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. Repeal and new rules filed August 6, 2019; effective November 4, 2019.*

1200-08-12-.02 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 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 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.

(Rule 1200-08-12-.02, continued)

(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(15).

(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 hospital capable of providing 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 hospital capable of providing 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 hospital capable of providing care for the acutely injured patient and which meets all requirements in these regulations defined as Level of Care III. 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) "Level IV" means a hospital capable of providing care for the acutely injured patient and which meets all requirements in these regulations defined as Level of Care IV. The hospital shall have treatment protocols for resuscitation, transfer protocols on record, shall submit trauma data elements to the state trauma registry as outlined in the Tennessee Trauma Data Dictionary, and participate in system performance improvement. The Level IV facility will maintain a good working relationship with the nearest Level I, II, or III trauma center.

(20) "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

(Rule 1200-08-12-.02, continued)

maintained in a facility that pertains to confinement or services rendered to patients admitted or receiving care.

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

(22) "PGY" means postgraduate year.

(23) "Physician Extender" means a health care professional, such as an advanced practice registered nurse or a physician assistant, whose skills have been enhanced by an appropriate course of trauma specific training e.g. ATLS education.

(24) "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.

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

(26) "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. §§ 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. Repeal and new rule filed December 5, 2011; effective March 4, 2012. Repeal and new rules filed August 6, 2019; effective November 4, 2019.*

1200-08-12-.03 FACILITY OUTREACH.

All Level I, II, and III trauma centers shall help facilitate their educational outreach to Level IV trauma centers in the form of professional education, consultation, or community outreach. A mechanism will exist between these centers to provide feedback about individual patient care and outcome analysis to the referring hospital.

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 May 13, 2013. Repeal and new rules filed August 6, 2019; effective November 4, 2019.*

1200-08-12-.04 REQUIREMENTS.

(1) Trauma registry requirements shall include the following:

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

(b) Each trauma center and CRPC shall submit trauma registry data to be received no later than ninety (90) days after the end of each quarter of the year. Trauma centers and CRPC's shall receive confirmation of successful submission no later than two weeks after submission.

(c) Trauma centers and CRPC's which fail to submit required data to the trauma registry for two (2) consecutive quarters risk not receiving compensation from the Tennessee Trauma Center Fund.

(2) Levels of Care

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

Hospital Origination

1.	Trauma Service	I	II	III	IV
	A recognizable program within the hospital which has a qualified trauma 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. Level I and II trauma centers shall have sufficient infrastructure and support to ensure adequate provision of care 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.	E	E	E	
	Written graded activation criteria. Criteria for highest level of activation are clearly defined and evaluated by the performance improvement program (PIPs).	E	E	E	E
	Administration supportive of the Trauma Program	E	E	E	E
	Evidence of an annual budget for the Trauma Program	E	E	E	E
	The Trauma Team may be organized by a qualified physician but care must be directed by a board certified or board eligible general surgeon on a trauma service that is committed to the care	E	E	E	D

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

	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.				
2.	Surgery Departments/Divisions/Services/Sections (each staffed by qualified specialists)				
	Cardiothoracic Surgery	E	E[1]		
	General Surgery	E	E	E	D
	Neurologic Surgery	E	E		
	Obstetrics-Gynecologic Surgery	E			
	Ophthalmic Surgery	E			
	Oral and Maxillofacial Surgery - Dentistry	E[2]			
	Orthopedic Surgery	E	E	E	
	Otorhinolaryngologic Surgery	E			
	Pediatric Surgery	E[3]			
	Plastic Surgery	E			
	Urologic Surgery	E			
	Surgical Critical Care	E	D		
3.	Emergency Department/Division/Service/Section (staffed by qualified specialists)	E[4]	E[4]	E[4]	E[9]
4.	Surgical Specialty Availability In-house 24 hrs a day				
	General Surgery	E[5]			
	Neurologic Surgery	E[6]			
	Surgical Critical Care	E[5]	D[5]		
5.	Surgical Specialty Availability from inside or outside hospital				
	Cardiac Surgery	E	E[1]		
	General Surgery		E[17]	E[17]	D
	Neurologic Surgery		E[17]	D	

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	Microsurgery capabilities	E[15]			
	Gynecologic Surgery	E			
	Hand Surgery	E[7]			
	Ophthalmic Surgery	E	E	D	
	Oral and Maxillofacial Surgery - Dentistry	E	E	D	
	Orthopedic Surgery	E	E	E	
	Otorhinolaryngologic Surgery	E	E	D	
	Pediatric Surgery	E[3]	E[3]		
	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[8]	E[8]	E	E[9]
	Anesthesiology	E	E[10]	E[11]	
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[12]	E[12]		
	Pediatrics	E	E		
	Psychiatry	E	E		
	Radiology	E[18]	E[18]	E[18]	

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

(b) Special Facilities/Resources/Capabilities

1.(i)	Emergency Department (ED) – Personnel	I	II	III	IV
	Designated Physician Director	E	E	E	E
	If managing trauma patients, physicians must be board certified or board eligible in Emergency Medicine and have current ATLS certification and who are a designated member of the trauma team and physically present in the ED 24 hours a day	E	E	D	D
	If managing trauma patients, physician or physician extender with ongoing certification in the management of the traumatically injured patient			E[9]	E[9]
	Full time emergency department; RN personnel 24 hours a day trained in trauma specific education/competencies	E	E	E	D
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	E
	Suction devices	E	E	E	E
	Electrocardiography defibrillator	E	E	E	E
	Bedside ultrasound capability for FAST examination	E	E	D	
	Capability for advanced hemodynamic monitoring i.e. central lines, ICP monitoring, arterial lines etc.	E	E	D	
	All standard intravenous fluids and administration devices, including intravenous catheters	E	E	E	E
	Sterile surgical sets for procedures standard for ED, such as thoracostomy, cutdown, etc.	E	E	E	E
	Drugs and supplies necessary for emergency care	E	E	E	E
	X-ray capability, 24 hour coverage by in-house technicians	E	E	E	E
	Two-way radio linked with vehicles of emergency medical services	E	E	E	E
	Cervical collars	E	E	E	E
	Long Spine Board	E	E	E	E

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	Splinting materials and devices	E	E	E	E
	Helipad or Helicopter Landing Area	E	E		
	End Tidal Carbon Dioxide Monitoring	E	E	E	E
	Tourniquets	E	E	E	E
	Appropriate sized catheters for the performance of needle chest decompression	E	E	E	E
	Appropriate equipment for the performance of interosseous cannulation	E	E	E	E
	A rapid volume infuser for the utilization of transfusion protocol	E	E	D	
2.(i)	Intensive Care Units (ICU) for Trauma Patients				
	Designated Surgeon Medical Director. Level I director must be a surgeon boarded in surgical critical care. Level II Director or co-director must be a surgeon boarded in surgical critical care. Level III director or co-director must be a surgeon boarded in general surgery.	E	E	E	
	If admitting traumatically injured patients, director or co-director must be a board certified general surgeon				E
	Physician on duty in ICU 24-hours a day or immediately available from in-hospital (PGY4/5 qualify)	E[5]	E[5]	E	
	Nurse-patient minimum ratio of 1:2 on each shift	E	E	E	
	Immediate access to clinical laboratory service	E	E	E	
2.(ii)	Equipment:				
	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 defibrillator	E	E	E	
	Cardiac output monitoring (e.g., Pulmonary Artery catheter)	E	E	D	
	End Tidal Carbon Dioxide Monitoring/Waveform capnography	E	E	E	D
	Electronic Arterial pressure monitoring	E	E	E	
	Mechanical ventilator-respirators	E	E	E	

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	Patient weighing devices	E	E	E	
	Temperature control devices	E	E	E	
	Drugs, intravenous fluids and supplies	E	E	E	
	Intracranial pressure monitoring devices	E	E	D	
	A rapid volume infuser for the utilization of transfusion protocol	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[13]	E[13]	
5.	Organized burn care: Physician directed burn center/unit staffed by personnel trained in burn care and equipped properly	E[14]	E[14]	E[14]	
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	E	D
	MRI (magnetic resonance imaging)	E	E	D	
9.	Organ donation protocol	E[16]	E[16]	E[16]	E[16]

(c) Operating suite special requirements

1.	Equipment/instrumentation	I	II	III	IV
	Operating room, dedicated to the trauma service, with nursing staff in-house and immediately available 24-hours a day	E	E	D	
	Operating room, dedicated to the trauma service, adequately staff and available within 30 minutes of notification			E	

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	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.g., ECG, blood pressure monitoring)	E	E	E	
	A rapid volume infuser for the utilization of transfusion protocol	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	E
2.	Blood typing and cross-matching	E	E	E	E
3.	Coagulation studies	E	E	E	E
4.	Blood bank or access to a community central blood bank and hospital storage facilities	E	E	E	E
5.	Blood gases and pH determinations	E	E	E	E
6.	Serum and urine osmolality	E	E	D	D
7.	Microbiology	E	E	E	E
8.	Drug and alcohol screening	E	E	D	D
9.	Thromboelastography (TEG)	E	E		
10.	Must have transfusion protocol developed collaboratively between the trauma service and blood bank	E	E	D	
11.	Must have adequate blood product availability (FFP, RBC's & Platelets)	E	E	E	

(e) Trauma Medical Director

1.	Board certified in general surgery	E	E	E	
2.	Minimum of three years clinical experience on a trauma service or trauma fellowship training	E	E	D	

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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	E	
4.	Participates 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	D	
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	E
12.	Participates in regional and national trauma organizations	E	E	D	
13.	Retain a current certification of ATLS and participates in the provision of trauma-related instruction to other health care personnel	E	E	E	E
14.	Is involved in trauma research	E	D		

(f) Attending General Surgeon on the Trauma Service

1.	Board Certified or board eligible in General Surgery	E	E	E	
2.	Current certification as an ATLS provider	E	E	E	E
3.	Trauma specific CME 16 hours/year or 48 hours every 3 years	E	E	D	D

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

1.	Must have a fulltime TNC/TPM dedicated to the trauma program	E	E	D	
2.	Must have a part time TNC/TPM with the trauma program as a major focus of their job description			E	E
3.	Must be a Registered Nurse licensed by the TN Board of Nursing in good standing or a licensed Registered Nurse in another state with a multistate privilege to practice in Tennessee	E	E	E	E

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

4.	Must possess experience in Emergency/Critical Care Nursing	E	E	D	D
5.	Must have a defined job description and organizational chart delineating the TNC/TPM role and responsibilities	E	E	D	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	D

(h) Trauma Registrar

1.	A full time equivalent registrar for each 500-750 admissions per year is required to assure high quality data collection	E	E	E	
2.	Shall receive initial training when they start their job and also complete a minimum of 4 hours continuing education per year	E	E	E	
3.	If hired after July of 2019, registrars must attend or have previously attended two nationally recognized trauma registrars courses or equivalent within 12 months of being hired	E	E	E	

(i) Programs for Quality Assurance

1.	Medical Care Education				
	Morbidity and Mortality Reviews to encompass all trauma deaths	E	E	E	E
2.	Trauma Process Improvement (PI)				
	The institution must provide resources to support the trauma process improvement program.	E	E	E	D
	Must have a performance improvement coordinator dedicated to the trauma program.	E	E	D	D
	Must have a Trauma Performance Improvement Committee that meets at least quarterly and includes physician liaisons from the following services: Orthopedics, Radiology, Anesthesia, Emergency Medicine, Neurosurgery, and core Trauma surgeons as well as Nursing, pre-hospital personnel and other healthcare providers. The Committee reviews policies and procedures as well as system issues, and its members or designees attend at least 50% of regular Committee meetings. The committee shall:	E	E	E	

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

	• 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/consult times for trauma surgeons, neurosurgeons, anesthesia, and orthopedists, all of whom must demonstrate 80% compliance	E	E		
	• Document and review response/consult times for trauma surgeons, anesthesia, and orthopedists, all of whom must demonstrate 80% compliance			E	
	• Monitor team notification times. For highest level of activation trauma attending must be present within 15 minutes of patient arrival 80% of the time.	E	E	D	
	• Monitor team notification times. For highest level of activation, trauma attending must be present within 30 minutes of patient arrival 80% of the time.			E	
	• Review pre-hospital trauma care to include patients dead on arrival	E	E	E	D
	• Review times and reasons for transfer of injured patients	E	E	E	
	• 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	
	The institution shall demonstrate that actions taken as a result of issues identified in the Process Improvement Program created a	E	E	E	D

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

	measurable improvement. Documentation shall include where appropriate: 1) problem identification; 2) analysis; 3) preventability; 4) action plan; 5) implementation; and 6) reevaluation				
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, and corrects overall program deficiencies to continue to optimize patient care. This should be held at least quarterly, attendance noted, and minutes recorded.	E	E	E	D
4.	Trauma Bypass Log				
	Trauma bypass/diversion shall not exceed 5%. Trauma surgeons shall be involved in bypass/diversion decisions. All bypass/diversions shall be reviewed.	E	E	E	

(j) System Development

1.	Level I and II centers shall maintain a commitment to provide ATLS and other educational activities deemed appropriate and timely to surrounding referral centers.	E	E		
2.	Be involved with local and regional EMS agencies and/or personnel and assist in trauma education, performance improvement, and feedback regarding care	E	E	E	
3.	All trauma centers shall participate in trauma system planning and development under the auspices of the Trauma Care Advisory Council	E	E	E	E
4.	The trauma center shall be involved in community awareness of trauma and the trauma system	E	E	E	D

(k) Injury Prevention

1.	Participate in statewide trauma center collaborative injury prevention efforts focused on common needs throughout the state	E	E	D	D
2.	Perform studies in injury control while monitoring the effects of prevention programs	E	E	D	
3.	Must have a full time injury prevention coordinator dedicated to the trauma program to ensure community and regional injury	E	E	D	D

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

	prevention activities are implemented and evaluated for effectiveness				

(l) Institutional Commitment

1.	Demonstrates knowledge, familiarity, and commitment of upper level administrative personnel to trauma service	E	E	E	E
2.	Upper level administration participation in multidisciplinary trauma conferences/committees	E	E	E	E
3.	Evidence of yearly budget for the trauma program	E	E	E	E
4.	Supports research efforts of the Trauma Service	E			
5.	Must have 5 peer-reviewed (per review cycle) articles or abstracts published in journals that shall be related to work from the trauma center	E	D		

(m) Activation Criteria

1.	Each center shall have clearly defined graded activation criteria. For the highest level of activation, the trauma team (trauma Chief resident: PGY 4/5 or ED attending) shall be immediately available and the trauma attending available within 15 minutes	E	E		
2.	For the highest level of activation for Level III centers, the trauma attending shall be available within 30 minutes, unless the patient is immediately being transferred to a higher level of care			E	

(n) Disaster Preparedness

1.	The trauma program must be a part of the hospital disaster planning process	E	E	E	E

(3) References

(a) The following References refer to the superscripts in the Table in paragraph (2) of this rule:

1. This requirement may be substituted by a current signed transfer agreement with an institution with Cardiothoracic Surgery and cardiopulmonary bypass capability.

2. This requirement may be substituted by a department or division capable of treating maxillofacial trauma as demonstrated by staff privileges.

3. This requirement may be substituted by a current signed transfer agreement with an institution having a Pediatric Surgery Service.

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

4. 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.

5. Requirements 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 15 minutes of patient arrival.

6. Requirements may be fulfilled by in-house neurosurgeon or neurosurgery resident, senior general surgery resident or trauma attending who has special competence as defined by the hospital, 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 thirty (30) minutes from notification.

7. This requirement may be substituted by a current signed transfer agreement with an institution having a Hand Surgery Service.

8. Requirements 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 thirty (30) minutes.

9. A physician or physician extender with current certification as an ATLS provider may fulfill this role.

10. Requirements for Level II Trauma Center may be fulfilled when local conditions assure that a staff anesthesiologist is on call and available within thirty (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.

11. Requirements for Level III Trauma Center may be fulfilled when local conditions assure that a staff anesthesiologist is on call and available within thirty (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.

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

13. This requirement may be substituted by current signed transfer agreement with hospital having hemodialysis capabilities.

14. This requirement may be substituted by current signed transfer agreement with burn center or hospital with burn unit.

15. This requirement may be substituted by a current signed transfer agreement with a hospital having Microsurgical capabilities.

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

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

17. All specialists must be available within thirty (30) minutes from notification.

18. Qualified radiologists must be available within 30 minutes in person or by teleradiology for interpretation of radiographs.

(4) Designation

(a) The Board shall implement and oversee the designation process.

(b) The preliminary designation process for facilities aspiring for designation as a Level I, II, III, or IV 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;

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 for Level I and Level II centers:

1. A trauma surgeon medical director or a trauma surgeon who has previously been a 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; and

4. The state trauma program manager/EMS director.

(d) The site visit team shall consist of the following for Level III centers:

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

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

3. The state trauma program manager/EMS director.

(e) The site visit team shall consist of the following for Level IV centers:

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

2. The state trauma program manager/EMS director.

3. If deficiencies are found necessitating a focused visit, a trauma surgeon from an in-state Level I trauma center shall be part of the focused site visit team.

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

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

1. The state trauma program manager/Director of EMS shall consult with the State Committee on Trauma of the American College of Surgeons for assistance 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.

(g) 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 designation level are in place.

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

(i) 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.

(j) 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 from report receipt 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.

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

1. The facility shall be prepared to provide:

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

(ii) A description of areas for 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 any deficiencies and areas for improvement.

(l) 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.

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

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.

(m) 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.

(n) If the Board denies the applicant trauma center designation, the facility may not reapply for at least one (1) year and will have its provisional status revoked.

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

(p) A facility requesting an American College of Surgeons trauma center consultation/verification site visit shall coordinate with the state trauma program manager/EMS Director to ensure his/her attendance at the review. If the state trauma manager/EMS Director is unable to attend the site visit, the facility shall share the finalized report from the site visit with the state trauma manager/EMS Director for presentation to the board if the facility seeks a reciprocal state designation.

(q) Denial of Provisional or Full Designation, When the Board denies provisional or full designation, it must provide the center with a written notification of the action and the basis for the action. The notice will inform the center of the right to appeal and the procedure to appeal the action under the provisions of the Uniform Administrative Procedures Act.

(5) 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. During the exit interview the team shall communicate the following:

1. The presence of deficiencies;

2. The facility’s strengths and weaknesses; and

3. 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 Trauma Medical Director and the Trauma Program Manager (TPM).

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

(f) If during the site visit the team identifies deficiencies, the center shall have a period not to exceed sixty (60) days to correct deficiencies.

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

(g) If the team ascertains that deficiencies have not been corrected within sixty (60) days, whether through desk review or an on-site visit, the center must present an explanation to the Board at its next scheduled meeting.

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

(i) If a trauma center already designated by the board elects to undergo an American College of Surgeons trauma center consultation/verification site visit, the facility shall coordinate with the state trauma program manager/EMS Director to ensure his/her attendance at the review. If the state trauma manager/EMS Director is unable to attend the site visit, the finalized report from the site visit shall be shared with the state trauma manager/EMS Director for presentation to the board if a reciprocal state designation is to be granted.

(6) Disciplinary Action

(a) The Board may, in accordance with the Uniform Administrative Procedures Act, revoke, suspend, place on probation, or otherwise discipline, a facility's trauma center designation.

(b) The Board may revoke, suspend, place on probation, or otherwise discipline, the designation or provisional status of a center when an owner, officer, director, manager, employee or independent contractor:

1. Fails or refuses to comply with the provisions of these rules;

2. Makes a false statement of material fact about the center's capabilities or other pertinent circumstances in any record or matter under investigation for any purposes connected with these rules;

3. Prevents, interferes with, or attempts to impede in any way, the work of a representative of the Board;

4. Falsely advertises, or in any way misrepresents the facility's ability to care for patients based on its designation status;

5. Is substantially out of compliance with these rules and has not rectified such noncompliance;

6. Fails to provide reports required by the trauma registry or the Department in a timely and complete fashion;

7. Fails to comply with or complete a plan of correction in the time or manner specified;

8. Has engaged in a deliberate and willful violation of these rules; or

9. Acts in a manner that endangers the public's health, safety, or welfare.

(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.

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

(b) Any facility the Board designates as a trauma center, at any level, shall comply with the requirements of EMTALA. The medical needs of a patient and the available medical resources of the facility, rather than the financial resources of a patient, shall be the determining factors concerning the scope of service provided.

(c) The term “trauma center” refers to a main hospital campus that has met all requirements to satisfy trauma center rule designation. Off campus sites are excluded in this designation

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 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. Repeal and new rules filed August 6, 2019; effective November 4, 2019.*

1200-08-12-.05 TRAUMA REGISTRY DATA.

(1) Reporting

(a) All designated Trauma Centers and CRPC’s shall participate in the collection of data for the Trauma Registry.

(b) All designated Trauma Centers and CRPC’s 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.

(c) Each trauma center and CRPC shall submit trauma registry data to be received no later than ninety (90) days after the end of each quarter.

(2) 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.

(Rule 1200-08-12-.05, continued)

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

(3) 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.

(Rule 1200-08-12-.05, continued)

(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.

(4) 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.

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

Authority: *T.C.A. §§ 4-5-202, 4-5-204, 68-11-202, 68-11-209, and 68-11-259.* ***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. Repeal and new rules filed August 6, 2019; effective November 4, 2019.*

1200-08-12-.06 REPEALED.

Authority: *T.C.A. §§ 68-11-209 and 68-11-259.* ***Administrative History:*** *New rule filed February 12, 2013; effective May 13, 2013. Repeal filed August 6, 2019; effective November 4, 2019.*