



PROPOSED RULE MAKING

CR-102 (June 2012)

(Implements RCW 34.05.320)

Do NOT use for expedited rule making

Agency: Department of Health

- Preproposal Statement of Inquiry was filed as WSR 14-21-111 ; or
- Expedited Rule Making--Proposed notice was filed as WSR ; or
- Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1).

- Original Notice
- Supplemental Notice to WSR
- Continuance of WSR

Title of rule and other identifying information: (Describe Subject)

WAC 246-976-320 Air ambulance services. The Department of Health is proposing to amend the air ambulance licensure requirements to align with federal law. The proposed rule adopts minimum standards from existing accreditation requirements that provide the department with a basis for determining whether an air ambulance service meets or exceeds the standards of the proposed rules and provides clear and enforceable standards needed to pursue complaints or disciplinary actions on a license.

Hearing location(s): Department of Health
111 Israel Road SE
Tumwater, Washington 98501
Building TC-2, Room 158

Date: 11/17/2016 Time: 10:30 AM

Submit written comments to:

Name: Catie Holstein, Supervisor EMS & Trauma
Address: PO Box 47853
Olympia, WA 98504
e-mail: <https://fortress.wa.gov/doh/policyreview>
fax 360-236-2830 by (date) 11/17/2016

Assistance for persons with disabilities: Contact

Denece Thomas (360)236-2857 by 11/03/2016

TTY (800) 833-6388 or () 711

Date of intended adoption: 11/28/2016

(Note: This is NOT the effective date)

Purpose of the proposal and its anticipated effects, including any changes in existing rules:

Currently, WAC 246-976-320 requires licensed air ambulance services to have and maintain accreditation by the Commission of Accreditation of Medical Transport Services (CAMTS) or another accrediting organization approved by the secretary as having equivalent requirements as CAMTS for aeromedical transport. Recent federal court rulings in other states have indicated a state regulation requiring all portions of CAMTS accreditation may be preempted by federal law. The proposed rule requires accreditation by a nationally recognized and department approved accreditation entity that meets the standards in the proposed rule yet provides exclusion from state regulation of activities preempted under the Federal Aviation Agency or Aviation Deregulation Act.

Reasons supporting proposal:

The federal government has authority over air ambulance rates, routes, services and aviation safety. Federal court cases and several state AAG opinions have ruled that state government has authority over air ambulance medical components only. Current accreditation entities use a hybrid criterion some of which may be preempted by federal law and a medical component only accreditation option does not exist. The proposed rule addresses federal preemption, preserves accreditation site review process, and includes provisions for standards related to air ambulance service medical components.

Statutory authority for adoption:

RCW 70.168.050

Statute being implemented:

RCW 18.73.081 and RCW 18.73.140

Is rule necessary because of a:

- Federal Law? Yes No
 - Federal Court Decision? Yes No
 - State Court Decision? Yes No
- If yes, CITATION: Yes No
49 U.S.C. Sec. 41713 and Eagle Air Med Corp v Colorado Bd of Health, 570 F.Supp.2d 1289(D.Col.2008)

DATE 09/28/2016

NAME (type or print)

John Wiesman, DrPH, MPH

SIGNATURE

, DrPH, MPH

TITLE

Secretary of Health

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: September 29, 2016

TIME: 10:16 AM

WSR 16-20-047

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:

None.

Name of proponent: (person or organization) Department of Health

- Private
 Public
 Governmental

Name of agency personnel responsible for:

Name	Office Location	Phone
Drafting..... Catie Holstein	111 Israel Road SE, Tumwater, WA 98501	(360) 236-2841
Implementation....Catie Holstein	111 Israel Road SE, Tumwater, WA 98501	(360) 236-2841
Enforcement.....Catie Holstein	111 Israel Road SE, Tumwater, WA 98501	(360) 236-2841

Has a small business economic impact statement been prepared under chapter 19.85 RCW or has a school district fiscal impact statement been prepared under section 1, chapter 210, Laws of 2012?

Yes. Attach copy of small business economic impact statement.

A copy of the statement may be obtained by contacting:

Name:
Address:

phone
fax
e-mail

No. Explain why no statement was prepared.

A small business economic impact statement was not prepared. The proposed rule would not impose more than minor costs on businesses in an industry.

Is a cost-benefit analysis required under RCW 34.05.328?

Yes A preliminary cost-benefit analysis may be obtained by contacting:

Name: Catie Holstein
Address: PO Box 47853
Olympia, WA 98504

phone (360) 236-2841
fax (360) 236-2830
e-mail catie.holstein@doh.wa.gov

No: Please explain:

WAC 246-976-320 Air ambulance services. The purpose of this rule is to ensure the consistent quality of medical care delivered by air ambulance services in the state of Washington.

~~((1) Air ambulance services must:~~

~~(a) Comply with all regulations and standards in this chapter pertaining to verified ambulance services and vehicles, except that WAC 246-976-290 and 246-976-300 are replaced for air ambulance services by subsection (4)(b) and (c) of this section;~~

~~(b) Comply with the standards in this section for all types of transports, including interfacility and prehospital transports;~~

~~(c) Provide proof of compliance with Federal Acquisition Regulation (FAR), 14 C.F.R. Part 135 (October 10, 1978) of the operating requirements; commuter and on demand operations and rules governing persons on board such aircraft.~~

~~(2) Air ambulance services currently licensed or seeking relicensure must have and maintain accreditation by the commission on accreditation of medical transport services (CAMTS) or another accrediting organization approved by the secretary as having equivalent requirements as CAMTS for aeromedical transport.~~

~~(3) Air ambulance services requesting initial licensure that are ineligible to attain accreditation because they lack a history of operation at the site, must meet the criteria of subsections (4) and (5) of this section and within four months of licensure must have completed an initial consultation with CAMTS or another accrediting organization approved by the secretary as having equivalent requirements as CAMTS for aeromedical transport. A provisional license will be granted for no longer than two years at which time the service must provide documentation that it is accredited by CAMTS or another accrediting organization approved by the secretary as having equivalent requirements as CAMTS for aeromedical transport.~~

~~(4) Air ambulance services must provide:~~

~~(a) A physician director:~~

~~(i) Licensed to practice in the state of Washington;~~

~~(ii) Trained and experienced in emergency, trauma, and critical care;~~

~~(iii) Knowledgeable of the operation of air medical services; and~~

~~(iv) Responsible for supervising and evaluating the quality of patient care provided by the air medical flight personnel;~~

~~(b) If the air medical service utilizes Washington certified EMS personnel:~~

~~(i) The physician director must be a delegate of the MPD in the county where the air service declares its primary base of operation.~~

~~(ii) Certified EMS personnel must follow department approved MPD protocols when providing care;~~

~~(c) Sufficient air medical personnel on each response to provide patient care, specific to the mission, including:~~

~~(i) One specially trained, experienced registered nurse or paramedic; and~~

~~(ii) One other person who must be a physician, nurse, physician's assistant, respiratory therapist, paramedic, EMT, or other appropriate specialist appointed by the physician director. If an air ambulance responds directly to the scene of an incident, at least one of the air medical personnel must be trained in prehospital emergency care;~~

~~(d) Aircraft that, when operated as air ambulances:~~

- ~~(i) Are configured so that the medical personnel can access the patient. The configuration must allow medical personnel to begin and maintain advanced life support and other treatment;~~
- ~~(ii) Allow loading and unloading the patient without excessive maneuvering or tilting of the stretcher;~~
- ~~(iii) Have appropriate communication equipment:~~
 - ~~(A) The capability to communicate between flight personnel, hospitals, medical control, and the services communication center;~~
 - ~~(B) Helicopters must also have the capability to communicate with ground EMS services and public safety vehicles;~~
- ~~(iv) Are equipped with:~~
 - ~~(A) Airway management equipment, including:~~
 - ~~(I) Oxygen;~~
 - ~~(II) Suction;~~
 - ~~(III) Ventilation and intubation equipment, adult and pediatric;~~
 - ~~(B) Cardiac monitor/defibrillator;~~
 - ~~(C) Supplies, equipment, and medication as required by the program physician director, for emergency, cardiac, trauma, pediatric care, and other missions; and~~
 - ~~(D) The ability to maintain appropriate patient temperature;~~
- ~~(v) Have interior lighting for patient care; and~~
- ~~(vi) Helicopter aircraft must have a protective barrier sufficiently isolating the cockpit, to minimize in flight distraction or interference.~~

~~(5) All air medical personnel must:~~

- ~~(a) Be certified in ACLS;~~
- ~~(b) Be trained in:~~
 - ~~(i) Emergency, trauma, and critical care;~~
 - ~~(ii) Altitude physiology;~~
 - ~~(iii) EMS communications;~~
 - ~~(iv) Aircraft and flight safety; and~~
 - ~~(v) The use of all patient care equipment on board the aircraft;~~
- ~~(c) Be familiar with survival techniques appropriate to the terrain;~~

~~(d) Perform under protocols.~~

~~(6) Exceptions:~~

- ~~(a) If aeromedical evacuation of a patient is necessary because of a life threatening condition and a licensed air ambulance is not available, the nearest available aircraft that can accommodate the patient may transport. The physician ordering the transport must justify the need for air transport of the patient in writing to the department within thirty days after the incident.~~
- ~~(b) Excluded from licensure requirements are:~~
 - ~~(i) Air services operating aircraft for primary purposes other than civilian air medical transport. These services may be called to initiate an emergency air medical transport of a patient to the nearest available treatment facility or rendezvous point with other means of transportation. Examples are: United States Army Military Assistance to Safety and Traffic, United States Navy, United States Coast Guard, Search and Rescue, and the United States Department of Transportation;~~
 - ~~(ii) Air ambulance services that solely transport patients into Washington state from points originating outside of the state of Washington.)~~

(1) An air ambulance service operating in the state of Washington must:

(a) Be licensed by the department in compliance with this section unless an exception in RCW 18.73.130 applies;

(b) Comply with all regulations and standards in this chapter pertaining to licensed and verified ambulance services and vehicles, except that WAC 246-976-290 and 246-976-300 are replaced for air ambulance services by subsections (7) and (8) of this section; and

(c) Comply with the standards in this section for all types of transports, including interfacility and prehospital transports.

(2) An air ambulance service applying for initial or renewal licensure must:

(a) Provide a completed application for licensure on forms provided by the department;

(b) Provide copies of the following current and valid documentation issued by the Federal Aviation Administration (FAA):

(i) Air Taxi Registration (OST Form 4507) showing the effective date of FAA registration and exemption under 14 C.F.R. 298;

(ii) Air carrier certificate authorizing common carriage under 14 C.F.R. 135, including Operations Specifications (FAA form 8430-18) authorizing aeromedical helicopter or fixed-wing air ambulance operations as applicable;

(iii) Certificate of Registration (AC form 8050-3) for each air ambulance operated; and

(iv) Standard Airworthiness Certificate (FAA form 8100-2) for each air ambulance operated;

(c) Provide a certificate of insurance establishing current and valid public and passenger liability insurance coverage for the air ambulance service;

(d) Provide a certificate of insurance establishing current and valid professional and general liability insurance coverage for the air ambulance service; and

(e) Provide proof of the air ambulance service's current accreditation status and a copy of the current accreditation report by a nationally recognized and department approved air ambulance accreditation entity that demonstrates that the air ambulance service meets the standards in this section. Failure to produce the accreditation report and supporting documentation to the department may be grounds for denial, suspension, or revocation of an ambulance license.

(3) An air ambulance service requesting initial licensure or renewal of licensure:

(a) That is ineligible to attain accreditation because it lacks a history of operation, must meet the standards in this section and provide proof that the air ambulance service is pursuing accreditation review with an accreditation entity approved by the department. A provisional license may be granted for no longer than two years at which time the service must provide documentation from a department approved accreditation entity that it meets the standards in this section.

(b) That has been unable to obtain accreditation may apply for a waiver of the full accreditation requirement if the air ambulance service met all components of accreditation that are consistent with the standards in this section other than criteria related to the Federal Aviation Agency or Airline Deregulation Act regulated activities. The applicant must supply a copy of the accreditation report and supporting documentation to the department to show that it meets the standards in this section.

(4) To meet the minimum standards for medical oversight and patient care protocols an air ambulance service must:

(a) Have a physician director. The physician director must be:

(i) The department-certified medical program director (MPD) of the county where the air ambulance service declares its primary base of operation or a physician delegate of that county's MPD, as provided in WAC 246-976-920(4);

(ii) Licensed to practice in the state of Washington and in current good standing; and

(iii) Able to provide proof of educational experience consistent with the mission statement and scope of care provided by the air ambulance service;

(b) Ensure that all medical team members hold current and valid Washington state health care profession licenses;

(c) Ensure that all prehospital personnel used by the air ambulance service per subsection (5) of this section hold current and valid Washington state certifications as defined in WAC 246-976-010 and in accordance with RCW 18.71.200 and 18.71.205. Certified prehospital personnel must comply with department approved, MPD patient care protocols;

(d) Have a quality management program; and

(e) Ensure data related to patient care and transport services is collected and reviewed regularly and protected health care information is handled according to state and federal law and regulations.

(5) An air ambulance service must meet the following minimum standards for staffing of air ambulances:

(a) All medical personnel on each transport must have education, experience, qualifications, and credentials consistent with the mission statement and scope of care provided by the air ambulance service;

(b) Each critical care transport (CCT) is staffed by a medical team of at least two individuals with at least the following qualifications and licensure:

(i) One paramedic or registered nurse trained in prehospital emergency care; and

(ii) One other person who must be a registered nurse, respiratory therapist, paramedic, advanced EMT, EMT, or other appropriate specialist as appointed by the physician director;

(c) Each advanced life support (ALS) transport is staffed by a medical team of at least two individuals with at least the following qualifications and licensure:

(i) One paramedic; and

(ii) One other person, who must be a paramedic, advanced EMT, EMT, or other appropriate specialist as appointed by the physician director; and

(d) Each basic life support (BLS) transport is staffed by a medical team of at least two individuals in accordance with ambulance personnel requirements listed in RCW 18.73.150.

(6) An air ambulance service must meet the following minimum standards for training of air ambulance medical personnel:

(a) Establish and maintain a structured training program. If prehospital personnel are used by the air ambulance service, the training program must also meet requirements as defined in chapter 246-976 WAC;

(b) Create and maintain a file for each medical team member containing documentation of the personnel member's qualifications including, as applicable, licenses, certifications, and training records; and

(c) Ensure that each medical team member completes training in the following subjects before serving on a transport:

(i) Aviation terminology;

(ii) Altitude physiology and stressors of flight;
(iii) Patient loading and unloading;
(iv) Safety in and around the aircraft;
(v) In-flight communications;
(vi) Use, removal, replacement, and storage of the medical equipment installed on the aircraft;
(vii) In-flight emergency procedures;
(viii) Emergency landing and evacuation procedures; and
(ix) Policies and procedures for the air ambulance service, including policies to address altitude limitations.

(7) An air ambulance service must meet the following minimum standards for aircraft configuration and equipment to safely and effectively treat ill and injured patients on air ambulance transports and that include:

(a) A climate control system to prevent temperature extremes that would adversely affect patient care;

(b) Interior lighting that allows for patient care and monitoring without interfering with the pilot's vision;

(c) At least one outlet per patient and electric current which is capable of operating all electrically powered medical equipment unless battery power is available that exceeds the flight time for the transport;

(d) A back-up source of electric current or batteries capable of operating all electrically powered life support equipment for at least a minimum of one hour;

(e) An entry that allows for patient loading and unloading without rotating a patient and stretcher more than thirty degrees about the longitudinal (roll) axis or forty-five degrees about the lateral (pitch) axis and without compromising the operation of monitoring systems, intravenous lines, or manual or mechanical ventilation;

(f) Adequate space 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;

(g) Adequate placement of stretcher and medical equipment that does not impede rapid egress by personnel or patient from the aircraft; and

(h) A communications system that is capable of air to ground communication with, ground fire and EMS services, public safety vehicles, hospitals, medical control, and communication centers and that allows the flight crew and medical team members to communicate with each other during the transport.

(8) An air ambulance service must meet the following minimum standards for medical equipment aboard air ambulances:

(a) Maintain and provide a minimum of the following equipment, supplies, and medications consistent with the mission statement and scope of care provided on transports. All equipment, supplies, and medications must be approved for use by the MPD and physician director.

(i) Minimum equipment available for each basic life support (BLS) transport must include:

(A) Oral/nasal pharyngeal airway;

(B) Nonrebreather oxygen mask;

(C) Bag valve mask;

(D) Pulse oximeter;

(E) Oxygen source;

(F) Automated external defibrillator;

- (G) Noninvasive vital sign measurement;
- (H) Glucometer;
- (I) Equipment for control of bleeding to include tourniquets;
- (J) Infection control;
- (K) Medications consistent with scope of practice and care required for the transport type;
- (L) Spinal motion restriction; and
- (M) Neonatal and pediatric equipment sufficient for all aspects of prehospital and interfacility specialized care, if the air ambulance service provides transport to this population.
- (ii) Minimum equipment available for each advanced life support (ALS) transport must include:
 - (A) All BLS equipment required in (a)(i) of this subsection; and
 - (B) Equipment for endotracheal intubation to include alternative airways such as supraglottic airways;
 - (C) Equipment for needle thoracostomy;
 - (D) Noninvasive carbon dioxide (CO₂) monitoring with numerical and waveform capability;
 - (E) Equipment to establish and maintain a peripheral IV;
 - (F) Equipment to establish and maintain an intraosseous infusion;
 - (G) Ventilator;
 - (H) Equipment to provide continuous positive airway pressure (CPAP);
 - (I) Cardiac monitor capable of performing twelve lead ECG, defibrillation, cardioversion, and external pacing;
 - (J) Medications consistent with scope of practice and care required for the transport type; and
 - (K) Neonatal and pediatric equipment sufficient for all aspects of prehospital and interfacility specialized care, if the air ambulance service provides transport to this population.
- (iii) Minimum equipment available for each critical care transport (CCT) must include:
 - (A) All BLS equipment required in (a)(i) of this subsection; and
 - (B) All ALS equipment required in (a)(ii) of this subsection; and
 - (C) Multimodality ventilators capable of invasive ventilation appropriate to all age groups transported;
 - (D) Invasive hemodynamic monitoring, transvenous pacemakers, central venous pressure and arterial pressure;
 - (E) Medications consistent with scope of practice and care required for the transport type; and
 - (F) Neonatal and pediatric equipment sufficient for all aspects of prehospital and interfacility specialized care, if the air ambulance service provides transport to this population.
- (iv) Ensure that during a transport, 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 transport;
- (v) Maintain and provide upon request equipment, supply and medication inventories that document what is included for each type of transport; and
- (vi) Ensure the equipment and supplies on an air ambulance are secured, stored, and maintained in a manner that prevents hazards to personnel and patients.