Regulatory Analysis

Notice of Intended Action to be published: 641—Chapter 134
"Trauma Care Facility Categorization and Verification"

Iowa Code section(s) or chapter(s) authorizing rulemaking: 147A.27
State or federal law(s) implemented by the rulemaking: Iowa Code section 147A.23

Public Hearing

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

November 6, 2024 10 a.m.	Microsoft Teams 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:

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Des Moines, Iowa 50319
Phone: 515.829.6021
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Purpose and Summary

This proposed rulemaking helps ensure all Iowa hospitals are verified to be equipped with the appropriate resources to provide trauma services and optimal care for injured patients. The chapter adopts by reference published national guidelines with required criteria/standards for hospitals to be verified trauma centers. The chapter also outlines the verification process, timeline, and disciplinary processes.

Analysis of Impact

1. Persons affected by the proposed rulemaking:

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

No costs are associated with the rulemaking.

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

Iowans in need of trauma care services 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:

The state trauma program maintains verification for all hospitals in the state of Iowa. There are currently 2 Level I adult trauma care facilities, 1 Level I pediatric trauma care facility, 2 Level II adult trauma care facilities, 1 Level II pediatric trauma care facility, 13 Level III trauma care facilities, and 100 Level IV trauma care facilities.

- Qualitative description of impact:

Iowa has had a proud tradition of a robust trauma system since the late 1990s. Iowa is considered a leader in trauma system development across the nation. It is a strength for Iowa that every hospital, no matter where it is located, is prepared to care for injured patients. Other states model their laws and rules on Iowa's.

3. Costs to the State:

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

Personnel and other administrative costs are borne by the agency.

- Anticipated effect on state revenues:

No impact on state revenues is anticipated.

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

Without this chapter, Iowa would not have an inclusive trauma system. Hospitals would not have consistent guidance and accountability to maintain the appropriate resources to provide optimal care to injured patients. The statewide trauma system would fall below national standards, impacting fatally and non-fatally injured Iowans.

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

This rulemaking is appropriate and required by law.

6. Alternative methods considered by the agency:

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

No alternative methods were considered.

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

Not applicable.

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 134 and adopt the following **new** chapter in lieu thereof:

CHAPTER 134
TRAUMA CARE FACILITY CATEGORIZATION AND VERIFICATION

641—134.1(147A) Definitions. For the purposes of these rules, the following definitions apply:

"ACS-COT" means the American College of Surgeons Committee on Trauma.

"Categorization" means the same as defined in Iowa Code section 147A.21.

"Certificate of verification" means a document awarded by the department that identifies a hospital or emergency care facility's level and term of verification as a trauma care facility.

"Criteria deficiency" or *"deficiency"* means a failure to meet criteria requirements as outlined in subrule 134.2(3).

"Emergency care facility" means the same as defined in Iowa Code section 147A.21.

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

"Final report" means the verification report issued by the department following a verification review conducted by trauma survey team members and department staff.

"Governing body" means a group of individuals responsible for the governance of a hospital, including but not limited to a board of directors or board of trustees.

"Hospital" means any hospital licensed under Iowa Code chapter 135B.

"On-site verification survey" means an on-site survey conducted by the department or survey team members to assess a hospital or emergency care facility's ability to meet the level of categorization requested.

"Persistently occurring deficiencies" means deficiencies identified in two sequential verification reviews.

"Trauma" means the same as defined in Iowa Code section 147A.21.

"Trauma care facility" means the same as defined in Iowa Code section 147A.21.

"Trauma survey team" means a group of health care providers contracted by the department to assist in verifying trauma care facilities' compliance with trauma criteria adopted in subrule 134.2(3).

"Type I criteria" or *"type I criteria deficiency"* indicates criteria requirements that may significantly impact a trauma care facility's ability to provide optimal care for trauma patients.

"Type II criteria" or *"type III criteria deficiency"* indicates criteria that are required but have a less critical impact on the trauma care facility's ability to provide optimal care for trauma patients than type I criteria.

"Verification" means the same as defined in Iowa Code section 147A.21.

641—134.2(147A) Trauma care facility categorization and verification. Categorization and verification of trauma care facilities will be made by the department in accordance with Iowa Code section 147A.23.

134.2(1) Categorization applications shall be submitted by all hospitals. New hospitals and emergency care facilities shall submit a categorization application no later than 90 days after licensing by the department of inspections, appeals, and licensing.

134.2(2) Categorization levels for trauma care facilities shall be identified as:

a. Level I.

b. Level II.

c. Level III.

d. Level IV.

134.2(3) Adoption by reference. Criteria specific to level I, II, and III trauma care facilities identified in the "Resources for Optimal Care of the Injured Patient" 2022 Standards published by the American College of Surgeons (ACS) is incorporated and adopted by reference for level I, II, and III hospital and emergency care facility categorization criteria. Criteria specific to level IV trauma care facilities identified in the "Resources for Optimal Care of the Injured Patient 2014" published by the ACS is incorporated and adopted by reference for level IV hospital and emergency care categorization criteria. For any differences that may occur between the adopted references and these administrative rules, the administrative rules shall prevail.

134.2(4) Categorization shall not be construed to imply any guarantee on the part of the department as to the level of trauma care services available at a trauma care facility.

134.2(5) A verified trauma care facility may apply to the department for a change in level of categorization through submission of a self-assessment categorization application.

134.2(6) Verification of a trauma care facility will be determined by the department upon successful completion of the categorization application and completion of a verification survey. All categorized hospitals and emergency care facilities shall be verified.

a. Level I and II trauma care facilities shall be verified by the ACS-COT.

b. Trauma care facilities verified by the ACS-COT will be accepted by the department as equivalent for categorization and verification as a trauma care facility in Iowa provided that all policy, reporting, and administrative rules have been met. The department may issue a certification of verification provided that the trauma care facility has been verified by the ACS-COT. The facility shall provide the department documentation including but not limited to a current copy of the ACS-COT verification.

c. A level I or II trauma care facility that fails to attain ACS-COT verification shall submit an application to the department to be verified as a level III or IV trauma care facility to ensure compliance with Iowa Code section 147A.23(2)*"a."*

d. Level III and IV trauma care facilities will be verified by the department in consultation with the trauma survey team.

134.2(7) The department will conduct a verification survey for categorized hospitals or emergency care facilities.

a. Type I and II criteria deficiencies identified during the verification process shall be resolved in accordance with the trauma care facility's final report. Failure to rectify deficiencies in accordance with the trauma care facility's final report may result in disciplinary action.

b. The department may conduct electronic review or on-site verification that criteria deficiencies have been resolved as outlined in final reports or disciplinary actions.

c. The department will notify the applicant in writing as to the approval or denial of verification as a trauma care facility within 90 days after the completion of a verification survey.

d. Verification cannot be construed to imply any guarantee on the part of the department as to the level of trauma care services available at a hospital or emergency care facility.

e. Trauma care facility verification is valid for a period of three years from the effective date unless otherwise specified on the certificate of verification or unless sooner suspended or revoked.

f. Trauma care facilities shall be fully operational at their verified level upon the effective date specified on the certificate of verification.

g. Trauma care facilities that are unable to maintain their categorization or verification, or both, must notify the department within 48 hours.

h. The director, pursuant to 441—Chapter 7, may grant a waiver from the requirements of rules adopted under this chapter for any trauma care facility.

i. Proceedings, records, and reports developed pursuant to this chapter constitute peer review records under Iowa Code section 147.135 and are not subject to discovery by subpoena or admissible as evidence. All information and documents received from a hospital, emergency care facility, or trauma care facility under Iowa Code chapter 147A are confidential pursuant to Iowa Code section 272C.6(4).

641—134.3(147A) Complaints, investigations and appeals.

134.3(1) The department may deny verification as a trauma care facility or may give a citation and warning, place on probation, suspend, or revoke existing verification if the department finds reason to believe that the facility has not been operating or will not be operated in compliance with Iowa Code section 147A.23 and these administrative rules or that there is insufficient assurance of adequate protection for the public. The denial, citation and warning, period of probation, suspension, or revocation shall be effected and may be appealed in accordance with the requirements of 441—Chapter 7.

134.3(2) All complaints regarding the operation of a trauma care facility, or those purporting to be or operating as the same, shall be reported to the department.

134.3(3) Complaints and the investigative process shall be treated as confidential to the extent that they are protected by Iowa Code sections 22.7 and 147A.24 and chapter 272C.

134.3(4) Complaint investigations may result in the department's issuance of a notice of denial, citation and warning, probation, suspension or revocation.

134.3(5) Notice of denial, citation and warning, probation, suspension or revocation shall be effected in accordance with the requirements of Iowa Code section 17A.12. Notice to the alleged violator of denial, citation and warning, probation, suspension, or revocation shall be served by certified mail, return receipt requested, or by personal service.

134.3(6) Final decisions of the department relating to disciplinary proceedings may be transmitted to the appropriate professional associations, news media or employer.

These rules are intended to implement Iowa Code section 147A.23.