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Jorie Klein, RN
EMS/Trauma Systems Director
Texas Department of State Health Services
1100 West 49th Street
Austin, TX 78756-3199

Re: Proposed rule changes - §157.125
Requirements for Trauma Facility Designation

Dear Ms. Klein:

Texas EMS, Trauma & Acute Care Foundation (TETAF) appreciates the opportunity to submit public comment on the proposed Requirements for Trauma Facility Designation, Texas Administrative Code §157.125 that were last approved in December 2016. TETAF has surveyed all 251 current Level III and Level IV trauma facilities and advocates for all 301 Texas trauma facilities. This experience has given our organization a comprehensive knowledge of the processes in hospitals that are providing care to trauma patients in Texas.

With consideration based on TETAF's established role in the verification of Level III and Level IV trauma centers in Texas, TETAF recommends the implementation for compliance to these rules be changed to one year from the date of adoption. This will allow hospitals reasonable and adequate time to implement new requirements.

TETAF provides the following additional comments regarding the proposed Requirements for Trauma Facility Designation:

Definitions:

§157.2(31): Concurrent performance improvement – Performance improvement reviews that occur at the same time as the patient's hospital admission, beginning on the next operational business day of the patient's admission, and continuing throughout the patient's hospital course. All events are identified within 30 business days after the patient is discharged allowing for timely review, interventions, and corrective actions.

§157.2(32): Concurrent trauma registry abstraction – Trauma registry data abstraction and registry data entry occurring at the same time as the patient's hospital admission, beginning on the next operational business day of the patient's admission, continuing throughout the hospital course, and completed within 60 days after the patient's discharge, allowing for timely access to data for performance improvement reviews and decision-making.

The next operational business day is stringent and does not specify a compliance percentage.

RECOMMENDATION: TETAF recommends that “next business day” be removed from both definitions. The performance improvement terminology should state “performed throughout the patient’s hospital course.” The registry definition should be consistent with (34)(C). The trauma registry must be concurrent. Registry, data abstraction, data entry, and coding must begin during the patient’s hospital admission, and be completed within 60 days of the patient’s hospital discharge, transfer, or death. This requirement must be met at a minimum of 80 percent.

§157.25(120): Rural county – A county with a population of less than 50,000 based on the latest estimated federal census population figures.

The definition of a rural county was changed by the 88th Texas Legislature to be defined as a county with a population of 68,750 or less.

RECOMMENDATION: TETAF recommends for the number 50,000 be changed to 68,750 to be consistent with state statute.

§157.2(124): Site survey – An on-site review of a trauma or stroke facility applicant to determine if it meets the criteria for a particular level of designation.

§157.125 references virtual survey options. The definition specifies on-site review.

RECOMMENDATION: TETAF recommends the definition be changed to, “a review” instead of “on-site review.”

Facility Requirements:

§157.2(9): Definition of Advanced Level III trauma facility – A hospital surveyed by a department-approved survey organization that meets the state requirements and American College of Surgeons (ACS) standards for a Level III trauma facility as described in §157.125 of this chapter (relating to Requirements for Trauma Facility Designation). The hospital is designated by the department; provides care to a defined trauma population based on the hospital's geographic location and proximity to other trauma facilities; provides injury prevention and outreach education; participates in its local RAC; submits data to the State Trauma Registry, the National Trauma Data Bank (NTDB), and the Trauma Quality Improvement Program (TQIP); and has appropriate services for dealing with stressful events for the emergency/trauma care providers.

§157.125(g)(3)(A): Advanced trauma facility designation (Level III). The facility, including a free-standing children's facility, must:

(A) meet the current ACS trauma verification standards for Level III and receive a letter of verification from the ACS, if utilizing the ACS as their survey organization, or complete a department approved survey organization survey.

The average cost of Level III TQIP is between \$8,500 and \$9,000 per year. This is a significant financial burden on the Level III trauma facilities for a limited benchmark report compared to the Level I and II reports. This poses a financial burden on the Level III trauma facilities for the cost of participation, registry costs for additional pages, and staff required to obtain and input data.

RECOMMENDATION: TETAF recommends that TQIP participation is encouraged but not be a mandatory requirement for Level III trauma facilities.

Trauma Program Personnel:

§157.125(j)(15)(A): Rural Level IV trauma facilities in a county with a population less than 30,000 may utilize telemedicine resources with an Advanced Practice Provider (APP) available to respond to the trauma patient's bedside within 15 minutes of notification, with written resuscitation and trauma management guidelines that are monitored through the trauma performance improvement and patient safety processes. (A) The APP must be current in Advanced Trauma Life Support (ATLS), annually maintain an average 16 hours of trauma-related continuing medical education and demonstrate adherence to the trauma patient management guidelines and documentation standards.

The ACS Resources for Optimal care for Injured Patient 2014 Standards, page 20, states providers must maintain current ATLS and complete at least eight hours of CME yearly.

RECOMMENDATION: TETAF recommends following the ACS guidelines that all Advanced Practice Providers providing initial evaluation and resuscitation in rural counties maintain current ATLS and complete eight hours of annual CME.

§157.125(j)(22): The facility must identify a TMD responsible for the provision of trauma care. The TMD must be credentialed and privileged by the facility for the treatment of trauma patients through all phases of care to discharge or transfer. The TMD must have authority and oversight of the trauma program and be dedicated to only one trauma facility.

This could be interpreted that the trauma medical director (TMD) cannot work at other trauma facilities.

RECOMMENDATION: TETAF recommends changing the terminology “dedicated to only one trauma facility” to align with the ACS Resources for Optimal Care of Injured Patient 2022 Standards statement of “serves as the director of a single trauma program.”

§157.125(j)(22)(A)(i-iii): The TMD must be a physician who meets the following criteria:

- (22) (A) Level I, II, III and non-rural Level IV trauma facilities must have a TMD who:
- (i) is a trauma or general surgeon that is board-certified or board-eligible;
 - (ii) demonstrates knowledge, expertise, and experience in caring for all types of trauma injuries; and
 - (iii) preferably, has completed a trauma fellowship.

RECOMMENDATION: TETAF recommends adding to (i) “or completes an alternate pathway defined by the hospital’s credentialing body for Level III and IV trauma facilities who have a trauma medical director (TMD) who is not board certified.”

The requirement that the TMD is a surgeon would impact 95 of the Level IV trauma facilities TETAF has surveyed that are classified as non-rural, by the proposed definition of greater than 50,000 in the county. Most of these have an emergency department (ED) physician as the TMD. General surgeons do not routinely participate in the care of trauma patients as multi-system trauma patients are transferred out.

RECOMMENDATION: TETAF recommends that Level IV trauma facilities that admit isolated single system orthopedic trauma are allowed to have an ED physician as the TMD with the requirement the performance improvement (PI) plan includes a physician involved in the inpatient care who will participate in the review of inpatient care and be involved in trauma PIPS and operational meetings.

A concern for statement (iii) regarding the trauma fellowship completion, especially for the Level III trauma facilities, is that most general surgeons working at Level III trauma facilities have not completed a trauma fellowship.

RECOMMENDATION: TETAF recommends trauma fellowship be removed for Level III and IV trauma facilities.

§157.125(j)(22)(K-L): The TMD must be a physician who meets the following criteria:
(22)(K) Completes a trauma performance improvement and patient safety course every four years or as updated, a course on the role of the TMD at least once; the Federal Emergency Management Agency (FEMA) Independent Study (IS) 100, 200, and 700 courses at least once or as updated; and a course on hospital preparedness, planning, and response to a disaster as defined by the ACS standards at least once
(L) Provides or facilitates annual training for trauma surgeons, trauma liaisons, or other physicians (for Level IV facilities).

The TMD at Level III and IV trauma facilities is historically a general surgeon or emergency physician in the community who has a full-time practice. The number of courses required is a financial concern for small trauma facilities including the time the provider would be away from his/her practice.

RECOMMENDATION: TETAF recommends the annual disaster preparedness training for all providers be removed from the TMD requirements. This should be the responsibility of the hospital's emergency preparedness leader and not the physician.

§157.125.(j)(B)(i-ii): Rural Level IV facilities that do not routinely admit patients meeting trauma activation guidelines and meeting NTDB registry inclusion criteria to their facility may choose to have a surgeon that is board-certified or board-eligible or an emergency medicine physician that is board-certified or board-eligible, or a family medicine physician that is board-certified or board-eligible and current in ATLS to serve as the facility's TMD:

- (i) if the individual serving as the Level IV TMD is not a surgeon or emergency medicine physician or family medicine physician that is board-certified or board-eligible, the physician must be current in ATLS; and
- (ii) the physician must annually maintain 16 hours of trauma-related continuing medical education.

The ACS Resources for Optimal Care of the Injured Patient 2014 guidelines for Level IV trauma facilities require eight hours of annual CME for the physician director who may be a PCP.

RECOMMENDATION: TETAF recommends following this guideline and reducing the required CME to eight hours annually.

§157.125(j)(23)(B): Each designated trauma facility must have an identified TPM responsible for monitoring trauma patient care throughout the continuum of care, from pre-hospital management to trauma activation, inpatient admission, rounding during inpatient stay, and transfer or discharge, to include transfer follow-up as appropriate. The role must be only for that facility and cannot cover multiple facilities. The TPM has the following authority and responsibility to:

(B) perform trauma registry data abstraction, entry, coding, and validation, injury prevention activities, and outreach education activities, and participate in RAC activities;

RECOMMENDATION: TETAF recommends the wording of (B) be changed from “perform” to “oversee” trauma registry data abstraction, entry, coding, and validation. Injury prevention and outreach are addressed in (E) using the terminology oversee instead of perform. Regional Advisory Council (RAC) participation is addressed in (I) of this section.

§157.125(j)(23)(Q): (23) Above, (Q) routinely participate or assist with trauma care at the facility.

This will result in the trauma program manager (TPM) being assigned shifts to staff the ED, especially at the Level III and IV trauma facilities.

RECOMMENDATION: TETAF recommends the terminology be changed to “be a clinically active and practicing registered nurse who oversees trauma care at the facility where the program manager services are provided.”

§157.125(j)(23)(O): (23) complete the Advancement of Automotive Medicine (AAAM) Injury Scaling Course, as it is updated; complete a TPM course at least once; and complete a trauma performance improvement course every four years, or as updated; (O) complete the FEMA IS 100, 200, and 300 courses and a disaster course on hospital preparedness, planning, and response, with the option that Level IV facilities may choose alternate trainings to the IS 300 and to the disaster course on hospital preparedness, planning, and response;

ICS 300 is an in-person course only and will require travel expenses. A prerequisite for ICS 300 is IS 100, 200, 700, and 800. The benefits of ICS 300 are questioned for the TPM position, unless the TPM is also the emergency preparedness coordinator for the trauma facility. The number of courses and frequency required is a financial concern for smaller trauma facilities.

RECOMMENDATION: TETAF recommends removing ICS 300 from the TPM requirements.

§157.125(j)(25)(A)(G)(F): The TMD, in conjunction with the trauma liaisons, defines the criteria and credentialing guidelines for the trauma service surgeons and specialty surgeons covering the trauma call schedule. The criteria must include:

(A) board-certification or board-eligibility in a defined specialty;

Not all surgeons and specialty surgeons at Level III trauma facilities are board certified or board eligible.

RECOMMENDATION: TETAF recommends adding “or meet alternate pathway as defined by hospital’s credentialing body” as an option to board certification.

(G) attendance at assigned facility-wide committees such as the medical staff committee, blood utilization committee, resuscitation committee, critical care committee, pharmacy committee.

RECOMMENDATION: TETAF recommends this be removed as it indicates every surgeon and specialty surgeon will be on a committee, or change “must include” to “may include.”

(F) participation for trauma surgeons and trauma liaisons in outreach education and injury prevention initiatives;

RECOMMENDATION: TETAF recommends this be changed from “must include” to “may include.” While this will be a challenge at all levels, it will be a burden on community surgeons and physicians providing coverage at Level III and IV trauma facilities.

§157.125(j)(35)(A)(D): The trauma facility must meet the current ACS standards for staffing requirements for the trauma registry.

(A) All trauma registrars must have a documented job description with defined core functions and an organizational structure that reports to the TPM.

(D) Trauma facilities that utilize a pool of trauma registrars must have an identified trauma registrar from the pool that is assigned to the facility to ensure data requests are addressed in a timely manner.

RECOMMENDATION: TETAF recommends an additional statement that if a pool of registrars is used, the registrar assigned to the facility may report to the TPM through a “dotted line” as most registrars report to a manager over the pool.

§157.125(j)(35)(B): All trauma registrars must complete the AAAM Injury Scaling Course, a trauma registry course, and the current International Classification of Diseases (ICD) coding class within 12 months of starting their role as a trauma registrar.

This requirement adds two additional courses for Level III trauma facilities and three courses for Level IV trauma facilities for each registrar. This poses a significant financial burden on the Level III and IV trauma facilities.

RECOMMENDATION: TETAF recommends that AAAM be the only required course and other courses are optional.

§157.125(j)(36)(C): There must be documented evidence that the highest level of trauma activation established by the facility has two registered nurses with the required education, certifications, and training responding to the activation.

Very small rural Level IV trauma facilities report they do not have two registered nurses (RNs) in the facility at all times. This would pose staffing and financial burdens on smaller trauma facilities and should be changed to one RN for rural trauma facilities.

RECOMMENDATION: TETAF recommends for this to be one RN with required certifications who will respond to activations.

Survey Team Composition:

§157.125(q)(1)(A-D): Level I or Level II facilities must be reviewed by a multidisciplinary team, consistent with current ACS standards, and include, at a minimum, two trauma or general surgeons with trauma expertise, an emergency medicine physician, and a TPM, all currently active in a verified trauma facility that currently participates in the management or oversight of trauma patients and practice outside of Texas. All aspects of the site survey process must follow the department survey guidelines.

Not all RN surveyors are TPMs.

RECOMMENDATION: TETAF recommends for all levels changing TPM to RN who is currently active in a leadership role in a verified trauma facility and currently participates in the management or oversight of trauma patients.

ACS has assigned surveyors who live in Texas to survey Texas hospitals.

RECOMMENDATION: TETAF recommends that surveyors practicing in Texas are eligible to survey within the state as long as there are no other identified conflict of interests.

§157.125(q)(3)(A): Level III facilities evaluating 1,000 or more patients per year meeting NTDB registry inclusion criteria must be reviewed by two trauma or general surgeons, an emergency medicine physician, and a TPM.

This requirement exceeds the ACS national requirement for Level I and II trauma facilities, which is two trauma surgeons for verification/reverification. While most states do include a nurse reviewer, Texas is one of five states that requires the addition of an emergency medicine physician.

RECOMMENDATION: TETAF recommends this be changed to two trauma or general surgeons or one trauma or general surgeon and one emergency medicine physician and one RN currently active in a leadership role in a verified trauma facility and who currently participates in the management or oversight of trauma patients.

§157.125(q)(3)(B): Level III facilities evaluating 300 to 999 patients per year meeting NTDB registry inclusion criteria must be reviewed by two trauma or general surgeons, or a trauma surgeon and emergency medicine physician, and a TPM.

See notes above.

RECOMMENDED: TETAF recommends this be changed to one surgeon and one RN currently active in a leadership role in a verified trauma facility and who currently participates in the management or oversight of trauma patients.

§157.125(q)(4)(A): Level IV facilities that evaluate and admit 1,000 or more patients per year meeting NTDB registry inclusion criteria must be reviewed by two trauma or general surgeons, an emergency medicine physician, and a TPM, all currently participating in trauma patient management or oversight at a Level I, II, or III designated facility.

TETAF requests clarification that the intent of this provision is based upon admissions and not total registry volume.

This requirement exceeds ACS requirements for Level I and II trauma facilities. Texas is one of five states that requires the addition of an emergency medicine physician.

RECOMMENDATION: TETAF recommends this be changed to two trauma or general surgeons or one trauma or general surgeon and one emergency medicine physician and one RN currently active in a leadership role in a verified trauma facility and who currently participates in the management or oversight of trauma patients.

§157.125(q)(4)(B): Level IV facilities that evaluate and admit 300 to 999 patients per year meeting NTDB registry inclusion criteria must be reviewed by a trauma or general surgeon, an emergency medicine physician, or two trauma surgeons or general surgeons, and a TPM, all currently participating in trauma patient management or oversight at a Level I, II, or III designated facility.

RECOMMENDATION: TETAF recommends this be changed to one general surgeon and one RN currently active in a leadership role in a verified trauma facility and who currently participates in the management or oversight of trauma patients.

§157.125(q)(4)(D): Level IV facilities that evaluate and admit 99 or fewer patients per year meeting NTDB registry inclusion criteria risk must be reviewed by a trauma or general surgeon, or an emergency medicine physician, or a TPM, currently participating in trauma patient management or oversight at a Level I, II, or III designated facility.

RECOMMENDATION: TETAF recommends this be changed to a trauma or general surgeon, an emergency medicine physician, or a RN currently active in a leadership role in a verified trauma facility and who currently participates in the management or oversight of trauma patients. The team member will be determined by the surveying organization in coordination with the facility.

§157.125(q)(4)(E): Rural Level IV or CAH facilities that evaluate fewer than 75 patients per year meeting NTDB registry inclusion criteria and do not admit these patients to their facility for trauma management, intensive care, or operative intervention will follow the department self-assessment survey guidelines and meet with the department to complete their designation survey.

RECOMMENDATION: TETAF recommends these facilities continue with a site survey conducted by a department approved surveying organization with a team composed of one RN who is active in a leadership role in a verified trauma facility and who currently participates in the management or oversight of trauma patients. Formal review by an approved surveying organization is imperative. Without formal review, it may result in less compliance by the facilities and could significantly impact care to patients across rural Texas.

Additional Comments:

RECOMMENDATION: TETAF recommends for a statement to be added that requires the department to notify the hospital of the results of its survey within 60 days of submission of required documents or will provide a detailed explanation for the delay.

RECOMMENDATION: TETAF recommends a statement be added that Level I and II trauma facilities that participate in TQIP will also participate in the Texas TQIP Collaborative and that the department will provide funding to these trauma facilities for participation in Texas TQIP.

RECOMMENDATION: TETAF recommends the implementation for compliance to these rules be changed to one year from the date of adoption. This will allow hospitals reasonable and adequate time to implement new requirements.

TETAF respectfully provides these comments and recommendations in an effort to further evolve and support trauma care across Texas. It is our hope that these joint efforts by the Texas Department of State Health Services (DSHS) and trauma stakeholders will positively enhance trauma designation requirements and result in greater quality care for trauma patients in Texas.

Please feel free to contact me with any questions or concerns.

Regards,



Dinah Welsh

President/CEO

Texas EMS, Trauma & Acute Care Foundation (TETAF)