TEXAS MEDICAL ASSOCIATION

Physicians Caring for Texans

February 16, 2024

Jorie Klein, Director of EMS/Trauma Systems Section
Texas Department of State Health Services
Attn: Proposed Trauma Rules

Submitted electronically to: DSHS.EMS-Trauma@dshs.texas.gov

Re: Comments on Proposed Trauma Designation Rules 21R151

Dear Ms. Klein:

On behalf of the Texas Medical Association (TMA), which represents more than 57,000 physicians and medical students, thank you for the opportunity to comment on the proposed revisions to the state's emergency medical system and trauma care rules (Texas Health and Safety Code, Title 25, Part 1, Chapter 157, Emergency Medical Care), as published in the *Texas Register* on Jan. 19, 2024.

The proposed revisions represent the cumulative work of a multi-year, informal rulemaking and stakeholder process designed to modernize the rules, which the Texas Department of State Health Services (DSHS) last overhauled nearly 20 years ago. Through TMA's Committee on Emergency Medical Services and Trauma (CEMST), TMA actively participated in the process, submitting comments on each iteration of revised rules. While differences of opinion on proposed changes have occurred along the way – as there are now – TMA nevertheless applauds DSHS for its collaborative, transparent approach to the rulemaking process as well as its abiding commitment to promoting a stable, statewide trauma system that fosters safe, timely, and appropriate emergency medical services and trauma care throughout the state.

Given the complexity of the rules and diverse stakeholders, we also commend DSHS for its foresight to establish an informal rule-review workgroup comprised of all major stakeholders, including TMA, who will provide pragmatic insight to the agency as it evaluates commenters' suggested revisions. We believe this process will result in the adoption of rules reflecting the agency's goals, while mitigating many of the practical and financial concerns the trauma community has regarding implementation and compliance with the new standards, if enacted.

TMA Review Process

To develop these comments, TMA's CEMST convened an informal workgroup comprised of diverse trauma-system physician stakeholders, including trauma medical directors; physician specialists with trauma care expertise (emergency medicine, trauma surgery, general surgery, orthopedics, and hospital-based care, among others); and physicians practicing in all four levels of trauma-designated hospitals.

Commenters, to a person, supported the general goals of the rules – to enhance patient safety, clinical outcomes, programmatic oversight and accountability, and physician leadership and involvement – as well as language aligning the state's trauma standards with those of the American College of Surgeons (ACS), a change that will help ensure the state's rules remain current with periodic ACS revisions to its designation criteria and national trauma standards. This change will be particularly important for Level I, II, and III trauma facilities, which ACS surveys during the designation process.

However, reviewers also felt many components of the rules are overly prescriptive or unrealistic, as enumerated in our comments below. Without revisions, the new requirements could inadvertently deter physicians from accepting leadership roles within trauma facilities. Moreover, compliance with several components of the proposed rules could dissuade Level IV facilities – the backbone of the trauma system – from maintaining trauma designation.

General and Specific Comments

1. §157.2. Definitions.

- ✓ **(121)** [~~(81)~~] Scope of practice or services--The procedures, actions, and processes that [~~an~~] EMS personnel are permitted to undertake in keeping with the terms of their professional license or certification and approved by their EMS provider's medical director; or the types of services and the resources to provide those services that a facility has available.

Comment: TMA has concerns with the combined definition for "scope of practice or services." "Scope of practice" and "scope of services" are distinct terms that are not interchangeable. Particularly, "scope of practice" refers to permissible conduct based on an individual's licensure or certification, while "scope of services" refers to the services available at a facility. Notably, the term "scope of practice or services" is not used or proposed anywhere in Chapter 157 except in the proposed §157.2(121), whereas "scope of practice" can be found in §157.11(k) and "scope of services" in proposed §157.125(j).

For these reasons, **TMA recommends amending proposed §157.2 to establish two separate definitions as follows:**

(121) [~~(81)~~] Scope of practice ~~or services~~--The procedures, actions, and processes that [~~an~~] EMS personnel are authorized to undertake in keeping with the terms of their professional license or certification and approved by the EMS provider's medical director.

New (122) Scope of services--~~; or the~~ The types of services and the resources to provide those services that a facility has available.

- ✓ **(146)** Trauma care--Care provided to an injured patient meeting the hospital's trauma activation guidelines and meeting NTDB registry inclusion criteria and the continuum of care throughout the system, including discharge and follow-up care or transfer.

Comment: As proposed, the rules will define "trauma care" to require that trauma activation guidelines *and* the National Trauma Data Bank (NTDB) registry inclusion criteria be met. The TMA workgroup expressed considerable concern about this definition, recommending DSHS amend the definition to specify that the term "trauma care" is defined based either on trauma activation guidelines *or* NTDB registry inclusion criteria (but not both).

If both the activation and registry criteria must be met, many patients who should be counted as trauma patients will be excluded from that count. At the same time, the workgroup recognized that there are pros and cons to each criterion. For example, trauma activation may include geriatric patients following a significant fall. However, if the clinical team determines the fall resulted from a medical condition, such as stroke, instead of trauma, the services provided will still be considered a trauma service under this definition. Likewise, some patients meet the requirements for NTDB registry inclusion, yet no trauma activation actually occurred. As such, the definition for "trauma care," as it stands, is too prescriptive and risks underestimating the state's volume of trauma patients.

We recommend DSHS, with input from its rule-review workgroup, reassess the merits of each criteria and create an accurate definition for "trauma care" that does not unduly affect the accounting of trauma patients in Texas. If facilities must meet both the trauma activation guidelines and NTDB registry inclusion criteria, TMA is very concerned the number of defined "trauma patients" will be inaccurately decreased.

Similarly, TMA asks DSHS to thoughtfully reconsider – with TMA's stated concerns in mind, and with input from DSHS's rule-review workgroup – each instance in the proposed rules that requires or depends on both trauma activation guidelines *and* NTDB registry inclusion criteria being met.[1]

2. §157.125. Requirements for Trauma Facility Designation.

✓ **Non-Contiguous Emergency Department of a Hospital Operating on a Single Hospital License**

(d)(3)(C) Each non-contiguous emergency department of a hospital operating on a single hospital license must recognize, respond, resuscitate, and transfer patients using the same trauma activation guidelines as the main hospital for trauma patients.

Comment: TMA disagrees with requiring non-contiguous emergency departments operating under a single hospital license to use the same trauma activation guidelines as the main facility.

We certainly agree that appropriate and timely trauma activation can improve patient outcomes by ensuring the facility has appropriate resources to diagnose, stabilize, and treat trauma patients. Moreover, studies indicate appropriate activation can "decrease time in the emergency department, decrease time to obtain imaging, decrease time to the operating room and fewer missed injuries." [2] At the same time, there is research indicating "trauma team activations should occur according to predetermined, *institution-specific criteria*."[3] (emphasis added)

We recommend basing activation on the facility's capabilities, not the main campus' designation. Many large trauma systems encompass facilities with a variety of trauma designations, suited to the campus, patient population, clinical services, and resources.

✓ **Level IV Requirements for Injured Patients with Injury Severity Score of 11 or Greater**

---

[1] See definitions for "calculation of the costs of uncompensated care," "operative or surgical intervention," "severe trauma patient," "trauma," and "trauma patient," in proposed §157.2(24), (99), (122), (142), and (151), respectively, as well as in proposed §157.123(h) and proposed §157.125 (j)(4)(N)-(O), (11)(Q), (12), (17), (22)(B), (23)(S), (24), (26)(B), and (36).

[2] CAN. J. OF SURG., A quality-improvement approach to effective trauma team activation (Oct. 2019).

[3] Id.

> **(h)** A Level IV facility that admits trauma patients to their intensive care unit (ICU) or performs operative interventions on injured patients meeting their trauma activation guidelines and meeting National Trauma Data Bank (NTDB) registry inclusion criteria and have a projected injury severity score (ISS) of 11 or greater must meet the Level III ACS verification standards for the laboratory, blood bank, operating suite, ICU, and rehabilitation.

Comment: TMA supports DSHS' efforts to ensure Level IV trauma facilities that routinely treat patients with severe injuries have appropriate resources onsite to promote timely and appropriate diagnosis, stabilization, and treatment. In earlier iterations of the rules, DSHS proposed a similar standard using a projected ISS score of 9, a score most stakeholders felt was too restrictive because it encompassed many non-trauma orthopedic services. TMA appreciates DSHS rejecting the earlier version and proposing a more workable compromise.

While physicians believe the new standard is an important patient safety measure, it also presents compliance challenges because facilities will be required to determine the patient's *projected* ISS score. As DSHS knows, ISS scores are calculated after evaluation and treatment, not concurrently at the bedside. Thus, it is unclear how facilities will determine a projected score without more guidance and uniformity in the criteria. If DSHS proceeds with the change, TMA recommends phasing in the requirement only after it develops criteria that facilities and medical staffs can use to develop a *projected* score.

- ✓ **Patient Rounding**

> **(j)(4)(I)** measures for *rounding* on admitted trauma patients to complete a tertiary exam and to facilitate the continuum of care through discharge or transfer; (emphasis added)
>
> **(j)(23)** 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. (emphasis added)

Comment: TMA agrees that patient rounding is a vital function. However, proposed §157.2(119) defines "rounding" to include functions beyond the role of the hospital's trauma services, including requiring: "continual patient assessment of the progression of care to ensure management guidelines are followed, identify potential complications or variances in care, ensure measures to facilitate the patient and family's goals of care and inclusion in the care plan, and facilitate patient discharge planning and understanding of post-discharge instructions."

Based on this proposed definition, the responsibilities for rounding are much broader than what is specified within proposed §157.125(j)(4)(I). We believe several elements outlined within the definition, including continual patient assessment of the progression of care…," are responsibilities better assigned to the facility's general medical and surgical departments, following the patient's transfer from trauma services. We recommend revising the proposed rules to differentiate the rounding requirements of the trauma services division and the other clinical services within the facility, while still promoting seamless hand off from trauma to other services.

- ✓ **Transfer Process Between Facilities**

(j)(11) Written trauma management guidelines specific to the hospital that align with evidence-based practices and current national standards must be reviewed a minimum of every three years by the trauma operations committee. Guidelines must be established for the following:

…

(Q) transfer processes to ensure that when the evaluating physician defines an acutely injured patient who meets trauma activation guidelines and meets NTDB registry inclusion criteria with a projected ISS of 11 or greater, the transfer must be to a higher-level trauma facility or specialty resource facility such as a burn center. If the patient is not transferred to a higher level of trauma facility:

(i) the transfer must be reviewed through the trauma performance improvement and patient safety process by the TMD for appropriateness of transfer and the patient's outcome; and

(ii) the TMD's review must include feedback from the accepting facility;

Comment: The rule specifies hospitals must have a transfer policy in place for injured patients with an ISS of 11 or greater to a *higher-level* trauma facility. However, in some situations, the transfer might be more appropriate to a facility with the same designation level, but that has necessary services, such as a burn unit, or from a Level I to a Level II facility for the same reason – the originating hospital does not have the services needed.

As worded, TMA is concerned that in such situations, hospital administrators will advise physicians they cannot transfer between Level II and Level I facilities when there are very appropriate, patient-centered reasons to do so. An example could be a patient who falls and suffers a hip fracture, multiple abrasions and contusions, and significant orbital/globe injury and needs acute care from an oculoplastic surgeon who is only available at a Level II facility. Any Level I or II facility that would transfer this patient would have "violated the rule," when it was in the best interest of the patient and care for the other injuries would not be compromised.

TMA recommends revising the language to mirror the American College of Surgeons' Verification Review Committee's *Resources for Optimal Care of the Injured Patient (2022 Standards)*:

> (Q) transfer processes to ensure that when the evaluating physician defines an acutely injured patient who meets trauma activation guidelines and meets NTDB registry inclusion criteria with a projected ISS of 11 or greater, the transfer must be based solely on the needs of the patient, without consideration of their health plan or payor status ~~to a higher-level trauma facility or specialty resource facility such as a burn center~~. If the patient is not transferred to a higher level of trauma facility: …

Alternatively, we recommend DSHS clarify that transfers be based solely on the needs of the patient.

> (Q) transfer processes to ensure that when the evaluating physician defines an acutely injured patient who meets trauma activation guidelines and meets NTDB registry inclusion criteria with a projected ISS of 11 or greater, the transfer must be based solely on the needs of the patient ~~to a higher-level trauma facility or specialty resource facility such as a burn center~~. If the patient is not transferred to a higher level of trauma facility: …

✓ **Trauma Medical Director (TMD)**

(j)(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.

Comment: **TMA strongly objects to proposed new language requiring non-rural Level IV facilities to appoint either a trauma or general surgeon as the TMD**. Already, Level I, II, and III trauma facilities struggle to attract general surgeons, particularly those with an interest in trauma care. State and national data indicate the number of physicians practicing general surgery has not kept up with the demographic trends, including the medical needs of an aging population.

Additionally, the scope of services provided at a non-rural Level IV facility does not necessarily require a TMD board certified in surgery or eligible within this specialty. Thus, instating this new provision will make it very difficult for non-rural Level IV facilities to comply, while also deterring urban hospitals from seeking a Level IV designation. More importantly, we believe the requirements will impede higher level facilities from recruiting and retaining these surgeons because they will be competing for them against even more facilities. Yet, it is Level I-III facilities that must have the specialized skills and expertise of these physicians in order to provide higher-level trauma services. Likewise, the requirement will make it more difficult for rural Level IV facilities to recruit and maintain a roster of general surgeons available for on-call care, including those called to assist in cases of obstetrical emergencies.

Additionally, proposed §157.125(j)(22)(A)(iii) establishes a preference for physicians with a trauma fellowship. While a trauma fellowship is not a requirement, the expectation is nevertheless unrealistic. Few physicians complete trauma fellowships. According to the American Association for the Surgery of Trauma, there are only 152 fellowships across the country focused on trauma, surgical critical care, acute care surgery, and burns. If this provision remains, it should be limited only to Level I facilities.

Generally: **(j)(22)(A)-(L)**

Comment: Proposed §157.125(j)(22) of the rules defines the roles and responsibilities a TMD must fulfill in order for a facility to obtain and maintain trauma designation. High-functioning trauma systems understand the key role the TMD plays in providing oversight and accountability for the delivery of trauma care as well as ensuring coordination with and participation in the facility's trauma region. With the exception of our comments above (regarding the requirement that non-rural Level IV facilities have a surgeon as the TMD), we do not quibble with the state's TMD expectations. After thoroughly reviewing each responsibility within this subsection, TMA agrees with each of them because they are all important.

At the same time, the definition of a TMD and the actual requirements must be aligned to allow greater flexibility to fulfill the TMD's numerous responsibilities.

Particularly, proposed §157.2(150) specifies that the TMD "has the authority and *oversight* for the trauma program." (emphasis added) Yet, throughout subsection (j)(22)(A)-(L), the language implies the TMD must personally fulfill many of the functions rather than delegating them to a qualified physician member of the facility's trauma team.

For example, proposed §157.125(j)(22)(G) requires the TMD to be a member of the facility's disaster planning and preparedness committee, yet participation in this committee might be better suited to another physician at the facility with expertise in disaster response, who in turn regularly meets with the TMD to inform him or her of that work. Likewise, proposed subsection (j)(22)(I) states the TMD "must

serve on the RAC trauma committee, disaster preparedness activities, and medical director committee as defined by the RAC bylaws," yet these functions might be better fulfilled either partially or fully by a TMD's designee(s).

Additionally, proposed §157.125(j)(22)(C) and (Y) rightly require the TMD to "regularly and actively participate in trauma care" and prepare for the TMD's succession, respectively. Yet, how is a TMD to fulfill either responsibility if so much of his or her time is required to attend operational, planning, and clinical meetings?

TMA recommends revising the rules to give the TMD discretion to delegate required functions to other physicians or clinicians (as appropriate), while also retaining responsibility and authority for ensuring the TMD's office is actively engaged in all trauma functions pertaining to system preparedness, operations, and clinical oversight.

✓ **Rural versus Non-Rural Level IV Trauma Facilities**

In lieu of establishing designation criteria for a Level IV facility based on county population – that is, the rural versus non-rural status of the facility – we recommend developing designation criteria that are focused on the hospital's capabilities. Some rural Level IV facilities have capabilities more similar to Level III, while some urban Level IV facilities operate trauma services akin to a small rural community.

While some statutory and/or budgetary provisions within the state's trauma program distinguish between rural and urban, we believe it is more appropriate to designate based on each facility's resources, capacity, and patient care capabilities.

Conclusion

Thank you again for DSHS' collaborative rule-making process as well as ongoing stakeholder dialogue. We believe this approach will help the state's trauma care stakeholders achieve our mutual goals to enhance patient safety and health outcomes, while also providing DSHS greater insight regarding why it must revisit new operational, managerial, and financial requirements that could inadvertently undercut compliance, increase costs, or deter hospitals from remaining within the trauma program.

Should you have any questions, please contact Kathryn Clarke, at kathryn.clarke@texmed.org, director of health care quality, or Kelly Flanagan, associate general counsel, at kelly.flanagan@texmed.org.

Sincerely,

Rick W. Snyder, II, MD
President, Texas Medical Association

cc: Hilary Fairbrother, MD, Chair, TMA Committee on EMS and Trauma