RULES
OF
THE TENNESSEE DEPARTMENT OF HEALTH
DIVISION OF HEALTH CARE FACILITIES

CHAPTER 1200-08-12
TRAUMA CENTERS

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1200-08-12-.01 PREAMBLE. The Tennessee Department of Health is empowered to adopt such regulations and standards pertaining to the operation and management of hospitals as are necessary for the public interest. On November 24, 1982, the EMS Advisory Council prepared and presented to the Board for Licensing Health Care Facilities ("Board") a recommendation that a formal review of the issues involved in the designation of trauma centers for the State of Tennessee be explored. Subsequently, on February 17, 1983, the Board requested a presentation regarding the City of Memphis Hospital Trauma Center in an effort to further define the need for action on trauma center designation and/or categorization. As a result of that presentation, the Board created a Task Force to evaluate and recommend criteria concerning the development of trauma systems and the operation of trauma centers in the state.

The process of Designation and Reverification is voluntary on the part of hospitals in the state. It is meant to identify those hospitals that make a commitment to provide a given level of care of the acutely injured patient. Knowledge of statewide trauma care capabilities and the use of trauma triage protocols will enable providers to make timely decisions, promote appropriate utilization of the trauma care delivery system, and ultimately save lives.

Authority: *T.C.A. § 68-11-201 et seq.* ***Administrative History:*** *Original rule filed September 18, 1985; effective October 18, 1985. Repeal and new rule filed December 5, 2011; effective March 4, 2012.*

1200-08-12-.02 AUTHORITY. The Board for Licensing Health Care Facilities issues these regulations under the authority granted at T.C.A. 68-11-201 et seq.

Authority: *T.C.A. § 68-11-201 et seq.* ***Administrative History:*** *Original rule filed September 18, 1985; effective October 18, 1985. Repeal and new rule filed December 5, 2011; effective March 4, 2012.*

1200-08-12-.03 DEFINITIONS.

(1) "ACS-COT" means American College of Surgeons Committee on Trauma.

(2) "Advisory Council" means the Tennessee Trauma Care Advisory Council.

(3) "ATLS" means Advanced Trauma Life Support.

(4) "Board" means the Board for Licensing Health Care Facilities.

(5) "Commissioner" means the Commissioner of the Tennessee Department of Health.

(6) "Comprehensive Regional Pediatric Center (CRPC)" means a facility designated as CRPC that shall be capable of providing comprehensive specialized pediatric medical and surgical care to all acutely ill and injured children. The center shall be responsible for serving as a regional referral center for the specialized care of pediatric patients or in special

(Rule 1200-08-12-.03, continued)

circumstances provide safe and timely transfer of children to other resources for specialized care. Rules and regulations governing CRPCs are delineated in Chapter 1200-08-30.

(7) "D" means desired.

(8) "Data" means the original information contained on the report required by the regulations, including, but not limited to, both identifying and non-identifying information.

(9) "Department" means the Tennessee Department of Health.

(10) "E" means essential.

(11) "Facility" shall have the same meaning as defined in T.C.A. § 68-11-201(18).

(12) "FAST" means focused abdominal sonography for trauma.

(13) "Health care practitioner" means a physician, surgeon, or other health care professional licensed under T.C.A. Title 63 or Title 68 who is engaged in diagnosing and/or treating patients within the trauma care system.

(14) "Identifying information" means any information that could lead to the identification of a patient who has been diagnosed or treated within the trauma care system.

(15) "Levels of Care" means the type of trauma service provided by the facility as shown by the degree of commitment in personnel and facilities made to the delivery of that service.

(16) "Level I" means a facility providing optimum care for the acutely injured patient and which meets all requirements in these regulations defined as Level of Care I.

(17) "Level II" means a facility providing optimum care for the acutely injured patient and which meets all requirements in these regulations defined as Level of Care II.

(18) "Level III" means a facility providing a maximum trauma care commensurate with community resources. The Level III facility generally serves communities without all the resources usually associated with Level I or II facilities. Planning for care of the injured in small communities or suburban settings usually calls for transfer agreements and protocols for the most severely injured patients. Designation of the Level III facility may also require innovative use of the region's resources. For example, if there is no neurosurgeon in a large, sparsely populated region it may require that a general surgeon be prepared to provide the emergency decompression of mass lesions and arrangement for patient transfer to the most appropriate Level I or II hospital after the surgeon has carried out the patient's life-saving operation. Staffing of the Level III hospital is another example of the innovative use of a region's resources. It will be impractical to require a general surgeon to be in-house in many instances. With modern communication systems it seems reasonable that the surgeon should be promptly available and in a great majority of instances meet the patient in the emergency room on arrival. When a Level III hospital first receives notification of a critically injured patient, it can activate on-call personnel to respond promptly to the hospital. The intent of this flexibility should be clear: to provide the best possible care even in the most remote circumstances.

(19) "Medical Record" means medical histories, records, reports, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries, x-rays, radiology interpretations, and other written, electronic, or graphic data prepared, kept, made or maintained in a facility that pertains to confinement or services rendered to patients admitted or receiving care.

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(20) "Person" means any member of the "medical, scientific, and academic research community."

(21) "Policies and Procedures Manual" means the document(s) maintained in the offices of the Tennessee Trauma Registry giving specific written instructions for the implementation of policies and procedures utilized by the registry and which may be updated from time to time.

(22) "PGY" means postgraduate year.

(23) "Trauma Center" shall have the same definition as provided in T.C.A. § 68-59-102(6).

(24) "Trauma Registry" means a central registry compiled of injury incidence information supplied by designated trauma centers and Comprehensive Pediatric Emergency Centers for the purpose of allowing the Board to analyze data and conduct special studies regarding the causes and consequences of traumatic injury.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-209 and 68-11-259.* ***Administrative History:*** *Original rule filed September 18, 1985; effective October 18, 1985. Amendment filed March 31, 1989; effective May 15, 1989. Amendment filed August 16, 2006; effective October 30, 2006. Repeal and new rule filed December 5, 2011; effective March 4, 2012. Amendment filed February 12, 2013; effective Amendment filed February 12, 2013; effective May 13, 2013.*

1200-08-12-.04 REQUIREMENTS.

(1) Trauma registry requirements shall include the following:

(a) Each trauma center shall submit trauma registry data electronically to the trauma registry on all closed patient files.

(b) Each trauma center shall submit trauma registry data for receipt no later than one hundred twenty (120) days after each quarter of the year. Trauma centers shall receive confirmation of successful submission no later than two weeks after submission.

(c) Trauma centers which fail to submit required data to the trauma registry for three (3) consecutive quarters shall risk not receiving compensation from the Tennessee Trauma Center Fund.

(2) Levels of Care

(a) Hospital Origination

1.	Trauma Service	I	II	III
	A recognizable program within the hospital which has a surgeon as its director/coordinator/physician in charge. The intent is to ensure the coordination of services and performance improvement for the trauma patient. The service includes personnel and other resources necessary to ensure appropriate and efficient provision of care and will vary according to facility and level of designation. In a Level I and II trauma center**,** the trauma team shall evaluate seriously injured patients based upon written institutional graded activation criteria and those patients shall be admitted by an identifiable surgical service staffed by credentialed trauma providers(1). Level I and II trauma centers shall have sufficient infrastructure and support to ensure adequate provision of care	E	E	E

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	for this service. Sufficient infrastructure and support may require additional qualified physicians, residents, nurse practitioners, physician's assistants, or other physician extenders. This composite should be determined by the volume of patients requiring care and the complexity of their conditions. In teaching facilities, the requirements of the Residency Review Committee also must be met. In Level III centers, the center may admit the injured patients to individual surgeons, but the structure of the program must allow the trauma director to have oversight authority for the care of those injured patients. The center shall ensure that there is a method to identify the injured patients, monitor the provision of health care services, make periodic rounds, and hold formal and informal discussions with individual practitioners. It is particularly important for team members to attend trauma committee meetings regularly and participate in peer review activities to maintain cohesion within the service.			
	Written graded activation criteria	E	E	E
	Administration supportive of the Trauma Program	E	E	E
	Evidence of an annual budget for the Trauma Program	E	E	E
	The Trauma Team may be organized by a qualified physician but care must be directed by a general surgeon expert in and committed to the care of the injured. All patients with multiple-system or major injury must be initially evaluated by the trauma team, and the surgeon who shall be responsible for overall care of a patient (the team leader) identified. A team approach is required for optimal care of patients with multiple-system injuries			E
2.	Surgery Departments/Divisions/Services/Sections (each staffed by qualified specialists)			
	Cardiothoracic Surgery	E	E (2)	
	General Surgery	E	E	E
	Neurologic Surgery	E	E	
	Obstetrics-Gynecologic Surgery	E		
	Ophthalmic Surgery	E		
	Oral and Maxillofacial Surgery - Dentistry	E		
	Orthopedic Surgery	E	E	D
	Otorhinolaryngologic Surgery	E(3)		
	Pediatric Surgery	E(4)		
	Plastic Surgery	E		
	Urologic Surgery	E		
	Surgical Critical Care	E	D	
3.	Emergency Department/Division/Service/Section (staffed by qualified specialists)	E(5)	E(5)	E(5)
4.	Surgical Specialty Availability In-house 24 hrs a day			
	General Surgery	E(6)		
	Neurologic Surgery	E(7)		
	Surgical Critical Care	E(6)	D(6)	
5.	Surgical Specialty Availability from inside or outside hospital			
	Cardiac Surgery	E	E(2)	
	General Surgery		E(17)	
	Neurologic Surgery		E(17)	D
	Microsurgery capabilities	E		
	Gynecologic Surgery	E		

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	Hand Surgery	E(8)		
	Ophthalmic Surgery	E	E	D
	Oral and Maxillofacial Surgery - Dentistry	E	E	D
	Orthopedic Surgery	E	E	D
	Otorhinolaryngologic Surgery	E	E	D
	Pediatric Surgery	E(4)	E(4)	
	Plastic Surgery	E	E	D
	Thoracic Surgery	E	E	D
	Urologic Surgery	E	E	D
6.	Non-Surgical Specialty Availability in-hospital 24 hours a day			
	Emergency Medicine	E(9)	E(9)	E
	Anesthesiology	E	E(11)	E(12)
7.	Non-Surgical Specialty Availability on call from inside or outside hospital			
	Cardiology	E	E	D
	Chest (pulmonary) Medicine	E	E	
	Gastroenterology	E	E	
	Hematology	E	E	D
	Infectious Diseases	E	E	
	Internal Medicine	E	E	E
	Nephrology	E	E	
	Pathology	E(13)	E	
	Pediatrics	E	E	
	Psychiatry	E	E	
	Radiology	E	E	

(b) Special Facilities/Resources/Capabilities

1(i).	Emergency Department (ED) – Personnel	I	II	III
	Designated Physician Director	E	E	E
	Physician with special competence in care of the critically injured who is a designated member of the trauma team and physically present in the ED 24 hours a day			E
	A physician or physician extender with ongoing certification in a recognized trauma course			
	Full time emergency department; RN personnel 24 hours a day	E	E	E
1(ii).	Emergency Department – Equipment for resuscitation and to provide support for the critically or seriously injured must include but shall not be limited to:			
	Airway control and ventilation equipment including laryngoscopes and endotracheal tubes of all sizes, bag-mask resuscitator, sources of oxygen, and mechanical ventilator	E	E	E
	Suction devices	E	E	E
	Electrocardiography-oscilloscope-defibrillator	E	E	E
	Bedside ultrasound capability for FAST examination	E	D	D
	Apparatus to establish central venous pressure monitoring	E	E	E
	All standard intravenous fluids and administration devices, including intravenous catheters	E	E	E
	Sterile surgical sets for procedures standard for ED, such as thoracostomy, cutdown, etc.	E	E	E
	Gastric lavage equipment	E	E	E
	Drugs and supplies necessary for emergency care	E	E	E

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	X-ray capability, 24 hour coverage by in-house technicians	E	E	E
	Two-way radio linked with vehicles of emergency transport system	E	E	E
	Skeletal tongs	E	E	E
	Cervical collars	E	E	E
	Spine Long Board	E	E	E
	Splinting materials and devices	E	E	E
	Helipad or Helicopter Landing Area	E	E	
2.	Intensive Care Units (ICU) for Trauma Patients			
	Designated Surgeon Medical Director	E	E	E
	Physician on duty in ICU 24-hours a day or immediately available from in-hospital (PGY4/5 qualify)	E(6)	E(6)	E
	Nurse-patient minimum ratio of 1:2 on each shift	E	E	E
	Immediate access to clinical laboratory service	E	E	E
	Equipment:	E	E	E
	Airway control and ventilation devices	E	E	E
	Oxygen source with concentration controls	E	E	E
	Cardiac emergency cart	E	E	E
	Temporary transvenous pacemaker	E	E	E
	Electrocardiograph-oscilloscope-defibrillator	E	E	E
	Cardiac output monitoring	E	E	D
	Electronic pressure monitoring	E	E	D
	Mechanical ventilator-respirators	E	E	E
	Patient weighing devices	E	E	E
	Pulmonary function measuring devices	E	E	E
	Temperature control devices	E	E	E
	Drugs, intravenous fluids and supplies (needed also as supply replacement time for EMS crews)	E	E	E
	Intracranial pressure monitoring devices	E	E	D
3.	Post-anesthetic recovery room (ICU is acceptable)			
	Registered nurses 24-hours a day	E	E	E
	Monitoring and resuscitation equipment	E	E	E
4.	Acute hemodialysis capability	E	E(14)	E(14)
5.	Organized burn care (15): Physician directed burn center/unit staffed by nursing personnel trained in burn care and equipped properly	E(15)	E(15)	E(15)
6.	Acute spinal cord management capability OR written transfer agreement with a hospital capable of caring for a spinal cord patient			E
7.	Acute head injury management capability OR written transfer agreement with a hospital capable of caring for a patient with a head injury			E
8.	Radiological Special Capabilities			
	Angiography of all types	E	E	D
	Sonography	E	E	D
	Nuclear scanning	E	E	D
	In-house computerized tomography	E	E	D
	MRI (magnetic resonance imaging)	E	E	D
9.	Organ donation protocol	E(16)	E(16)	D

(c) Operating suite special requirements

1.	Equipment/instrumentation	I	II	III
	Operating room, dedicated to the trauma service, with nursing	E	E	D

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	staff in-house and immediately available 24-hours a day			
	Cardiopulmonary bypass capability	E		
	Operating microscope	E	E	
	Thermal control equipment for patient	E	E	E
	Thermal control equipment for blood	E	E	E
	X-ray capability	E	E	E
	Endoscopes, all varieties	E	E	E
	Craniotomy instrumentation	E	E	D
	Monitoring equipment	E	E	E

(d) Clinical Laboratory Services available 24 hours a day

1.	Standard analysis of blood, urine, and other body fluids	E	E	E
2.	Blood typing and cross-matching	E	E	E
3.	Coagulation studies	E	E	E
4.	Blood bank or access to a community central blood bank and hospital storage facilities	E	E	E
5.	Blood gases and pH determinations	E	E	E
6.	Serum and urine osmolality	E	E	D
7.	Microbiology	E	E	E
8.	Drug and alcohol screening	E	E	D

(e) Trauma Medical Director

1.	Board certified general surgeon	E	E	E
2.	Minimum of three years clinical experience on a trauma service or trauma fellowship training	E	D	D
3.	48 hours of category I trauma/critical care CME every 3 years or 16 hours each year and attend one national meeting whose focus is trauma or critical care	E	E	D
4.	Participate in call	E	E	E
5.	Has the authority to manage all aspects of trauma care	E	E	E
6.	Authorizes trauma service privileges of the on-call panel	E	E	E
7.	Works in cooperation with nursing administration to support the nursing needs of trauma patients	E	E	E
8.	Develops treatment protocols along with the trauma team	E	E	
9.	Coordinates performance improvement and peer review processes	E	E	E
10.	With the assistance of the hospital administrator and the TPM, be involved in coordinating the budgetary process for the trauma program	E	E	E
11.	Participates in the Tennessee Chapter of the ACS-COT	E	E	E
12.	Participates in regional and national trauma organizations	E	E	
13.	Remains a current provider of ACS-ATLS course and in the provision of trauma-related instruction to other health care personnel	E	E	E
14.	Is involved in trauma research	E		

(f) Attending General Surgeon on the Trauma Service

1.	Board Certified in General Surgery	E	E	E
2.	Completion of an ATLS course	E	E	E
3.	Trauma specific CME 16 hours/year or 48 hours every 3 years	E	E	D

(Rule 1200-08-12-.04, continued)

(g) Emergency Department Physician

1.	Be Board Certified in Emergency Medicine or have ATLS certification	E	E	E

(h) Trauma Program Manager (TPM)/Trauma Nurse Coordinator (TNC)

1.	Must have a dedicated fulltime TNC/TPM	E	E	D
2.	Must have a part time TNC/TPM with the trauma program as a major focus of their job description (Level III)			E
3.	Must be a Registered Nurse licensed by the TN Board of Nursing (Level I/II/III)	E	E	E
4.	Must possess experience in Emergency/Critical Care Nursing (Level I/II)	E	E	D
5.	Must have a defined job description and organizational chart delineating the TNC/TPM role and responsibilities (Level I/II)	E	E	D
6.	Must be provided the administrative and budgetary support to complete educational, clinical, research, administrative and outreach activities for the trauma program	E	E	
7.	Shall attend one national meeting within the 3 year verification cycle	E	E	D

(i) Trauma Registrar

1.	A full time equivalent registrar for each 750-1000 admissions per year is required to assure high quality data collection	E	E	D
2.	Shall receive initial training when they start their job and also complete 4 hours of registry-specific continuing education per year (Level I/II)	E	E	D

(j) Programs for Quality Assurance

1.	Medical Care Education			
	Morbidity and Mortality Reviews to encompass all trauma deaths	E	E	E
2.	Trauma Process Improvement (PI)			
	The institution must provide resources to support the trauma process improvement program	E	E	E
	Must have a Trauma Performance Committee that meets at least quarterly to include physicians, nurses, pre-hospital personnel and a variety of other healthcare providers, and reviews policies and procedures, system issues, and whose members or designees attend at least 50% of regular meetings. The committee shall:	E	E	E
	• Identify discretionary and non-discretionary audit filters	E	E	E
	• Document and review times and reasons for trauma related diversion of patients from the scene or referral hospitals	E	E	E
	• Document and review response times for trauma surgeons, neurosurgeons, anesthesia or airway managers, and orthopedists, all of whom must demonstrate 80% compliance	E	E	
	• Document and review response times for trauma surgeons, anesthesia or airway managers, and orthopedists, all of whom must demonstrate 80% compliance	E	E	E
	• Monitor trauma team notification times	E	E	E

(Rule 1200-08-12-.04, continued)

	• Review pre-hospital trauma care to include patients dead on arrival • Review times and reasons for transfer of injured patients • Document availability of the surgeon on-call for trauma, such that compliance is 90% or greater where there is no trauma surgeon back-up call schedule	E	E	E E
	The institution shall demonstrate that actions taken as a result of issues identified in the Process Improvement Program created a measurable improvement. Documentation shall include where appropriate: 1) problem identification; 2) analysis; 3) preventability; 4) action plan; 5) implementation; and 6) reevaluation	E	E	E
3.	Operational Process Improvement (Evaluation of System Issues)			
	This is a multidisciplinary conference presided over by the Trauma Medical Director and shall include hospital administrative staff over trauma services as well as the staff in charge of all trauma-program related services. This committee addresses, assesses, and corrects global trauma program and system issues, corrects overall program deficiencies to continue to optimize patient care. This should be held at least quarterly, attendance noted, and minutes recorded.	E	E	D
4.	Trauma Bypass Log			
	Trauma bypass shall not exceed 5%. Trauma surgeons shall be involved in diversion/bypass decisions	E	E	E
5.	Outreach/Training Programs			
	Level I centers shall maintain a commitment to provide ATLS and other educational activities deemed appropriate and timely to surrounding referral centers.	E	D	
	Be involved with local and regional EMS agencies and/or personnel and assist in trauma education, performance improvement, and feedback regarding care	E	E	D
6.	Public Education			
	The trauma center shall be involved in community awareness of trauma and the trauma system	E	D	D
	Participate in statewide trauma center collaborative injury prevention efforts focused on common needs throughout the state	E	E	D
	Perform studies in injury control while monitoring the effects of prevention programs	E	D	D
7.	Institutional Commitment			
	Demonstrates knowledge, familiarity, and commitment of upper level administrative personnel to trauma service	E	E	E
	Upper level administration participation in multidisciplinary trauma conferences/committees	E	E	E
	Evidence of yearly budget for the trauma program	E	E	E
	Supports research efforts of the Trauma Service	E		
8.	Trauma System Development			
	All trauma centers shall participate in trauma system planning and development under the auspices of the Trauma Care Advisory Council	E	E	E
9.	Activation Criteria			
	Each center shall have clearly defined graded activation criteria. For the highest level of activation, the PGY 4/5 shall be immediately available and the trauma attending available within 20 minutes	E	E	E

(3) Designation

(Rule 1200-08-12-.04, continued)

(a) The Board shall implement the designation process.

(b) The preliminary designation process for facilities aspiring to designation as a Level I, II, or III Trauma Center shall consist of the following:

1. Each facility desiring designation shall submit an application to the Board;

2. A Department site visit team ("team") shall review each submitted application and shall act in an advisory capacity to the Board;

3. The team shall communicate deemed application deficiencies to the facility in writing by certified letter;

4. The facility shall have thirty (30) days to submit required information; and

5. Arrangements shall be made for a provisional site visit for those facilities meeting application requirements.

(c) The site visit team shall consist of the following:

1. A trauma surgeon medical director from an out-of-state trauma center who shall serve as team leader;

2. A trauma surgeon from an in-state Level I trauma center;

3. An in-state trauma nurse coordinator/program manager from a Level I trauma center;

4. The state trauma program manager/EMS director; and

5. For the provisional site visit, an Emergency Department physician from a Level I or Level II trauma center.

(d) The team shall be appointed by the following organizations:

1. The National and/or State Committees on Trauma of the American College of Surgeons shall assist in identifying the out-of-state surgeon; and

2. The state trauma program manager/Director of EMS, in consultation with the chairman and vice chairpersons of the Tennessee Committee on Trauma, shall select the in-state members of the site visiting team.

(e) The team shall conduct a provisional visit to ensure compliance with all criteria required for designation as a Trauma Center with the requested level of designation before the Board grants an institution designation as a Trauma Center. During the provisional visit, the applicant shall demonstrate that the required mechanisms to meet the criteria for the desired accreditation level are in place.

(f) The team shall identify deficiencies and areas of improvement it deems necessary for designation.

(g) If the team does not cite any deficiencies and concludes that the facility is otherwise in compliance with all applicable standards, it shall approve the applicant to function with provisional status for a period of one (1) year.

(Rule 1200-08-12-.04, continued)

(h) If, during the provisional visit, the team cites deficiencies, it shall not approve provisional status for the applicant to function as a trauma center. Centers with deficiencies shall have fifteen (15) days to provide documentation demonstrating compliance. If the facility is unable to correct the deficiencies within fifteen (15) days, the application shall be denied and the applicant may not resubmit an application for trauma center designation for at least one (1) year from the date of denial.

(i) Facilities granted provisional status as a trauma center shall adhere to the following:

1. The facility shall submit an interim report at the end of one (1) year that shall include the following:

(i) A description of changes made after the grant of provisional status;

(ii) A description of areas of improvement cited during the provisional visit; and

(iii) A summary of the hospital's trauma service based on the trauma registry report.

2. The team shall conduct a site visit at the termination of the applicant's one (1) year provisional designation as a trauma center.

3. During the follow-up visit, the team shall identify the presence of deficiencies and areas of improvement.

(j) Upon completion of the follow-up visit, the team shall submit its findings and designation recommendations to the Board.

1. If the team cites deficiencies found during its follow-up visit, they shall be included in its report to the Board.

2. The facility requesting trauma center designation shall be allowed to present evidence demonstrating action taken to correct cited deficiencies to the Board during the ratification process.

(k) The final decision regarding trauma center designation shall be rendered by the Board. If granted, trauma center designation is applicable for a period of three (3) years.

(l) If the Board denies the applicant trauma center designation, the facility may not reapply for at least one (1) year.

(m) The facility applying for trauma center designation shall bear all costs of the application process; including costs of a site visit.

(4) Verification

(a) Following designation as a trauma center, a verification site visit shall be conducted at the facility every three (3) years.

(b) The team shall advise the center of an upcoming verification visit at least sixty (60) days prior to the visit. After the facility receives notice of the upcoming verification site visit, it shall prepare all materials the team requests for submission.

(c) The team shall conduct an exit interview with the facility at the conclusion of the verification visit.

(Rule 1200-08-12-.04, continued)

1. During the exit interview the team shall communicate the following:

(i) The presence of deficiencies;

(ii) The facility's strengths and weaknesses; and

(iii) Recommendations for improvements and correction of deficiencies.

(d) The team shall submit a site visit report within sixty (60) days of completion of the site visit. It shall submit a copy of the report to the Board, the Chief Executive Officer of the hospital, the hospital board, and the Trauma Advisory Council within sixty (60) days of the site visit.

(e) If the team does not cite deficiencies and the center is in compliance with all applicable standards, it shall recommend that the facility be confirmed at its current level of trauma designation for a period of three (3) years.

(f) If during the site visit the team identifies deficiency(ies), the center shall have a period not to exceed thirty (30) days to correct the deficiencies

(g) If the team ascertains that deficiencies have not been corrected within thirty (30) days, either through desk review or an on-site visit, the center must present an explanation to the Board at its next scheduled meeting.

(h) The Board may, in accordance with the Uniform Administrative Procedures Act, revoke a facility's trauma center designation.

(i) The facility shall bear all costs of the verification process, including the costs of a site visit.

(5) All designated Trauma Centers shall participate in the collection of data for the Trauma Registry and in the review of the Trauma Registry.

(6) All designated Trauma Centers shall record and report the payor source for patient care on patient discharge. Final payment data shall be classed as self pay, commercial insurance, Medicare, Medicaid, or worker compensation.

(7) Prohibitions

(a) It shall be a violation of these regulations for any health care facility to hold out, advertise or otherwise represent itself to be a "trauma center" as licensed by the Board unless it has complied with the regulations set out herein and the Board has so licensed it.

(b) Any facility the Board designates as a trauma center, at any level, shall provide hospital emergency services to any applicant who applies for the same in case of injury or acute medical condition where the same is liable to cause death or severe injury or illness. The medical needs of an applicant and the available medical resources of the facility, rather than the financial resources of an applicant, shall be the determining factors concerning the scope of service provided.

References:

1. Credentialed trauma provider: Level I/II – Providers shall remain knowledgeable in trauma care principles through participation in 16 hours of trauma-related CME per year or 48 hours every 3

(Rule 1200-08-12-.04, continued)

years. The Trauma Medical Director shall identify the core group covering trauma which shall take at least 60% of the total trauma calls per month and attend at least fifty (50) per cent of the multidisciplinary review committee meetings.

2. Or substituted by a current signed transfer agreement with an institution with Cardiothoracic Surgery and cardiopulmonary bypass capability.

3. Or substituted by a department or division capable of treating maxillofacial trauma as demonstrated by staff privileges.

4. Or substituted by a current signed transfer agreement with an institution having a Pediatric Surgery Service.

5. The emergency department staffing must provide immediate and appropriate care for the trauma patient. The emergency department physician must function as a designated member of the trauma team.

6. Requirement may be fulfilled by a Senior surgical Resident (PGY 4 or higher) capable of assessing emergency situations in trauma patients and initiating proper treatment. A staff surgeon trained and capable of carrying out definitive treatment must be available within 20 minutes.

7. Requirement may be fulfilled by in-house neurosurgeon or neurosurgery resident, or senior general surgery resident who has special competence, as documented by the Chief of Neurosurgery Service, in the care of patients with neural trauma, and who is capable of initiating measures directed toward stabilizing the patient and initiating diagnostic procedures. An attending neurosurgeon dedicated to the hospital's trauma service must be available within 30 minutes.

8. Or substituted by a current signed transfer agreement with an institution having a Hand Surgery Service.

9. Requirement may be fulfilled by senior level (last year in training) Emergency Medicine Residents capable of assessing emergency situations and initiating proper treatment. The staff specialist responsible for the resident must be available within 30 minutes.

10. A physician extender may fulfill this role.

11. Requirements for Level II Trauma Center may be fulfilled when local conditions assure that a staff anesthesiologist is on call and available within 30 minutes. During the interim period prior to the arrival of a staff anesthesiologist, a Certified Registered Nurse Anesthetist (CRNA) operating under the direction of the anesthesiologist, the trauma team surgeon director or the emergency medicine physician, may initiate appropriate supportive care.

12. Requirement for Level II Trauma Center may be fulfilled when local conditions assure that a staff anesthesiologist is on call and available within 30 minutes. However, when there is not an anesthesiologist on the hospital staff, this requirement may be fulfilled by a CRNA operating under the supervision of the surgeon, the anesthesiologist, and/or the responsible physician.

13. Forensic pathologist must be available either as part of the hospital staff or on a consulting basis.

14. Or substituted by current signed transfer agreement with hospital having hemodialysis capabilities.

15. Or substituted by current signed transfer agreement with burn center or hospital with burn unit.

(Rule 1200-08-12-.04, continued)

16. Each Level I and II Center must have an organized protocol with a transplant team or service to identify possible organ donors and assist in procuring organs for donation.

17. All specialists must be available within 30 minutes.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed September 18, 1985; effective October 18, 1985. Amendment filed March 31, 1989; effective May 15, 1989. Amendment filed August 31, 1990; effective October 15, 1990. Amendment filed October 20, 1992; effective December 4, 1992. Amendment filed July 21, 1993; effective October 4, 1993. Amendment filed August 16, 2006; effective October 30, 2006. Repeal and new rule filed December 5, 2011; effective March 4, 2012.*

1200-08-12-.05 REPEALED.

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed March 31, 1989; effective May 18, 1989. Amendment filed July 21, 1993; effective October 4, 1993. Repeal filed December 5, 2011; effective March 4, 2012.*

1200-08-12-.06 TRAUMA REGISTRY DATA.

(1) Confidentiality.

(a) T.C.A. § 68-11-259 provides for the confidentiality of data obtained from the reports of trauma patients.

(b) Information contained in the trauma registry that reasonably could be expected to reveal the identity of any patient or a reporting facility may not be made available to the public.

(c) Trauma registry responsibilities

1. The trauma registry shall take strict measures to ensure that all patient identifying information is treated as confidential and privileged.

2. All employees and consultants, including auditors of the trauma registry, shall sign a Tennessee Trauma Registry Employee Confidentiality Pledge and these signed pledges shall be kept on file.

3. Protection of report sources. Hospitals, laboratories, facilities, or health care practitioners who disclose trauma care data to the trauma registry or its employees in conformity with T.C.A. § 68-11-259 and rules and regulations promulgated thereto shall not be held liable for the release of such data to the department, unless the person or entity has knowledge of any falsity of the information reported or disclosed.

(d) Protection of patient identifying information obtained by special studies and other research studies

1. All identifying information such as records of interviews, questionnaires, reports, statements, notes, and memoranda that are procured or prepared by employees or agents of the trauma registry shall be used solely for statistical, scientific and medical research purposes and shall be held strictly confidential by the trauma registry.

2. This applies also to identifying information procured by any other person, agency, or organization, including public or private colleges and universities

(Rule 1200-08-12-.06 continued)

acting jointly with the trauma registry in connection with special health studies and research investigations.

(2) Release of Data

(a) Release of non-identifying information

1. To the Tennessee Department of Health:

(i) The trauma registry shall work closely with the Tennessee Department of Health in investigating the causes and consequences of traumatic injuries and in evaluating programs.

(ii) Because the trauma registry data are an integral part of the Tennessee Department of Health traumatic injury prevention and control programs, the use of trauma registry data by public health officials shall be considered an in-house activity.

2. To the general public:

(i) Public reports published by the trauma registry shall include aggregate, not patient identifying information or facility identifying information.

(ii) Information that would potentially identify a trauma patient shall not be published.

(iii) Non-identifying information may be made available to the general public upon request to the department.

(iv) The availability of any data shall depend upon the department's financial or other ability to comply with such requests. The trauma registry shall respond to public requests as quickly as possible, subject to staffing constraints.

(b) Release of identifying information

1. Identifying information collected from any hospital, laboratory, facility, or health care practitioner may be released to qualified persons for the purposes of traumatic injury prevention, control, care, and research, provided that each request for identifying information follows the established procedure outlined in the trauma registry Policies and Procedures Manual and receives prior approval by the department.

2. Identifying information that is collected solely by the trauma registry for its own special studies shall not be released.

(c) Annual Report.A statistical report shall be prepared at the completion of each year's data collection cycle and will be distributed as requested.

(3) Request procedure for patient identifying information

(a) Requests for identifying information shall be reviewed and approved by the department according to the policies of the Tennessee Department of Health and the trauma registry.

(Rule 1200-08-12-.06 continued)

(b) A detailed description of the procedures for requesting identifying information can be obtained from the trauma registry.

Authority: *T.C.A. §§ 68-11-209 and 68-11-259.* ***Administrative History:*** *New rule filed February 12, 2013; effective May 13, 2013.*