

PUBLIC HEALTH DEPARTMENT[641]

Adopted and Filed

Pursuant to the authority of Iowa Code sections 147A.2 and 147A.27, the Department of Public Health hereby amends Chapter 134, “Trauma Care Facility Categorization and Verification,” Iowa Administrative Code.

The rules in Chapter 134 define the categorization levels for Iowa trauma care facilities and the criteria standards used to verify that hospitals meet the identified categorization levels. Minor changes to Chapter 134 have been made in the past five years, but significant updates have not been made to the trauma facility verification criteria standards since the early 2000s. The previously adopted Iowa criteria are based on criteria established by the American College of Surgeons Committee on Trauma (ACS-COT). The ACS-COT criteria were modified by Iowa physicians to tailor the criteria for application in Iowa. The Iowa modified criteria created inconsistencies from national trauma standards, resulting in inconsistencies within Iowa’s verified trauma facilities based on whether the facility completed an ACS-COT review or an Iowa review.

The ACS-COT has the national subject matter experts in the field of trauma. The ACS-COT conducted an Iowa trauma system consultation in February 2015. The consultation resulted in multiple recommendations. Two recommendations were to adopt and utilize ACS-COT criteria as outlined in the Resources for Optimal Care of the Injured Patient 2014 (6th edition) and to seek ACS-COT verification of trauma care facilities instead of conducting verification based on Iowa modified criteria. Since February 2015, the Trauma System Advisory Committee (TSAC) and its verification subcommittee have worked to review and implement recommendations from the ACS-COT. The verification subcommittee consists of representatives from every level of trauma care facility. Multiple meetings were held in 2015 and early 2016 to identify the positive impacts and unintended consequences associated with adoption of the ACS-COT criteria for all trauma care facility levels, verification of all Iowa Level I and Level II hospitals by the ACS-COT, and modifications to the verification review processes. Iowa’s trauma care facilities can expect the following impacts:

1. Level I trauma care facilities: No impact from the rule changes. All Iowa Level I trauma care facilities currently complete ACS-COT verification.
2. Level II trauma care facilities: There are four trauma care facilities verified as Level II in Iowa. Two Iowa facilities complete ACS-COT verification, and the other two Iowa facilities complete Iowa verification using Iowa modified criteria. The ACS-COT verified Level II trauma care facilities are held to a higher standard related to resources and trauma care capabilities than the Iowa verified trauma care facilities due to the inconsistencies in ACS-COT criteria and Iowa verification criteria. Having trauma care facilities within the state with the same categorization level but not the same verification standard creates inconsistencies within the system.

Level I and II trauma care facilities provide definitive care for the most significantly injured trauma patients. These facilities must have the physicians, staff, and resources needed to provide definitive care for any type of trauma patient, except patients with significant burns. Patients with significant burns are treated at accredited burn centers. There is only one accredited burn center in Iowa.

These amendments will have no impact on the ACS-COT verified Level II facilities because these facilities currently complete ACS-COT verification. The ACS-COT criteria include robust requirements related to hospital and surgical capabilities, performance improvement, and outreach activities inclusive of emergency medical service (EMS) and rural trauma care facilities.

The Iowa verified Level II trauma care facilities identified the following concerns with ACS-COT verification and utilization of ACS-COT criteria:

- The cost associated with ACS-COT verification. The increased costs originate from the actual cost of the ACS-COT verification process and visit and from the costs for additional physicians and staffing.

- Transition to a Level III facility (if unable to achieve ACS-COT Level II verification) may lead to a lower level of care available at the trauma care facility and diminish the hospital's ability to recruit physicians. (Transition to the ACS-COT verification using ACS-COT criteria substantially raises the verification criteria requirements for Iowa verified Level II trauma care facilities.)

3. Level III trauma care facilities: Iowa has 17 verified Level III trauma care facilities (all verified by Iowa). For the majority of the facilities, transition to the ACS-COT Level III criteria will have little or no impact on the facility. Three of the facilities may have difficulty achieving the orthopedic surgical services requirements identified in the criteria (previously not required by Iowa modified criteria). Transition to the ACS-COT criteria minimally to moderately raises the verification criteria requirements for the Iowa Level III trauma care facilities depending on the facilities' capabilities.

4. Level IV trauma care facilities: Iowa has 95 verified Level IV trauma care facilities (all verified by Iowa). The transition to the ACS-COT criteria has a significant benefit to the Level IV facilities. The ACS-COT criteria reduce the financial burden on the hospitals by allowing the use of advanced registered nurse practitioners (ARNPs) and physician assistants (PAs) in the hospital emergency departments without maintaining a physician on call. The education requirements are reduced for physicians at Level IV facilities. These changes are consistent with the needs of Iowa's rural facilities. Transition to the ACS-COT criteria lowers verification criteria requirements for the Iowa Level IV trauma care facilities while ensuring trained staff and quality access to life-sustaining trauma care in Iowa's rural communities. Level IV trauma care facilities primarily provide initial life-sustaining stabilization to a trauma patient before patient transfer occurs to a Level I, II, or III trauma care facility for definitive treatment. Transport decisions address the needs of the patient and consider the closest available resources to provide optimal care for the patient.

The TSAC verification subcommittee made the following recommendations to the TSAC in January 2016:

- ACS-COT verification of all Level I and II facilities in Iowa.
- Utilization of ACS-COT criteria for all trauma categorization levels (I-IV).
- Weighted criteria and a more clearly outlined disciplinary process.

The TSAC recommended that the Department provide notice of administrative rule changes to Chapter 134 reflecting the recommendations from the verification subcommittee. Iowa's trauma facility coordinators were engaged during the drafting process to provide comments and suggestions, and their comments and suggestions influenced the development of the Department's Notice of Intended Action (**ARC 3075C**, 5/24/17 Iowa Administrative Bulletin).

During the 2016 Legislative Session, language was introduced to amend Iowa Code section 147A.23(2)"c" to indefinitely suspend modifications to Level II trauma verification criteria from the criteria that were in effect on July 1, 2015. The legislative language passed through the Health and Human Services appropriations bill. The Governor subsequently vetoed this language at the end of the 2016 session.

Throughout 2016, TSAC requested that the Department pursue implementation of the recommendations made in January 2016. The Department continued to review the recommendations and began engaging the Iowa Hospital Association (IHA) and hospitals that specifically notified the Department about concerns over the proposed changes.

Several conference calls and face-to-face meetings occurred with IHA and hospital representatives to identify acceptable compromises in association with the proposed amendments to Chapter 134. The Department coordinated with TSAC during the November 2016, January 2017, and April 2017 council meetings to modify these amendments and to establish consensus amongst the trauma system constituency.

One Iowa verified Level II facility requested that two verification cycles (six years) be allowed before transitioning to ACS-COT verification. Some members of the TSAC recommended one year for transition (which is consistent with the time provided to ACS-COT facilities to meet criteria when the criteria are updated on the national level). TSAC ultimately recommended a three-year period for the Iowa Level II facilities to transition to the ACS-COT criteria.

The Iowa Level II facility continued to advocate for six years to transition. The Department met with the requesting hospital face-to-face on two occasions and participated in several conference calls to find a compromise. The Department is adopting a four-year period, from September 6, 2017, the effective date of these amendments, for the Iowa verified Level II facilities to transition to ACS-COT verification or to transition to an Iowa verified Level III or Level IV trauma care facility. The Department believes it to be a reasonable compromise to allow four years for facilities to recruit necessary medical staff needed to achieve ACS-COT Level II verification.

The Department is adopting amendments to Chapter 134 for the following reasons:

- ACS-COT criteria are evidence-based national standards developed by nationally recognized subject matter experts in the field of trauma. The “Resources for Optimal Care of the Injured Patient 2014” (6th edition) can be used as a consistent reference across Iowa’s trauma system.
- Utilization of only ACS-COT teams to verify Level II trauma care facilities in Iowa will eliminate inconsistencies between ACS-COT verification teams and Iowa verification teams.
- Hospitals verified at each categorization level will have consistent criteria to meet as well as consistent resources and capabilities for that level.

The following is a summary of the amendments to Chapter 134:

1. Throughout the chapter, references to hospital and emergency facilities are replaced with references to trauma facilities, where appropriate, and the terms resource, regional, area and community facilities are replaced with the appropriate level categorization designation I, II, III, or IV. Updates are made to the name of the bureau and its Web site address.

2. In rule 641—134.1(147A), definitions are added for “criteria deficiency,” “final report,” “governing body,” “persistently occurring deficiencies,” “trauma survey team,” “type I criteria,” and “type II criteria.” Edits are made to the definitions of “trauma care facility,” “on-site verification survey,” and “verification.”

3. In subrule 134.2(3), the “Resources for Optimal Care of the Injured Patient 2014” (6th edition) as published by the American College of Surgeons Committee on Trauma is adopted by reference.

4. New paragraph 134.2(3)“c” provides that trauma care facilities shall transition to the criteria outlined in the national reference “Resources for Optimal Care of the Injured Patient 2014” (6th edition) as published by the American College of Surgeons Committee on Trauma and provides the specific time lines for each level of trauma care facility to complete the transition.

5. The amendments to subrule 134.2(6) clarify that Level I and Level II trauma care facilities shall be verified by the American College of Surgeons Committee on Trauma (ACS-COT) and that the Level III and Level IV trauma care facilities will be verified by the Department. An ACS-COT verification shall be accepted by the Department as state verification as a trauma care facility. If Level I and II facilities fail an ACS-COT verification, the trauma care facility will submit to the Department an application for a Level III or IV verification until the ACS-COT recommendations are met and the trauma care facility can be visited and verified by the ACS-COT.

6. The amendments to subrule 134.2(7) provide that 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 paragraph 134.2(3)“a.” Clarification related to these types of criteria deficiencies and resulting disciplinary action is provided. The amendments also provide that the Department may conduct electronic review or on-site verification for deficiency resolution, that the Department may conduct chart reviews, that all proceedings, records and reports from site visits are peer review records and are not subject to discovery by subpoena or admissible evidence, and that all information and documents are confidential.

Notice of Intended Action was published in the Iowa Administrative Bulletin as **ARC 3075C** on May 24, 2017. A public hearing was held on June 13, 2017, from 1 to 2 p.m. in Room 517, Lucas State Office Building, 321 East 12th Street, Des Moines, Iowa. The Department received one comment in support of the amendments. These amendments are identical to those published under Notice of Intended Action.

The State Board of Health adopted these amendments on July 12, 2017.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code section 147A.2.

These amendments will become effective September 6, 2017.

The following amendments are adopted.

ITEM 1. Amend rule 641—134.1(147A) as follows:

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 ~~Resource (Level I)~~ Level I, ~~Regional (Level II)~~ Level II, ~~Area (Level III)~~ Level III or ~~Community (Level IV)~~ Level IV care capabilities and has been issued a certificate of verification pursuant to Iowa Code section 147A.23, subsection 2, paragraph “c.” 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 ~~hospital or emergency trauma~~ hospital or emergency trauma care facility’s capacity to provide trauma care in accordance with criteria established for ~~Resource (Level I)~~ Level I, ~~Regional (Level II)~~ Level II, ~~Area (Level III)~~ Level III or ~~Community (Level IV)~~ Level IV trauma care facilities and these rules.

ITEM 2. Amend rule 641—134.2(147A), introductory paragraph, as follows:

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

ITEM 3. Amend paragraph **134.2(1)“c”** as follows:

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

ITEM 4. Amend subrules 134.2(2) to 134.2(7) as follows:

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

- a. ~~Resource (Level I)~~ Level I.
- b. ~~Regional (Level II)~~ Level II.
- c. ~~Area (Level III)~~ Level III.
- d. ~~Community (Level IV)~~ 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” (2006) (6th edition) published by the American College of Surgeons Committee on Trauma (ACS-COT) is incorporated and adopted by reference for Resource (Level I) Level I hospital and emergency care facility categorization criteria. “Iowa Trauma System Regional (Level II) Hospital and Emergency Care Facility Categorization Criteria” (2013) 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 Regional (Level II) Level II hospital and emergency care facility categorization criteria. “Iowa Trauma System Area (Level III) Hospital and Emergency Care Facility Categorization Criteria” (2013) 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 Area (Level III) Level III hospital and emergency care facility categorization criteria. “Iowa Trauma System Community (Level IV) Hospital and Emergency Care Facility Categorization Criteria” (2013) 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 Community (Level IV) 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. “Iowa Trauma System Regional (Level II) Hospital and Emergency Care Facility Categorization Criteria” (2013), “Iowa Trauma System Area (Level III) Hospital and Emergency Care Facility Categorization Criteria” (2013) and “Iowa Trauma System Community (Level IV) Hospital and Emergency Care Facility Categorization Criteria” (2013) are “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 EMS Emergency and Trauma Services (BETS), Lucas State Office Building, Des Moines, Iowa 50319-0075, or the bureau of EMS BETS Web site (www.idph.state.ia.us/ems) (<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 ~~hospital or emergency~~ trauma care facility.

134.2(5) ~~A hospital, emergency care facility, or 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.

b. 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.

~~e. 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.

~~f. 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.

~~e. 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.

~~f. 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.

~~g. 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.

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

~~i. m.~~ The director, pursuant to ~~rule 641—Chapter 178~~, may grant a variance from the requirements of rules adopted under this chapter for any hospital or emergency trauma care facility provided that the variance is related to undue hardships in complying with this chapter or the rules adopted pursuant to this chapter.

~~j.~~ Hospitals currently verified by the American College of Surgeons shall be accepted as equivalent for categorization and verification as a trauma care facility in Iowa provided that all policy, reporting, and administrative rules have been met. Documentation shall be provided to the department including, but not limited to, a current copy of the ACS verification certification, the hospital's completed ACS verification application or a completed Self-Assessment Categorization Application (SACA).

~~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).

ITEM 5. Amend subrules 134.3(2) to 134.3(4) as follows:

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 ~~Medical~~ 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 ~~Medical~~ 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 ~~section~~ sections 22.7 and 147A.24 and Iowa Code chapter 272C.

ITEM 6. Amend subrule 134.3(7) as follows:

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 ~~Medical~~ 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.

ITEM 7. Amend subrule 134.3(15) as follows:

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 ~~Medical~~ and Trauma Services, Lucas State Office Building, Des Moines, Iowa 50319-0075.

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