Texas Administrative Code

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TITLE 25	HEALTH SERVICES
PART 1	DEPARTMENT OF STATE HEALTH SERVICES
CHAPTER 157	EMERGENCY MEDICAL CARE
SUBCHAPTER G	EMERGENCY MEDICAL SERVICES TRAUMA SYSTEMS
RULE §157.125	**Requirements for Trauma Facility Designation**

(a) 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 designation of an applicant/healthcare facility (facility) as a trauma facility at the level(s) for each location of a facility the office deems appropriate.

(1) Comprehensive (Level I) trauma facility designation--The facility, including a free-standing children's facility, meets the current American College of Surgeons (ACS) essential criteria for a verified Level I trauma center for adult and/or pediatric criteria; meets the "Advanced Trauma Facility Criteria" in subsection (x) of this section; actively participates on the appropriate Regional Advisory Council (RAC); has appropriate services for dealing with stressful events available to emergency/trauma care providers; and submits data to the Texas EMS/Trauma Registry.

(2) Major (Level II) trauma facility designation--The facility, including a free-standing children's facility, meets the current ACS essential criteria for adult and/or pediatric criteria, a verified Level II trauma center; meets the "Advanced Trauma Facility Criteria" in subsection (x) of this section; actively participates on the appropriate RAC; has appropriate services and resources for emergency management available to emergency/trauma care providers; and submits data to the Texas EMS/Trauma Registry.

(3) Advanced (Level III) trauma facility designation--The facility, including free standing children’s facility, meets the "Advanced Trauma Facility Criteria" in subsection (x) of this section; actively participates on the appropriate RAC; has appropriate services and resources for emergency management available to emergency/trauma care providers; and submits data to the Texas EMS/Trauma Registry. (4) Basic (Level IV) trauma facility designation--The facility meets the "Basic Trauma Facility Criteria" including free standing children’s facility, in subsection (y) of this section; actively participates on the appropriate RAC; has appropriate services and resources for emergency management and submits data to the Texas EMS/Trauma Registry.

(b) A healthcare facility is defined under these rules as a single location where inpatients receive hospital services or each location if there are multiple buildings where inpatients receive hospital services and are covered under a single hospital license.

(1) Each location shall be considered separately for designation and the Department of State Health Services (department) will determine the designation level for that location, based on, but not limited to, the location's own resources and levels of care capabilities; Trauma Service Area

(TSA) capabilities; and the essential criteria and requirements outlined in subsection (a)(1) - (4) of this section. The final determination of the level(s) of designation may not be the level(s) requested by the facility.

(2) A facility with multiple locations that is applying for designation at one location shall be required to apply for designation at each of its other locations where there are buildings where inpatients receive hospital services and such buildings are collectively covered under a single hospital's license. All acute care facilities sharing the same license with multiple locations shall be required to designate.

(c) The designation process shall consist of three phases.

(1) First phase--The application phase begins with submitting to the office a timely and sufficient application for designation as a trauma facility and ends when the survey report is received by the office.

(2) Second phase--The review phase begins with the office's review of the survey report and ends with its recommendation to the commissioner whether or not to designate the facility and at what level(s). This phase also includes an appeal procedure governed by the department's rules for a contested case hearing and by Government Code, Chapter 2001.

(3) Third phase--The final phase begins with the commissioner reviewing the recommendation and ends with his/her final decision.

(d) For a facility seeking initial designation, a timely and sufficient application shall be submitted 12 months prior to designation expiration. The Pre-Application Review is defined as follows. :

(1) the department's current "Minimal Application" form for the appropriate level, with all fields correctly and legibly filled-in and all essential documents attached, defined below that are hand-delivered or sent by postal services to the office

a. Narrative description of hospital
b. Organizational charts
c. Medical Staff and Board Resolutions
d. RAC letter of participation
e. Job descriptions for the Trauma Medical Director, Trauma Program Manager and Trauma Registrar
f. Trauma Team Activation Protocol
g. Trauma Team Roles and Responsibilities Protocol
h. Trauma Resuscitation Protocol
i. Trauma Admission and Transfer Protocol
g. Trauma Process Improvement Plan and associated documents
h. Statistical overview reflecting the number of trauma activations, number of trauma admissions, number of trauma admissions to the ICU by ISS breakdown, number of trauma admissions to the OR by ISS breakdown, number of deaths, number of transfers in, number of transfers out.
i. Evidence of submission to the regional and state trauma registry

(2) full payment of the application fee enclosed with the submitted PAR.

(3) any subsequent documents submitted by the date requested by the office;
(4) A full application including all required documents and policies must be submitted thirty days prior to designation site survey to the defined surveyor and designation agency.
(5) a trauma designation survey completed within one year of the date of the receipt of the initial application by the office; and
(6) a complete survey report, including patient care reviews, that is within 60 days of the date of the survey and is hand-delivered or sent by postal services to the office.
(e) If a hospital seeking initial designation fails to meet the requirements in subsection (d)(1) - (5) of this section, the application shall be denied.
(f) For a facility seeking re-designation, a timely and sufficient application shall include:
(1) PAR as defined in (d) (1) for the appropriate level, with all fields correctly and legibly filled-in and all requested documents attached, hand-delivered or sent by postal services to the office one year or greater from the designation expiration date;
(2) full payment of the application fee enclosed with the submitted PAR. (3) any subsequent documents submitted by the date requested by the office; and
(4) a complete survey report, including patient care reviews, that is within 180 days of the date of the survey and is hand-delivered or sent by postal services to the office no less than 60 days prior to the designation expiration date.
(g) If a healthcare facility seeking re-designation fails to meet the requirements outlined in subsection (f)(1) - (4) of this section, the original designation will expire on its expiration date.
(h) The office's analysis of the submitted PAR form may result in recommendations for corrective action when deficiencies are noted and shall also include a review of:
(1) the evidence of current participation in RAC/regional system planning; and
(2) the completeness and appropriateness of the PAR materials submitted, including the submission of a non-refundable PAR fee as follows:
(A) for Level I and Level II trauma facility applicants, including free standing children's facilities, 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) for Level III trauma facility applicants, including free standing children's facilities, 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) for Level IV trauma facility applicants, including free standing children's facilities, the fee will be no more than $10 per licensed bed with an upper limit of $1000 and a lower limit of $500.
(i) When a PAR for initial designation or re-designation from a facility is received, 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 essential criteria for Levels I, II, III, and IV trauma facilities. In general, physician services capabilities described in the PAR must be in place 24 hours a day/7 days a week. In determining whether a physician services capability is present, the department may use the concept of substantial compliance that is defined as having

said physician services capability at least 90% of the time.

(1) If a facility disagrees with the level(s) determined by the office to be appropriate for pursuit of designation or re-designation, it may 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.

(2) The written appeal may 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.

(3) 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.

(4) The facility may, 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 (assistant commissioner).

(j) When the analysis of the PAR results in acknowledgement by the office that the facility is seeking an appropriate level of designation or re-designation, the facility may then contract for the survey, as follows.

(1) Level I and II facilities including free-standing children's facilities shall request a survey through the ACS trauma verification program.

(2) Level III facilities, including free standing children’s facilities, shall request a survey through the ACS trauma verification program or through a comparable organization approved by the department.

(3) Level IV facilities, including free standing children’s facilities, shall request a survey through an organization approved by the department. (4) The surveying agency, upon receipt of a complete application including all required documents and policies will coordinate the surveying team and date; and shall notify the office of the date of the planned survey and the composition of the survey team.

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

(6) 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.

(k) The survey team composition shall be as follows.

(1) Level I or Level II facilities shall be surveyed by a team that is multi-disciplinary and includes at a minimum: 2 general surgeons and a trauma program manager active in the management of trauma patients.

(2) Level 1 and Level II free-standing children's facilities shall be surveyed by a team consistent with current ACS policy and includes at a minimum: a pediatric surgeon; a general surgeon;; and a pediatric trauma program manager

(3) Level III facilities shall be surveyed by a team that is multi-disciplinary and includes at a minimum: a trauma surgeon and a trauma program manager (ACS or department-credentialed),

both active in the management of trauma patients. Level 3 free standing children's facilities shall be surveyed by a pediatric trauma surgeon, and a pediatric trauma program manger with pediatric experience.

(4) Level IV facilities shall be surveyed by a department-credentialed surveyor. A second surveyor may be requested by the facility, the surveying agency or by the department. Level 4 free standing children's facilities shall be surveyed by a pediatric trauma surgeon and a trauma nurse coordinator with pediatric experience.

(5) Department-credentialed surveyors must meet the following criteria:

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

(B) be currently employed in the management of care for trauma patients;

(C) have direct experience in the preparation for and successful completion of trauma facility verification/designation for no less than 2 successful surveys;

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

(E) have current credentials as follows:

(i) for 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 site survey internship.

(6) All members of the survey team, except department staff, shall come from a TSA outside the facility's location and at least 100 miles from the facility. There shall be no potential conflict of interest between the surveyor or the surveyor's place of employment and the facility being surveyed.

(7) Surveyors shall be active participants in the state Trauma System.

(l) The survey team shall evaluate the facility's compliance with the designation criteria, by:

(1) reviewing medical records; staff rosters and schedules; process improvement committee meeting minutes; and other documents relevant to trauma care;

(2) reviewing equipment and the physical plant;

(3) conducting interviews with facility personnel;

(4) evaluating compliance with participation in the Texas EMS/Trauma Registry; and

(5) Evaluating appropriate use of telemedicine capabilities where applicable.

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

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January 28, 2011; July 15 & 16, 2011; August 3 & 4, 2011

TETAF TRAUMA DIVISION RULE REVISION WORKGROUP RED LINE COPY WORKING DOCUMENT, GETAC Trauma System Committee and participating stakeholders

(n) The surveyor(s) shall provide the facility with a written, signed survey report regarding their evaluation of the facility's compliance with trauma facility criteria. This survey report shall be forwarded to the facility within 30 business days of the completion date of the survey. The facility is responsible for forwarding a copy of this report to the office if it intends to continue the designation process.

(o) The office shall review the findings of the survey report for compliance with trauma facility criteria.

(1) A recommendation for designation shall be made to the commissioner based on compliance with the criteria.

(2) If a facility does not meet the criteria for the level of designation deemed appropriate by the office, the office shall notify the facility of the requirements it must meet to achieve the appropriate level of designation.

(3) If a facility does not comply with criteria, the office shall notify the facility of deficiencies and recommend corrective action.

(A) The facility shall submit to the office a report that outlines the corrective action(s) taken. The office may require a second survey to ensure compliance with the criteria. If the office substantiates action that brings the facility into compliance with the criteria, the Office shall recommend designation to the commissioner.

(B) 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. Membership on a designation review committee will:

(i)be uncompensated;

(ii) be appointed by the office director;

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

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

(C) 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.

(D) 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.

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

(q) If the commissioner concurs with the recommendation to designate, the facility shall receive a letter and a certificate of designation valid for 3 years. Additional actions, such as a site review or submission of information/reports to maintain designation, may be required by the department.

(r) 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.

(s) A designated trauma facility shall:

(1) comply with the provisions within these sections; all current state and system standards as described in this chapter; and all policies, protocols, and procedures as set forth in the system plan;

(2) continue its commitment to provide the resources, personnel, equipment, and response as required by its designation level;

(3) participate in the Texas EMS/Trauma Registry. Data submission requirements for designation purposes are as follows.

(A) Initial designation--Six months of data prior to the initial designation survey must be uploaded. Subsequent to initial designation, data should be uploaded to the Texas EMS/Trauma Registry on at least a quarterly basis (with monthly submissions recommended) as indicated in §103.19 of this title (relating to Electronic Reporting).

(B) Re-designation--The facility's trauma registry should be current with at least quarterly uploads of data to the Texas EMS/Trauma Registry (monthly submissions recommended) as indicated in §103.19 of this title;

(4) notify the office, its RAC plus other affected RACs of all changes that affect air medical access to designated landing sites.

(A) Non-emergent changes shall be implemented no earlier than 120 days after a written notification process.

(B) Emergency changes related to safety may be implemented immediately along with immediate notification to department, the RAC, and appropriate Air Medical Providers.

(C) Conflicts relating to helipad air medical access changes shall be negotiated between the facility and the EMS provider.

(D) Any unresolved issues shall be handled utilizing the nonbinding alternative dispute resolution (ADR) process of the RAC in which the helipad is located;

(5) A facility that is unable to comply with essential criterion, shall, within 5 days notify the DSHS office; its RAC plus other affected RACs; and the healthcare facilities to which it customarily transfers-out trauma patients or from which it customarily receives trauma transfers-in if temporarily unable to comply with a designation criterion. If the healthcare facility intends to comply with the criterion and maintain current designation status, it must also submit to the office a plan for corrective action and a request for a temporary exception to criteria within 5 days.

(A) If the requested essential criterion exception is not critical to the operations of the healthcare facility's trauma program and the office determines that the facility has intent to comply, a 30-day to 90-day exception period from the onset date of the deficiency may be granted for the facility to achieve compliancy.

(B) If the requested essential criterion exception is critical to the operations of the healthcare facility's trauma program including laboratory and basic x-ray capability and the office determines that the facility has intent to comply, no greater than a 30-day exception period from the onset date of the deficiency may be granted for the facility to achieve compliancy. Essential criteria that are critical includes but not limited to:

(i) neurological surgery capabilities (Level I, II);

(ii) orthopedic surgery capabilities (Level I, II, III);
(iii) general/trauma surgery capabilities (Level I, II, III);
(iv) anesthesiology (Levels I, II, III);
(v) emergency physicians (all levels);
(vi) trauma medical director (all levels);
(vii) trauma program manager (all levels); and
(viii) trauma registry (all levels).

(C) 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:

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

(ii) propose to re-designate the facility at the level appropriate to its revised capabilities;

(iii) propose to suspend the facility's designation status. If the facility is amenable to this action, the office will develop a plan for corrective action for the facility and a specific timeline for compliance by the facility; or

(iv) propose to extend the facility's temporary exception to criteria for an additional period not to exceed 90 days. The department will develop a plan for corrective action for the facility and a specific timeline for compliance by the facility.

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

(II) If the facility disagrees with a proposal by the office, or is unable or unwilling to meet the office-imposed timelines for completion of specific actions plans, it may request a secondary review by a designation review committee as defined in subsection (o)(3)(B) of this section.

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

(IV) 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.

(V) 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.

(VI) 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;

(6) notify the office; its RAC plus other affected RACs; and the healthcare facilities to which it customarily transfers-out trauma patients or from which it customarily receives trauma transfers-in, if it no longer provides trauma services commensurate with its designation level.

(A) If the facility chooses to apply for a lower level of trauma designation, it may do so at any time; however, it shall be necessary to repeat the designation process. There shall be a paper review by the office to determine if and when a full survey shall be required.

(B) If the facility chooses to relinquish its trauma designation, it shall provide at least 30 days notice to the Office, the RAC, other affected RACs; and healthcare facilities to which it customarily transfers-out trauma patients or from which it customarily receives trauma patients of the change(s) in capabilities defining existing trauma designation level.

(C) It shall be necessary to repeat the trauma designation process.

(D) There shall then be a paper review by the office to determine if and when a full survey shall be required.

(t) Any facility seeking trauma designation shall have measures in place that define the trauma patient population evaluated at the facility and/or at each of its locations, and the ability to track trauma patients throughout the course of their care within the facility and/or at each of its locations in order to maximize funding opportunities for uncompensated care.

(u) 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.

(v) 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 Office and the results to the healthcare facility.

(w) 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.

(x) Advanced (Level III) Trauma Facility Criteria.

Attached Graphic

(y) Basic (Level IV) Trauma Facility Criteria.

Attached Graphic