
CHAPTER FIVE – RULES PERTAINING TO AIR AMBULANCE LICENSING

Section 1 – Purpose

- 1.1 These rules are promulgated pursuant to Section 25-3.5-307 and 25-3.5-307.5, C.R.S.
- 1.2 Pursuant to §25-3.5-307.5 (2), C.R.S., these rules do not include activities preempted by the Federal Aviation Administration or the federal “Airline Deregulation Act”, 49 U.S.C. sec. 41713 *et seq.* Therefore, any regulations adopted by the board pursuant to section 25-3.5-307 and 307.5. C.R.S establishing reasonable minimum standards for licensing and operation of an air ambulance service must:
 - 1.2.1 Except as otherwise provided in 1.2.2, be based on the medical aspects of the operation of an air ambulance, and
 - 1.2.2 Not be based on economic factors, including, without limitation, factors related to the prices, routes, or nonmedical services of an air ambulance.
- 1.3 An air ambulance service may be authorized to operate in Colorado by either:
 - A) Holding an accreditation by an accrediting organization approved by the Department and complying with section 5.1;
 - B) Meeting the standards set forth in these rules (sections 5.1 and 5.3); or
 - C) An air ambulance service may obtain a recognition instead of license if it picks up patients within the state of Colorado for out of state transport no more than 12 times per calendar year as set forth in section 4.

Section 2 – Definitions

- 2.1 **Air Ambulance:** A fixed-wing or rotor-wing aircraft that is equipped to provide air transportation and is specifically designed to accommodate the medical needs of individuals who are ill, injured, or otherwise mentally or physically incapacitated and who require in-flight medical supervision.
- 2.2 **Air Ambulance Service or Service:** Any public or private entity that uses an air ambulance to transport patients to a medical facility.
- 2.3 **Aircraft:** A rotor or fixed wing vehicle.
- 2.4 **Base Location(s):** Physical address and/or location where the crew, medical equipment and supplies, and the service’s air ambulance(s) are located.
- 2.5 **Department:** The Colorado Department of Public Health and Environment.
- 2.6 **Licensee:** The person, business entity or agency that is granted a license to operate an air ambulance service and that bears legal responsibility for compliance with all applicable federal and state statutes and regulations.
- 2.7 **Medical Protocol or Guidelines:** Written standards for patient medical assessment and management.
- 2.8 **Patient Care Report (PCR):** A medical record of an encounter between any patient and a provider of medical care.

- 2.9 Rescue Unit: Any organized group chartered by this state as a corporation not for profit or otherwise existing as a nonprofit organization whose purpose is the search for and the rescue of lost or injured persons and includes, but is not limited to, such groups as search and rescue, mountain rescue, ski patrols, (either volunteer or professional), law enforcement posses, civil defense units, or other organizations of governmental designation responsible for search and rescue.

Section 3 – Licensing

3.1 Licensing Required

Except as provided in sections 3.2, 3.3 and 4.2 of these rules, no person, agency, or entity, private or public, shall transport a sick or injured person by aircraft from any point within Colorado, to any point within or outside Colorado unless that person, agency, or entity holds a valid air ambulance license to do so that has been issued by the Department.

3.2 Exception from Licensing-Exigent Circumstances

Upon request, the Department may authorize an air ambulance service that does not hold an air ambulance license to provide a particular transport upon a showing of exigent circumstances. Exigent circumstances include but are not limited to:

- A) A humanitarian transport as determined by the Department. In determining whether to authorize a humanitarian transport, the Department shall consider the following factors:
- 1) Whether the transport is provided directly or indirectly by an organization whose mission is primarily dedicated toward non-profit or charitable or community care services;
 - 2) Other available options for the transport;
 - 3) Whether the transport will be of no cost to the patient;
 - 4) Whether the transport is subsidized by a person or entity associated with the patient;
 - 5) The qualifications of the transport personnel;
 - 6) Information obtained from facilities and/or staff involved in the transport;
 - 7) The air ambulance service's membership in organizations that support safe medical care;
 - 8) Air ambulance service insurance coverage as applicable;
 - 9) Authorization under local and federal laws to conduct operations;
 - 10) Licensure in other states or by other governmental agencies;
 - 11) The air ambulance service's safety record;
 - 12) Whether or not the air ambulance service has been subject to disciplinary sanctions in any jurisdictions;

- 13) The air ambulance service's prior contacts with the Department, if any; and
 - 14) Any other considerations deemed relevant by the Department on a case-by-case basis.
- B) A disaster or mass casualty event in Colorado that limits or exceeds the availability of licensed air ambulance services;
 - C) A need for specialized equipment not otherwise readily available through Colorado licensed air ambulance services.
- 3.3 Licensing Not Required
- 3.3.1 An air ambulance service that solely transports patients from points originating outside Colorado is not required to be licensed in Colorado.
 - 3.3.2 Rescue unit aircraft that are not specifically designed to accommodate the medical needs of individuals who are ill, injured, or otherwise mentally or physically incapacitated and who require in-flight medical supervision.
 - 3.3.3 An air ambulance or air ambulance service operated by an agency of the United States government.

Section 4 – Out Of State Air Ambulance Services Licensing and Out of State License Recognition Requirements

- 4.1 Air ambulance services that are based outside the state, but pick up patients in Colorado, are required to be licensed in Colorado by the Department, except as provided in Sections 3.2 and 3.3, above, and 4.2, below, of these rules.
- 4.2 Application for Recognition of Out of State License in Limited Circumstances and Recognition Process
 - 4.2.1 The Department may recognize an air ambulance service license issued by another state if that air ambulance service makes no more than twelve (12) flights per calendar year to pick up a patient(s) in Colorado and transport the patient(s) out of Colorado.
 - 4.2.2 To receive out of state licensure recognition, the air ambulance service must:
 - A) Not have a base location in Colorado;
 - B) Hold a current license in good standing without restrictions or conditions from the state in which it has a base location and submit a copy of the license to the Department; and
 - C) Submit a completed application on the form required by the Department and submit the fee as set forth in section 6 to the Department prior to transporting a patient out of Colorado for the first time.
 - 4.2.3 Out of state licensure recognition is valid for one year from the date of issuance unless revoked or suspended by the Department.

- 4.2.4 An air ambulance service that is granted out of state licensure recognition shall submit an annual report to the Department detailing the number of flights, patients and the health care facilities in Colorado the patients were transported from during the previous year, in the form and manner prescribed by the Department.
- 4.2.5 As it relates to the medical aspects of the operation of an air ambulance service, the Department may conduct an inspection at any time of the air ambulance service and its aircraft to assure compliance with these rules and as needed, the Department may conduct complaint and other investigations of an air ambulance service recognized by the Department.
- 4.2.6 The air ambulance service shall immediately notify the Department of any disciplinary or licensing action taken against it by the licensing authority in any state.
- 4.2.7 If the Department deems it necessary, the Department may request and the applicant shall provide any of the information set forth in section 5.2.
- 4.2.8 If the licensee has made a timely and sufficient application for renewal of the out of state licensure recognition, the existing recognition shall not expire until the Department has acted upon the renewal application.

Section 5 – Application for Colorado Licensing, Licensing Processes, And Base Locations

5.1 Mandatory Requirements for All Applicants Seeking Colorado Licensure

5.1.1 All applicants must:

- A) Demonstrate compliance with applicable federal, state and local laws and regulations to operate an air ambulance service in Colorado, including but not limited to, laws and regulations governing medical personnel and emergency medical service providers, licensing and certifications, and professional liability insurance. Applicants are not required to prove compliance with those provisions of federal law that govern activities preempted by the Federal Aviation Act, 49 U.S.C. §40101, *et seq.*, or the federal "Airline Deregulation Act of 1978" 49 U.S.C. § 41713(b)(1).
- B) Submit to the Department a completed application form and the application fee as set forth in section 6 of these rules.
- C) Upon request, submit to the Department copies of the air ambulance service's written policy and procedure manual, operation/medical protocols, and other documentation the Department may deem necessary.
- D) Submit a copy of air ambulance service license(s) concurrently issued and on file with other states.
- E) Provide the Department with results of any investigations, disciplinary actions, or exclusions that impact or have the potential to impact the quality of medical care provided to patients as requested by the Department.

- F) For an air ambulance service that is not granted qualified immunity under the Colorado Governmental Immunity Act, section 24-10-101 *et seq.*, C.R.S., shall provide proof of professional malpractice and liability insurance for injuries to persons in amounts of at least \$1,000,000 for each individual claim and a total of \$3,000,000 for all claims made against the air ambulance service or its medical personnel from an insurance company authorized to write liability insurance in Colorado or through a self-insurance program.
- 1) The air ambulance service shall provide the Department with a copy of its certificate of insurance demonstrating compliance with this section or proof of financial viability if self-insured; and
- G) Any air ambulance service that is granted qualified immunity under the Colorado Governmental Immunity Act, section 24-10-101 *et seq.*, C.R.S., shall provide proof of professional malpractice and liability insurance coverage, or proof of self-insurance to the maximum extent required by section 24-10-114, C.R.S.
- H) Provide proof of worker's compensation coverage as required by Colorado law.
- I) Provide a list of all air ambulances to be licensed and inspected for medical compliance by the Department, including tail number (n-number) and designation of (rotor or fixed wing) capabilities.
- J) Provide a statement signed and dated contemporaneously with the application stating whether, within the previous ten (10) years of the date of application, the applicant has been the subject of, or a party to, one of more of the following events, regardless of whether action has been stayed in a judicial appeal or otherwise settled between the parties.
- 1) Been convicted of a felony or misdemeanor involving moral turpitude under the laws of any state or of the United States. A guilty verdict, a plea of guilty or a plea of *nolo contendere* (no contest) accepted by the court is considered a conviction.
 - 2) Had a state license or federal certification denied, revoked, or suspended by another jurisdiction.
 - 3) Had a civil judgment or a criminal conviction in a case brought by federal, state or local authorities that resulted from the operation, management, or ownership of a health facility or other entity related to substandard patient care or health care fraud.
- K) If applicable, provide any statement regarding the information requested in paragraph (J) to include the following:
- 1) If the event is an action by federal, state or local authorities; the full name of the authority, its jurisdiction, the case name, and the docket, proceeding or case number by which the event is designated, and a copy of the consent decree, order or decision.
 - 2) If the event is a felony or misdemeanor conviction involving moral turpitude, the court, its jurisdiction, the case name, the case number, a description of the matter or a copy of the indictment or charges, and any plea or verdict entered by the court.

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- 3) If the event involves a civil action or arbitration proceeding, the court or arbiter, the jurisdiction, the case name, the case number, a description of the matter or a copy of the complaint, and a copy of the verdict, the court or arbitration decision.
- 5.1.2 Air ambulance service licenses are not transferable.
 - 5.1.3 The Department has the authority to conduct an inspection or reinspection of the medical aspects of the air ambulance service operation including equipment and documentation, at any time it deems necessary to ensure compliance with these rules and to protect the public health and medical safety.
 - 5.1.4 The applicant shall provide accurate and truthful information to the Department during inspections, investigations and licensing activities.
- 5.2 Mandatory Reporting Requirements for all Existing Licensees
- 5.2.1 Except for requiring proof of compliance with those provisions of federal law that govern activities preempted by the Federal Aviation Act , 49 U.S.C. §40101, *et seq.*, or the federal "Airline Deregulation Act of 1978" 49 U.S.C. § 41713(b)(1), all licensed air ambulance services must notify the Department:
 - A) At least thirty (30) calendar days prior to the effective date of the change of any name of the air ambulance service and submit a new air ambulance service application and applicable fees.
 - B) At least thirty (30) calendar days prior to the effective date of any change of ownership, pursuant to section 5.8, the new owner or operator must file for and obtain an air ambulance license from the Department prior to beginning operations.
 - C) Within five (5) calendar days when there has been a reduction or loss of insurance coverage.
 - D) Within sixty (60) calendar days of all other changes in insurance coverage.
 - E) Within seven (7) calendar days of knowing about any of the following events impacting patient medical care occurring on or during transport onto or off of an air ambulance, report to the Department and the approved accreditation organization, if applicable:
 - 1) Invasive procedure performed on the wrong site.
 - 2) Wrong other procedure performed on a patient.
 - 3) Unintended retention of a foreign object in a patient after an invasive procedure.
 - 4) Immediately post procedure death in an American society of anesthesiologists class I patient.
 - 5) Patient death or serious injury associated with the use of contaminated drugs, devices, or biologics provided by the service.

- 6) Patient death or serious injury associated with the use or function of a device in which the device is used in a manner other than as intended.
- 7) Patient death or serious injury associated with intravascular air embolism.
- 8) Release of a patient of any age, who is unable to make decisions, to other than an authorized person.
- 9) Patient suicide, attempted suicide, or self-harm that results in serious injury.
- 10) Patient death or serious injury associated with any medication error.
- 11) Patient death or serious injury associated with any unsafe administration of blood products.
- 12) Maternal death or serious injury associated with labor or delivery in a low-risk pregnancy.
- 13) Death or serious injury of a neonate associated with labor or delivery in a low-risk pregnancy.
- 14) Patient death or serious injury resulting from failure to follow up or communicate laboratory, pathology, or radiology test results.
- 15) Patient or staff death or serious injury associated with an electric shock in the course of patient care.
- 16) Any incident in which systems designated for oxygen or other gas to be delivered to a patient contains no gas, the wrong gas, or are contaminated by toxic substances.
- 17) Patient or staff death or serious injury associated with a burn incurred from any source in the course of patient care.
- 18) Patient death or serious injury associated with the use of physical restraints during the course of patient care.
- 19) Death or serious injury of a patient or staff associated with the introduction of a metallic object into the MRI area.
- 20) Any instance of care ordered by or provided by someone impersonating a licensed health care provider.
- 21) Any instance of alleged unlawful sexual behavior on a patient or staff member, as defined by section 18-3-401 *et seq.*, C.R.S.
- 22) Patient or staff death or serious injury resulting from a physical assault.
- 23) Appropriating or possessing without authorization medications, supplies, equipment, or personal items of a patient or employer.

5.3 State Licensing Process.

- 5.3.1 With respect to those applicants seeking to acquire licensure pursuant to this section, the Department shall review the applicant's fitness to provide appropriate medical care as a licensed air ambulance service. The Department shall determine by on-site inspection or other appropriate investigation the applicant's compliance with applicable statutes and regulations concerning the medical aspects of the air ambulance service. The Department shall consider the information contained in the air ambulance service's application and may request access to and consider other information concerning the medical aspects of the air ambulance service operation including, without limitation, aspects related to patient care, such as:
- A) Whether the applicant has legal status to provide the medical and related patient care services for which the license is sought as conferred by articles of incorporation, statute or other governmental declaration,
 - B) The applicant's previous compliance history, including compliance with requirements of other states or accreditation organizations where the applicant was licensed or accredited within the previous 5 years,
 - C) The applicant's policies and procedures as delineated in section 9 of these rules,
 - D) The applicant's quality improvement plans, other quality improvement documentation as may be appropriate, and accreditation reports,
 - E) Credentials of patient care staff,
 - F) Interviews with staff, and
 - G) Other documents deemed appropriate by the Department.
- 5.3.2 Where an air ambulance service is licensed and subject to inspection, certification, or review by other agencies, states or accrediting organizations, the air ambulance service shall provide and/or release to the Department, upon request, any correspondence, reports or recommendations concerning the air ambulance service applicant that were prepared by such organizations.
- 5.3.3 The applicant shall provide, upon request, access to such individual patient records as the Department requires for the performance of its licensing and regulatory oversight responsibilities.
- 5.3.4 An applicant shall provide, upon request, access to or copies of reports and information required by the Department including, but not limited to, medical staffing reports, statistical information, and such other records pertaining to medical and patient care objectives as the Department requires for the performance of its licensing and regulatory oversight responsibilities.
- 5.3.5 the Department shall not release to any unauthorized person any information defined as confidential under state law or the Health Insurance Portability and Accountability Act of 1996, codified at 42 U.S.C. section 300gg, 42 U.S.C. 1320d *et seq.*, and 29 U.S.C. section 1181, *et seq.*

- 5.3.6 As it relates to the medical aspects of the operation of an air ambulance service, the Department may conduct an inspection of the air ambulance service and its aircraft to assure compliance with these rules, and as needed, the Department may conduct complaint and other investigations of an air ambulance service.
- 5.3.7 The applicant shall submit to the Department the applicable fee(s) set forth in section 6 of these rules.
- 5.4 Licensure through Accreditation by Organization Approved by Department.
- 5.4.1 In addition to meeting the requirements in 5.1, applicants that are currently accredited by an organization approved by the Department pursuant to section 5.5 may receive an air ambulance license upon completion of the documentation and payment of fees that are required by the Department. The air ambulance service shall authorize the accrediting organization to submit directly to the Department copies of any documentation within the accrediting organization's control concerning its evaluation of the air ambulance service's compliance with the organization's standards during the previous accreditation cycle. Such documentation shall include but is not limited to, surveys, inspections, final audit reports, plans of correction, and the most recent letter of accreditation showing the service has received accreditation status.
- 5.4.2 As it relates to the medical aspects of the operation of an air ambulance service, the Department may conduct an inspection of the air ambulance service and its aircraft to assure compliance with these rules and, as needed, the Department may conduct complaint and other investigations of an air ambulance service accredited by an organization approved by the Department.
- A) Any air ambulance service licensed under this section shall immediately notify the Department in the event that it receives any notice that its accreditation has been withdrawn, revoked, suspended or modified, or that it is no longer accredited by the accreditation organization approved by the Department.
- B) If the licensed air ambulance service voluntarily surrenders its accreditation, or is notified by the accrediting organization that the service's accreditation is at risk of being revoked, suspended, withdrawn, preliminarily denied, deferred, or modified in any way—such as being placed on probation, placed under review or under special review, or placed on-hold--the licensed service must provide the Department within one (1) business day with information describing the circumstances the accrediting organization states for the reason(s) for the possible action. The Department may:
- 1) Initiate appropriate actions it deems necessary to evaluate the licensed service's performance;
 - 2) Elect to revoke or summarily suspend the service's Colorado license that is based on the accreditation in section 5.4; and/or
 - 3) Require the licensed service to immediately apply for state licensure through the process set forth in section 5.3.

- C) If the licensed air ambulance service's accreditation has been withdrawn or revoked, the licensed service must provide the Department with information describing the circumstances the accrediting organization states for the reason(s) for the action. The service shall immediately cease operations. If the air ambulance service wishes to continue to operate it must submit an application and receive a state license as set forth in section 5.3, before it may continue to operate under these rules as a licensed air ambulance service.
 - 1) The Department may allow the service to continue operating under a provisional license as described in section 5.6, below.
 - 2) If the Department allows the service to operate under a provisional license, the provisional license period shall begin on the date of the accreditation withdrawal or revocation. In no event shall the service be allowed to operate under a provisional license for more than one hundred eighty (180) days.
- 5.4.3 If the Department deems it necessary, the Department may request, and the applicant shall provide, any of the information set forth in section 5.2.
- 5.4.4 The Department shall publish a list of the accrediting organizations that it has approved on its website.
- 5.4.5 The applicant shall submit to the Department the applicable fee(s) set forth in section 6 of these rules.
- 5.4.6 If the licensed air ambulance has made a timely and sufficient application for renewal of the license, the existing license shall not expire until the Department has acted upon the renewal application.
- 5.5. Requirements for Approval of Accreditation Organization
 - 5.5.1 To be approved by the Department as an acceptable accreditation organization for the purposes of section 5.4, the accrediting organization must meet the following minimum standards:
 - A) Has standards that are equivalent to or exceed the standards in this chapter.
 - B) Provides accreditation for no more than three consecutive years without an updated inspection and reaccreditation.
 - C) Has a multidisciplinary board of directors with members consisting of, at a minimum, individuals who are medical transport professionals and related health professionals that:
 - 1) Seek input and guidance from national professional medical organizations in the development of its standards, and
 - 2) Assure that the organization allows for multidisciplinary input in the development and implementation of its standards and review processes.
 - D) Uses trained site-surveyors with experience in medical transport at the level of accreditation and license.

- E) Assures that air ambulance services with identified deficiencies will implement corrective action or improvement plans to correct any deficiencies.
- F) Has an open process that encourages and accepts comments on its accreditation standards.
- G) Provides transparency to the public on its standards and procedures.
- H) Maintains insurance (general liability, medical professional liability, directors & officers and travel) and be able to present its current certificates of insurance to the Department.
- I) In addition to its right to conduct independent inspections of equipment and documentation pursuant to section 5.1.3 of these rules, allows a Department representative to accompany accreditation surveyors on site surveys or during any accreditation inspections at the request of the Department.
- J) Has a clear conflict of interest policy.

5.6 Provisional License.

5.6.1 The Department may issue a provisional license to an applicant for an initial license to operate an air ambulance service if:

- A) The applicant is temporarily unable to conform to all the minimum standards required under title 25, part 3.5 and these rules;
- B) The operation of the applicant's air ambulance service will not adversely affect patient care or the health, safety and welfare of the public; and
- C) The applicant air ambulance service demonstrates it is making its best efforts to achieve compliance with the applicable rules.

5.6.2 A provisional license issued by the Department shall be valid for a period not to exceed ninety (90) calendar days, except that the Department may issue a second provisional license for the same duration and shall charge the same fee as for the first provisional license. If the licensee has made a timely and sufficient application for renewal of the provisional license, the existing license shall not expire until the Department has acted upon the renewal application. The Department may not issue a third or subsequent provisional license to the applicant, and in no event shall a service be provisionally licensed for a period to exceed one hundred eighty (180) calendar days.

5.6.3 The applicant shall submit to the Department the applicable fee(s) set forth in section 6 of these rules.

5.7 Conditional License

5.7.1 The Department may impose conditions or limitations upon a license prior to issuing an initial or renewal license or during an existing license term. If the Department imposes conditions or limitations on a license, the licensee shall immediately comply with all conditions or limitations until and unless said conditions are overturned or stayed on appeal.

- A) If conditions or limitations are imposed at the same time as an initial or renewal license, the applicant shall pay the applicable initial or renewal license fee plus the conditional fee as set forth in section 6 of these rules. If conditions or limitations are imposed during the license term, the licensee shall pay the conditional fee and the conditions or limitations shall run concurrently with the existing license term. If the conditions are renewed in whole or in part for the next license term, the licensee shall pay the applicable renewal fee along with the conditional fee in effect at the time of renewal.
 - B) If the Department imposes conditions or limitations of continuing duration that require only minimal administrative oversight, it may waive the conditional fee after the licensee has complied with the conditions or limitations for a full license term.
- 5.7.2 Unless consented to by the air ambulance service, a limitation imposed prior to issuance of an initial or renewal license shall be treated as a denial. A modification of an existing license during its term, unless consented to by the air ambulance service, shall be treated as a revocation.
- 5.8 Change of Ownership/Management
- 5.8.1 When a currently licensed air ambulance service anticipates a change of ownership, the current licensee shall notify the Department within the specified time frame and the prospective new licensee shall submit an application for change of ownership along with the requisite fees and documentation within the same time frame. The time frame for submittal of such notification and documentation shall be at least thirty (30) calendar days before a change of ownership involving any air ambulance service.
- 5.8.2 in general, the conversion of an air ambulance service's legal structure, or the legal structure of an entity that has a direct or indirect ownership interest in the air ambulance service is not a change of ownership unless the conversion also includes a transfer of at least 50 percent of the licensed air ambulance service's direct or indirect ownership interest to one or more new owners. Specific instances of what does or does not constitute a change of ownership are set forth below in section 5.8.3.
- 5.8.3 The Department shall consider the following criteria in determining whether there is a change of ownership of an air ambulance service that requires a new license:
- A) Sole proprietors:
 - 1) The transfer of at least 50 percent of the ownership interest in an air ambulance service from a sole proprietor to another individual, whether or not the transaction affects the title to real property, shall be considered a change of ownership.
 - 2) Change of ownership does not include forming a corporation from the sole proprietorship with the proprietor as the sole shareholder.
 - B) Partnerships:
 - 1) Dissolution of the partnership and conversion into any other legal structure shall be considered a change of ownership if the conversion also includes a transfer of at least 50 percent of the direct or indirect ownership to one or more new owners.

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- 2) Change of ownership does not include dissolution of the partnership to form a corporation with the same persons retaining the same shares of ownership in the new corporation.
- C) Corporations:
- 1) Consolidation of two or more corporations resulting in the creation of a new corporate entity shall be considered a change of ownership if the consolidation includes a transfer of at least 50 percent of the direct or indirect ownership to one or more new owners.
 - 2) Formation of a corporation from a partnership, a sole proprietorship or a limited liability company shall be considered a change of ownership if the change includes a transfer of at least 50 percent of the direct or indirect ownership to one or more new owners.
 - 3) The transfer, purchase or sale of shares in the corporation such that at least 50 percent of the direct or indirect ownership of the corporation is shifted to one or more new owners shall be considered a change of ownership.
- D) Limited liability companies:
- 1) The transfer of at least 50 percent of the direct or indirect ownership interest in the company shall be considered a change of ownership.
 - 2) The termination or dissolution of the company and the conversion thereof into any other entity shall be considered a change of ownership if the conversion also includes a transfer of at least 50 percent of the direct or indirect ownership to one or more new owners.
 - 3) Change of ownership does not include transfers of ownership interest between existing members if the transaction does not involve the acquisition of ownership interest by a new member. For the purposes of this subsection, "member" means a person or entity with an ownership interest in the limited liability company.
- 5.8.4. Management contracts, leases or other operational arrangements:
- A) If the owner of an air ambulance service enters into a lease arrangement or management agreement whereby the owner retains no authority or responsibility for the operation and management of the air ambulance service, the action shall be considered a change of ownership that requires a new license.
- 5.8.5 Each applicant for a change of ownership shall provide the following information:
- A) The legal name of the entity and all other names used by it to provide health care services. The applicant has a continuing duty to notify the Department of all name changes at least thirty (30) calendar days prior to the effective date of the change.
 - B) Contact information for the entity including mailing address, telephone and facsimile numbers, e-mail address and website address, as applicable.

- C) The identity of all persons and business entities with a controlling interest in the air ambulance service, including administrators, directors, managers and management contractors.
 - 1) A non-profit corporation shall list the governing body and officers.
 - 2) A for-profit corporation shall list the names of the officers and stockholders who directly or indirectly own or control five percent or more of the shares of the corporation.
 - 3) A sole proprietor shall include proof of lawful presence in the united states in compliance with section 24-76.5-103(4), C.R.S.
- D) The name, address and business telephone number of every person identified in section 5.8.5 (C) and the individual designated by the applicant as the chief executive officer of the entity.
 - 1) If the addresses and telephone numbers provided above are the same as the contact information for the entity itself, the applicant shall also provide an alternate address and telephone number for at least one individual for use in the event of an emergency or closure of the air ambulance service.
- E) Proof of professional liability insurance obtained and held in the name of the license applicant as required by section 5.1.1 (F) & (G) of these rules. Such coverage shall be maintained for the duration of the license term and the Department shall be notified of any change in the amount, type or provider of professional liability insurance coverage during the license term.
- F) Articles of incorporation, articles of organization, partnership agreement, or other organizing documents required by the secretary of state to conduct business in Colorado; and by-laws or equivalent documents that govern the rights, duties and capital contributions of the business entity.
- G) The address of the entity's physical location and the name(s) of the owner(s) of each structure on the campus where licensed services are provided if different from those identified in paragraph (C) of this section.
- H) A copy of any management agreement pertaining to operation of the entity that sets forth the financial and administrative responsibilities of each party.
- I) If an applicant leases one or more building(s) to operate as a licensed air ambulance service, a copy of the lease shall be filed with the license application and show clearly in its context which party to the agreement is to be held responsible for the physical condition of the property.
- J) A statement signed and dated contemporaneously with the application stating whether, within the previous ten (10) years, any of the new owners have been the subject of, or a party to, one of more of the following events, regardless of whether action has been stayed in a judicial appeal or otherwise settled between the parties.

- 1) Been convicted of a felony or misdemeanor involving moral turpitude under the laws of any state or of the United States. A guilty verdict, a plea of guilty or a plea of nolo contendere (no contest) accepted by the court is considered a conviction.
 - 2) Had a state license or federal certification denied, revoked, or suspended by another jurisdiction.
 - 3) had a civil judgment or a criminal conviction in a case brought by federal, state or local authorities that resulted from the operation, management, or ownership of a health facility or other entity related to substandard patient care or health care fraud.
- K) Any statement regarding the information requested in paragraph (J) shall include the following, if applicable:
- 1) If the event is an action by federal, state or local authorities; the full name of the authority, its jurisdiction, the case name, and the docket, proceeding or case number by which the event is designated, and a copy of the consent decree, order or decision.
 - 2) If the event is a felony or misdemeanor conviction involving moral turpitude, the court, its jurisdiction, the case name, the case number, a description of the matter or a copy of the indictment or charges, and any plea or verdict entered by the court.
 - 3) If the event involves a civil action or arbitration proceeding, the court or arbiter, the jurisdiction, the case name, the case number, a description of the matter or a copy of the complaint, and a copy of the verdict, the court or arbitration decision.
- 5.8.6 The existing licensee shall be responsible for correcting all rule violations and deficiencies in any current plan of correction before the change of ownership becomes effective. In the event that such corrections cannot be accomplished in the time frame specified, the prospective licensee shall be responsible for all uncorrected rule violations and deficiencies including any current plan of correction submitted by the previous licensee unless the prospective licensee submits a revised plan of correction, approved by the Department, before the change of ownership becomes effective.
- 5.8.7 If the Department issues a license to the new owner, the previous owner shall return its license to the Department within five (5) calendar days of the new owner's receipt of its license.
- 5.9 Base Locations in Colorado
- 5.9.1 If an air ambulance service has a base located within Colorado, the air ambulance service shall at all times:
- A) Maintain or have readily available records of operation;
 - B) Have security measures in place to protect the air ambulance from tampering and the unauthorized access to medical equipment and supplies, including pharmaceuticals. This would include direct visual monitoring or closed circuit television or the air ambulance must be in a secured location with locked perimeter fencing or hangar;

- C) Display its Colorado air ambulance service license within a building at the base location;
 - D) Display its drug enforcement agency registration in the building where controlled substances, if any, are stored;
 - E) Maintain a current post-accident incident plan;
 - F) Comply with applicable state and local building and fire codes;
 - G) Maintain or have readily available documentation of the professional certifications and/or licenses and continuing education documentation for staff responsible for providing patient care.
- 5.9.2 An air ambulance service that has a base location in Colorado is not eligible for out of state licensure recognition pursuant to section 4 of these rules.

Section 6 – Fees

- 6.1 All applicants seeking air ambulance licensure by the Department under these rules shall submit the non-refundable fees required by this section 6.
- 6.2 Licensing Fees
- 6.2.1 Each air ambulance service seeking initial or renewal licensure pursuant to section 5.3 or 5.4 shall submit a licensing fee of \$3,400 to the Department.
 - 6.2.2 All applicants seeking an initial or renewal recognition of out of state licensure pursuant to section 4 shall pay an annual fee of \$1700 to the Department.
 - 6.2.3 All applicants seeking a provisional license pursuant to section 5.6 shall pay a fee of \$1700 to the Department. An applicant seeking a second provisional license shall pay the same fee amount as rendered for the first provisional license.
 - 6.2.4 All applicants subject to a conditional license pursuant to section 5.7 may be assessed a fee based on the direct and indirect costs incurred by the Department in addition to the required initial or renewal fee in section 6.2.1 of these rules.
- 6.3 Per Aircraft Fees
- 6.3.1 In addition to licensing fees set forth in 6.2.1, each air ambulance service seeking initial or renewal licensure pursuant to sections 5.3 and 5.4 of these rules shall pay a per aircraft fee of \$400 to the Department for each aircraft used by the air ambulance service.
 - 6.3.2 In addition to the licensing fees set forth in 6.2.2, each air ambulance service seeking an initial or renewal recognition of out of state licensure pursuant to section 4 shall pay a per aircraft fee of \$200 to the Department for each aircraft used by the air ambulance service in the state.
 - 6.3.3 In addition to the licensing fees set forth in 6.2.3, each air ambulance service seeking an initial or second provisional license pursuant to 5.6 shall pay a per aircraft fee of \$400 to the Department for each aircraft used by the air ambulance service.

- 6.3.4 In addition to the licensing fees set forth in 6.2.4, each air ambulance service subject to a conditional license pursuant to section 5.7 shall pay a per aircraft fee of \$400 to the Department for each aircraft used by the air ambulance service.
- 6.4 In addition to the applicable fees set forth in 6.2 and 6.3 of these rules, the Department shall assess a variable on-site inspection fee for all applicants seeking state licensure pursuant to section 5.3.
- 6.5 If, after obtaining a license, an air ambulance service expands its fleet of aircraft licensed in Colorado, the service shall pay the appropriate per aircraft fee as set forth in 6.2 for every additional aircraft at the time it is placed in service. Moreover, if the Department deems it necessary to inspect the additional aircraft it shall assess upon the licensee the inspection fee as set forth in 6.4.
- 6.6 Any air ambulance service changing ownership pursuant to section 5.8 shall pay the Department a fee of \$3400.
- 6.7 Any air ambulance service changing its name shall pay the Department a fee of \$600.

Section 7 – Licensing Period

- 7.1 Except as provided in sections 4.2.3 and 5.6.2, any air ambulance license issued by the Department shall be valid for a period not to exceed two (2) years.

Section 8 – Licensing Renewal and Recognition of Out of State License Renewal

- 8.1 To renew an existing air ambulance license, the licensee shall submit a renewal application and fees, as set by the Department, no later than thirty (30) calendar days prior to the date of air ambulance license expiration.
- 8.2 A renewal inspection may be required by the Department to assure air ambulance service compliance with these rules.
- 8.3 Except as otherwise provided in section 5.6 of these rules, the Department shall renew a license when it is satisfied that the requirements of these rules have been met. If the licensee has made a timely and sufficient application for renewal of the license, the existing license shall not expire until the Department has acted upon the renewal application.
- 8.4 If an air ambulance service is authorized to operate in Colorado because of the Department's recognition of out of state licensure pursuant to section 4, the licensee shall submit a renewal application, documentation of current out of state licensure and fees, as set forth in section 6, no later than thirty (30) calendar days prior to the date of the Colorado air ambulance recognition expiration.
- 8.5 [Emergency rule expired 08/08/2020]

Section 9 – General Medical Operational Requirements for Air Ambulance Services Licensed by the Department

- 9.1 Policies and Procedures
- 9.1.1 To assess the adequacy of patient care, every applicant or licensee shall make available for reference and inspection a detailed manual of its policies and procedures. Service personnel shall be familiar and comply with policies contained within the manual. The manual shall include:

- A) Procedures for acceptance of requests, referrals, and/or denial of service for medically related reasons;
- B) A written description of the geographical boundaries and features for the service area, and a copy of the service area map;
- C) Scheduled hours of operation;
- D) Criteria for the medical conditions and indications or medical contraindications for flight;
- E) Field triage criteria for all trauma patients;
- F) Medical communication procedures, including but not limited to medically-related dispatch protocol, call verification and advisories to the requesting party, to include procedures for informing requesting party of flight procedures, anticipated time of aircraft arrival, and cancellation of flight;
- G) Criteria regarding acceptable destinations based upon medical needs of the patient;
- H) Non-aviation safety procedures for medical crew assignments and notification, including rosters of medical personnel;
- I) Written policy that ensures air medical personnel shall not be assigned or assume cockpit duties concurrent with patient care duties and responsibilities;
- J) Written policy that directs air ambulance personnel to honor a patient request for a specific service or destination when the circumstances will not jeopardize patient safety;
- K) On-ground medical communications procedures;
- L) Flight referral procedures;
- M) A written plan that addresses the actions to be taken in the event of an emergency, diversion, or patient crisis during transport operations;
- N) Patient tracking procedures that shall assure air/ground position reports at intervals not to exceed fifteen (15) minutes inflight and forty-five (45) minutes while landed on the ground;
- O) Written procedures governing the air ambulance service's medical complaint resolution process and protocols. At minimum, the air ambulance service shall designate personnel responsible for its dispute resolution process and provide the protocols it shall follow when investigating, tracking, documenting, reviewing and resolving the complaint. The service's complaint resolution procedures shall emphasize resolution of complaints and problems within a specified period of time; and
- P) Policy for delineating methods for maintaining medical communications during power outages and in disaster situations.

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- 9.1.2. To ensure proper patient care and the effective coordination of statewide emergency medical and trauma services, services that respond to incident scenes and/or support disaster response shall provide aircraft safety and landing zone procedures in a written format to all fire, rescue, ems, public safety, law enforcement agencies and medical facility personnel who interface with the medical service that includes but is not limited to the following:
- A) The identification, designating and preparation of appropriate landing zones;
 - B) Provider safety in and around the aircraft;
 - C) Air to ground communications; and
 - D) crash recovery procedures
- 9.2. Each licensed air ambulance service shall complete and submit to the Department a profile that includes information to be used by the Department to provide effective communications, planning and coordination of statewide emergency medical and trauma services.
- 9.2.1 All air ambulance service agencies licensed in Colorado shall provide the Department with the required data and information as specified below in a format determined by the Department or in an alternate media acceptable to the Department.
- 9.2.2 Air ambulance service agencies shall provide organizational profile data in a manner designated by the Department.
- 9.2.3 Agencies shall update organizational profile data whenever changes occur and at least annually.
- 9.3 Medical Transport Plans
- 9.3.1 To ensure proper patient care and the effective coordination of statewide emergency medical and trauma services, all air ambulance services shall have an integrated medical transport plan for each air ambulance licensed by the Department that describes the following:
- A) Base location
 - B) Hours of operation
 - C) Emergency (dispatch) and non-emergency (business) contact information
 - D) Description of primary and secondary service areas
 - E) Medical criteria for utilization
 - F) Description of medical capabilities (including availability of specialized medical transport equipment)
 - G) Communications capabilities including (but not limited to) radio frequencies and talk groups.
 - H) Procedures for communicating with the air medical crew
 - I) Mutual aid or backup procedures when the service is not available
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9.4 Medically-Related Dispatch Protocols

9.4.1 When air ambulance transport is indicated, requests shall be appropriately coordinated after consultation with the requesting party. All air ambulance services shall maintain communication with all appropriate entities involved in the response, including the receiving facility.

9.5 Medical Communications

9.5.1 An air ambulance service shall have a two-way wireless communication system with reliable equipment that will allow clear voice communication among and between all agencies necessary for the safe and effective transport and medical care of the patient and crew.

9.5.2 An air ambulance service's two-way communication equipment system shall allow for or have:

- A) Real-time patient tracking that shall be maintained and documented every fifteen (15) minutes including the time the air ambulance returns to service following transport.
- B) Appropriate wireless communications capabilities with local first responders, to include fire, rescue, emergency medical services (EMS), and law enforcement as published in the State EMS Telecommunications Plan.
- C) A system of communications, exclusive of the air traffic control system, that must be capable of communications with medical services (EMS), and law enforcement as published in the State EMS Telecommunications Plan.
- D) Dedicated telephone number for the air ambulance service dispatch center.
- E) The air ambulance service communications center must be staffed during all phases of patient treatment and transport.
- F) An emergency plan for communications during power outages and in disaster situations.

9.6 Medical Personnel

9.6.1 At a minimum an air ambulance service must have the following medical personnel:

- A) An air ambulance service medical director who oversees the practice of emergency medical services during patient transport for a Colorado licensed service must be familiar with Colorado state medical standards, practices, and licensing requirements. Therefore, except as provided in section 9.6.1(B), a medical director must be a Colorado licensed physician in good standing to supervise the medical care provided in an air medical environment. The medical director must also:
 - 1) Be board certified or board-eligible in EMS, emergency medicine, or other specialty serving the patient population involved;
 - 2) Have experience in the care of patients consistent with the licensing and mission profile of the air ambulance service;

- 3) Have access to medical specialists for consultation regarding patients whose illness and care needs are outside the medical director's area of practice;
 - 4) Have a current DEA registration; and
 - 5) Have current credentials achieved through active participation in patient care and continuing medical education activities appropriate for the role of an air ambulance service medical director.
- B) For air ambulance services operating pursuant to section 4 of these rules, the medical director who is licensed and in good standing, without restrictions or conditions, in the state in which the service is based, and who is exempt from Colorado licensure requirements pursuant to section 12-36-106(3)(b), C.R.S., may supervise the medical care provided to a patient in an air medical transport that either originates or terminates in Colorado. Under these circumstances the medical director must:
- 1) Be board certified or board-eligible in EMS, emergency medicine, or other specialty serving the patient population involved;
 - 2) Have experience in the care of patients consistent with the licensing and mission profile of the air ambulance service;
 - 3) Have access to medical specialists for consultation regarding for patients whose illness and care needs are outside the medical director's area of practice;
 - 4) Have a current DEA registration; and
 - 5) Have current credentials achieved through active participation in patient care and CME activities appropriate for the role of an air ambulance service medical director.
- C) An air ambulance service medical director who oversees the practice of emergency medical services during transport of a patient that originates and terminates in Colorado must be a Colorado licensed physician in good standing that meets the requirements set forth in section 9.6.1(A).
- D) Medically qualified Colorado licensed, or certified, individuals appropriate to the scope and mission of the air ambulance service, or providers recognized under an interstate compact of which Colorado is a member. Acceptable medical personnel include, but are not limited to physicians, certified emergency medical services providers, registered nurses, registered nurse practitioners, advanced practice nurses, physician assistants, respiratory therapists, or other allied health professionals.
- 9.6.2 Each patient transport by a licensed air ambulance service shall be staffed by a minimum of two (2) medical personnel who are licensed or certified according to Colorado and/or providers recognized under an interstate compact of which Colorado is a member who provide direct patient care, plus a vehicle operator.
- A) One of the medical personnel must be the primary care provider, who, as the team leader with a higher level of license, is ultimately responsible for the patient.

- 1) The primary care provider may be a licensed nurse, a resident or staff physician, or a paramedic.
 - 2) If the primary care provider is a licensed nurse, s/he must have CEN, CCRN, CFRN or CTRN [or equivalent national certification] within two (2) years of hire and must have pre-hire experience in the medications and interventions listed necessary for the service's scope of care. The licensed nurse must also have three (3) years critical care experience, which is no less than 4000 hours experience in an ICU or an emergency department.
 - 3) If the primary care provider is a paramedic, s/he must have pre-hire experience in the medications and interventions listed necessary for the service's scope of care. The paramedic must also have 3 years critical care experience, which is no less than 4000 hours experience in an ICU or an emergency department.
- B) If the second medical provider is a paramedic, then the paramedic must have a FP-C or CCP-C, or Colorado critical care endorsement, or equivalent required within two (2) years of hire, along with three (3) years (minimum of 4000 hours) of advanced life support experience.
- C) If the second medical provider is a registered respiratory therapist (RRT), the RRT is required to have a minimum of 4000 hours of emergency department or ICU experience.
- D) The composition of the medical team may be altered for specialty missions and teams upon approval and credentialing by the air ambulance service medical director.
- E) The medical team must demonstrate affective and psychomotor education sufficient to meet the clinical needs for the type of patient served in an air ambulance medical environment without restrictions.
- F) Medical personnel shall operate only within their scope of practice, including an emergency medical service provider acting in accordance with a waiver granted pursuant to Chapter Two, 6 CCR 1015-3.

9.6.3 Training Requirements

- A) An air ambulance service shall have a training and educational program that is required for all medical air ambulance personnel, including the medical director.
- B) At a minimum, the training and educational program shall contain program orientation, initial and recurrent training which is consistent with the air ambulance service's scope of care, patient population, mission statement and medical direction. The air ambulance service shall document that its air ambulance medical personnel have completed training, met the learning objectives and have ongoing clinical experience in the following:
- 1) Care of patients in the air medical environment including the impact of altitude and other stressors;
 - 2) Advanced airway management;

- 3) Applicable medical device specific training (automatic implantable cardioverter defibrillator (AICD), extracorporeal membrane oxygenation (ECMO), intra-aortic balloon pump (IABP), left ventricular assist device (LVAD), medication pumps, ventilators, etc.;
 - 4) Cardiology;
 - 5) Mechanical ventilation and respiratory physiology for adult, pediatric, and neonatal patients as it relates to the mission statement and scope of care of the medical transport service specific to the equipment;
 - 6) High risk obstetrical emergencies and obstetrics care;
 - 7) Pediatrics and neonatal care;
 - 8) Emergency/critical care for all applicable patient populations, including special needs populations;
 - 9) Hazardous materials recognition and response;
 - 10) Management of disaster and mass casualty events;
 - 11) Infection control and prevention; and
 - 12) Ethical and legal issues.
- C) The air ambulance service medical director shall have familiarity in the following areas:
- 1) Care of patients in the air medical environment, including the impact of altitude and other patient stressors, in-flight assessment and care, monitoring capabilities, and limitations of the flight environment;
 - 2) Hazardous materials recognition and response;
 - 3) Management of disaster and mass casualty events;
 - 4) Infection control and prevention;
 - 5) Advanced resuscitation and care of adult, pediatric and neonatal patients with both traumatic and non-traumatic diagnoses;
 - 6) Quality improvement theories and applications;
 - 7) Principles of adult learning;
 - 8) Capabilities and limitations of care in an air ambulance;
 - 9) Applicable federal, state and local law, rules and protocols related to air medical services and state trauma rule guidelines;
 - 10) Air medical dispatch and communications; and
 - 11) Ethical and legal issues.

9.6.4 Air Ambulance Service Medical Director Roles and Responsibilities

- A) The air ambulance service medical director roles and responsibilities shall include:
- 1) Responsibility for oversight of medical care provided by the air medical service and ensure competency and currency of all medical personnel;
 - 2) Active engagement in the evaluation, credentialing, initial training and continuing education of all personnel who provide patient care;
 - 3) Development and/or approval of written patient care guidelines (when available), policies and protocols including but not limited to those addressing the adverse impact of altitude on patient physiology and stresses of transport; and
 - 4) Active engagement in quality management, utilization review and patient care and safety reviews.

9.7 Medical Equipment

9.7.1 Each air ambulance operator shall ensure that all medical equipment is appropriate to the air medical service's scope and mission and maintained in working order according to the manufacturer's recommendations. Medical equipment shall be available on the aircraft to meet the local/state protocols for ems providers in which the service intends to operate and in line with the mission of the air ambulance service.

- A) Required equipment
- 1) Isolation equipment including isolation goggles and masks or mask/shield combination, isolation gowns and isolation gloves
 - 2) High particulate filter washes (HEPA filter or n95 mask-assorted sizes)
 - 3) Containers (bags) for infectious medical waste
 - 4) Sharps container
 - 5) Disinfectant/germicidal cleaners, wipes or solutions
 - 6) Waterless hand cleaner
 - 7) Airway equipment, consisting of:
 - a. Complete set of oropharyngeal airway devices: adult and pediatric,
 - b. Complete set of nasopharyngeal airway devices: adult, pediatric, and infant
 - c. Complete set of intubation equipment-adult, pediatric, and infant
 - 8) Syringes, assorted sizes
 - 9) Magill forceps (adult and pediatric sizes)

- 10) Thermometer
- 11) Intubation equipment
- 14) Pediatric weight based drug tape, chart or wheel
- 15) Water soluble lubricant
- 16) End-tidal CO2 monitor
- 17) Advanced airway procedure kit, as applicable
- 18) Appropriate medications as defined by clinical guidelines or per medical treatment guidelines.
- 19) ECG monitor/defibrillator and appropriate adult and pediatric pads, including external pacemaker pads (secure positioning of cardiac monitors, defibrillators, and external pacers so that displays are visible to medical personnel)
- 20) Pulse oximeter with adult and pediatric probes
- 21) Spare batteries as appropriate for powered medical devices
- 22) Ventilator as approved by medical director
- 23) Bandages and dressings
- 24) Suction equipment including tubing
 - a. Wall mounted suction unit
 - b. Portable suction unit powered or hand operated
- 25) Pharyngeal hard tip suction
- 26) Soft tip suction catheter set
 - a. Adult sizes
 - b. Pediatric sizes
- 27) Suction bags or replaceable reservoirs
- 28) Sterile gloves
- 29) Oxygen equipment - oxygen flow capable of being stopped at the oxygen source from inside the air ambulance and measurement of the liter flow and quantity of oxygen remaining is accessible to air medical personnel while in flight:
 - a. Main oxygen source
 - b. Wall mounted oxygen flow meter 0-15 l/min. minimum

- i. Oxygen equipment shall be furnished capable of adjustable flow from 0 to 15 liters per minute. Masks and supply tubing for adult and pediatric patients shall allow administration of variable oxygen concentrations from 24% to 95% fraction inspired oxygen. Medical oxygen shall be provided for 150% of the scheduled flight time by a unit secured within the air ambulance.
- 30) Compressed air as appropriate (each gas outlet clearly marked for identification)
 - 31) Portable oxygen cylinder with portable variable flow regulator 0-15 l/min. Minimum
 - 32) Bag-valve-mask with reservoir to provide one hundred per cent oxygen flow (adult, pediatric and infant sizes)
 - 33) Oxygen masks (adult, pediatric and infant sizes)
 - 34) Nasal cannulas (adult and pediatric sizes)
 - 35) Nebulizer and appropriate connecting tubing
 - 36) Adjunct equipment
 - a. Trauma shears
 - b. Stethoscope (adult and pediatric)
 - c. Tourniquets
 - 37) Blood pressure cuffs: (large adult, adult, pediatric, infant)
 - 38) Patient hearing protection
 - 39) Assorted tape
 - 40) Exam gloves
 - 41) Obstetrical kit
 - 42) Nasogastric tubes (adult and pediatric)
 - 43) Patient restraints
 - 44) Pediatric restraining system
 - 45) Intravenous equipment, including but limited to:
 - a. Alcohol, chlorhexidine, or betadine skin cleanser (preferably prep pads)
 - b. IV administration sets
 - c. IV infusion pump tubing

- d. IV catheters, assorted sizes 24-14
 - e. Intraosseous needles
 - f. IV solutions, per protocol
- 46) Needles, assorted sizes
- 47) Associated adjunct equipment
- a. Invasive line set-up
 - b. Pressure bags
- 48) One or more cots/stretchers capable of being secured in the aircraft that meet the following criteria:
- a. Accommodates an adult of a height and weight appropriate for the capacity of the air ambulance, and restraining devices or additional appliances available to provide adequate restraint of all patients including those under 60 pounds or 36 inches in height.
 - b. The head of the primary stretcher is capable of being elevated up to 30 degrees. The elevating section shall not interfere with or require that the patient or stretcher securing straps and hardware be removed or loosened.
 - c. Sturdy and rigid enough that it can support cardiopulmonary resuscitation. If a backboard or equivalent device is required to achieve this, such device will be readily available.
 - d. A pad or mattress impervious to moisture and easily cleaned and disinfected according to occupational safety and health administration (OSHA) blood borne pathogen requirements (29 C.F.R § 1910.1030 2016).
 - e. A supply of linen for each patient.
- 49) Survival kit for all medical crew members and patient

9.8 Patient Compartment

9.8.1 An applicant or licensee shall ensure that an air ambulance has the following:

- A) A climate control system to prevent temperature variations that would adversely affect patient care.
- B) An adequate interior lighting system so that patient care can be given and the patient's status monitored.
- C) 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 air ambulance equipment.

- D) A back-up source of electrical power or batteries capable of operating all electrically powered life-support equipment for at least one hour.
- E) An appropriate power source that is sufficient to meet the requirements of the complete specialized equipment package without compromising the operation of any electrical air ambulance equipment.
- F) An entry that allows for patient loading and unloading without excessive maneuvering and without compromising the operation of monitoring systems, intravenous lines, or manual or mechanical ventilation.
- G) If an isolette is used during patient transport, an isolette that is able to be opened from its secured in-flight position in order to provide full access to the patient.
- H) Adequate access and necessary space to maintain the patient's airway and to provide adequate ventilator support by an attendant from the secured, seat-belted position within the air ambulance.
- I) A configuration that allows for rapid exit of personnel and patients, without obstruction from stretchers and medical equipment.
- J) An interior that is sanitary and in good working order at all times.
- K) Appropriate storage for medications that maintains temperatures within manufacturer recommendations. Glass containers shall not be used unless required by medication specifications and properly vented. Medications, fluids and controlled substances shall be securely maintained by air ambulance licensees in compliance with local, state, and federal drug laws.
- L) Secure positioning of cardiac monitors, defibrillators, and external pacers so that displays are visible to medical personnel.

9.9 Data Collection and Submission

- 9.9.1 All services shall have a system in place to collect, submit, monitor, and track all flight requests that result in patient transport. This information shall be submitted and made readily available to the Department upon request.
- 9.9.2 Colorado licensed air ambulance services shall submit data and information as required in 6 CCR 1015-3, Chapter Three Rules Pertaining to Emergency Medical Services Data and Information Collection and Record Keeping and section 18 of these rules, to the extent data collection and submission serve a medical or quality improvement purpose.

9.10 Continuous Quality Improvement Program

- 9.10.1 Air ambulance services shall establish a quality management team and a program implemented by this team to assess and improve the quality and appropriateness of patient care provided by the air ambulance service. The program shall include:
 - A) Development of protocols, standing orders, training, policies, procedures.
 - B) Approval of medications and techniques permitted for field use by service personnel in accordance with regulations of the Department.

- C) Direct observation, field instruction, in-service training or other means available to assess quality of field performance.

9.10.2 All services shall have a written policy that outlines a process to identify, document and analyze sentinel events, adverse medical events or potentially adverse events with specific goals to improve patient medical safety and/or quality of patient care. Goals shall include the following:

- A) Review of events should address the effectiveness and efficiency of the organization, its support systems, as well as that of individuals within the organization.
- B) When a sentinel event is identified, a method of information gathering shall be developed. This shall include outcome studies, chart review, case discussion, or other methodology.
- C) Findings, conclusions, recommendations and actions shall be made and recorded. Follow-up, if necessary, shall be determined, recorded, and performed.
- D) Training and education needs, individual performance evaluations, equipment or resource acquisition, patient medical safety and risk management issues all shall be integrated with the continuous quality improvement process.

9.10.3 All services shall have a written policy outlining a utilization review process.

9.11 Medical Staff and Patient Safety Welfare

9.11.1. Medical personnel scheduling and individual work schedules must demonstrate strategies to minimize duty-time fatigue, length of shift, number of shifts per week and day-to-night rotation.

9.11.2 On-site shifts scheduled for a period to exceed twenty-four (24) hours are not acceptable under most circumstances. The following criteria must be met for shifts scheduled more than twelve (12) hours.

- A) Medical personnel are not required to routinely perform any duties beyond those associated with the transport service.
- B) Medical personnel are provided with access to and permission for uninterrupted rest after daily medical personnel duties are met.
- C) The physical base of operations includes an appropriate place for uninterrupted rest.
- D) Medical personnel must have the right to call "time out" and be granted a reasonable rest period if the team member (or fellow team member) determines that he or she is unfit or unsafe to continue duty, no matter the shift length. There must be no adverse personnel action or undue pressure to continue in this circumstance.
- E) Management must monitor transport volumes and personnel's use of a "time out" policy.

- 9.11.3 Shifts extended over several days may be scheduled to address long commutes at programs with low volumes. The program must clearly demonstrate and document it meets the above criteria for shifts over twelve (12) hours. In addition:
- A) A program's base averages less than one (1) transport per day.
 - B) Provides at least ten (10) hours of rest in each twenty-four (24) hour period.
 - C) Location of the base or program is remote and one-way commutes are more than two (2) hours.
 - D) Fatigue risk management tools are utilized.
- 9.11.4. Scheduling of on-call shifts must be evaluated to address fatigue in a written policy based on monitoring of duty times by managers, quality management tracking and fatigue risk management.
- 9.11.5. Physical well-being is promoted through:
- A) Protective clothing and dress code pertinent to:
 - 1) Mission profile such as turn-out gear available at scene for medical personnel who assist with heavy extrication
 - 2) Safe operations, which shall include:
 - a. Boots or sturdy footwear,
 - b. Appropriate outerwear to protect the provider from adverse environmental conditions and
 - c. If medical crews and vehicle operators respond to night scenes, the ambulance medical crew members must wear high visibility reflective vests or Department of Transportation-approved clothing that meets industry standards.
 - 3) In addition to the mandatory requirements in 9.11.5(A), safe operations may include:
 - a. Wearing reflective material or striping on uniforms for night operations; and
 - b. Flame retardant clothing (strongly encouraged for rotor wing services according to a risk assessment)
- 9.11.6. The air ambulance service shall establish an infection control protocol that complies with occupational safety and health administration (OSHA) standards, including 29 C.F.R. § 1910.1030 (2016), 29 C.F.R. § 1910.132 (2016), and 29 C.F.R. 1910.134 (2016).
- 9.11.7 The air ambulance services shall have an appropriate dress code that addresses jewelry, hair and other personal items of medical personnel that may interfere with patient care.

Section 10 – Complaints

- 10.1 Complaints relating to the quality and conduct of any air ambulance service may be made by any person or may be initiated by the Department. The Department may make inquiry as to the validity of such complaint prior to initiating an investigation. If the Department determines that the complaint warrants a more extensive review, an investigation may be initiated. If the complaint does not warrant further review or the inquiry determines that the complaint is not within regulatory jurisdiction of the Department, the Department will notify the complainant of the results of the inquiry.
- 10.2 The Department does not have jurisdiction over billing disputes or aviation complaints.
- 10.3 Every licensed service shall report patient medical care complaints to the Department within seven (7) calendar days of its receipt. Every licensed service shall provide the Department with any response it makes to the complaint within seven (7) calendar days of its issuance. If the Department determines that the complaint warrants review, it may initiate an investigation.
- 10.4 Nothing in this section prohibits the Department from conducting a complaint investigation under circumstances it deems necessary.
- 10.5 The Department may refer complaints that are related to the requirements an accrediting organization approved by the Department to that accrediting for investigation. The Department may forward complaints to other regulatory agencies.

Section 11 – Plans of Correction

- 11.1 After any Department inspection or complaint investigation, the Department may request a plan of correction from an air ambulance service.
- 11.1.1 A plan of correction shall be in the format prescribed by the Department and shall include but not be limited to, the following:
- A) Identification of the problem(s) with the current activity and what the air ambulance service will do to correct each deficiency,
 - B) A description of how the air ambulance service will accomplish the corrective action,
 - C) A description of how the air ambulance service will monitor the corrective action to ensure the deficient practice is remedied and will not recur, and
 - D) A timeline with the expected implementation and completion date. The completion date is the date that the air ambulance service deems it can achieve compliance.
- 11.1.2 Completed plans of correction shall be:
- A) Submitted to the Department in the form and manner required by the Department,
 - B) Submitted within ten (10) calendar days after the date of the Department's mailing of the written notice of deficiencies to the air ambulance service, unless otherwise required or approved by the Department, and
 - C) Signed by the air ambulance service program director and medical director.

- 11.1.3 The Department has the discretion to approve, modify or reject plans of correction.
- A) If the plan of correction is accepted, the Department shall notify the air ambulance service by issuing a written notice of acceptance within thirty (30) calendar days of receipt of the plan.
 - B) If the plan of correction is unacceptable, the Department shall notify the air ambulance service in writing, and the service shall re-submit a revised plan of correction to the Department within fifteen (15) calendar days of the date of the written notice.
 - C) If the air ambulance service fails to comply with the requirements or deadlines for submission of a plan or fails to submit a revised plan of correction, the Department may reject the plan of correction and impose disciplinary sanctions as set forth in sections 12 or 13.
 - D) If the air ambulance service fails to timely implement the actions agreed to in the plan of correction, the Department may impose disciplinary sanctions as set forth in sections 12 or 13.

Section 12 – Denial, Revocation, Suspension, Summary Suspension, or Limitations of Air Ambulance Licenses and Out of State License Recognitions

- 12.1 For good cause shown, the Department may deny, revoke, suspend limit, or condition the license or out of state recognition of an air ambulance service, or impose civil penalties as set forth in section 13 of these rules.
- 12.2 Good cause for sanctions include but are not limited to:
- 12.2.1 An applicant or licensee who fails to meet the requirements as set forth in these rules.
 - 12.2.2 An applicant or licensee who has committed fraud, misrepresentation, or deception in applying for a license or out of state license recognition.
 - 12.2.3 Falsifying reporting information provided to the Department.
 - 12.2.4 Violating any state or federal statute, rule or regulation that would jeopardize or may impact the health or medical safety of a patient or the public.
 - 12.2.5 Unprofessional conduct, which hinders, delays, eliminates, or deters the provision of medical care to the patient or endangers the public.
 - 12.2.6 Failure to maintain accreditation without obtaining a state license pursuant to section 5.3.
 - 12.2.7 Altering, removing or obliterating any portion of or any official entry on an application or other document.
 - 12.2.8 Interfering with the Department in the performance of its duties.
 - 12.2.9 Failing to reapply for a license or out of state licensure recognition in a timely manner and in accordance with these rules.
 - 12.2.10 Providing patient care that fails to meet acceptable minimum standards.
 - 12.2.11 Being disciplined by a licensing authority or approved accreditation agency.

- 12.2.12 Failing to maintain confidentiality of protected patient information.
- 12.2.13 Failing to comply with the terms of any agreement or stipulation regarding licensing or recognition entered into with the Department.
- 12.3 In accordance with section 24-4-104(4) C.R.S., the Department may summarily suspend an air ambulance license or out of state license recognition when the Department has objective and reasonable grounds to believe and finds, upon a full investigation, that the holder of the license or recognition has been guilty of deliberate and willful violation or that the public health, safety or welfare imperatively requires emergency action by the Department. If the Department summarily suspends a license or out of state license recognition, the Department shall provide the air ambulance service with notice of such suspension in writing. The notice shall state that the air ambulance service is entitled to a prompt hearing on the matter.
- 12.4 Notice of Appeal
- 12.4.1 The Department shall notify the air ambulance service of its right to appeal the denial, revocation, suspension, summary suspension, or limitation, and the procedure for appealing. Appeals of Departmental denials, revocations, suspensions, summary suspensions, or limitations shall be conducted in accordance with the State Administrative Procedure Act, section 24-4-101, *et seq.*, C.R.S.

Section 13 – Civil Penalties

- 13.1 The Department may impose a civil penalty of up to five thousand dollars per violation or for each day of a continuing violation upon an air ambulance operator, service, or provider or other person who:
- 13.1.1 Violates section 25-3.5-307, C.R.S.;
- 13.1.2 Violates section 25-3.5-307.5, C.R.S.;
- 13.1.3 Violates any rule of the board; or
- 13.1.4 Operates without a current and valid license.
- 13.2 The Department shall assess and collect these penalties.
- 13.3 Notice and hearing. Before collecting a penalty, the Department shall provide the alleged violator with notice and the opportunity for a hearing in accordance with the State Administrative Procedure Act, section 24-4-101, *et seq.*, C.R.S, and all applicable rules of the board.

Section 14 – Waivers

- 14.1 The Department may grant a waiver of a rule if the applicant satisfactorily demonstrates:
- 14.1.1 The proposed waiver does not adversely affect the health and safety of a patient; and
- 14.1.2 In the particular situation, the requirement serves no beneficial purpose; or
- 14.1.3 Circumstances indicate that the public benefit of waiving the requirement outweighs the public benefit to be gained by strict adherence to the requirement.
- 14.2 To apply for a waiver, the applicant must submit a completed application in the form and manner determined by the Department. The application shall contain the following information:

- 14.2.1 The text or substance of the regulation that the applicant wants waived;
- 14.2.2 The nature and extent of the relief sought;
- 14.2.3 Any facts, views and data available to support the waiver, including an explanation of why the application satisfies the criteria set forth in section 14.1.
- 14.3 An application shall not be considered complete until the required information is submitted.
- 14.4 The completed waiver application shall be submitted to the Department in a timely fashion as specified by the Department.
- 14.5 The application and supporting information shall be a matter of public record and is subject to disclosure under the Colorado Open Records Act (§24-72-200.1 *et seq.*, C.R.S.)
- 14.6 The Department may also consider any other information it deems relevant, including but not limited to complaint investigation reports, compliance history, including in other states, related to the applicant.
- 14.7 Waivers are generally granted for a limited term and shall be granted for a period no longer than the license term. Waivers cannot be granted for any statutory requirement under state or federal law, or for requirements under local codes or ordinances.

Section 15 – Incorporation by Reference

- 15.1 These rules incorporate by reference the following materials:
 - 15.1.1 Occupational Safety and Health Administration (OSHA) standards, including 29 C.F.R. § 1910.1030 (2016), 29 C.F.R. § 1910.132 (2016), and 29 C.F.R. § 1910.134 (2016) are incorporated by reference.
 - 15.1.2 Such incorporation does not include later amendments to or editions of the referenced material. The Health Facilities and Emergency Medical Services Division of the Colorado Department of Public Health and Environment maintains copies of the incorporated federal regulations for public inspection during regular business hours and 29 C.F.R. § 1910.132 (2016), and 29 C.F.R. § 1910.134 (2016) may be accessed at <https://www.gpo.gov/fdsys/pkg/CFR-2016-title29-vol5/pdf/CFR-2016-title29-vol5-part1910.pdf> and 29 C.F.R. § 1910.1030 (2016) may be accessed at <https://www.gpo.gov/fdsys/pkg/CFR-2016-title29-vol6/pdf/CFR-2016-title29-vol6-part1910.pdf> . Interested persons may obtain certified copies of any non-copyrighted material from the Department at cost upon request. Information regarding how the incorporated materials may be obtained or examined is available from the division by contacting:
 - EMTS Branch Chief
 - Health Facilities and EMS Division
 - Colorado Department of Public Health and Environment
 - 4300 Cherry Creek Drive South
 - Denver, Colorado 80246-1530
- 15.2 These materials have been submitted to the state publications depository and distribution center and are available for interlibrary loans. The incorporated material may be examined at any state publications depository library.

Editor's Notes

History

Section 13 eff. 03/01/2008.

Section 11 eff. 05/30/2008.

Sections 1-6 eff. 12/30/2009.

Chapter Two eff. 12/15/2010.

Entire rule eff. 06/30/2011.

Chapter One eff. 03/17/2013.

Chapter Two eff. 06/14/2013.

Chapters One, Two eff. 07/15/2014.

Chapter Five Section 6.2 eff. 12/15/2014.

Chapter One Section 5.2 eff. 01/14/2016.

Chapters One, Five eff. 07/01/2017.

Chapter One Sections 2, 3, 5, 7, Chapter Two Sections 2, 3, 4, 8, 10, 11, 12, 14, Appendices A, B, Section 15, Appendix D, Section 16, Appendix F, Section 17, Appendix G, Chapter Five eff. 01/01/2018.

Chapter Four eff. 01/14/2019.

Chapter One Section 5.5, Chapter Five Section 8.5 emer. rules eff. 04/10/2020; expired 08/08/2020.

Chapters One, Two eff. 01/01/2021.

Chapter Two Sections 1.1, 3.2, 3.2.1, Appendix B.3, Appendix F.1 eff. 12/30/2021.

Chapter Three eff. 06/14/2022.

Chapter Four eff. 02/14/2024.

Annotations

Rule 5.4.1.D (adopted 11/18/2009) was not extended by Senate Bill 11-078 and therefore expired 05/15/2011.