§157.125. Requirements for Trauma Facility Designation.

(a) General Provisions. The goal of the trauma system is to reduce the morbidity and mortality of the trauma patient. The objective of the trauma system is to get the right patient, to the right place, at the right time, to receive the right care. The purpose of this section is to set forth the requirements for a health care facility to become a designated trauma facility.

(1) The Department of State Health Services (department) shall determine the designation level for each location, based on, but not limited to, the location's own resources and levels of care capabilities; Trauma Service Area (TSA) capabilities; and compliance with the essential criteria and standard requirements outlined in this section.

(2) The Office of Emergency Medical Services (EMS)/Trauma Systems Coordination (office) shall recommend to the Commissioner of the Department of State Health Services (commissioner) the trauma designation of a facility at the level the office deems appropriate.

(3) Facilities eligible for trauma designation include:

(A) A General Hospital, licensed or otherwise meeting the description (in accordance with Texas Administrative Code (TAC) Hospital Licensing Section 133.21)

(B) a general hospital owned and operated by the state of Texas, or

(C) a general hospital owned and operated by the federal government.

(i) Each facility operating on a single general hospital license with multiple locations (multi-location license) shall be considered separately for designation.

(ii) Designation does not include provider based departments of the designated facility, which are not contiguous with the designated facility; and

(iii) Departments or services within a facility shall not be separately designated.

(4) a trauma facility designation is issued for the physical location and to the legal owner of the operations of the facility. If a designated facility has a change of ownership or a change of the physical location of the facility, the designation shall not be transferred or assigned.

(5) The four levels of trauma designation and the requirements for each are as follows:

(A) Comprehensive (Level I) trauma facility designation. The facility shall meet the current American College of Surgeons (ACS) essential criteria for a verified Level I trauma center.

(B) Major (Level II) trauma facility designation. The facility shall meet the current ACS essential criteria for a verified Level II trauma center.

(C) Advanced (Level III) trauma facility designation. The facility shall meet the "Level III Program Requirements" in subsection (m) of this section, or the facility shall meet the current ACS essential criteria for a verified Level III trauma center.

(D) Basic (Level IV) trauma facility designation. The facility shall meet the Level IV Program Requirements in subsection (n) of this section.

(6) In Active Pursuit of Designation (IAP) -- subsection applies only to an undesignated facility in accordance with Texas Administrative Code (TAC) Designated Trauma Facility and Emergency Medical Services Account Section 157.131(a)(10).

(b) Designation Process.

(1) Initial designation of a trauma facility. The CEO, TMD and TPM of the facility shall attend a presurvey conference at the office designated by the department. The purpose of the presurvey conference, conducted by department staff, is to review and discuss the designation requirements for the applicable level prior to the initial onsite designation survey. The department may waive the presurvey conference requirement.

(2) Application. A facility seeking designation, shall submit a completed application to include:

(A) an accurate and complete designation application form for the appropriate level of requested designation, including full payment of the non-refundable, non-transferrable, designation fee as follows;

(i) Level I and Level II trauma facility applicants, the fee will be no more than $10 per licensed bed with an upper limit of $5,000 and a lower limit of $4,000;

(ii) Level III trauma facility applicants, the fee will be no more than $10 per licensed bed with an upper limit of $2,500 and a lower limit of $1,500; and

(iii) Level IV trauma facility applicants, the fee will be no more than $10 per licensed bed with an upper limit of $1000 and a lower limit of $500.

(B) any subsequent documents submitted by the date requested by the office;

(C) a completed trauma designation survey report, including patient care reviews, if required by the department, submitted no later than 180 days from the date of the survey;

(D) a plan of correction (POC), detailing how the facility will correct any deficiencies cited in the survey report, to include: statement of the cited deficiency, the corrective action to ensure compliance with the requirement, the title of the individual(s) responsible for ensuring the correction action(s) is implemented, the date by which the corrective action will be implemented, not to exceed 90 days from the date the facility received the official survey report, and how the corrective action will be monitored.;

(E) evidence of participation in the applicable Regional Advisory Council (RAC); and

(F) evidence of submission of data to the department trauma registry.

(3) If a facility seeking initial designation fails to meet the requirements in subsections (b)(1) – (2) above, the application shall be considered withdrawn by the facility.

(4) Renewal of designation. The applicant shall submit the documents described in subsection (b)(2)(A) – (F) above, to the office at least 90 days prior to the designation expiration date.

(5) If a facility seeking redesignation fails to meet the requirements in subsection (b)(2)(A) – (F) above, the application shall be denied and the original designation will expire on its expiration date.

(c) Survey Process. A facility seeking designation shall undergo an onsite survey as outlined in this section.

(1) The facility shall be responsible for scheduling a verification or trauma designation survey as follows:

(A) Level I and II facilities shall request a trauma verification survey through the American College of Surgeons (ACS) trauma verification program;

(B) Level III facilities shall request a trauma verification survey through the ACS trauma verification program, or request a trauma designation survey through an organization approved by the office; or

(C) Level IV facilities shall request a trauma designation survey through an organization approved by the office.

(2) The surveying organization shall notify the office of the date of the scheduled survey and shall schedule the members of the survey team.

(A) The facility shall be responsible for any expenses associated with the survey.

(B) The office, at its discretion, may appoint an observer to accompany the survey team. In this event, the cost for the observer shall be borne by the office.

(3) The survey team shall evaluate the facility's compliance and document the noncompliance with this section 157.125 by:

(A) reviewing documents, including a minimum of 10 closed medical records per surveyor;

(B) tour of the physical plant; and

(C) staff interviews to include:

(i) the Chief Executive Officer
(ii) the Chief Nursing Officer
(iii) the current Trauma Medical Director
(iv) the current Executive Sponsor of the trauma program

(4) The surveyor(s) shall provide the facility with a written, signed survey report regarding their evaluation of the facility's compliance / noncompliance with §157.125. This survey report shall be forwarded to the facility no later than 30 calendar days of the completion date of the survey. The facility is responsible for forwarding a copy of this report, including patient care reviews, to the office if it intends to continue the designation process.

(5) The trauma designation survey report and patient care reviews in its entirety shall be part of a facility's quality assessment and performance improvement (QAPI)/Multidisciplinary Trauma PI and peer review program and subject to confidentiality as articulated in the Health and Safety Code, §773.095.

(6) The office shall review the findings of the survey report, patient care reviews and any POC submitted by the facility to determine compliance with the requirements.

(7) A recommendation for designation will be made to the commissioner if the facility meets the requirements for designation found in this section.

(8) If the commissioner concurs with the recommendation to designate, the facility shall receive a letter of designation valid for 3 years and a certificate of designation.

(A) Display: The hospital shall prominently and conspicuously display the trauma designation certificate and the current letter awarding designation from the Commissioner, in a public area of the licensed premises that is readily visible to patients, employees, and visitors.

(B) The trauma designation certificate shall be valid only when displayed with the current letter awarding designation.

(C) If the facility closes or loses trauma designation, the certificate shall be returned to the office.

(D) Alteration: the trauma designation certificate and the award letter shall not be altered. Any alteration to either document voids trauma designation for the remainder of that cycle.

(9) The facility shall have the right to withdraw its application at any time prior to being recommended for trauma facility designation by the office.

(10) It shall be necessary to repeat the designation process as described in this section prior to expiration of a facility's designation or the designation expires.

(11) The office shall post the current designation status of each facility on the office website.

(12) If a facility disagrees with the office's decision regarding its designation status, the facility has a right to a hearing, in accordance with the department's rules for contested cases, and Government Code, Chapter 2001.

(d) Exceptions and Notifications

(1) Any event or decision impacting the ability of a trauma facility to comply with any critical elements, as defined in (c)(1-2) of this section or an increase in the trauma facility's resources that affect the region, the facility shall notify in writing within 5 calendar days :

(A) the office,
(B) applicable RAC(s),
(C) the emergency medical services providers, and
(D) the healthcare facilities to which it customarily transfers-out and/or transfers-in trauma patients.

(2) If the healthcare facility is unable to comply with program requirements to maintain the current designation status, it shall submit to the office a POC as described in (b)(2)(D) of this section, and a request for a temporary exception to criteria. Any request for an exception shall be submitted in writing from an executive officer of the facility. The office shall review the request and the POC and either grant or deny the exception. If the healthcare facility has not come into compliance at the end of the exception period, the office may at its discretion elect one of the following:

(A) allow the facility to request designation at the level appropriate to its revised capabilities;

(B) redesignate the facility at the level appropriate to its revised capabilities; or

(C) suspend the facility's designation status or the facility may relinquish designation status.

(e) Upgrade or Downgrade of designation levels.

(1) An application for a higher or lower level designation may be submitted to the office at any time.

(2) A designated trauma facility that is increasing its trauma capabilities may choose to apply for a higher level of trauma designation at any time. It shall be necessary to repeat the designation process for the higher level. The facility must notify the RAC when the facility's trauma capabilities have changed.

(3) A designated trauma facility that is unable to maintain compliance with the level of the current designation may choose to apply for a lower level of trauma designation at any time. It shall be necessary to repeat the designation process for the lower level. There shall be a paper review by the office to determine if and when a full survey shall be required. The facility must notify the office within 5 days of the date that it no longer provides trauma services commensurate with its designation level.

(f) Relinquishment of designation. If the facility chooses to relinquish its trauma designation, it shall provide at least 30 day notice to the department, the applicable RAC(s), the emergency medical services providers, and healthcare facilities to which it customarily transfers-out and/or transfers-in trauma patients if it no longer provides trauma services.

(g) A healthcare facility may not use the terms "trauma facility", "trauma hospital", "trauma center", or similar terminology in its signs, advertisements or in printed materials and information it provides to the public unless the healthcare facility is currently designated as a trauma facility according to the process described in this section.

(h) The office shall have the right to review, inspect, evaluate, and audit all trauma patient records, trauma QAPI/performance improvement and peer review committee minutes and other documents relevant to trauma care in any designated trauma facility or applicant/healthcare facility at any time to verify compliance with the statute and this rule, including the designation criteria. The office shall maintain confidentiality of such records to the extent authorized by the Texas Public Information Act, Government Code, Chapter 552, and consistent with current laws and regulations related to the Health Insurance Portability and Accountability Act of 1996. Such inspections shall be scheduled by the office when deemed appropriate. The office shall provide a survey report with results, for surveys conducted by or contracted for the department, to the healthcare facility.

(i) The office may grant an exception to this section if it finds that compliance with this section would not be in the best interests of the persons served in the affected local system.

(j) Program Requirements.

(1) Program Plan. The facility shall develop a written plan of the trauma program that includes a detailed description of the scope of services available to all trauma patients, defines the trauma patient population evaluated and/or treated by the facility, transferred, or transported by the facility, that is consistent with accepted professional standards of practice for trauma care, and ensures the health and safety of patients.

(A) The written plan and the program policies and procedures shall be reviewed and approved by the facility's governing body. The governing body shall ensure that the requirements of this chapter are implemented and enforced.

(B) The written program plan shall include, at a minimum:

(i) policies and procedures based on national evidence-based standards of practice of trauma care, that are adopted, implemented, and enforced for compliance by the facility, that governs the trauma program through all phases of care for all patient populations;

(ii) A periodic review and revision schedule for all trauma care policies and procedures;

(iii) written triage, stabilization and transfer guidelines for the trauma patient that include consultation and transport services;

(iv) the availability of all necessary equipment and services to provide the appropriate level of care and support of the patient population served;

(v) a written policy and procedure for massive transfusion developed collaboratively between the trauma service and the blood bank and appropriate resources for implementation;

(vi) requirements for minimal credentials for all staff participating in the care of trauma patients;

(vii) provisions for staff education; including annual competency and skills assessment that is appropriate for the patient population served;

(viii) telemedicine utilization in the Emergency Department (ED);

(ix) the role of the hospitalists in the care of the trauma patient;

(x) provisions for consistent participation by the TMD, TPM, TR, or other members of the trauma program in the regional advisory council (RAC);

(xi) a trauma staff registered nurse as a representative on the nurse staffing committee as established in accordance with TAC §§133.41(o)(2)(F);

(xii) identify a program sponsor who is a member of the executive leadership at the facility;

(xiii) contingency plans to ensure the immediate continuation of an active trauma program in the event that the Trauma Medical Director or the Trauma Program Manager position becomes vacant;

(2) Medical Records. Maintain medical records that contain information to justify and support the immediate evaluation, activation, resuscitation, diagnosis, treatment, and describe the patient's progress and response to medication and interventions from arrival in the Emergency Department through discharge. Records include evidence of documentation of the following as appropriate:

(i) Trauma team response times, mechanism of injury, assessments, interventions, and response to interventions;

(ii) Vital signs and other information necessary for ongoing monitoring of the patient's condition; and

(iii) Daily physician notes by the admitting physician and all sub-speciality physicians participating in the patient's care;

(3) Quality Assessment and Performance Improvement Plan. The facility shall develop, implement, maintain, and evaluate an effective, ongoing, facility-wide, data-driven, outcomes based multidisciplinary quality assessment and performance improvement (QAPI) plan. The plan shall be individualized to the facility and meet the requirements described in this section.

(A) The Trauma QAPI plan shall be reviewed and approved by the facility's governing body. The governing body shall ensure that the requirements of this section are implemented and enforced.

(B) The trauma QAPI plan shall include, at a minimum:

(i) A description of the facility's trauma program and the services provided. All facility services (including those services furnished under contract or arrangement) shall focus on decreasing deviations from the trauma standards

of care to ensure achievement of optimal trauma outcomes, patient safety standards and cost effective care.

(ii) Demonstrate how the staff evaluate the provision of trauma care and patient services, identify opportunities for improvement, develop and implement improvement plans, and evaluate the implementation of those plans until resolution is achieved. Evidence shall support that aggregate patient data, including identification and tracking of trauma patient complications or variances from standards of care, is continuously reviewed for trends by the trauma multidisciplinary QAPI committee.

(iii) Composition of the Trauma Multidisciplinary QAPI committee to include the trauma medical director (TMD), the trauma program manager (TPM), an executive officer of the facility, a trauma nurse active in the management of trauma patients, a trauma nurse active in the management of pediatric trauma patients as applicable, and physicians and surgeons that provide coverage or care to trauma patients, and other healthcare professionals participating in the care of major or severe trauma patients.

(iv) Committee meeting documentation of the attendance, activities, actions, and follow-up with ongoing monthly review of key elements of trauma care.

(4) Outreach and Education.

(A) A defined individual to coordinate the facility's community outreach and education programs for the public and professionals is evident;

(B) Provide education to and consultations with physicians of the community and outlying areas; and

(C) Training programs in trauma continuing education provided by facility for staff and community members involved in trauma care based on needs identified from the QAPI program for:

(i) staff physicians;
(ii) nurses;
(iii) Advanced Practice clinicians including Physician Assistants and Advanced Nurse Practitioners;
(iv) allied health personnel
(v) specialty and community physicians;
(vi) prehospital personnel; and

(vii) other appropriate personnel involved in trauma care

(5) Injury Prevention and Public Education.

(A) A public education program to address the major injury problems identified within the facility's service area; and

(B) Coordination and/or participation in community and/or RAC injury prevention activities.

(6) Medical Staff. The facility must have an organized, effective trauma program that is recognized in the medical staff bylaws and approved by the governing body. Medical staff credentialing shall include a process for requesting and granting delineation of privileges for trauma care.

(7) Medical Director. There shall be an identified Trauma Medical Director (TMD) responsible for the provision of trauma care and credentialed by the facility for the treatment of trauma patients.

(i) The TMD shall be a member of the Medical Executive Committee (MEC);

(ii) The TMD shall have responsibility for the overall clinical direction and oversight of the trauma service;

(iii) The responsibilities and authority of the TMD shall include but are not limited to:

(I) reviewing credentials of medical staff requesting privileges on the trauma team and making recommendations to the MEC for either approval or denial of such privileges;

(II) ensuring that a published, on-call schedule and a backup on-call schedule is readily available to all staff in the emergency department, for obtaining surgical care for all surgical specialties;

(III) regularly and actively participating in or on the trauma call panel;

(IV) the authority to exclude those trauma team members from trauma call who do not maintain trauma program requirements;

(V) ensuring the use of medical staff peer review outcomes, including deviations from trauma standards of care trending, when considering re-credentialing members of the trauma team. All follow-up and feedback from peer review activity must be made available to the reviewers at the time of the onsite survey;

(VI) developing and providing ongoing maintenance of treatment protocols based on current standards of trauma care;

(VII) participating in the ongoing education of the medical and nursing staff in the care of the trauma patient;

(VIII) ensuring that the trauma QAPI/Multidisciplinary PI and peer review meeting is specific to trauma care, is ongoing, is data driven and effective; TMD serves as chair of trauma QAPI committee meetings;

(VIX) participation in the applicable RAC(s) and reviewing the RAC(s) trauma system plan;

(XI) participates in the facility, community, and regional disaster preparedness activities.

(XII) evidence that the TMD is aware of the multidisciplinary team findings on all trauma patients;

(XIII) averaging 9 hours of continuing trauma medical education (CME) annually;

(XIV) maintains active staff privileges as defined in the facility's medical staff bylaws;

(8) Trauma Program Manager (TPM). There shall be an identified Trauma Program Manager responsible for monitoring trauma patient care throughout the continuum of care and through discharge.

(A) The TPM:

(i) shall be a registered nurse;

(ii) is current in the Trauma Nurse Core Course (TNCC) or Advanced Trauma Course for Nurses (ATCN) or a DSHS-approved equivalent;

(iii) is current in a nationally recognized pediatric advanced life support course ((e.g. Pediatric Advanced Life Support (PALS) or the Emergency Nurse Pediatric Course (ENPC));

(iv) has completed a course designed for his/her role which provides essential information on the structure, process, organization and administrative responsibilities of a trauma

program (e.g. Trauma Coordinators Core Course (TCCC) or an office approved equivalent course);

(v) has completed a course designed for his/her role which provides essential information of a trauma PI program to include trauma outcomes and performance improvement (e.g. Trauma Outcomes Performance Improvement Course (TOPIC) or an office approved equivalent course);

(vi) is responsible for the integration of trauma nursing standards of care;

(vii) has the responsibility and authority to:

(I) monitor the clinical outcomes, direction and oversight of the trauma program.

(II) monitor trauma patient care from ED arrival through operative intervention(s), ICU care, stabilization, rehabilitation care, and discharge, including the trauma performance improvement (PI) program;

(viii) participates in a leadership role in the facility including the facility-wide QAPI Committee, community, and regional emergency management (disaster) response committee; and

(k) Trauma Designation Level I (Comprehensive). The facility shall meet the current American College of Surgeons (ACS) essential criteria for a verified Level I trauma center.

(l) Trauma Designation Level II (Major). The facility shall meet the current ACS essential criteria for a verified Level II trauma center.

(m) Trauma Designation Level III (Advanced). The Level III trauma designated facility will meet the following requirements:

(1) The Trauma Medical Director shall be a physician who is:

(A) a board certified general surgeon or a general surgeon eligible for certification by the American Board of Surgery according to current requirements or an equivalent course approved by the office; or

(B) a general surgeon who has continuously served as the Trauma Medical Director at the designated facility for the last consecutive five years and is currently credentialed in Advanced Trauma Life Support (ATLS).

(2) General Surgery.

(A) All surgeons who provide trauma coverage or participates in trauma call coverage shall:

(i) be board certified in general surgery and successfully completed ATLS; or

(ii) be board eligible in general surgery and currently credentialed in Advanced Trauma Life Support (ATLS) or an equivalent course approved by the office; or

(iii) prior to (the effective date of this rule) have continuously provided trauma coverage and participated in trauma call at the designated facility for the last consecutive five years and be currently credentialed in Advanced Trauma Life Support (ATLS); and

(iv) be appropriately credentialed through the trauma program;

(v) average at least 9 hours of trauma-related continuing medical education annually;

(vi) maintain compliance with trauma protocols;

(vii) participate in the trauma QAPI program and attend at least 50% of the trauma multidisciplinary and peer review trauma committee meetings;

(viii) be present in the ED at the time of arrival for a full trauma team activation of a trauma patient; maximum response time 30 minutes from trauma team activation;

(ix) be present in the ED within 60 minutes or less when called for a limited trauma team activation; and

(x) be the admitting physician on all multi-system trauma patients requiring the consultation of one or more specialty services;

(B) If a facility has a surgical residency program, and a team of surgical residents start the evaluation and treatment of the trauma patient, the team shall have, at a minimum, a postgraduate year 4 (PGY-4) or more senior surgical resident who is a member of the facility's residency program. The presence of a surgical resident does not take the place of the attending physician. The attending physician must be compliant with all response times.

(C) If the facility has a surgical residency program and a team of surgical residents start the evaluation and treatment of the trauma patient, the attending surgeon shall participate in all major therapeutic decisions, be present in the emergency department for major resuscitations, and be present during all phases of operative procedures.

(3) In addition to continuous general surgery coverage the facility shall have continuous orthopedic surgical coverage.

(4) Trauma Surgical Specialties.

(A) Orthopedic and Neurosurgery surgeons shall:

(i) be board certified or board eligible in the applicable surgical specialty; or

(ii) prior to (the effective date of this rule) have continuously provided trauma coverage and participated in trauma call at the designated facility for the last consecutive five years; and

(iii) be appropriately credentialed through the trauma service;

(iv) average at least 9 hours of trauma-related continuing medical education annually;

(v) maintain compliance with trauma protocols;

(vi) participate in the trauma QAPI/Multidisciplinary PI program and a designated liaison shall attend at least 50% of the trauma multidisciplinary and peer review trauma committee meetings; and

(vii) at a minimum, orthopedic surgeons and neurosurgeons, participate in the published, on-call schedule and backup on-call schedule or plan readily available to all staff to obtain specialty surgical care.

(5) Emergency Medicine. Any emergency medicine physician who is providing trauma coverage shall be in-house 24 hours a day and shall:

(A) be board certified in emergency medicine and have successfully completed ATLS; or

(B) be board eligible in emergency medicine and currently credentialed in Advanced Trauma Life Support (ATLS) or an equivalent course approved by the office; or

(C) prior to (the effective date of this rule) have continuously provided trauma coverage in the emergency department at the designated facility for the last consecutive five years and be currently credentialed in Advanced Trauma Life Support (ATLS); or

(D) be board eligible in their applicable specialty and currently credentialed in Advanced Trauma Life Support (ATLS) or an equivalent course approved by the office; and

(E) be appropriately credentialed through the trauma program;

(F) average at least 9 hours of trauma-related continuing medical education annually;

(G) maintain compliance with trauma protocols; and

(H) participate in the trauma QAPI/Multidisciplinary PI program and a designated liaison shall attend at least 50% of the trauma multidisciplinary PI and peer review committee meetings.

(6) Anesthesia Services. If the facility furnishes anesthesia services, it shall do so in compliance with 25 TAC 133.41 Hospital Functions and Services. The anesthesiologist providing trauma coverage shall:

(A) be a board certified anesthesiologist; or

(B) be a candidate in the American Board of Anesthesiology examination system; or

(C) prior to (the effective date of this rule) have continuously provided anesthesia coverage at the designated facility for the last consecutive five years; average at least 9 hours of continuing medical education annually; and

(D) be appropriately credentialed through the trauma program;

(E) maintain compliance with trauma protocols;

(F) participate in the trauma QAPI/Multidisciplinary PI program; and

(G) a designated liaison shall attend at least 50% of the trauma multidisciplinary PI and peer review committee meetings.

(7) Radiology Services.

(A) A radiologist shall be on-call and promptly available within 30 minutes of request from inside or outside the hospital. This system shall be continuously monitored by the trauma PI program.

(B) The rate of change in interpretation of radiologic studies must be routinely monitored and reviewed with the radiology department. Identified cases should be reviewed to determine the reason for misinterpretation, adverse outcomes, and opportunities for improvement.

(8) Advanced Practice clinicians (advanced practice registered nurses or physician assistants) utilized in the care of major and/or severe trauma patients, shall not be a substitute for the required physician response, in patient care planning nor in QAPI activities. Any Advanced Practice clinician who provides care to trauma patients shall be current in ATLS and be appropriately credentialed by the Texas Board of Nursing (TBON) or the Texas Medical Board (TMB) respectively.

(9) Nursing Staff. As part of the facility's trauma program approved by the governing body, the program will have an identified Trauma Program Manager with equivalent authority and responsibility as granted to other department or nurse managers. There shall be a demonstrated commitment by the facility for furthering the education and understanding of trauma standards of care for all nursing staff caring for the trauma patient.

(10) Nursing Services for all critical care and patient care areas shall provide evidence of the following:

(A) all nurses caring for trauma patients throughout the continuum of care have ongoing documented knowledge and skills in trauma nursing for patients of all ages to include trauma specific orientation, annual clinical competencies, and continuing education;

(B) written standards on nursing care for trauma patients for all units (i.e. ED, ICU, OR, PACU, general inpatient) in the trauma facility shall be implemented;

(C) a facility approved acuity-based patient classification system is utilized to define workload and number of nursing staff to provide safe patient care for all trauma patients throughout their hospitalization;

(D) a written plan, developed by the hospital, for acquisition of additional staff on a 24 hour basis to support units with increased patient acuity, multiple emergency procedures and admissions (i.e. written surge plan.);

(E) a minimum of two registered nurses shall participate in initial resuscitations for full and limited or trauma activations, have successfully completed and hold current credentials in an advanced cardiac life support course

(ACLS); a nationally recognized pediatric advanced life support course (PALS or ENPC); and TNCC or ATCN; or an office approved equivalent for each course;

(F) nursing documentation for trauma patients is systematic, meets the trauma registry guidelines, and includes at a minimum: the sequence of care, primary and secondary survey with interventions, outcomes, serial vital signs, Glasgow Coma Score (GCS), consulting services assessment, plan of care with disposition and documents the response time of all trauma team members.

(G) documentation that 100% of nursing staff working in the Emergency Department (ED) and responding to trauma activations or caring for trauma patients have successfully completed and hold current credentials in an advanced cardiac life support course (e.g. ACLS or hospital equivalent), a nationally recognized pediatric advanced life support course (e.g. PALS or ENPC) and TNCC or ATCN or a DSHS-approved equivalent, within 18 months of date of employment in the ED.

(H) A stand-alone children's facility shall have documentation that 100% of nursing staff who care for trauma patients have successfully completed and hold current credentials in a nationally recognized pediatric advanced life support course (e.g. PALS or ENPC) and TNCC or ATCN or a DSHS-approved equivalent, within 18 months of date of employment in the ED.

(11) Texas EMS/Trauma Registry Requirements. Any designated trauma facility must participate in the Texas EMS/Trauma Registry. Participation shall include:

(A) Data submission for designation purposes.

(i) Initial designation. Six months of data prior to the initial designation survey must be uploaded to the Texas EMS/Trauma System Registry. Subsequent to initial designation, data shall be uploaded to the Texas EMS/Trauma Registry as indicated in Chapter 103, Injury Prevention and Control of this title within 45 days of discharge with a 90% acceptance or accuracy rate.

(ii) Re-designation. Data shall be uploaded to the Texas EMS/Trauma Registry as indicated in Chapter 103, Injury Prevention and Control of this title within 45 days of patient discharge with a 90% acceptance rate.

(B) Identified Trauma Registrar who has appropriate education, training in injury severity scaling, and four hours of continuing education annually specific to trauma data quality.

(C) Data validation. The Trauma Registrar must participate in ongoing data validation through the department and/or the RAC PI committee.

(12) Trauma Registrar. There shall be an identified Trauma Registrar, who is separate from but supervised by the TPM, who has had appropriate training within 24 months of hire into the position of trauma registrar which includes:

(A) the Association for the Advancement of Automotive Medicine (AAAM) course or a an office approved equivalent; and

(B) the American Trauma Society (ATS) Trauma Registrar Course or an office approved equivalent.

(13) Pre-hospital EMS Communication. There shall be two-way communication with all pre-hospital emergency medical services vehicles.

(14) Emergency Department Equipment. Equipment for the evaluation, resuscitation, and life support for critically or seriously injured patients of all ages shall be available for resuscitation, temperature warming and cooling management, hemorrhage control, hemodynamic monitoring and orthopedic splinting.

(A) The facility shall provide equipment and supplies in compliance with 25 TAC 133.41 Hospital Functions and Services (e)(3)-(4).

(B) Additional Required Emergency Department Equipment.

(i) Mechanical ventilator;

(ii) Supraglottic airway management device (LMA);

(iii) Quantitative end tidal CO_2 monitor;

(iv) Central venous pressure monitoring equipment;

(v) Internal age-specific paddles;

(vi) Standard intravenous fluids and administration devices, including large-bore intravenous catheters and a rapid infuser system;

(vii) Sterile surgical sets for procedures standard for emergency care including but not limited to: thoracostomy, thoracotomy, diagnostic peritoneal lavage, venous cutdown, central line insertion, airway control/cricothyrotomy;

(viii) Current length-based pediatric body weight & tracheal tube size evaluation system, resuscitation medications and equipment that are dose-appropriate for all ages;

(ix) Long bone stabilization capability;

(x) Pelvic stabilization capability; and

(xi) Thermal control equipment for patients and a rapid warming device for blood and fluids;

(15) Surgery Department Equipment and Services. Services for the care of the trauma patient for operative interventions as defined by the center's trauma plan to include resuscitation, temperature warming and management, hemorrhage control, hemodynamic monitoring and orthopedic splinting to ensure that trauma standards of care are met.

(A) Equipment. Appropriate equipment to ensure that trauma standards of care are met.

(B) Services.

(i) Operating Suite. Operating room services shall be available 24 hours a day. With advanced notice, the Operating Room shall be opened and ready to accept a patient within 30 minutes.

(ii) Post-Anesthesia Care Unit. A post-anesthesia care unit or surgical intensive care unit shall have registered nurses and other essential personnel available 24 hours a day.

(16) Intensive Care Capability. Intensive care capability shall be available for the trauma critical care patient and interventions as defined by the facility's trauma plan to include resuscitation, temperature warming and cooling management, hemorrhage control, hemodynamic monitoring and orthopedic splinting to ensure that trauma standards of care are met.

(A) Designated physician surgical director or surgical co-director responsible for setting policies, developing protocols and management guidelines related to trauma ICU patients. A physician providing this coverage must be a board certified or board-eligible surgeon and meets the credentialing requirements as defined in the facility trauma program plan; or

(B) A physician credentialed in critical care on duty in the ICU 24 hours a day or immediately available from in-hospital and meets the credentialing requirements as defined in the facility trauma program plan.

(C) Arrangements for 24-hour surgical coverage of all trauma patients shall be provided for emergencies and routine care. This system shall be continuously monitored by the trauma PI program;

(17) Clinical Support Services.

(A) Respiratory Services. Respiratory services shall be in-house and available 24 hours per day.

(B) Clinical Laboratory Service. Laboratory services shall be in-house and available 24 hours per day;

(C) Standard Radiological Services. An in-house technician shall be available 24-hours a day or be on-call and promptly available on-site within 30 minutes of request. . This system shall be continuously monitored by the trauma PI program;

(D) Special Radiological Capabilities shall be available for the trauma patient as defined by the facility's trauma plan to include:

(i) Sonography;

(ii) Computerized Tomography. In-house CT technician 24-hours per day or on-call and promptly available on-site within 30 minutes of request. This system shall be continuously monitored by the trauma PI program;

(iii) Angiography of all types; and

(iv) Nuclear scanning.

(18) Specialized Capabilities/Services/Units.

(A) Acute hemodialysis capability. A Transfer plan shall be implemented if there is no capability for this standard.

(B) Organized Burn Care. Established criteria for care of major or severe burn patients and/or a process to expedite the transfer of burn patients to a burn center or higher level of care to include written protocols and written transfer plan.

(C) Spinal cord/head injury rehabilitation management capability.

(i) In circumstances where a designated spinal cord injury rehabilitation center exists in the region, a transfer plan must be in effect.

(ii) In circumstances where a moderate to severe head injury center exists in the region, a transfer plan must be in effect.

(D) Rehabilitation Medicine.

(i) A physician-directed rehabilitation service, staffed by personnel trained in rehabilitation care and equipped properly for care of the critically injured patient, or transfer plan when medically feasible to a rehabilitation facility and a process to expedite the transfer of rehabilitation patients to include written protocols, or a written transfer plan.

(ii) The facility shall have the following services available for a critically injured patient:

(I) Physical therapy;

(II) Occupational therapy;

(III) Speech therapy; and

(IV) Social services.

(n) Trauma Designation Level IV (Basic). The Level IV trauma designated facility will meet the following requirements:

(1) The Trauma Medical Director shall be a physician who is:

(A) board certified in emergency medicine by the American Board of Emergency Medicine (ABMS or AOBEM), or eligible for board certification in emergency medicine and currently credentialed in Advanced Trauma Life Support (ATLS) or an equivalent course approved by the office; or

(B) board certified or board eligible in their applicable medical or surgical specialty and currently credentialed in Advanced Trauma Life Support (ATLS) or an equivalent course approved by the office; or

(D) has continuously served as the Trauma Medical Director at the designated facility for the last consecutive five years and is currently credentialed in Advanced Trauma Life Support (ATLS).

(2) Emergency Medicine. A physician providing trauma coverage shall be on-call (if not in-house 24/7), promptly available onsite within 30 minutes of request from inside or outside the hospital and shall:

(A) be board certified in emergency medicine and have successfully completed ATLS; or

(B) be board eligible in emergency medicine and currently credentialed in Advanced Trauma Life Support (ATLS) or an equivalent course approved by the office; or

(C) prior to (the effective date of this rule) have continuously provided trauma coverage in the emergency department at the designated facility for the last consecutive five years and be currently credentialed in Advanced Trauma Life Support (ATLS); or

(D) be board eligible in their applicable specialty and currently credentialed in Advanced Trauma Life Support (ATLS) or an equivalent course approved by the office; and

(E) be appropriately credentialed through the trauma program;

(F) average at least 9 hours of trauma-related continuing medical education annually;

(G) maintain compliance with trauma protocols; and

(H) participate in the trauma QAPI/multidisciplinary PI program and a designated liaison shall attend at least 50% of the trauma multidisciplinary PI and peer review committee meetings.

(3) Radiology Services.

(A) A radiologist shall be on-call and promptly available within 30 minutes of request from inside or outside the hospital. This system shall be continuously monitored by the trauma PI program.

(B) The rate of change in interpretation of radiologic studies must be routinely monitored and reviewed with the radiology department. Identified cases should be reviewed to determine the reason for misinterpretation, adverse outcomes, and opportunities for improvement.

(4)Advanced Practice clinicians (advanced practice registered nurses or physician assistants) utilized in the care of major and/or severe trauma patients, shall not be a substitute for the required physician response, in patient care planning nor in QAPI activities. Any Advanced Practice clinician who provides care to trauma patients shall be current in ATLS and be appropriately credentialed by the Texas Board of Nursing (TBON) or the Texas Medical Board (TMB) respectively.

(5) Nursing Staff. As part of the facility's trauma program approved by the governing body, the program will have an identified Trauma Program Manager with equivalent authority and responsibility as granted to other department or nurse managers. There shall be a demonstrated commitment by the facility for furthering the education and understanding of trauma standards of care for all nursing staff caring for the trauma patient.

(6) Nursing Services for all critical care and patient care areas shall provide evidence of the following:

(A) all nurses caring for trauma patients throughout the continuum of care have ongoing documented knowledge and skills in trauma nursing for patients of all ages to include trauma specific orientation, annual clinical competencies, and continuing education;

(B) written standards on nursing care for trauma patients for all units (i.e. ED, ICU, OR, PACU, general inpatient) in the trauma facility shall be implemented;

(C) a facility approved acuity-based patient classification system is utilized to define workload and number of nursing staff to provide safe patient care for all trauma patients throughout their hospitalization;

(D) a written plan, developed by the hospital, for acquisition of additional staff on a 24 hour basis to support units with increased patient acuity, multiple emergency procedures and admissions (i.e. written surge plan.);

(E) a minimum of two registered nurses shall participate in initial resuscitations for full and limited or trauma activations, have successfully completed and hold current credentials in an advanced cardiac life support course (ACLS); a nationally recognized pediatric advanced life support course (PALS or ENPC); and TNCC or ATCN; or an office approved equivalent for each course;

(F) nursing documentation for trauma patients is systematic and meets the trauma registry guidelines, includes at a minimum:: the sequence of care, primary and secondary survey with interventions, outcomes, serial vital signs, GCS, consulting services assessment, plan of care with disposition and documents the response time of all trauma team members.

(G) documentation that 100% of nursing staff working in the Emergency Department (ED) and responding to trauma activations or caring for trauma patients have successfully completed and hold current credentials in an advanced cardiac life support course (e.g. ACLS or hospital equivalent), a nationally recognized pediatric advanced life support course (e.g. PALS or ENPC) and TNCC or ATCN or a DSHS-approved equivalent, within 18 months of date of employment in the ED.

(H) A stand-alone children's facility shall have documentation that 100% of nursing staff who care for trauma patients have successfully completed and hold current credentials in a nationally recognized pediatric advanced life support course (e.g. PALS or ENPC) and TNCC or ATCN or a DSHS-approved equivalent, within 18 months of date of employment in the ED.

(8) Texas EMS/Trauma Registry Requirements. Any designated trauma facility must participate in the Texas EMS/Trauma Registry. Participation shall include:

(A) Data submission for designation purposes.

(i) Initial designation. Six months of data prior to the initial designation survey must be uploaded to the Texas EMS/Trauma System Registry. Subsequent to initial designation, data shall be uploaded to the Texas EMS/Trauma Registry as indicated in Chapter 103, Injury Prevention and Control of this title within 45 days of discharge with a 90% acceptance or accuracy rate.

(ii) Re-designation. Data shall be uploaded to the Texas EMS/Trauma Registry as indicated in Chapter 103, Injury Prevention and Control of this title within 45 days of patient discharge with a 90% acceptance rate.

(B) Identified Trauma Registrar who has had appropriate training within 24 months of hire into the position of trauma registrar which includes:

(i) the Association for the Advancement of Automotive Medicine (AAAM) course, or

(ii) other office approved equivalent course; and

(V) four hours of continuing education annually specific to trauma data quality.

(C) Data validation. The Trauma Registrar must participate in ongoing data validation through the department and/or the RAC PI committee.

(9) Pre-hospital EMS Communication. There shall be two-way communication with all pre-hospital emergency medical services vehicles.

(10) Emergency Department Equipment and Services. Equipment and services for the evaluation, resuscitation, and life support for critically or seriously injured patients of all ages shall be available for resuscitation, temperature warming and cooling management, hemorrhage control, hemodynamic monitoring and orthopedic splinting.

(A) Equipment. The facility shall provide equipment and supplies in compliance with 25 TAC 133.41 Hospital Functions and Services (e)(3)-(4).

(B)Additional Required Emergency Department Equipment.

(i) Airway control and ventilation equipment including laryngoscope and endotracheal tubes of all sizes;

(ii) Mechanical ventilator;

(iii) Supraglottic airway management device (e.g. LMA);

(iv) Quantitative end tidal CO_2 monitor;

(v) Apparatus to establish central venous pressure monitoring equipment;

(vi) Standard intravenous fluids and administration devices, including large-bore intravenous catheters and a rapid infuser system;

(vii) Sterile surgical sets for procedures standard for emergency care including but not limited to: thoracostomy, central line insertion, and airway control/cricothyrotomy;

(viii) Current length-based pediatric body weight & tracheal tube size evaluation system, resuscitation medications and equipment that are dose-appropriate for all ages;

(ix) Long bone stabilization capability;

(x) Pelvic stabilization capability;

(xi) Thermal control equipment for patients and a rapid warming device for blood and fluids;

(11)Clinical Support Services.

(A) Respiratory Services. Respiratory services shall be in-house and available 24 hours per day.

(B) Clinical Laboratory Service. Laboratory services shall be in-house and available 24 hours per day;

(C) Standard Radiological Capability/Services. An in-house technician shall be available 24-hours a day or be on-call and promptly available on-site within 30 minutes of request.

(D)Special Radiological Capability. In-house Computerized Tomography technician 24-hours per day or on-call and promptly available on-site within 30 minutes of request. This system shall be continuously monitored by the trauma PI program;

(12) Specialized Capabilities/Services/Units.

(A) Organized Burn Care. Established criteria for care of major or severe burn patients and/or a process to expedite the transfer of burn patients to a burn center or higher level of care to include written protocols and

a written transfer plan for patients requiring a higher level of care or specialty services.

(B) Spinal cord/head injury rehabilitation management capability.

(i) In circumstances where a designated spinal cord injury rehabilitation center exists in the region, transfer plan must be in effect.

(ii) In circumstances where a moderate to severe head injury center exists in the region, transfer plan must be in effect.

(o) Survey Team.

(1) The multi-disciplinary survey team shall consist of the following members:

(A) Level I or Level II facilities shall be surveyed by The American College of Surgeons (ACS) with a multi-disciplinary team that includes at a minimum: 2 general surgeons, and a trauma nurse all currently active in the management of trauma patients. Pediatric facilities shall be surveyed by the ACS with a multi-disciplinary team that includes at a minimum: (2) pediatric trauma surgeons, and a Pediatric Trauma Program Manager all active in the management of pediatric trauma patients.

(B) Level III facilities shall be surveyed by the ACS or other office-approved organization, with a multi-disciplinary team that includes at a minimum: a trauma surgeon and a trauma nurse, both currently active in the management of trauma patients. Pediatric facilities shall be surveyed by the ACS, or an office-approved equivalent organization with a multi-disciplinary team that includes at a minimum: a pediatric trauma surgeon, a pediatric trauma nurse with pediatric experience. An additional surveyor may be requested by the facility, or required by the department.

(C) Level IV facilities shall be surveyed by an office-approved organization by a surveyor that is either at a minimum: a registered nurse or a licensed physician, currently active in the management of trauma patients. Pediatric facilities shall be surveyed by an office-approved organization by a surveyor that is either a pediatric trauma surgeon, or a pediatric trauma nurse, or a Trauma Program Manager with pediatric experience. An additional surveyor may be requested by the facility, or required by the department.

(2) Each member of the survey teams described above shall:

(A) be currently employed at a designated trauma facility that is greater than 100 miles from the requesting facility;

(B) not be employed in the same TSA as the designating facility;

(C) not be a current or former employee of the facility that is the subject of the survey or of an affiliated facility;

(D) not be employed at a facility that is a primary transfer facility with the facility being surveyed, with the exception of a burn facility;

(E) not survey the facility program and physical location on consecutive designation cycles; and

(F) not have been requested by the facility;

(G) not possess other potential conflict of interest between the surveyor or the surveyor's place of employment and the facility being surveyed.

(3) Each member of the survey team shall:

(A) have at least 5 years experience in the care of trauma patients;

(B) be currently employed in the management of or providing direct care services to trauma patients;

(C) have direct experience in the preparation for and successful completion of trauma facility designation for no fewer than 2 successful designation cycles;

(D) have successfully completed an office-approved trauma facility site surveyor course and be successfully re-credentialed every 4 years; and

(E) have current credentials as follows:

(i) for registered nurses: Trauma Nurses Core Course (TNCC) or Advanced Trauma Course for Nurses (ATCN); and Pediatric Advanced Life Support (PALS) or Emergency Nurses Pediatric Course (ENPC);

(ii) for physicians: Advanced Trauma Life Support (ATLS); and

(iii) have successfully completed a trauma designation surveyor internship.