

CHAPTER 134
TRAUMA CARE FACILITY CATEGORIZATION
AND VERIFICATION

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

“*Categorization*” means a preliminary determination by the department that a hospital or emergency care facility is capable of providing trauma care at Level I, II, III or IV care capabilities.

“*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 paragraph 134.2(3)“a.”

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

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

“*Emergency care facility*” means a physician’s office, clinic, or other health care center which provides emergency medical care in conjunction with other primary care services.

“*Emergency medical care provider*” means emergency medical care provider as defined in 641—131.1(147A).

“*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 a single or multisystem life-threatening or limb-threatening injury, or an injury requiring immediate medical or surgical intervention or treatment to prevent death or permanent disability.

“*Trauma care facility*” means a hospital or emergency care facility which provides trauma care and has been verified by the department as having Level I, Level II, Level III or Level IV care capabilities and has been issued a certificate of verification pursuant to Iowa Code section 147A.23(2)“c.”

“*Trauma care system*” means an organized approach to providing personnel, facilities, and equipment for effective and coordinated trauma care.

“*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 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 II 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 a process by which the department certifies a trauma care facility’s capacity to provide trauma care in accordance with criteria established for Level I, Level II, Level III or Level IV trauma care facilities and these rules.

[ARC 1079C, IAB 10/2/13, effective 1/6/14; ARC 3240C, IAB 8/2/17, effective 9/6/17]

641—134.2(147A) Trauma care facility categorization and verification. Categorization and verification of trauma care facilities shall be made by the department based upon the trauma care facilities’ resources available for providing trauma care services.

134.2(1) Categorization.

a. Categorization as a trauma care facility shall be determined by the department from self-reported information provided to the department by a hospital or emergency care facility through a self-assessment categorization application provided by the department.

b. Categorization applications shall be submitted by all hospitals. New hospitals shall submit a categorization application no later than 90 days after licensing by the department of inspections and appeals, health facilities division. Categorization applications may be submitted by emergency care facilities. New emergency care facilities may submit a categorization application no later than 90 days after opening or reopening.

c. Categorization applications may be obtained from the department upon written request to: Iowa Department of Public Health, Bureau of Emergency and Trauma Services, Lucas State Office Building, Des Moines, Iowa 50319-0075.

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.

a. Criteria specific to Level I trauma care facilities identified in the “Resources for Optimal Care of the Injured Patient 2014” (6th edition) published by the American College of Surgeons Committee on Trauma (ACS-COT) is incorporated and adopted by reference for Level I hospital and emergency care facility categorization criteria. Criteria specific to Level II trauma care facilities identified in the “Resources for Optimal Care of the Injured Patient 2014” (6th edition) published by the American College of Surgeons Committee on Trauma is incorporated and adopted by reference for Level II hospital and emergency care facility categorization criteria. Criteria specific to Level III trauma care facilities identified in the “Resources for Optimal Care of the Injured Patient 2014” (6th edition) published by the American College of Surgeons Committee on Trauma is incorporated and adopted by reference for Level 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” (6th edition) published by the American College of Surgeons Committee on Trauma is incorporated and adopted by reference for Level IV hospital and emergency care categorization criteria. For any differences which may occur between the adopted references and these administrative rules, the administrative rules shall prevail.

b. “Resources for Optimal Care of the Injured Patient 2014” (6th edition) published by the American College of Surgeons Committee on Trauma is available through the Iowa Department of Public Health, Bureau of Emergency and Trauma Services (BETS), Lucas State Office Building, Des Moines, Iowa 50319-0075, or the BETS Web site (<http://idph.iowa.gov/BETS/Trauma>).

c. Trauma care facilities shall transition to the criteria outlined in paragraph 134.2(3) “*a.*”

(1) Level IV trauma care facilities shall transition to the criteria outlined in paragraph 134.2(3) “*a.*” on or before October 1, 2017.

(2) Level III trauma care facilities shall maintain, at a minimum, the criteria requirements effective in 2013 until a transition to the criteria in paragraph 134.2(3) “*a.*” at the next scheduled verification visit. Transition to paragraph 134.2(3) “*a.*” criteria shall be completed on or before December 31, 2020.

(3) Level II trauma care facilities shall maintain, at a minimum, the criteria requirements effective in 2013 until American College of Surgeons Committee on Trauma verification on or before October 31, 2021.

d. The 2013 criteria for all levels of trauma care facilities are available through the Iowa Department of Public Health, Bureau of Emergency and Trauma Services, Lucas State Office Building, Des Moines, Iowa 50319-0075, or the BETS Web site (<http://idph.iowa.gov/BETS/Trauma>).

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 trauma care facility may apply to the department for a change in level of categorization through submission of a self-assessment categorization application. Hospitals, emergency care facilities,

or trauma care facilities applying for initial verification or a change in level of categorization shall be verified based on the criteria outlined in paragraph 134.2(3)“a.”

134.2(6) Verification. Verification of a trauma care facility shall 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 Level II trauma care facilities shall be verified by the American College of Surgeons Committee on Trauma on or before October 31, 2021.

b. Trauma care facilities verified by the American College of Surgeons Committee on Trauma shall 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 American College of Surgeons Committee on Trauma. 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 Level II trauma care facility which fails to attain American College of Surgeons Committee on Trauma verification shall submit an application to the department to be verified as a Level III or Level IV trauma care facility to ensure compliance with Iowa Code section 147A.23(2)“a.”

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

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

a. A verification survey shall assess the ability of the hospital or emergency care facility to meet criteria for the level of categorization pursuant to 134.2(3).

b. Verification criteria are weighted by criteria types, Type I and Type II, as indicated in the “Resources for Optimal Care of the Injured Patient 2014” (6th edition) published by the American College of Surgeons Committee on Trauma and adopted in 134.2(3)“a.”

c. Type II criteria deficiencies identified during the verification process may result in disciplinary action. Criteria deficiencies 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 shall result in disciplinary action.

d. Type I criteria deficiencies or persistently occurring Type II criteria deficiencies identified during the verification process shall result in disciplinary action. The department shall notify the trauma care facility’s governing body of Type I or persistently occurring Type II criteria deficiencies. The trauma care facility shall implement a plan of correction within 45 days of issuance of the trauma facility’s final report. Criteria deficiencies shall be resolved in accordance with the trauma care facility’s final report and the implemented plan of correction. Failure to rectify deficiencies shall result in disciplinary action.

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

f. The department shall approve trauma care facility verification when the department is satisfied that the proposed facility will provide services and be operated in compliance with Iowa Code section 147A.23 and these administrative rules.

g. The department shall 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.

h. Verification 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 hospital or emergency care facility.

i. 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.

j. Trauma care facilities shall be fully operational at their verified level upon the effective date specified on the certificate of verification. Trauma care facilities shall meet all requirements of Iowa Code section 147A.23 and these administrative rules.

k. As part of the verification and renewal process, the department or its designated trauma survey team may conduct periodic on-site reviews of the services and facilities of trauma care facilities including chart review at those facilities.

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

m. The director, pursuant to 641—Chapter 178, may grant a variance from the requirements of rules adopted under this chapter for any trauma care facility.

n. 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 shall be confidential pursuant to Iowa Code section 272C.6(4).

134.2(8) Prohibited acts. A hospital or emergency care facility that imparts or conveys, or causes to be imparted or conveyed, that it is a trauma care facility, or that uses any other term to indicate or imply that the hospital or emergency care facility is a trauma care facility without having obtained a certificate of verification by the department is subject to civil penalty not to exceed \$100 per day for each offense. The director may apply to the district court for a writ of injunction to restrain the use of the term “trauma care facility.”

134.2(9) Nothing in Iowa Code section 147A.23 or these administrative rules shall be construed to restrict a hospital or emergency care facility from providing any services for which it is duly authorized. [ARC 9445B, IAB 4/6/11, effective 5/11/11; ARC 1079C, IAB 10/2/13, effective 1/6/14; ARC 3240C, IAB 8/2/17, effective 9/6/17]

641—134.3(147A) Complaints and investigations and appeals—denial, citation and warning, probation, suspension, and revocation of verification as a trauma care facility.

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 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 Iowa Code section 17A.12.

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. The address is: Iowa Department of Public Health, Bureau of Emergency and Trauma Services, Lucas State Office Building, Des Moines, Iowa 50319-0075.

134.3(3) An EMS provider who has knowledge of a hospital, emergency care facility or trauma care facility that has violated Iowa Code section 147A.23, or these administrative rules, shall immediately report such information to the department. The address is: Iowa Department of Public Health, Bureau of Emergency and Trauma Services, Lucas State Office Building, Des Moines, Iowa 50319-0075.

134.3(4) Complaints and the investigative process shall be treated as confidential to the extent they are protected by Iowa Code sections 22.7 and 147A.24 and Iowa Code chapter 272C.

134.3(5) Complaint investigations may result in the department’s issuance of a notice of denial, citation and warning, probation, suspension or revocation.

134.3(6) 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(7) Any request for a hearing concerning the denial, citation and warning, probation, suspension or revocation 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 to take action. The address is: Iowa Department of Public Health, Bureau of Emergency and Trauma Services, Lucas State Office Building, Des Moines, Iowa 50319-0075. If the request is made within the 20-day time period, the notice to take action shall be deemed to be suspended pending the hearing. 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. If no request for a hearing 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.

134.3(8) Upon receipt of a request for hearing, the request 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.

134.3(9) The hearing shall be conducted according to the procedural rules of the department of inspections and appeals found in 481—Chapter 10, Iowa Administrative Code.

134.3(10) When the administrative law judge makes a proposed decision and order, it shall be served by 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.

134.3(11) 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.

134.3(12) 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 on them.
- e. All proposed findings and exceptions.
- f. The proposed decision and order of the administrative law judge.

134.3(13) 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 certified mail, return receipt requested, or by personal service.

134.3(14) 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.

134.3(15) 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: Iowa Department of Public Health, Bureau of Emergency and Trauma Services, Lucas State Office Building, Des Moines, Iowa 50319-0075.

134.3(16) 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.

134.3(17) Final decisions of the department relating to disciplinary proceedings may be transmitted to the appropriate professional associations, news media or employer.

[ARC 3240C, IAB 8/2/17, effective 9/6/17]

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

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