RULES
OF
THE TENNESSEE HEALTH FACILITIES COMMISSION

CHAPTER 0720-22
TRAUMA CENTERS

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0720-22-.01 PREAMBLE.

The Tennessee Health Facilities Commission~~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. Trauma Rules were transferred from chapter 1200-08-12 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.

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. Transferred from chapter 1200-08-12 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

0720-22-.02 DEFINITIONS.

(1) "AAAM" means Association for the Advancement of Automotive Medicine

(2~~1~~) "ACS-COT" means American College of Surgeons Committee on Trauma.

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

(4~~3~~) "ATLS" means Advanced Trauma Life Support.

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

(5) "CAISS" means Certified Abbreviated Injury Scale Specialists

(6) "CE" means Continuing Education

(7) "CME" means Continuing Medical Education

(Rule 0720-22-.02, continued)

(85) "Commissionner" means the Health Facilities Commissioner ~~Commissioner of the Tennessee Department of Health.~~

(96) "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 0720-31.

(10) "CT" means Computed Tomography

(117) "D" means desired and is strongly recommended for patient care at the corresponding facility level, but not required for designation.~~.~~

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

"Deficiencies" means components of the site review that do not meet designation criteria.
(13)

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

(14) "DIED" means Died in the Emergency Department

(15) "DMEP" means Disaster Management and Emergency Preparedness

(16) "DOA" means Dead on Arrival

(17) ~~(10)~~ "E" means essential and is required for designation at the corresponding facility level.~~essential.~~

(18) "ECG" means Electrocardiogram

(19) "ED" means Emergency Department

(20) "EMTALA" means Emergency Medical Treatment and Labor Act

(2111) "Facility" shall have the same meaning as defined in T.C.A. § 68-11-201(15).

(22) ~~(12)~~ "FAST" means Focused Assessment with Sonography in Trauma ~~focused abdominal sonography for trauma.~~

(23) "FTE" means Full Time Equivalent

(24) "GCS" means Glascow Coma Scale

(2513) "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.

(26) "ICP" means Increased Intracranial Pressure

(2714) "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.

(Rule 0720-22-.02, continued)

(28) "ICU" means Intensive Care Unit

(29) "ISS" means Injury Severity Score

(3015) "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.

(3116) "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.

(3217) "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.

(3318) "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.

(34) ~~(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.

(35) "MTP" means Massive Transfusion Protocol

(3620) "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.

(37) "Non-physician Practitioner (NPP)" means a nurse practitioner (NP), clinical nurse specialist (CNS), or physician assistant (PA).

(38) "OR" means Operating Room

(3921) "Person" means any member of the "medical, scientific, and academic research community."

(4022) "PGY" means postgraduate year.

(Rule 0720-22-.02, continued)

~~(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.~~

(41) "PI" means Performance Improvement

(42) "PIPS" means Performance Improvement and Patient Safety

~~(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.~~

(43) "Reporting Period" means interval of time over which components of designation assessment occurs.

(44) "RN" means Registered Nurse

(45) "TBI" means Traumatic Brain Injury

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

(47) "TMD" means Trauma Medical Director

(48) "TPM" means Trauma Program Manager

(49~~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 Commission~~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. Transferred from chapter 1200-08-12 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

0720-22-.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. Transferred from chapter 1200-08-12 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

0720-22-.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.

(Rule 0720-22-.04, continued)
(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

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, or non-physician practitionersnurse 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. Level I trauma centers must care for at least 1200 trauma patients per year or at least 240 pts with an ISS>15 per year 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	E	E	E	

(Rule 0720-22-.04, continued)

	maintain cohesion within the service.				
	Written graded activation criteria. Criteria for highest level of activation ~~are~~is 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~~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 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	E	E	D
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]	E[2]		
	Orthopedic Surgery	E	E	E	
	Otorhinolaryngologic Surgery	E[2]	E[2]		
	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]
~~3.~~	~~Emergency Department/Division/Service/Section~~	~~E[4]~~	~~E[4]~~	~~E[4]~~	~~E[9]~~

(Rule 0720-22-.04, continued)

	~~(staffed by qualified specialists)~~				
4.	Surgical Specialty Availability In-house 24 hrs a day				
	General Surgery	E[5]			
	Neurologic Surgery	E[6]			
	Neurosurgical evaluation must occur within 30 minutes of request for the following: i. Severe TBI (GCS less than 9) with head CT evidence of intracranial trauma ii. Moderate TBI (GCS 9–12) with head CT evidence of potential intracranial mass lesion iii. Neurologic deficit as a result of potential spinal cord injury (applicable to spine surgeon, whether a neurosurgeon or orthopedic surgeon) iv. Trauma surgeon discretion Neurosurgery attending must be involved in the clinical decision making for the care of these patients	E	E		
	Level I and II trauma centers must have a neurotrauma contingency plan and must implement the plan when neurosurgery capabilities are encumbered or overwhelmed	E	E		
	Level III and level IV trauma centers must have a written plan approved by the TMD that defines the types of neurotrauma injuries that may be treated at the center			E	E
	Surgical Critical Care	E[5]	D[5]		
5.	Surgical Specialty Availability from inside or outside hospital 24/7/365. All specialists are required for level I & II centers.				
	Cardiac Surgery	E	E[1]		
	General Surgery		E[17]	E[17]	D
	Neurologic Surgery		E[17]	D	
	Microsurgery capabilities	E[15]	E[15]		
	Gynecologic Surgery	E	E		
	Hand Surgery	E[7]	E[7]		
	Obstetrics	E	E		
	Ophthalmic Surgery	E	E	D	
	Oral and Maxillofacial Surgery - Dentistry	E[2]	E[2]	D	
	Orthopedic Surgery	E	E	E	

(Rule 0720-22-.04, continued)

	Must have an orthopedic surgeon who has completed Orthopedic Trauma Association fellowship, alternate training criteria.	E	E[19]		
	In trauma centers, an orthopedic surgeon (resident, non-physician practitioner, trauma surgeon with ortho privileges) must be at bedside within 30 minutes of request for the following: i. hemodynamically unstable, secondary to pelvic fracture ii. suspected extremity compartment syndrome iii. fractures/dislocations with risk of avascular necrosis (e.g., femoral head or talus) iv. vascular compromise related to a fracture or dislocation trauma surgeon discretion The orthopedic surgeon must be involved in the clinical decision-making for care of these patients	E	E	E	
	Otorhinolaryngologic Surgery	E[2]	E[2]	D	
	Pediatric Surgery	E[3]	E[3]		
	Plastic Surgery	E	E	D	
	Thoracic Surgery	E	E	D	
	Urologic Surgery	E	E	D	
	Vascular Surgery	E	E		
	Obstetrics	E	E		
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		

(Rule 0720-22-.04, continued)

	Pathology	E[12]	E[12]		
	Pediatrics	E	E		
	Psychiatry	E	E		
	Radiology	E[18]	E[18]	E[18]	
	i. Interventional Radiology response for hemorrhage control	E	E		
	ii. Level I & II centers must have necessary human & physical resources continuously available for so that an endovascular or interventional radiology procedure for hemorrhage control can begin within 60 minutes of request	E	E		
	Allied Health				
	i. Respiratory therapy 24/7/365	E	E	E	
	ii. Nutrition support	E	E	E	
	iii. Speech Therapy	E	E	E	
	iv. Social Worker	E[20]	E[20]	E[21]	
	v. Occupational Therapy	E[20]	E[20]	E[21]	
	vi. Physical Therapy	E[20]	E[20]	E[21]	
	Intensivists: at least one intensivist must be board certified or board eligible in critical care	E	E		

(b) Special Facilities/Resources/Capabilities

1.(i)	Emergency Department (ED) – Personnel	I	II	III	IV
	Designated Physician Director	E	E	E	E
	In all trauma centers, emergency medicine physicians must be board certified, board eligible or have been approved through the Alternate Pathway. All emergency medicine physicians must have taken the ATLS course at least once. Physicians who are board certified or board eligible in a specialty other than emergency medicine must hold current ATLS certification. All physicians must be physically present in the ED 24 hours a day	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~~	~~E~~	~~E~~	~~D~~	~~D~~

(Rule 0720-22-.04, continued)

	~~team and physically present in the ED 24 hours a day~~				
	~~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	E ~~D~~
	~~Advanced Practice Providers (adopt definition)~~	~~E?~~	~~E?~~	~~E?~~	
	Non-physician practitioners that are clinically involved in the initial evaluation and resuscitation of trauma patients during the activation phase must have current ATLS certification	E	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	E
	All trauma centers must have a provider and equipment immediately available to establish an emergency airway	E	E	E	E
	Suction devices	E	E	E	E
	Electrocardiography defibrillator	E	E	E	E
	Bedside ultrasound capability for FAST examination	E	E	E ~~D~~	E
	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
	Splinting materials and devices	E	E	E	E

(Rule 0720-22-.04, continued)

	Helipad or Helicopter Landing Area	E	E	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	E ~~D~~	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	
	Provider coverage must be available within 30 minutes of request, with a formal plan in place for emergency coverage.			E[22]	
	Nurse-patient minimum ratio of 1:2 on each shift depending on patient acuity.	E	E	E	
	Immediate access to clinical laboratory service	E	E	E	
2.(ii)	Equipment:				
	Airway control and ventilation devices	E	E	E	E[23]
	Oxygen source with concentration controls	E	E	E	E[23]
	Cardiac emergency cart	E	E	E	E[23]
	Temporary transvenous pacemaker	E	E	E	E[23]
	Electrocardiograph defibrillator	E	E	E	E[23]
	Cardiac output monitoring ~~(e.g., Pulmonary Artery catheter)~~	E	E	D	
	End Tidal Carbon Dioxide Monitoring/Waveform capnography	E	E	E	~~D~~ E[23]
	Electronic Arterial pressure monitoring	E	E	E	E[23]

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	Mechanical ventilator-respirators	E	E	E	E[23]
	Patient weighing devices	E	E	E	E[23]
	Temperature control devices	E	E	E	E[23]
	Drugs, intravenous fluids and supplies	E	E	E	E[23]
	Intracranial pressure monitoring devices	E	E	D	D
	A rapid volume infuser for the utilization of transfusion protocol	E	E	E ~~D~~	E[23]
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	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	E
8.	Radiological Special Capabilities				
	Interventional radiology (includes angiography)	E	E	D	
	Angiography of all types	E	E	D	
	Sonography	E	E	E ~~D~~	
	Nuclear scanning	E	E	D	
	In-house computerized tomography. In all trauma centers, documentation of the final interpretation of CT scans must occur no later than 12 hours after completion of the scan	E	E	E	E ~~D~~
	MRI (magnetic resonance imaging)	E	E	D	
	Must have mechanism to remote view images from referring hospitals in catchment area	E	E		
9.	Organ donation protocol	E[16]	E[16]	E[16]	E[16]

(Rule 0720-22-.04, continued)

(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 within 15 minutes of notification	E	E	D	
	If first operating room is occupied an additional operating room must be staffed and available	E	E		
	Operating room, dedicated to the trauma service, adequately staff and available within 30 minutes of notification			E	
	Must have dedicated operating room prioritized for fracture care in nonemergent orthopedic trauma	E	E		
	Cardiopulmonary bypass ~~capability~~ equipment must be immediately available when required, or a contingency plan must exist to provide emergency cardiac surgical care	E[1]	E[1]		
	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

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6.	Serum and urine osmolality	E	E	E ~~D~~	D
7.	Microbiology	E	E	E	E
8.	Drug and alcohol screening	E	E	E ~~D~~	~~D~~ E
9.	Thromboelastography (TEG)	E	E		
10.	Must have transfusion protocol developed collaboratively between the trauma service and blood bank	E	E	E ~~D~~	E
11.	Must have adequate supply of blood products ~~availability (FFP, RBC's & Platelets)~~	E	E	E	E

(e) Trauma Medical Director

1.	A physician b~~B~~oard certified in general surgery	E	E	E	D
	In level IV centers, there must be a Trauma Medical Director who is a physician and has, at a minimum, the following authority and responsibilities: i. Develop and enforce clinical protocols and practice management guidelines relevant to the care of the injured patient. ii. Ensure clinicians meet all requirements and adhere to institutional standards of practice related to trauma care. iii. Work across departments and /or other administrative units to address deficiencies in care. iv. Determine clinician participation in trauma care, which might be guided by findings from the PIPS process or professional practice reviews. v. Oversee the structure and process of the trauma PIPS program. vi. Participate in committees relevant to the regional trauma system. vii. Chair or co-chair (with the TPM) the committee where discussions/decisions occur related to trauma operations. viii. Lead discussions pertaining to trauma multidisciplinary case reviews. ix. Be active in the participation of trauma care in the trauma center.				E
2.	Minimum of three years clinical experience on a trauma service or trauma fellowship training	E	E	D	
3.	36 ~~48~~ hours of category I trauma/critical care CME every 3 years or 12 ~~6~~ hours each year and attend one national meeting whose focus is trauma or critical care	E	E	E	
	Provide evidence of 24 hours of trauma-related continuing medical education (CME/CE) per 3 years				E
4.	Participates in call	E	E	E	

(Rule 0720-22-.04, continued)

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	E
8.	Develops treatment protocols along with the trauma team	E	E	D	
9.	Coordinates performance improvement and peer review processes	E	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	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		
15.	In trauma centers, the shared roles and responsibilities of trauma surgeons and emergency medicine physicians for trauma resuscitation must be defined and approved by the Trauma Medical Director	E	E	E	D

(f) Attending General Surgeon on the Trauma Service

1.	Must be currently Board Certified or board eligible in General Surgery	E	E	E	E
2.	~~Current certification as an ATLS provider~~All attending general surgeons on the trauma service must have taken the ATLS course at least once.	E	E	E	E
~~3.~~	~~Trauma specific CME 16 hours/year or 48 hours every 3 years~~	~~E~~	~~E~~	~~D~~	~~D~~
3.	Surgery coverage must be continually available	E	E	E	
4.	In level I and II trauma centers, the trauma surgeon must be dedicated to a single trauma center while on call	E	E		
5.	Level I and II trauma centers must have a published backup call schedule for trauma surgery	E	E		
7.	Trauma surgeon must be present in the operating room for key	E	E	E	

(Rule 0720-22-.04, continued)

	portions of operative procedures for which they are the responsible surgeon and must be immediately available throughout the procedure				
8.	In level I centers with surgery training programs, they must: i. have a trauma rotation with defined objectives and curriculum for PGY3, PGY4, or PGY5 general surgical residents. ii. general surgery residents must be assigned to the trauma rotation for a minimum of three months during their PGY4 or PGY5 to ensure sufficient exposure to trauma care. For pediatric trauma centers, PGY3 surgical residents are acceptable. iii. must have trauma surgery coverage by PGY4 or PGY5 general surgery residents. If the number of PGY4 or PGY5 residents is insufficient to ensure coverage, PGY3 surgical residents and/or fellows are acceptable. All general surgery residents and/or fellows must be from an Accreditation Council for Graduate Medicine Education (ACGME) accredited program.	E			

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

1.	Must have a fulltime TPM~~NC~~/TNC~~PM~~ dedicated to the trauma program	E	E	E ~~D~~	D
2.	Must have a part time TPM~~NC~~/TNC~~PM~~ with the trauma program as a major focus of their job description			~~E~~	E
3.	Must be a Registered Nurse licensed by the Tennessee~~N~~ 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
4.	Must possess experience in Emergency/Critical Care Nursing	E	E	E ~~D~~	~~D~~ E
5.	Must have a defined job description and organizational chart delineating the TNC/TPM role and responsibilities including a reporting structure that includes the TMD	E	E	E ~~D~~	~~D~~ E
6.	Must be provided the administrative and budgetary support to complete educational, clinical, research, administrative and outreach activities for the trauma program	E	E	E	
7.	Shall attend one national meeting within the ~~3 year~~3-year designation ~~verification~~ cycle, 36 hour continuing education (CE) during the designation cycle, and hold current membership in national organization	E	E	E~~D~~	~~D~~ E

Commented [RS1]: If registrar needs CE's so should the TPM.

(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~~	

(Rule 0720-22-.04, continued)

1.	A full-time equivalent registrar for each 500 patients per year who were admitted and/or who met institutional criteria for trauma team activation and were discharged home from the ED	E	E	E	E
2.	At least one registrar must be a current CAISS specialist	E	E	E	E
3.	Staff members that have a registry role in data abstraction and entry, injury coding, ISS calculation, data reporting, or data validation for the trauma registry must fulfill all of the following requirements i. Participate and pass the most current version of the AAAM's Abbreviated Injury Scale (AIS) course that your center is using ii. Participate on a trauma registry course that includes all of the following content: a. Abstraction b. Data management c. Reports/report analysis d. Data validation e. HIPAA iii. Participate in an ICD-10 course or an ICD-10 refresher course every five years	E	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~~	
4.	Each trauma registrar must accrue at least 24 hours trauma-related CE during the designation cycle	E	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	E ~~D~~
	In all trauma centers, the trauma PIPS program must be independent of the hospital or departmental PI program, but it must report to the hospital or departmental PI program	E	E	E	E
	Trauma centers must have a written PIPS plan that: i. Outlines the organizational structure of the trauma PIPS process, with a clearly defined relationship to the hospital PI program ii. Specifies the processes for event identification. As an	E	E	E	E

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	example, these events may be brought forth by a variety of sources, including but not limited to: individual personnel reporting, morning report or daily signouts, case abstraction, registry surveillance, use of clinical guideline variances, patient relations, or risk management. The scope for event review must extend from prehospital care to hospital discharge. iii. Includes a list of audit filters, event review, and report review that must include, at minimum, those listed as audit filters, events, or report reviews below. iv. Defines levels of review (primary, secondary, tertiary, and/or quaternary), with a listing for each level that clarifies: ○ Which cases are to be reviewed ○ Who performs the review ○ When cases can be closed or must be advanced to the next level v. Specifies the members and responsibilities of the trauma multidisciplinary PIPS committee vi. Outlines an annual process for identification of priority areas for PI, based on audit Audit filters, event or report reviews: i. Surgeon arrival time for the highest level of activation ii. Delay in response for urgent assessment by the neurosurgery and orthopedic specialists iii. Delayed recognition of or missed injuries iv. Compliance with prehospital triage criteria, as dictated by regional protocols v. Delays or adverse events associated with prehospital trauma care vi. Compliance of trauma team activation, as dictated by program protocols vii. Accuracy of trauma team activation protocols viii. Delays in care due to the unavailability of emergency department physician (Level III) ix. Unanticipated return to the OR x. Unanticipated transfer to the ICU or intermediate care xi. Transfers out of the facility for appropriateness and safety xii. All nonsurgical admissions (excludes isolated hip fractures) xiii. Radiology interpretation errors or discrepancies between the preliminary and final reports xiv. Delays in access to time-sensitive diagnostic or therapeutic interventions xv. Compliance with policies related to timely access to the OR for urgent surgical intervention xvi. Delays in response to the ICU for patients with critical needs xvii. Lack of availability of essential equipment for resuscitation or monitoring xviii. MTP activations xix. Significant complications and adverse events xx. Transfers to hospice xxi. All deaths: inpatient, died in emergency department (DIED), DOA xxii. Inadequate or delayed blood product availability xxiii. Patient referral and organ procurement rates xiv. Screening of eligible patients for psychological sequelae				

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	xv. Delays in providing rehab services xvi. Screening of eligible patients for alcohol misuse xvii. Pediatric admissions to non-pediatric trauma centers viii. Neurotrauma care at Level III trauma centers xix. Neurotrauma diversion				
	Must have a performance improvement coordinator dedicated to the trauma program. 0.5 FTE when annual volume exceeds 500 patients. 1 FTE when annual volume exceeds 1,000 pt. entries	E	E	E ~~D~~	E ~~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, Geriatric 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 Trauma Medical Director must attend at least 60 percent of regular Trauma Performance Improvement Committee meetings. Attendance cannot be delegated to the associate Trauma Medical Director. The committee shall:	E	E	E	E
	i. 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	
	ii. 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	
	~~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~~	~~D~~
	All trauma centers must have documented evidence of event identification; effective use of audit filters; demonstrated loop closure; attempts at corrective actions; and strategies for sustained improvement measured over time	E	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, and corrects overall program deficiencies to continue to optimize patient care. This should be held at least quarterly, attendance	E	E	E	~~D~~ E

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	noted, and minutes recorded.				
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~~	
	All trauma centers must not exceed 400 hours of diversion during the reporting period	E	E	E	E
5.	Trauma centers must have evidence-based clinical practice guidelines, protocols, or algorithms that are reviewed at least every three years	E	E	E	D
6.	Level I and II trauma centers must have the following protocols for care of the injured older adult: i. Identification of vulnerable geriatric patients ii. Identification of patients who will benefit from the input of a health care provider with geriatric expertise iii. Prevention, identification, and management of dementia, depression, and delirium iv. Process to capture and document what matters to patients, including preferences and goals of care, code status, advanced directives, and identification of a proxy decision maker v. Medication reconciliation and avoidance of inappropriate medications vi. Screening for mobility limitations and assurance of early, frequent, and safe mobility Implementation of safe transitions to home or other health care facility	E	E	D	
7.	All trauma centers must have a process in place to assess children for nonaccidental trauma	E	E	E	E
8.	All trauma centers must have a rapid reversal protocol in place for patients on anticoagulants	E	E	E	E
9.	In all trauma centers, the emergency department must evaluate its pediatric readiness and have a plan to address any deficiencies	E	E	E	E
10.	Trauma centers must have treatment guidelines for, at minimum, the following orthopedic injuries: i. Patients who are hemodynamically unstable attributable to pelvic ring injuries ii. Long bone fractures in patients with multiple injuries (e.g., time to fixation, order of fixation, and damage control versus definitive fixation strategies) iii. Open extremity fractures (e.g., time to antibiotics, time to OR for operative debridement, and time to wound coverage for open fractures) iv. Hip fractures in geriatric patients (e.g., expected time to OR)	E	E	E	

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11.	Trauma centers must meet the rehabilitation needs of trauma patients by: i. Developing protocols that identify which patients will require rehabilitation services during their acute inpatient stay ii. Establishing processes that determine the rehabilitation care, needs, and services required during the acute inpatient stay iii. Ensuring that the required services during acute inpatient stay are provided in a timely manner	E	E	E	
12.	Rehabilitation and discharge planning. Trauma centers must have a process to determine the level of care patients require after trauma center discharge, as well as the specific rehabilitation care services required at the next level of care. The level of care and services required must be documented in the medical record	E	E	E	
13.	Trauma centers must meet the mental health needs of trauma patients by having a protocol to screen patients at high risk for psychological sequelae with subsequent referral to a mental health provider	E	E		
14.	A process for referral to a mental health provider when required			E	D
15.	Alcohol misuse screening. Trauma centers must screen all admitted trauma patients greater than 12 years old for alcohol misuse with a validated tool or routine blood alcohol content testing. Programs must achieve a screening rate of at least 80 percent	E	E	E	D
	Alcohol misuse intervention. Trauma centers, at least 80 percent of patients who have screened positive for alcohol misuse must receive a brief intervention by appropriately trained staff prior to discharge. This intervention must be documented. Level III trauma centers must have a mechanism for referral if brief intervention is not available as an inpatient	E	E	E	D
16.	Trauma centers must have a written data quality plan and demonstrate compliance with that plan. At minimum, the plan must require quarterly review of data quality	E	E	E	
17.	Trauma centers must participate in a risk-adjusted benchmarking program and use the results to determine whether there are opportunities for improvement in patient care and registry data quality	E	E	E	D
18.	All nonsurgical trauma admissions must be reviewed by the trauma program. Nonsurgical admissions (NSA) without trauma or other surgical consultation, with ISS > 9, or with identified opportunities for improvement must, at a minimum, be reviewed by the TMD in secondary review	E	E	E	D

(j) System Development

(Rule 0720-22-.04, continued)

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~~ E

(k) Injury Prevention

1.	Participate in statewide trauma center collaborative injury prevention efforts focused on common needs throughout the state	E	E	E ~~D~~	~~D~~ E
2.	Perform studies in injury control while monitoring the effects of prevention programs. Implement at least two activities over the course of the designation cycle with specific objectives and deliverables that address separate major causes of injury in the community	E	E	D	
3.	Must have a ~~full time~~full-time injury prevention coordinator dedicated to the trauma program to ensure community and regional injury prevention activities are implemented and evaluated for effectiveness	E	E	D	D

(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.	Hospital administration must demonstrate support for research efforts of the Trauma Service ~~Supports research efforts of the Trauma Service~~	E	D		
~~5.~~	~~Must have 5 peer-reviewed (per review cycle) articles or abstracts published in journals that shall be related to work from the trauma~~	~~E~~	~~D~~		

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	~~center~~				
5.	Must demonstrate the following scholarly activities during the verification (designation) cycle: i. At least 10 trauma-related research articles ii. Participation by at least one trauma program faculty member as a visiting professor, invited lecturer, or speaker at a regional, national, or international trauma conference Support of residents or fellows in any of the following scholarly activities: laboratory experience; clinical trials; resident trauma paper competition at the state, regional, or national level; and other resident trauma research presentations	E			

(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 of patient arrival	E	E		
2.	For the highest level of activation for Level III centers, the trauma attending shall be available within 30 minutes of patient arrival~~,~~ 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
	A trauma surgeon from the trauma panel must be a part of the disaster planning committee	E	E	E	
	Ortho trauma surgeon from the trauma panel must be a part of the disaster planning committee.	E			
	Trauma programs must participate in two hospital drills/exercise per year	E	E	E	
	Surgeon liaison to disaster committee must complete DMEP course at least once	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.~~ If cardiopulmonary bypass equipment is not immediately available, a

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contingency plan, including immediate transfer to an appropriate center and one hundred percent performance review of all patients transferred must be in place.

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.

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 non-physician practitioner~~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.

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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.

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.

19. This requirement may be substituted by a current signed transfer agreement with a hospital having an orthopedic surgeon who has completed Orthopedic Trauma Association fellowship alternate training criteria.

20. For level I and II centers, these requirements will/shall be available 7 days a week.

21. For level III centers, 7 day a week coverage is not required.

22. Coverage may include an intensivist, hospitalist, or non-physician practitioner. The formal plan for emergency coverage should allow for patients' immediate needs to be met until the attending surgeon is available.

23. For level IV centers. All equipment is to be required if admitting trauma patients to the ICU, except cardiac output monitoring.

(4) Designation

(a) The CommissionBoard 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 CommissionBoard;

2. The A CommissionDepartment site visit team ("team") shall review each submitted application and shall communicate deemed application deficiencies to the facility in writingact in an advisory capacity to the Board;

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

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

4 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:

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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; If the out-of-state surgeon is not available, he/she may be substituted by an in-state surgeon from a different grand division at the discretion of the center being reviewed.

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 system director~~program manager~~/asst.~~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 or Level II trauma center;

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

3. The state trauma system director~~program manager~~/asst.~~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 system director~~program manager~~/asst.~~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.

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

1. The state trauma system director~~program manager~~/asst. d~~D~~irector ~~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 system director~~program manager~~/asst. 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 Commission~~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

(Rule 0720-22-.04, continued)
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 CommissionBoard.

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

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

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

(n) If the CommissionBoard 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 system director/ program manager/EMS asst. dDirector to ensure his/her attendance at the review. If the state trauma system directormanager//EMS asst. dDirector is unable to attend the site visit, the facility shall share the finalized report from the site visit with the state trauma system directormanager/EM/S asst. dDirector for presentation to the Commissionboard if the facility seeks a reciprocal state designation.

(q) Denial of Provisional or Full Designation, When the CommissionBoard 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

(Rule 0720-22-.04, continued)

(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 Commission~~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.~~

~~(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 Commission~~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 director/~~manager/~~Asst.~~EMS~~ d~~D~~irector is unable to attend the site visit, the finalized report from the site visit shall be shared with the state trauma director~~manager~~/Asst.~~EMS~~ d~~D~~irector for presentation to the Commission~~board~~ if a reciprocal state designation is to be granted.

(6) Disciplinary Action

(a) If during the site visit the team determines that deficiencies exist, the centers designation shall be placed on provisional status and the center shall have a period not to exceed thirty (30) days to submit a corrective action plan (CAP) that shall include the process for deficiency resolution and a timeline for compliance. A focused review will be scheduled within one (1) year either through a desk review or on-site review to ensure compliance, if deemed necessary by the site review team.

(b) Whether a desk review or onsite visit shall be required is dependent upon the scope and severity of the deficiency cited and is within the purview of the site team to make the decision on the type of revisit required.

(b) If the team ascertains that deficiencies have not been corrected within one (1) year, whether through desk review or an on-site visit, the center must present an explanation to the Commission at its next scheduled meeting.

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

(d~~b~~) The Commission~~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 Commission~~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 Commission~~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 Commission~~Board~~ unless it has complied with the regulations set out herein and the Commission~~Board~~ has so licensed it.

(b) Any facility the Commission~~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. Transferred from chapter 1200-08-12 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

(Rule 0720-22-.04, continued)

0720-22-.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.~~

2~~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 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:~~

(Rule 0720-22-.05, continued)

~~(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.~~

1~~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 Commission.~~department.~~

(iv) The availability of any data shall depend upon the Commission's~~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 completes~~follows~~ the~~e established~~ individual level data release ~~procedure~~ forms and agreements as outlined in the individual level data release policy ~~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.

(4) Request procedure for patient identifying information

(a) Requests for identifying information shall be reviewed and approved by the Commission~~department~~ according to the policies of the Health Facilities Commission~~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. Transferred from chapter 1200-08-12 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*

0720-22-.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. Transferred from chapter 1200-08-12 pursuant to Public Chapter 1119 of 2022 effective July 1, 2022.*