**PUBLIC HEALTH DEPARTMENT[641]**

## Regulatory Analysis

Notice of Intended Action to be published: 641—Chapter 132

"Emergency Medical Services—Service Program Authorization"

Iowa Code section(s) or chapter(s) authorizing rulemaking: 147A.4

State or federal law(s) implemented by the rulemaking: Iowa Code chapters 147A, 147D, and 272C; section 321.231; 49 CFR 396; and 2024 Iowa Acts, House File 2507

### *Public Hearing*

A public hearing at which persons may present their views orally or in writing will be held as follows:

| | |
|---|---|
| November 6, 2024 | Microsoft Teams |
| 10 a.m. | Meeting ID: 268 876 122 100 |
| | Passcode: QXqezE |

### *Public Comment*

Any interested person may submit written or oral comments concerning this Regulatory Analysis, which must be received by the Department of Health and Human Services no later than 4:30 p.m. on the date of the public hearing. Comments should be directed to:

Victoria L. Daniels
Department of Health and Human Services
Lucas State Office Building
321 East 12th Street
Des Moines, Iowa 50319
Phone: 515.829.6021
Email: compliancerules@hhs.iowa.gov

**PUBLIC HEALTH DEPARTMENT[641]**

*Purpose and Summary*

This proposed chapter provides clarity and creates a process for Emergency Medical Services (EMS) service program authorization.

*Analysis of Impact*

1. Persons affected by the proposed rulemaking:

- Classes of persons that will bear the costs of the proposed rulemaking:

There are no costs associated with this rulemaking.

- Classes of persons that will benefit from the proposed rulemaking:

Iowans who utilize EMS programs will benefit.

2. Impact of the proposed rulemaking, economic or otherwise, including the nature and amount of all the different kinds of costs that would be incurred:

- Quantitative description of impact:

There are 729 authorized EMS service programs in Iowa that serve 896 locations. There are over 450,000 patient encounters by EMS service programs per year.

- Qualitative description of impact:

These rules outline defined service program processes and service program authorization, setting a minimum standard for the health and safety of Iowans who access the EMS system.

3. Costs to the State:

- Implementation and enforcement costs borne by the agency or any other agency:

Personnel and other administrative costs will be borne by the Department.

- Anticipated effect on state revenues:

There is no impact on state revenues.

4. Comparison of the costs and benefits of the proposed rulemaking to the costs and benefits of inaction:

Without the rules, there would be no standards for EMS programs and Iowans needing services could potentially receive substandard care, resulting in harm.

5. Determination whether less costly methods or less intrusive methods exist for achieving the purpose of the proposed rulemaking:

Rulemaking is both appropriate and required by law.

6. Alternative methods considered by the agency:

- Description of any alternative methods that were seriously considered by the agency:

None were seriously considered.

- Reasons why alternative methods were rejected in favor of the proposed rulemaking:

Rulemaking is both appropriate and required by law.

*Small Business Impact*

If the rulemaking will have a substantial impact on small business, include a discussion of whether it would be feasible and practicable to do any of the following to reduce the impact of the rulemaking on small business:

- Establish less stringent compliance or reporting requirements in the rulemaking for small business.
- Establish less stringent schedules or deadlines in the rulemaking for compliance or reporting requirements for small business.
- Consolidate or simplify the rulemaking's compliance or reporting requirements for small business.
- Establish performance standards to replace design or operational standards in the rulemaking for small business.

- Exempt small business from any or all requirements of the rulemaking.

If legal and feasible, how does the rulemaking use a method discussed above to reduce the substantial impact on small business?

There is no impact on small business.

*Text of Proposed Rulemaking*

ITEM 1. Rescind 641—Chapter 132 and adopt the following **new** chapter in lieu thereof:

CHAPTER 132

EMERGENCY MEDICAL SERVICES—SERVICE PROGRAM AUTHORIZATION

**641—132.1(147A) Definitions.** For the purpose of these rules, the following definitions apply:

*"Advanced emergency medical technician level service"* or *"AEMT level service"* means a service program that provides emergency medical care that does not exceed the scope of practice of a certified AEMT provider as outlined in 641—subrule 131.5(2).

*"Advanced registered nurse practitioner"* or *"ARNP"* means a nurse licensed pursuant to 655—7.1(152) with current licensure as a registered nurse in Iowa who is registered in Iowa to practice in an advanced role.

*"Ambulance"* means any privately or publicly owned ground, fixed wing or rotor wing vehicle equipped with life-support systems and specifically designed to transport the sick or injured who require emergency medical care.

*"Applicant"* means an owner of a transport or nontransport program or service program that is applying to the department for authorization as a service program or renewal of current authorization as a service program.

*"Biomedical hazardous waste"* means waste product that may be contaminated with a biological material that is an infectious disease transmission risk.

*"Communication system"* means but is not limited to a telecommunication system, radio communication system, or mobile data communication system.

*"Conditional service level authorization"* means an enhanced service program authorization under which a service program may provide an advanced level of service from that routinely provided under the service program's full authorization level, on an intermittent basis with department and medical director approval.

*"Continuous quality improvement"* or *"CQI"* means a program that is an ongoing process to monitor standards at all EMS operational levels.

*"Credentialing"* means a clinical determination that is the responsibility of a physician medical director. It is the employer or affiliating organization's responsibility to act on the clinical credentialing status of EMS personnel in making employment or deployment decisions.

*"Critical care transport"* or *"CCT"* means a paramedic level service program that has received an endorsement from the department to provide specialty care patient transportation and that is staffed by one or more paramedics with a critical care paramedic endorsement from the department or that is staffed by other health care professionals in an appropriate specialty area.

*"Deficiency"* means noncompliance with Iowa Code chapter 147A or these administrative rules.

*"Emergency medical care"* means any medical procedure authorized by Iowa Code chapter 147A and 641—Chapter 131.

*"Emergency medical care provider"* means the same as defined in Iowa Code section 147A.1.

*"Emergency medical responder level service"* or *"EMR level service"* means a nontransport service program that provides emergency medical care that does not exceed the scope of practice of a certified EMR provider as outlined in 641—subrule 131.5(2).

*"Emergency medical services"* or *"EMS"* means the same as defined in Iowa Code section 147A.1.

*"Emergency medical technician-basic"* or *"EMT-B"* means an individual who has successfully completed the current U.S. 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 level service"* or *"EMT level service"* means a service program that provides emergency medical care that does not exceed the scope of practice of a certified EMT provider as outlined in 641—subrule 131.5(2).

*"Emergency medical transportation"* means transportation of a patient by an ambulance.

*"Emergency vehicle driver"* or *"driver"* means a currently licensed driver rostered with the service program or other emergency response personnel with emergency vehicle driving training.

*"EMS clinical guidelines"* or *"minimum EMS clinical guidelines"* means a minimum clinical standard approved by the department upon which a service program's medical director will base service program protocols.

*"Endorsement"* means an approval granted by the department authorizing a paramedic level service program to provide critical care transport (CCT).

*"FAA"* means Federal Aviation Administration.

*"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.

*"First response vehicle"* means any privately or publicly owned vehicle that is not an ambulance and that is used solely for the transportation of personnel and equipment to and from the scene of an emergency.

*"Full authorization"* means a service program authorization under which a service is authorized to provide and routinely provides a specific level of emergency medical care for initial 911 or emergency calls 24 hours per day, seven days per week.

*"Hospital"* means any hospital licensed under the provisions of Iowa Code chapter 135B.

*"Medical direction"* means direction, advice, or orders provided by a medical director, supervising physician, PA, or ARNP to emergency medical care personnel.

*"Medical director"* means a physician designated by the service program and responsible for providing medical direction and overall supervision of the medical aspects of the service program.

*"Nontransport service"* means any privately or publicly owned service program that does not provide patient transportation and provides emergency medical care at the scene of an emergency.

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

*"Paramedic level service"* or *"PM level service"* means a service program that provides emergency medical care that does not exceed the scope of practice of a certified paramedic provider as outlined in 641—subrule 131.4(2).

*"Paramedic specialist"* or *"PS"* means an individual who has successfully completed the current U.S. 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 report that documents the assessment and management of the patient by the emergency care provider.

*"Physician"* means an individual licensed under Iowa Code chapter 148.

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

*"Primary response ambulance"* means any ambulance utilized by a service program and dispatched as the initial ambulance response to a 911 or emergency call.

*"Protocols"* means written directions and orders approved by a service program's medical director utilizing the EMS clinical guidelines.

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

*"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 designated by the service program who is responsible for the operation and administration of a service program.

*"Service program"* or *"service"* means any ground or air medical transport service or nontransport service, inclusive of associated satellites, that has received full or conditional authorization from the department.

*"Service program affiliate"* or *"affiliate"* means an independently owned service program affiliated with one or more service programs or a separate management entity.

*"Service program affiliate agreement"* or *"affiliate agreement"* means a written agreement executed between one or more service programs or one or more management entities and filed with the department that clearly defines the responsibilities of each service program to ensure compliance with these rules.

*"Service program base of operation"* means the physical location from which a service program responds and at which the service program houses emergency medical care personnel and equipment.

*"Service program ownership"* means the legal owner of the service program responsible for providing emergency medical care and compliance with Iowa Code chapter 147A and these rules.

*"Service program satellite"* or *"satellite"* means one or more additional service program locations owned by the same service program.

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

*"Tiered response"* means a rendezvous between service programs to allow the transfer, continuation, or enhancement of patient care.

*"Transport agreement"* means a written agreement executed between two or more service programs and filed with the department that ensures response and transportation for initial 911 or emergency calls. A transport agreement may be a component of an affiliate agreement.

*"Transport service"* means any privately or publicly owned service program that utilizes ambulances in order to provide patient transportation.

**641—132.2(147A) Service program—authorization and renewal procedures and inspections.**

**132.2(1)** *Requirements for initial service program authorization.*

*a.* An entity that desires to provide emergency medical care services in the out-of-hospital setting in this state shall apply to the department for service program full authorization.

*b.* Information for initial authorization can be found on the department's website or upon request.

*c.* Transport service—full authorization. An entity seeking authorization as a transport service program shall apply for full authorization at a minimum of the EMT level or the level of care that will be provided by the service program or through a transport agreement for initial 911 or emergency calls 24 hours per day, seven days per week at the following EMS service levels:

(1) EMT.

(2) AEMT.

(3) Paramedic.

*d.* Transport service—conditional service level authorization. An entity seeking authorization as a transport service that is capable of providing emergency medical care beyond the full authorization level on an intermittent basis may apply for conditional service level authorization at one or more of the following conditional service levels:

(1) AEMT.

(2) Paramedic.

*e.* Nontransport service—full authorization. An entity seeking authorization as a nontransport service program shall apply for full authorization at a minimum of the EMR level or at the level of care that will be provided for initial 911 or emergency calls 24 hours per day, seven days per week at the following EMS service levels:

(1) EMR.

(2) EMT.

(3) AEMT.

(4) Paramedic.

The nontransport service program shall have an executed written transport agreement ensuring simultaneous dispatch with an authorized transport service program for all 911 or emergency calls.

*f.* Nontransport service—conditional service level authorization. An entity seeking authorization as a nontransport service program that has an executed written transport agreement ensuring simultaneous dispatch with an authorized transport service program for all 911 or emergency calls and is capable of providing emergency medical care beyond the full authorization level on an intermittent basis may apply for conditional service level authorization at one or more of the following conditional service levels:

(1) EMT.

(2) AEMT.

(3) Paramedic.

*g.* Conditional service level authorization requirements.

(1) A service program that has been granted conditional service level authorization shall only advertise or otherwise hold itself out to the public as an authorized service program at the level of full authorization.

(2) A service program authorized to operate at a conditional service level shall operate at such level only when an emergency medical care provider certified at the advanced certification level is listed on the service roster, physically present and directly responsible for patient care.

*h.* Initial service program authorization is valid for a period of one year from its effective date unless otherwise specified on the certificate of authorization or unless sooner suspended or revoked or surrendered.

*i.* An applicant shall provide evidence of liability insurance coverage for the service program and emergency medical care provider staff. Any change in insurance status must be reported to the department no later than 30 days from the change.

*j.* An applicant seeking endorsement must submit a department-approved application.

**132.2(2)** *Requirements for renewal of service program authorization.*

*a.* A service program seeking renewal of current authorization shall submit all required documentation to the department at least 90 days prior to the current authorization expiration date.

*b.* Transport service—full authorization. An entity seeking renewal authorization as a transport service program shall apply for full authorization at a minimum of the EMT level or the level of care that will be provided by the service program or through a transport agreement for initial 911 or emergency calls 24 hours per day, seven days per week at the following EMS service levels:

(1) EMT.

(2) AEMT.

(3) Paramedic.

*c.* Transport service—conditional service level authorization. An entity seeking renewal authorization as a transport service that is capable of providing emergency medical care beyond the full authorization level on an intermittent basis may apply for conditional service level authorization at one or more of the following conditional service levels:

(1) AEMT.

(2) Paramedic.

*d.* Nontransport service—full authorization. An entity seeking renewal authorization as a nontransport service program shall apply for full authorization at a minimum of the EMR

level or at the level of care that will be provided for initial 911 or emergency calls 24 hours per day, seven days per week at the following EMS service levels:

(1) EMR.

(2) EMT.

(3) AEMT.

(4) Paramedic.

*e.* Nontransport service—conditional service level authorization. An entity seeking renewal authorization as a nontransport service program that is capable of providing emergency medical care beyond the full authorization level on an intermittent basis may apply for conditional service level authorization at one or more of the following conditional service levels:

(1) EMT.

(2) AEMT.

(3) Paramedic.

*f.* Air medical requirements.

(1) 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 clinician who is certified or licensed in the state from which the aircraft launches and is certified as an EMS-Basic or higher level; and

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

(2) Staff rotor craft ambulances, at a minimum on each flight request, with the following staff while a patient is being transported:

1. Two health care clinicians 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.

(3) Medical crew members trained in the following areas:

1. Patient care limitations in flight.

2. Altitude physiology.

3. Appropriate utilization of air medical services.

4. Air medical communication systems.

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.* Conditional service level authorization requirements.

(1) A service program that has been granted conditional service level authorization shall only advertise or otherwise hold itself out to the public as an authorized service program at the level of full authorization.

(2) A service program authorized to operate at a conditional service level shall operate at such level only when an emergency medical care provider certified at the advanced certification level is listed on the service roster, physically present and directly responsible for patient care.

*h.* A service program that has submitted to the department fewer than 100 data reports per year for each of the previous two consecutive calendar years shall only be eligible for renewal of current authorization as an affiliate. The department will provide technical assistance in developing affiliations.

*i.* A service program shall be fully operational upon the effective date specified on the certificate of authorization and shall ensure compliance with Iowa Code chapter 147A and these rules.

*j.* A service program renewal authorization is valid for a period not to exceed three years from its effective date unless otherwise specified on the certificate of authorization or unless sooner revoked or suspended or surrendered.

**132.2(3)** *Reinstatement of service program authorization.*

*a.* A service program whose full authorization or conditional service level authorization has been revoked or suspended or surrendered may apply to the department for reinstatement in accordance with the terms and conditions of the order of revocation or suspension, unless the order of revocation provides that the authorization is permanently revoked.

*b.* If the authorization was voluntarily surrendered, an initial application for reinstatement may not be made until one year has elapsed from the date of the order or the date of the voluntary surrender.

**132.2(4)** *Out-of-state service programs.*

*a.* An emergency medical service program authorized and based in another state shall provide the department with verification of current state authorization upon request and may provide emergency medical care to patients in Iowa.

*b.* A service program authorized and based in another state shall meet all requirements of Iowa Code chapter 147A and these rules and must be authorized by the department to respond to 911 requests in Iowa to transport patients in Iowa to locations within Iowa.

**132.2(5)** *Service program inspections.*

*a.* The department, at a minimum, will complete an inspection of each base of operations, all associated satellites, and all affiliate locations prior to initial authorization or renewal of

current full authorization or conditional service level to ensure compliance with Iowa Code chapter 147A and these rules.

*b.* The department without prior notification may make additional inspections at times, at places and under such circumstances as it deems necessary to ensure compliance with Iowa Code chapter 147A and these rules.

*c.* Service program inspection forms are available on the department's website.

*d.* A service program shall correct deficiencies identified during a service program inspection within the time period specified by the department on the inspection form. Failure to correct identified deficiencies within the specified time period may result in disciplinary action.

*e.* The department may request additional information from or may inspect the records of any service program or associated satellite or associated affiliate that is currently authorized or that is seeking authorization to ensure continued compliance or to verify the validity of any information presented on the application for initial service program authorization or renewal of current authorization.

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

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

*h.* Interference with or failure to allow an inspection by the department or its agents may be cause for disciplinary action.

**641—132.3(147A) Service program operations.**

**132.3(1)** *Ownership.*

*a.* Each service program will have a unique authorization number assigned by the department.

*b.* A service program with satellites will have a single authorization number assigned by the department for all locations.

*c.* A service program owner shall ensure compliance with Iowa Code chapter 147A and these rules.

*d.* A service program shall report any change in ownership to the department at least seven days prior to the change.

*e.* A service program changing ownership shall apply to the department at least seven days prior to the change in ownership for initial authorization in accordance with 132.2(1).

**132.3(2)** *Medical director.*

*a.* Each service program shall have a designated medical director at all times.

*b.* A medical director shall:

(1) Be accessible for medical direction 24 hours per day, seven days per week or ensure accessibility to alternate medical direction.

(2) Ensure that all duties and responsibilities of the medical director are not relinquished before a new or temporary replacement is functioning in that capacity.

(3) Complete a department-sponsored medical director training within one year of assuming duties as a medical director and at a minimum once every three years thereafter.

(4) Develop, approve, and update service program guidelines that meet or exceed the minimum EMS clinical guidelines approved by the department.

(5) Ensure that the emergency medical care providers rostered with the service program are credentialed in the emergency medical skills to be provided and the duties of the emergency medical care provider do not exceed the provider's scope of practice as referenced in 641—subrule 131.4(2) and the service program's EMS service level of authorization.

(6) Be available for individual evaluation and consultation with service program personnel.

(7) Have authority to restrict a service program's authorized functional EMS service level.

(8) Have the authority to permanently or temporarily restrict a service program member to function within a lower level scope of practice or prohibit a service program member from providing patient care.

(9) Approve the service program's CQI program.

(10) Perform or complete, or appoint a designee to perform or complete, the medical audits in the service program's established CQI policy.

(11) Randomly audit (on at least a quarterly basis) documentation of calls where emergency medical care was provided.

(12) Randomly review audits performed by the qualified appointee.

*c.* A medical director may:

(1) Make additions to the department-approved EMS clinical guidelines when developing service guidelines, provided the additions are within the service program's level of authorization, the EMS provider's scope of practice, and acceptable medical practice.

(2) Request that service program providers provide additional emergency medical care skills on a limited pilot project basis. The pilot project applications are available from the department upon request.

(3) Approve the physician, PA and RN exception form identifying the level of EMS provider equivalency not to exceed the service program's EMS service level authorization for each physician, PA and RN who will be providing emergency medical care as part of the service program.

*d.* A medical director who receives no compensation for the performance of the director's volunteer duties under this chapter is considered a state volunteer as provided in Iowa Code section 669.24 while performing volunteer duties as an emergency medical services medical director. Compensation does not include payments for reimbursement of expenses.

*e.* A medical director, supervising physician, PA, or ARNP who gives orders 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.

*f.* Nothing in these rules requires or obligates a medical director, supervising physician, PA, or ARNP to approve requests for orders received from an emergency medical care provider.

*g.* A service program medical director who fails to comply with Iowa Code chapter 147A or these rules may be referred to the Iowa board of medicine.

**132.3(3)** *Service director.*

*a.* Each service program shall have a designated service director at all times.

*b.* A service director shall:

(1) Be accessible 24 hours per day, seven days per week or ensure accessibility to a service director designee.

(2) Be responsible for providing direction and overall supervision of the administrative and operational aspects of the service program.

(3) Ensure that all duties and responsibilities of the service director are not relinquished before a new or temporary replacement is functioning in that capacity.

(4) Complete a department-sponsored training within one year of assuming duties as a service director and at a minimum once every three years thereafter.

(5) Ensure the service program is in compliance with service program policy, Iowa Code chapter 147A and these rules.

(6) Ensure that duties of the service program's emergency medical care providers do not exceed the providers' scope of practice as referenced in 641—subrule 131.4(2) or the service program's EMS service level of authorization.

**132.3(4)** *Service program requirements.*

*a.* A service program shall:

(1) Not advertise or otherwise imply or hold itself out to the public as a service program unless currently authorized by the department.

(2) Only advertise at or otherwise hold itself out as having the level of full authorization.

(3) Select a new or temporary medical director if 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.

(4) Notify the department in writing within seven days prior to any change in medical director or any reduction or discontinuance of operations.

(5) Select a new or temporary service director if the current service director cannot or no longer wishes to serve in that capacity. Selection shall be made before the current service director relinquishes the duties and responsibilities of that position.

(6) Notify the department in writing within seven days prior to any change in service director or any reduction or discontinuance of operations.

(7) Notify the department within seven days prior to any change in location of a service program base of operations, administrative office, satellite, or affiliate.

(8) Notify the department within seven days when entering into agreements with one or more service programs or a management entity to form multiservice systems for shared service program management, administration, data submission, or other services to ensure compliance with these rules.

(9) Report the termination or resignation in lieu of termination of an emergency medical care provider due to negligence, professional incompetency, unethical conduct, substance use, or violation of any of these rules to the department in writing within seven days.

(10) Report theft of drugs to the department in writing within 48 hours following the occurrence of the incident.

(11) Develop a notification process for service members in the event of a motor vehicle collision involving a first response vehicle, ambulance, rescue vehicle or personal vehicle when used by a service program member responding as a member of the service program.

(12) Notify the department in writing within 48 hours of a motor vehicle collision resulting in personal injury or death.

(13) Ensure a response to an initial 911 or emergency call request to the service program, 24 hours per day, seven days per week.

(14) Utilize guidelines developed and approved by the service program medical director that meet or exceed the minimum EMS clinical guidelines approved by the department.

(15) Ensure alterations to the minimum EMS clinical guidelines by the service program's medical director are approved by and filed with the department.

(16) Maintain a communication system at a minimum between medical direction, receiving facility, and other emergency responders.

(17) Maintain a current personnel roster utilizing a department-approved registry system. Ensure all rostered personnel are currently certified as active EMS providers in the state of Iowa.

(18) Maintain files with the medical director and department-approved physician, PA and RN exception forms for appropriate personnel. PA and RN forms are available on the department's website.

(19) Ensure all service program members who operate motorized emergency response vehicles, ambulances, and rescue vehicles when used by a service member responding as a member of the service have a valid driver's license and attend driver training prior to driving an emergency vehicle.

(20) Develop, maintain and follow a written driver training policy that includes a review of Iowa laws regarding emergency vehicle operations (Iowa Code section 321.231), frequency of service required driver training, a review of service program policies and criteria for response with lights or sirens or both, speed limits, procedure for approaching intersections, and use of the service program communications equipment.

(21) Ensure the emergency medical care provider with the highest level of certification attends the patient unless otherwise indicated by patient assessment and approved by the service program's guidelines.

*b.* A transport service program shall:

(1) Provide as a minimum, on initial 911 or emergency calls, the following staff on each primary response ambulance:

1. One currently certified emergency medical care provider certified at the service program full level of authorization.

2. One driver.

(2) Provide as a minimum on each subsequent call or nonemergency call, when responding, the following staff:

1. One currently certified EMT.

2. One driver.

(3) Establish a transport decision policy that requires a complete assessment of a patient in order to determine transport needs. The service transport decision policy shall include:

1. The Out-of-Hospital Trauma and Triage Destination Decision Guideline as described in 641—Chapter 135.

2. Time critical condition considerations for transport to facilities that specialize in conditions such as cardiac conditions or stroke.

3. A process for a service program provider to determine transportation to a hospital, medical clinic, extended care facility, or other facilities where health care is routinely provided.

4. A process for patient refusal or nontransport if emergency transport is not warranted. The service program provider will obtain a signed transport/treatment refusal document or liability release if transport is not required.

5. A process by which a service program provider may make arrangements for alternate transport if emergency transport is not needed and remain with the patient until alternate transport arrives unless the provider is called to respond to another emergency.

*c.* Nontransport service programs.

(1) Nontransporting service programs, when responding to 911 or emergency calls, shall provide as a minimum one currently certified emergency medical care provider certified at the service program full level of authorization.

(2) Nontransport service programs shall have an executed written transport agreement ensuring simultaneous dispatch with an authorized transport service program for all 911 or emergency calls.

(3) Nontransport service programs may transport patients in an ambulance only in an emergency situation when lack of transporting resources would cause an unnecessary delay in patient care.

**132.3(5)** *Data reporting.*

*a.* A service program shall report data electronically to the department.

*b.* A service program shall submit data in a format approved by the department.

*c.* A service program shall submit reportable data to the department no later than the last day of the month following the month services were provided.

*d.* The data collected by the EMS data registry and furnished to the department pursuant to this rule 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 section 22.7(2). However, information that individually identifies patients shall not be disclosed, and state and federal law regarding patient confidentiality shall apply.

*e.* The department may approve requests for reportable patient data for special studies and analysis provided:

(1) The request has been reviewed and approved by the department with respect to the scientific merit and confidentiality safeguards.

(2) The department has given administrative approval for the proposal.

(3) The confidentiality of patients is protected pursuant to Iowa Code section 22.7 and chapter 147A.

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

*f.* For the purpose of ensuring the completeness and quality of reportable data, the department or authorized representative may examine all or part of the data record as necessary to verify or clarify all reportable data submitted by a service program.

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

*h.* A service program will develop, maintain and follow a written data submission policy.

**132.3(6)** *Patient care reporting.*

*a.* Each service program, satellite, and affiliate shall complete and maintain a patient care report documenting the care provided to each patient.

*b.* The patient care report is a confidential document and is exempt from disclosure pursuant to Iowa Code section 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 that prevents the identification of any patient or person named in these reports.

*c.* To facilitate the continuum of care, transport service programs shall provide at a minimum, upon delivery of a patient to a receiving facility, a verbal patient care report that contains details of the assessment and care provided.

*d.* Transport service programs shall provide a final patient care report within 24 hours to the receiving facility. Transport services and receiving facilities must work together to initiate reasonable and realistic mechanisms (including but not limited to paper, secure email, secure links, secure electronic system retrieval, and access to printers at the receiving facility) to ensure the delivery of the patient care report.

*e.* A service program will develop, maintain, and follow a written patient care report policy.

**132.3(7)** *Continuous quality improvement (CQI).*

*a.* A service program shall develop, maintain, and follow a CQI program that follows a written CQI policy.

*b.* The CQI program shall include medical audits that review patient care provided.

*c.* The CQI program shall be utilized to identify deficiencies or potential deficiencies regarding medical knowledge or skill or procedure performance.

*d.* The CQI program shall review at a minimum 911 response and scene times.

*e.* The CQI program shall develop a written plan that monitors, identifies and documents at a minimum continuing education, credentialing of skills and procedures, and personnel

performance for the service program's emergency medical care providers, drivers, physicians, PA and RN exceptions.

*f.* The CQI program shall establish measurable outcomes that reflect the goals and standards of the service program.

*g.* The CQI program shall ensure completion of loop closure/resolution of identified areas of concern.

**132.3(8)** *Medications in service programs.*

*a.* A service program shall have written pharmacy agreements in accordance with the Iowa board of pharmacy's 657—Chapter 11.

*b.* A service program shall maintain all medications in accordance with the rules of the Iowa board of pharmacy's 657—Chapters 10 and 11.

*c.* A service program shall develop, maintain, and follow a written pharmacy policy.

**132.3(9)** *Vehicle standards, supplies, equipment and maintenance.*

*a.* All service programs, regardless of their designation as governmentally owned, not-for-profit, or privately operated, shall annually systematically inspect, repair, and maintain, or cause to be systematically inspected, repaired, and maintained, all ambulances operated by the service program.

*b.* A service program shall utilize a vehicle inspection report approved by the department to record the results of an annual ambulance safety inspection. Annual safety inspection forms that comply with the requirements of 49 CFR 396 as amended to August 1, 2024, shall be approved by the department. A sample annual vehicle inspection form that complies with the reporting requirements of 49 CFR 396 as amended to August 1, 2024, can be found on the department's website.

*c.* A service program shall ensure individuals performing annual safety inspections are qualified and capable of performing an inspection by reason of experience, training, or both.

*d.* A service program shall not use an ambulance that fails to meet or maintain the requirements of this subrule to transport patients.

*e.* A service program shall house primary response ambulances in a garage or other enclosed facility that is maintained in a clean, safe condition, free of debris or other hazards; is temperature controlled; and has an unobstructed exit to the street.

*f.* A service program shall secure all equipment stored in the ambulance patient compartment so the patient and service program personnel are not injured by moving equipment.

*g.* New ambulances manufactured and placed into service shall meet at a minimum either the Commission on Accreditation of Ambulance Services (CAAS) Ground Vehicle Standard for Ambulances or the National Fire Protection Association (NFPA) Standard for Automotive Ambulances (NFPA 1917).

*h.* A service program shall maintain first response and rescue vehicles in safe operating condition and provide regular maintenance. Vehicles shall have the exterior clean and the interior clean and disinfected.

*i.* A service program shall ensure medical and patient care supplies are monitored for expiration dates, cleaned, laundered or disinfected. All medical supplies shall be stored in clean environments.

*j.* A service program shall ensure personal protection equipment and supplies are available to ensure emergency medical care responder safety during every response.

*k.* A service program shall ensure supplies to properly dispose of biomedical hazardous waste are available in all response vehicles, and all waste shall be disposed of according to accepted biomedical waste practices.

*l.* A service program shall ensure medical equipment is maintained per manufacturer requirements for safe emergency medical care provider and patient use.

*m.* A service program will develop, maintain, and follow vehicle standards, supplies, and equipment maintenance policies.

**641—132.4(147A) Waivers.** If during a period of authorization, a service program is unable to maintain compliance with Iowa Code chapter 147A and these rules, the department may grant a waiver.

**132.4(1)** The department may grant waivers of these rules to a currently authorized service program.

**132.4(2)** Requests for waivers shall apply only to the service program requesting the waiver and shall apply only to those requirements and standards for which the department is responsible.

**132.4(3)** A service program shall apply for a waiver in accordance with 441—Chapter 6.

**641—132.5(147A) Complaints and investigations—denial, citation and warning, probation, suspension or revocation of service program authorization or renewal.**

**132.5(1)** All complaints regarding the operation of authorized emergency medical care service programs, or those purporting to be or operating as the same, shall be reported to the department.

**132.5(2)** Complaints and the investigative process will be treated as confidential in accordance with Iowa Code section 22.7 and chapter 272C. 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 following knowledge of the violation.

**132.5(3)** Service program authorization may be denied, issued a civil penalty not to exceed $1,000, issued a citation and warning, placed on probation, suspended, revoked, or otherwise disciplined by the department in accordance with Iowa Code section 147A.5(3) 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.

*j.* Engaging in any conduct that subverts or attempts to subvert a department investigation.

*k.* Failure to comply with a subpoena issued by the department or failure to cooperate with an investigation of the department.

*l.* Failure to comply with the terms of a department order or the terms of a settlement agreement or consent order.

*m.* Knowingly aiding, assisting or advising a person to unlawfully practice EMS.

*n.* Acceptance of any fee by fraud or misrepresentation.

*o.* Repeated failure to comply with standard precautions for preventing transmission of infectious diseases as issued by the Centers for Disease Control and Prevention of the United States Department of Health and Human Services.

*p.* Violating privacy and confidentiality. A service program shall not disclose or be compelled to disclose patient information unless disclosure is required or authorized by law.

*q.* Practicing emergency medical services or using a designation of certification or otherwise holding itself out as practicing emergency medical services at a certain level of authorization when the service program is not authorized at such level.

*r.* Failure to respond within 30 days of receipt, unless otherwise specified, of communication from the department which was sent by registered or certified mail.

**132.5(4)** The department will notify the applicant of the granting or denial of authorization or renewal, or will notify the alleged violator of action to issue a citation and warning, place on probation or 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 will be served by restricted certified mail, return receipt requested, or by personal service.

**132.5(5)** 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. 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, citation and warning, probation, suspension or revocation shall become the department's final agency action.

**132.5(6)** Upon receipt of an appeal that meets contested case status, the appeal shall be forwarded within five working days to the department of inspections, appeals, and licensing 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 that may be provided by the aggrieved party shall also be provided to the department of inspections, appeals, and licensing.

**132.5(7)** The hearing shall be conducted according to the procedural rules of the department of inspections, appeals, and licensing, found in 481—Chapter 10.

**132.5(8)** 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 132.5(9).

**132.5(9)** Any appeal to the director for review of the proposed decision and order of the administrative law judge shall be filed in accordance with 441—Chapter 7.

These rules are intended to implement Iowa Code chapter 147A and 2024 Iowa Acts, House File 2507.