CHAPTER 136
TRAUMA REGISTRY

641—136.1(147A) Definitions. For the purposes of these rules, the following definitions shall apply:

"Department" means the Iowa department of public health.

"Director" means the director of the Iowa department of public health.

"ICD9" means International Classification of Diseases, 9th Revision.

"Inclusion criteria" means criteria determined by the department and adopted by reference to determine which trauma patients are to be included in the trauma registry.

"Reportable patient data" means data elements and definitions determined by the department and adopted by reference to be reported to the trauma registry or reported to a trauma care facility on trauma patients meeting the inclusion criteria.

"Service program" or *"service"* means any medical care ambulance service, or nontransport service that has received authorization by the department.

"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), Regional (Level II), Area (Level III) or Community (Level IV) care capabilities and has been issued a certificate of verification pursuant to Iowa Code section 147A.23, subsection 2, paragraph *"c."*

"Trauma patient" means a victim of an external cause of injury that results in major or minor tissue damage or destruction caused by intentional or unintentional exposure to thermal, mechanical, electrical or chemical energy, or by the absence of heat or oxygen (ICD9 Codes E800.0 - E999.9).

"Trauma registry" means the data repository operated by the department to collect and analyze reportable patient data on the incidence, severity, and causes of trauma, including the central registry for brain and spinal cord injuries (IAC 641—21.1(135)) and farm-related injuries.

641—136.2(147A) Trauma registry.

136.2(1) Adoption by reference.

a. "Iowa Trauma Patient Data Dictionary" (April 2003) is incorporated by reference for inclusion criteria and reportable patient data to be reported to the trauma registry or reported to a trauma care facility. For any differences which may occur between the adopted reference and this chapter, the administrative rules shall prevail.

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

c. "Iowa EMS Patient Registry Data Dictionary" (January 2004) is incorporated by reference for inclusion criteria and reportable patient data to be reported to the department. For any differences which may occur between the adopted reference and this chapter, the administrative rules shall prevail.

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

136.2(2) A verified trauma care facility shall:

a. Submit reportable patient data identified in 136.2(1) via electronic transfer or in writing to the department. Data shall be submitted in a format approved by the department.

b. Submit reportable patient data identified in 136.2(1) to the department for each calendar quarter. Reportable patient data shall be submitted no later than 90 days after the end of the quarter.

c. Submit reportable patient data identified in 136.2(1) to the receiving trauma care facility upon delivery of the injured patient. Data shall be submitted in a format approved by the department.

136.2(3) A service program shall:

a. Submit reportable patient data identified in 136.2(1) via electronic transfer or in writing. Data shall be submitted in a format approved by the department.

b. Submit reportable patient data identified in 136.2(1) to the department for each calendar quarter. Reportable patient data shall be submitted no later than 90 days after the end of the quarter.

c. Submit reportable patient data identified in 136.2(1) to the receiving trauma care facility upon delivery of the injured patient. Data shall be submitted in a format approved by the department.

136.2(4) Reportable patient data compilations. The department shall prepare compilations for release or dissemination on all reportable patient data entered into the trauma registry during the reporting period. The compilations shall include, but not be limited to, trends and patient care outcomes for local, regional and statewide evaluations. The compilations shall be made available to all providers submitting reportable patient data to the registry.

136.2(5) Access and release of reportable patient data and information.

a. The data collected by and furnished to the department pursuant to this section 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, subsection 2. However, information which individually identifies patients shall not be disclosed and state and federal law regarding patient confidentiality shall apply.

b. 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; and

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

(3) The confidentiality of patients and trauma care facilities is protected pursuant to Iowa Code section 22.7.

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

136.2(6) Data collection methods. To the extent possible, activities under this section shall be coordinated with other health data collection methods.

136.2(7) Quality assurance.

a. For the purpose of ensuring the completeness and quality of reportable patient data, the department or authorized representative may examine all or part of the patient's medical records as necessary to verify or clarify all reportable patient data submitted by a trauma care facility or a service program.

b. Review of a patient's medical record by the department shall be scheduled in advance with the trauma care facility or service program and completed in a timely manner.

c. The director, pursuant to rule, may grant a variance from the requirements of rules adopted under this chapter for any hospital, emergency care facility, or service program provided that the variance is related to undue hardships in complying with this chapter or the rules adopted pursuant to this chapter.

641—136.3(147A) Offenses and penalties.

136.3(1) The department may deny verification as a trauma care facility or deny authorization as a service program or may give a citation and warning, place on probation, suspend, or revoke existing trauma care facility verification or service program authorization if the department finds reason to believe that the facility or service program has not been or will not be operated in compliance with Iowa Code section 147A.26 and these administrative rules. 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.

136.3(2) All complaints regarding the operation of a trauma care facility or service program or those purporting to be or operating as the same, shall be reported to the department. The address is: Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075.

136.3(3) Complaints and the investigative process shall be treated as confidential to the extent they are protected by Iowa Code section 22.7.

136.3(4) Complaint investigations may result in the department's issuance of a notice of denial, citation and warning, probation, suspension or revocation.

136.3(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.

136.3(6) 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 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.

136.3(7) 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.

136.3(8) 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.

136.3(9) 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.

136.3(10) Any appeal to the director for review of the proposed decision and order of the administrative law judge shall be filed in writing and mailed to the director by certified mail, return receipt requested, or delivered by personal service within ten days after the receipt of the administrative law judge's proposed decision and order by the aggrieved party. A copy of the appeal shall also be mailed to the administrative law judge. Any request for an appeal shall state the reason for appeal.

136.3(11) Upon receipt of an appeal request, the administrative law judge shall prepare the record of the hearing for submission to the director. The record shall include the following:

a. All pleadings, motions, and rules.

b. All evidence received or considered and all other submissions by recording or transcript.

c. A statement of all matters officially noticed.

d. All questions and offers of proof, objections and rulings on them.

e. All proposed findings and exceptions.

f. The proposed decision and order of the administrative law judge.

136.3(12) The decision and order of the director becomes the department's final agency action upon receipt by the aggrieved party and shall be delivered by certified mail, return receipt requested, or personal service.

136.3(13) It is not necessary to file an application for a rehearing to exhaust administrative remedies when appealing to the director or the district court as provided in Iowa Code section 17A.19. The aggrieved party to the final agency action of the department who has exhausted all administrative remedies may petition for judicial review of that action pursuant to Iowa Code chapter 17A.

136.3(14) Any petition for judicial review of a decision and order shall be filed in the district court within 30 days after the decision and order becomes final. A copy of the notice of appeal shall be sent to the department by certified mail, return receipt requested, or by personal service. The address is: Iowa Department of Public Health, Bureau of Emergency Medical Services, Lucas State Office Building, Des Moines, Iowa 50319-0075.

136.3(15) The party who appeals a final agency action to the district court shall pay the cost of the preparation of a transcript of the contested case hearing for the district court.

136.3(16) 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.26.

[Filed 11/14/96, Notice 10/9/96—published 12/4/96, effective 1/8/97]
[Filed 1/13/05, Notice 11/24/04—published 2/2/05, effective 3/9/05]