

Legend: (Proposed Amendment(s))

Single Underline = Proposed new language

[Bold, Print, and Brackets] = Current language proposed for deletion

Regular Print = Current language

(No change.) = No changes are being considered for the designated subdivision

§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.

Comment [1]: Add location to the definition 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 (in accordance with Texas Administrative Code (TAC) Hospital Licensing Section 133.21)

(i) Each facility operating on a single general hospital license with multiple locations (multi-location license) shall be considered separately for designation. Each location operating on a multi-location license, once a single location has been designated, all other locations operating on the same multi-location license shall designate within 24 months.

(ii) Departments or services within a facility shall not be separately designated, or,

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

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

(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, including a free-standing children's facility, shall meet:

(i) the current American College of Surgeons (ACS) essential criteria for a verified Level I trauma center for adult and/or pediatric criteria and

(ii) the Level III Program Requirements in subsection (k).

(B) Major (Level II) trauma facility designation--The facility, including a free-standing children's facility, shall meet:

(i) the current ACS essential criteria for a verified Level II trauma center for adult and/or pediatric criteria and

(ii) the "Level III Program Requirements" in subsection (k) of this section.

(C) Advanced (Level III) trauma facility designation--The facility, including a free standing children's facility, shall meet the "Program Requirements in subsection (k)

(D) Basic (Level IV) trauma facility designation--The facility meets the Level IV Program Requirements in subsection (k)

(6) A healthcare facility is defined under these rules as a general or special hospital, which offers services, facilities, and beds for use for more than 24 hours for two or more unrelated individuals requiring diagnosis, treatment, or care for illness, injury, deformity, abnormality, or pregnancy; and regularly maintains, at a minimum, clinical laboratory services, diagnostic X-ray services, treatment facilities including surgery or obstetrical care or both, and other definitive medical or surgical treatment of similar extent.

(b) Designation Process. The designation process shall consist of three stages.

(1) The application stage begins with the submission to the office of an appropriate completed application for designation as a trauma facility and ends with the commencement of the onsite survey.

(2) The survey stage begins with the commencement of the onsite survey. The steps of the survey stage are set forth in (XXXXX) of this section, and the stage is complete upon submission to the office of the survey report including a Plan of Correction (PoC) as described in section (XXXXX) if applicable.

(3) The final action stage begins with the office's review of the survey report and any applicable Plan of Correction (POC) and ends with the DSHS issuance of its decision.

Comment [ep2]: Lisa, need her direction. Does this need to be moved to clean it up in Definitions 157.2 or can it be deleted because "licensed general hospital" is referenced above this definition is from the TAC 133 definitions.

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

- (1) the DSHS current applicable application form, with all fields correctly and legibly filled-in;
- (2) full payment of the non-refundable, non-transferrable designation fee enclosed with the submitted application form;
- (3) any subsequent documents submitted by the date requested by the office;
- (4) attendance of the applicant's executive officer and the Trauma Medical Director at the department's Presurvey Conference prior to the trauma designation survey. The department may waive, in its discretion, the Presurvey Conference requirement.

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

(1) A trauma designation survey completed within six months of the date of the receipt of the completed application form by the office; and

(2) A complete survey report, including patient care reviews, and applicable Plan of Correction (POC), shall be submitted within 90 days of the date of the survey.

(3) 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 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 department; and

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

(4) The surveying organization shall notify the office of the date of the planned 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.

(5) The multi-disciplinary survey team shall consist of the follows members:

(A) Level I or Level II facilities shall be surveyed by The American College of Surgeons (ACS) with a multi-disciplinary team and includes at a minimum: 2 general surgeons, an emergency physician, and a trauma nurse all active in the management of trauma patients. Children's facilities shall be surveyed by the ACS with a multi-disciplinary team and includes at a minimum: a pediatric emergency physician; a general surgeon; and a pediatric trauma nurse all active in the management of pediatric trauma patients.

(B) Level III facilities shall be surveyed by the Texas EMS Trauma & Acute Care Foundation (TETAF) or other department-approved equivalent 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. Children's facilities shall be surveyed by the Texas EMS Trauma & Acute Care Foundation (TETAF) or other department-approved equivalent organization with a multi-disciplinary team that includes at a minimum: a pediatric trauma surgeon, a pediatric trauma nurse or a trauma nurse coordinator with pediatric experience. An additional surveyor may be requested by the facility, or required by the DSHS.

(C) Level IV facilities shall be surveyed by the Texas EMS Trauma & Acute Care Foundation (TETAF) or other department-approved equivalent organization by a surveyor that is either at a minimum: a registered nurse or licensed physician surveyor, who is active in the management of trauma patients. Children's facilities shall be surveyed by the Texas EMS Trauma & Acute Care Foundation (TETAF) or other department-approved equivalent organization, whose surveyor is a pediatric trauma surgeon, or a pediatric trauma nurse, or a trauma nurse coordinator with pediatric experience. A second surveyor may be requested by the facility, or required by the DSHS.

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

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

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

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

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

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

(vi) not have been requested by the facility;

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

(6) 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;

Comment [G(3)]: Revisit at the August TSC.

(D) have successfully completed a DSHS-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 survey internship.

(7) The survey team shall evaluate and document the facility's compliance or 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 staff interviews to include:

(i) the current trauma medical director

(ii) the current Chief Executive Officer

(iii) the Chief Nursing Officer

Comment [G(4)]: Administrative Sponsor?

(8) The trauma designation survey report in its entirety shall be part of a facility's quality assessment and performance improvement (QAPI) program and subject to confidentiality as articulated in the Health and Safety Code, §773.095.

(9) The surveyor(s) shall provide the facility with a written, signed survey report documenting the findings of the facility's compliance with §157.125. The survey report shall be forwarded to the facility within 30 calendar days of the completion date of the survey.

The facility is responsible for forwarding a copy of the survey report, [including patient record reviews](#), to the office if it intends to continue the designation process.

(10) If a hospital seeking designation fails to meet the requirements of this section, the application shall be denied and, for facilities seeking re-designation, the original designation will expire on its expiration date.

(11) The non-refundable, non-transferrable designation fee shall be as follows:

(A) 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;

(B) 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

(C) 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.

(e) In Active Pursuit of Designation. This subsection applies only to an undesignated facility that is in active pursuit of designation (IAP). The facility must file a written statement of intent to seek the designation, comply with the following not later than the 180th day after the date the statement of intent is filed, and notify the department of the facility's compliance with the following:

- (1) submission of an application as described in (b)(4)(A-F);
 - (2) submission of data to the department trauma registry;
 - (3) participation in trauma service area regional advisory council initiatives;
- and
- (4) creation of a hospital trauma performance improvement committee.

(5) The office will review the findings of the survey report and POC. A recommendation for designation will be made to the commissioner if the facility meets the requirements for designation found in this section.

(6) If deficiencies are identified on the survey report, the facility shall develop and implement a plan of correction (POC). The POC shall be submitted along with the trauma designation survey report and chart review tools. The POC shall include:

- (A) a statement of the cited deficiency
- (B) a statement describing the corrective action by the facility to ensure compliance with the requirement;

(C) the identity, by title, of the individual(s), responsible for ensuring the corrective action is completed;

(D) the date by which the corrective action will be accomplished, not to exceed 60 days from the survey conference exit date.

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

(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.

(9) 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.

(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.

(f) Exceptions and Notifications

(1) The office will determine the level it deems appropriate for pursuit of designation or re-designation for each of the facility's locations based on, but not limited to: the facility's resources and levels of care capabilities at each location, TSA resources, and the designation requirements for Levels I, II, III, and IV trauma facilities.

(2) If a facility disagrees with the level(s) determined by the office to be appropriate for pursuit of designation or re-designation, it shall make an appeal in writing within 60 days to the director of the office. The written appeal must include a signed letter from the facility's governing board with an explanation as to why designation at the level determined by the office would not be in the best interest of the citizens of the affected TSA or the citizens of the State of Texas.

(3) The written appeal shall include a signed letter (s) from the executive board of its RAC or individual healthcare facilities and/or EMS providers within the affected TSA with an explanation as to why designation at the level determined by the office

would not be in the best interest of the citizens of the affected TSA or the citizens of the State of Texas.

(4) If the office upholds its original determination, the director of the office will give written notice of such to the facility within 30 days of its receipt of the applicant's complete written appeal.

(5) The facility shall, within 30 days of the office's sending written notification of its denial, submit a written request for further review. Such written appeal shall then go to the Assistant Commissioner, Division for Regulatory Services.

(1) If a facility is unable to comply with any of the essential requirements, the facility shall notify the applicable RAC(s), the emergency medical services providers, and 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 the criterion to maintain the current designation status for a period exceeding 30 days, it shall submit to the office a POC as described in (b) (17) (A) (i – iii) 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) re-designate the facility at the level appropriate to its revised capabilities;

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

(D) extend the facility's temporary exception for an additional period not to exceed 90 days as outlined in (c) (2) above.

(i) If the facility disagrees with a proposal by the office, or is unable or unwilling to meet the office-imposed timelines for completion of a corrective action plans, it may request a secondary review by a designation review committee as defined in subsection (b)(18)(C) of this section.

(ii) The office may at its discretion choose to activate a designation review committee at any time to solicit technical advice regarding criteria deficiencies.

Comment [G(5): Give cites, list out occurrences.

Comment [G(6): Medical staff Peer Review is doing trauma peer review, medical staff office will not give the surveyor access to the trauma peer review.

Comment [G(7): Add the reverse. If a facility does not comply with the RAC requirements at anytime during the designation cycle, have the RAC report that to the office.

(iii) If the designation review committee disagrees with the office's recommendation for corrective actions, the case shall be referred to the assistant commissioner for recommendation to the commissioner.

(iv) If a facility disagrees with the office's recommendation at the end of the secondary review process, the facility has a right to a hearing, in accordance with the department's rules for contested cases and Government Code, Chapter 2001.

(v) Designated trauma facilities seeking exceptions to essential criteria shall have the right to withdraw the request at any time prior to resolution of the final appeal process;

(3) Suspensions of a facility's designation status and exceptions to criteria for facilities will be documented on the office website.

(g) Downgrade of designation levels or relinquishment of designation

(1) 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 shall notify 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 commensurate with its designation level.

(2) 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.

(h) A healthcare facility may not use the terms "trauma facility", "trauma hospital", "trauma center", or similar terminology in its signs or advertisements or in the 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.

(i) The office shall have the right to review, inspect, evaluate, and audit all trauma patient records, trauma performance improvement 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 copy of the survey report, for surveys conducted by or contracted for the department and the results to the healthcare facility.

Comment [8]: Ask Don and/or Lisa to verify if accurate government code; language may have updated or changed.

(j) 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.

(k) **Program Requirements.**

(1) **Written Plan of Trauma Service Basis and Scope; Levels I-IV.** The facility shall develop a written plan of the organized trauma service that includes the scope of services available to all trauma patients, defines the trauma patient population evaluated or treated by the facility, is consistent with accepted professional standards of practice for trauma care, and ensures the health and safety of patients.

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

(B) The written trauma service plan must shall include, at a minimum:

(i) polices and procedures developed based on national evidence based practices of trauma care, that are adopted, implemented, and monitored for compliance by the facility that govern the trauma services through all phases of care for all patient populations. The plan shall address for the major and severe trauma patient entering into the trauma center and those patients having ISS of 9 or greater at discharge, telemedicine utilization in the Emergency Department (ED), trauma team activations, staff qualifications, and the role of the hospitalists in the care of the trauma patient. A periodic review and revision schedule for all trauma care polices and procedures must shall be established;

(ii) provisions for ongoing interdisciplinary trauma care meetings;

(iii) a quality assurance and performance improvement (QAPI) program to evaluate performance of all trauma services that is hospital wide, ongoing, and data driven;

(iv) provisions for staff education; and

(v) provisions for consistent participation in the applicable trauma service area (TSA) regional advisory council (RAC);

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

(vii) contingency plans to ensure the continuation of an active trauma program in the event that the Trauma Medical Director or the Trauma Program Manager positions become vacant.

(vii) identify a program sponsor who is a member of the executive leadership at the facility.

Comment [PA(9)]: Departments or services shall not be excluded from designation; this captures pedi services reviewed in facility PI (add in PI criteria) program and at survey (add also in survey section of rule) (the example: Christus Santa Rosa now has its pedi surveyed and reviewed in program)

Comment [G(10)]: This is how we addressed the pediatric and geriatric populations.

Comment [G(11)]: Rework this sentence.

Comment [G(12)]: Check the feedback from the TSC feedback on definition; include ISS or not?

Comment [ep13]: "trauma team" and "activation" and "transfer" policies/procedures, "outreach program", and "public education/IP program" are mentioned later or in current rule but not aforementioned as part of plan/how required; should it be outlined as item here or elsewhere?

(2) Medical Records Content. The medical record must contain information to justify and support the diagnosis, treatment, and describe the patient's progress and response to medications and services. Maintain medical records that document evidence of the following as appropriate:

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

(B) Vital signs and other information necessary to monitor the patient's condition;

(C) Daily physician notes

(3) Medical Staff. The hospital 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.

(A) Trauma Medical Director. There shall be an identified Trauma Medical Director (TMD) responsible for the provision of trauma care services and credentialed by the facility for the treatment of trauma patients. The TMD shall not have medical director responsibilities at more than one designated facility.

(i) The trauma medical director shall be a member of the medical executive committee;

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

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

(I) ~~examining~~ reviewing credentials of medical staff requesting privileges on the trauma team and making recommendations to the medical executive committee 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) has 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 nursing staff in the care of the trauma patient;

(VIII) ensuring that the quality assessment and performance improvement (QAPI) is specific to trauma care [trauma performance improvement (PI) program], is ongoing, is data driven and effective; TMD serves as chair of trauma QAPI meetings;

(IX) maintaining participation in the applicable trauma service area regional advisory council; and

(X) actively participates in the hospital, community, and regional disaster preparedness activities.

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

(XII) averaging 16 hours of continuing trauma medical education (CME) annually;

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

(iv) The medical director for Level I, II or III shall be a physician who is:

(I) 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 Department of State Health Services

Comment [G(14)]: EMter ACS language.

(II) 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).

(v) The medical director for Level IV shall be a physician who is:

Comment [15]: Check the suggestions from the trauma committee for qualifications of the TMD

(I) 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 Department of State Health Services; or

(II) 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 Department of State Health Services; or

(III) 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).

(4) Standard: General Surgery.

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

(i) be board certified in general surgery; or

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

(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 interdisciplinary and peer review trauma committee meetings;

(viii) be present in the ED at the time of arrival of the major or severe trauma patient; maximum response time 30 minutes from trauma team activation;

(ix) respond within 60 minutes or less when called for an urgent surgical consult; and

(x) be the admitting physician on all multi-system trauma patients;

Comment [16]: Verify language regarding residency programs.

(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.

(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.

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

(6) Additional Trauma Surgical Specialty Services include: Orthopedic and Neurosurgery surgeons shall:

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

(B) 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 completes an average of 16 hours of trauma related CME annually.

(D) be appropriately credentialed through the trauma service;

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

(F) maintain compliance with trauma protocols;

(G) participate in the trauma QAPI program and a designated liaison shall attend at least 50% of the trauma interdisciplinary and peer review trauma committee meetings; and

Comment [G(17)]: Consider PIPS add to QAPI language

(H) 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.

(6) 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 Department of State Health Services; 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);

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

(E) be appropriately credentialed through the trauma program;

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

(F) maintain compliance with trauma protocols; and

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

(7) Anesthesia Services. If the facility furnishes anesthesia services, it shall do so in compliance with 25 TAC 133.41 Hospital Functions and Services.

(A) The anesthesiologist providing trauma coverage shall:

(i) be a board certified anesthesiologist; or

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

(iii) 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 16 hours of trauma-related continuing medical education annually;

(iv) be appropriately credentialed through the trauma program;

(vi) maintain compliance with trauma protocols;

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

(B) Advanced Practice clinician (advanced practice registered nurses or physician assistants) are utilized in the care of major and or severe trauma patients, their presence shall not 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.

(8) Radiology Services. Radiology for a Level III shall have on-call radiology services promptly available within 30 minutes of request from inside or outside the hospital.

(A) 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.

(B) The Radiologist

Comment [G(18): Insert language from ACS regarding reads and rereads, and PIPS; include liaison statement here.

(9) Nursing Staff. As part of the hospital'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 heads 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) Trauma Program Manager (TPM).

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

- (i) shall be a registered nurse who;
- (ii) is current in the Trauma Nurse Core Course (TNCC) or Advanced Trauma Course for Nurses (ATCN) or a DSHS-approved equivalent; or
- (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) shall be a standing member of the hospital nurse staffing committee as established in accordance with Health and Safety Code (HSC), §§161.031 - 161.033; and

(iii) shall have responsibility for the monitoring the clinical outcomes, direction and oversight of the trauma program.

(B) Each facility shall identify a registered nurse as the trauma program manager who is responsible for the integration of trauma nursing standards of care. The responsibilities and authority of the Trauma Program Manager shall include:

(iii) the authority and responsibility to monitor trauma patient care from ED admission through operative intervention(s), ICU care, stabilization, rehabilitation care, and discharge, including the trauma performance improvement (PI) program;

(iv) participation in a leadership role in the hospital, community, and regional emergency management (disaster) response committee;

(v) being full-time with a minimum of 80% of the time dedicated to the Trauma program; and

(vi) completion of a course designed for his/her role which provides essential information on the structure, process, organization and administrative responsibilities of a PI program to include a trauma outcomes and performance improvement course (e.g. Trauma Outcomes Performance Improvement Course (TOPIC) or Trauma Coordinators Core Course (TCCC)).

(11) 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 skill 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 validated 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 surg plan.);

(E) a minimum of two registered nurses shall participate in initial resuscitations for Level I or Level II trauma activations have successfully completed and holds 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. A free-standing children's facility is exempt from the ACLS requirement;

(H) nursing documentation for trauma patients is systematic and meets the trauma registry guidelines; nursing documentation for trauma activation patients is on a trauma flow sheet, may be electronic or paper, defines the sequence of care, primary and secondary survey with

Comment [G(19)]: One TMP per hospital, not multiple hospitals.

Comment [G(20)]: Copy the language from the TMD for the disaster stuff.

Comment [G(21)]: Brenda P. will send language that was provided by DSHS for inclusion.

Comment [G(22)]: Spell out in the body of the rule or list in definitions? Charles, need your guidance

Comment [G(23)]: Add the 100% of nursing staff taking care of the trauma patient have TNCC.

interventions, outcomes, serial vital signs, GCS and components of the **RTS**, consulting services assessment and plan of care with disposition meets the trauma registry guidelines and documents the response time of all trauma team members.

Comment [G(24): Spell out

(I) 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 or the date of designation.

Comment [G(25): Jorie and Jane will fix language for August meeting.

(J) requirements specific to a free-standing children's **facility**:

Comment [G(26): Consolidate with other requirements if possible. ?? Jorie will check with Lori.

(i) 100% of nursing staff who care for trauma patients have successfully completed; and

(ii) hold current credentials in ENPC or in a nationally recognized pediatric advanced life support course and TNCC or ATCN or a DSHS-approved equivalent, within 18 months of date of employment in the ED or date of designation.

(12) Texas EMS/Trauma Registry Requirements. Any designated trauma facility shall 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) **Identifying a trauma registrar** who has appropriate education and training in injury severity scaling, and four hours of continuing education annually specific to trauma data quality.

Comment [ep27]: Ask Kristi for terminology for 90% rate.

(C) **Data** validation. The registrar must participate in ongoing data validation through the **RAC PI committee**.

Comment [G(28): Wrap into the trauma plan to include data validation.

Comment [ep29]: In RAC rule, outline that RAC PI Cmte develop a peer review with data validation program for hospitals to identify education and training for registrars to improve data quality submitted to the state registry.

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

course, and

- (i) the Association for the Advancement of Automotive Medicine (AAAM)
- (ii) American Trauma Society (ATS) Trauma Registrar Course in injury severity scaling; or
- (iii) other course approved by the department. ~~Typically, one full time equivalent (FTE) employee dedicated to the registry shall be required to process approximately 500 patients annually.~~

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

(15) Emergency Department Equipment and Services. Equipment and services for the evaluation and resuscitation of, and to provide 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.

Comment [G(30)]: Revisit in August

(A) Equipment.

(i) Standard: Emergency Department Equipment.

(I) Airway control and ventilation equipment including laryngoscope and endotracheal tubes of all sizes, bag-valve-mask devices (BVMs), pocket masks, oxygen;

(II) Mechanical ventilator;

(III) Pulse oximetry;

(IV) Suction devices;

(V) Electrocardiograph-oscilloscope-defibrillator;

(VI) Internal age-specific paddles;

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

(VIII) Central venous pressure monitoring equipment;

(IX) All standard intravenous fluids and administration devices, including large-bore intravenous and a rapid infuser system;

(X) Sterile surgical sets for procedures standard for emergency room such as thoracostomy, venous cutdown, central line insertion, thoracotomy, diagnostic peritoneal lavage, airway control/cricothyrotomy, etc.;

Comment [G(31)]: This is not a standard treatment in the ED. Statistics prove this is not an effective treatment in the ED, pts don't survive.

- (XI) Drugs and supplies necessary for emergency care;
- (XII) Cervical spine stabilization device;
- (XIII) Length-based body weight & tracheal tube size evaluation system (such as Broselow tape) and resuscitation medications and equipment that are dose-appropriate for all ages;
- (XIX) Long bone stabilization device;
- (XX) Pelvic stabilization device;
- (XXI) Thermal control equipment for patients and a rapid warming device for blood and fluids;
- (XXII) Non-invasive continuous blood pressure monitoring devices;
- (XXIII) Qualitative end tidal CO₂ monitor;

(ii) Surgery Department Equipment and Services. Equipment and services for the care of the trauma patient 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.

~~Operating Suite Equipment. Special requirements shall include but not be limited to:~~

- ~~(I) Thermal control equipment for patient and for blood and fluids;~~
- ~~(II) X ray capability including c arm image intensifier with technologist available 24 hours a day;~~
- ~~(III) Endoscopes, all varieties, and bronchoscope;~~
- ~~(IV) Equipment for long bone and pelvic fixation;~~
- ~~(V) Rapid infuser system;~~
- ~~(VI) Appropriate monitoring and resuscitation equipment;~~
- ~~(VII) The capability to measure pulmonary capillary wedge pressure;~~

~~(VIII) The capability to measure invasive systemic arterial pressure.~~

(B) Services.

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

(ii) Operating Suite. For a Level I, II, and III, 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.

(iii) Post-Anesthesia Care Unit. For a Level III, a post-anesthesia care unit or surgical intensive care unit shall have available:

(I) Registered nurses and other essential personnel available 24 hours a day;

(II) Appropriate equipment to ensure that trauma standards of care are met. ~~monitoring and resuscitation equipment;~~

~~(III) Pulse oximetry;~~

~~(IV) Thermal control equipment for patients and a rapid warming device for blood and fluids.~~

(iv) Intensive Care Capability

For a Level I, II and III, intensive care capability shall be available for the trauma critical care patient and interventions as defined by the center's trauma plan to include resuscitation, temperature warming and cooling management, hemorrhage control, hemodynamic monitoring and orthopedic splinting to ensure that **national** trauma standards of care are **met**.

Comment [G(32)]: Can we us "national"

Comment [G(33)]: Look at ACS language

(I) Designated surgical director or surgical co-director who is responsible for setting policies, developing protocols and management guidelines related to trauma ICU patients. A physician who is providing this coverage must be a surgeon who is credentialed by the TMD to participate in the resuscitation and treatment of trauma patients who is ~~to include requirements such as board certified or board-eligible surgeon trauma continuing medical education, compliance with trauma protocols, and participation in the trauma PI program;~~ who meets the credentialing requirements as defined in the facility trauma plan.

(II) Physician, credentialed in critical care by the trauma director, who is on duty in the ICU 24 hours a day or immediately available from in-hospital. 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;

Comment [G(34): Make consistent with other PI language.

(III) Registered Nurse-patient minimum ratio of 1:2 on each shift for patients identified as critical acuity;

Comment [G(35): Insert language about acuity staffing. Pull from the TAC 133 for nurse staffing committee.

~~(IV) Appropriate monitoring and resuscitation equipment;~~

~~(V) Pulse oximetry;~~

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

~~(VII) The capability to measure pulmonary capillary wedge pressure;~~

~~(VIII) The capability to measure invasive systemic arterial pressure.~~

(v) Clinical Support Services.

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

(vii) Clinical Laboratory Service

Comment [G(36): Clean up, look at CLIA language. CLIA certified?

(I) Services available 24 hours per day;

~~(II) Standard analyses of blood, urine, and other body fluids, including microsampling;~~

~~(III) Blood typing and cross matching, to include massive transfusion and emergency release of blood policies;~~

~~(IV) Comprehensive blood bank or access to a community central blood bank and adequate hospital storage facilities;~~

~~(V) Coagulation studies;~~

~~(VI) Blood gases and pH determinations;~~

~~(VII) Microbiology;~~

~~(VIII) Drug and alcohol screening; results should be included in all trauma PI reviews;~~

and

~~(IX) Infectious disease Standard Operating Procedures;~~

~~(X) Serum and urine osmolality;~~

Comment [G(37)]: Include pedi and geriatric criteria or reference in the trauma plan and possibly in the body of the rule. Look at TSC suggestions.

(viii) Special Radiological Capabilities Level III.

(I) Sonography;

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

(III) Angiography of all types;

(IV) Nuclear scanning.

(ix) Specialized Capabilities/Services/Units for Level III.

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

(xi) 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, written transfer agreements, and a regional trauma system transfer plan for patients needing a higher level of care or specialty services.

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

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

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

(xiii) Rehabilitation Medicine.

(I) Physician-directed rehabilitation service, staffed by personnel trained in rehabilitation care and equipped properly for care of the critically injured patient, or transfer agreement when medically feasible to a rehabilitation facility and a process to expedite the transfer of rehabilitation patients to include ~~such things as~~ written protocols, written transfer agreements, and a regional trauma

(II) Physical therapy;

(III) Occupational therapy;

(IV) Speech therapy;

(IV) Social services.

(xix) Outreach program.

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

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

(xx) Public education/injury prevention.

(I) A public education program to address the major injury problems within the hospital's service area. Documented participation in a RAC injury prevention program is acceptable.

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

(xxi) Training programs. Formal programs in trauma continuing education provided by hospital for staff based on needs identified from the performance improvement program for:

(I) staff physicians;

(II) nurses;

(III) allied health personnel, including mid-level providers such as physician assistants and nurse practitioners;

(IV) community physicians;

(V) prehospital personnel.

(xxii) Research. Trauma registry performance improvement activities.

(-i-) Quality assessment and performance improvement.

Comment [G(38)]: PIPS

(I) A facility shall develop, implement, maintain, and evaluate an effective, ongoing, facility-wide, data-driven, interdisciplinary quality assessment and performance improvement (QAPI) program. The program shall be individualized to the facility and meet the criteria and standards described in this section.

(II) The program shall reflect the complexity of the facility's trauma service plan and the services involved. All facility services (including those services furnished under contract or arrangement) shall focus on decreasing the deviations from the trauma standards of care to ensure optimal trauma outcomes, patient safety standards and cost effective care.

(III) The trauma center shall demonstrate that the facility 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 interdisciplinary team TIT. [Trauma Interdisciplinary team (TIDT)--A group composed of the trauma medical director (TMD), the trauma program manager, 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.]

Comment [ep39]: Revise to fit our needs and add to definitions. Check elsewhere in this rule for use of multidisciplinary to substitute IDT.

(V) The trauma interdisciplinary team (TIDT) shall lead the QAPI meetings and activities; the QAPI meetings shall be documented and include the attendance, activities, actions, and follow-up.

(VI) The trauma center's QAPI program shall include ongoing monthly review of system key elements of trauma care using comparative and trend data to include, the following aggregate patient data.

Comment [ep40]: Review Trauma Systems Committee feedback as possible input into QAPI program requirements.

(-VII-) All events and decisions of a trauma center impacting the ability of the trauma center to comply with any essential criterion, as defined in (c) (1-2) of this section or changes in the trauma centers resources that affect the region shall require that the trauma center notify the office, the local RAC plus other affected RACs, including all changes that affect air medical access to designated landing sites.

Comment [G(41): Rework the wording

Comment [G(42): Make consistent through out standard/ criterion/ etc.

Comment [43]: Verify (c)(1-2) is still accurate.

(m) Appeals Process. If a facility disagrees with the office's decision regarding its designation application or status, it may request a secondary review by a designation review committee.

Comment [G(44): Move to the end of the rule

(1) Membership on a designation review committee will:

(A) be voluntary;

(B) be appointed by the office director;

~~(C) be representative of trauma care providers and appropriate levels of designated trauma facilities; and~~

~~(D) include representation from the department and the Trauma Systems Committee of the Governor's EMS and Trauma Advisory Council (GETAC).~~

~~(2) If a designation review committee disagrees with the office's recommendation for corrective action, the records shall be referred to the assistant commissioner for recommendation to the commissioner.~~

(3) If a facility disagrees with the office's recommendation at the end of the secondary review, the facility has a right to a hearing, in accordance with the department's rules for contested cases, and Government Code, Chapter 2001.

Comment [DSH45]: DSHS-need further explanation if state or federal

Trauma System Committee 7/2/14