

PROPOSED RULES

Proposed rules include new rules, amendments to existing rules, and repeals of existing rules. A state agency shall give at least 30 days' notice of its intention to adopt a rule before it adopts the rule. A state agency shall give all interested persons a reasonable opportunity to

submit data, views, or arguments, orally or in writing (Government Code, Chapter 2001).

Symbols in proposed rule text. Proposed new language is indicated by underlined text. [~~Square brackets and strikethrough~~] indicate existing rule text that is proposed for deletion. "(No change)" indicates that existing rule text at this level will not be amended.

TITLE 25. HEALTH SERVICES

PART 1. DEPARTMENT OF STATE HEALTH SERVICES

CHAPTER 157. EMERGENCY MEDICAL CARE

The Executive Commissioner of the Texas Health and Human Services Commission (HHSC), on behalf of the Department of State Health Services (DSHS), proposes amendments to §157.2, concerning Definitions, and §157.128, concerning Denial, Suspension, and Revocation of Trauma Facility Designation; the repeal of §157.123, concerning Regional Emergency Medical Services/Trauma Systems; §157.125, concerning Requirements for Trauma Facility Designation; §157.130, concerning Emergency Medical Services and Trauma Care System Account and Emergency Medical Services, Trauma Facilities, and Trauma Care System Fund; and §157.131, concerning Designated Trauma Facility and Emergency Medical Services Account; and new §157.123, concerning Regional Advisory Councils; §157.125, concerning Requirements for Trauma Facility Designation; and §157.130, concerning Funds for Emergency Medical Services, Trauma Facilities, and Trauma Care Systems, and the Designated Trauma Facility and Emergency Services Account.

BACKGROUND AND PURPOSE

The purpose of the proposal is to update the content and processes with the advances, evidence-based practices, and system processes that have developed since these rules were adopted. The rules also require updates since legislation has been passed since the rules were adopted. Senate Bill (S.B.) 330, 79th Legislature, Regular Session, 2005, requires the development of regional stroke plans. House Bill (H.B.) 15, 83rd Legislature, Regular Session, 2013, and H.B. 3433, 84th Legislature, Regular Session, 2015, require the development of perinatal care regions. S.B. 984, 87th Legislature, Regular Session, 2021, directs the Regional Advisory Councils (RACs) to collect specific health care data. S.B. 969, 87th Legislature, Regular Session, 2021, directs the RACs to provide public information regarding public health disasters to stakeholders. S.B. 1397, 87th Legislature, Regular Session, 2021, directs a RAC to track all transfers and the reason for the transfer out of its region.

SECTION-BY-SECTION SUMMARY

The amendment to §157.2, concerning Definitions, integrates terminology for the RACs, emergency medical systems, trauma facilities, and stroke facilities. The definitions include stroke designation terminology and current national standards. The defini-

tions reflect terms for the trauma and emergency health care system, emergency medical services (EMS), trauma center management, and stroke center management.

The repeal of §157.123, concerning Regional Emergency Medical Services/Trauma Systems is replaced with new §157.123, concerning Regional Advisory Councils (RACs), which defines the requirements and functions of the RACs. S.B. 330 amended Texas Health and Safety Code Chapter 773, directing the development of systems of stroke survival, creating a process for stroke designation and regional stroke system plans. H.B. 15 and H.B. 3433 require the development of rules for maternal and neonatal facility designation and the development of perinatal care regions to develop perinatal systems of care. S.B. 1397 adds Texas Health and Safety Code §773.1141, requiring the tracking of all patients transfers out of the identified RAC and the reasons for the transfers. S.B. 984 directs the RACs to collect specific health care data to facilitate emergency response planning and preparedness. S.B. 969 directs the RACs to provide public information regarding public health disasters to stakeholders. The proposed new language of §157.123 integrates these legislative requirements into the rule. New §157.123 uses the term "department" instead of the legacy name "bureau of emergency management (bureau)." Subsection (a) describes a RAC. Subsection (b)(2)(A) requires the RAC to submit a summary of activities validating that all performance criteria are met. Subsection (b)(2)(C) requires the RAC to complete a regional self-assessment, revise the system plan the following year, and have documented evidence that all RAC performance criteria are met. Subsection (c) defines the elements of a regional trauma and emergency health care system plan. Subsection (d) integrates language from S.B. 969 and S.B. 984 into the RAC requirements. Subsection (e) integrates S.B. 1397 requirements for the identified RAC to establish an advisory committee that will develop regional protocols for managing dispatch, triage, transport, and transfer of patients. EMS providers and hospitals are required to collect and report to the RAC data on patients transferred outside of the RAC following established regional protocols. Subsection (f) states the RAC must meet performance criteria to ensure the mission of the regional system is maintained. Subsection (g) defines the relinquishment procedures for a RAC. Subsection (h) describes the procedures to validate RAC documents for compliance.

The repeal of §157.125, concerning Requirements for Trauma Facility Designation, is replaced with new §157.125, concerning Requirements for Trauma Facility Designation. The new section replaces the rule adopted in December 2006, with specific changes from 2019 to integrate the use of telemedicine for facilities that are in a county of less than 30,000 people. New §157.125 defines the requirements hospitals must meet to achieve trauma facility designation. The new rule reflects the national standards for trauma centers as outlined by the Amer-

ican College of Surgeons (ACS). New §157.125 uses the word "department" instead of the legacy name "Office of Emergency Medical Services (EMS)/Trauma Systems Coordination (office)." Subsection (a) defines that the department designates hospital applicants as trauma facilities. Subsection (b) describes the documents required for a designation application. Section (c) outlines the steps for approval of a designation application. Subsection (d) defines the eligibility requirements for trauma facility designation. Subsection (e) clarifies that each facility location where inpatients receive hospital services and care may choose to seek separate designation. Subsection (f) describes facilities seeking trauma designation to be validated by a survey organization. Subsection (g) defines the four levels of trauma facility designation. Subsection (g)(1)(A), (2)(A), (3)(A), and (4)(A) integrate the ACS standards into the rule requirements for designation for all levels of trauma centers. Subsection (h) states that Level IV facilities that admit trauma patients to their intensive care unit (ICU) or perform operative interventions on injured patients meeting their trauma activation guidelines or National Trauma Data Bank (NTDB) inclusion criteria or have a projected injury severity score of 11 or greater must meet the Level III ACS verification standards for the laboratory, blood bank, operating suite, ICU, and rehabilitation. Subsection (i) states that Level IV facilities will utilize the most current ACS criteria in addition to the state trauma facility requirements to achieve designation.

Subsection (j) defines the requirements for trauma designation. Subsections (j)(1) and (2) define that facilities seeking trauma designation must meet RAC participation requirements. Subsection (j)(2) states facilities must have evidence of quarterly submission to the State Trauma Registry. Subsection (j)(4) states the facility must maintain a written trauma operational plan for the program. Subsection (j)(10) requires the Chief Executive Officer, Chief Nursing Officer (CNO), Chief Operating Officer, and trauma administrator, in conjunction with the Trauma Medical Director (TMD) and Trauma Program Manager (TPM), to have processes to monitor and track trauma fees and trauma patient uncompensated care; the operational cost of the trauma program; data to assist with completing the uncompensated care grant application; and provide evidence of how these funds are used to demonstrate improvements in the facility's trauma program. Subsection (j)(11) requires the facility to have written trauma management guidelines for the hospital. Subsection (j)(13) states the facilities must complete an annual online Pediatric Readiness Survey. Subsection (j)(15) states rural Level IV trauma facilities in a county with a population of less than 30,000 may utilize telemedicine resources with an Advanced Practice Provider (APP). Subsections (j)(20) state that the facility must maintain medical records that facilitate documentation and integrate the EMS wristband number and substance misuse screening and interventions. Subsection (j)(21) states the facility must have an organized, effective trauma service that is recognized in the medical staff bylaws. Subsection (j)(22) defines that a trauma facility must have a TMD responsible for the provision of trauma care and defines the requirements. Subsection (j)(22)(B) states rural Level IV facilities that do not routinely admit patients meeting trauma activation guidelines and meeting NTDB inclusion criteria may choose to have a board-certified surgeon, emergency medicine physician, or family practice physician serve as their TMD. Subsection (j)(23) states each designated trauma facility must have an identified TPM. Subsection (j)(24) allows rural Level IV or critical access hospital facilities that have 75 or fewer patients annually meeting trauma activation guidelines or NTDB inclusion criteria and do not admit these patients to their facility

for injury management, operative intervention, or intensive care, may choose to utilize a part-time registered nurse in the TPM role, or to integrate the TPM job functions into the CNO's position, as long as the performance improvement process and trauma registry processes are concurrent. Subsection (j)(25) states the TMD, in conjunction with the trauma liaison, defines the criteria and credentialing guidelines for the trauma service surgeons and specialty surgeons covering trauma calls. Subsection (j)(27) states a trauma facility must have a continuous trauma Performance Improvement Patient Safety (PIPS) plan. Subsection (j)(30) states the trauma PIPS plan must outline the roles and responsibilities of the trauma operations committee and its membership. Subsection (j)(31) requires the trauma facility to define who will attend the trauma multidisciplinary peer review committee and have documentation that reflects a minimum of 50 percent attendance. Subsection (j)(34) requires the facility to submit required trauma data every 90 days or quarterly to the State Trauma Registry and have documented evidence of data validation and correction of identified errors or blank fields. Subsection (j)(37)(A) requires the Level I trauma facilities to provide outreach education to the rural facilities in their region. Subsection (j)(38) defines that the trauma facility must have an individual responsible for injury prevention and public education. Subsection (j)(40) states the trauma facility must have a process in place to provide trauma patient outcomes and feedback to EMS providers.

Subsection (k) outlines the process for facilities seeking trauma designation or renewal of designation to submit the application packet. Subsection (l) defines the process for initial trauma facility designation. Subsection (m) states that facilities seeking designation renewal must submit the required documents to the department no later than 90 days before the facility's current trauma designation expiration date. Subsection (n) clarifies the application will not be processed if a facility fails to submit the required application documents and designation fee. Subsection (o) clarifies requirements if a facility requests a different level of care or change in ownership or physical address. Subsection (p) outlines the facility's requirements for scheduling a designation survey through a department-approved survey organization. Subsection (q) defines the requirements for the survey team composition. Subsection (r) requires the survey organizations to follow the department survey guidelines and outlines the conflict of interest for site survey team members. Subsection (s) clarifies that Level I, II, and III facilities using the ACS verification program who do not receive a letter of verification and facilities surveyed by the department-approved survey organization with four or more requirements not met must schedule a conference call with the department. Subsection (t) defines that if a facility's trauma designation expires, the facility must wait six months and begin the process again if they choose to continue as a designated trauma facility. Subsection (u) defines the appeal process for trauma facilities. Subsection (v) outlines the processes for facilities to notify their RAC when the facility's capabilities or capacity to manage trauma patients change and outlines the process to request a waiver or exception for a specific designation requirement. Subsection (w) clarifies that facilities seeking a higher level of designation cannot claim or advertise the higher level of designation until the facility has been awarded the designation level. Subsection (x) states that a hospital providing trauma service must not use or authorize any public communication or advertising containing false, misleading, or deceptive claims regarding their designation level. Subsection (y) states that during a survey, the department or surveyor has the right to review and evaluate trauma patient records, trauma multidisciplinary

plinary performance improvement plan and process documents, and appropriate committee minutes. Subsection (z) states that the department and department-approved survey organizations comply with all relevant laws related to confidentiality.

Section 157.128, concerning Denial, Suspension, and Revocation of Trauma Facility Designation was adopted in September 2000. The amendment changes the legacy name "Office of EMS/Trauma Systems Coordination (office)" to "department" throughout the rule. Subsection (a) updates the reasons why a facility designation may be denied, suspended, or revoked. Subsection (c) describes the appeal process. Subsection (d) clarifies that six months after a facility is denied designation, the facility may reapply for designation. Subsection (e) clarifies that one year after a facility's designation is revoked, the facility may reapply for designation. Subsection (f) adds that the department will inform the facility of the potential funding implications related to the designation denial, suspension, or revocation.

The repeal of §157.130, concerning Emergency Medical Services and Trauma Care System Account and Emergency Medical Services, and the repeal of §157.131, concerning Designated Trauma Facility and Emergency Medical Services Account, are necessary to integrate the rule text in new §157.130, concerning Funds for Emergency Medical Services, Trauma Facilities, and Trauma Care Systems, and the Designated Trauma Facility and Emergency Medical Services Account. New §157.130(a)(1) integrates the subdivision of a fund under Texas Health and Safety Code Chapter 780. Subsection (a)(4) reorganizes all funding requirements specific to the EMS allocation. Subsection (a)(4)(B) describes how EMS providers may contribute funds for a specified purpose within a trauma service area (TSA). Subsection (a)(5) reorganizes all requirements for the TSA allocation into one section. Subsection (a)(6) reorganizes all requirements for hospital allocation into one section. Subsection (b) outlines the formula calculation allocations for EMS, RACs, and hospitals. Subsection (c) states that if the department finds that an EMS, RAC, or hospital has violated Texas Health and Safety Code Chapter 773 or fails to comply with this chapter, the department may withhold account monies for a period of three years, depending on the seriousness of the infraction.

FISCAL NOTE

Christy Havel Burton, DSHS Chief Financial Officer, has determined that for each year of the first five years that the rules will be in effect, enforcing or administering the rules will not have foreseeable implications relating to costs or revenues of state or local governments.

GOVERNMENT GROWTH IMPACT STATEMENT

DSHS has determined that during the first five years that the rules will be in effect:

- (1) the proposed rules will not create or eliminate a government program;
- (2) implementation of the proposed rules will not affect the number of DSHS employee positions;
- (3) implementation of the proposed rules will result in no assumed change in future legislative appropriations;
- (4) the proposed rules will not affect fees paid to DSHS;
- (5) the proposed rules will create new rules;
- (6) the proposed rules will expand existing rules by providing telemedicine options in non-rural counties, allowing facilities to

request an exception for a designation requirement, and providing structure for the designation appeal process;

(7) the proposed rules will not change the number of individuals subject to the rules; and

(8) the proposed rules will not affect the state's economy.

SMALL BUSINESS, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYSIS

Christy Havel Burton has determined that there may be an adverse economic effect on small businesses, micro businesses, or rural communities relating to hospitals meeting the designation requirements due to the advances in trauma care practices, advances in technology, and clinical resource needs since the adoption of the rule in 2004. Costs are associated with complying with requirements.

Texas has approximately 108 rural trauma designated facilities that may incur additional costs to comply with the proposed Level IV trauma designation requirements.

LOCAL EMPLOYMENT IMPACT

Texas Government Code §2001.0045 does not apply to these rules because the rules are necessary to protect the health, safety, and welfare of the residents of Texas; and are necessary to implement legislation that does not specifically state that §2001.0045 applies to the rules.

PUBLIC BENEFIT AND COSTS

Timothy Stevenson has determined that for each year of the first five years the rules are in effect, the public benefit includes improved quality of care, improved data reflecting trauma outcomes, improved regional system development, and advancements in the EMS/Trauma Systems by aligning the Texas trauma system to current national standards, advances in clinical care, evidence-based practice for trauma care, data management, and regional coordination.

Christy Havel Burton has also determined that for the first five years the rules are in effect, any economic costs to the persons regarding the proposed rules are related to complying with the requirements that align the Texas system with current national standards. Trauma designation is voluntary and the choice of the facility.

TAKINGS IMPACT ASSESSMENT

DSHS has determined that the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Texas Government Code §2007.043.

PUBLIC COMMENT

Written comments on the proposal may be submitted to Jorie Klein, Director of EMS/Trauma Systems Section, DSHS, Attn: Proposed Trauma Rules, P.O. Box 149347, Mail Code 1876, Austin, Texas 78714-3247; street address 1100 West 49th Street, Austin Texas 78756; or by email to DSHS.EMS-Trauma@dshs.texas.gov.

To be considered, comments must be submitted no later than 31 days after the date of this issue of the *Texas Register*. Comments must be (1) postmarked or shipped before the last day of the comment period, (2) hand-delivered before 5:00 p.m. on the last working day of the comment period, or (3) emailed before midnight on the last day of the comment period. If the last day to submit comments falls on a holiday, comments must be

postmarked, shipped, or emailed before midnight on the following business day to be accepted. When emailing comments, please indicate "Comments on Proposed Trauma Designation Rules 21R151" in the subject line.

SUBCHAPTER A. EMERGENCY MEDICAL SERVICES - PART A

25 TAC §157.2

STATUTORY AUTHORITY

The amendment is authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies; Texas Health and Safety Code Chapter 773 (Emergency Health Care Act), which authorizes the commissioner to adopt rules to implement emergency medical services and trauma care systems; Texas Health and Safety Code Chapter 773, Subchapter G, which provides for the authority to adopt rules related to emergency medical services and trauma services; and Texas Health and Safety Code §1001.075, which authorizes the Executive Commissioner of HHSC to adopt rules and policies for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code Chapter 1001.

The amendment is authorized by Texas Government Code Chapter 531; and Texas Health and Safety Code Chapters 773 and 1001.

§157.2. Definitions.

The following words and terms, when used in this chapter [these sections], [shall] have the following meanings, unless the context clearly indicates otherwise:

(1) Abandonment--Leaving a patient without appropriate medical care once patient contact has been established, unless emergency medical services personnel are following the medical director's protocols or [;] a physician directive₂, or the patient signs a release; or turning the care of a patient over to an individual of lesser education when advanced treatment modalities have been initiated.

(2) Accreditation--Formal recognition by a national association of a provider's service or an education program based on standards established by that association.

(3) Act--Emergency Health Care [Medical Services] Act, Texas Health and Safety Code Chapter 773.

(4) Active pursuit of department designation as a trauma facility--An undesignated facility that is recognized by the department after applying for designation as a trauma facility and has met the requirement to be eligible for uncompensated trauma care funds.

(5) Acute Stroke-Ready Level IV stroke facility--A hospital that is reviewed by a department-approved survey organization and meets the national stroke standards of care for an acute stroke-ready facility as described in §157.133 of this chapter (relating to Requirements for Stroke Facility Designation). The hospital is designated by the department, participates in its local Regional Advisory Council (RAC), participates in the regional stroke plan, and submits data to the department, as requested.

(6) [(4)] Administrator of Record (AOR)--The administrator for an emergency medical services (EMS) [EMS] provider who meets the requirements of the Texas Health and Safety Code [;] §773.05712 [and §773.0415].

(7) [(5)] Advanced Emergency Medical Technician (AEMT)--An individual who is certified by the department and is minimally proficient in performing the basic life support skills required to provide emergency prehospital or interfacility care and initiating and maintaining, under medical supervision, certain advanced life support procedures, including intravenous therapy and endotracheal or esophageal intubation.

(8) Advanced Level II stroke facility--A hospital that completes a site survey with a department-approved survey organization and meets the national stroke standards for Non-Comprehensive Thrombectomy Stroke Center. The hospital is designated by the department, participates in the hospital's local RAC, participates in the regional stroke plan, and submits data to the department, as requested, as defined by §157.133 of this chapter.

(9) 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.

(10) [(6)] Advanced life support (ALS)--Emergency prehospital or interfacility care that uses invasive medical acts, [and] which would include ALS assessment. The provision of advanced life support must [shall] be under the medical supervision and control of a licensed physician.

[(7) Advanced life support (ALS) vehicle--A vehicle that is designed for transporting the sick and injured and that meets the requirements of §157.11(j)(2) of this title (relating to Requirements for an EMS Provider License) as an advanced life support vehicle and has sufficient equipment and supplies for providing advanced level of care based on national standards and the EMS provider's medical director approved treatment protocols.]

(11) [(8)] Advanced life support [Life Support] assessment--Assessment performed by an AEMT or paramedic that qualifies [qualify] as advanced life support based upon initial dispatch information, when it could reasonably be believed that the patient was suffering from an acute condition that may require advanced skills.

(12) Advanced life support vehicle--A vehicle that is designed for transporting the sick and injured and that meets the requirements of §157.11 of this chapter (relating to Requirements for an EMS Provider License) as an advanced life support vehicle and has sufficient equipment and supplies for providing an advanced level of care based on national standards and the EMS provider's medical director-approved treatment protocols.

(13) Advanced Practice Provider (APP)--A nurse practitioner, physician assistant, or certified registered nurse anesthetist that has been reviewed and credentialed by the facility and may have additional credentialing to participate in the trauma program.

(14) [(9)] Air ambulance provider--A person who uses, operates, maintains, or leases [operates/leases] a fixed-wing or rotor-wing air ambulance aircraft, equipped and staffed to provide a medical care environment on-board appropriate to the patient's needs. The term air ambulance provider is not synonymous with and does not refer to the

Federal Aviation Administration (FAA) air carrier certificate holder unless they also maintain and control the medical aspects that are consistent with EMS provider licensure.

(15) ~~[(10)]~~ Ambulance--A vehicle for transportation of the sick or injured patient ~~[person]~~ to, from, or between places of treatment for an illness or injury ~~;~~ and that provides out-of-hospital ~~[provide out of hospital]~~ medical care to the patient.

(16) American College of Surgeons (ACS)--The organization that sets the national standards for trauma center requirements, trauma verification, the National Trauma Data Standards (NTDS), NTDB, TQIP, and regional system integration and coordination.

(17) Approved survey organization--An organization that meets the department's standards and expectations and is approved to complete designation site surveys in Texas.

(18) ~~[(11)]~~ Authorized ambulance vehicle--A vehicle authorized to be operated by the licensed provider and that meets all criteria for approval as described in §157.11(e) of this chapter ~~[title]~~.

(19) Bad debt--The unreimbursed cost for patient care to a hospital providing trauma care.

(20) Basic Level IV trauma facility--A hospital surveyed by a department-approved survey organization or defined survey process that meets the state requirements and ACS standards for a Level IV trauma facility as described in §157.125 of this chapter. The hospital is designated by the department, provides trauma care to the hospital's population served in their geographic region, participates in injury prevention and outreach education, participates in its local RAC, submits data to the State Trauma Registry, and has appropriate services for dealing with stressful events for the emergency/trauma care providers.

(21) ~~[(12)]~~ Basic life support (BLS)--Emergency prehospital or interfacility care that uses noninvasive medical acts. The provision of basic life support will have sufficient equipment and supplies for providing basic-level ~~[basic level]~~ care based on national standards and the EMS provider's medical ~~director-approved~~ ~~[director approved]~~ treatment protocols.

(22) ~~[(13)]~~ Basic life support ~~[(BLS)]~~ vehicle--A vehicle that is designed for transporting the sick or injured and that has sufficient equipment and supplies for providing basic life support based on national standards and the EMS provider's medical ~~director-approved~~ ~~[director approved]~~ treatment protocols.

~~[(14)]~~ Basic trauma facility - A hospital designated by the department as having met the criteria for a Level IV trauma facility as described in §157.125 of this title (relating to Requirements for Trauma Facility Designation). Basic trauma facilities provide resuscitation, stabilization, and arrange for appropriate transfer of major and severe trauma patients to a higher level trauma facility, provide ongoing educational opportunities in trauma related topics for health care professionals and the public, and implement targeted injury prevention programs.]

(23) ~~[(15)]~~ Bypass--Direction given to a prehospital emergency medical services unit~~;~~ by direct or online ~~[direct/on-line]~~ medical control or predetermined triage criteria ~~;~~ to pass the nearest hospital for the most appropriate ~~[hospital/trauma]~~ facility. Bypass protocols ~~must~~ ~~[should]~~ have local physician input into their development and must be reviewed through the regional performance improvement process.

(24) Calculation of the costs of uncompensated trauma care--A calculation of a hospital's total costs of uncompensated trauma care for patients meeting the hospital's trauma activation guidelines

and meeting NTDB registry inclusion criteria determined by summing its charges related to uncompensated trauma care as defined in this chapter (relating to Emergency Medical Care), then applying the cost-to-charge ratio derived in accordance with generally accepted accounting principles.

(25) ~~[(16)]~~ Candidate--An individual who is requesting emergency medical services personnel certification, ~~[or]~~ licensure, recertification, or re-licensure ~~[relicensure]~~ from the department ~~[Texas Department of State Health Services]~~.

(26) ~~[(17)]~~ Certificant--Emergency medical services personnel with current certification from the department ~~[Texas Department of State Health Services]~~.

(27) Charity care--The unreimbursed cost to a hospital providing health care services for an inpatient, emergency department, transferred, or expired person classified by the hospital as "financially indigent."

(28) Commissioner--The commissioner of the Texas Department of State Health Services.

(29) Comprehensive Level I stroke facility--A hospital surveyed by a department-approved survey organization that meets the national standards of care for a Comprehensive Stroke Center, participates in its local RAC, participates in the regional stroke plan, and submits data to the department, as requested.

(30) Comprehensive Level I trauma facility--A hospital surveyed by a department-approved survey organization that meets the state requirements and ACS standards for a Level I trauma facility as described in §157.125 of this chapter and designated by the department. A Level I trauma facility serves as a resource trauma facility for its community and RAC. The facility must have continual access to surgical and medical subspecialty services 24 hours a day, 7 days a week. A comprehensive Level I trauma facility manages major, severe, and all types of trauma injuries; provides ongoing educational opportunities on trauma-related topics for health care professionals and the public; implements targeted injury prevention programs with outcome measures; conducts trauma research; participates in its local RAC; submits data to the State Trauma Registry, TQIP, and the NTDB; and ensures availability of appropriate services for dealing with stressful events for emergency/trauma care providers.

(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.

(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.

(33) Consumer Protection Division (CPD)--A division within the Texas Department of State Health Services responsible for the oversight of EMS provider licensure, certification, and education, and complaint investigation. The division is responsible for the hospital designation process for trauma, stroke, maternal, and neonatal facilities; the RAC system development and advances; and funding, grant management, and distribution of funding for the division.

(34) Contingent designation--A designation awarded to a facility with one to three unmet designation requirements. The department develops a corrective action plan (CAP) for the facility, and the facility must complete this plan and meet requirements to remain designated. Contingent designations may require a focused survey to validate requirements are met.

(35) Contingent probationary designation--A designation awarded to a facility with four or more unmet designation requirements. The department develops a CAP for the facility and the facility must complete this plan and meet requirements to remain designated. The facility may be required to submit documentation reflecting the CAP to the department at defined intervals. Contingent probationary designation requires a full survey within 12 to 18 months after the original survey date. The facility must demonstrate that requirements are met to maintain designation.

(36) Corrective action plan (CAP)--A plan for the facility developed by the department that describes the actions required of the facility to correct requirements that are not met during their designation survey.

(37) Cost-to-charges ratio--A ratio that covers all applicable hospital costs and charges relating to inpatient care determined by the Texas Health and Human Services Commission from the hospital's Medicaid cost report.

(38) County of licensure--The county in which the physical address of a licensed EMS provider is located, as indicated by the provider on the application for licensure that is filed with the department.

~~[(18) Comprehensive trauma facility - A hospital designated by the department as having met the criteria for a Level I trauma facility as described in §157.125 of this title. Comprehensive trauma facilities manage major and severe trauma patients, provide ongoing educational opportunities in trauma related topics for health care professionals and the public, implement targeted injury prevention programs, and conduct trauma research.]~~

(39) [(19)] Course medical director--A Texas-licensed [Texas licensed] physician, approved by the department, with experience in and current knowledge of emergency care who must [shall] provide direction over all instruction and clinical practice required in EMS training courses.

(40) [(20)] Credit hour--Continuing education credit unit awarded for successful completion of a unit of learning activity as defined in §157.32 of this chapter [title] (relating to Emergency Medical Services [EMS] Education Program and Course Approval).

(41) [(21)] Critically injured person--A person suffering major or severe trauma, with severe multi-system [multi system] injuries or major unisystem injury; the extent of the injury may be difficult to ascertain, but [which] has the potential of producing mortality or major disability. Retrospectively, typically defined with an injury severity score of 25 or greater.

~~[(22) Current--Within active certification or licensure period of time.]~~

(42) Definitive care--The phase of care in which therapeutic interventions, treatments, or procedures are performed to stop or control an injury, illness, or disease and promote recovery.

(43) [(23)] Department--The Texas Department of State Health Services.

(44) Designated facility administrator--Administrator responsible for the oversight, funding, contracts, and leadership of designated programs.

(45) [(24)] Designated infection control officer--A designated officer who serves as a liaison between the employer and their employees [employer's employees] who have been or believe they have been exposed to a potentially life-threatening infectious disease [;] through a person who was treated or [and/or] transported [;] by the EMS provider.

(46) [(25)] Designation--A formal recognition by the department of a hospital's capabilities, commitment, care practices, and participation in the RAC to serve as a trauma or stroke facility [trauma care capabilities and commitment].

(47) Designation appeal--The process for a hospital that has been downgraded or denied a specific level of designation to appeal the designation decision and provide information and justification that the hospital meets the criteria for a higher level of designation.

(48) Dispatch--The sending of persons and equipment by EMS for assessment and prompt, efficient transportation of a sick or injured patient, if required.

(49) [(26)] Distance learning--A method of learning remotely without being in regular face-to-face contact with an instructor in the classroom.

(50) [(27)] Diversion--A procedure put into effect by a health care [trauma] facility to ensure appropriate patient care when that facility is unable to provide the level of care required for [by] trauma [patient's] injuries or stroke care when the facility has temporarily lost capacity or capabilities [exhausted its resources].

(51) [(28)] Emergency call--A [new] call or other similar communication from a member of the public, as part of a 9-1-1 system or other emergency access communication system, made to obtain emergency medical services.

(52) [(29)] Emergency care attendant (ECA)--An individual who is certified by the department as minimally proficient in performing [to provide] emergency prehospital care by providing initial aid that promotes comfort and avoids aggravation of an injury or illness.

(53) [(30)] Emergency medical services (EMS)--Services used to respond to an individual's perceived need for immediate medical care [and to prevent death or aggravation of physiological or psychological illness or injury].

(54) [(31)] Emergency medical services [(EMS)] operator--A person who, as an employee of a public agency[;] as [that term is] defined by Texas Health and Safety Code, §771.001, receives emergency calls and may provide medical information or medical instructions to the public during those emergency calls.

~~[(32) Emergency medical services and trauma care system - An arrangement of available resources that are coordinated for the effective delivery of emergency health care services in geographical regions consistent with planning and management standards.]~~

(55) [(33)] Emergency medical services [(EMS)] personnel--

- (A) emergency care attendant (ECA);
- (B) emergency medical technician (EMT);
- (C) advanced emergency medical technician (AEMT);

(D) emergency medical technician-intermediate [technician intermediate] (EMT-I); [or]

(E) emergency medical technician-paramedic (EMT-P); or

(F) licensed paramedic (LP).

(56) [(34)] Emergency medical services [(EMS)] provider--A person who uses, operates, or maintains EMS vehicles and EMS personnel to provide emergency medical services [EMS].

(57) Emergency medical services vehicle--

(A) basic life support (BLS) vehicle;

(B) advanced life support (ALS) vehicle;

(C) mobile intensive care unit (MICU);

(D) MICU rotor-wing and MICU fixed-wing air medical vehicles; or

(E) specialized emergency medical service vehicle.

[(35) Emergency medical services (EMS) volunteer provider--An EMS provider that has at least 75% of the total personnel as volunteers and is a nonprofit organization. See §157.11 of this title regarding fee exemption.]

(58) [(36)] Emergency medical services [(EMS)] volunteer--EMS personnel who provide emergency prehospital or interfacility care in affiliation with a licensed EMS provider or a registered first responder [First Responder] organization (FRO) without remuneration, except for reimbursement of [for] expenses.

(59) Emergency medical services volunteer provider--An EMS provider that has at least 75 percent of the total personnel as volunteers and is a nonprofit organization. See §157.11 of this chapter regarding fee exemption.

(60) [(37)] Emergency medical technician (EMT)--An individual who is certified by the department as minimally proficient in performing [to perform] emergency prehospital care that is necessary for basic life support and that includes the control of hemorrhaging and cardiopulmonary resuscitation.

(61) [(38)] Emergency medical technician-paramedic (EMT-P)--An individual who is certified by the department as minimally proficient in performing [to provide] emergency prehospital or interfacility care in a health care facility's emergency or urgent care clinical setting, including a hospital emergency room and a freestanding emergency medical care facility, by providing advanced life support that includes initiation and maintenance under medical supervision of certain procedures, including intravenous therapy, endotracheal or esophageal intubation or both, electrical cardiac defibrillation or cardioversion, and drug therapy.

[(39) Emergency medical services vehicle--]

[(A) basic life support (BLS) vehicle;]

[(B) advanced life support (ALS) vehicle;]

[(C) mobile intensive care unit (MICU);]

[(D) MICU rotor wing and MICU fixed wing air medical vehicles; or]

[(E) specialized emergency medical service vehicle.]

[(40) Emergency Medical Task Force (EMTF) - A unit specially organized to provide coordinated emergency medical response operation systems during large scale EMS incidents.]

(62) [(41)] Emergency prehospital care--Care provided to the sick and injured within a health care facility's emergency or urgent care clinical setting, including a [hospital emergency room and a] freestanding emergency medical care facility, by EMS personnel, before or during transportation to a medical facility, including any necessary stabilization of the sick or injured in connection with that transportation.

(63) Emergency transfer--An event in which a patient at a facility requires emergency transport to another facility for stabilization or definitive care.

(64) En route--When an EMS vehicle is responding to an EMS dispatch or transporting to a receiving facility.

(65) Event--A variation from the established care management guidelines or system operations such as delays in response, delays in care, complications, or death. An event creates a need for review of the care to identify opportunities for improvement.

(66) Event resolution--An event, as described in paragraph (65) of this section, that is identified and reviewed to determine if opportunities for improvement in care or the system exist, with a specific action plan tracked with data analysis to demonstrate that the plan reached the desired outcomes to meet the desired goal, and the improved outcomes are sustained.

(67) Extraordinary emergency--A serious, unexpected event or situation requiring immediate action to reduce or minimize disruption to established health care services within the EMS and trauma care system.

(68) Field triage--The process of determining which facility is most appropriate for patients based on injury severity, time-sensitive disease factors, and facility availability. Refer to paragraph (104) of this section.

[(42) Facility triage - The process of assigning patients to an appropriate trauma facility based on injury severity and facility availability.]

(69) Financially indigent--An uninsured or underinsured patient unable to pay for the trauma services rendered based on the hospital's eligibility system.

(70) [(43)] Fixed location--The address as it appears on the initial or [and/or] renewal EMS provider license application in which the patient care records[,] and administrative offices are [will be] located.

[(44) General trauma facility - A hospital designated by the department as having met the criteria for a Level III and Level IV trauma facility as described in §157.125 of this title. General trauma facilities provide resuscitation, stabilization, and assessment of injury victims and either provide treatment or arrange for appropriate transfer to a higher level trauma facility, provide ongoing educational opportunities in trauma related topics for health care professionals and the public, and implement targeted injury prevention programs.]

(71) [(45)] Governmental entity--A county, a city or town, a school district, or a special district or authority created in accordance with the Texas Constitution, including a rural fire prevention district, an emergency services district, a water district, a municipal utility district, and a hospital district.

(72) Governor's EMS and Trauma Advisory Council (GETAC)--A committee appointed by the Governor of Texas that provides professional recommendations to the EMS/Trauma System Section regarding EMS and trauma system development and serves as a forum for stakeholder input. GETAC reviews and recommends

changes to rules, assesses the need for EMS and health care resources in rural areas of the state, develops a strategic plan for refining the educational requirements for certification and maintaining certification as EMS personnel, regional system development, and advances the trauma and emergency health care system of Texas. GETAC is supported by various committees defined by the council.

(73) [(46)] Health care entity--A first responder, EMS provider, physician, nurse, hospital, designated trauma facility, or a rehabilitation program.

(74) [(47)] Inactive EMS provider status--The period when a licensed EMS provider is not able to respond or be response-ready for [response ready to] an emergency or non-emergency medical dispatch.

(75) [(48)] Industrial ambulance--Any vehicle owned and operated by an industrial facility as defined in the Texas Transportation Code §541.201, and used for initial transport or transfer of company employees who become urgently ill or injured on company premises to an appropriate health care [medical] facility.

(76) Injury severity score (ISS)--An anatomical scoring system that provides an overall score for trauma patients. The ISS standardizes the severity of trauma injuries based on the three worst abbreviated injury scales (AIS) from the body regions. These regions are the head and neck, face, chest, abdomen, extremity, and external as defined by the Association for the Advancement of Automotive Medicine (AAAM). The highest abbreviated injury score in the three most severely injured body regions have their scores squared, then added together to define the patient's ISS.

- (A) ISS of 1-9 is considered moderate trauma injury.
- (B) ISS of 10-15 is a major trauma injury.
- (C) ISS of 16-24 is a severe trauma injury.
- (D) ISS of 25 or greater is a critical trauma injury.

(77) [(49)] Interfacility care--Care provided while transporting a patient between health care [medical] facilities.

[(50)] Lead trauma facility - A trauma facility which usually offers the highest level of trauma care in a given area, and which includes receipt of major and severe trauma patients transferred from lower level trauma facilities. It also includes on-going support of the regional advisory council and the provision of regional outreach, prevention, and trauma educational activities to all trauma care providers in the trauma service area regardless of health care system affiliation.]

(78) [(51)] Legal entity name--The name of the lawful or legally standing association, corporation, partnership, proprietorship, trust, or individual. Has legal capacity to:

- (A) enter into agreements or contracts;
- (B) assume obligations;
- (C) incur and pay debts;
- (D) sue and be sued in its own right; and
- (E) to be accountable for illegal activities.

(79) Level of harm--A classification system that defines the impact of an event to the patient. There are five levels of harm used to define the impact to the patient as defined by the American Society for Health Care Risk Management:

(A) No harm - The patient was not symptomatic, or no symptoms were detected, and no treatment or intervention was required.

(B) Mild harm - The patient was symptomatic, symptoms were mild, loss of function or harm was either minimal or intermediate but short-term, and no interventions or only minimal interventions were needed.

(C) Moderate harm - The patient was symptomatic, required intervention such as additional operative procedure, therapeutic treatment, or an increased length of stay, required a higher level of care, or may experience permanent or long-term loss of function.

(D) Severe harm - The patient was symptomatic, required life-saving or other major medical or surgical intervention, or may experience shortened life expectancy, and may experience major permanent or long-term loss of function.

(E) Death - The event was a contributing factor in the patient's death.

(80) Levels of review--Describes the levels of performance improvement review for an event in the quality improvement or performance improvement patient safety plan. There are four levels of review:

(A) Primary level of review - Initial investigation of identified events by the program's performance improvement personnel to capture the event details and to validate and document the timeline, contributing factors, and level of harm. The program manager usually addresses system issues with no level of harm, including identifying the opportunities for improvement and action plan appropriate for the event, keeping the trauma medical director (TMD) updated. This must be written in the facility's performance improvement plan.

(B) Secondary level of review - The level of review by the TMD in which the program personnel prepare the documentation and facts for the review. The program medical director reviews the documentation and either agrees or corrects the level of harm, defines the opportunities for improvement with action plans, or refers to the next level of review.

(C) Tertiary level of review - The third level of review by the program to evaluate care practices and compliance to defined management guidelines, identify opportunities for improvement, and define a CAP. Minutes capturing the event, discussion and identified opportunities for improvement with action plans must be documented.

(D) Quaternary level of review - The highest level of review, which may be conducted by an entity external to the program as an element of the performance improvement plan.

(81) [(52)] Licensee--A person who holds a current paramedic license from the department, [Texas Department of State Health Services (department)] or a person who uses, maintains, or operates EMS vehicles and provides EMS personnel to provide emergency medical services, [EMS] and who holds an EMS provider license from the department.

(82) Major Level II trauma facility--A hospital surveyed by a department-approved survey organization that meets the state requirements and ACS standards for a Level II trauma facility as described in §157.125 of this chapter. The hospital is designated by the department; provides care to moderate, severe, and critical trauma patients; provides educational opportunities on trauma-related topics for health care professionals and the public; implements injury prevention and outreach initiatives; participates in its local RAC; submits data to the State Trauma Registry, TQIP, and the NTDB; and has appropriate services for dealing with stressful events for emergency/trauma care providers.

[(53)] Major trauma facility - A hospital designated by the department as having met the criteria for a Level II trauma facility as

described in §157.125 of this title. Major trauma facilities provide similar services to the Level I trauma facility although research and some medical specialty areas are not required for Level II facilities; provide ongoing educational opportunities in trauma related topics for health care professionals and the public, and implement targeted injury prevention programs.}]

(83) [(54)] Major trauma patient--A person with injuries, or potential injuries, who may [severe enough to] benefit from treatment at a trauma facility. These patients may or may not present with alterations in vital signs or level of consciousness or with obvious significant injuries [(see severe trauma patient)], but they have been involved in an event that produces [incident which results in] a high index of suspicion for significant injury and potential [and/or] disability. Co-morbid factors such as age or [and/or] the presence of significant medical problems are [should] also [be] considered. These patients [should] initiate a system response to include field [system's or health care entity's trauma response, including prehospital] triage to the most appropriate [a] designated trauma facility. For performance improvement purposes, these patients are also identified retrospectively by an ISS [injury severity score] of 10-15 [9 or above].

(84) [(55)] Medical control--The supervision of prehospital EMS [emergency medical service] providers by a licensed physician. This encompasses on-line (direct voice contact) and off-line (written protocol and procedural review).

(85) [(56)] Medical Director--The licensed physician who provides medical supervision to the EMS personnel of a licensed EMS provider or a recognized FRO [First Responder Organization] under the terms of the Medical Practice [Practises] Act (Texas Occupations Code[;] Chapters 151 - 165) and rules promulgated by the Texas Medical Board; may also [- Also may] be called "off-line medical control." [referred to as off-line medical control.}]

(86) [(57)] Medical oversight--The assistance and management given to health care providers and [and/or] entities involved in regional EMS/trauma systems planning by a physician or group of physicians designated to provide technical assistance.

(87) [(58)] Medical supervision--Direction given to EMS [emergency medical services] personnel by a licensed physician under the terms of the Medical Practice Act[;] (Texas Occupations Code[;] Chapters 151-165) and rules promulgated by the Texas Medical Board [pursuant to the terms of the Medical Practice Act].

(88) [(59)] Mobile intensive care unit [(MICU)]--A vehicle that is designed for transporting the sick or injured, [and that] meets the requirements of the advanced life support vehicle, and [which] has sufficient equipment and supplies to provide cardiac monitoring, defibrillation, cardioversion, drug therapy, and two-way communication with at least one paramedic on the vehicle when providing EMS.

(89) National EMS Compact--The agreement among states to allow the day-to-day movement of EMS personnel across state boundaries in the performance of their duties.

(90) National EMS Information System (NEMSIS)--A universal standard for how patient care information resulting from an EMS response is collected.

(91) National Trauma Data Bank (NTDB)--The national repository for trauma registry data, defined by the ACS with inclusion criteria and data elements required for submission.

(92) National Trauma Data Standards (NTDS)--The American College of Surgeons' standard data elements with definitions that are required for submission to the NTDB, as defined in paragraph (91) of this section.

(93) [(60)] Off-line medical director [direction] --The licensed physician who provides approved protocols and medical supervision to the EMS personnel of a licensed EMS provider under the terms of the Medical Practice [Practises] Act (Texas Occupations Code [;] Chapters 151 - 165) and [a] rules promulgated by the Texas Medical Board [(22 Texas Administrative Code, §197.3)].

(94) [(61)] Online course--A directed learning process comprising [; comprised of] educational information (articles, videos, images, web links), communication (messaging, discussion forums) for virtual learning [with a process] and measures to evaluate the student's [some way to measure a students'] knowledge.

(95) On-scene time--The time the EMS vehicle, equipment, and staff arrive at the location of a dispatch for EMS, as stated in Texas Health and Safety Code §773.050 concerning Minimum Standards.

(96) [(62)] Operational name--Name under which the business or operation is conducted and presented to the world.

(97) [(63)] Operational policies--Policies and procedures that [which] are the basis for the provision of EMS and that [which] include [; but are not limited to] such areas as vehicle maintenance[;] proper maintenance and storage of supplies, equipment, medications, and patient care devices; complaint investigations; multi-casualty [investigation; multicasualty] incidents[;] and hazardous materials; but do not include personnel or financial policies.

(98) Operations Committee--Committee that provides administrative oversight for a program or organization and is responsible for the approval of protocols, patient management guidelines, or operational changes within the program or system that have the potential to impact care practices before implementing the change to the program or organization.

(99) Operative or surgical intervention--Any surgical procedure provided to address trauma injuries for patients taken directly from the scene, emergency department, or other hospital location to an operating suite for patients meeting the hospital's trauma activation guidelines and meeting NTDB registry inclusion criteria.

(100) [(64)] Out of service vehicle--The period when a licensed EMS provider [Provider] vehicle is unable to respond or be response-ready [response ready] for an emergency or non-emergency response.

(101) Performance Improvement and Patient Safety (PIPS) plan--The written plan and processes for evaluating patient care, system response, and adherence to established patient management guidelines; defining variations from care or system response; assigning the level of harm and level of review; identifying opportunities for improvement; and developing the CAP. The CAP outlines data analysis and measures to track the action plan to ensure the desired changes are met and maintained to resolve the event. The medical director, program manager, and administrator have the authority and oversight of PIPS.

(102) Plan of correction (POC)--A report submitted to the department by the facility detailing how the facility will correct one or multiple requirements defined as "not met" during a trauma designation site survey review that is reported in the survey summary or documented in the self-attestation.

[(65) Person--An individual, corporation, organization, government, governmental subdivision or agency, business, trust, partnership, association, or any other legal entity.]

[(66) Prehospital triage--The process of identifying medical/injury acuity or the potential for severe injury based upon physi-

ological criteria, injury patterns, and/or high-energy mechanisms and transporting patients to a facility appropriate for their medical/injury needs. Prehospital triage for injury victims is guided by the prehospital triage protocol adopted by the regional advisory council (RAC) and approved by the department.]

(103) [(67)] Practical exam--An [Sometime referred to as psychomotor, is an] evaluation [exam] that assesses the person's [subject's] ability to perceive instructions and perform motor responses, also referred to as a psychomotor exam.

(104) Prehospital triage--The process of identifying medical/injury acuity or the potential for severe injury based upon physiological criteria, injury patterns, and high-energy mechanisms and transporting patients to a facility appropriate for the patient's medical/injury needs. Prehospital triage for injured patients or time-sensitive disease events is guided by the approved prehospital triage guidelines in the trauma and emergency health care system plan prehospital triage protocol adopted by the RAC and approved by the department. May also be referred to as "field triage" or "prehospital field triage."

(105) Primary EMS provider response area--The geographic area in which an EMS provider routinely provides EMS as agreed upon by a local or county governmental entity or by contract.

(106) Primary Level III stroke facility--A hospital that is designated by the department and meets the department-approved national stroke standards of care for a Primary Stroke Center, participates in its RAC, participates in the regional stroke plan, and submits data as requested by the department.

(107) [(68)] Protocols--A detailed, written set of instructions by the EMS provider's [Provider] medical director, which may include delegated standing medical orders, to guide patient care or the performance of medical procedures as approved.

[(69) Primary EMS provider response area--The geographic area in which an EMS agency routinely provides emergency EMS as agreed upon by a local or county governmental entity or by contract.]

(108) [(70)] Public safety answering point (PSAP)--The call center responsible for answering calls to an emergency telephone number for ambulance services; sometimes called "public safety access point [;]" or "dispatch center."

(109) [(71)] Quality management--Quality assessment [assurance], quality improvement, and [and/or] performance improvement activities. See definition PIPS in paragraph (101) in this section.

[(72) Regional Advisory Council (RAC) - An organization serving as the Department of State Health Services recognized health care coalition responsible for the development, implementation and maintenance of the regional trauma and emergency health care system within the geographic jurisdiction of the Trauma Service Area. A Regional Advisory Council must maintain §501(e)(3) status.]

[(73) Regional EMS/trauma system - A network of health-care providers within a given trauma service area (TSA) collectively focusing on traumatic injury as a public health problem, based on the given resources within each TSA.]

[(74) Regional medical control--Physician supervision for prehospital emergency medical services (EMS) providers in a given trauma service area or other geographic area intended to provide standardized oversight, treatment, and transport guidelines, which should, at minimum, follow the regional advisory council's regional EMS/trauma system plan components related to these issues and 22 Texas Administrative Code, §197.3 (relating to Off-line Medical Director)].

[(75) Recertification--The procedure for renewal of emergency medical services certification.]

(110) [(76)] Receiving facility--A health care facility to which an EMS vehicle may transport a patient who requires prompt continuous medical care, or a facility that is receiving a patient being transferred for definitive care.

(111) Recertification--The procedure for renewal of EMS certification.

(112) [(77)] Reciprocity--The recognition of certification or privileges granted to an individual from another state or recognized EMS system.

(113) Regional Advisory Council (RAC)--An identified trauma service area (TSA) that has established bylaws and is approved by the department as the coordinating agency responsible for system development; coordination of health care services; and responsible for the development, implementation, and maintenance of the regional trauma and emergency health care system plan, performance criteria, and self-assessment within the geographic jurisdiction of the TSA.

(114) Regional Advisory Council Performance Improvement Plan--A written plan of the RAC's processes to review identified or referred events, identify opportunities for improvement, define action plans and data required to correct the event, and establish measures to evaluate the action plan through to event resolution.

(115) Regional medical control--Physician supervision for prehospital EMS providers in a given TSA or other geographic area intended to provide standardized oversight, treatment, and transport guidelines, which should, at minimum, follow the RAC's regional EMS/trauma system plan components related to these issues and 22 Texas Administrative Code, §197.3 (relating to Off-line Medical Director).

(116) [(78)] Relicensure--The procedure for renewal of a paramedic license as described in §157.40 of this chapter [title] (relating to Paramedic Licensure); the procedure for renewal of an EMS provider license as described in §157.11 of this chapter [title].

(117) [(79)] Response pending status--The status of an EMS vehicle that just delivered a patient to a final receiving facility[;] and for which the dispatch center has another EMS response waiting [that EMS vehicle].

(118) [(80)] Response ready--When an EMS vehicle is equipped and staffed in accordance with §157.11 of this chapter [title] (relating to Requirements for a Provider License) and is immediately available to respond to any emergency call 24 hours per day, 7 [seven] days per week (24/7).

(119) Rounding--The 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.

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

(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.

(122) [(82)] Severe trauma patient--A person with injuries or potential injuries defined as high risk for mortality or disability and meets facility trauma activation guidelines and meets NTDB registry inclusion criteria that benefit from definitive [require] treatment at a designated [tertiary] trauma facility. These patients may be identified by an alteration in vital signs or [and/or] level of consciousness or by the presence of significant injuries and must [shall] initiate a [system's and/or health care entity's highest] level of trauma response defined by the facility, including prehospital triage to a designated trauma facility. For performance improvement purposes, these patients are also identified retrospectively by an ISS [injury severity score] of 16-24 [15 or above].

(123) Simulation training--Training that is typically scenario-based or skill-based utilizing simulated patients or system events to improve or test knowledge, competencies, or skills.

[(83) Shall - Mandatory requirements.]

(124) [(84)] 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.

(125) [(85)] Sole provider--The only licensed EMS [emergency medical service] provider in a geographically contiguous service area and in which the next closest provider is greater than 20 miles from the limits of the area.

(126) [(86)] Specialized EMS [emergency medical services] vehicle--A vehicle that is designed for responding to and transporting sick or injured persons by any means of transportation other than by standard automotive ground ambulance or rotor or fixed-wing aircraft [fixed wing air craft] and that has sufficient staffing, equipment, and supplies to provide for the specialized needs of the patient transported. This category includes[; but is not limited to,] watercraft [water craft], off-road vehicles, and specially designed, configured, or equipped vehicles used for transporting special care patients such as critical neonatal or burn patients.

(127) [(87)] Specialty resource centers--Entities that care for specific types of patients such as [trauma,] pediatric, [stroke,] cardiac, [hospitals] and burn injuries [units] that have received certification, categorization, verification, or other forms [form] of recognition by an appropriate agency regarding their capability to definitively treat these types of patients.

(128) [(88)] Staffing plan--A document that [which] indicates the overall working schedule patterns of EMS personnel or hospital personnel.

(129) [(89)] Standard of care--Care equivalent to what any reasonable, prudent person of like education or certification level would have given in a similar situation, based on locally, regionally, and nationally documented evidence-based practices or [adopted standard] adopted standard EMS [emergency medical services] curricula as adopted by reference in §157.32 of this chapter; also refers to the documented standards of care that reflect evidence-based practice [title (relating to Emergency Medical Services Training and Course Approval)].

(130) State EMS Registry--State repository for the collection of EMS response data as defined by Chapter 103 of this title (relating to Injury Prevention and Control).

(131) State Trauma Registry--State repository for the collection of reportable injuries that meet the state inclusion criteria as defined by Chapter 103 of this title.

(132) Stroke--A time-sensitive medical condition that occurs when the blood supply to the brain is reduced or blocked, caused by a ruptured blood vessel or clot, preventing brain tissue oxygenation.

(133) Stroke activation--The process of mobilizing the stroke care team when a patient screens positive for stroke symptoms; may be referred to as a "stroke alert" or "code stroke."

(134) Stroke facility--A hospital that has successfully completed the designation process and is capable of resuscitating and stabilizing, transferring, or providing definitive treatment to stroke patients and actively participates in its local RAC and system plan.

(135) Stroke Medical Director (SMD)--A physician that meets the department's requirements for the stroke medical director and has the authority and oversight for the stroke program, including the performance improvement process, data management, and outcome reviews.

(136) Stroke Program Manager (SPM)--A registered nurse that meets the requirements for the stroke program manager and has the authority and oversight for the stroke program, including the performance improvement process, data management, and outcome reviews.

(137) [(90)] Substation--An EMS provider station location that is not the fixed station and [which] is likely to provide rapid access to a location to which the EMS vehicle may be dispatched.

(138) Telemedicine medical service--A health care service delivered by a physician licensed in this state, or a health professional acting under the delegation and supervision of a physician licensed in this state and acting within the scope of the physician's or health professional's license to a patient at a different physical location than the physician or health professional using telecommunications or technology as defined in Texas Occupations Code §111.001.

(139) Tertiary exam--A documented reassessment of the admitted trauma patient within 24 hours of admission, which includes a detailed primary and secondary head-to-toe evaluation combined with the reassessment of pertinent labs and images, to identify new injuries that may require further evaluation. In situations where the patient's mental status is altered, or distracting injuries are present, the tertiary evaluation may need to be repeated multiple times until the mental status clears or the distracting injury lessens.

(140) Transport mode--As documented on the patient care record, the usage or not of red lights and sirens when responding to an EMS dispatch and when transporting to a receiving facility.

(141) Transport time--The time from when a patient is transported by EMS from the scene location to a receiving facility.

(142) [(91)] Trauma--An injury or wound to a living body caused by the application of an external force or violence, including burn injuries, and meets the trauma program's trauma activation guidelines and meets NTDB registry inclusion criteria. Poisonings, near-drownings, and suffocations, other than those due to external forces, are to be excluded from this definition.

(143) Trauma activation guidelines--Established criteria that identifies the potential injury risk to the human body and defines the resources and response times required to evaluate, resuscitate, and stabilize the trauma patient. The guidelines must meet the national recommendations, but each trauma program defines the activation guidelines for their facility. The facility chooses to have one activation level, two activation levels, or three activation levels.

(A) The highest level of trauma activation is commonly based on physiological changes in the patient's level of consciousness,

airway or potential respiratory compromise, hypotension or signs of shock, significant hemorrhage, or evidence of severe trauma.

(B) The secondary level of trauma activation is commonly based on the patient's physiological stability with anatomical injuries or mechanisms of injury that have the potential for serious injuries.

(C) The third level of trauma activation is designed for low-energy or single-system injuries that may require specialty service evaluation and intervention.

(144) Trauma administrator--Administrator responsible for the facility oversight, funding, contracts, and collaborative leadership of the program, and serves as an interface with the chief executive team as defined by the facility's organizational structure.

(145) Trauma and emergency health care system plan--The inclusive system that refers to the care rendered after a traumatic injury or time-sensitive disease or illness where the optimal outcome is the critical determinant. The system components encompass epidemiology, risk assessments, surveillance, regional leadership, system integration, business/finance models, prehospital care, definitive care facilities, system coordination for patient flow, prevention and outreach, rehabilitation, emergency preparedness and response, system performance improvement, data management, and research. These components are integrated into the system plan.

(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.

(147) Trauma Designation Review Committee--Committee responsible for reviewing trauma designation appeals, reviewing requirement exception and waiver requests, and outlining specific requirements not met in order to identify potential opportunities to improve future rule amendments.

(148) [(92)] Trauma facility--A hospital that has successfully completed the designation process and[;] is capable of resuscitating and stabilizing or transferring or providing [stabilization and/or] definitive treatment to patients who meet trauma activation criteria, [of critically injured persons] and actively participates in its local RAC and system plan [a regional EMS/trauma system].

(149) Trauma-informed care--Care that utilizes the core principles of safety, trustworthiness, collaboration, empowerment, and peer support to foster patient-centered care and engages the patient in their plan of care; practices that prevent "secondary trauma" for the patient.

(150) Trauma Medical Director (TMD)--A physician who meets the requirements and demonstrates the competencies and leadership for the oversight and authority of the trauma program as defined by the level of designation, and who has the authority and oversight for the trauma program, including the performance improvement and patient safety processes, trauma registry, data management, peer review processes, outcome reviews, and participation in the RAC and system plan.

(151) Trauma patient--Any injured person who has been evaluated by EMS, a registered nurse, or a physician and meets trauma activation guidelines and meets NTDB registry inclusion criteria; and requires care in a designated trauma facility based on local, regional, or national standards.

(152) Trauma Program Manager (TPM)--A registered nurse who in partnership with the TMD and hospital administration is responsible for oversight and authority of the trauma program as

defined by the level of designation, including the trauma performance improvement and patient safety processes, the trauma registry, data management, injury prevention, outreach education, outcomes reviews, and research as appropriate to the level of designation. The TPM is responsible for regional participation and system planning, to include mass casualty response.

(153) Trauma Quality Improvement Program (TQIP)--The ACS risk-adjusted benchmarking program that uses submitted data to evaluate specific types of injuries and events to compare cohorts' outcomes with other trauma centers; assists in defining opportunities for improvement in specific patient cohorts.

(154) Trauma registrar--An individual who meets the requirements and whose job responsibilities include trauma patient data abstraction, trauma registry data entry, injury coding, and injury severity scoring, in addition to registry report writing and data management skills specific to the trauma registry and trauma program.

[(93) Trauma nurse coordinator/trauma program manager - A registered nurse with demonstrated interest, education, and experience in trauma care and who, in partnership with the trauma medical director and hospital administration, is responsible for coordination of trauma care at a designated trauma facility. This coordination should include active participation in the trauma performance improvement program, the authority to positively impact trauma care of trauma patients in all areas of the hospital, and targeted prevention and education activities for the public and health care professionals.]

[(94) Trauma patient - Any critically injured person who has been evaluated by a physician, a registered nurse, or emergency medical services personnel, and found to require medical care in a trauma facility based on local, regional or national medical standards.]

(155) [(95)] Trauma registry--A trauma facility [statewide] database that captures required elements of [which documents and integrates medical and system information related to the provision of] trauma care for each patient [by health care entities].

(156) [(96)] Trauma service area (TSA) [Service Area]--Described in §157.122 of this chapter [An organized geographical area of at least three counties administered by a regional advisory council for the purpose of providing prompt and efficient transportation and/or treatment of sick and injured patients].

(157) Uncompensated trauma care--The sum of "charity care" and "bad debt." Contractual adjustments in reimbursement for trauma services based upon an agreement with a payor (including Medicaid, Medicare, Children's Health Insurance Program (CHIP), or other health insurance programs) are not uncompensated trauma care.

(158) Urban county--A county with a population of 50,000 or more based on the latest estimated federal census population figures.

(159) Verification--Process used by the ACS to review a facility seeking trauma verification to validate that the defined standards are met with documented compliance for successful trauma center verification. If a Level I or Level II facility is not verified by the ACS, the department cannot designate the facility.

(160) [(97)] When in service--The period of time when an EMS vehicle is responding to an EMS dispatch, at the scene, or en route [when enroute] to a facility with a patient.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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SUBCHAPTER G. EMERGENCY MEDICAL SERVICES TRAUMA SYSTEMS

25 TAC §§157.123, 157.125, 157.130, 157.131

STATUTORY AUTHORITY

The repeals are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies; Texas Health and Safety Code Chapter 773 (Emergency Health Care Act), which authorizes the commissioner to adopt rules to implement emergency medical services and trauma care systems; Texas Health and Safety Code Chapter 773, Subchapter G, which provides for the authority to adopt rules related to emergency medical services and trauma services; and Texas Health and Safety Code §1001.075, which authorizes the Executive Commissioner of HHSC to adopt rules and policies for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code Chapter 1001.

The repeals are authorized by Texas Government Code Chapter 531; and Texas Health and Safety Code Chapters 773 and 1001.

§157.123. *Regional Emergency Medical Services/Trauma Systems.*

§157.125. *Requirements for Trauma Facility Designation.*

§157.130. *Emergency Medical Services and Trauma Care System Account and Emergency Medical Services, Trauma Facilities, and Trauma Care System Fund.*

§157.131. *Designated Trauma Facility and Emergency Medical Services Account.*

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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25 TAC §§157.123, 157.125, 157.128, 157.130

STATUTORY AUTHORITY

The new sections are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies; Texas Health

and Safety Code Chapter 773 (Emergency Health Care Act), which authorizes the commissioner to adopt rules to implement emergency medical services and trauma care systems; Texas Health and Safety Code Chapter 773, Subchapter G, which provides for the authority to adopt rules related to emergency medical services and trauma services; and Texas Health and Safety Code §1001.075, which authorizes the Executive Commissioner of HHSC to adopt rules and policies for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code Chapter 1001.

The new sections are authorized by Texas Government Code Chapter 531; and Texas Health and Safety Code Chapters 773 and 1001.

§157.123. *Regional Advisory Councils.*

(a) The department shall recognize a Regional Advisory Council (RAC) as the coordinating entity for the development and advancement of the regional trauma and emergency health care system within the defined trauma service area (TSA) as described in §157.122 of this subchapter (relating to Trauma Service Areas).

(1) The department shall recognize only one RAC for each TSA.

(2) Trauma, prehospital, perinatal, stroke, cardiac, disaster response, and emergency health care stakeholders in the TSA must be eligible for participation or membership in the RAC.

(b) A RAC must meet the following department requirements to be recognized as a RAC:

(1) maintain incorporation as an entity that is exempt from federal income tax under §501(a) of the United States Internal Revenue Code of 1986, and its subsequent amendments, by being listed as an exempt organization under §501(c)(3) of the code, and to be eligible to distribute the emergency medical services (EMS), Uncompensated Care and TSA allotments;

(2) submit required documentation to the department that includes, at a minimum, the following:

(A) a summary of regional trauma, prehospital, pediatric, perinatal, stroke, cardiac, and emergency health care system activities;

(B) evidence of an annual summary of the EMS, trauma, and emergency health care system performance improvement plan;

(C) a completed regional self-assessment within the first year of the RAC's contract with the department and a current trauma and emergency health care system plan during the second year of the department contract with documented evidence the performance criteria are met, as outlined in Texas Health and Safety Code §773.122 and §780.004;

(i) the initial performance criteria and initial regional self-assessment are used for the years of 2024 and 2025; and

(ii) the inclusive performance criteria and inclusive regional self-assessment are used for the year of 2026 and continuing years;

(3) maintain external financial audits and financial statements as defined in contract; and

(4) maintain a current website with regional bylaws, board members, completed self-assessment, and current trauma and emergency health care system plan posted.

(c) Each RAC must develop and maintain a regionally specific comprehensive trauma and emergency health care system plan that integrates trauma, prehospital, pediatric, perinatal, stroke, cardiac, and emergency health care into the plan and is revised at a minimum of every two years utilizing the completed regional self-assessment. The plan must include all counties within the TSA and must be based on current industry standards and guidelines.

(1) The system plan must address the following elements:

(A) trauma, prehospital, pediatric, perinatal, stroke, and cardiac epidemiology data resources available;

(B) integration of regional stakeholders, identified coalitions, and community partners pertinent to the priorities and needs identified through the regional self-assessment;

(C) regional guidelines for prehospital field triage and destination, treatment, transport, and transfer of patients with time-sensitive health care injuries or illnesses;

(D) prevention and outreach activities guided by the trauma, prehospital, pediatric, perinatal, stroke, and cardiac data available;

(E) system coordination and patient flow;

(F) meaningful participation in regional disaster preparedness, planning, response, recovery, after-action review, data tracking needs, and support of the hospital preparedness stakeholders, including the identified health care coalition and the department;

(G) identification of system-wide health care education for trauma, prehospital, pediatric, perinatal, stroke, cardiac, and the emergency health care system sponsored or coordinated through the RAC;

(H) execution of a systems performance improvement plan that aligns with the department's trauma and emergency health care system performance improvement plan, and includes regional outcome data;

(I) current pediatric readiness capabilities for the regional prehospital and hospital environment and identifies opportunities to improve pediatric readiness within the region;

(J) integration of public health and business community stakeholders; and

(K) guidelines to support regional research projects.

(2) All health care entities and identified coalition partners should participate in the regional planning process.

(d) A RAC must collect from each hospital continual data within their TSA to facilitate emergency preparedness and response planning for a public health disaster, public health emergency, or outbreak of communicable disease, and report the data to the department at least monthly via the electronic reporting system specified by the department, consistent with Texas Health and Safety Code §§81.027, 81.0443, 81.0444, and 81.0445.

(1) The data collected must include all adult and pediatric data specific to:

(A) general beds available and occupied;

(B) intensive care unit (ICU) beds available and occupied;

(C) emergency department visits in the last 24 hours;

(D) hospital admissions in the last 24 hours;

(E) ventilators available and in use; and

(F) hospital deaths in the last 24 hours.

(2) The department may request more or less frequent reporting or may request different information from individual RACs to adequately respond to any public health disaster, public health emergency, or outbreak.

(3) RACs must make the collected data publicly available by posting the data on the RAC's internet website during any public health disaster or public health emergency and, when asked by the department, during outbreaks not associated with a public health disaster or emergency.

(e) A RAC with at least one county within the region located on the international border of Texas and at least one county within the region that is adjacent to the Gulf of Mexico must provide guidelines and protocols related to trauma patient transfer and related services that meet the following requirements:

(1) The RAC must develop an advisory committee composed of equal representation from designated trauma facilities within the RAC.

(2) The advisory committee must develop regional protocols for managing the dispatch, triage, transport, and transfer of patients.

(A) The advisory committee must periodically review patient transfers ensuring the applicable protocols are met.

(B) Each hospital and EMS provider operating within this TSA must collect and report to the RAC data on patients transferred outside of the TSA following the developed and approved regional protocols.

(C) The advisory committee and activities must be integrated into the regional trauma and health care system plan.

(f) A RAC must meet the defined performance criteria to ensure the mission of the regional system is maintained. A RAC must:

(1) notify the department and RAC membership within five days of the loss of capabilities to maintain the infrastructure to oversee and maintain the regional systems as required by the provisions within subsections (a) and (b) of this section or the department contract;

(2) provide the department with a plan of correction (POC) no more than 90 days from the onset of the deficiency for the RAC; and

(3) comply with the provisions of subsections (a) and (b) of this section, all current state and system standards as described in this chapter, and all guidelines and procedures as set forth in the regional trauma and emergency health care system plan.

(g) If a RAC chooses to relinquish services, it must provide at least a 30-day written advance notice to the department, all RAC membership, RAC coalition partners, and county judges within the impacted TSA.

(1) The RAC must submit a written plan to the department for approval before the 30-day notice to relinquish services.

(2) The RAC funding and assets must be dissolved in accordance with state and federal requirements.

(3) The department must consider options of realigning the TSA with another RAC to continue services.

(h) The department has the authority to schedule conferences, in-person or virtual, to review, inspect, evaluate, and audit all RAC

documents to validate the department RAC performance criteria are met.

§157.125. Requirements for Trauma Facility Designation.

(a) The department designates hospital applicants as trauma facilities, which are part of the trauma and emergency health care system.

(b) The facility seeking trauma designation submits a designation application to the department. The department reviews the facility application documents for the appropriate level of designation. The complete designation application must include the following:

(1) an application packet for trauma facility designation and an annual summary of the trauma performance improvement and patient safety (PIPS) plan;

(2) a completed department designation assessment questionnaire;

(3) the documented trauma designation site survey summary report that includes findings of requirements met and medical record reviews;

(4) evidence of validation by the survey organization that the designation requirements are successfully met; and

(5) full payment of the non-refundable, non-transferrable designation fee.

(c) The department's designation unit reviews the designation application and determines the level of designation requirements are met and forwards the approval for designation to the Consumer Protection Division (CPD) Associate Commissioner who awards the designation to the facility.

(d) Eligibility requirements for trauma designation.

(1) Health care facilities eligible for trauma designation include:

(A) a hospital in Texas, licensed or otherwise, in accordance with Chapter 133 of this title (relating to Hospital Licensing);

(B) a hospital owned and operated by the State of Texas;

or
(C) a hospital owned and operated by the federal government, in Texas.

(2) Each hospital must demonstrate the capability to stabilize and transfer or treat an acute trauma patient, have written trauma management guidelines for the hospital, have a written operational plan, and have a written trauma PIPS plan.

(3) Each hospital operating on a single hospital license with multiple locations (multi-location license) may apply for trauma designation separately by physical location for each designation.

(A) Hospital departments or services within a hospital must not be designated separately.

(B) Hospital departments located in a separate building that is not contiguous with the designated facility must not be designated separately.

(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.

(e) A facility is defined under subsection (d) of this section as a single location where inpatients receive hospital services and inpatient

care. If there are multiple buildings covered under a single hospital license, each facility location where inpatients receive hospital services and care may choose to seek designation.

(1) Each facility location must be considered separately for designation. The department determines the designation level for each facility based on the facility's ability to demonstrate designation requirements are met.

(2) Each facility must submit a separate trauma designation application based on its resources and the level of designation the facility is seeking.

(3) A facility with multiple locations that is applying for designation at one location may have other locations where the hospital provides services apply separately for designation if they all are under a single hospital license.

(4) Trauma designation is issued for the physical location and to the legal owner of the operations of the designated facility and is non-transferable.

(f) Facilities seeking trauma designation must meet department-approved requirements and have them validated by a department-approved survey organization.

(g) The four levels of trauma designation are:

(1) Comprehensive trauma facility designation (Level I). The facility, including a free-standing children's facility, must:

(A) meet the current American College of Surgeons (ACS) trauma verification standards for Level I and receive a letter of verification from ACS;

(B) meet the state trauma facility requirements;

(C) have the Trauma Medical Director (TMD) and Trauma Program Manager (TPM) actively participate and meet the participation requirements for their local RAC;

(D) have appropriate services for dealing with stressful events available to emergency/trauma care providers;

(E) submit trauma data to the State Trauma Registry, defined in §103.2(14) of this title (relating to Definitions); and

(F) annually submit a 12-month trauma performance improvement summary report to the department.

(2) Major trauma facility designation (Level II). The facility, including a free-standing children's facility, must:

(A) meet the current ACS trauma verification standards for Level II and receive a letter of verification from the ACS;

(B) meet the state trauma facility requirements;

(C) have the TMD and TPM actively participate in their local RAC;

(D) have appropriate services for dealing with stressful events available to emergency/trauma care providers;

(E) submit trauma data to the State Trauma Registry;

and

(F) annually submit a 12-month performance improvement summary report to the department.

(3) 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;

(B) meet the state trauma facility requirements;

(C) have the TMD and TPM actively participate and meet the participation requirements for their local RAC;

(D) have appropriate services for dealing with stressful events available to emergency/trauma care providers;

(E) submit trauma data to the State Trauma Registry;
and

(F) annually submit a 12-month performance improvement summary report to the department.

(4) Basic trauma facility designation (Level IV). The facility, including a free-standing children's facility, must:

(A) meet the current ACS trauma verification standards for Level IV and complete a site survey conducted by a department-approved organization or complete a facility self-assessment and meet with the department;

(B) meet the state trauma facility requirements;

(C) have the TMD and TPM actively participate and meet the participation requirements for their local RAC;

(D) have appropriate services for dealing with stressful events available to emergency/trauma care providers;

(E) submit trauma data to the State Trauma Registry;
and

(F) annually submit a 12-month performance improvement summary report to the department.

(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.

(i) Level IV facilities will continue to utilize the most current ACS criteria in addition to the state trauma facility requirements to achieve designation.

(j) All facilities seeking trauma designation must meet the following requirements:

(1) Facilities must have documented evidence of participation in their RAC:

(A) evidence of submitting quarterly trauma registry data for the past three years; and

(B) evidence the TMD and TPM are participating in the trauma system planning and regional disaster planning through the RAC.

(2) Facilities must have evidence of quarterly trauma registry submissions to the State Trauma Registry for patients that meet NTDB registry inclusion criteria, following the NTDS definitions.

(3) Facilities must demonstrate trauma registry performance measures for the following:

(A) data validations and correction of issues identified;
and

(B) measures to ensure accurate coding and ISS and that all patient profiles submitted to the State Trauma Registry have an ISS.

(4) Facilities must maintain a written trauma operational plan for the program to include:

(A) description of the scope of services available to support trauma care;

(B) trauma program authority and oversight;

(C) trauma population evaluated and treated by the trauma program to identify those patients routinely admitted and those patients routinely transferred for definitive care;

(D) trauma activation guidelines that meet the national recommendations;

(E) trauma management guidelines based on evidence-based practice;

(F) trauma policies and procedures;

(G) description of the trauma program staffing;

(H) trauma medical staff credentialing and education requirements;

(I) measures for rounding on admitted trauma patients to complete a tertiary exam and to facilitate the continuum of care through discharge or transfer;

(J) data management procedures to ensure all performance improvement documents and registry documents are secured to maintain confidentiality;

(K) measures to promote a safe culture;

(L) documented transfer guidelines with evidence of medical and nursing staff education on trauma transfers;

(M) resources available for trauma patient population inpatient areas, including the operating suite, ICU, general units, and rehabilitation services;

(N) evidence of staff orientation, skills credentialing, and ongoing education for all areas providing care to injured patients that meet trauma activation guidelines and meet NTDB registry inclusion criteria;

(O) ancillary services available to support the injured patients who meet trauma activation guidelines and meet NTDB registry inclusion criteria;

(P) psychosocial support services for the trauma patient and families;

(Q) trauma operations committee with defined goals and objectives, members, minutes, and attendance requirements;

(R) processes to ensure all trauma designation requirements are monitored for compliance;

(S) trauma registry procedures;

(T) injury prevention resources;

(U) outreach education resources;

(V) TMD and TPM participation in the RAC;

(W) processes to provide EMS feedback and transfer follow-up feedback;

(X) measures to support trauma research as appropriate for the level of designation; and

(Y) succession planning for the TMD, TPM, and trauma registrar.

(5) The trauma program's written operational plan and all associated documents must be approved by the trauma operations committee and forwarded to the hospital's governing body for review and approval.

(6) Chief Executive Officer (CEO), Chief Nursing Officer (CNO), Chief Operating Officer (COO), and Chief Medical Officer (CMO), and the trauma administrator have documented evidence of implementing measures to continually promote a safe culture.

(7) The hospital's CEO, CNO, COO, CMO, and the trauma administrator have documented evidence of implementing trauma-informed care practices in all areas of receiving, assessing, evaluating, and caring for injured patients, and psychosocial support or wellness programs for staff.

(8) The hospital's CEO, CNO, COO, Chief Financial Officer (CFO), and the trauma administrator are responsible for providing adequate resources to ensure the trauma program's performance improvement and patient safety processes and trauma registry maintain concurrent operations.

(9) The hospital's CEO, CMO, trauma administrator, and TMD have measures in place to:

(A) monitor the trauma physicians' contract deliverables, ensuring adequate trauma coverage, with backup coverage when needed;

(B) ensure there are defined requirements for credentialing, education, training, and timeliness of response to trauma activations;

(C) ensure attendance at required meetings, including RAC meetings;

(D) ensure disaster mass casualty response requiring surge intensive care or operating room capabilities; and

(E) ensure all other physician designation requirements are met.

(10) The hospital's CEO, CNO, COO, CFO, and trauma administrator, in conjunction with the TMD and TPM, establish processes to monitor and track:

(A) trauma fees and trauma patient uncompensated care;

(B) the operational cost of the trauma program;

(C) data required to complete the uncompensated care application; and

(D) how the uncompensated care funds are used to improve the facility's trauma program and trauma care.

(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:

(A) trauma activation and response time based on national recommendations;

(B) trauma resuscitation and documentation;

(C) consultation services response;

(D) admission and transfer;

(E) burn injury management;

(F) management of trauma patients with a defined or suspected neurologic deficit due to spinal cord injury, including neurogenic shock;

(G) management of patients with mild, moderate, and severe traumatic brain injury;

(H) hemorrhage control and management of shock;

(I) complex orthopedic pelvic, acetabular, or long bone fractures, hemodynamically unstable pelvic fractures, fractures with the potential for vascular compromise, and partial or complete amputation of a long bone extremity;

(J) screening, management, and appropriate interventions or referral for both suspected and confirmed abuse of all patient populations;

(K) measures to prevent over-imaging for patients requiring transfer, and processes to share medical images with the receiving facility;

(L) pain management for all populations;

(M) massive transfusion;

(N) management of the acutely injured pregnant patient that is greater than 20 weeks gestation;

(O) providing screening, interventions, and resources for substance use and misuse and mental health;

(P) management guidelines for morbidly obese patients;

(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;

(R) if greater than 15 percent of the patients meeting trauma activation guidelines are less than 15 years-of-age, the facility must have pediatric management guidelines, and if 15 percent of the patients meeting trauma activation guidelines are 65 years or older, the facility must have geriatric trauma management guidelines;

(S) patient and family-centered care;

(T) documentation standards pertinent to the care of trauma patients in all nursing units providing care to the trauma patient; and

(U) processes to measure and report adherence must be integrated into the trauma PIPS plan and aggregately reported through the trauma operations committee.

(12) The trauma program must have provisions for the availability of all necessary equipment and services to administer the appropriate level of care and support for the injured patient meeting the hospital's trauma activation guidelines and meeting NTDB registry inclusion criteria through the continuum of care to discharge or transfer.

(13) Adult trauma facilities must meet and maintain the Emergency Medical Services for Children's Pediatric Readiness Criteria as evidenced by the following:

(A) annual completion of the online Pediatric Readiness Survey (<https://pedsready.org>), including a written corrective action plan (CAP) for identified opportunities for improvement that is monitored through the trauma PIPS plan until resolution;

(B) pediatric equipment and resources immediately available at the facility, and staff with defined and documented competency skills and training on the pediatric equipment;

(C) education and training requirements for Emergency Nursing Pediatric Course (ENPC) or Pediatric Advanced Life Support (PALS) for the nurses responding to pediatric trauma activations;

(D) assessments and documentation include Glasgow Coma Score (GCS); complete vital signs to include temperature, heart rate, respirations, and blood pressure; pain assessment; and weight recorded in kilograms;

(E) serial vital signs, GCS, and pain assessments are completed and documented for the highest level of trauma activations or when shock, a traumatic brain injury, or multisystem injuries are identified;

(F) pediatric imaging guidelines and processes to monitor for over imaging; and

(G) documented evidence that the trauma program has completed a minimum of one quarterly pediatric trauma resuscitation simulation with medical staff participation, including a completed critique that identifies opportunities for improvement that is integrated into the trauma performance improvement initiatives and tracked until the identified opportunities are corrected, and an adult trauma facility that has evidence of evaluating and managing 200 or more patients less than 15 years of age with an ISS of 9 or greater are exempt from this requirement of pediatric trauma simulations.

(14) Free-standing children's trauma facilities must have resources and equipment immediately available for adult trauma resuscitations, adherence to the nursing requirements for Trauma Nurse Core Course (TNCC) or Advanced Trauma Care for Nurses (ATCN), documented evidence that the trauma program has completed a minimum of one quarterly adult trauma resuscitation simulation with medical staff participation, including a completed critique that identifies opportunities for improvement that is integrated into the trauma performance improvement initiatives and tracked until the identified opportunities are corrected. Free-standing children's trauma facilities with evidence of evaluating and managing 200 adult patients 15 years or older with an ISS of 9 or greater are exempt from this requirement for adult trauma simulations.

(15) 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 Advance 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.

(B) The on-call physician must respond within 30 minutes, when requested.

(C) The facility must have a documented telemedicine physician credentialing process.

(D) All assessments, physician orders, and interventions initiated through telemedicine must be documented in the patient's medical record.

(16) Telemedicine in trauma facilities in a county with a population of 30,000 or more, if utilized, must have a documented physician credentialing process, written trauma protocols for utilization of telemedicine that include physician response times, and measures to ensure the trauma management guidelines and evidence-based practice are monitored through the trauma performance improvement and patient safety processes.

(A) Telemedicine cannot replace the requirement for the trauma on-call physician to respond to the trauma activations in-person, to conduct inpatient rounds, or to respond to the inpatient units, when requested.

(B) All telemedicine assessments, physician orders, and interventions initiated through telemedicine must be documented in the patient's medical record.

(C) Telemedicine services or the telemedicine physician may be requested to assist in trauma performance improvement committee reviews.

(17) The TMD must define the role and expectations of the hospitalist or intensivist in providing care to the admitted injured patient that meets trauma activation guidelines and meets NTDB registry inclusion criteria.

(18) The trauma program has an identified administrator or executive leader who assists with the trauma program budget, oversight of trauma contracts, trauma billing, and securing transfer and transport agreements, and who attends a minimum of 50 percent of the trauma operations committee meetings annually. This individual serves as a trauma liaison to the CEO.

(19) A trauma registered nurse is a participating member of the nurse staffing committee.

(20) The facility maintains medical records that facilitate the documentation of trauma patient arrival, level of activation, physician response and team response times, EMS time-out, resuscitation, assessments, vital signs, GCS, serial evaluation of needs, interventions, patient response to interventions, reassessments, and re-evaluation through all phases of care to discharge or transfer, including:

(A) integration of the EMS patient care records, including the EMS wristband tracking number; and

(B) substance misuse screening and interventions.

(21) The facility must have an organized, effective trauma service that is recognized in the medical staff bylaws and approved by the governing body. Medical staff credentialing must include a process for requesting and granting delineation of privileges for the TMD to oversee the providers participating in trauma call coverage, the trauma panel, and trauma management through all phases of care.

(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. The TMD must be a physician who meets the following criteria:

(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.

(B) 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.

(C) Regularly and actively participate in trauma care at the trauma facility where TMD services are provided, including taking trauma call monthly or providing coverage in the emergency department for Level IV facilities utilizing an emergency medicine or family medicine physician as the TMD.

(D) Maintains current verification in ATLS or a department-recognized equivalent course, and preferably, is an ATLS instructor.

(E) Demonstrates effective administrative skills and oversight of the trauma PIPS plan, chairs the secondary level of performance reviews, chairs the trauma operations committee, chairs the trauma multidisciplinary peer review committee, and communicates and collaborates with trauma liaisons for emergency medicine, orthopedics, neurosurgery, critical care, radiology, anesthesia, rehabilitation, and other surgical and medical specialists.

(F) Has the responsibility for credentialing the trauma service surgeons participating in the call schedule, advanced practice providers participating in trauma care, and trauma liaisons, or appropriate physicians for the Level IV facilities, utilizing established and approved guidelines.

(G) Is a member of the facility's disaster planning and preparedness committee with a specific focus on mass casualty, multiple casualties, and events requiring response planning and patient flow management for potential surges in the operating suite or ICU.

(H) Collaborates with the trauma service surgeons participating in the call schedule, advanced practice providers, trauma liaisons, TPM, trauma administrator, and nursing leaders to develop the trauma management guidelines for the trauma facility that are consistent with national evidence-based practice guidelines.

(I) Participates in the RAC trauma committee, disaster preparedness activities, and medical director committee as defined by the RAC bylaws.

(J) Has a documented job description that defines the TMD's authority and oversight of the trauma program through all phases of care.

(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) on the facility's mass casualty response and focuses on the develop of surge capacity and capabilities for resuscitation, operating room, ICU, patient flow coordination, and job action sheets, which may be completed through table-top simulation training or other educational measures in collaboration with the TPM, emergency department medical director, and the facility's emergency management leader.

(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. The TPM has the following authority and responsibility to:

(A) identify and address trauma performance improvement and patient safety issues through all phases of care in the trauma facility, including validating and documenting identified events and preparing them for the secondary level of review, and implementing and tracking the action plans to address opportunities for improvement or managing the personnel completing these job functions;

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

(C) organize, track, and follow-through on the trauma performance improvement and patient safety processes to ensure resolution and reporting;

(D) comply with the trauma registry processes outlined in the trauma operations plan and data submission requirements to the State Trauma Registry;

(E) oversee the injury prevention, outreach education, and research initiatives of the trauma program in conjunction with the TMD;

(F) co-chair the trauma operations committee;

(G) record the minutes of the trauma multidisciplinary peer review committee discussion;

(H) attend specific facility-wide meetings representing the trauma program;

(I) participate in the RAC trauma committee, disaster preparedness activities, and other committees as defined by the RAC bylaws;

(J) assist with the orientation and education of staff in areas providing trauma care;

(K) serve as the trauma liaison with the facility risk and quality departments;

(L) maintain certification in TNCC or ATCN, and ENPC or PALS; 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;

(M) select to attend an alternate course on data management, rather than the AAAM Injury Scaling Course, and have processes in place for continual support for the trauma registry services, which

may include outsourcing, when functioning at a Level IV rural trauma facility with an annual volume of fewer than 75 patients meeting NTDB registry inclusion criteria;

(N) demonstrate expertise in trauma care, and have administrative organization skills;

(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;

(P) routinely collaborate with the TMD, trauma liaisons, nursing leaders, staff, and other resources to identify opportunities for trauma facility improvements;

(Q) routinely participate or assist with trauma care at the facility;

(R) have a documented job description that defines the TPM's authority and oversight of the trauma program through all phases of care;

(S) be a full-time employee of the facility to ensure that the TPM is current with the facility's policies and procedures and available during business hours to address trauma-related issues to ensure concurrent processes and the hours dedicated to the trauma program are based on the number of injured patients who meet trauma activation guidelines and meet NTDB registry inclusion criteria; and

(T) have an organizational structure that allows the TPM to assess and review trauma care from admission to discharge, provide recommendations to improve care through all phases of care, and a reporting structure to an administrator that has the authority to recommend and monitor facility system changes and oversees the trauma program.

(24) Rural Level IV or Critical Access Hospital (CAH) facilities that annually have 75 or fewer patients that meet trauma activation guidelines, meet NTDB registry inclusion criteria, and registry submissions demonstrate evidence that they do not admit these patients to the hospital for injury management may choose to utilize a part-time registered nurse in the TPM role, or to integrate the TPM responsibilities with the CNO, as long as the trauma performance improvement and trauma registry processes are concurrent, and resources are available to respond to the facility for high trauma volume or high trauma acuity.

(25) 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;

(B) adherence to trauma activations guidelines and response times;

(C) participation in the trauma PIPS plan;

(D) compliance with ATLS and continuing medical education if not board-certified or board-eligible;

(E) participation and attendance for trauma surgeons and trauma liaisons at the trauma operations committee and trauma multidisciplinary peer review committee meetings maintaining a minimum of 50 percent participation;

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

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

(H) adherence to transfer guidelines;

(I) adherence to diversion guidelines;

(J) adherence to established evidence-based practice or trauma management guidelines;

(K) adherence to supervision expectations; and

(L) specific activation guidelines, established in collaboration with orthopedic surgery and neurosurgery, which require a 30-minute response to orthopedic and neurosurgical trauma injuries and include monitoring compliance and reporting aggregate response summaries at the operations committee.

(26) The TMD is responsible for the trauma call schedule for the trauma and general surgeons, and for collaborating with trauma liaisons and other specialty services to complete their trauma call schedule and to ensure trauma facility coverage is adequate and that individuals are not on-call for two facilities at the same time. Trauma or general surgeons responsible for responding to trauma activations must be dedicated to no more than one trauma facility while they are on-call.

(A) In Level III facilities, if the specialty physician on trauma call is covering two facilities, there must be a documented contingency plan. The facility must have documented guidelines for on-call practices. This process must be monitored through the trauma PIPS plan and reported through the trauma operations committee.

(B) In Level IV facilities that utilize an emergency medicine physician or family medicine physician as their TMD and do not routinely admit patients to the ICU or operative suite that meet their trauma activation guidelines and meet NTDB registry inclusion criteria, the TMD is responsible for assisting with scheduling physician coverage in the emergency department to ensure trauma requirements are followed.

(27) The trauma facility must maintain a continuous trauma PIPS plan. The plan must be data-driven and must:

(A) define variances in care or events for review, including system issues, delays in care, hospital events such as complications, and all trauma deaths;

(B) define the levels of harm;

(C) define levels of review;

(D) identify opportunities for improvement;

(E) establish action plans to address the opportunities for improvement;

(F) monitor the action plan until the desired change is met and sustained;

(G) identify opportunities to establish a concurrent PIPS plan;

(H) meet staffing standards that meet the ACS standards for performance improvement personnel; and

(I) utilize terminology for classifying morbidity and mortality with the terms:

(i) morbidity or mortality without opportunity;

(ii) morbidity or mortality with opportunity for improvement; and

(iii) morbidity or mortality with regional opportunity for improvement.

(28) The trauma PIPS plan must be approved by the TMD, TPM, and the trauma operations committee and disseminated to all departments providing care to the trauma patient to ensure they are knowledgeable of their role in the plan and the data they share at the trauma operations committee.

(29) The TMD must chair the secondary level of performance review, the trauma multidisciplinary peer review committee, and co-chair the trauma operations committee with the TPM.

(30) The trauma PIPS plan must outline the roles and responsibilities of the trauma operations committee and its membership.

(A) The required members of the trauma operations committee include:

(i) TMD and TPM;

(ii) performance improvement personnel and lead registry staff, if utilized;

(iii) administrator or executive leader;

(iv) nursing managers or leaders for units that provide trauma care;

(v) trauma surgeons, trauma liaisons, and representatives for the trauma APPs;

(vi) ancillary departments that support the trauma program, such as diagnostic radiology, interventional radiology, laboratory, blood bank, respiratory therapy, pharmacy, rehabilitation services, and EMS representatives, as appropriate; and

(vii) managed care contract and billing leaders that attend the committee meeting at least twice a year to review trauma finances and billing status, to share current activities, and to identify opportunities for improvements. Attendance may be in-person or virtually.

(B) Trauma facilities that participate in benchmarking programs must share the facility's benchmark reports with the trauma operations committee to identify successes and opportunities for improvement, develop action plans for the identified opportunities, and monitor the action plan outcomes.

(31) The trauma program must define who will attend the trauma multidisciplinary peer review committee, have documentation that reflects their attendance, and monitor attendance to validate a minimum of 50 percent attendance.

(32) The trauma facility must complete a 12-month summary of the facility's trauma PIPS plan, share the report with its facility quality program, and submit the report to the department.

(33) The trauma facility must document and include in its trauma PIPS plan the external review of the trauma verification and designation pre-review questionnaire, site survey activities, the site survey summary report, including the medical record reviews, and all communication with the department.

(34) Trauma facilities must submit required trauma data every 90 days or quarterly to the State Trauma Registry and have documented evidence of data validation and correction of identified errors or blank fields.

(A) The facility must have procedures that identify the trauma registry inclusion criteria for the Texas reporting requirements. All trauma facilities must include patients meeting NTDB registry inclusion criteria.

(B) Level I, II, and III trauma facilities must submit the validated trauma registry data to the NTDB each quarter.

(C) The trauma registry processes 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.

(D) The trauma registry must have sufficient personnel and technical infrastructure support to ensure concurrent data abstraction and complete data entry within the 60-day timeline.

(E) The trauma program must have documented procedures for trauma registry validation, trauma registry data submission to the State Trauma Registry and NTDB as appropriate, and to request data from the facility's trauma registry that are approved by the TMD and TPM and are reviewed at the trauma operations committee.

(35) 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.

(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.

(C) Rural Level IV trauma facilities that have 75 or fewer injured patients meeting NTDB registry inclusion criteria and do not admit trauma patients for intensive care or trauma operative interventions may have the trauma registrar attend an alternate data management course or outsource their registry requirements.

(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.

(E) The EMS wristband tracking number must be included in the registry abstraction and submission of data to the State Trauma Registry.

(36) The trauma facility must have education requirements, certification requirements, skills competency requirements, and evidence of trauma continuing education for trauma nursing staff providing care for patients meeting trauma activation guidelines and meeting NTDB registry inclusion criteria that are monitored for compliance.

(A) There must be documented role-specific orientation plans for new staff for all units that provide trauma care.

(B) Registered nurses assigned to care for arriving patients that meet trauma activation guidelines must have current TNCC or ATCN, ENPC or PALS, and Advanced Cardiac Life Support certifications (ACLS). Those that are new to the facility or the facility's trauma resuscitation area must meet these requirements within 12 months of their hiring date.

(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.

(D) Nurses providing care to the trauma patient through the continuum of care must have documented evidence of trauma training and education for the trauma population they care for, training in trauma-informed care, and access to trauma-related continuing education.

(37) The trauma facility must provide outreach training programs for trauma-related continuing education for staff, community trauma providers, APPs, nurses, EMS, and other staff participating in trauma care or trauma system development.

(A) Level I trauma facilities must have documented evidence of outreach education to the rural facilities in their regions and contiguous region, if a Level I trauma facility is not available in the contiguous region, to include:

- (i) trauma management guidelines for all injuries;
- (ii) designation assistance;
- (iii) transfers; and
- (iv) trauma registry assistance.

(B) The outreach education job functions may be integrated into the TPM's job descriptions for the Level III and IV facilities.

(C) Level III and IV facilities may assist with RAC educational activities or collaborate with other health care systems to provide outreach education.

(38) The trauma facility must have an individual responsible for injury prevention and public education (IPPE).

(A) The Level III and IV facilities may integrate the IPPE job functions into the TPM job description, and IPPE activities may be integrated with RAC activities or provided in collaboration with other health care facilities.

(B) Trauma facilities must participate in all statewide IPPE initiatives, such as the Stop the Bleed course, and provide the appropriate documentation to demonstrate their activities.

(39) The trauma facility must have a comprehensive facility all-hazard disaster response and business continuity plan with procedures for establishing incident command and department-specific guidelines or job action sheets that guide actions and responses.

(A) All trauma program surgeons, trauma liaisons, trauma program personnel, operating suite leaders, and critical care medical director and nursing leaders must complete a mass casualty response training on their role and potential job functions and a job action sheet, to ensure competency regarding measures for surge capacity, capabilities, and patient flow management from resuscitation to inpatient admission, operative suite, and critical care during a multiple casualty or mass casualty event.

(B) The trauma program must have documented evidence of an annual mass casualty or a no-notice multiple casualty simulation training that integrates EMS and is planned by the TMD, emergency department medical director, TPM, trauma administrator, operating suite leaders, critical care leaders, and facility emergency management leaders.

(40) The trauma facility must have a process in place to provide trauma patient outcomes and feedback to EMS providers.

(A) The facility must have documented guidelines to provide EMS time-out for the arriving injured patient that are a collaborative outcome between the TMD, emergency department medical director, and the EMS medical directors.

(B) Trauma patient outcomes and feedback data must be handled in compliance with the Health Information Portability Accountability Act (HIPAA) and relevant state law.

(C) Processes must be established and agreed to between the TMD and the EMS medical directors for the top three EMS transporting agencies to receive trauma patient outcomes, feedback, and identified opportunities for improvement for the patients they transport to the facility on a scheduled basis.

(D) Trauma facilities must provide EMS feedback within 30 days of arrival on trauma patients the EMS providers transported to the facility, as requested.

(E) Feedback must include the first 24 hours of care, resuscitation disposition, injury diagnosis available, operative interventions, and demographic information.

(F) All identified EMS opportunities for improvement are shared with the specific transporting EMS provider following HIPAA guidelines.

(k) A facility seeking trauma designation or renewal of designation must submit the completed designation application packet, have the required documents available at the time of the site survey, and submit the survey summary and medical record reviews following the completed site survey.

(1) A complete application packet contains the following:

(A) a trauma designation application for the requested level of designation;

(B) a completed department pre-review questionnaire and documentation that no potential conflict of interest exists;

(C) full payment of the designation fee and department remit form submitted to the department Cash Branch per the designation application instructions;

(D) evidence of the TMD and TPM attendance at RAC meetings throughout the designation cycle;

(E) evidence of documented data validation and quarterly submission to the State Trauma Registry and NTDB for the past 12 months;

(F) the documentation in subparagraphs (A) - (D) of this paragraph must be submitted to the department and department-approved survey organization no later than 45 days before the facility's scheduled site survey.

(2) The facility must have the required documents available and organized for the actual site survey review process, including:

(A) documentation of a minimum of 12 months of trauma performance improvement and patient safety reviews, including minutes and attendance of the trauma operations meetings and the trauma multidisciplinary peer review committee meetings, all trauma-documented management guidelines or evidence-based practice guidelines, and all trauma-related policies, procedures, protocols, and diversion times;

(B) evidence of 12 months of trauma registry data abstraction and data entry, with completed registry files demonstrating 80 percent of files completed within 60 days of patient discharge, transfer, or death;

(C) documentation of all injury prevention, outreach education, public education, and research activities; and

(D) documentation to reflect the Texas designation requirements and that ACS standards for verification are met.

(3) Not later than 90 days after the trauma site survey, the facility must submit to the department the following documentation:

(A) the documented trauma designation site survey summary report that includes the requirements met and not met, and the medical record reviews; and

(B) a POC, if required by the department, which addresses all designation requirements defined as "not met" in the trauma designation site survey summary report and must include:

(i) a statement of the cited designation requirement not met;

(ii) a statement describing the corrective action taken by the facility seeking trauma designation to meet the requirement;

(iii) the title of the individuals responsible for ensuring the corrective actions are implemented and monitored;

(iv) the date the corrective actions are implemented;

(v) a statement on how the corrective action will be monitored and what data is measured to identify change;

(vi) documented evidence that the POC is implemented within 60 days of the survey date; and

(vii) any subsequent documents requested by the department.

(4) The application includes full payment of the non-refundable, non-transferrable designation fee listed:

(A) For 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) For 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.

(C) For 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.

(5) All application documents except the designation fee will be submitted electronically to the department.

(l) Facilities seeking initial trauma designation must complete a scheduled conference call with the department and include the facility's CEO, CNO, COO, trauma administrative or executive leader, TMD, and TPM before scheduling the designation site survey. The following information must be provided to the department before the scheduled conference call with the department:

(1) job descriptions for the trauma administrator, TMD, TPM, and trauma registrar;

(2) trauma operational plan;

(3) trauma PIPS plan;

(4) trauma activation and trauma management guidelines;
and

(5) trauma registry procedures.

(m) Facilities seeking designation renewal must submit the required documents described in subsection (l) of this section to the department no later than 90 days before the facility's current trauma designation expiration date.

(n) The application will not be processed if a facility seeking trauma designation fails to submit the required application documents and designation fee.

(o) A facility requesting designation at a different level of care or experiencing a change in ownership or a change in physical address must notify the department and submit a complete designation application packet and application fee.

(p) Facilities will schedule a designation site survey with a department-approved survey organization. All initial designation site surveys must be performed in person unless approval for virtual review is given by the department.

(1) Facilities requesting Level I and II trauma facility designation must request a verification site survey through the ACS. This includes facilities seeking pediatric Level I and II designation that are in the facility's main campus and those that are pediatric stand-alone facilities.

(2) Level III facilities must request a site survey through either the ACS trauma verification program or through a department-approved survey organization.

(3) Level IV facilities must request a site survey with a department-approved survey organization or follow the defined departmental process.

(4) The facility must notify the department of the date of the scheduled site survey a minimum of 60 days before the survey.

(5) The facility is responsible for any expenses associated with the site survey.

(6) The department, at its discretion, may appoint a department observer to accompany the survey team with the observer costs borne by the department.

(q) The survey team composition must be as follows:

(1) 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.

(2) Level I or Level II adult and pediatric facilities must be reviewed by a multidisciplinary team, consistent with current ACS standards, and include, at a minimum, a pediatric surgeon, a trauma or general surgeon with trauma expertise, a pediatric emergency medicine physician, and a pediatric TPM, all currently active in a verified or designated trauma facility that currently participates in the management or oversight of pediatric trauma patients and practice outside of Texas. All aspects of the site survey process must follow the department survey guidelines.

(3) Level III facilities must be reviewed by a multidisciplinary team with trauma expertise and current participation in the management or oversight of trauma patients at a Level I, II, or III trauma designated facility. All aspects of the site survey process must follow the department survey guidelines.

(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.

(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.

(C) Level III facilities evaluating 299 or fewer patients per year meeting NTDB registry inclusion criteria must be reviewed by a trauma or general surgeon, and a TPM.

(4) Level IV facilities that evaluate and admit patients who meet NTDB registry inclusion criteria must be reviewed by a multi-disciplinary team with trauma expertise, all currently participating in trauma management or oversight at a Level I, II, or III designated facility. All aspects of the site survey process must follow the department survey guidelines.

(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.

(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.

(C) Level IV facilities that evaluate and admit 100 to 299 patients per year meeting NTDB registry inclusion criteria must be reviewed by a trauma or general surgeon and a TPM, currently participating in trauma patient management or oversight at a Level I, II, or III designated facility.

(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.

(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.

(5) In Level III and Level IV facilities, the second surgeon may be replaced with an orthopedic surgeon for those facilities with predominately orthopedic trauma cases or a neurosurgeon for those facilities with neurotrauma cases. This individual must currently participate in trauma patient management at a designated Level I, II, or III trauma facility.

(r) Trauma facilities seeking designation or redesignation and department-approved survey organizations must follow the department survey guidelines and ensure all surveyors follow these guidelines.

(1) All members of the survey team for Level III or IV, except department staff, cannot be from the same TSA or a contiguous TSA of the facility's location. There must be no business or patient care relationship or any known conflict of interest between the surveyor or the surveyor's place of employment and the facility being surveyed.

(2) The facility must not accept surveyors with any known conflict of interest. If a conflict of interest is present, the facility seeking trauma designation must decline the assigned surveyor through the survey organization.

(A) A conflict of interest exists when the surveyor has a direct or indirect financial, personal, or other interest which would limit or could reasonably be perceived as limiting the surveyor's ability to serve in the best interest of the public.

(B) The conflict of interest may include a surveyor who, in the past four years:

(i) has trained or supervised key hospital or medical staff in residency or fellowship;

(ii) collaborated professionally with key members of the facility's leadership team;

(iii) was employed in the same health care system in state or out of state;

(iv) participated in a designation consultation with the facility;

(v) had a previous working relationship with the facility or facility leader;

(vi) conducted a designation survey for the facility;

or

(vii) is the EMS medical director for an agency that routinely transports trauma patients to the facility.

(3) If a designation survey occurs with a surveyor who has a known conflict of interest, the trauma designation site survey summary report and medical record review may not be accepted by the department.

(4) A survey organization must complete an application requesting to perform designation surveys in Texas and be approved by the department. Each organization must renew its application every four years.

(s) Level I, II, and III facilities using the ACS verification program who do not receive a letter of verification and facilities surveyed by a department-approved survey organization with four or more requirements not met must schedule a conference call with the department.

(t) If a health care facility seeking re-designation fails to meet the requirements outlined in subsection (j) of this section, the original designation will expire on its expiration date. The facility must wait six months and begin the process again if they choose to continue as a designated trauma facility.

(u) If a facility disagrees with the designation level awarded by the department, the CEO, CNO, or COO may request an appeal, in writing, sent to the EMS/Trauma Systems Section Director not later than 30 days after receiving a designation award.

(1) All written appeals are reviewed quarterly by the EMS/Trauma Systems Section Director in conjunction with the Trauma Designation Review Committee.

(A) The Trauma Designation Review Committee consists of the following individuals for trauma designation appeals, exception requests, or contingent designation survey summaries:

(i) Chair of Governor's EMS and Trauma Advisory Council (GETAC);

(ii) Immediate past-chair of GETAC;

(iii) Chair of the GETAC Trauma Systems Committee;

(iv) Chair of the GETAC EMS Medical Directors Committee;

(v) Chair of the GETAC Pediatric Committee;
(vi) Current President of the Texas Trauma Coordinators Forum;

(vii) three individuals who each have a minimum of 10 years of trauma facility oversight as an administrator, medical director, program manager or director, or program liaison, all selected by the current Chair of GETAC and approved by the EMS/Trauma Systems Section Director and CPD Associate Commissioner; and

(viii) three department representatives from the EMS/Trauma Systems Section.

(B) The Trauma Designation Review Committee meetings are closed to maintain confidentiality for all reviews.

(C) The GETAC Chair and the Chair of the Trauma System Committee are required to attend the Trauma Designation Review Committee, in addition to a minimum of five of the other members, to conduct meetings with the purpose of reviewing trauma facility designation appeals, exception requests, and contingent designation survey summaries that identify requirements not met. Agreement of a majority of the members present is required.

(2) If the Trauma Designation Review Committee supports the department's designation determination, the EMS/Trauma Systems Section Director will give written notice of the review and determination to the facility not later than 30 days after the committee's recommendation.

(3) If the Trauma Designation Review Committee recommends a different level of designation, it will provide information to support a designation change to the department. The department reviews the recommendation and determines the approved level of designation. Additional actions, such as a focused review, re-survey, or submission of information and reports to maintain designation, may be required by the department for identified designation requirements that are not met or are partially met.

(4) If a facility disagrees with the Trauma Designation Review Committee's recommendation and department's awarded level of designation, the facility may request a second appeal review with the department's CPD Associate Commissioner in writing and electronically submit to the EMS/Trauma Systems Section no later than 15 days after the date of the department's designation notice. If the CPD Associate Commissioner disagrees with the Trauma Designation Review Committee's recommendation, the CPD Associate Commissioner decides the appropriate level designation awarded. The department sends a notification letter of the second appeal decision within 30 days of receiving the second appeal request.

(5) If the facility continues to disagree with the second level of appeal, the facility has a right to a hearing in the manner referenced for contested cases in Texas Government Code Chapters 1 and 2001.

(v) All designated facilities must follow the exceptions and notifications process outlined in the following paragraphs.

(1) A designated trauma facility must provide written or electronic notification of any significant change to the trauma program impacting the capacity or capabilities to manage and care for a trauma patient. The notification must be provided to the following:

(A) all EMS providers that transfer trauma patients to or from the designated trauma facility;

(B) the hospitals to which it customarily transfers out or from which it transfers in trauma patients;

(C) applicable RACs; and

(D) the department.

(2) If the designated trauma facility is unable to meet the requirements to maintain its current designation, it must submit to the department a documented POC and a request for a temporary exception to the designation requirements. Any request for an exception must be submitted in writing from the facility's CEO and define the facility's timeline to meet the designation requirements. The department reviews the request and the POC and either grants the exception with a timeline based on access to care, including geographic location, other levels of trauma facilities available, transport times, impact on trauma outcomes, and the regional trauma system, or denies the exception. If the facility is not granted an exception or it does not meet the designation requirements at the end of the exception period, the department will elect one of the following:

(A) review the exception request with the Trauma Designation Review Committee with consideration of geographic location, access to trauma care in the local area of the facility, and impact on the regional system;

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

(C) outline an agreement with the facility to satisfy all designation requirements for the level of care designation within a time specified under the agreement, which may not exceed the first anniversary of the effective date of the agreement; or

(D) accept the facility's surrender of its trauma designation certificate.

(3) If the facility is relinquishing its trauma designation, the facility must provide 30 days written advance notice of the relinquishment to the department. The facility informs the applicable RACs, EMS providers, and facilities to which it customarily transfers out or from which it transfers in trauma patients. The facility is responsible for continuing to provide trauma care services or ensuring a plan for trauma care continuity for 30 days following the written notice of relinquishment of its trauma designation.

(w) A designated trauma facility may choose to apply for a higher level of designation at any time. The facility must follow the initial designation process described in subsection (j) of this section to apply for a higher level of trauma designation. The facility cannot claim or advertise the higher level of designation until the facility has received written notification of the award of the higher level of designation.

(x) A hospital providing trauma services must not use or authorize the use of any public communication or advertising containing false, misleading, or deceptive claims regarding its trauma designation status. Public communication or advertising is deemed false, misleading, or deceptive if the facility uses these, or similar, terms:

(1) trauma facility, trauma hospital, trauma center, functioning as a trauma center, serving as a trauma center, or similar terminology if the facility is not currently designated as a trauma center or designated trauma center at that level; or

(2) comprehensive Level I trauma center, major Level II trauma center, advanced Level III trauma center, basic Level IV trauma center, or similar terminology in its signs, website, advertisements, social media, or in the printed materials and information it provides to the public that is different than the current designation level awarded by the department.

(y) During a virtual, on-site, or focused designation review conducted by the department or a survey organization, the department or surveyor has the right to review and evaluate the following documentation to validate that designation requirements are met in this section and the Texas Health and Safety Code Chapter 773:

- (1) trauma patient records;
- (2) trauma performance improvement plan and process documents;
- (3) appropriate committee documentation for attendance, meeting minutes, and documents demonstrating why the case was referred, the date reviewed, pertinent discussion, and any actions taken specific to improving trauma care and outcomes; and
- (4) documents relevant to trauma care in a designated trauma facility or facility seeking trauma facility designation to validate evidence that designation requirements are met.

(z) The department and department-approved survey organizations must comply with all relevant laws related to the confidentiality of such records.

§157.128. Denial, Suspension, and Revocation of Trauma Facility Designation.

(a) An applicant [applicant/healthcare] facility's trauma application for designation may be denied, or a [healthcare] facility's trauma designation may be suspended or revoked for failure to meet designation requirements, and [; but not limited to;] the following reasons:

- (1) failure to comply with the statute and this chapter [these sections];
- (2) willful preparation or filing of false reports or records;
- (3) fraud or deceit in obtaining or attempting to obtain designation status;
- (4) failure to submit trauma data to the State Trauma [Texas EMS/Trauma] Registry;
- (5) failure to maintain required licenses, designations, and accreditations or when disciplinary action has been taken against the health care [healthcare] facility by a state or national licensing agency;
- (6) failure to have appropriate staff, [or] equipment, or resources required for designation routinely available [as described in §157.125 of this title (relating to Requirements for Trauma Facility Designation)];
- ~~(7) abuse or abandonment of a patient;~~
- (7) [8] unauthorized disclosure of medical or other confidential information;
- (8) [9] alteration or inappropriate destruction of medical records; or
- (9) [10] refusal to render care because of a patient's race, color, gender, [sex, creed,] national origin, sexual preference, age, disability [handicap], medical problem, or inability to pay.[; or]

~~[(11) criminal conviction(s) as described in the Occupations Code, Chapter 53, Subchapter B.]~~

(b) Intermittent [Occasional] failure of a [healthcare] facility to meet designation criteria shall not be grounds for denial, suspension, or revocation by the department [Office of EMS/Trauma Systems Coordination (office)], if the circumstances under which the failure occurred:

- (1) do not reflect an overall deterioration in quality of trauma care; and

(2) are corrected within a reasonable timeframe by the [healthcare] facility.

(c) If the department [office] proposes to deny, suspend, or revoke a designation, the department must [office shall] notify the [healthcare] facility at the address shown in the current department records [of the department]. The notice must [shall] state the alleged facts that warrant the proposed action and state that the [healthcare] facility has an opportunity to appeal the proposed action through the Trauma Designation Review Committee as described in §157.125(u) of this subchapter or request a hearing in the manner referenced for contested cases in Texas [accordance with] Government Code[;] Chapter 2001.

(1) A request for a hearing shall be in writing and submitted to the department [Office of EMS/Trauma Systems Coordinator] and postmarked within 15 days of the date the notice was sent.

(2) If the healthcare facility fails to timely submit a written request for a hearing, it will be deemed to have waived the opportunity for a hearing and the proposed action will be ordered.

(d) Six months after the denial of an applicant [applicant/healthcare] facility's designation, the applicant [applicant/healthcare] facility may reapply for [trauma] facility designation [as described in §157.125 of this title].

(e) One year after the revocation of a [healthcare] facility's designation, the [healthcare] facility may reapply for designation [as described in §157.125 of this title]. The department [office] may deny designation if the department [office] determines that the reason for the revocation continues to exist or if the facility otherwise does not continuously meet the designation requirements.

(f) The department will inform the facility of the potential funding implications related to the designation denial, suspension, or revocation as outlined in:

(1) Title 1 of the Texas Administrative Code (TAC), Part 15, Chapter 355, Subchapter J, Division 4, §355.8052 and §355.8065; and

(2) Section 157.130 of this subchapter (relating to Funds for Emergency Medical Services, Trauma Facilities, and Trauma Care Systems, and the Designated Trauma Facility and Emergency Services Account).

§157.130. Funds for Emergency Medical Services, Trauma Facilities, and Trauma Care Systems, and the Designated Trauma Facility and Emergency Services Account.

(a) Allocations determination under Texas Health and Safety Code §773.122 and Chapter 780.

(1) Department determination. The department determines each year:

(A) eligibility criteria for emergency medical services (EMS), trauma service area (TSA), and hospital allocations; and

(B) the amount of EMS, TSA, and hospital allocations based on language described in Texas Health and Safety Code §773.122 and Chapter 780.

(2) Eligibility requirements. To be eligible for funding from the accounts, all potential recipients must maintain the regional participation requirements.

(3) Extraordinary emergency funding.

(A) To be eligible to receive extraordinary emergency funding, an entity must meet the following requirements:

(i) be a licensed EMS provider, a designated trauma facility, or a recognized first responder organization (FRO);

(ii) submit a completed application and any additional documentation requested by the department; and

(iii) provide documentation of active participation in its local Regional Advisory Council (RAC).

(B) Incomplete applications will not be considered for extraordinary emergency funding.

(4) EMS allocation.

(A) The department will contract with each eligible RAC to distribute the county funds to eligible EMS providers based within counties that are aligned with the relevant TSA.

(i) The department will evaluate submitted support documents per the contract statement of work. Awarded funds must be used in addition to current operational EMS funding of eligible recipients and must not supplant the operational budget.

(ii) Funds are allocated by county to be awarded to eligible providers in each county. Funds are non-transferable to other counties within the RAC if there are no eligible providers in a county.

(B) Eligible EMS providers may contribute funds for a specified purpose within the TSA when:

(i) all EMS providers received communication regarding the intent of the contributed funds;

(ii) the EMS providers voted and approved by majority vote to contribute funds; and

(iii) all EMS providers that did not support contributing funds for the specific purpose receive their total funding.

(C) To be eligible for funding from the EMS allocation, providers must:

(i) maintain and comply with all licensure requirements as described in §157.11 of this chapter (relating to Requirements for an EMS Provider License);

(ii) follow RAC regional protocols regarding patient destination and transport in all TSAs in which they operate (verified by each RAC);

(iii) follow actual patient referral patterns of each RAC to which it provides services, if the provider is licensed in a county or contracted to provide EMS in a contiguous county in a neighboring TSA;

(iv) notify the RACs of any potential eligibility to receive funds and meet the RAC's participation requirements, if a provider is contracted to provide EMS within a county of any one TSA and whose county of licensure is another county not in or contiguous with that TSA; and

(v) provide the department evidence of a contract or letter of agreement with each additional county government or taxing authority in which EMS is provided in any county beyond its county of licensure.

(D) Inter-facility transfer letters of agreement and contracts or mutual aid letters of agreement and contracts do not meet this requirement.

(E) Contracts or letters of agreement must be submitted to the department on or before the stated department contract deadline of the respective year and provide evidence of continued coverage

throughout the effective contract dates for which the eligibility of the EMS provider is being considered.

(F) EMS providers with contracts or letters of agreement on file with the department that meet the effective contract dates do not need to resubmit a copy of the contract or letter of agreement unless it has expired or will expire before the effective date of the next contract.

(G) The submitted contracts or letters of agreement must include effective dates to determine continued eligibility.

(H) EMS providers are responsible for ensuring that all necessary portions of their contracts or letters of agreement have been received by the department on or before the listed deadline to be considered for eligibility.

(I) Air ambulance providers must meet the same requirements as ground transport EMS providers to be eligible to receive funds from a specific county other than the county of licensure.

(J) If an EMS provider is licensed in a particular county for a service area that is considered a geo-political subdivision and whose boundary lines cross multiple county lines, it will be considered eligible for the EMS Allocation for all counties overlapped by that geo-political subdivision's boundary lines. Verification from local jurisdictions will be requested for every county that comprises the geo-political subdivision to determine funding eligibility for each county. The eligibility of EMS providers whose county of licensure is in a geo-political subdivision other than those listed in clauses (i) - (v) of this subparagraph will be evaluated on a case-by-case basis. Geo-political subdivisions include:

(i) municipalities;

(ii) school districts;

(iii) emergency service districts (ESDs);

(iv) utility districts; or

(v) prison districts.

(5) TSA allocation.

(A) The department will contract with eligible RACs to distribute the funds for the operation of the 22 TSAs and for equipment, communications, education, and training for the areas.

(B) To be eligible to distribute funding on behalf of eligible recipients in each county to the TSA, a RAC must be:

(i) officially recognized by the department as described in §157.123 of this subchapter (relating to Regional Advisory Councils);

(ii) in compliance with all RAC performance criteria and expectations, have a current RAC self-assessment, and have a current regional trauma and emergency health care system plan; and

(iii) incorporated as an entity that is exempt from federal income tax under Section 501(a), Internal Revenue Code of 1986, and its subsequent amendments by being listed as an exempt organization under Section 501(c)(3).

(C) The TSA allocation distributed under this paragraph will be based on the relative geographic size and population of each TSA and on the relative amount of trauma care provided.

(6) Hospital allocation. The department will distribute funds to designated trauma facilities to subsidize a portion of uncompensated trauma care provided or to enhance the facility's delivery of trauma care.

(A) Funds distributed from the hospital allocations will be made based on:

(i) the hospital being designated as a trauma facility by the department as defined in Texas Health and Safety Code Chapter 773;

(ii) the percentage of the hospital's uncompensated trauma care cost for patients who meet the National Trauma Data Bank (NTDB) registry inclusion criteria relative to the total uncompensated trauma care cost reported for the identified patient population by qualified facilities that year;

(iii) availability of funds; and

(iv) submission of a complete application to the department within the stated time frame. Incomplete applications will not be considered.

(B) Additional information may be requested by the department to determine eligibility for funding.

(C) A designated trauma facility in receipt of funding from the hospital allocation that fails to maintain its designation as required in §157.125 of this subchapter (relating to Requirements for Trauma Facility Designation) must return to the department all hospital allocation funds received in the prior 12 months within 90 days of failure to maintain trauma designation.

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

(E) A facility must have no outstanding balance owed to the department or other state agencies before receiving any future disbursements from the hospital allocation.

(7) Department allocations. The department's process for funding allocations defined in this subsection applies to the account defined in Texas Health and Safety Code Chapter 780 and includes designated trauma facilities and those in active pursuit of trauma designation in the funding allocation.

(8) Department unawarded designation. An undesignated facility in active pursuit of designation but that has not been awarded a trauma designation by the department pursuant to Texas Health and Safety Code §780.004(i) must return to the account all funds received from the hospital allocation, plus a penalty of 10 percent of the awarded amount.

(b) Calculation methods. Calculation of county portions of the EMS allocation, the RAC portions of the TSA allocation, and the hospital allocation will be the following:

(1) EMS allocation.

(A) EMS allocation will be derived by adjusting the weight of the statutory criteria to ensure, as closely as possible, that:

(i) 40 percent of the funds go to urban counties; and

(ii) 60 percent of the funds go to rural counties.

(B) An individual county's portion of the EMS allocation will be based on its geographic size, population, and the number of emergency health care runs, multiplied by adjustment factors determined by the department, so that the distribution approximates the required percentages for urban and rural counties.

(C) The formula will be:

(i) the county's population multiplied by an adjustment factor;

(ii) plus, the county's geographic size multiplied by an adjustment factor;

(iii) plus, the county's total emergency health care runs multiplied by an adjustment factor;

(iv) divided by 3; and

(v) multiplied by the total EMS allocation.

(D) The adjustment factors will be manipulated so that the distribution approximates the required percentages for urban and rural counties.

(E) Total emergency health care runs will be the number of emergency patient care records electronically transmitted to the department in a given calendar year by EMS providers.

(2) TSA allocation.

(A) The TSA allocation will be based on its relative geographic size, population, and trauma care provided as compared to all other TSAs.

(B) The formula will be:

(i) the TSA's percentage of the state's total population;

(ii) plus, the TSA's percentage of the state's total geographic size;

(iii) plus, the TSA's percentage of the state's total trauma care;

(iv) divided by 3; and

(v) multiplied by the total TSA allocation.

(C) Total trauma care will be the number of trauma patient records electronically transmitted to the department in a given calendar year by EMS providers and hospitals.

(3) Hospital allocation.

(A) Distributions, including unexpended portions of the EMS and TSA allocations, are determined by an annual application process.

(B) An annual application must be submitted each fiscal year. Incomplete applications will not be considered for the hospital allocation calculation.

(C) Based on the information provided in the approved application, each facility will receive allocations as follows:

(i) An equal amount, not to exceed 20 percent of the available hospital allocation, to reimburse designated trauma facilities and those facilities in active pursuit of designation under the program and not located in a rural county as defined in §157.2 of this chapter (relating to Definitions).

(ii) Any funds not allocated in paragraphs (1) and (2) of this subsection will be included in the distribution formula in subparagraph (E) of this paragraph.

(D) If the total cost of uncompensated trauma care for patients meeting NTDB registry inclusion criteria exceeds the amount appropriated from the account, minus the amount referred to in subparagraph (C)(i) of this paragraph, the department will allocate funds based on a facility's percentage of uncompensated trauma care costs in

relation to the total uncompensated trauma care cost reported by qualified hospitals for the funding year.

(E) The hospital allocation formula for trauma designated facilities will be:

(i) the facility's reported costs of uncompensated trauma care;

(ii) minus any collections received by the facility for any portion of the facility's uncompensated trauma care previously reported for the purposes of this section;

(iii) divided by the total reported costs of uncompensated trauma care by eligible facilities;

(iv) multiplied by the total money available after reducing the amount to be distributed in subparagraph (C)(i) of this paragraph.

(F) The reporting period of a facility's uncompensated trauma care must apply to costs incurred during the preceding calendar year.

(c) Loss of funding eligibility. If the department finds that an EMS provider, RAC, or hospital has violated Texas Health and Safety Code Chapter 773 or fails to comply with this chapter, the department may withhold account monies for a period of one to three years, depending upon the seriousness of the infraction.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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TRD-202400015

Cynthia Hernandez

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Department of State Health Services

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For further information, please call: (512) 535-8538



CHAPTER 229. FOOD AND DRUG

The Executive Commissioner of the Texas Health and Human Services Commission (HHSC), on behalf of the Department of State Health Services (DSHS), proposes amendments to Subchapter U, §§229.370 - 229.374, relating to Permitting Retail Food Establishments; and amendments to Subchapter Z, §§229.470 - 229.474, relating to Inspection Fees for Retail Food Establishments.

BACKGROUND AND PURPOSE

The purpose of the proposal is to update definitions, citations, and other language in 25 TAC Chapter 229, Subchapters U and Z due to the 2021 adoption-by-reference of the 2017 U.S. Food and Drug Administration Food Code in 25 TAC Chapter 228, Retail Food Establishments.

The proposal also removes references to "child care center" in §§229.371, 229.372, and 229.471 since permitting and inspections of food service operations of child care centers transferred to HHSC Regulatory Services Division. Those rules are in 26 TAC Chapter 746 and minimum standards for food preparation and food service are in §746.3317.

SECTION-BY-SECTION SUMMARY

The proposed amendments include non-substantive editorial changes and revisions to improve clarity that are not specifically enumerated here.

The proposed amendments replace "these sections" and "these rules" for "this subchapter" throughout the subchapters.

SUBCHAPTER U, PERMITTING RETAIL FOOD ESTABLISHMENTS

The proposed amendment to §229.371, concerning Definitions, adds language to reference the applicability of definitions contained in §228.2. The amendment revises definitions for "food establishment," "nonprofit organization," "retail food store," and "school food establishment." The definitions of "bed and breakfast extended," "bed and breakfast food establishment," "mobile food unit," "outfitter operation," "pushcart," and "roadside food vendor" are removed to avoid redundancy. The definitions of "child care center," "department," "person," and "potentially hazardous food" are removed as these definitions are no longer necessary. A new definition is added for "time and temperature control for safety food (TCS food)." The updated definitions provide clarity to the rule language and ensure consistency in interpretation of the rules.

The proposed amendment to §229.372(a)(3)(A) changes the deadline for a mobile food unit to comply with minimum standards before paying a new permit fee from one to two years.

The proposed amendment to §229.372(a)(5) removes the rule language regarding the permitting of child care centers providing food service and replaces it with new language regarding "use fees" for permit applications submitted through Texas.gov.

The proposed amendment removes §229.372(a)(8) regarding the verification of gross annual volume of food sales.

The proposed amendment adds language regarding food establishments that are not required to pay a fee or obtain a permit to §229.372(b)(2). The language is moved from the definition of "food establishment" in renumbered §229.371(2).

The proposed amendment adds §229.372(d)(6) requiring an applicant to provide any other information DSHS may need to issue a retail food establishment permit.

The proposed amendment removes §229.372(e) since it is included in §229.372(c).

The proposed amendment to renumbered §229.372(e)(1) and (2) adds language stating the fees for temporary food establishment single-event and multiple-event permit applications are non-refundable.

The proposed amendment to renumbered §229.372(f) clarifies the application process for an owner of two or more establishments.

The proposed amendment to renumbered §229.372(h) changes the address to the current website.

The proposed amendment of renumbered §229.372(j) removes change of "ownership" as a trigger for amendment of a permit and clarifies fee amounts for amendments of current permits.

The proposed amendment removes §229.372(l) to avoid redundancy, since Texas.gov fees are included in §229.372(a)(5).

The proposed amendment to §229.373 removes language about obtaining printed copies of 25 TAC Chapter 228 and changes the address to the current website.

The proposed amendment to §229.374(b) adds a reference to Texas Government Code Chapter 2001, Administrative Procedure Act, concerning formal hearing procedures.

SUBCHAPTER Z, INSPECTION FEES FOR RETAIL FOOD ESTABLISHMENTS

The proposed amendment to §229.471, concerning Definitions, adds language to reference the applicability of definitions contained in §228.2. The amendment revises definitions for "food establishment," "nonprofit organization," and "school food establishment." The definitions of "mobile food unit," "pushcart," and "roadside food vendor" are removed to avoid redundancy. The definitions of "child care center," "department," "person," and "potentially hazardous food" are removed as these definitions are no longer necessary. A new definition is added for "time and temperature control for safety food (TCS food)." The updated definitions provide clarity to the rule language and ensure consistency in interpretation of the rules.

The proposed amendment to moves language from §229.472(a)(1)(A) to renumbered §229.472(a)(1) and adds language specifying the fee for inspection of a school food establishment is non-refundable.

The proposed amendment removes §229.472(a)(1)(B) concerning requiring applications for school food establishment inspections to be submitted annually between September 15 and October 31.

The proposed amendment adds language regarding food establishments that are not required to pay a fee or obtain a permit to new §229.472(d). The language is moved from the definition of "food establishment" in renumbered §229.471(3).

The proposed amendment to renumbered §229.472(g) changes the address to the current website.

The proposed amendment removes §229.472(g), concerning Texas Online.

The proposed amendment to §229.473 removes language about obtaining printed copies of 25 TAC Chapter 228 and changes the address to the current website.

The proposed amendment to §229.474 revises the reference to the Administrative Procedure Act.

FISCAL NOTE

Christy Havel Burton, Chief Financial Officer, has determined for each year of the first five years the rules will be in effect, enforcing or administering the rules do not have foreseeable implications relating to costs or revenues of state or local governments.

GOVERNMENT GROWTH IMPACT STATEMENT

DSHS has determined during the first five years the rules will be in effect:

- (1) the proposed rules will not create or eliminate a government program;
- (2) implementation of the proposed rules will not affect the number of DSHS employee positions;
- (3) implementation of the proposed rules will result in no assumed change in future legislative appropriations;
- (4) the proposed rules will not affect fees paid to DSHS;
- (5) the proposed rules will not create a new rule;

(6) the proposed rules will not expand, limit, or repeal existing rules;

(7) the proposed rules will not change the number of individuals subject to the rules; and

(8) the proposed rules will not affect the state's economy.

SMALL BUSINESS, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYSIS

Christy Havel Burton, Chief Financial Officer, has also determined there will be no adverse economic effect on small businesses, micro-businesses, or rural communities.

LOCAL EMPLOYMENT IMPACT

The proposed rules will not affect a local economy.

COSTS TO REGULATED PERSONS

Texas Government Code §2001.0045 does not apply to these rules because the rules are necessary to protect the health, safety, and welfare of the residents of Texas.

PUBLIC BENEFIT AND COSTS

Dr. Timothy Stevenson, Associate Commissioner, Consumer Protection Division, has determined for each year of the first five years the rules are in effect, the public benefit will be retail food permitting and inspection application rules that are clear, up-to-date, and aligned with program policies and procedures.

Christy Havel Burton has also determined for the first five years the rules are in effect, there are no anticipated economic costs to persons who are required to comply with the proposed rules because the rules will not require these persons to alter their current business practices.

REGULATORY ANALYSIS

DSHS has determined this proposal is not a "major environmental rule" as defined by Texas Government Code §2001.0225. "Major environmental rule" is defined to mean a rule the specific intent of which is to protect the environment or reduce risk to human health from environmental exposure and that may adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment or the public health and safety of a state or a sector of the state. This proposal is not specifically intended to protect the environment or reduce risks to human health from environmental exposure.

TAKINGS IMPACT ASSESSMENT

DSHS has determined the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Texas Government Code §2007.043.

PUBLIC COMMENT

Written comments on the proposal may be submitted to DSHS Consumer Protection Division, Food and Drug Section, Retail Food Safety Operations, Mail Code 1987, Texas Department of State Health Services, P.O. Box 149347, Austin, Texas 78714-9347, hand-delivered to 1100 West 49th Street, Austin, Texas 78756, or by email to foodestablishments@dshs.texas.gov.

To be considered, comments must be submitted no later than 31 days after the date of this issue of the *Texas Register*. Comments must be (1) postmarked or shipped before the last day of the comment period; (2) hand-delivered before 5:00 p.m. on the last working day of the comment period; or (3) emailed before

midnight on the last day of the comment period. If the last day to submit comments falls on a holiday, comments must be post-marked, shipped, or emailed before midnight on the following business day to be accepted. When emailing comments, please indicate "Comments on Proposed Rule 23R014" in the subject line.

SUBCHAPTER U. PERMITTING RETAIL FOOD ESTABLISHMENTS

25 TAC §§229.370 - 229.374

STATUTORY AUTHORITY

The proposed amendments are authorized by Texas Health and Safety Code §437.0056 and §437.0125, which direct the Executive Commissioner of HHSC to adopt rules necessary for the implementation of food safety laws; and Texas Government Code §531.0055 and Texas Health and Safety Code §1001.075, which authorize the Executive Commissioner of HHSC to adopt rules and policies necessary for the operation and provision of services by the health and human services by DSHS, and for the administration of Texas Health and Safety Code Chapter 1001.

The proposed amendments implement Texas Government Code Chapter 531 and Texas Health and Safety Code Chapters 437 and 1001.

§229.370. Purpose.

The purpose of this subchapter [these sections] is to implement Texas Health and Safety Code[.] Chapter 437, which requires the department to establish a permitting system for the regulation of food establishments and to ensure uniform requirements for retail food operations.

§229.371. Definitions.

All definitions found in §228.2 of this title (relating to Definitions) are applicable to this subchapter. The following words and terms, when used in this subchapter [these sections], shall have the following meanings, unless the context clearly indicates otherwise.[.]

[(1) Bed and breakfast extended means:]

[(A) an establishment with more than seven rooms for rent; or]

[(B) that provides for food service other than breakfast to overnight guests; and]

[(C) for the purposes of these rules, such facilities are classified as food establishments.]

[(2) Bed and breakfast food establishment means:]

[(A) an establishment that provides food service other than to its overnight guests;]

[(B) the establishment must meet the rules and regulations applicable to retail food establishments; and]

[(C) for the purposes of these rules, such facilities are classified as food establishments.]

[(3) Child care center--Any facility licensed by the regulatory authority to receive 13 or more children for child care which prepares food for on-site consumption. A child care center is classified as a food establishment.]

[(4) Department--The Department of State Health Services.]

(1) [(5)] Food--A raw, cooked, or processed edible substance, ice, beverage, or ingredient used or intended for use or for sale in whole or in part for human consumption, or chewing gum.

(2) [(6)] Food establishment--

(A) A food establishment is an [An] operation that:

(i) stores, prepares, packages, serves, or vends food directly to the consumer, or otherwise provides food for human consumption, such as:

(I) a restaurant [~~food service establishment~~];

(II) a retail food store;

(III) a satellite or catered feeding location;

(IV) a catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people;

(V) a market;

(VI) a vending machine location;

(VII) a self-service food market [~~remote catered operations~~];

(VIII) a conveyance used to transport people;^[.]

(IX) an institution; or

(X) a food bank; and

(ii) [~~that~~] relinquishes possession of food to a consumer directly, or indirectly through a delivery service, such as home delivery of grocery orders or restaurant takeout orders, or delivery service [~~that is~~] provided by common carriers.

[(A) The term includes an element of the operation such as a transportation vehicle or a central preparation facility that supplies a vending location or satellite feeding location unless the vending or feeding location is permitted by the regulatory authority; a restaurant; a grocery store; an operation that is conducted in a mobile, roadside, stationary, temporary, or permanent facility or location; group residence; outfitter operations; bed and breakfast extended and bed and breakfast food establishments; where consumption is on or off the premises; and regardless of whether there is a charge for the food.]

(B) A food establishment includes:

(i) an element of the operation, such as a transportation vehicle or a central preparation facility supplying a vending machine location or satellite feeding location unless the vending machine or feeding location is permitted by the regulatory authority; and

(ii) an operation conducted in a mobile, stationary, temporary, or permanent facility or location and where consumption is on or off the premises regardless if there is a charge for the food.

(C) A food establishment does not include:

(i) an establishment offering only prepackaged foods that are not time and temperature control for safety (TCS) foods;

(ii) a produce stand only offering whole, uncut fresh fruits and vegetables;

(iii) a food processing plant, including one located on the premises of a food establishment;

(iv) a cottage food production operation;

(v) a bed and breakfast limited as defined in §228.2(5) of this title (relating to Definitions); or

(vi) a private home receiving catered or home-delivered food.

[(B) The term does not include: an establishment that offers only prepackaged foods that are not potentially hazardous; a produce stand that only offers whole, uncut fresh fruits and vegetables; a food processing plant; a kitchen in a private home if only food that is not potentially hazardous is prepared for sale or service at a function, such as a religious or charitable organization's bake sale; a Bed and Breakfast Limited facility as defined in these rules; or a private home.]

[(C) All definitions found in §228.2 of this title (relating to Definitions) under the Retail Food rules are applicable to these sections except that, for purposes of obtaining a permit and payment of fees only, the term "food establishment" does not include:]

[(i) food establishments permitted and inspected under authority granted to Home-Rule or Type A General-Law Municipalities;]

[(ii) federally inspected food establishments on federal property;]

[(iii) correction facilities under the inspection of the Texas Department of Criminal Justice;]

[(iv) nursing homes under the inspection authority of Long Term Care Regulatory in the Texas Department of Human Services;]

[(v) hospitals under the inspection of the Health Facility Licensure Division in the department and which do not serve food to the general public;]

[(vi) food establishments on state campuses inspected by state college or university personnel in accordance with the requirements of §229.373 of this title (relating to Minimum Standards for Permitting and Operation);]

[(vii) food establishments licensed under the Health and Safety Code, Chapter 431, as manufacturers of food, provided the fee for licensure exceeds the permit fee required under §229.372 of this title (relating to Permitting Fees and Procedures);]

[(viii) food establishments under the inspection of the Texas Department of Mental Health and Mental Retardation;]

[(ix) nonprofit organizations as defined in these rules. Nonprofit organizations which meet the definition of "manufacturers of food" under Health and Safety Code, Chapter 431, or the definition of "food salvage establishments" under Health and Safety Code, Chapter 432, are not exempt from licensure in those categories;]

[(x) food and beverage vending machines; and]

[(xi) mobile food units permitted and inspected under the authority granted to Home-Rule or Type A General-Law Municipalities and which operate only within their respective jurisdictions. Except for units which handle only pre-packaged non-potentially hazardous foods, a mobile food unit is classified as a food establishment, regardless of whether or not food preparation occurs on the unit.]

(3) [(7)] Food Service Establishment--A food establishment as defined in these rules.

[(8) Mobile food unit--A vehicle-mounted mobile food establishment designed to be readily moveable.]

(4) [(9)] Nonprofit organization--A civic or fraternal organization, charity, lodge, association, proprietorship, or corporation possessing a 501(c)(3) [501(C)] exemption under the Internal Revenue Code; or a religious organization [organizations meeting the definition of "church" under the Internal Revenue Code, §170(b)(1)(A)(i)].

[(10) Outfitter operation--Any operations such as trail rides or river raft trips where food is offered to patrons and which operates out of a central preparation location or food establishment. An outfitter operation is classified as a food establishment.]

(5) [(11)] Permit holder--The person [that is] legally responsible for the operation of the food establishment such as the owner, the owner's agent, or other person; and who possesses a valid permit to operate a food establishment.

[(12) Person--An association, corporation, individual, partnership, other legal entity, government, or governmental subdivision or agency.]

[(13) Potentially hazardous food--A food that is natural or synthetic and that requires temperature control because it is in a form capable of supporting the rapid and progressive growth of infectious or toxigenic microorganisms; the growth and toxin production of *Clostridium botulinum*; or in raw shell eggs, the growth of *Salmonella enteritidis*.]

[(14) Pushcart--A non self-propelled mobile food unit limited to serving nonpotentially hazardous food or potentially hazardous foods requiring a limited amount of preparation as authorized by the regulatory authority. A pushcart is classified as a mobile food unit.]

(6) [(15)] Retail food store--A food establishment or section of an establishment where food and food products are offered to the consumer and intended for off-premises [off-premise] consumption. The term includes delicatessens offering [that offer] prepared food in bulk quantities only. The term does not include establishments which handle only prepackaged, non-TCS food products [nonpotentially hazardous foods]; roadside markets offering [that offer] only unprocessed fresh fruits and fresh vegetables [for sale]; or farmers markets; except [that], for the purposes of obtaining a permit and payment of fees only, the term "retail food store" does not include establishments permitted and inspected under authority granted to municipalities [Home-Rule and Type A General-Law Municipalities].

[(16) Roadside food vendor--A person who operates a mobile retail food store from a temporary location adjacent to a public roadway or highway. Foods shall not be prepared or processed by roadside food vendors. A roadside vendor is classified as a food establishment.]

(7) [(17)] School food establishment--A food service establishment where food is prepared and intended for service primarily to students in [institutions of learning including, but not limited to,] public and private schools, including kindergarten, preschool and elementary schools, junior high schools, high schools, colleges, and universities. A school food establishment is [classified as] a food establishment and may include concession stands located on the school premises or other school-sponsored venues. School food establishments are managed and operated under the supervision of school district employees.

(8) [(18)] Temporary food establishment--A food establishment operating [that operates] for a period of no more than 14 consecutive days in conjunction with a single event or celebration.

(9) Time and temperature control for safety food (TCS food)--A food requiring time and temperature control for safety to limit pathogen growth or toxin production. The term includes a food that must be held under proper temperature controls, such as refrigeration, to prevent the growth of bacteria that may cause human illness. A TCS food may include a food containing protein and moisture and that is neutral or slightly acidic, such as meat, poultry, fish, and shellfish products; pasteurized and unpasteurized milk and dairy products; raw seed sprouts; baked goods that require refrigeration, including cream

or custard pies or cakes; and ice products. The term does not include a food using TCS food as ingredients if the final food product does not require time or temperature control for safety to limit pathogen growth or toxin production.

§229.372. Permitting Fees and Procedures.

(a) Permitting fees.

(1) A person who operates a food establishment shall obtain a permit from the department and pay a permit fee for each establishment unless specifically exempted under subsection (b) or (c) of this section. All permit fees are nonrefundable. Permits are issued for a two-year term. The fees are based on gross annual volume of sales as follows:

(A) for an establishment with gross annual volume of food sales of \$0 - \$49,999.99, the fee is \$250;

(B) for an establishment with gross annual volume of food sales of \$50,000 - \$149,999.99, the fee is \$500; or

(C) for an establishment with gross annual volume of food sales of \$150,000 or more, the fee is \$750.

(2) A person who contracts with a school to provide food services on a for-profit basis shall obtain a permit and pay a permit fee for each school where food services are provided. Permits are issued for a two-year term. The permit fee is \$250.

(3) A person who operates a mobile food unit shall obtain a permit from the department for each mobile food unit operated.

(A) Each mobile food unit shall be inspected and comply [be in compliance] with §228.221 of this title (relating to Mobile Food Units)[;] and pay a nonrefundable permit fee before a permit is issued. If a request for inspection is not received or if the mobile food unit does not meet the minimum standards contained in §228.221 of this title within two years [one year] of paying the permit fee, a new fee shall be paid.

(B) Mobile food unit permits [Permits] are issued for a two-year term. The permit fee is \$250.

(4) Each roadside food vendor shall obtain a permit and pay a fee. All fees are nonrefundable. A permit will be issued for a two-year term. The permit fee is \$250.

(5) For all initial and renewal applications submitted through Texas.gov, the department is authorized to collect fees in amounts determined by the Department of Information Resources to recover costs associated with using Texas.gov.

[(5) Each child care center providing food services shall obtain a permit and pay a fee. All fees are nonrefundable. A permit will be issued for a two-year term. The permit fee is \$250.]

(6) If the license or permit category changes during the license or permit period, the license or permit shall be renewed in the proper category at the time of the renewal.

(7) An establishment required to be licensed as a food manufacturer under Texas [the] Health and Safety Code[;] Chapter 431, and also required to be permitted under this subchapter [Chapter], will be issued only one license or permit. The license or permit fee to be paid will be the higher fee of the two applicable fees.

[(8) Gross annual volume of food sales may be verified by data from the Texas Comptroller of Public Accounts.]

(b) Exemptions from permit and fees.

(1) Food establishments permitted and inspected by a county or public health district under [the] Texas Health and Safety

Code[;] Chapter 437, provided [the] inspections are based on the requirements of §229.373 of this subchapter [title] (relating to Minimum Standards for Permitting and Operation), are exempted from obtaining a permit and [from] paying a fee to the department.

(2) The following meet the definition of "food establishment" in §229.371 of this subchapter (relating to Definitions), but are not required to pay a fee or obtain a Retail Food Establishment permit under this subchapter:

(A) food establishments permitted and under the inspection authority granted to municipal health departments;

(B) food establishments on federal property under federal inspection authority;

(C) food establishments under the inspection authority of state college or university personnel in accordance with the requirements of §229.373 of this subchapter;

(D) food establishments licensed under Texas Health and Safety Code Chapter 431, as manufacturers of food, provided the fee for licensure exceeds the permit fee required under this section;

(E) food establishments under the inspection authority of the Texas Health and Human Services Commission (HHSC) Regulatory Services Division;

(F) facilities under the inspection authority of the HHSC Regulatory Services Division;

(G) hospitals under the inspection authority of the HHSC Regulatory Services Division and that do not serve food to the general public;

(H) correctional facilities under the inspection authority of the Texas Department of Criminal Justice;

(I) nonprofit organizations as defined in §229.371(3) of this subchapter; (Nonprofit organizations which meet the definition of "manufacturers of food" under Texas Health and Safety Code Chapter 431, or the definition of "food salvage establishments" under Texas Health and Safety Code Chapter 432, are not exempt from licensure in those categories.)

(J) food and beverage vending machines; and

(K) mobile food units permitted and inspected under the authority granted to municipalities and which operate only within their respective jurisdictions. (Except for units which handle only pre-packaged, non-TCS foods, a mobile food unit is classified as a food establishment, regardless of whether food preparation occurs on the unit.)

(c) Nonprofit fee exemption. Nonprofit organizations as defined in §229.371(3) [§229.371(9)] of this subchapter [title] (relating to Definitions) are exempt from payment of the permit fee. Nonprofit organizations shall comply with the requirements of §229.373 of this subchapter [title]. The department shall provide guidelines for the safe handling of foods prepared by nonprofit organizations. Any civic or fraternal organization, charity, lodge, association, proprietorship, corporation, or church not meeting the definition of "nonprofit organization" shall [must] obtain a permit, pay the required fee, and comply with the requirements.

(d) Application for permit. The permit application shall be [completed] on a form furnished by the department and shall contain the following information:

(1) the name under which the establishment operates [business is operated];

(2) the mailing address and street address of the establishment;

(3) if a sole proprietorship, the name of the proprietor; if a partnership, the names of all partners; if a corporation, the date and place of incorporation and the name and address of its registered agent in the State; or if any other type of association, the names of the principals of such association;

(4) the names of those individuals in an actual administrative capacity which, in the case of a sole proprietorship, shall be the managing proprietor; in a partnership, the managing partner; in a corporation, the officers and directors; in any other association, those in a managerial capacity; ~~and~~

(5) the signature of the owner, operator, or other authorized person; ~~and~~[-]

(6) any other information the department may require issuing a permit.

~~[(e) Nonprofit organizations. A nonprofit organization is exempt from the permit fee. Internal Revenue Service documentation of nonprofit status shall be provided if requested by the department to verify an exemption.]~~

~~[(e) Temporary food establishments. An organizer of an event at which a temporary food establishment operates [is operated] shall obtain a permit for each temporary food establishment. In the absence of an event organizer, each temporary event operator shall obtain a permit. The application and permit fee for a temporary food establishment must be submitted to the department at least 30 days before [prior to] the event. The permit fees are as follows.~~

(1) Single-event permit. The permit fee is \$50 and is valid for the duration of a single event not to exceed 14 consecutive days from the initial effective date specified in the permit application. The fee is non-refundable.

(2) Multiple-event permit. A multiple-event permit is [Multiple-event permits are] issued for a two-year term and the permit fee is \$200. The fee is non-refundable.

~~[(f) Two or more establishments. Each establishment shall submit an application even if it is owned by the same person. [If a person owns or operates two or more establishments, each establishment shall be permitted separately by listing the name and address of each establishment on separate application forms.]~~

~~[(g) Pre-permit inspection. The department may conduct a pre-permit inspection to determine [for the purpose of determining] compliance with this subchapter [these rules].~~

~~[(h) Issuance of a permit. The department may issue a permit or a renewal permit for an establishment based on compliance with [specified in] Chapter 228 of this title (relating to Retail Food Establishments), and payment of all fees. Copies of the permit application are available by sending a request to [may be obtained from] the department at[-] 1100 West 49th Street, Austin, Texas 78756-3182 or by downloading online at: <https://www.dshs.texas.gov/retail-food-establishments/permitting-information-retail-food-establishments> [<http://www.dshs.state.tx.us/license.shtml>].~~

(1) The permit or proof of permit shall be posted in a location in the food establishment ~~[that is]~~ conspicuous to consumers.

(2) Permits for mobile food units, including pushcarts and roadside food vendors, shall be displayed on the unit [units] at all times.

(3) A permit shall only be issued when all past due and delinquency fees are have been paid. This applies to any delinquent penalties due under an order issued by the department.

(i) ~~[(i)]~~ Renewal of a permit.

(1) The permit holder shall submit a renewal application and permit fees before [prior to] the expiration date of the permit. A person filing [who files] a renewal application after the expiration date shall pay an additional \$100 as a delinquency fee.

(2) The department may renew a permit if the applicant is compliant [in compliance] with Chapter 228 of this title, and all fees are paid.

(3) Failure to [A person who does not] submit a renewal application and permit fee before [prior to] the expiration date, while continuing [and who continues] to operate, is a [in] violation of Texas Health and Safety Code[-] Chapter 437, and is subject to enforcement proceedings under that chapter, and §229.374 of this subchapter [title] (relating to Refusal, Revocation, or Suspension of a Permit; Administrative Penalties).

(j) ~~[(k)]~~ Amendment of permit.

(1) Fee. A permit amendment ~~[that is amended], including a change of name or physical location[-] ownership, or a notification of a change in location]~~ of a ~~[permitted]~~ food establishment requiring a permit ~~[required]~~ under Texas Health and Safety Code[-] §437.0125, shall pay [will require submission of fees] as follows: [outlined in subsection (a) of this section.]

(A) for an establishment with gross annual volume of food sales of \$0 - \$49,999.99, the fee is \$125;

(B) for an establishment with gross annual volume of food sales of \$50,000.00 - \$149,999.99, the fee is \$250;

(C) for an establishment with gross annual volume of food sales of \$150,000.00 or more, the fee is \$375; or

(D) for each mobile food unit, roadside vendor, school food establishment, or central preparation facility, the fee is \$125.

(2) Change of location. A permit is not transferrable to another location for any non-mobile food establishment [upon change of location with the exception of a permit issued to an operator of a mobile food unit or roadside food vendor].

~~[(l) Texas Online. Applicants may submit applications and renewal applications for a permit under these sections electronically by the Internet through Texas Online at www.texasonline.state.tx.us. The department is authorized to collect fees, in amounts determined by the Texas Online Authority, to recover costs associated with application and renewal application processing through Texas Online.]~~

§229.373. Minimum Standards for Permitting and Operation.

All food establishments shall be operated in accordance with the requirements specified in Chapter 228 of this title (relating to Retail Food Establishments). Copies may be ~~[obtained from the department, 1100 West 49th Street, Austin, Texas 78756-3182, or may be]~~ downloaded from ~~[the following website]:~~ <https://www.dshs.texas.gov/retail-food-establishments/statutes-laws-retail-food-establishments> [<http://www.dshs.state.tx.us/license.shtml>].

§229.374. Refusal, Revocation, or Suspension of a Permit; Administrative Penalties.

(a) Basis. The department may refuse an application for a permit or may revoke or suspend a permit for violations of ~~[the requirements of]~~ §229.372 of this subchapter ~~[title]~~ (relating to Permitting Fees and Procedures) or §229.373 of this subchapter ~~[title]~~ (relating to

Minimum Standards for Permitting and Operation), or for interference with a department representative in the performance of their duties under this subchapter [these sections].

(b) Hearings. Any hearings for the refusal, revocation, or suspension of a permit are governed by §§1.21, 1.23, 1.25, and 1.27 of this title (relating to Formal Hearing Procedures) or under the provisions of the Texas Government Code Chapter 2001, Administrative Procedure Act.

(c) Reinstatement. A former permit holder may apply for reinstatement of a suspended permit by demonstrating [that] corrections and controls are [have been] implemented to prevent future violations [recurrence of violative conditions]. The department may reinstate the permit after the department has determined [that] the food establishment no longer poses a risk to public health and safety. The department may also require employees of a food establishment to successfully complete a department-accredited [department accredited] training course on food safety principles before [prior to the] reinstatement of the permit.

(d) Administrative penalties. Administrative penalties[;] as provided in Texas [the] Health and Safety Code[;] §437.018, and in §229.261 of this chapter [title] (relating to Assessment [assessment] of Administrative [or Civil] Penalties), may be assessed for violations [violation] of this subchapter [these sections].

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on January 2, 2024.

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Department of State Health Services

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For further information, please call: (512) 834-6753



SUBCHAPTER Z. INSPECTION FEES FOR RETAIL FOOD ESTABLISHMENTS

25 TAC §§229.470 - 229.474

STATUTORY AUTHORITY

The proposed amendments are authorized by Texas Health and Safety Code §437.0056 and §437.0125, which direct the Executive Commissioner of HHSC to adopt rules necessary for the implementation of food safety laws; and Texas Government Code §531.0055 and Texas Health and Safety Code §1001.075, which authorize the Executive Commissioner of HHSC to adopt rules and policies necessary for the operation and provision of services by the health and human services by DSHS, and for the administration of Texas Health and Safety Code Chapter 1001.

The proposed amendments implement Texas Government Code Chapter 531 and Texas Health and Safety Code Chapters 437 and 1001.

§229.470. Purpose.

The purpose of this subchapter [these sections] is to implement Texas Health and Safety Code[;] Chapter 437, which authorizes the department to collect fees and to conduct inspections requested or required by certain food establishments when exempt [exempted] from permitting by the department.

§229.471. Definitions.

All definitions found in §228.2 of this title (relating to Definitions) are applicable to this subchapter. The following words and terms, when used in this subchapter [these sections], shall have the following meanings, unless the context clearly indicates otherwise.[;]

~~[(1) Child care center--Any facility licensed by the regulatory authority to receive 13 or more children for child care which prepares food for on-site consumption. A child care center is classified as a food establishment.]~~

~~[(2) Department--The Department of State Health Services.]~~

~~[(3) Food--A raw, cooked, or processed edible substance, ice, beverage, or ingredient used or intended for use or for sale in whole or in part for human consumption, or chewing gum.~~

~~[(4) Food employee--An individual working with unpackaged food, food equipment or utensils, or food-contact surfaces.~~

~~[(5) Food establishment--~~

~~(A) A food [Food] establishment is [means] an operation that:~~

~~(i) stores, prepares, packages, serves, or vends food directly to the consumer, or otherwise provides food for human consumption, such as:~~

~~(I) [(+)] [such as] a restaurant;~~

~~(II) a retail food store;~~

~~(III) a satellite or catered feeding location;~~

~~(IV) a catering operation if the operation provides food directly to a consumer or to a conveyance used to transport people;~~

~~(V) a market;~~

~~(VI) a vending machine location;~~

~~(VII) a self-service food market;~~

~~(VIII) a conveyance used to transport people;~~

~~(IX) an institution; or~~

~~(X) a food bank; and~~

~~(ii) [that] relinquishes possession of food to a consumer directly, or indirectly through a delivery service, such as home delivery of grocery orders or restaurant takeout orders, or delivery service [that is] provided by common carriers.~~

~~(B) A food [Food] establishment includes:~~

~~(i) an element of the operation, such as a transportation vehicle or a central preparation facility supplying [that supplies] a vending machine location or satellite feeding location unless the vending machine or feeding location is permitted by the regulatory authority; and~~

~~(ii) an operation [that is] conducted in a mobile, stationary, temporary, or permanent facility or location and[;] where consumption is on or off the premises[;] and regardless if [of whether] there is a charge for the food.~~

~~(C) A food [Food] establishment does not include:~~

~~(i) an establishment offering [that offers] only prepackaged foods that are not time and temperature control for safety (TCS) foods [potentially hazardous];~~

(ii) a produce stand [that] only offering [offers] whole, uncut fresh fruits and vegetables;

(iii) a food processing plant, including one located on the premises of a food establishment;

(iv) a cottage food production operation;

(iv) a kitchen in a private home if only food that is not potentially hazardous is prepared for sale or service at a function such as a religious or charitable organization's bake sale if allowed by law;]

(iv) an area where food that is prepared as specified in clause (iv) of this subparagraph is sold or offered for human consumption;]

(v) [(vi)] a bed and breakfast limited [Bed and Breakfast Limited facility] as defined in §228.2(5) [§228.2] of this title (relating to Definitions); or

(vi) [(vii)] a private home receiving [that receives] catered or home-delivered food.

(D) All definitions found in Chapter 228 of this title (relating to Retail Food) are applicable to these sections except that, for purposes of inspection or payment of inspection fees only, the term "food establishment" does not include:]

(i) food establishments permitted and inspected under authority granted to Home-Rule or Type A General-Law Municipalities;]

(ii) federally inspected food establishments on federal property;]

(iii) food establishments at correction facilities under the inspection authority of the Texas Department of Criminal Justice;]

(iv) food establishments on state campuses inspected by state college or university personnel in accordance with the requirements of §229.373 of this chapter (relating to Minimum Standards for Permitting and Operation);]

(v) food establishments licensed under the Health and Safety Code, Chapter 431, as manufacturers of food;]

(vi) mobile food units permitted and inspected under the authority granted to Home-Rule or Type A General-Law Municipalities and which operate only within their respective jurisdictions.;

(4) [(6)] Food service establishment--A food establishment as defined in these rules.

(5) [(7)] Group residence--A private or public housing corporation or institutional facility providing [that provides] living quarters and meals. The term includes a domicile for unrelated persons such as a retirement home, correctional facility, or a long-term care facility.

(8) Mobile food establishment--A vehicle mounted food establishment that is readily moveable.;

(6) [(9)] Nonprofit organization--A civic or fraternal organization, charity, lodge, association, proprietorship, or corporation possessing a 501(c)(3) [501(C)] exemption under the Internal Revenue Code; or a religious organization [organizations meeting the definition of "church" under the Internal Revenue Code, §170(b)(1)(A)(i)]. Nonprofit organizations are exempt [exempted] from obtaining a permit as specified in §229.372(c) [§229.372(e)] of this chapter [title] (relating to Permitting Fees and Procedures). Nonprofit organizations are not exempt [exempted] from the payment of an inspection fee as required

under §229.472 of this subchapter (relating to Inspection Fees and Procedures) [title].

{(10) Person--An association, corporation, individual, partnership, other legal entity, government, or governmental subdivision or agency.;

{(11) Potentially hazardous food--]

{(A) Potentially hazardous food (PHF) means a food that requires time and temperature control for safety (TCS) to limit pathogen growth or toxin production.;

{(B) Potentially hazardous food includes:]

{(i) an animal food (a food of animal origin), including fresh shell eggs, that is raw or heat-treated; a food of plant origin that is heat-treated or consists of raw seed sprouts; cut melons; and garlic-in-oil mixtures that are not modified in a way that results in mixtures that do not support growth as specified under subparagraph (A) of this paragraph; and]

{(ii) a food whose pH/a_w interaction is designated as PHF/TCS in one of the tables listed in subparagraph (D) of this paragraph, unless a product assessment or vendor documentation acceptable to the regulatory authority is provided.;

{(C) Potentially hazardous food does not include:]

{(i) an air-cooled hard-boiled egg with shell intact, or a shell egg that is not hard-boiled, but has been treated to destroy all viable Salmonellae;]

{(ii) a food whose pH/a_w interaction is designated as non-PHF/non-TCS in one of the tables in subparagraph (D) of this paragraph;]

{(iii) a food, in an unopened hermetically sealed container, that is commercially processed to achieve and maintain commercial sterility under conditions of non-refrigerated storage and distribution;]

{(iv) a food for which a product assessment, including laboratory evidence, demonstrates that time and temperature control for safety is not required and that may contain a preservative, other barrier to the growth of microorganisms, or a combination of barriers that inhibit the growth of microorganisms; or]

{(v) a food that does not support the growth of microorganisms as specified under subparagraph (A) of this paragraph even though the food may contain an infectious or toxigenic microorganism or chemical or physical contaminant at a level sufficient to cause illness.;

{(D) Potentially hazardous food does not include food that, because of pH, water activity (a_w) or the interaction of pH and a_w, is considered non-PHF/non-TCS in Table A or B below. Guidance for using the tables is provided in the document entitled "Using pH, a_w or the Interaction of pH and a_w to Determine If a Food Requires Time/Temperature Control for Safety (TCS)". Copies of the guidance document may be downloaded from the following website: <http://www.dshs.state.tx.us>, or may be obtained from the department, 1100 West 49th Street, Austin, Texas 78756-3182.;

{(i) Table A.;

{(ii) Table B.;

{(12) Pushcart--A non self-propelled mobile food unit limited to serving nonpotentially hazardous food or potentially hazardous

foods requiring a limited amount of preparation as authorized by the regulatory authority. A pushcart is a mobile food unit. A pushcart does not include non self-propelled units owned and operated within a retail food store.]

~~[(13) Roadside food vendor--A person who operates a mobile retail food store from a temporary location adjacent to a public roadway or highway. Foods shall not be prepared or processed by a roadside food vendor. A roadside vendor is classified as a mobile food establishment.]~~

~~(7) [(44) School food establishment--A food service establishment where food is prepared or served and intended for service primarily to students in [institutions of learning including, but not limited to,] public and private schools, including kindergarten, preschool and elementary schools, junior high schools, high schools, colleges, and universities. A school food establishment is [classified as] a food establishment and may include concession stands located on the school premises or other school-sponsored venues. School food establishments are managed and operated under the supervision of school district employees.~~

~~(8) [(45) Temporary food establishment--A food establishment operating [that operates] for a period of no more than 14 consecutive days in conjunction with a single event or celebration.~~

~~(9) Time and temperature control for safety food (TCS food)--A food requiring time and temperature control for safety to limit pathogen growth or toxin production. The term includes a food that must be held under proper temperature controls, such as refrigeration, to prevent the growth of bacteria that may cause human illness. A TCS food may include a food containing protein and moisture and that is neutral or slightly acidic, such as meat, poultry, fish, and shellfish products; pasteurized and unpasteurized milk and dairy products; raw seed sprouts; baked goods requiring refrigeration, including cream or custard pies or cakes; and ice products. The term does not include a food using TCS food as ingredients if the final food product does not require time or temperature control for safety to limit pathogen growth or toxin production.~~

§229.472. Inspection Fees and Procedures.

(a) Inspection fees. A person operating [who operates] a non-permitted food establishment, who [that] requests an inspection be conducted by the department, shall pay an inspection fee for each inspection of the establishment. All inspection fees are nonrefundable.

(1) A school food establishment requesting [that requests] two inspections per year shall pay for both inspections before the first inspection is conducted by the department.

~~[(A)] The school food establishment fee is \$300 for two inspections. The fee is non-refundable.~~

~~[(B)] An application and inspection fee must be submitted between September 15 and October 31 annually.]~~

(2) A person operating [who operates] a non-permitted food establishment that is not a school food establishment shall pay an inspection fee for each inspection of the establishment.

(A) The inspection fee is \$150 per inspection.

(B) An application and inspection fee must be submitted to the department at least 6 weeks before [prior to] the earliest desired inspection date.

(b) Non-permitted food establishments, other than schools, inspection fee requirement. Non-permitted food establishments, that are nonprofit organizations as defined in §229.471(7) [§229.471(9)] of this subchapter [title] (relating to Definitions), are not exempt

[exempted] from paying [the payment of] an inspection fee as required under subsection (a) of this section. Nonprofit organizations are exempt [exempted] from obtaining a permit as specified in §229.372(c) [§229.372(e)] of this chapter [title] (relating to Permitting Fees and Procedures). Nonprofit organizations shall comply with [the requirements of] §229.473 of this subchapter [title] (relating to Minimum Standards for Permitting and Operation). Any civic or fraternal organization, charity, lodge, association, proprietorship, corporation, or church not meeting the definition of "nonprofit organization" shall [must] obtain a permit, pay the required fee, and comply with the requirements for permitted food establishments. Internal Revenue Service documentation of nonprofit status shall be provided, if requested by the department.

(c) Food establishments under the jurisdiction of county health departments or public health districts. The department shall not inspect or collect an inspection fee from food establishments permitted or inspected by a county or public health district under [the] Texas Health and Safety Code[;] Chapter 437, or food establishments permitted or inspected under authority granted to municipalities [Home-Rule or Type A General-Law Municipalities].

(d) Exemptions from fees. The following meet the definition of "food establishment" in §229.471 of this subchapter, but are not required to pay a fee to the department or obtain a Retail Food Establishment inspection under this subchapter:

(1) food establishments permitted and inspected under authority granted to municipalities;

(2) food establishments inspected by state college or university personnel in accordance with the requirements of §229.373 of this chapter (relating to Minimum Standards for Permitting and Operation);

(3) food establishments licensed under Texas Health and Safety Code Chapter 431, as manufacturers of food, provided the fee for licensure exceeds the permit fee required under §229.372 of this chapter;

(4) food establishments under the inspection authority of the Texas Health and Human Services Commission (HHSC) Regulatory Services Division;

(5) facilities under the inspection authority of the HHSC Regulatory Services Division;

(6) hospitals under the inspection authority of the HHSC Regulatory Services Division and that do not serve food to the general public;

(7) federally inspected food establishments on federal property;

(8) correctional facilities under the inspection authority of the Texas Department of Criminal Justice; and

(9) mobile food units permitted and inspected under the authority granted to municipalities and which operate only within their respective jurisdictions. (Except for units which handle only pre-packaged, non-TCS foods, a mobile food unit is classified as a food establishment, regardless of whether food preparation occurs on the unit.)

(c) ~~[(d)]~~ Application for inspection request. The inspection request shall be submitted on an application [shall be completed on a] form furnished by the department and shall contain the following information:

(1) the name under which an establishment [the business] is operated;

(2) the mailing address and street address of the establishment; and

(3) the signature of the owner, operator, or other authorized person.

(f) [(e)] Two or more establishments. If a person owns or operates two or more establishments, each establishment shall request inspections separately by listing the name and address of each establishment on separate application forms. A school district may submit a single application and attach a listing of each school food establishment requesting inspection [to be inspected].

(g) [(f)] Application form. Copies of the application for inspection request form may be obtained from the department, 1100 West 49th Street, Austin, Texas 78756-3182, or online at <https://www.dshs.texas.gov/retail-food-establishments/permitting-information-retail-food-establishments> [www.dshs.state.tx.us/fdlicense.shtm].

[(g) Texas Online. Applicants may submit an application for inspection request under these sections electronically by the Internet through Texas Online at www.texasonline.state.tx.us, when available. The department is authorized to collect fees, in amounts determined by the Texas Online Authority, to recover costs associated with application and renewal application processing through Texas Online.]

§229.473. *Minimum Standards for Permitting and Operation.*

All food establishments shall be operated in accordance with the requirements of [specified in] Chapter 228 of this title (relating to Retail Food Establishments). Copies may be [obtained from the department, 1100 West 49th Street, Austin, Texas 78756-3182, or may be] downloaded from [the following website]: <https://www.dshs.texas.gov/retail-food-establishments/statutes-laws-retail-food-establishments> [www.dshs.texas.gov/foodeestablishments].

§229.474. *Refusal of Inspection Request; Administrative Penalties.*

(a) Basis. The department may refuse an application for an inspection if there are outstanding [for] violations of the requirements of §229.472 of this subchapter [title] (relating to Inspection Fees and Procedures) or §229.473 of this subchapter [title] (relating to Minimum Standards for Permitting and Operation), or for interference with a department representative in the performance of their duties under this subchapter [these sections].

(b) Hearings. Hearings [Any hearings] for the refusal of an inspection are governed by §§1.21, 1.23, 1.25, and 1.27 of this title (relating to Formal Hearing Procedures) or under the provisions of the Texas Government Code[;] Chapter 2001, [the] Administrative Procedure [Procedures] Act.

(c) Administrative penalties. Administrative penalties[; as provided] in Texas [the] Health and Safety Code[;] §437.018, and in §229.261 of this chapter [title] (relating to Assessment of Administrative Penalties), may be assessed for violations [violation] of this subchapter [these sections] or of [requirements specified in] Chapter 228 of this title (relating to Retail Food Establishments).

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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Cynthia Hernandez

General Counsel

Department of State Health Services

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For further information, please call: (512) 834-6753

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CHAPTER 265. GENERAL SANITATION
SUBCHAPTER L. PUBLIC SWIMMING
POOLS AND SPAS

25 TAC §265.190

The Executive Commissioner of the Texas Health and Human Services Commission (HHSC), on behalf of the Department of State Health Services (DSHS), proposes an amendment to §265.190, concerning Safety Features for Pools and Spas.

BACKGROUND AND PURPOSE

The purpose of the proposal is to revise the requirement for pool and spa signs. The changes to the rule clarify that prohibiting persons under the age of 14 years from being in a pool or spa without adult supervision applies only to pools and spas where a lifeguard is not required or provided.

The changes are needed because previous amendments to Chapter 265, Subchapter L, effective January 2021, inadvertently left out the key phrase, "where no lifeguard is required or provided" from signage requirements on signs stating that persons under the age of 14 may not be in a pool or spa without adult supervision. Recent repeal and adoption of new Chapter 265, Subchapter L, effective January 2023, to comply with House Bill (H.B.) 2205, 87th Legislature, Regular Session, 2021, also failed to include the key phrase. DSHS has received legislative inquiries and public comments regarding the applicability of this signage requirement to public pools and spas with lifeguards present, and the unintended consequences of omitting this key phrase from the signage requirements.

The proposed amendment also clarifies lighting requirements and makes editorial changes for clearer language throughout the rule.

SECTION BY SECTION

The amendment adds the key phrase, "where no lifeguard is required or provided" to the figures for required signs reading: "Persons under the age of 14 must not be in the pool without adult supervision" and "Persons under the age of 14 must not be in the spa without adult supervision." The figure at §265.190(h)(4) is removed. The signage requirement is found in figures §265.190(e)(5) and new §265.190(g)(1). Edits to the rule text in §265.190(e)(5) and §265.190(g)(4) delete the term "subchapter" and replace it with "section" to specify the date for compliance with the signage requirements is the effective date of the section and not the subchapter.

The amendment revises §265.190(i) to clarify lighting requirements for a pool or spa operating at night.

The amendment includes editorial changes for clearer language throughout the rule.

FISCAL NOTE

Christy Havel Burton, Chief Financial Officer, has determined, for each year of the first five years the rule will be in effect, enforcing

or administering the rule does not have foreseeable implications relating to costs or revenues of state or local governments.

GOVERNMENT GROWTH IMPACT STATEMENT

DSHS has determined during the first five years the rule will be in effect:

- (1) the proposed rule will not create or eliminate a government program;
- (2) implementation of the proposed rule will not affect the number of DSHS employee positions;
- (3) implementation of the proposed rule will result in no assumed change in future legislative appropriations;
- (4) the proposed rule will not affect fees paid to DSHS;
- (5) the proposed rule will not create a new rule;
- (6) the proposed rule will not expand, limit, or repeal existing rule;
- (7) the proposed rule will not change the number of individuals subject to the rule; and
- (8) the proposed rule will not affect the state's economy.

SMALL BUSINESS, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYSIS

Christy Havel Burton has also determined there will be no adverse economic effect on small businesses, micro-businesses, or rural communities. The rule does not impose any additional costs on small businesses, micro-businesses, or rural communities that are required to comply with the rule.

LOCAL EMPLOYMENT IMPACT

The proposed rule will not affect a local economy.

COSTS TO REGULATED PERSONS

Texas Government Code §2001.0045 does not apply to this rule because the rule:

- is necessary to protect the health, safety, and welfare of the residents of Texas;
- does not impose a cost on regulated persons; and
- is amended to reduce the burden or responsibilities imposed on regulated persons by the rule.

PUBLIC BENEFIT AND COSTS

Timothy Stevenson, DSHS Associate Commissioner, Consumer Protection Division, has determined, for each year of the first five years the rule is in effect, the public will benefit from the amendment. The amended rule eliminates a burdensome and unnecessary requirement for owners of public pools and spas having a lifeguard present to post signs prohibiting persons under the age of 14 from being in a pool or spa without adult supervision. This benefit applies for newly constructed pools and spas and pools and spas with new signage. The amendment eliminates a requirement preventing pool and spa access for children under the age of 14 without adult supervision even when a lifeguard is present. The amendment also eliminates safety signage inconsistent with public pool and spa rules in other states.

Christy Havel Burton has also determined, for the first five years the rule is in effect, there are no anticipated economic costs to persons who are required to comply with the proposed rule. Pool and spa signage in the proposed rule is required for pools and spas constructed on or after the effective date of the amended

section or, for pools and spas constructed before the effective date of the amended section, whenever they replace their signage.

TAKINGS IMPACT ASSESSMENT

DSHS has determined the proposal does not restrict or limit an owner's right to his or her property that would otherwise exist in the absence of government action and, therefore, does not constitute a taking under Texas Government Code §2007.043.

PUBLIC COMMENT

Written comments on the proposal may be submitted to the Environmental Operations Branch Rules Coordinator, DSHS, Mail Code 2835, P.O. Box 149347, Austin, Texas 78714-9347, hand delivered to the Environmental Operations Branch Rules Coordinator, DSHS, Mail Code 2835, 1100 West 49th Street, Austin, Texas 78756 or by e-mail to EHGRulesCoordinator@dshs.texas.gov.

To be considered, comments must be submitted no later than 31 days after the date of this issue of the *Texas Register*. Comments must be (1) postmarked or shipped before the last day of the comment period; (2) hand-delivered before 5:00 p.m. on the last working day of the comment period; or (3) emailed before midnight on the last day of the comment period. If the last day to submit comments falls on a holiday, comments must be post-marked, shipped, or emailed before midnight on the following business day to be accepted. When emailing comments, please indicate "Comments on Proposed Rule 24R011" in the subject line.

STATUTORY AUTHORITY

The amendment is authorized by Texas Health and Safety Code §341.002, which authorizes the Executive Commissioner of HHSC to adopt rules and establish standards and procedures for the management and control of sanitation and for health protection measures; and by Texas Government Code §531.0055 and Texas Health and Safety Code §1001.075, which authorize the Executive Commissioner of HHSC to adopt rules and policies necessary for the operation and provision of health and human services by DSHS and for the administration of Texas Health and Safety Code Chapter 1001.

The amendment implements Texas Health and Safety Code Chapters 341 and 1001; and Texas Government Code Chapter 531.

§265.190. *Safety Features for Pools and Spas.*

(a) Safety rope and float lines and floor markings.

(1) Class A pools not being used for competitive events or lap swimming must have a rope and float line.[:]

(A) A rope and float line must be located [provided] between 1 and 2 feet from the 5-foot depth location, toward [on] the shallow end of the pool. Floats [water side of the 5-foot depth and floats] must be spaced at no more [not greater] than 7-foot intervals and secured so they do [will] not slide or bunch. The size of [up, and] the stretched rope and float line must [be a size to] provide a good handhold and be strong enough to support the load [loads] normally imposed by users.[: and]

(B) A rope and float line must be [be securely] fastened securely to a wall or deck anchor [anchors] made of corrosion-resistant material [corrosion-resisting materials of the type] that is recessed or removable and does not create a hazardous [must have no] projection [that will constitute a hazard] when the line is removed.

(2) Class B pools [that are] over 5 feet [5-feet] deep must have:

(A) a permanent method to mark the transition point of the pool floor from the shallow area to the deep area using a color contrasting with the bottom of the pool, such as a 4-inch minimum width row of floor tile [or other permanent method using a color contrasting with the bottom of the pool at the transition point of the pool floor from the shallow area to the deep area of the pool];

(B) a rope and float line located between 1 and 2 feet from [on the shallow water side of] the 5-foot depth location, toward the shallow end of the pool and floats must be spaced at no more [not greater] than 7-foot intervals and secured so they do [will] not slide or bunch [up]; and

(i) the size of the stretched rope and float line must [be a size to] provide a good handhold and be strong enough to support the load [loads] normally imposed by users; and

(ii) the rope and float line may be removed when the pool is used for lap swimming or [for] competitive events; and

(C) the rope and float line is [rope and float lines] securely fastened to a wall or deck anchor [anchors] made of corrosion-resistant material [corrosion-resisting materials of the type] that is recessed or removable and does not create a hazardous [must have no] projection [that will constitute a hazard] when the line is removed.

(3) Class C pools [that are] over 5 feet [5-feet] deep must have a permanent method to mark the transition point of the pool floor from the shallow area to the deep areas using a color contrasting with the bottom of the pool, such as a 4-inch minimum width row of floor tile [or other permanent method using a color contrasting with the bottom of the pool at the transition point of the pool floor from the shallow area to the deep area of the pool].

(A) A rope and float line may [also] be used in addition to the transition line and must be located [provided] between 1 and 2 feet from [on the shallow water side of] the 5-foot depth location, toward the shallow end of the pool. Floats [The floats] must be spaced at no more [not greater] than 7-foot intervals and secured so they do [will] not slide or bunch [up]. The size of the stretched rope and float line must provide [be a size to offer] a good handhold and be strong enough to support the load [loads] normally imposed by users.

(B) Rope and float lines must be securely fastened to a wall or deck anchor [anchors] made of corrosion-resistant material [corrosion-resisting materials of the type] that is recessed or removable and does not create a hazardous [must have no] projection [that will constitute a hazard] when the line is removed.

(4) Wave pools, surf pools, and waterslide landing pools are not required to provide a safety rope on the shallow side of the change in floor slope.

(b) Depth markers.

(1) Depth markers [in pools and spas constructed or renovated after the effective date of the rules of this subchapter or that are being replaced] must be placed in the top 4-1/2 inches of the pool or spa wall just under the coping and be positioned to be read by a user while in the pool or spa.

(2) There must be no less than two depth markers for each pool or spa, regardless of size and shape.

(3) Depth markers must be permanent with numbers and letters no less than 4 inches in height and be clearly marked in a color contrasting the background of the deck and vertical wall of the pool or spa.

(4) Depth markers must be spaced uniformly around the perimeter of the pool or spa in intervals of no more than 25 feet.

(5) Deck depth markers must be slip-resistant and positioned to be read while standing on the deck of the pool or spa.

(6) Depth markers must have units of measurement that either spell out "feet" or "inches" or abbreviate "FT," "IN," or fractions of a foot.

{(e) Depth markers in spas. Spa depth markers must comply with the following:}

{(1) There must be no less than two depth markers for each spa, regardless of spa size and shape.}

{(2) Depth markers in spas must be permanent in nature with numbers and letters not less than 4 inches in height and must be clearly marked in a color contrasting to the background on which they are applied both on the deck and on the vertical wall of the spa.}

{(3) Depth markers in spas on the vertical wall must be positioned in the top 4-1/2 inches of the spa wall and be positioned to be read by a user while in the spa.}

{(4) Depth markers in spas must be spaced at not more than 25-foot intervals and must be uniformly located around the perimeter of the spa.}

{(5) Deck depth markers for spas must be positioned to be read while standing on the deck and must be slip-resistant.}

{(6) Depth markers for spas must have units of measurement that either spell out "feet" or "inches" or abbreviate "FT," "IN," or fractions of a foot.}

(c) [(d)] Deck "NO DIVING" marker and symbol. Where a [no] diving marker [markers] and symbol are [symbols are] required in pools, the marker [markers] and symbol [symbols] must comply with the requirements in the International Swimming Pool and Spa Code (ISPSA) and [with the following]:

(1) The no diving marker and symbol must [may] not be less than 4 inches in height. The no diving symbol must consist of a diver's profile in a circle with a 45-degree slash through the diver.

(2) The color of the letters and symbol must be permanent and contrast with the background [on which they are applied, and the color must be permanent in nature].

(3) The no diving marker [markers] and symbol [symbols] on the deck must be slip resistant.

(4) The no diving marker and symbol on the deck must be within 18 inches of the water's edge and positioned to be read while standing on the deck facing the water.

(5) If a permanent structure above the pool deck is within 5 feet of the water's surface, the 4-inch no diving marker and symbol must be on [affixed to] the structure so [that] the warning is visible to persons attempting [who may attempt] to use the structure for diving. The no diving marker and symbol [and warning] are not required on diving boards or diving platforms, Americans with Disabilities Act-compliant [ADA-compliant] chair lifts, slide flumes, lifeguard stands, or bridges over the water.

(6) The no diving marker and symbol are [is] not required on the interior tile line of a pool or [in a] spa.

(d) [(e)] Starting platforms. Starting platforms must be used during official competition only or when there is direct supervision by the team coach, a qualified instructor, or a lifeguard. Starting platforms

must be removed or secured to prevent inadvertent use without direct supervision [when the starting platforms are not directly supervised].

(c) ~~[(f)]~~ Certain safety requirements for pools [Safety signage]. In addition to safety signs required in the ISPSC, the following pool [additional] safety signs and operational procedures [signs] are required [for pools as follows].

(1) Signs must be [in the pool yard], securely mounted as applicable, [and] readily visible to the pool user, and [must] be posted within the pool yard unless otherwise stated within this subchapter.

(2) Sign panels and lettering must be durable for the weather conditions [and the message surface must be clean and smooth and readily accept paint or precut lettering adhesives].

(3) Branding [Theming] or artwork applied to signs must not distract from [invade] the message panel, and signs must have a distinct border.

(4) Safety signs can be combined on one sign or posted individually [Multiple signs may be used or messages may be combined on one sign].

(5) Safety signs for pools constructed on or after the effective date of this section [subchapter] or safety signs [that are] replaced at pools constructed before the effective date of this section, [subchapter] must comply [be in compliance] with Figure: 25 TAC §265.190(c)(5) [Figure: 25 TAC §265.190(f)(5)].

Figure: 25 TAC §265.190(c)(5)
[Figure: 25 TAC §265.190(f)(5)]

(6) In areas of Texas where most [the majority of] residents are non-English speakers [speaking; in addition to signs in English], signs and other written warnings or information required by [the rules in] this subchapter may be posted in the predominant language, in addition to English.

(7) Variations of the language of the required safety signs in Figure: 25 TAC §265.190(c)(5) [Figure: 25 TAC §265.190(f)(5)] are allowed if the language of the safety signs is substantially equivalent to the language in Figure: 25 TAC §265.190(c)(5) [Figure: 25 TAC §265.190(f)(5)] and [if] local swimming pool and spa regulatory officials [that regulate swimming pools and spas] approve the variation [variations] before the sign is posted in the pool yard.

(f) ~~[(g)]~~ Rescue equipment. A pool must have at least one ring buoy with throwing rope and a reaching pole for every 2000 square feet of pool surface area up to 6000 square feet. A [If the] pool with more than [has over] 6000 square feet of surface area must have an additional ring buoy, throw rope, and reaching pole [must be provided] for each additional 4000 square feet of surface area or fraction thereof. Reaching [The reaching] poles and ring buoys with rope must be visible and readily accessible from all areas of the pool yard.

(1) The reaching pole must be light, strong, non-telescoping, and at least 12 feet long. The pole must be constructed of fiberglass or other material that does not conduct electricity and must have a body hook or shepherd's crook with blunted ends attached.

(2) The throwing rope must be 1/4-inch to 3/8-inch in diameter and, [with a length] at least two-thirds the maximum width of the pool in length. A USCG-approved ring buoy, [maximum 24-inches in diameter], must be attached to the throwing rope.

(g) ~~[(h)]~~ Certain safety requirements for spas.

(1) Safety signs, [Signs] for spas constructed on or after the effective date of this section [subchapter] or safety signs [that are] replaced at spas constructed before the effective date of this section, [subchapter] must be securely mounted, [and] readily visible to spa

users, and [must be] inside the spa enclosure, as required in Figure: 25 TAC §265.190(g)(1) [Figure: 25 TAC §265.190(h)(4), Required Spa Signs].

Figure: 25 TAC §265.190(g)(1)

(2) Safety signs can be combined on one sign or posted individually.

(3) Variations of the language of the required safety signs in Figure: 25 TAC §265.190(g)(1) [Figure: 25 TAC §265.190(h)(4)] are allowed if the language of the safety signs is substantially equivalent to the language in Figure: 25 TAC §265.190(g)(1) [Figure: 25 TAC §265.190(h)(4)] and [if] local swimming pool and spa regulatory officials [that regulate swimming pools and spas] approve the variation [variations] before the sign is posted in the pool yard or spa yard.

(4) Safety signs for spas constructed on or after the effective date of this section [subchapter], or safety signs [that are] replaced at spas [pools] constructed before [prior to] the effective date of this section [subchapter], must comply [be in compliance] with Figure: 25 TAC §265.190(g)(1) [Figure: 25 TAC §265.190(h)(4)].

[Figure: 25 TAC §265.190(h)(4)]

(h) ~~[(i)]~~ Emergency summoning device. A pool or spa must have a minimum of one emergency telephone, emergency monitoring contact device, or alternative communication system that is capable of immediately summoning emergency services and that is readily accessible, within 200 feet of the water, and [is] functioning when [at all times] the pool or spa is open for use. An emergency summoning device for [Where] a pool or spa with [has] a seasonal operation schedule, the emergency summoning device] must function [be functioning] 24 hours a day during the [entire] season the pool or spa is [will be] in use. Clear operating instructions for the emergency summoning device must be posted [provided].

(1) The [A] fixed-location telephone, emergency monitoring device, or alternative communication system must be visible, easily identified by users, and have no obstruction to access, and have some method of identification that enables the telephone or other device or system to be easily identified by users].

(2) The [A] telephone or emergency monitoring device must not be answered by an on-site office. An alternative communication system may be [must not be] answered by an on-site office if the [unless the alternative communication] system complies with paragraph (5) of this subsection.

(3) The [A] telephone must be capable of making calls to 911 dispatch or to an emergency service.

(4) When activated, the [An] emergency monitoring contact device, when activated,] must directly connect to a 24-hour monitoring service, [or directly to] 911 dispatch, or [to] emergency medical services.

(5) An alternative communication system contacting [that contacts] an on-site office may be used if the pool or spa is in a remote area with limited or delayed emergency medical services response times and [there are] employees on-site [that] are trained and certified or licensed to perform emergency medical intervention when the pool or spa is open for use.

(6) A cell phone [that is] dedicated for use at the pool or spa, [that is] mounted in the pool yard or spa yard for public use, and labeled as the emergency phone may be used if the cell phone is activated by a service provider, has [is provided with] a permanent power supply, and can reach [is capable of reaching] the emergency service provider or 911 emergency services.

(7) A sign must be posted above the emergency summoning device [whether it is a phone, emergency monitoring device, or alternative communication device] with the precise location of the pool or spa, such as an address, building number, Global Positioning System (GPS) [GPS] location, or other location identifying information in letters a minimum of 1-inch in height.

(i) ~~[(j)]~~ Lighting at pools and spas. A pool or spa operating at night must have lighting providing visibility to all areas of the pool or spa while standing on the deck at the water's edge. [Lighting at pools and spas that operate before sunrise and after sunset must be provided a minimum 30 minutes before sunrise and a minimum of 30 minutes after sunset or while the pool or spa is open.]

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

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