

PUBLIC HEALTH DEPARTMENT[641]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)“b.”

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 147A.4, the Department of Public Health hereby gives Notice of Intended Action to adopt new Chapter 144, “Emergency Medical Services—Air Medical Service Program Authorization,” Iowa Administrative Code.

The rules in proposed Chapter 144 describe the requirements for authorization of emergency medical services’ air medical services.

Any interested person may make written comments or suggestions on the proposed rules on or before February 16, 2010. Such written comments should be directed to Kirk Schmitt, Bureau of Emergency Medical Services, Department of Public Health, 321 East 12th Street, Des Moines, Iowa 50319. E-mail may be sent to kschmitt@idph.state.ia.us.

These rules are intended to implement Iowa Code chapter 147A.

The following amendment is proposed.

Adopt the following **new** 641—Chapter 144:

CHAPTER 144

EMERGENCY MEDICAL SERVICES—AIR MEDICAL SERVICE PROGRAM AUTHORIZATION

641—144.1(147A) Definitions. For the purposes of this chapter, the following definitions shall apply:

“*Air ambulance*” means any privately or publicly owned rotorcraft or fixed-wing aircraft which may be specifically designed, modified, constructed, equipped, staffed and used regularly to transport the sick, injured or otherwise incapacitated who are in need of out-of-hospital emergency medical care or whose condition requires treatment or continuous observation while being transported.

“*Air ambulance crew member*” means an individual who has been trained to provide emergency and nonemergency medical care at the certification or licensure levels recognized by the department and who has been issued a certificate or license by the department.

“*Air ambulance service*” means any privately or publicly owned service program which utilizes rotorcraft or fixed-wing aircraft in order to provide patient transportation and emergency medical services.

“*Continuous quality improvement*” or “*CQI*” means a program that is an ongoing process to monitor standards at all EMS operational levels including the structure, process, and outcomes of the patient care event.

“*Critical care paramedic*” or “*CCP*” means a currently certified paramedic specialist who has successfully completed a critical care course of instruction approved by the department and has received endorsement from the department as a critical care paramedic.

“*Critical care transport*” or “*CCT*” means specialty care patient transportation when medically necessary, for a critically ill or injured patient needing CCP skills, between medical care facilities, and provided by an authorized ambulance service that is approved by the department to provide critical care transportation and staffed by one or more critical care paramedics or other health care professional in an appropriate specialty area.

“*Deficiency*” means noncompliance with Iowa Code chapter 147A or these rules.

“*Department*” means the Iowa department of public health.

“*Director*” means the director of the Iowa department of public health.

“Direct supervision” means services provided by an EMS provider in a hospital setting or other health care entity in which health care is ordinarily performed when in the personal presence of a physician or under the direction of a physician who is immediately available or under the direction of a physician assistant or registered nurse who is immediately available and is acting consistent with adopted policies and protocols of a hospital or other health care entity.

“Emergency medical care” means such medical procedures as:

1. Administration of intravenous solutions.
2. Intubation.
3. Performance of cardiac defibrillation and synchronized cardioversion.
4. Administration of emergency drugs as provided by protocol.
5. Any medical procedure authorized by 641—subrule 131.3(3).

“Emergency medical care provider” means an individual who has been trained to provide emergency and nonemergency medical care at the first responder, EMT-basic, EMT-intermediate, EMT-paramedic, paramedic specialist or other certification levels recognized by the department before 1984 and who has been issued a certificate by the department.

“Emergency medical services” or *“EMS”* means an integrated medical care delivery system to provide emergency and nonemergency medical care at the scene or during out-of-hospital patient transportation in an ambulance.

“Emergency medical technician-basic” or *“EMT-B”* means an individual who has successfully completed the current United States Department of Transportation’s Emergency Medical Technician-Basic curriculum and department enhancements, has passed the department’s approved written and practical examinations, and is currently certified by the department as an EMT-B.

“Emergency medical technician-paramedic” or *“EMT-P”* means an individual who has successfully completed the current United States Department of Transportation’s (DOT) EMT-intermediate curriculum or the 1985 or earlier DOT EMT-P curriculum, has passed the department’s approved written and practical examinations, and is currently certified by the department as an EMT-P.

“Emergency medical transportation” means the transportation by ambulance of sick, injured or otherwise incapacitated persons who require emergency medical care.

“EMS advisory council” means a council appointed by the director to advise the director and develop policy recommendations concerning regulation, administration, and coordination of emergency medical services in the state.

“EMS system” means any specific arrangement of emergency medical personnel, equipment, and supplies designed to function in a coordinated fashion.

“Endorsement” means providing approval in an area related to emergency medical care including, but not limited to, CCP and emergency medical services.

“FAA” means Federal Aviation Administration.

“FAR” means Federal Aviation Regulation.

“Fixed-wing ambulance” means any privately or publicly owned fixed-wing aircraft specifically designed, modified, constructed, equipped, staffed and used regularly to transport the sick, injured or otherwise incapacitated who are in need of out-of-hospital emergency medical care or whose condition requires treatment or continuous observation while being transported.

“Hospital” means any hospital licensed under the provisions of Iowa Code chapter 135B.

“Inclusion criteria” means criteria determined by the department and adopted by reference to determine which patients are to be included in the Iowa EMS service program registry or the trauma registry.

“Iowa EMS Patient Registry Data Dictionary” means reportable data elements for all ambulance service responses and definitions determined by the department and adopted by reference.

“Medical direction” means direction, advice, or orders provided by a medical director, supervising physician, or physician designee (in accordance with written parameters and protocols) to emergency medical care personnel.

“*Medical director*” means any physician licensed under Iowa Code chapter 148, who shall be responsible for overall medical direction of the service program and who has completed a medical director workshop, sponsored by the department, within one year of assuming duties.

“*Nonemergency transportation*” means transportation that may be provided for those persons determined to need transportation only.

“*NTSB*” means National Transportation Safety Board.

“*Off-line medical direction*” means the monitoring of EMS providers through retrospective field assessments and treatment documentation review, critiques of selected cases with the EMS personnel, and statistical review of the system.

“*On-line medical direction*” means immediate medical direction provided directly to service program EMS providers, in accordance with written parameters and protocols, by the medical director, supervising physician or physician designee either on-scene or by any telecommunications system.

“*Paramedic*” or “*EMT-P*” means an emergency medical technician-paramedic.

“*Paramedic specialist*” or “*PS*” means an individual who has successfully completed the current United States Department of Transportation’s EMT-Paramedic curriculum or equivalent, has passed the department’s approved written and practical examinations, and is currently certified by the department as a paramedic specialist.

“*Patient*” means any individual who is sick, injured, or otherwise incapacitated.

“*Patient care report*” or “*PCR*” means a computerized or written report that documents the assessment and management of the patient by the emergency care provider in the out-of-hospital setting.

“*Physician*” means any individual licensed under Iowa Code chapter 148.

“*Physician assistant*” or “*PA*” means an individual licensed pursuant to Iowa Code chapter 148C.

“*Physician designee*” means any registered nurse licensed under Iowa Code chapter 152, or any physician assistant licensed under Iowa Code chapter 148C and approved by the board of physician assistants. The physician designee acts as an intermediary for a supervising physician in accordance with written policies and protocols in directing the care provided by emergency medical care providers.

“*Preceptor*” means an individual who has been assigned by the training program, clinical facility or service program to supervise students while the students are completing their clinical or field experience. A preceptor must be an emergency medical care provider certified at the level being supervised or higher, or must be licensed as a registered nurse, physician assistant or physician.

“*Protocols*” means written directions and orders, consistent with the department’s standard of care, that are to be followed by an emergency medical care provider in emergency and nonemergency situations. Protocols must be approved by the service program’s medical director and must address the care of both adult and pediatric patients.

“*Registered nurse*” or “*RN*” means an individual licensed pursuant to Iowa Code chapter 152.

“*Reportable patient data*” means data elements and definitions determined by the department and adopted by reference to be reported to the Iowa EMS service program registry or the trauma registry or a trauma care facility on patients meeting the inclusion criteria.

“*Rotorcraft ambulance*” means any privately or publicly owned rotorcraft specifically designed, modified, constructed, equipped, staffed and used regularly to transport the sick, injured or otherwise incapacitated who are in need of out-of-hospital emergency medical care or whose condition requires treatment or continuous observation while being transported.

“*Service director*” means an individual who is responsible for the operation and administration of a service program.

“*Service program*” or “*service*” means any medical care air ambulance service that has received authorization by the department.

“*Service program area*” means the geographic area of responsibility served by any given ambulance or nontransport service program.

“*Student*” means any individual enrolled in a training program and participating in the didactic, clinical, or field experience portions.

“*Supervising physician*” means any physician licensed under Iowa Code chapter 148. The supervising physician is responsible for medical direction of emergency medical care personnel when such personnel are providing emergency medical care.

“*Training program*” means an NCA-approved Iowa college, the Iowa law enforcement academy or an Iowa hospital approved by the department to conduct emergency medical care training.

“*Transport agreement*” means a written agreement between two or more service programs that specifies the duties and responsibilities of the agreeing parties to ensure appropriate transportation of patients in a given service area.

641—144.2(147A) Authority of emergency medical care provider.

144.2(1) An emergency medical care provider who holds an active certification issued by the department may:

a. Render via on-line medical direction emergency and nonemergency medical care in those areas for which the emergency medical care provider is certified, as part of an authorized service program:

- (1) At the scene of an emergency;
- (2) During transportation to a hospital;
- (3) While in the hospital emergency department;
- (4) Until patient care is directly assumed by a physician or by authorized hospital personnel; and
- (5) During transfer from one entity where health care is normally provided to another.

b. Function in any hospital or any other entity in which health care is ordinarily provided only when under the direct supervision of a physician when:

- (1) Enrolled as a student in and approved by a training program;
- (2) Fulfilling continuing education requirements;
- (3) Employed by or assigned to a hospital or other entity in which health care is ordinarily provided only when under the direct supervision of a physician as a member of an authorized service program, or in an individual capacity, by rendering lifesaving services in the facility in which employed or assigned pursuant to the emergency medical care provider’s certification and under direct supervision of a physician, physician assistant, or registered nurse. An emergency medical care provider shall not routinely function without the direct supervision of a physician, physician assistant, or registered nurse. However, when the physician, physician assistant, or registered nurse cannot directly assume emergency care of the patient, the emergency medical care personnel may perform, without direct supervision, emergency medical care procedures for which certified, if the life of the patient is in immediate danger and such care is required to preserve the patient’s life;

(4) Employed by or assigned to a hospital or other entity in which health care is ordinarily provided only when under the direct supervision of a physician, as a member of an authorized service program, or in an individual capacity, to perform nonlifesaving procedures for which certified and designated in a written job description. Such procedures may be performed after the patient is observed by and when the emergency medical care provider is under the supervision of the physician, physician assistant, or registered nurse, including when the registered nurse is not acting in the capacity of a physician designee, and where the procedure may be immediately abandoned without risk to the patient.

144.2(2) When emergency medical care personnel are functioning in a capacity identified in paragraph 144.2(1)“*a,*” they may perform emergency and nonemergency medical care without contacting a supervising physician or physician designee if written protocols have been approved by the service program medical director which clearly identify when the protocols may be used in lieu of voice contact.

144.2(3) An emergency medical care provider who has knowledge of an emergency medical care provider, service program or training program that has violated Iowa Code chapter 147A or these rules shall report such information to the department within 30 days.

641—144.3(147A) Air ambulance service program—authorization and renewal procedures, inspections and transfer or assignment of certificates of authorization.

144.3(1) General requirements for air ambulance authorization and renewal of authorization.

a. An air ambulance service in this state that desires to provide emergency medical care in an out-of-hospital setting shall apply to the department for authorization to establish a program utilizing certified emergency medical care providers for delivery of care at the scene of an emergency or a nonemergency, during transportation to a hospital, during transfer from one medical care facility to another, or while in the hospital emergency department and until care is directly assumed by a physician or by authorized hospital personnel. Application for authorization shall be made on forms provided by the department. Applicants shall complete and submit the forms to the department at least 30 days prior to the anticipated date of authorization.

b. To renew service program authorization, the service program shall continue to meet the requirements of Iowa Code chapter 147A and these rules. The renewal application shall be completed and submitted to the department at least 30 days before the current authorization expires.

c. Applications for authorization and renewal of authorization may be obtained upon request to: Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075, or the bureau of EMS Web site (www.idph.state.ia.us/ems).

d. The department shall approve an application when the department is satisfied that the program proposed by the application will be operated in compliance with Iowa Code chapter 147A and these rules.

e. Service program authorization is valid for a period of three years from its effective date unless otherwise specified on the certificate of authorization or unless sooner suspended or revoked.

f. Service programs shall be fully operational upon the effective date and at the level specified on the certificate of authorization and shall meet all applicable requirements of Iowa Code chapter 147A and these rules. Deficiencies that are identified shall be corrected within a time frame determined by the department.

g. Any service program owner in possession of a certificate of authorization as a result of transfer or assignment shall continue to meet all applicable requirements of Iowa Code chapter 147A and these rules. In addition, the new owner shall apply to the department for a new certificate of authorization within 30 days following the effective date of the transfer or assignment.

h. Service programs that acquire and maintain current status with a nationally recognized EMS service program accreditation entity that meets or exceeds Iowa requirements may be exempted from the service application/inspection process. A copy of the state service application and accreditation inspection must be filed with the department for approval.

144.3(2) Out-of-state air ambulance service programs.

a. Service programs located in other states which wish to provide emergency medical care in Iowa must meet all requirements of Iowa Code chapter 147A and these rules and must be authorized by the department except when:

- (1) Transporting patients from locations within Iowa to destinations outside of Iowa;
- (2) Transporting patients from locations outside of Iowa to destinations within Iowa;
- (3) Transporting patients to and from locations outside of Iowa when doing so requires travel through Iowa;
- (4) Responding to a request for mutual aid in this state; or
- (5) Making less than 30 EMS responses per year to locations within Iowa and then transporting the patients to destinations within Iowa.

b. An out-of-state service program that meets any of the exception criteria established in this subrule shall be authorized to provide emergency medical care by the state in which the program resides and shall provide the department with verification of current state authorization upon request.

144.3(3) Air ambulance service program inspections.

a. The department shall inspect each service program at least once every three years. The department without prior notification may make additional inspections at times, places and under such circumstances as it deems necessary to ensure compliance with Iowa Code chapter 147A and these rules.

b. The department may request additional information from or may inspect the records of any service program which is currently authorized or which is seeking authorization to ensure continued compliance or to verify the validity of any information presented on the application for service program authorization.

c. The department may inspect the patient care records of a service program to verify compliance with Iowa Code chapter 147A and these rules.

d. No person shall interfere with the inspection activities of the department or its agents pursuant to Iowa Code section 135.36.

e. Interference with or failure to allow an inspection by the department or its agents may be cause for disciplinary action in reference to service program authorization.

144.3(4) Temporary service program authorization.

a. A temporary service program authorization may be issued to services that wish to operate during special events that may need emergency medical care coverage at a level other than basic care. Temporary authorization is valid for a period of 30 days unless otherwise specified on the certificate of authorization or unless sooner suspended or revoked. Temporary authorization shall apply to those requirements and standards for which the department is responsible. Applicants shall complete and submit the necessary forms to the department at least 30 days prior to the anticipated date of need.

b. The service shall meet applicable requirements of these rules but may apply for a variance using the criteria outlined in rule 641—144.7(147A).

c. The service shall submit a justification which demonstrates the need for the temporary service program authorization.

d. The service shall submit a report to the department within 30 days after the expiration of the temporary authorization which includes as a minimum:

- (1) Number of patients treated;
- (2) Types of treatment rendered;
- (3) Any operational or medical problems.

641—144.4(147A) Service program levels of care and staffing standards.

144.4(1) An air ambulance service program seeking authorization shall:

a. Apply for authorization at the following levels:

- (1) EMT-Basic.
- (2) Paramedic specialist.
- (3) Critical care transport.

b. Conduct all air ambulance service flights under a minimum of FAR rules, Part 135.

c. Maintain an adequate number of aircraft and personnel to provide 24-hour-per-day, 7-day-per-week coverage. The number of aircraft and personnel to be maintained shall be determined by the service and shall be based upon, but not limited to, the following:

- (1) Number of calls;
- (2) Service area and population; and
- (3) Availability of other services in the area.

d. Staff fixed-wing ambulances, at a minimum on each flight request, with the following staff while a patient is being transported:

(1) One health care provider who is certified or licensed in the state from which the aircraft launches and is certified as an EMT-Basic or higher level; and

(2) One FAA-certified commercial pilot who is appropriately rated in the aircraft being used for the transport.

e. Staff rotorcraft ambulances, at a minimum on each flight request, with the following staff while a patient is being transported:

(1) Two health care providers who are certified or licensed in the state from which the aircraft launches, one of whom must at a minimum be certified as a paramedic specialist; and

(2) One FAA-certified commercial pilot who is appropriately rated in the aircraft being used for the transport.

- f.* Train medical crew members in the following areas:
- (1) Patient care limitations in flight.
 - (2) Altitude physiology.
 - (3) Appropriate utilization of air medical services.
 - (4) Communication system.
 - (5) Aircraft operations and safety.
 - (6) Emergency safety and survival.
 - (7) Prehospital scene response and safety.
 - (8) Crew resource management.
 - (9) Program flight risk assessment procedures.
- g.* Apply to the department to receive approval to provide critical care transportation based upon appropriately trained staff and approved equipment.
- h.* Ensure that the health care provider with the highest level of certification (on the transporting service) attends the patient, unless otherwise established by protocol approved by the medical director.
- 144.4(2)** Air ambulance service program operational requirements. Air ambulance service programs shall:
- a.* Complete and maintain a patient care report concerning the care provided to each patient. Services shall provide, at a minimum, a verbal report upon delivery of a patient to a receiving facility and shall provide a complete PCR within 24 hours to the receiving facility.
 - b.* Ensure that personnel duties are consistent with the level of certification and the service program's level of authorization.
 - c.* Maintain current personnel rosters and personnel files. The files shall include the names and addresses of all personnel and documentation that verifies EMS provider credentials including, but not limited to:
 - (1) Current provider level certification.
 - (2) Current course completions/certifications/endorsements as may be required by the medical director.
 - d.* If requested by the department, notify the department in writing of any changes in personnel rosters.
 - e.* Have a medical director and 24-hour-per-day, 7-day-per-week on-line medical direction available.
 - f.* Ensure that the appropriate service program personnel respond as required in this rule and that personnel respond in a reasonable amount of time.
 - g.* Notify the department in writing within seven days of any change in service director or ownership or control or of any reduction or discontinuance of operations.
 - h.* Select a new or temporary medical director if for any reason the current medical director cannot or no longer wishes to serve in that capacity. Selection shall be made before the current medical director relinquishes the duties and responsibilities of that position.
 - i.* Within seven days of any change of medical director, notify the department in writing of the selection of the new or temporary medical director who must have indicated in writing a willingness to serve in that capacity.
 - j.* Implement a continuous quality improvement program for patient transport missions to include as a minimum:
 - (1) Medical audits.
 - (2) Skills competency.
 - (3) Flight safety procedures.
 - (4) Appropriateness of air medical response.
 - (5) Review of flight risk assessment.
 - (6) Loop closure requiring physician review of patient transport missions.
 - k.* Document an equipment maintenance program to ensure proper working condition and appropriate quantities.

144.4(3) Air ambulance equipment and vehicle standards.

a. All air ambulance service programs shall carry equipment and supplies in quantities as determined by the medical director and appropriate to the service program's level of care and available medical crew member personnel, and as established in the service program's approved protocols.

b. Pharmaceutical drugs may be carried and administered by appropriate staff upon completion of training and pursuant to the service program's established protocols approved by the medical director.

c. All pharmaceuticals shall be maintained in accordance with the rules of the state board of pharmacy.

d. Accountability for drug exchange, distribution, storage, ownership, and security shall be subject to applicable state and federal requirements. The method of accountability shall be described in the written pharmacy agreement. A copy of the written pharmacy agreement shall be submitted to the department.

e. Each aircraft shall be equipped and maintained in accordance with FAA operating requirements.

f. Each aircraft shall be equipped with a survival kit.

144.4(4) Communications and flight dispatch program.

a. Each service program shall maintain a telecommunications system between the medical crew member and the source of the service program's medical direction and other appropriate entities.

b. All telecommunications shall be conducted in an appropriate manner and on a frequency approved by the Federal Communications Commission and the department.

c. A flight-following policy shall be adopted. This policy shall at a minimum contain the following:

(1) Minimum time between communications with aircraft and its monitoring center;

(2) Documentation of communications with flight;

(3) Lost communications procedures; and

(4) Overdue aircraft procedures.

d. Flight programs shall provide staff or contract with a flight dispatch system for receiving flight requests. Communication specialists shall be trained in the following:

(1) Flight operations;

(2) Aviation weather;

(3) Aviation maintenance;

(4) Flight following;

(5) Flight risk assessment;

(6) Flight service minimum safety standards; and

(7) Overdue aircraft procedures.

144.4(5) Flight risk assessment policy.

a. Each service shall have a flight risk assessment policy in accordance with current FAA guidelines.

b. Flight risk assessment policies shall mandate adherence to policy for all flights.

c. Flight risk assessment policies shall address other flight services being requested, en route, or having been denied request to same incident.

144.4(6) Air ambulance service program—incident and accident response and reports.

a. Air medical services shall have a policy in place outlining missing/overdue/accident issues. This policy will contain at a minimum the following:

(1) Overdue aircraft procedures; and

(2) Postincident action plans.

b. Incidents of fire or other destructive or damaging occurrences or theft of a service program aircraft, vehicle, equipment, or drugs shall be reported to the department within 48 hours following the occurrence of the incident.

c. A report relating to an accident resulting in personal injury, death or property damage shall be submitted to the department within seven days following an accident involving a service program aircraft or vehicle. A complete FAA/NTSB accident report shall be submitted to the bureau of EMS upon completion of the report.

144.4(7) Reportable patient data—adoption by reference.

a. The department shall prepare compilations for release or dissemination on all reportable patient data entered into the EMS service program registry during the reporting period. The compilations shall include, but not be limited to, trends and patient care outcomes for local, regional, and statewide evaluations. The compilations shall be made available to all service programs submitting reportable patient data to the registry.

b. Access and release of reportable patient data and information.

(1) The data collected by and furnished to the department pursuant to this subrule are confidential records of the condition, diagnosis, care, or treatment of patients or former patients, including outpatients, pursuant to Iowa Code section 22.7. The compilations prepared for release or dissemination from the data collected are not confidential under Iowa Code subsection 22.7(2). However, information which individually identifies patients shall not be disclosed, and state and federal law regarding patient confidentiality shall apply.

(2) The department may approve requests for reportable patient data for special studies and analysis provided that the request has been reviewed and approved by the deputy director of the department with respect to the scientific merit and confidentiality safeguards and the department has given administrative approval for the proposal. The confidentiality of patients and the EMS service program shall be protected.

(3) The department may require entities requesting the data to pay any or all of the reasonable costs associated with furnishing the reportable patient data.

c. To the extent possible, activities under this subrule shall be coordinated with other health data collection methods.

d. Quality assurance.

(1) For the purpose of ensuring the completeness and quality of reportable patient data, the department or an authorized representative may examine all or part of the patient care report as necessary to verify or clarify all reportable patient data submitted by a service program.

(2) Review of a patient care report by the department shall be scheduled in advance with the service program and completed in a timely manner.

e. “Iowa Trauma Patient Data Dictionary” is available through the Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075, or the bureau of EMS Web site (www.idph.state.ia.us/ems).

f. “Iowa EMS Patient Registry Data Dictionary” identified in 641—paragraph 136.2(1)“*c*” is incorporated by reference for inclusion criteria and reportable patient data to be reported to the department. For any differences which may occur between the adopted reference and this chapter, the administrative rules shall prevail.

g. “Iowa EMS Patient Registry Data Dictionary” identified in 641—paragraph 136.2(1)“*c*” is available through the Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075, or the bureau of EMS Web site (www.idph.state.ia.us/ems).

144.4(8) An air ambulance service program shall:

a. Submit reportable patient data identified in subrule 144.4(7) via electronic transfer. Data shall be submitted in a format approved by the department.

b. Submit reportable patient data identified in subrule 144.4(7) to the department for each calendar quarter. Reportable patient data shall be submitted no later than 90 days after the end of the quarter.

144.4(9) The patient care report is a confidential document and shall be exempt from disclosure pursuant to Iowa Code subsection 22.7(2) and shall not be accessible to the general public. Information contained in these reports, however, may be utilized by any of the indicated distribution recipients and may appear in any document or public health record in a manner which prevents the identification of any patient or person named in these reports.

144.4(10) Implementation. The director may grant exceptions and variances from the requirements of this chapter for any air medical service. Exceptions or variations shall be reasonably related to undue hardships which existing services experience in complying with this chapter. Services requesting exceptions and variances shall be subject to other applicable rules adopted pursuant to Iowa Code

chapter 147A. Nothing in this chapter shall be construed to require any service to provide a level of care beyond minimum basic care standards.

641—144.5(147A) Air ambulance service program—off-line medical direction.

144.5(1) The medical director shall be responsible for providing appropriate medical direction and overall supervision of the medical aspects of the service program and shall ensure that those duties and responsibilities are not relinquished before a new or temporary replacement is functioning in that capacity.

144.5(2) The medical director’s duties include, but need not be limited to:

- a.* Developing, approving and updating protocols to be used by service program personnel that meet or exceed the minimum standard protocols developed by the department.
- b.* Developing and maintaining liaisons between the service, other physicians, physician designees, hospitals, and the medical community served by the service program.
- c.* Monitoring and evaluating the activities of the service program and individual personnel performance, including establishment of measurable outcomes that reflect the goals and standards of the EMS system.
- d.* Assessing the continuing education needs of the service and individual service program personnel and assisting them in the planning of appropriate continuing education programs.
- e.* Being available for individual evaluation and consultation to service program personnel.
- f.* Performing or appointing a designee to complete the medical audits required in subrule 144.5(4).

g. Developing and approving an applicable continuous quality improvement policy to be used for all patient care encounters, including an action plan and follow-up.

h. Informing the medical community of the emergency medical care being provided according to approved protocols in the service program area.

i. Helping to resolve service operational problems.

j. Approving or removing an individual from service program participation.

144.5(3) Supervising physicians, physician designees, or other appointees as defined in the continuous quality improvement policy referenced in paragraph 144.5(2) “g” may assist the medical director by:

- a.* Providing medical direction.
- b.* Reviewing the emergency medical care provided.
- c.* Reviewing and updating protocols.
- d.* Providing and assessing continuing education needs for service program personnel.
- e.* Helping to resolve operational problems.

144.5(4) The medical director or other qualified designees shall randomly audit (at least quarterly) documentation of calls where emergency medical care was provided. The medical director shall randomly review audits performed by the qualified appointee. The audit shall be in writing and shall include, but need not be limited to:

- a.* Reviewing the patient care provided by service program personnel and remedying any deficiencies or potential deficiencies that may be identified regarding medical knowledge or skill performance.
- b.* Response time and time spent at the scene.
- c.* Overall EMS system response to ensure that the patient’s needs were matched to available resources including, but not limited to, mutual aid and tiered response.
- d.* Completeness of documentation.

144.5(5) On-line medical direction when provided through a hospital.

a. The medical director shall designate in writing at least one hospital which has established a written on-line medical direction agreement with the department. It shall be the medical director’s responsibility to notify the department in writing of changes regarding this designation.

b. Hospitals signing an on-line medical direction agreement shall:

(1) Ensure that the supervising physicians or physician designees will be available to provide on-line medical direction via telecommunications on a 24-hour-per-day basis.

(2) Identify the service programs for which on-line medical direction will be provided.

(3) Establish written protocols for use by supervising physicians and physician designees who provide on-line medical direction.

(4) Administer a quality assurance program to review orders given. The program shall include a mechanism for the hospital and service program medical directors to discuss and resolve any identified problems.

c. A hospital which has a written medical direction agreement with the department may provide medical direction for any or all service program authorization levels and may also agree to provide backup on-line medical direction for any other service program when that service program is unable to contact its primary source of on-line medical direction.

d. Only supervising physicians or physician designees shall provide on-line medical direction. However, a physician assistant, registered nurse or EMT (of equal or higher level) may relay orders to emergency medical care personnel, without modification, from a supervising physician. A physician designee may not deviate from approved protocols.

e. The hospital shall provide, upon request to the department, a list of supervising physicians and physician designees providing on-line medical direction.

f. The department may verify a hospital's communications system to ensure compliance with the on-line medical direction agreement.

g. A supervising physician or physician designee who gives orders (directly or via communications equipment from some other point) to an emergency medical care provider is not subject to criminal liability by reason of having issued the orders and is not liable for civil damages for acts or omissions relating to the issuance of the orders unless the acts or omissions constitute recklessness.

h. Nothing in these rules requires or obligates a hospital, supervising physician or physician designee to approve requests for orders received from emergency medical care personnel.

NOTE: Hospitals in other states may participate provided that the applicable requirements of this subrule are met.

641—144.6(147A) Complaints and investigations—denial, citation and warning, probation, suspension or revocation of service program authorization or renewal.

144.6(1) All complaints regarding the operation of authorized air medical service programs, or those purporting to be or operating as the same, shall be reported to the department. The address is: Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075.

144.6(2) Complaints and the investigative process will be treated as confidential in accordance with Iowa Code section 22.7 and chapter 272C.

144.6(3) Air ambulance service program authorization may be denied or a program may be disciplined as provided in subrule 144.6(4) by the department in accordance with Iowa Code subsections 147A.5(3) and 272C.3(2) for any of the following reasons:

a. Knowingly allowing the falsifying of a patient care report (PCR).

b. Failure to submit required reports and documents.

c. Delegating professional responsibility to a person when the service program knows that the person is not qualified by training, education, experience or certification to perform the required duties.

d. Practicing, condoning, or facilitating discrimination against a patient, student or employee based on race, ethnicity, national origin, color, sex, sexual orientation, age, marital status, political belief, religion, mental or physical disability diagnosis, or social or economic status.

e. Knowingly allowing sexual harassment of a patient, student or employee. Sexual harassment includes sexual advances, sexual solicitations, requests for sexual favors, and other verbal or physical conduct of a sexual nature.

f. Failure or repeated failure of the applicant or alleged violator to meet the requirements or standards established pursuant to Iowa Code chapter 147A or the rules adopted pursuant to that chapter.

g. Obtaining or attempting to obtain or renew or retain service program authorization by fraudulent means or misrepresentation or by submitting false information.

h. Engaging in conduct detrimental to the well-being or safety of the patients receiving or who may be receiving emergency medical care.

i. Failure to correct a deficiency within the time frame required by the department.

144.6(4) Method of discipline. The department has the authority to impose the following disciplinary sanctions against an authorized service program:

a. Issue a citation and warning.

b. Impose a civil penalty not to exceed \$1,000.

c. Require additional education or training.

d. Impose a period of probation under specified conditions.

e. Prohibit permanently, until further order of the department, or for a specific period a service program's ability to engage in specific procedures, methods, acts, or activities incident to the practice of the profession.

f. Suspend an authorization until further order of the department or for a specific period.

g. Revoke an authorization.

h. Impose such other sanctions as allowed by law and as may be appropriate.

144.6(5) The department shall notify the applicant of the granting or denial of authorization or renewal, or shall notify the alleged violator of action to issue a citation and warning, place on probation, suspend or revoke authorization or renewal pursuant to Iowa Code sections 17A.12 and 17A.18. Notice of issuance of a denial, citation and warning, probation, suspension or revocation shall be served by restricted certified mail, return receipt requested, or by personal service.

144.6(6) Any requests for appeal concerning the denial, citation and warning, probation, suspension or revocation of service program authorization or renewal shall be submitted by the aggrieved party in writing to the department by certified mail, return receipt requested, within 20 days of the receipt of the department's notice. The address is: Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075. If such a request is made within the 20-day time period, the notice shall be deemed to be suspended. Prior to or at the hearing, the department may rescind the notice upon satisfaction that the reason for the denial, citation and warning, probation, suspension or revocation has been or will be removed. After the hearing, or upon default of the applicant or alleged violator, the administrative law judge shall affirm, modify or set aside the denial, citation and warning, probation, suspension or revocation. If no request for appeal is received within the 20-day time period, the department's notice of denial, probation, citation and warning, suspension or revocation shall become the department's final agency action.

144.6(7) Upon receipt of an appeal that meets contested case status, the appeal shall be forwarded within five working days to the department of inspections and appeals pursuant to the rules adopted by that agency regarding the transmission of contested cases. The information upon which the adverse action is based and any additional information which may be provided by the aggrieved party shall also be provided to the department of inspections and appeals.

144.6(8) The hearing shall be conducted according to the procedural rules of the department of inspections and appeals found in 481—Chapter 10.

144.6(9) When the administrative law judge makes a proposed decision and order, it shall be served by restricted certified mail, return receipt requested, or delivered by personal service. That proposed decision and order then becomes the department's final agency action without further proceedings ten days after it is received by the aggrieved party unless an appeal to the director is taken as provided in subrule 144.6(10).

144.6(10) Any appeal to the director for review of the proposed decision and order of the administrative law judge shall be filed in writing and mailed to the director by certified mail, return receipt requested, or delivered by personal service within ten days after the receipt of the administrative law judge's proposed decision and order by the aggrieved party. A copy of the appeal shall also be mailed to the administrative law judge. Any request for an appeal shall state the reason for appeal.

144.6(11) Upon receipt of an appeal request, the administrative law judge shall prepare the record of the hearing for submission to the director. The record shall include the following:

- a.* All pleadings, motions, and rules.
- b.* All evidence received or considered and all other submissions by recording or transcript.
- c.* A statement of all matters officially noticed.
- d.* All questions and offers of proof, objections, and rulings thereon.
- e.* All proposed findings and exceptions.
- f.* The proposed decision and order of the administrative law judge.

144.6(12) The decision and order of the director becomes the department's final agency action upon receipt by the aggrieved party and shall be delivered by restricted certified mail, return receipt requested, or by personal service.

144.6(13) It is not necessary to file an application for a rehearing to exhaust administrative remedies when appealing to the director or the district court as provided in Iowa Code section 17A.19. The aggrieved party to the final agency action of the department who has exhausted all administrative remedies may petition for judicial review of that action pursuant to Iowa Code chapter 17A.

144.6(14) Any petition for judicial review of a decision and order shall be filed in the district court within 30 days after the decision and order becomes final. A copy of the notice of appeal shall be sent to the department by certified mail, return receipt requested, or by personal service. The address is: Bureau of Emergency Medical Services, Iowa Department of Public Health, Lucas State Office Building, Des Moines, Iowa 50319-0075.

144.6(15) The party who appeals a final agency action to the district court shall pay the cost of the preparation of a transcript of the contested case hearing for the district court.

144.6(16) Final decisions of the department relating to disciplinary proceedings may be transmitted to the appropriate professional associations, the news media or an employer.

144.6(17) This rule is not subject to waiver or variance pursuant to 641—Chapter 178 or any other provision of law.

144.6(18) Emergency adjudicative proceedings.

a. Necessary emergency action. To the extent necessary to prevent or avoid immediate danger to the public health, safety, or welfare, and consistent with the Constitution and other provisions of law, the department may issue a written order in compliance with Iowa Code section 17A.18 to suspend authorization in whole or in part, order the cessation of any continuing activity, order affirmative action, or take other action within the jurisdiction of the department by emergency adjudicative order.

b. Before issuing an emergency adjudicative order, the department shall consider factors including, but not limited to, the following:

(1) Whether there has been a sufficient factual investigation to ensure that the department is proceeding on the basis of reliable information;

(2) Whether the specific circumstances which pose immediate danger to the public health, safety, or welfare have been identified and determined to be continuing;

(3) Whether the program required to comply with the emergency adjudicative order may continue to engage in other activities without posing immediate danger to the public health, safety, or welfare;

(4) Whether imposition of monitoring requirements or other interim safeguards would be sufficient to protect the public health, safety, or welfare; and

(5) Whether the specific action contemplated by the department is necessary to avoid the immediate danger.

c. Issuance of order.

(1) An emergency adjudicative order shall contain findings of fact, conclusions of law, and policy reasons to justify the determination of an immediate danger in the department's decision to take immediate action. The order is a public record.

(2) The written emergency adjudicative order shall be immediately delivered to the service program that is required to comply with the order by utilizing one or more of the following procedures:

1. Personal delivery.
2. Certified mail, return receipt requested, to the last address on file with the department.

3. Facsimile. Fax may be used as the sole method of delivery if the service program required to comply with the order has filed a written request that agency orders be sent by fax and has provided a fax number for that purpose.

(3) To the degree practicable, the department shall select the procedure for providing written notice that best ensures prompt, reliable delivery.

(4) Unless the written emergency adjudicative order is provided by personal delivery on the same day that the order issues, the department shall make reasonable immediate efforts to contact by telephone the service program that is required to comply with the order.

(5) After the issuance of an emergency adjudicative order, the department shall proceed as quickly as feasible to complete any proceedings that would be required if the matter did not involve an immediate danger.

(6) Issuance of a written emergency adjudicative order shall include notification of the date on which department proceedings are scheduled for completion. After issuance of an emergency adjudicative order, continuance of further department proceedings to a later date will be granted only in compelling circumstances upon application in writing unless the service program that is required to comply with the order is the party requesting the continuance.

641—144.7(147A) Temporary variances.

144.7(1) If during a period of authorization there is some occurrence that temporarily causes a service program to be in noncompliance with these rules, the department may grant a temporary variance. Temporary variances from these rules (not to exceed six months in length per any approved request) may be granted by the department to a currently authorized service program. Requests for temporary variances shall apply only to the service program requesting the variance and shall apply only to those requirements and standards for which the department is responsible.

144.7(2) To request a variance, the service program shall:

a. Notify the department verbally (as soon as possible) of the need to request a temporary variance. Submit to the department, within ten days after having given verbal notification to the department, a written explanation for the temporary variance request. The address and telephone number are Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075; (515)725-0326.

b. Cite the rule from which the variance is requested.

c. State why compliance with the rule cannot be maintained.

d. Explain the alternative arrangements that have been or will be made regarding the variance request.

e. Estimate the period of time for which the variance will be needed.

144.7(3) Upon notification of a request for variance, the department shall consider, but shall not be limited to the following:

a. Examining the rule from which the temporary variance is requested to determine if the request is appropriate and reasonable.

b. Evaluating the alternative arrangements that have been or will be made regarding the variance request.

c. Examining the effect of the requested variance upon the level of care provided to the general populace served.

d. Requesting additional information if necessary.

144.7(4) Preliminary approval or denial shall be provided verbally within 24 hours. Final approval or denial shall be issued in writing within ten days after department receipt of the written explanation for the temporary variance request and shall include the reason for approval or denial. If approval is granted, the effective date and the duration of the temporary variance shall be clearly stated.

144.7(5) Any request for appeal concerning the denial of a request for temporary variance shall be in accordance with the procedures outlined in rule 641—144.6(147A).

641—144.8(147A) Transport options for air medical services.

144.8(1) Upon responding to an emergency call, air medical services may make a determination at the scene as to whether air medical transportation is needed. The determination shall be made by a medical crew member and shall be based upon protocol and concurrence of medical control approved by the service program's medical director. When the medical crew member applies this protocol to determine the appropriate transport option, the following criteria, as a minimum, shall be used :

- a.* Primary assessment;
- b.* Focused history and physical examination;
- c.* Chief complaint;
- d.* Name, address and age of the individual in need of emergency assistance; and
- e.* Nature of the call for assistance.

144.8(2) Air medical transportation shall be provided whenever any of the above criteria indicate that treatment should be initiated. If treatment is not indicated, the air medical service program shall make arrangements for alternate transportation, if indicated.

These rules are intended to implement Iowa Code chapter 147A.