DEPARTMENT APPROVALS

ECONOMIC, SMALL BUSINESS, AND CONSUMER IMPACT STATEMENT

October 2021

ECONOMIC, SMALL BUSINESS, AND CONSUMER IMPACT STATEMENT TITLE 9. HEALTH SERVICES 2022 APR -- 6

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CHAPTER 25. EMERGENCY MEDICAL SERVICES ARTICLE 7. AIR AMBULANCE SERVICE LICENSING ARTICLE 8. AIR AMBULANCE REGISTRATION ARTICLE 12. TIME-FRAMES FOR DEPARTMENT APPROVALS

1. An identification of the rulemaking

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 for air ambulance services in Arizona Administrative Code (A.A.C.) Title 9, Chapter 25, Articles 7 and 8.

The rules in 9 A.A.C. 25, Article 7 and 8, establish requirements for licensing air ambulance services and for registration of air ambulances, respectively, to ensure the health and safety of patients being transported. In a five-year-review report approved by the Governor's Regulatory Review Council on July 6, 2017, the Department identified several issues with the rules in Articles 7 and 8 and proposed a rulemaking to address these issues. These issues include non-compliance with A.R.S. § 41-1080, unnecessary or duplicative requirements, unclear requirements, obsolete requirements, and poor organization of the rules. All of these issues may affect the effectiveness of the rules and, thus, threaten the health and safety of patients being transported. The Department also requested input from stakeholders to identify additional issues. The Department is revising the rules in 9 A.A.C. 25, Articles 7 and 8, to address these issues and other issues identified by stakeholders as part of the rulemaking process and to restructure the rules to improve clarity, remove duplication, and increase effectiveness. To correct cross-references to renumbered Sections in Articles 7 and 8 and to clarify requirements related to allowing corrective action plans, the Department is also making changes in Article 12.

2. Identification of the persons who will be directly affected by, bear the costs of, or directly benefit from the rules

- The Department
- Air ambulance services, ground ambulance services, and other EMS providers
- Emergency medical care technicians (EMCTs)
- Hospitals and other health care institutions
- Patients and their families
- General public

3. Cost/Benefit Analysis

This analysis covers costs and benefits associated with the rule changes and does not describe effects imposed by statutes. No new FTEs will be required due to this rulemaking. Annual costs/revenues changes are designated as minimal when more than \$0 and \$2,000 or less, moderate when between \$2,000 and \$20,000, and substantial when \$20,000 or greater in additional costs or revenues. A cost is listed as significant when meaningful or important, but not readily subject to quantification. A summary of the economic impact of the rules is given in the Table below, while the economic impact is explained more fully in the paragraphs following the Table.

Description of Affected Groups	Description of Effect	Increased Cost/ Decreased Revenue	Decreased Cost/ Increased Revenue
A. State and Local Gov	ernment Agencies and Federal or Tribal	Health Care Institutio	ns
Department	Having rules that are clearer and easier to understand	None	Significant
	Clarifying existing requirements	None	Minimal
	Revising application requirements	None	Significant
	Receiving more accurate, complete, and useful date to enable the Department to assess the emergency medical services system in Arizona	None-to-minimal	Significant
	Allowing for use of corrective action plans in lieu of other enforcement actions	None-to-minimal	Minimal-to-moderate
	Adding requirements related to an air ambulance service terminating operations at a specific location	None-to minimal	Significant

Description of Affected	Description of Effect	Increased Cost/	Decreased Cost/	
Groups		Decreased Revenue	Increased Revenue	
Federal or tribal	Clarifying existing requirements	None	Significant	
hospitals	Specifying the content of the protocol for communicating information during a transfer of care	None	Significant	
	Adding requirements related to an air ambulance service terminating operations at a specific location	None	Significant	
B. Privately Owned Bus	inesses			
Air ambulance services	Having rules to follow that are clearer and easier to understand and follow	None	Significant	
	Clarifying existing requirements	None-to-moderate	Significant	
	Revising application requirements	None-to-minimal	Significant	
	Removing duplicative, unnecessary, or unenforceable requirements	None	Significant	
	Allowing for the use of leased aircraft	None	None-to-substantial	
	Adding/clarifying requirements for documentation	None-to-moderate	None-to-moderate	
	Specifying the content of the protocol for communicating information during a transfer of care	None-to-moderate	None-to-moderate	
	Adding requirements related to an air ambulance service terminating operations at a specific location	None-to-moderate	None-to-moderate	
	Allowing for use of corrective action plans in lieu of other enforcement actions	None-to-substantial	None-to-substantial	
	Changing requirements for supplies and equipment to current standards			
	Changing language for agent requirements so air ambulances only	None-to-moderate	None-to-moderate	
	have to carry agents from the Department's list that are authorized for use by the administrative medical director	None	None-to-moderate	
Other ambulance	Clarifying existing requirements	None	Significant	
services or EMS providers	Specifying the content of the protocol for communicating information during a transfer of care	None	Significant	
Hospitals and other	Clarifying existing requirements	None	Significant	
health care institutions	Specifying the content of the protocol for communicating information during a transfer of care	None	Significant	

Description of Affected Groups	Description of Effect	Increased Cost/ Decreased Revenue	Decreased Cost/ Increased Revenue
	Adding requirements related to an air ambulance service terminating operations at a specific location	None	Significant
EMCTs	Adding/clarifying requirements for documentation	Significant	Significant
	Changing requirements for supplies and equipment to current standards	None	Significant
	Changing language for agent requirements so air ambulances only have to carry agents from the Department's list that are authorized for use by the administrative medical director	None	Significant
C. Consumers			
Patients and their families	Having rules that include updated requirements and are clearer and easier to understand	None	Significant
General public	Having rules to follow that are clearer and easier to understand	None	Significant

• The Department

The rules in 9 A.A.C. 25, Articles 7 and 8 were adopted by final rulemaking, effective April 8, 2006. Since then, the only rules that have been revised are the current R9-25-701, R9-25-704, R9-25-711, R9-25-715, and Table 8.1, which were revised by exempt rulemaking in 2013 to address statutory changes. Under the rules in 9 A.A.C. 25, Article 7, the Department licenses 19 entities as air ambulance services. As of July 2021, together these entities operate 131 air ambulances registered under Article 8 of the Chapter. Those entities licensed under Article 7 are called licensees, while the entities to which air ambulances are registered are termed certificate holders.

As part of this rulemaking, the Department is establishing rules that are clearer and easier to understand. The revised rules also address issues that had been identified in the 2017 five-year-review report for the rules in 9 A.A.C. 25, as well as issues identified by stakeholders during a survey in anticipation of the rulemaking conducted by the Department in 2019 or as part of informal rulemaking to develop proposed rules. In the new rules, eight definitions are being removed, most of these because the term is no longer being used or is being defined/described where it is being used, consistent with the 2017 five-year-review report. The Department is also adding definitions for seven terms, to define terms that had been used but were undefined in the current rules, and revising two others to clarify what the terms mean as used in the new rules. Language throughout the rest of Articles 7 and 8 is also being updated and revised to improve clarity and understandability, and several Sections are being repealed or renumbered to eliminate duplication and improve the organization of the rules, requiring correction of cross-references, including those in Article 12 of the Chapter.

In addition, many requirements currently in the rules are being clarified to reflect current practice. These include the clarification of: the Department's response to a change in eligibility for a certificate of registration; the term of registration and the time period within which the Department will inspect an air ambulance; requirements for inspections of air ambulance services with CAMTS accreditation and those without, including what may be inspected and by when an applicant or a certificate holder is required to make an air ambulance available for inspection; requirements for establishing, documenting, and implementing a quality improvement program currently in R9-25-711(C)(4) and R9-25-715(A)(2); who is required to apply for and obtain a new certificate of registration when there is a change in ownership or of lawful possession of an aircraft being used as an air ambulance; and when the Department will issue a certificate of registration after approving an application. The new rules also clarify a licensee's responsibilities. The Department anticipates that these clarifying changes may provide a significant benefit to the Department by increasing the understanding by a regulated entity or an applicant of the requirements, leading to fewer misunderstandings and the need

to explain current requirements to ensure compliance. This may decrease the amount of time that staff spend providing technical assistance and answering questions about the rules, providing a minimal decrease in costs.

The Department currently receives and processes approximately two initial applications per year and 18 renewal applications during a three-year period for an air ambulance service license under Article 7. In 2020, the Department received 55 initial applications and 88 renewal applications for an air ambulance registration under Article 8. The new rules contain changes to the applications in R9-25-704, now containing requirements for both initial and renewal applications, and in the new R9-25-801 (old R9-25-802). These changes reflect current requirements and include removing duplicate requirements for document submission now in both Articles 7 and 8; adding statutory requirements in A.R.S. § 41-1080 for demonstrating lawful presence in the country; moving into R9-25-704 requirements for providing information about mission levels, now part of the application for an air ambulance registration; replacing a list of the primary contact and each officer and board member of an applying entity with a cross-reference to R9-25-102; and requiring e-mail addresses. For registration of an air ambulance, the application also includes requirements for providing the air ambulance service's license number for renewals and the location at which the aircraft is usually based. In addition, the new rules account for the fact that an applicant for an air ambulance license or a licensee may lease an aircraft, rather than buying it outright. Since this is a common practice in the industry, making these changes allows the Department to enforce the rule as written. The new rules also clarify and set a time limit within which an air ambulance service must make the air ambulance available for inspection, rather than stating "at the request of the Department." The Department expects these changes to provide a significant benefit to the Department in processing an application.

While R9-25-710(A)(7) in the current rules require an air ambulance service to create a prehospital incident history report, the content of that report is unspecified. The content of the report is clarified in R9-25-705(A)(8) in the new rules, making it consistent with the information currently being reported into the AZ-PIERS system by approximately 50% of air ambulance services. These reporting air ambulance services include all of the larger volume air ambulance services, with approximately 83% of all transports already being reported to AZ-PIERS. This change will provide the Department with more accurate, complete, and useful data to enable the Department to assess the emergency medical services system in Arizona. The Department anticipates that the change may cause the Department to spend more time with staff of air ambulance services not currently submitting data to AZ-PIERS and to assess submitted data for accuracy and completeness, incurring as much a minimal increase in cost. However, having this data may provide a significant benefit to the Department.

If an air ambulance service is not compliant with requirements in A.R.S. Title 36, Chapter 21.1 or applicable rules in 9 A.A.C. 25, the Department may take enforcement action against the air ambulance service. The types of enforcement actions are specified in the current R9-25-709 and R9-25-806. Because a licensee is ultimately responsible for noncompliance related to an air ambulance registered under the license as part of the air ambulance service, the new rules consolidate the content of both rules into the new R9-25-712, specifying the enforcement actions that the Department may take. The Department prefers to work with a regulated entity to achieve compliance, rather than immediately taking action to suspend or revoke a license, as long as patient health and safety are not compromised. The Department may allow the regulated entity to submit a corrective action plan, describing the actions the regulated entity will take to come back into compliance and the time line for the completion of these actions, in lieu of suspension/revocation action. Because the new rules allow an air ambulance service to submit a corrective action plan to address issues of compliance that do not directly affect the health or safety of a patient, the new R9-25-712 includes provisions for when an air ambulance service either chooses not to submit a corrective action plan according to R9-25-711(G) that is acceptable to the Department or does not complete such a corrective action plan. The Department believes that these changes may cause the Department to incur as much as a minimal increase in costs to review submitted corrective action plans, but may also cause a minimal-tomoderate decrease in costs related to enforcement.

In the last few years, there have been several instances in which an air ambulance service abruptly stopped transporting patients to or from a hospital. This caused these hospitals and the Department to scramble to ensure patient safety. At the request of stakeholders, the new rules add requirements related to an air ambulance service terminating operations at a specific location. The Department anticipates this change may provide a significant benefit to the Department, while causing a most a minimal increase in costs to work with such an air ambulance service and hospital.

· Air ambulance services

As stated above, the Department licenses 19 entities as air ambulance services under the rules in 9 A.A.C. 25, Article 7. Of the 131 air ambulances operated by these licensees and registered under Article 8, as of July 2021, 51 are fixed-wing aircraft and the remainder are rotor-wing aircraft. As of July 2021, 10 air ambulance services operate only fixed-wing air ambulances and four only rotor-wing air ambulances. The remaining operate both fixed-wing and rotor-wing aircraft. Ten held CAMTS accreditation. The number of aircraft operated by an air ambulance service varies greatly, with two operating 31 and 29 aircraft, respectively, while 10 operate five or fewer aircraft.

Many of the clarifying changes described above related to definitions, updated language, inspections, and registrations, are also expected to provide a significant benefit to air ambulance

services and applicants through their making the rules more understandable and easier to follow. Additional changes that clarify existing requirements may also provide a benefit to stakeholders. These include making clearer the staffing for critical care missions and advanced life support missions; requirements for medical direction/medical guidance for medical team members, some moved from the current R9-25-717 or R9-25-718; and the structure of the rules. For example, requirements have been moved into R9-25-705 for verifying qualifications of medical team members for interfacility maternal or neonatal transports from the current R9-25-718 and R9-25-717, respectively; for recordkeeping from the current R9-25-716; for communication equipment from the current R9-25-714; and for creation of records that include documentation of the justification for removing unnecessary equipment from current R9-25-807. In addition, staffing requirements for interfacility maternal transport missions and interfacility neonatal transport missions have been moved into R9-25-706 from the current R9-25-718 and R9-25-717, respectively. The Department anticipates that these changes may provide a significant benefit to air ambulance services and applicants. If an air ambulance service has not been complying with these current requirements due to misunderstanding the requirement, the Department believes their clarification could cause an air ambulance service to incur as much as moderate costs to come into compliance.

Revisions to application requirements, reflecting how the Department is currently enforcing the requirements, may also affect air ambulance services. As described above, requirements for both initial and renewal applications are now in a single rule, and duplicate requirements for document submission, now listed in both Articles 7 and 8, have been removed, which may provide a significant benefit to air ambulance services. A list of the primary contact and each officer and board member of an applying entity has been replaced with a cross-reference to R9-25-102. Complying with statutory requirements for demonstrating lawful presence in the country may impose a minimal cost on an applicant, but these costs are due to the statute rather than the rules. Other changes that may cause an applicant to incur minimal costs are the addition of e-mail addresses and, for Article 8, the requirements for providing the air ambulance service's license number for renewals and the location at which the aircraft is usually based. The new rules also clarify how far in advance (at least 30 days before the anticipated change of ownership) an application for transfer of a license is required to be submitted to the Department. The Department has received no requests for transfer in the past five years but wants to retain these requirements because they are statutorily possible. This time period is consistent with the time-frame in Table 12.1 for the determination of administrative completeness for an initial air ambulance service license application and would help ensure adequate time for the Department to begin processing the application, providing a significant benefit to the entity to which the license is being transferred, despite the possibility of causing a minimal burden on the applicant.

One of the changes that may be most beneficial to an applicant under the new rules accounts for the fact that an applicant for an air ambulance license or a licensee may lease an aircraft, rather than buying it outright. As of July 2021, there were at least ten air ambulance services that use leased aircraft, and a total of at least 33 registered air ambulances are leased. Since this is a common practice in the industry, the new rules, instead, contain requirements for an applicant to provide information about the owner of the aircraft if not the applicant and show lawful possession of aircraft if required documentation about the aircraft is not in the name of the applicant. The new rules also add the ability of an applicant to use electronic payment to pay for registration. The Department expects these changes to provide as much as a substantial benefit to an applicant.

The new rules consolidate requirements related to the operation of an air ambulance service into one Section, the new R9-25-705, allowing many short rules to be repealed. In this rule are included exceptions to equipment and staffing requirements, some moved from other Sections. These exceptions require the creation of records that include documentation of the justification for using the exception. Requirements for establishing, documenting, and implementing a quality improvement program, now in the current R9-25-711(C)(4) and R9-25-715(A)(2), are also included in this rule. The rules also add or clarify other requirements for documentation, stating what information the currently required prehospital incident history report is required to contain, and including a requirement for an air ambulance service to document staffing of a mission and the estimated time of arrival to ensure compliance with current requirements. Requirements for the content of the protocol for communicating information during a transfer of care are also specified, as are requirements related to an air ambulance service terminating operations at a specific location. The new rules also remove duplicative, unnecessary, or unenforceable requirements, such as an unenforceable requirement for an air ambulance service to check on the qualification of an individual in a health care institution requesting transport and an unnecessary requirement for an air ambulance, conducting an interfacility critical care mission with only the supplies and equipment necessary for a patient being transported, to return to its base location before being dispatched on another mission. The Department anticipates that these changes may cause an air ambulance service to incur as much as moderate costs to come into compliance, if not already performing these activities as a standard of care. The Department believes that some of these changes may also provide up to a moderate benefit to an air ambulance service.

As mentioned above, the Department has included in the new R9-25-711 provisions for an air ambulance service to submit a corrective action plan, describing the actions the air ambulance service will take to come back into compliance and the time line for the completion of these actions, in lieu of suspension/revocation action. The new R9-25-712 includes provisions for when an air ambulance

service that is not in compliance with requirements either chooses not to submit a corrective action plan that is acceptable to the Department or does not complete such a corrective action plan. While the preparation and implementation of a corrective action plan may cause an air ambulance service that wishes to use this alternative to other enforcement actions to incur up to substantial costs, the Department believes that the inclusion of provisions for submission of a corrective action plan may provide as much as a substantial benefit to an air ambulance service.

In 2020, air ambulance services carried out over 21,000 transport missions, of which 14% were as a result of a 9-1-1 call and 86% were interfacility transports. The largest two air ambulance services provided over 5,300 transport missions each. Another two provided approximately 3,300 each, while nine provided fewer than 50 transport missions during the year. No air ambulance service provides transport missions at only the basic life support mission level, so requirements related to this mission level are being removed as unnecessary. There are also very few differences in requirements for minimum equipment and supplies for fixed-wing versus rotor-wing aircraft. Table 8.1 is very confusing, convoluting requirements for type of aircraft with requirements based on mission level. In the new rules, the Table is being repealed, and the requirements currently in the Table are clarified and included in the new R9-25-802(C).

Requirements for supplies and equipment are also being changed to reflect the current standards of care. The new rules add requirements for nasal airways (\$35), supraglottic airway devices (\$25 - \$50 each), endotracheal tube cuff pressure manometers (\$350 each), in-line viral/bacterial filters (\$4 each), and trauma arterial tourniquets. Requirements for meconium aspirators (\$8 each), automatic external defibrillators (\$2,000), and bedpans (\$2 each) and disposable urinals (\$2 each) for rotor wing aircraft are being removed. The new rules allow the use of self-adhesive tape and rechargeable flashlights, and clarify the types of required masks (N-95 or better for ambulance attendants and face coverings for patients — rather than unspecified masks and HEPA masks), both of which should already be in use. The language related to agent requirements is also being changed so an air ambulance is only required to carry agents from the Department's list that are authorized for use by the administrative medical director. The Department believes that these changes may provide as much as a moderate benefit to an air ambulance service, depending on the number of aircraft used by the air ambulance service, the number of missions performed, and list of agents the administrative medical director has authorized for use, while potentially causing the air ambulance service to incur as much as moderate costs.

Other ambulance services or EMS providers

Although this information is not currently collected by the Department, the Department believes that there are many instances in which an air ambulance service either receives a patient for transport

from a ground ambulance service or other EMS provider or transfers care of a patient to a ground ambulance service or other EMS provider after completing a transport mission. As mentioned above, the new rules make existing requirements easier to understand and, thus, to comply with. Their clarity also makes it easier for another ambulance service or EMS provider involved in a transfer of care with an air ambulance service to know what to expect from the air ambulance service. Therefore, the Department believes that clarifications of existing requirements for air ambulance services may provide a significant benefit to another ambulance service or EMS provider involved in a transfer of care with an air ambulance service.

The new rules also specify the content of the protocol for communicating information during a transfer of care required in R9-25-201(E)(2)(d)(i). Having information about a patient and the treatment provided to the patient available to EMCTs of the other ambulance service or EMS provider upon transfer of care of the patient to the ambulance service or EMS provider makes it possible for the EMCTs of the ambulance service or EMS provider to provide better care to the patient upon assuming responsibility for the care. The Department anticipates that adding these requirements to the rules to clarify an existing requirement in Article 2 of the Chapter may provide a significant benefit to another ambulance service or EMS provider.

• Hospitals and other health care institutions, including federal or tribal hospitals

Hospitals and other health care institutions also receive patients transported by an air ambulance service or use an air ambulance service to transport patients to a facility providing a more appropriate level of care. Rule changes clarifying existing requirements would also be expected to provide a significant benefit to a hospital or other health care institution involved in a transfer of care with an air ambulance service. As for other ambulance services or EMS providers, adding requirements for the content of the protocol for communicating information during a transfer of care would also be expected to provide a significant benefit to a hospital or other health care institution involved in a transfer of care.

In the past few years, there have been several instances in which an air ambulance service decided to terminating operations at a specific location, with little or no notice to hospitals or other health care institutions that relied on them for patient transports. In the new R9-25-705(A)(10), the rules require an air ambulance service to establish, document, and, if necessary, implement a plan to address and minimize potential issues of patient health and safety due to the air ambulance service terminating operations at a physical address used for the air ambulance service. The Department anticipates that adding these requirements to the rules may provide a significant benefit to a hospital or other health care institution.

EMCTs

The Department believes that clarifications of existing requirements for air ambulance services may provide a significant benefit to EMCTs employed by an air ambulance service by better explaining requirements. For an EMCT not currently complying with new or clarified requirements for documentation, the Department believes that these changes may impose a significant burden on an EMCT, but allow the EMCT to provide better patient care. Changing requirements for supplies and equipment to current standards may also provide an EMCT with a significant benefit. The change to the language for agent requirements, so air ambulances only have to carry agents from the Department's list that are authorized for use by the administrative medical director, may prove especially beneficial in that an EMCT would no longer be responsible for inventorying and being responsible for agents that the EMCT does not use.

• Patients and their families

In the past 10 years, the number of transports using air ambulances for trauma cases has decreased, mainly due to decreases in Maricopa and Pima Counties, while the rate of use in rural counties has been fairly stable, declining to a much lesser degree. In 2017, the rate of transport for trauma cases in Maricopa and Pima Counties was 13 and 11 per 100,000 residents, respectively, while the rates were highest in Navajo County (342/100,000 residents), La Paz (361/100,000 residents), and Gila County (735/100,000 residents). In 2020, a total of over 21,000 transport missions were performed by air ambulance services in Arizona. Each of these transport missions represent a seriously ill or injured patient. These patients and their families benefit from the oversight provided by the Department over air ambulance services. Having rules that include updated requirements and are clearer and easier to understand enable the Department to provide better oversight and air ambulance services to better understand and comply with the rules, as well as provide better services to patients. The Department anticipates that these factors improve the health and safety of patients and, thus, proved a significant benefit to patients and their families.

• General public

Any individual in Arizona may receive services that fall under the requirements in these rules. The Department anticipates that the general public will receive a significant benefit from the changes to the rules, which were developed to clarify existing requirements, make the rules more understandable, and ensure that the rules are consistent with the current standard of care. Having rules to follow that are clearer and easier to understand may allow air ambulance services to more easily comply with requirements and help ensure the health and safety of Arizona citizens.

4. A general description of the probable impact on private and public employment in businesses, agencies, and political subdivisions of this state directly affected by the rulemaking

Public and private employment in the State of Arizona is not expected to be affected due to the changes required in the rule.

- 5. A statement of the probable impact of the rules on small business
 - a. Identification of the small businesses subject to the rules
 Small businesses subject to the rules may include small hospitals and small air ambulance services.
 - b. The administrative and other costs required for compliance with the rules

 Anticipated costs for complying with the rules are described under paragraph 3.
 - c. A description of the methods that the agency may use to reduce the impact on small businesses

Including requirements that specifically allow for leased aircraft may provide a particular benefit to small air ambulance services that do not have the funds or generate sufficient revenue to justify buying aircraft.

d. The probable costs and benefits to private persons and consumers who are directly affected by the rules

The costs to private persons and consumers from the rules changes are described in paragraph 3.

- 6. A statement of the probable effect on state revenues
 - The rulemaking does not include any fee changes, so the Department does not expect the rules to affect state revenues.
- 7. A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed rulemaking

There are no less intrusive or less costly alternatives for achieving the purpose of the rule.

8. A description of any data on which the rule is based with a detailed explanation of how the data was obtained and why the data is acceptable data

Not applicable