The existing rules in Texas Administrative Code (TAC) [Title 25, Part 1, Chapter 131, Subchapters A through E](https://texreg.sos.state.tx.us/public/readtac$ext.ViewTAC?tac_view=4&ti=25&pt=1&ch=131), relating to Freestanding Emergency Medical Care Facilities, are being repealed and updated new rules, relating to Freestanding Emergency Medical Care Facilities, are being proposed in 26 TAC new Chapter 509. The proposed rules in Chapter 509 implement House Bill (H.B.) 2041 and H.B. 1112, update the inspections, investigations, and enforcement sections, and correct any outdated references and citations.

TITLE 26 HEALTH AND HUMAN SERVICES

PART 1 HEALTH AND HUMAN SERVICES COMMISSION

CHAPTER 509 FREESTANDING EMERGENCY MEDICAL CARE FACILITIES

SUBCHAPTER A GENERAL PROVISIONS

§509.1. Purpose.

(a) The purpose of this chapter is to implement Texas Health and Safety Code, Chapter 254, which requires freestanding emergency medical care facilities to be licensed by the Texas Health and Human Services Commission.

(b) This chapter provides procedures for obtaining a freestanding emergency medical care facility license; minimum standards for freestanding emergency medical care facility functions and services; patient rights standards; discrimination or retaliation standards; patient transfer and other policy and protocol requirements; reporting, posting, and training requirements relating to abuse and neglect; standards for voluntary agreements; inspection and investigation procedures; enforcement standards; fire prevention and protection requirements; general safety standards; physical plant and construction requirements; and standards for the preparation, submittal, review, and approval of construction documents.

(c) Compliance with this chapter does not constitute release from the requirements of other applicable federal, state, or local laws, codes, rules, regulations, and ordinances. This chapter must be followed where it exceeds other codes and ordinances.

§509.2. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Act--Texas Health and Safety Code, Chapter 254, titled Freestanding Emergency Medical Care Facilities.

(2) Action plan--A written document that includes specific measures to correct identified problems or areas of concern; identifies strategies for implementing system improvements; and includes outcome measures to indicate the effectiveness of system improvements in reducing, controlling, or eliminating identified problem areas.

(3) Administrator--A person who is a physician, is a registered nurse, has a baccalaureate or postgraduate degree in administration or a health-related field, or has one year of administrative experience in a health-care setting.

(4) Advanced practice registered nurse (APRN)--A registered nurse approved by the Texas Board of Nursing to practice as an advanced practice registered nurse in Texas. The term includes a nurse practitioner, nurse midwife, nurse anesthetist, and clinical nurse specialist. The term is synonymous with "advanced nurse practitioner."

(5) Adverse event--An event that results in unintended harm to the patient by an act of commission or omission rather than by the underlying disease or condition of the patient.

(6) Applicant--A person who seeks a freestanding emergency medical care facility license from HHSC and who is legally responsible for the operation of the freestanding emergency medical care facility, whether by lease or ownership.

(7) Certified registered nurse anesthetist (CRNA)--A registered nurse who has current certification from the Council on Certification of Nurse Anesthetists and who is currently authorized to practice as an advanced practice registered nurse by the Texas Board of Nursing.

(8) Change of ownership--Change in the person legally responsible for the operation of the facility, whether by lease or by ownership.

(9) Designated provider--A provider of health care services, selected by a health maintenance organization, a self-insured business corporation, a beneficial society, the Veterans Administration, TRICARE, a business corporation, an employee organization, a county, a public hospital, a hospital district, or any other entity to provide health care services to a patient with whom the entity has a contractual, statutory, or regulatory relationship that creates an obligation for the entity to provide the services to the patient.

(10) Disposal--The discharge, deposit, injection, dumping, spilling, leaking, or placing of any solid waste or hazardous waste (containerized or uncontainerized) into or on any land or water so that solid waste or hazardous waste, or any constituent thereof, may enter the environment or be emitted into the air or discharge into any waters, including groundwaters.

(11) Emergency care--Health care services provided in a freestanding emergency medical care facility to evaluate and stabilize a medical condition of a recent onset and severity, including severe pain, psychiatric disturbances, or symptoms of substance abuse, that would lead a prudent layperson possessing an average knowledge of medicine and health to believe that the person's condition, sickness, or injury is of such a nature that failure to get immediate medical care could result in:

(A) placing the person's health in serious jeopardy;

(B) serious impairment to bodily functions;

(C) serious dysfunction of a bodily organ or part;

(D) serious disfigurement; or

(E) in the case of a pregnant woman, serious jeopardy to the health of the woman or fetus.

(12) Facility--A freestanding emergency medical care facility.

(13) Freestanding emergency medical care facility--A facility that is structurally separate and distinct from a hospital and which receives an individual and provides emergency care as defined in paragraph (11) of this section.

(14) HHSC—Texas Health and Human Services Commission.

(15) Hospital--A facility that is licensed under the Texas Hospital Licensing Law, Texas Health and Safety Code, Chapter 241, or if exempt from licensure, certified by the United States Department of Health and Human Services as in compliance with the conditions of participation for hospitals in Title XVIII, Social Security Act (42 USC §§1395 et seq.), or owned and operated by the state of Texas.

(16) Governing body--The governing authority of a freestanding emergency medical care facility that is responsible for a facility's organization, management, control, and operation, including appointment of the medical staff; and includes the owner or partners for a freestanding emergency medical care facility owned or operated by an individual or partners or corporation.

(17) Freestanding emergency medical care facility administration--The administrative body of a freestanding emergency medical care facility headed by an individual who has the authority to represent the facility and who is responsible for the operation of the facility according to the policies and procedures of the facility's governing body.

(18) Licensed vocational nurse (LVN)--A person who is currently licensed by the Texas Board of Nursing as a licensed vocational nurse.

(19) Licensee--The person or governmental unit named in the application for issuance of a facility license.

(20) Medical director--A physician who is board certified or board eligible in emergency medicine, or board certified in primary care with a minimum of two years of emergency care experience.

(21) Medical staff--A physician or group of physicians, a podiatrist or group of podiatrists, and a dentist or group of dentists who by action of the governing body of a facility are privileged to work in and use the facilities.

(22) Owner--One of the following persons or governmental unit that will hold, or does hold, a license issued under the Act in the person's name or the person's assumed name:

(A) a corporation;

(B) a governmental unit;

(C) a limited liability company;

(D) an individual;

(E) a partnership, if a partnership name is stated in a written partnership agreement, or an assumed name certificate;

(F) all partners in a partnership if a partnership name is not stated in a written partnership agreement, or an assumed name certificate; or

(G) all co-owners under any other business arrangement.

(23) Patient--An individual who presents for diagnosis or treatment.

(24) Person--An individual, firm, partnership, corporation, association, or joint stock company, and includes a receiver, trustee, assignee, or other similar representative of those entities.

(25) Physician--An individual licensed by the Texas Medical Board and authorized to practice medicine in the State of Texas.

(26) Physician assistant--A person licensed as a physician assistant by the Texas State Board of Physician Assistant Examiners.

(27) Practitioner--A health care professional licensed in the State of Texas, other than a physician, podiatrist, or dentist. A practitioner shall practice in a manner consistent with their underlying practice act.

(28) Premises--A building where patients receive emergency services from a freestanding emergency medical care facility.

(29) Presurvey conference--A conference held with HHSC staff, and the applicant or the applicant's representative, to review licensure rules and survey documents and provide consultation before the on-site licensure inspection.

(30) Quality assessment and performance improvement (QAPI)--An ongoing program that measures, analyzes, and tracks quality indicators related to improving health outcomes and patient care emphasizing a multidisciplinary approach. The program implements improvement plans and evaluates the implementation until resolution is achieved.

(31) Registered nurse (RN)--A person who is currently licensed by the Texas Board of Nursing as a registered nurse.

(32) SAFE-ready facility--A facility designated by HHSC as a sexual assault forensic exam ready facility.

(33) Sexual assault forensic examiner--A certified sexual assault nurse examiner, or a physician with specialized training on conducting a forensic medical examination.

(34) Sexual assault survivor--An individual who is a victim of a sexual assault, regardless of whether a report is made, or a conviction is obtained in the incident.

(35) Stabilize--To provide necessary medical treatment of an emergency medical condition to ensure, within reasonable medical probability, that the condition is not likely to deteriorate materially from or during the transfer of the individual from a facility.

(36) Transfer--The movement (including the discharge) of an individual outside a facility at the direction of and after personal examination and evaluation by the facility physician. Transfer does not include the movement outside a facility of an individual who has been declared dead or who leaves the facility without the permission of the facility physician.

(37) Transfer agreement--A referral, transmission, or admission agreement with a hospital licensed in this state.

(38) Universal precautions--Procedures for disinfection and sterilization of reusable medical devices and the appropriate use of infection control, including hand washing, the use of protective barriers, and the use and disposal of needles and other sharp instruments, as those procedures are defined by the Centers for Disease Control and Prevention (CDC) of the United States Department of Health and Human Services. This term includes standard precautions as defined by CDC, which are designed to reduce the risk of transmission of blood borne and other pathogens in healthcare facilities.

(39) Violation--Failure to comply with the Act, a rule or standard, special license provision, or an order issued by the commissioner of HHSC or the commissioner's designee, adopted or enforced under the Act.

# TITLE 26 HEALTH AND HUMAN SERVICES

# PART 1 HEALTH AND HUMAN SERVICES COMMISSION

# CHAPTER 509 FREESTANDING EMERGENCY MEDICAL CARE FACILITIES

# SUBCHAPTER B LICENSING REQUIREMENTS

§509.21. General.

(a) License required.

(1) Except as provided in §509.22 of this subchapter (related to Exemptions from Licensure), a person may not establish or operate a freestanding emergency medical care facility in this state without a license issued by the Texas Health and Human Services Commission (HHSC).

(3) Except as provided in paragraph (2) of this subsection, a facility or person shall not hold itself out to the public as a freestanding emergency medical care facility or advertise, market, or otherwise promote the services using the terms "emergency," "ER," or any similar term that would give the impression that the facility or person is providing emergency care.

(4) Upon written request, HHSC shall furnish a person with an application for a facility license. Applications may also be obtained from HHSC’s website.

(5) The license application shall be submitted in accordance with §509.24 of this subchapter (relating to Application and Issuance of Initial License). The applicant shall retain copies of all application documents submitted to HHSC.

(b) A facility shall comply with the provisions of the Texas Health and Safety Code, Chapter 254, Freestanding Emergency Medical Care Facilities (Act) and this chapter during the licensing period.

(c) Scope of facility license.

(1) Each separate facility location shall have a separate license.

(2) A facility license is issued for the premises and person or governmental unit named in the application.

(3) A facility shall not have more than one health facility license for the same physical address. The premises of a facility license shall be separated from any other occupancy or licensed health facility by a minimum of a one-hour fire rated wall.

(4) A facility license authorizes only emergency care services and those procedures that are related to providing emergency care.

(d) A facility shall prominently and conspicuously display the facility license in a public area of the licensed premises that is readily visible to patients, employees, and visitors.

(e) A facility license shall not be altered.

(f) A facility license shall not be transferred or assigned. The facility shall comply with the provisions of §509.27 of this subchapter (relating to Change of Ownership) in the event of a change in the ownership of a facility.

(g) Changes that affect the license.

(1) A facility shall notify HHSC in writing before the occurrence of any of the following:

(A) request to change license classification;

(B) any construction, renovation, or modification of the facility buildings as described in Chapter 520 of this title (relating to Guidelines for Design, Construction, and Fire Safety in Health Care Facilities); and

(C) facility operations cease.

(2) A facility shall notify HHSC in writing not later than the 10th calendar day after the effective date of the change of any of the following:

(A) change in certification or accreditation status; and

(B) change in facility name, mailing address, telephone number, or administrator.

(3) A facility that becomes inactive or closes shall meet the requirements set forth in §509.26 of this subchapter (relating to Inactive Status and Closure).

§509.22. Exemptions from Licensure.

The following facilities are not required to be licensed under this chapter:

(1) an office or clinic owned and operated by a manufacturing facility solely for the purposes of treating its employees and contractors;

(2) temporary emergency clinics in disaster areas;

(3) an office or clinic of a licensed physician, dentist, optometrist, or podiatrist;

(4) a licensed nursing home;

(5) a licensed hospital;

(6) a hospital that is owned and operated by this state;

(7) a facility located within or connected to a hospital described by paragraph (5) or (6) of this section;

(8) a facility that is owned or operated by a hospital described by paragraph (5) or (6) of this section and is:

(A) inspected as a service of the hospital by an organization that has been granted deeming authority as a national accreditation program for hospitals by the Centers for Medicare and Medicaid Services (CMS); or

(B) granted provider-based status by CMS; or

(9) a licensed ambulatory surgical center.

§509.23. Unlicensed Facilities.

(a) If HHSC has reason to believe that a person or facility may be providing emergency medical care services, as defined in this chapter, without a license, HHSC shall so notify the person or facility in writing by certified mail, return receipt requested. The notified facility shall submit to HHSC the following information not later than the twentieth calendar day after the date the facility receives the notice:

(1) an application for a license and the nonrefundable license fee;

(2) a claim for exemption under §509.22 of this subchapter (relating to Exemptions from Licensure); or

(3) documentation necessary to establish that freestanding emergency medical care services are not being provided. Documentation shall include a notarized statement attesting to the fact that freestanding emergency medical care services are not provided and a statement of the types of services that are provided.

(b) If the person or facility has submitted an application for a license, the application shall be processed in accordance with §509.25 of this subchapter (relating to Application and Issuance of Initial License).

(c) If the person or facility submits a claim for exemption, the exemption claim shall be processed in accordance with §509.22 of this subchapter.

(d) If the person or facility submits sufficient documentation to establish that the facility does not provide freestanding emergency medical services, HHSC shall so notify the person or facility in writing within 30 calendar days that no license is required. If HHSC determines that the documentation submitted is insufficient, HHSC shall notify the person or facility in writing. The person or facility shall have the opportunity to respond not later than the 10th calendar day after the date the facility receives the notice. Not later than the 10th calendar day after the date HHSC receives the facility's response, if any, HHSC shall notify the person or facility in writing of HHSC’s determination.

§509.24. Application and Issuance of Initial License.

(a) All first-time applications for licensing are applications for an initial license, including applications from unlicensed operational facilities and licensed facilities for which a change of ownership or relocation is anticipated.

(b) Upon written or oral request, HHSC shall furnish a person with an application form for a facility license. Applications may also be obtained from the HHSC website.

(c) The applicant shall submit the completed original application, the information required in subsection (d) of this section, and the nonrefundable license fee to HHSC before the projected opening date of the facility.

(d) The applicant shall disclose to HHSC the following, if applicable:

(1) the name, address, and social security number of the owner or sole proprietor, if the owner of the facility is a sole proprietor;

(2) the name, address, and social security number of each general partner who is an individual, if the facility is a partnership;

(3) the name, address, and social security number of any individual who has an ownership interest of more than 25 percent in the corporation, if the facility is a corporation;

(4) the name, Texas license number, and license expiration date of any physician licensed by the Texas Medical Board and who has a financial interest in the facility or in any entity that has an ownership interest in the facility;

(5) the name, Texas license number, and license expiration date of the medical chief of staff;

(6) the name, Texas license number, and license expiration date of the director of nursing of the facility;

(7) the affirmation that at least one physician licensed in the State of Texas and at least one registered nurse licensed in the State of Texas are on site during all hours of operation;

(8) the following information concerning the applicant, the applicant's affiliates, and the managers of the applicant:

(A) denial, suspension, probation, or revocation of a facility license in any state, a license for any health care facility, or a license for a home and community support services agency in any state; or any other enforcement action, such as court civil or criminal action in any state;

(B) denial, suspension, probation, or revocation of or other enforcement action against a facility license in any state, a license for any health care facility in any state, or a license for a home and community support services agency in any state that is or was proposed by the licensing agency and the status of the proposal;

(C) surrendering a license before expiration of the license or allowing a license to expire in lieu of HHSC proceeding with enforcement action;

(D) federal or state (any state) criminal felony arrests or convictions;

(E) Medicare or Medicaid sanctions or penalties relating to the operation of a health care facility or home and community support services agency;

(F) operation of a health care facility or home and community support services agency that has been decertified or terminated from participation in any state under Medicare or Medicaid; or

(G) debarment, exclusion, or contract cancellation in any state from Medicare or Medicaid;

(9) for the two-year period preceding the application date, the following information concerning the applicant, applicant's affiliates, and managers of the applicant:

(A) federal or state (any state) criminal misdemeanor arrests or convictions;

(B) federal or state (any state) tax liens;

(C) unsatisfied final judgments;

(D) eviction involving any property or space used as a health care facility in any state;

(E) injunctive orders from any court; or

(F) unresolved final federal or state (any state) Medicare or Medicaid audit exceptions;

(10) whether the facility has applied for certification under Title XVIII of the Social Security Act (42 United States Code §§1395 et seq.);

(11) the number of emergency treatment stations;

(12) a copy of the facility's patient transfer policy and procedure for the immediate transfer to a hospital of patients requiring emergency care beyond the capabilities of the facility which is developed in accordance with §509.66 of this chapter (relating to Patient Transfer Policy) and is signed by both the chairman and secretary of the governing body attesting to the date the policy was adopted by the governing body and the effective date of the policy;

(13) a copy of the facility's memorandum of transfer form, which contains at a minimum the information described in §509.66 of this chapter;

(14) a copy of a written agreement the facility has with a hospital, which provides for the prompt transfer to and the admission by the general hospital of any patient when services are needed but are unavailable or beyond the capabilities of the facility in accordance with §509.67 of this chapter (relating to Patient Transfer Agreements); and

(15) a copy of a fire safety inspection indicating approval by the local fire authority in whose jurisdiction the hospital is based that is dated no earlier than one year prior to the opening date of the facility.

(e) All documents submitted to HHSC shall be originals, unless otherwise indicated. The address provided on the application shall be the physical location at which the facility is or will be operating.

(f) Upon receipt of the application, HHSC shall review the application to determine whether it is complete.

(g) The applicant or the applicant's representative shall attend a presurvey conference at the office designated by HHSC. The designated survey office may waive the presurvey conference requirement.

(h) After a presurvey conference has been held or waived at HHSC’s discretion and the facility has received an approved architectural inspection conducted by HHSC, HHSC may issue a license to a facility to provide freestanding emergency medical care services in accordance with this chapter.

(i) When HHSC determines that the facility is in compliance with subsections (c) - (e) of this section, HHSC shall issue the license to the applicant.

(j) The license shall be effective on the date the facility is determined to be in compliance with subsections (c) - (e) of this section.

(1) If the effective date of the license is the first day of a month, the license expires on the last day of the 11th month after issuance.

(2) If the effective date of the license is the second or any subsequent day of a month, the license expires on the last day of the 12th month after issuance.

(k) If an applicant decides not to continue the application process for a license, the applicant may withdraw its application. The applicant shall submit to HHSC a written request to withdraw. HHSC shall acknowledge receipt of the request to withdraw.

(l) During the initial licensing period, HHSC shall conduct an inspection of the facility to ascertain compliance with the provisions of the Texas Health and Safety Code, Chapter 254, titled Freestanding Emergency Medical Care Facilities (Act) and this chapter.

(1) The facility shall request that an on-site inspection be conducted after the facility has provided services to a minimum of one patient.

(2) The facility shall be providing services at the time of the inspection.

(3) If the facility has applied to participate in the federal Medicare program, the Medicare inspection may be conducted in conjunction with the licensing inspection.

§509.25. Application and Issuance of Renewal License.

(a) The Texas Health and Human Services Commission (HHSC) shall send written notice of expiration of a license to an applicant at least 60 calendar days before the expiration date. If the applicant has not received notice, it is the duty of the applicant to notify HHSC and request a renewal application.

(b) The facility shall submit the following to HHSC no later than the 30th calendar day before the expiration date of the license:

(1) a completed renewal application form;

(2) a nonrefundable license fee;

(3) a copy of a fire safety inspection indicating approval by the local fire authority in whose jurisdiction the facility is based. The fire safety inspection shall be conducted annually and both inspections shall be submitted; and

(4) if the facility is accredited by the Joint Commission or other accrediting organization, documented evidence of current accreditation status.

(c) HHSC shall issue a renewal license to a facility that submits a renewal application in accordance with subsection (b) of this section and meets the minimum standards for a license set forth in this chapter.

(d) Renewal licenses shall be valid for two years.

(e) If the applicant fails to timely submit an application and fee in accordance with subsection (b) of this section, HHSC shall notify the applicant that the facility shall cease providing freestanding emergency medical care services. If the applicant can provide HHSC with sufficient evidence that the submission was completed in a timely manner and all dates were adhered to, the cease to perform shall be dismissed. If the applicant cannot provide sufficient evidence, the applicant shall immediately thereafter return the license to HHSC within 30 days of HHSC’s notification.

(f) If a license expires and an applicant wishes to provide freestanding emergency medical care services after the expiration date of the license, the applicant shall reapply for a license under §509.24 of this subchapter (relating to Application and Issuance of Initial License).

§509.26. Inactive Status and Closure.

(a) A facility that does not provide services under its license for more than five calendar days shall inform the Texas Health and Human Services Commission (HHSC), and HHSC will change the status of the facility license to inactive.

(1) To be eligible for inactive status, a facility must be in good standing with no pending legal action or investigation.

(2) The licensee shall be responsible for any license renewal requirements or fees, and for proper maintenance of patient records, while the license is inactive.

(3) A license may not remain inactive for more than 60 calendar days.

(4) To reactivate the license, the facility must inform HHSC no later than the 60th day after the facility stopped providing services under its license.

(5) If the facility does not reactivate its license by the 60th day after the facility stopped providing services, HHSC will consider the license to be surrendered and the facility closed.

(b) A facility shall notify HHSC in writing before closure of the facility.

(1) The facility shall dispose of medical records in accordance with §509.53 of this chapter (relating to Medical Records).

(2) The facility shall appropriately discharge or transfer all patients before the facility closes.

(3) A license becomes invalid when a facility closes. The facility shall return the licensure certificate to HHSC not later than the 30th calendar day after the facility closes.

(c) A facility that closes, or for which a license issued under this chapter expires or is suspended or revoked, shall immediately remove or cause to be removed any signs within view of the general public indicating that the facility is in operation.

§509.27. Change of Ownership.

(a) When a facility plans to change its ownership, the new owner shall submit an application for an initial license and nonrefundable fee to the Texas Health and Human Services Commission (HHSC) at least 30 calendar days before the date of the change of ownership. The application shall be in accordance with §509.24 of this subchapter (relating to Application and Issuance of Initial License).

(b) In addition to the documents required in §509.24 of this subchapter, the applicant shall submit a copy of the signed bill of sale or lease agreement that reflects the effective date of the sale or lease.

(c) The applicant is not required to submit a transfer agreement that HHSC has previously approved if the applicant notifies HHSC in writing that it has adopted the transfer agreement.

(d) A facility is not required to submit an application for change of ownership if the facility changes only its name. If a facility changes its name, the facility must notify HHSC not later than the 10th calendar day after the effective date of the change.

(e) HHSC may waive the on-site construction and health inspections required by Chapter 520 of this title (relating to Guidelines for Design, Construction, and Fire Safety in Health Care Facilities) and Subchapter D of this chapter (relating to Inspection and Investigation Procedures).

(f) When the new owner has complied with the provisions of §509.24 of this subchapter, HHSC shall issue a license that shall be effective the date of the change of ownership.

(g) The expiration date of the license shall be in accordance with §509.24 of this subchapter.

(h) The previous owner's license shall be void on the effective date of the new owner's license.

§509.28. Conditions of Licensure.

(a) A facility license is issued only for the premises and person or governmental unit named on the application.

(b) A facility license is issued for a single physical location and shall not include multiple buildings or offsite locations.

(c) No license may be transferred or assigned from one person to another person.

(d) No license may be transferred from one facility location to another.

(e) If a facility is relocating, the facility shall complete and submit a license application and nonrefundable fee at least 30 calendar days before relocation of the facility. The application shall be processed in accordance with §509.24 of this subchapter (relating to Application and Issuance of Initial License). An initial license for the relocated facility shall be effective on the date the relocation occurred. The previous license shall be void on the date of relocation.

(f) A facility that changes its telephone number shall send the Texas Health and Human Services Commission written notice of the change not later than the 30th calendar day after the number has changed.

(g) If the name of a facility is changed, the facility shall notify HHSC in writing not later than the 30th calendar day after the effective date of the name change.

§509.29. Time Periods for Processing and Issuing Licenses.

(a) General.

(1) The date a license application is received is the date the application reaches HHSC.

(2) An application for an initial license is complete when the Texas Health and Human Services Commission (HHSC) has received, reviewed, and found acceptable the information described in §509.24 of this subchapter (relating to Application and Issuance of Initial License).

(3) An application for a renewal license is complete when HHSC has received, reviewed, and found acceptable the information described in §509.25 of this subchapter (relating to Application and Issuance of Renewal License).

(b) Time Periods. An application from a facility for an initial license or a renewal license shall be processed in accordance with the following time periods.

(1) The first time period begins on the date HHSC receives the complete application and ends on the date the license is issued. The first time period is 45 calendar days.

(2) If HHSC receives an incomplete application, the first time period ends on the date HHSC issues a written notice to the facility that the application is incomplete. The written notice shall describe the specific information that is required before the application is considered complete.

(3) For incomplete applications, the second time period begins on the date the last item necessary to complete the application is received and ends on the date the license is issued. The second time period is 45 calendar days.

(c) Reimbursement of fees.

(1) In the event the application is not processed in the time periods stated in subsection (b) of this section, the applicant has the right to request that HHSC reimburse in full the fee paid in that particular application process. If HHSC does not agree that the established periods have been violated or finds that good cause existed for exceeding the established periods, HHSC shall deny the request.

(2) Good cause for exceeding the period established is considered to exist if:

(A) the number of applications for licenses to be processed exceeds by 15 percent or more the number processed in the same calendar quarter the preceding year;

(B) another public or private entity used in the application process caused the delay; or

(C) other conditions existed giving good cause for exceeding the established periods.

(d) If the request for reimbursement as authorized by subsection (c) of this section is denied, the applicant may then appeal to the commissioner for a resolution of the dispute. The applicant shall give written notice to the commissioner requesting reimbursement of the fee paid because the application was not processed within the established time period. HHSC shall submit a written report of the facts related to the processing of the application and good cause for exceeding the established time periods. HHSC shall make the final decision and provide written notification of the decision to the applicant and HHSC.

(e) If a hearing is proposed during the processing of the application, the hearing shall be conducted under Texas Government Code, Chapter 2001, Administrative Procedure Act; 25 TAC Chapter 1, Subchapter B (relating to Formal Hearing Procedures; and 1 TAC, Chapter 155 (relating to Rules of Procedure).

§509.30. Fees.

(a) The fee for an initial license (includes change of ownership or relocation) is $14,820. The license term is two years.

(b) The fee for a renewal license is $6,070. The license term is two years.

(c) HHSC shall not consider an application as officially submitted until the applicant pays the application fee and submits the application form.

(d) Fees paid to HHSC are not refundable, except as indicated in §509.29 of this subchapter (relating to Time Periods for Processing and Issuing Licenses).

(e) All fees shall be paid to HHSC.

(f) HHSC will review its fee schedule periodically. If adjustments are necessary to meet expenses, HHSC will amend fees through rulemaking.

(g) HHSC is authorized to collect subscription and convenience fees, in amounts determined by the TexasOnline Authority, to recover costs associated with application and renewal application processing through TexasOnline, in accordance with Texas Government Code §2054.111 and §2054.252.

TITLE 26 HEALTH AND HUMAN SERVICES

PART 1 HEALTH AND HUMAN SERVICES COMMISSION

CHAPTER 509 FREESTANDING EMERGENCY MEDICAL CARE FACILITIES

SUBCHAPTER C OPERATIONAL REQUIREMENTS

§509.41. Operational Standards.

(a) The facility shall have an identified governing body fully responsible for the organization, management, control, and operation of the facility, including the appointment of the facility's medical director. The medical director shall be board certified or board eligible in emergency medicine, or board certified in primary care with a minimum of two years emergency care experience.

(b) The governing body shall adopt, implement, and enforce written policies and procedures for the total operation and all services provided by the facility.

(c) The governing body shall be responsible for all services furnished in the facility, whether furnished directly or under contract. The governing body shall ensure that services are provided in a safe and effective manner that permits the facility to comply with all applicable rules and standards.

(d) The governing body shall ensure that the medical staff has on file current written by laws, rules, and regulations that are adopted, implemented, and enforced.

(e) The governing body shall address and is fully responsible, either directly or by appropriate professional delegation, for the operation and performance of the facility. Governing body responsibilities include:

(1) determining the mission, goals, and objectives of the facility;

(2) ensuring that facilities and personnel are adequate and appropriate to carry out the mission;

(3) ensuring a physical environment that protects the health and safety of patients, personnel, and the public;

(4) establishing an organizational structure and specifying functional relationships among the various components of the facility;

(5) adopting, implementing, and enforcing bylaws or similar rules and regulations for the orderly development and management of the facility;

(6) adopting, implementing, and enforcing policies or procedures necessary for the orderly conduct of the facility;

(7) reviewing and approving the facility's training program for staff;

(8) ensuring that all equipment used by facility staff or by patients is properly used and maintained per manufacturer recommendations;

(9) adopting, implementing, and enforcing policies or procedures related to emergency planning and disaster preparedness; the governing body shall review the facility's disaster preparedness plan at least annually;

(10) ensuring there is a quality assessment and performance improvement (QAPI) program to evaluate the provision of patient care; the governing body shall review and monitor QAPI activities quarterly;

(11) reviewing legal and ethical matters concerning the facility and its staff when necessary and responding appropriately;

(12) maintaining effective communication throughout the facility;

(13) establishing a system of financial management and accountability that includes an audit or financial review appropriate to the facility;

(14) adopting, implementing, and enforcing policies for the provision of radiological services;

(15) adopting, implementing, and enforcing policies for the provision of laboratory services;

(16) adopting, implementing, and enforcing policies for the provision of pharmacy services;

(17) adopting, implementing, and enforcing policies for the collection, processing, maintenance, storage, retrieval, authentication, and distribution of patient medical records and reports;

(18) adopting, implementing, and enforcing a policy on the rights of patients and complying with all state and federal patient rights requirements;

(19) adopting, implementing, and enforcing policies for the provision of an effective procedure for the immediate transfer to a licensed hospital of patients requiring emergency care beyond the capabilities of the facility; all facilities must have a transfer agreement with a hospital licensed in this state as a requirement for licensure as defined in §509.67 of this subchapter (relating to Patient Transfer Agreements);

(20) adopting, implementing, and enforcing policies for all individuals that arrive at the facility to ensure they are provided an appropriate medical screening examination within the capability of the facility, including ancillary services routinely available to determine whether or not the individual needs emergency care as defined in §509.2 of this chapter (relating to Definitions); if emergency care is determined to be needed, the facility shall provide any necessary stabilizing treatment or arrange an appropriate transfer the individual as defined in §509.66 of this subchapter (relating to Patient Transfer Policy);

(21) adopting, implementing, and enforcing a policy to ensure that the facility shall remain open when necessary to continue appropriate patient care or services. This policy shall apply to a patient who is under the care of the facility, and shall ensure that the patient's course of treatment at the facility is completed, regardless of the facility's hours of operation;

(22) approving all major contracts or arrangements affecting the medical care provided under its auspices, including those concerning:

(A) the employment of physicians and practitioners;

(B) the use of external laboratories; and

(C) an effective procedure for obtaining emergency laboratory, radiology, and pharmaceutical services when these services are not immediately available due to system failure;

(23) formulating long-range plans in accordance with the mission, goals, and objectives of the facility;

(24) operating the facility without limitation because of color, race, age, sex, religion, national origin, or disability;

(25) ensuring that all marketing and advertising concerning the facility does not imply that it provides care or services that the facility is not capable of providing; and

(26) developing a system of risk management appropriate to the facility, including:

(A) periodic review of all litigation involving the facility, its staff, physicians, and practitioners regarding activities in the facility;

(B) periodic review of all incidents reported by staff and patients;

(C) review of all deaths, trauma, or adverse reactions occurring on premises; and

(D) evaluation of patient complaints.

(f) The governing body shall provide for full disclosure of ownership to the Texas Health and Human Services Commission (HHSC).

(g) The governing body shall meet at least annually and keep minutes or other records necessary for the orderly conduct of the facility. Each meeting held by the facility governing body shall be a separate meeting with separate minutes from any other governing body meeting.

(h) If the governing body elects, appoints, or employs officers and administrators to carry out its directives, the authority, responsibility, and functions of all such positions shall be defined.

(i) The governing body shall develop a process for appointing or reappointing medical staff, and for assigning or curtailing medical privileges.

(j) The governing body shall provide (in a manner consistent with state law and based on evidence of education, training, and current competence) for the initial appointment, reappointment, and assignment or curtailment of privileges and practice for non-physician health care personnel and practitioners.

(k) The governing body shall encourage personnel to participate in continuing education that is relevant to their responsibilities within the facility.

(l) The governing body shall adopt, implement, and enforce written policies to ensure compliance with applicable state and federal laws.

(m) In accordance with Texas Health and Safety Code §254.157, the facility may not advertise or hold itself out as a network provider, including by stating that the facility "takes" or "accepts" any insurer, health maintenance organization, health benefit plan, or health benefit plan network, unless the facility is a network provider of a health benefit plan issuer.

(1) A facility may not post the name or logo of a health benefit plan issuer in any signage or marketing materials if the facility is an out-of-network provider for all of the issuer's health benefit plans.

(2) A violation of this section is a false, misleading, or deceptive act or practice under Business and Commerce Code, Subchapter E, Chapter 17, and is actionable under that subchapter.

(n) The facility shall assess, and the governing body shall review, patient satisfaction with services and environment no less than annually.

§509.42. Administration.

(a) Administrative policies, procedures, and controls shall be adopted, implemented, and enforced to ensure the orderly and efficient management of the facility. Administrative responsibilities shall include:

(1) enforcing policies delegated by the governing body;

(2) employing qualified management personnel;

(3) long-range and short-range planning for the needs of the facility, as determined by the governing body;

(4) using methods of communicating and reporting, designed to ensure the orderly flow of information within the facility;

(5) controlling the purchase, maintenance, and distribution of the equipment, materials, and facilities of the facility;

(6) establishing lines of authority, accountability, and supervision of personnel;

(7) establishing controls relating to the custody of the official documents of the facility; and

(8) maintaining the confidentiality, security, and physical safety of data on patients and staff.

(b) Personnel policies shall be adopted, implemented, and enforced to facilitate attainment of the mission, goals, and objectives of the facility. Personnel policies shall:

(1) define and delineate functional responsibilities and authority;

(2) require the employment of personnel with qualifications commensurate with job responsibilities and authority, including appropriate licensure or certification;

(3) require documented periodic appraisal of each person's job performance;

(4) specify responsibilities and privileges of employment;

(5) be made known to employees at the time of employment; and

(6) provide and document adequate orientation and training to familiarize all personnel with the facility's policies, procedures, equipment, and facilities.

(c) A facility shall include all employee categories in personnel policies and shall develop appropriate job descriptions.

§509.43. Medical Director.

(a) The medical director shall be on-site at the facility when necessary to fulfill the responsibilities of the position, as described by these rules and the governing body.

(b) Notwithstanding subsection (a) of this section, each facility's medical director shall be on-site at the facility for a minimum of 12 hours per month.

(c) The medical director's responsibilities shall include:

(1) organizing the emergency services to be provided at the facility;

(2) supervising and overseeing the infection control program and quality assessment and performance improvement program; and

(3) regularly attending meetings of the infection control program and quality assessment and performance improvement program.

(d) The medical director shall have the authority to contract with outside persons for the performance of the facility's peer review activities as necessary.

§509.44. Medical Staff.

(a) The medical staff shall periodically conduct appraisals of its members according to medical staff bylaws.

(b) The medical staff shall examine credentials of candidates for medical staff membership and make recommendations to the governing body on the appointment of the candidate.

(c) The medical staff shall be well-organized and accountable to the governing body for the quality of the medical care provided to patients.

(1) The medical staff shall be organized in a manner approved by the governing body.

(2) If the medical staff has an executive committee, the members of the committee shall be Doctor of Medicine or osteopathy.

(3) The facility shall maintain records of medical staff meetings.

(4) The responsibility for organization and conduct of the medical staff shall be assigned only to an individual physician.

(5) Each medical staff member shall sign a statement signifying that he or she will abide by medical staff and facility policies.

(d) The medical staff shall adopt, implement, and enforce written by laws, rules, and regulations to carry out its responsibilities. The bylaws shall:

(1) be approved by the governing body;

(2) include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, consultant);

(3) describe the organization of the medical staff;

(4) describe the qualifications to be met by a candidate for the medical staff to recommend that the candidate be appointed by the governing body; and

(5) include criteria for determining the privileges to be granted and a procedure for applying the criteria to individuals requesting privileges. To be privileged, a physician must have a minimum of one year of experience in emergency services, and current certification in advanced cardiac life support, pediatric advanced life support, and advanced trauma life support.

§509.45. Facility Staffing and Training.

(a) A facility shall have personnel qualified to operate emergency equipment and to provide emergency care to patients on site and available at all treatment times.

(b) Nursing services.

(1) There shall be an organized nursing service under the direction of a qualified registered nurse (RN). The facility shall be staffed to ensure that the nursing needs of all patients are met.

(2) There shall be a written plan of administrative authority for all nursing services with responsibilities and duties of each category of nursing personnel delineated and a written job description for each category. The scope of nursing services shall be limited to nursing care rendered to patients as authorized by the Nursing Practice Act, Occupations Code Chapter 301.

(A) The responsible individual for nursing services shall be a qualified RN whose responsibility and authority shall be clearly defined and shall include supervision of both personnel performance and patient care.

(B) There shall be a written delineation of functions, qualifications, and patient care responsibilities for all categories of nursing personnel.

(C) Nursing services shall be provided in accordance with current recognized standards or recommended practices.

(3) There shall be an adequate number of RNs on duty to meet minimum staff requirements to include supervisory and staff RNs to ensure the immediate availability of an RN for emergency care or for any patient when needed.

(4) There shall be other nursing personnel in sufficient numbers to provide nursing care not requiring the service of an RN. An RN shall assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the preparation and qualifications of the nursing staff available.

(5) An RN qualified, at a minimum, with current certification in advanced cardiac life support and Pediatric Advanced Life Support shall be on duty at the facility at all times whenever patients are present in the facility.

(6) All direct care staff members shall maintain current certification and competency in Basic Cardiac Life Support.

(c) In addition to meeting the requirements for nursing staff under subsection (b) of this section, facilities shall comply with the following minimum staffing requirements.

(1) Facilities that provide only topical anesthesia, local anesthesia, or minimal sedation are required to have a second individual on duty at the facility who is trained and currently certified in basic cardiac life support, until all patients have been discharged from the facility.

(2) Facilities that provide moderate sedation/analgesia are required to have the following additional staff:

(A) a second individual on duty at the facility who is trained and currently certified in basic cardiac life support, until all patients have been discharged from the facility; and

(B) an individual trained and currently certified in advanced cardiac life support and pediatric advanced life support shall be available until all patients have been discharged.

(3) Facilities that provide deep sedation/analgesia or regional anesthesia shall have the following additional staff:

(A) a second individual on duty at the facility who is trained and currently certified in basic cardiac life support, until all patients have been discharged from the facility; and

(B) an individual who is trained and currently certified in advanced cardiac life support and pediatric advanced life support shall be on duty at the facility and sufficiently free of other duties to enable the individual to respond rapidly to emergency situations, until all patients have been discharged.

§509.46. Emergency Services.

(a) A facility shall provide to each patient, without regard to the individual's ability to pay, an appropriate medical screening, examination, and stabilization within the facility's capability, including ancillary services routinely available to the facility, to determine whether an emergency medical condition exists and shall provide any necessary stabilizing treatment.

(b) The organization of the emergency services shall be appropriate to the scope of the services offered. The services shall be organized under the direction of a qualified physician member of the medical staff who is the medical director or clinical director.

(c) A facility shall maintain patient medical records for all emergency patients. The medical records shall contain patient identification, complaints, name of physician, name of nurse, time admitted to the emergency suite, treatment, time discharged, and disposition.

(d) Personnel.

(1) There shall be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.

(2) There shall always be on duty and on site at least one person qualified, as determined by the medical staff, to initiate immediate appropriate lifesaving measures; and at least one nurse with current advanced cardiac life support and pediatric advanced life support certification.

(3) Qualified personnel must always be physically present in the emergency treatment area.

(4) One or more physicians shall always be on-site during facility hours of operation.

(5) Schedules, names, and telephone numbers of all physicians and others on emergency call duty, including alternates, shall be maintained. The facility shall retain the schedules for at least one year.

(e) Adequate age-appropriate supplies and equipment shall be available and in readiness for use. Equipment and supplies shall be available for the administration of intravenous medications as well as facilities for the control of bleeding and emergency splinting of fractures. The emergency equipment shall be periodically tested according to the policy adopted, implemented, and enforced by the hospital.

(f) At a minimum, the age-appropriate emergency equipment and supplies shall include the following:

(1) emergency call system;

(2) oxygen;

(3) mechanical ventilatory assistance equipment, including airways, manual breathing bag, and mask;

(4) cardiac defibrillator;

(5) cardiac monitoring equipment;

(6) laryngoscopes and endotracheal tubes;

(7) suction equipment;

(8) emergency drugs and supplies specified by the medical staff;

(9) stabilization devices for cervical injuries;

(10) blood pressure monitoring equipment; and

(11) pulse oximeter or similar medical device to measure blood oxygenation.

(g) Facilities shall participate in the local Emergency Medical Service (EMS) system, based on the facility's capabilities and capacity, and the locale's existing EMS plan and protocols.

(h) Emergency services for survivors of sexual assault. If a facility does not provide diagnosis or treatment services to victims of sexual assault, the facility shall refer a victim seeking a forensic medical examination to a hospital or other health care facility that provides services to those victims.

§509.47. Anesthesia.

(a) If the facility furnishes anesthesia services, these services shall be provided in a well-organized manner under the medical direction of a physician approved by the governing body and qualified in accordance with the Texas Medical Practice Act, Texas Occupations Code, Subtitle B, and the Texas Nursing Practice Act, Texas Occupations Code, Chapter 301, as appropriate.

(b) A facility that furnishes anesthesia services shall comply with Occupations Code, Chapter 162, Subchapter C, unless the facility is exempt under Occupations Code, §162.103.

(c) The facility is responsible for and shall document all anesthesia services administered in the facility.

(d) Anesthesia services provided in the facility shall be limited to those that are recommended by the medical staff and approved by the governing body, which may include the following.

(1) Topical anesthesia--An anesthetic agent applied directly or by spray to the skin or mucous membranes, intended to produce transient and reversible loss of sensation to the circumscribed area.

(2) Local anesthesia--Administration of an agent that produces a transient and reversible loss of sensation to a circumscribed portion of the body.

(3) Regional anesthesia--Anesthetic injected around a single nerve, a network of nerves, or vein that serves the area involved in a surgical procedure to block pain.

(4) Minimal sedation (anxiolysis)--A drug-induced state during which patients respond normally to oral commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

(5) Moderate sedation/analgesia ("conscious sedation")--A drug-induced depression of consciousness during which patients respond purposefully to oral commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. (Reflex withdrawal from a painful stimulus is not considered a purposeful response.)

(6) Deep sedation/analgesia--A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. (Reflex withdrawal from a painful stimulus is not considered a purposeful response.)

(e) The medical staff shall develop written policies and practice guidelines for the anesthesia service, which shall be adopted, implemented, and enforced by the governing body. The policies and guidelines shall include consideration of the applicable practice standards and guidelines of the American Society of Anesthesiologists, the American Association of Nurse Anesthetists, and the licensing rules and standards applicable to those categories of licensed professionals qualified to administer anesthesia.

(f) Only personnel who have been approved by the facility to provide anesthesia services shall administer anesthesia. All approvals or delegations of anesthesia services as authorized by law shall be documented and include the training, experience, and qualifications of the person who provided the service. A qualified registered nurse (RN) who is not a certified registered nurse anesthetist (CRNA), in accordance with the orders of the physician or CRNA may administer topical anesthesia, local anesthesia, minimal sedation and moderate sedation, in accordance with all applicable rules, polices, directives, and guidelines issued by the Texas Board of Nursing. When an RN who is not a CRNA administers sedation, as permitted in this paragraph, the facility shall:

(1) verify that the RN has the requisite training, education, and experience;

(2) maintain documentation to support that the RN has demonstrated competency in the administration of sedation;

(3) with input from the facility's qualified anesthesia providers, develop, implement and enforce detailed written policies and procedures to guide the RN; and

(4) ensure that, when administering sedation during a procedure, the RN has no other duties except to monitor the patient.

(g) Anesthesia shall not be administered unless the physician has evaluated the patient immediately before the procedure to assess the risk of the anesthesia and of the procedure to be performed.

(h) Patients who have received anesthesia shall be evaluated for proper anesthesia recovery by the physician, or the person administering the anesthesia, before discharge using criteria approved by the medical staff.

(i) Patients shall be evaluated immediately before leaving the facility by a physician, the person administering the anesthesia, or an RN acting in accordance with physician's orders and written policies, procedures, and criteria developed by the medical staff.

(j) Emergency equipment and supplies appropriate for the type of anesthesia services provided shall always be maintained and accessible to staff.

(k) Functioning equipment and supplies that are required for all facilities include:

(1) suctioning equipment, including a source of suction and suction catheters in appropriate sizes for the population being served;

(2) a source of compressed oxygen;

(3) basic airway management equipment, including oral and nasal airways, face masks, and self-inflating breathing bag valve set;

(4) blood pressure monitoring equipment; and

(5) emergency medications specified by the medical staff and appropriate to the type of procedures and anesthesia services provided by the facility.

(l) In addition to the equipment and supplies required under subsection (k) of this section, facilities which provide moderate sedation/analgesia, deep sedation/analgesia, or regional analgesia shall provide:

(1) intravenous equipment, including catheters, tubing, fluids, dressing supplies, and appropriately sized needles and syringes;

(2) advanced airway management equipment, including laryngoscopes and an assortment of blades, endotracheal tubes, and stylets in appropriate sizes for the population being served;

(3) a mechanism for monitoring blood oxygenation, such as pulse oximetry;

(4) electrocardiographic monitoring equipment;

(5) cardiac defibrillator; and

(6) pharmacologic antagonists, as specified by the medical staff and appropriate to the type of anesthesia services provided.

§509.48. Laboratory and Pathology Services.

(a) The facility shall maintain directly, or have immediately available on the premises, adequate laboratory services to meet the needs of its patients.

(b) Laboratory services shall comply with the Clinical Laboratory Improvement Amendments of 1988 (CLIA 1988), in accordance with the requirements specified in 42 CFR, §§493.1 - 493.1780. CLIA 1988 applies to all facilities with laboratories that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment, or for health assessment.

(c) The facility shall ensure that all laboratory services provided to its patients through a contractual agreement are performed in a facility certified in the appropriate specialties and subspecialties of service in accordance with the requirements specified in 42 CFR Part 493 to comply with CLIA 1988.

(d) Emergency laboratory services shall be available on the premises during hours of operation, including:

(1) assays for cardiac markers;

(2) hematology;

(3) chemistry; and

(4) pregnancy testing.

(e) A written description of services provided shall be available to the medical staff.

(f) The laboratory shall ensure proper receipt and reporting of tissue specimens.

(g) The medical staff and a pathologist shall determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examination.

(h) When blood and blood components are stored, the facility shall have written procedures readily available containing directions on how to maintain the blood and blood components within permissible temperatures and including instructions to follow in the event of a power failure or other disruption of refrigeration.

(1) Blood transfusions shall be prescribed in accordance with facility policy and administered in accordance with a written protocol for the administration of blood and blood components and the use of infusion devices and ancillary equipment.

(2) Personnel administering blood transfusions and intravenous medications shall have special training for this duty according to adopted, implemented, and enforced facility policy.

(3) Blood and blood components shall be transfused through a sterile, pyrogen-free transfusion set that has a filter designed to retain particles potentially harmful to the recipient.

(4) Facility staff must observe the patient for potential adverse reactions during the transfusion and for an appropriate time thereafter and document the observations and patient's response.

(5) Pretransfusion and posttransfusion vital signs shall be recorded.

(6) Following the transfusion, the blood transfusion record or a copy shall be made a part of the patient's medical record.

(i) The facility shall establish a mechanism for ensuring that the patient's physician or other licensed health care professional is made aware of critical value lab results, as established by the medical staff, before or after the patient is discharged. A physician shall read, date, sign, and authenticate all laboratory reports.

(j) A facility that provides laboratory services shall adopt, implement, and enforce written policies and procedures to manage, minimize, or eliminate the risks to laboratory personnel of exposure to potentially hazardous chemicals in the laboratory.

§509.49. Pharmaceutical Services.

(a) The facility shall provide drugs, controlled substances, and biologicals in a safe and effective manner in accordance with professional practices. The facility shall be in compliance with all state and federal laws and regulations. The facility shall be licensed as required by the Texas State Board of Pharmacy. The facility shall adopt, implement, and enforce policy and procedures for pharmaceutical services.

(b) The facility may make pharmaceutical services available through contractual agreement. Pharmaceutical services provided under contract shall meet the same ethical practices, professional practices, and legal requirements that would be required if those services were provided directly by the facility.

§509.50. Radiology.

(a) The facility shall adopt, implement, and enforce policies and procedures for emergency radiological procedures.

(b) The facility shall provide radiological services that are immediately available on the premises to meet the emergency needs of patients and to adequately support the facility's clinical capabilities, including plain film x-ray.

(c) Facilities shall provide computed tomography (CT) scan services and ultrasound services that are immediately available on the premises.

(d) A physician shall read, date, sign, and authenticate all examination reports.

(e) The radiology department shall meet all applicable federal, state, and local laws, codes, standards, rules, regulations, and ordinances.

(f) Procedure manuals shall include procedures for all examinations performed, infection control in the facility, treatment and examination rooms, dress code of personnel, and cleaning of equipment.

(g) Policies shall address the quality aspects of radiology services, including:

(1) performing radiology services only upon the written order of a physician, advanced practice registered nurse, or other authorized practitioner (such orders shall be accompanied by a concise statement of the reason for the examination); and

(2) limiting the use of any radioactive sources in the facility to physicians who have been granted privileges for such use based on their training, experience, and current competence.

(h) Policies shall address safety, including:

(1) regulation of the use, removal, handling, and storage of any radioactive material that is required to be licensed by the Texas Department of State Health Services Radiation Control Program;

(2) precautions against electrical, mechanical, and radiation hazards;

(3) proper shielding where radiation sources are used;

(4) acceptable monitoring devices for all personnel who might be exposed to radiation (monitoring devices shall be worn by such personnel in any area with a radiation hazard);

(5) maintenance of radiation exposure records on personnel; and

(6) authenticated dated reports of all examinations performed added to the patient's medical record.

§509.51. Respiratory Services.

(a) The facility shall meet the respiratory needs of the patients in accordance with acceptable standards of practice.

(b) The facility shall adopt, implement, and enforce policies and procedures that describe the provision of respiratory care services in the facility.

(c) The organization of the respiratory care services shall be appropriate to the scope and complexity of the services offered.

(d) Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures shall be designated in writing.

(e) If blood gases or other clinical laboratory tests are performed, staff shall comply with Clinical Laboratory Improvement Amendments of 1988 in accordance with the requirements specified in 42 CFR Part 493.

(f) Respiratory services shall be provided only on, and in accordance with, the orders of a physician, advanced practice registered nurse, or other authorized practitioner.

§509.52. Surgical Services within the Scope of the Practice of Emergency Medicine.

(a) Surgical procedures performed in the facility shall be limited to those emergency procedures that are approved by the governing body upon the recommendation of medical staff.

(b) Adequate supervision of surgical procedures conducted in the facility shall be a responsibility of the governing body, recommended by medical staff, and provided by appropriate medical staff.

(c) Surgical procedures shall be performed only by physicians or practitioners who are licensed to perform surgical procedures in Texas and who have been granted privileges to perform those procedures by the governing body, upon the recommendation of the medical staff, and after medical review of the physician's or practitioner's documented education, training, experience, and current competence.

(d) Surgical procedures to be performed in the facility shall be reviewed periodically as part of the peer review portion of the facility's quality assessment and performance improvement program.

(e) An appropriate history, physical examination, and pertinent preoperative diagnostic studies shall be incorporated into the patient's medical record prior to surgical procedures.

(f) Unless otherwise provided by law, the necessity or appropriateness of the proposed surgical procedure, as well as any available alternative treatment techniques, shall be discussed with the patient, or if applicable, with the patient's legal representative before the surgical procedure.

(g) Licensed nurses and other personnel assisting in the provision of surgical services shall be appropriately trained and supervised and shall be available in sufficient numbers for the surgical care provided.

(h) Each treatment or examination room shall be designed and equipped so that the types of surgical procedures conducted can be performed in a manner that protects the lives and ensures the physical safety of all persons in the area.

(1) If flammable agents are present in a treatment or examination room, the room shall be constructed and equipped in compliance with standards established by the National Fire Protection Association (NFPA 99, Annex 2, Flammable Anesthetizing Locations, 1999) and with applicable state and local fire codes.

(2) If nonflammable agents are present in a treatment or examination room, the room shall be constructed and equipped in compliance with standards established by the National Fire Protection Association (NFPA 99, Chapters 4 and 8, 1999) and with applicable state and local fire codes.

(i) With the exception of those tissues exempted by the governing body after medical review, tissues removed shall be examined by a pathologist, whose signed or authenticated report of the examination shall be made a part of the patient's medical record.

(j) A description of the findings and techniques of surgical procedures shall be accurately and completely incorporated into the patient's medical record immediately after the procedure by the physician or practitioner who performed the procedure. If the description is dictated, an accurate written summary shall be immediately available to the physicians and practitioners providing patient care and shall become a part of the patient's medical record.

(k) The facility shall provide adequate space, equipment, and personnel to ensure a safe environment for treating patients during surgical procedures, including adequate safeguards to protect the patient from cross infection.

(1) The facility shall isolate patients with communicable diseases.

(2) Acceptable aseptic techniques shall be used by all persons.

(3) Suitable equipment for rapid and routine sterilization shall be available.

(4) The facility shall implement environmental controls that ensure a safe and sanitary environment.

(l) Written policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies shall be adopted, implemented, and enforced as described in §509.56 of this subchapter (relating to Sterilization).

(m) Emergency power adequate for the type of surgical procedures performed shall be available.

(n) Periodic calibration and preventive maintenance of all equipment shall be provided in accordance with manufacturer's guidelines.

(o) Unless otherwise provided by law, the informed consent of the patient or, if applicable, of the patient's legal representative shall be obtained before a surgical procedure is performed.

(p) A written procedure shall be established for observation and care of the patient during and after surgical procedures.

(q) Written protocols shall be established for instructing patients in self-care after surgical procedures, including written instructions to be given to patients who receive conscious sedation or regional anesthesia.

(r) Patients who have received anesthesia, other than solely topical anesthesia, shall be allowed to leave the facility only in the company of a responsible adult, unless the physician, physician assistant, or an advanced practice registered nurse writes an order that the patient may leave without the company of a responsible adult.

(s) The facility shall develop an effective written procedure for the immediate transfer to a hospital of patients requiring emergency care beyond the capabilities of the facility. The facility shall have a written transfer agreement with a hospital as set forth in §509.66 of this subchapter (relating to Patient Transfer Policy).

§509.53. Medical Records.

(a) The facility shall develop and maintain a system for the collection, processing, maintenance, storage, retrieval, authentication, and distribution of patient medical records.

(b) The facility shall establish an individual medical record for each person receiving care.

(c) All clinical information relevant to a patient shall be readily available to physicians or practitioners involved in the care of that patient.

(d) Except when otherwise required or permitted by law, any record that contains clinical, social, financial, or other data on a patient shall be strictly confidential and shall be protected from loss, tampering, alteration, improper destruction, and unauthorized or inadvertent disclosure.

(e) The facility shall designate a person to be in charge of medical records. The person's responsibilities include:

(1) the confidentiality, security, and safe storage of medical records;

(2) the timely retrieval of individual medical records upon request;

(3) the specific identification of each patient's medical record;

(4) the supervision of the collection, processing, maintenance, storage, retrieval, and distribution of medical records; and

(5) the maintenance of a predetermined organized medical record format.

(f) The facility shall retain medical records in their original or legally reproduced form for a period of at least 10 years. A legally reproduced form is a medical record retained in hard copy, microform (microfilm or microfiche), or electronic medium. Films, scans, and other image records shall be retained for a period of at least five years.

(1) The facility shall not destroy medical records that relate to any matter that is involved in litigation if the facility knows the litigation has not been finally resolved.

(2) For medical records of a patient less than 18 years of age at the time of last treatment, the facility may dispose of those medical records after the date of the patient's 20th birthday or after the 10th anniversary of the date on which the patient was last treated, whichever date is later, unless the records are related to a matter that is involved in litigation that the facility knows has not been finally resolved.

(3) If a facility plans to close, the facility shall arrange for disposition of the medical records in accordance with applicable law. The facility shall notify HHSC at the time of closure of the disposition of the medical records, including where the medical records will be stored and the name, address, and phone number of the custodian of the records.

(g) Except when otherwise required by law, the content and format of medical records, including the sequence of information, shall be uniform.

(h) Medical records shall be available to authorized physicians and practitioners any time the facility is open to patients.

(i) The facility shall include the following in patients' medical records:

(1) complete patient identification;

(2) date, time, and means of arrival and discharge;

(3) allergies and untoward reactions to drugs recorded in a prominent and uniform location;

(4) all medications administered and the drug dose, route of administration, frequency of administration, and quantity of all drugs administered or dispensed to the patient by the facility and entered on the patient's medical record;

(5) significant medical history of illness and results of physical examination, including the patient's vital signs;

(6) a description of any care given to the patient before the patient's arrival at the facility;

(7) a complete detailed description of treatment and procedures performed in the facility;

(8) clinical observations including the results of treatment, procedures, and tests;

(9) diagnostic impression;

(10) a pre-anesthesia evaluation by an individual qualified to administer anesthesia when administered;

(11) a pathology report on all tissues removed, except those exempted by the governing body;

(12) documentation of a properly executed informed consent when necessary;

(13) for patients with a length of stay greater than eight hours, an evaluation of nutritional needs and evidence of how identified needs were met;

(14) evidence of evaluation of the patient by a physician or advanced practice registered nurse before dismissal; and

(15) conclusion at the termination of evaluation or treatment, including final disposition, the patient's condition on discharge or transfer, and any instructions given to the patient or family for follow-up care.

(j) Medical advice given to a patient by telephone shall be entered in the patient's medical record and dated, timed, and authenticated.

(k) Entries in medical records shall be legible, accurate, complete, dated, timed, and authenticated by the person responsible for providing or evaluating the service provided no later than 48 hours after discharge.

(l) When necessary for ensuring continuity of care, summaries or photocopies of the patient's record shall be transferred to the physician or practitioner to whom the patient was referred and, if appropriate, to the facility where future care will be rendered.

§509.54 Infection Control.

(a) The facility shall provide a sanitary environment to avoid sources and transmission of infections and communicable diseases. The facility shall have an infection control program for the prevention, control, and surveillance of infections and communicable diseases.

(1) The facility shall designate an infection control professional. The facility shall ensure that policies governing prevention, control, and surveillance of infections and communicable diseases are adopted, implemented, and enforced.

(2) The facility shall have a system for identifying, reporting, investigating, and controlling health care associated infections and communicable diseases between patients and personnel.

(3) The infection control professional shall maintain a log of all reportable diseases and health care associated infections designated as epidemiologically significant according to the facility's infection control policies.

(4) The facility shall adopt, implement, and enforce a written policy for reporting all reportable diseases to the local health authority and the Texas Department of State Health Services Infectious Disease Prevention Section, in accordance with Title 25, Chapter 97 (relating to Communicable Diseases).

(5) The infection control program shall include active participation by the medical staff, nursing staff, pharmacist, and other practitioners as appropriate.

(b) The medical director shall be responsible for ensuring that the facility-wide quality assessment and performance improvement program and training programs address problems identified by the infection control professional.

(c) The medical director shall be responsible for ensuring that the facility implements successful corrective action plans in affected problem areas.

(d) The facility shall adopt, implement, and enforce a written policy to monitor compliance of the facility and its personnel and medical staff with universal precautions in accordance with Texas Health and Safety Code, Chapter 85.

§509.55. Sanitary Conditions and Hygienic Practices.

(a) General infection control measures. Universal precautions shall be followed in the facility for all patient care activities in accordance with 29 CFR §1910.1030(d)(1) - (3) and Texas Health and Safety Code, Chapter 85, Subchapter I.

(b) Physical environment.

(1) A facility shall develop, implement, and enforce policies and procedures to provide and actively monitor a safe, functional, comfortable, and sanitary environment which minimizes or prevents transmission of infectious diseases for all patients and visitors and the public.

(2) Blood spills shall be cleaned immediately or as soon as is practical with a disposable cloth and an appropriate chemical disinfectant.

(A) The surface shall be subjected to intermediate-level disinfection in accordance with the manufacturer's directions for use, if a commercial liquid chemical disinfectant is used.

(B) If a solution of chlorine bleach (sodium hypochlorite) is used, the solution shall be at least 1:100 sodium hypochlorite and mixed in accordance with the manufacturer's directions for use. The surface to be treated shall be compatible with this type of chemical treatment.

(C) The facility shall use dedicated cleaning supplies (i.e., mop, bucket) for cleaning blood spills.

§509.56. Sterilization.

(a) A person qualified by education, training, and experience shall supervise the sterilization of all supplies and equipment. Staff responsible for sterilizing supplies and equipment shall participate in a documented continuing education program. New employees shall receive initial orientation and on-the-job training. Staff using chemical disinfectants shall have received training on their use.

(b) Written policies and procedures for decontamination and sterilization activities shall be adopted, implemented, and enforced. Policies shall include receiving, cleaning, decontaminating, disinfecting, preparing, and sterilizing reusable items, as well as assembly, wrapping, storage, distribution, and quality control of sterile items and equipment. The infection control practitioner or committee shall review and approve these written policies at least every other year.

(c) Every facility shall provide equipment adequate for sterilizing supplies and equipment, as needed. Equipment shall be maintained and operated to perform, with accuracy, sterilization of the various materials required.

(d) Where cleaning, preparation, and sterilization functions are performed in the same room or unit, the physical facilities, equipment, and policies and procedures for their use, shall effectively separate soiled or contaminated supplies and equipment from clean or sterilized supplies and equipment. Hand-washing facilities shall be provided, and a separate sink shall be provided for safe disposal of liquid waste.

(e) All containers for solutions, drugs, flammable solvents, ether, alcohol, and medicated supplies shall be clearly labeled to indicate contents. Containers that are sterilized by the facility shall be labeled to be identifiable before and after sterilization. Sterilized items shall have a load control identification that indicates the sterilizer used, the cycle or load number, and the date of sterilization.

(f) Sterilizers.

(1) Steam sterilizers (saturated steam under pressure) shall be used to sterilize heat and moisture stable items. Steam sterilizers shall be used according to manufacturer's written instructions.

(2) Ethylene oxide (EO) sterilizers shall be used for processing heat and moisture sensitive items. EO sterilizers and aerators shall be used and vented according to the manufacturer's written instructions.

(3) Flash sterilizers shall be used for emergency sterilization of clean, unwrapped instruments and porous items only.

(g) Preparation for sterilization.

(1) All items to be sterilized shall be prepared to reduce the bioburden. All items shall be thoroughly cleaned, decontaminated, and prepared in a clean, controlled environment.

(2) All articles to be sterilized shall be arranged so all surfaces will be directly exposed to the sterilizing agent for the prescribed time and temperature.

(3) All wrapped articles to be sterilized shall be packaged in materials recommended for the specific type of sterilizer and material to be sterilized.

(h) External chemical indicators.

(1) External chemical indicators, also known as sterilization process indicators, shall be used on each package to be sterilized, including items being flash sterilized to indicate that items have been exposed to the sterilization process.

(2) The indicator results shall be interpreted according to manufacturer's written instructions and indicator reaction specifications.

(3) A log shall be maintained with the load identification, indicator results, and identification of the contents of the load.

(i) Biological indicators are commercially-available microorganisms (e.g., United States Food and Drug Administration approved strips or vials of Bacillus species endospores) that can be used to verify the performance of waste treatment equipment and processes (or sterilization equipment and processes).

(1) The efficacy of the sterilizing process shall be monitored with reliable biological indicators appropriate for the type of sterilizer used.

(2) Biological indicators shall be included in at least one run each week of use for steam sterilizers, at least one run each day of use for low-temperature hydrogen peroxide gas sterilizers, and every load for EO sterilizers.

(3) Biological indicators shall be included in every load that contains implantable objects.

(4) A log shall be maintained with the load identification, biological indicator results, and identification of the contents of the load.

(5) If a test is positive, the sterilizer shall immediately be taken out of service.

(A) Implantable items shall be recalled and reprocessed if a biological indicator test (spore test) is positive.

(B) All available items shall be recalled and reprocessed if a sterilizer malfunction is found and a list of those items not retrieved in the recall shall be submitted to infection control.

(C) A malfunctioning sterilizer shall not be put back into use until it has been serviced and successfully tested according to the manufacturer's recommendations.

(j) Disinfection.

(1) Written policies, approved by the infection control committee, shall be adopted, implemented, and enforced for the use of chemical disinfectants.

(2) The manufacturer's written instructions for the use of disinfectants shall be followed.

(3) An expiration date, determined according to manufacturer's written recommendations, shall be marked on the container of disinfection solution currently in use.

(4) Disinfectant solutions shall be kept covered and used in well-ventilated areas.

(5) Chemical germicides that are registered with the United States Environmental Protection Agency as "sterilants" may be used either for sterilization or high-level disinfection.

(6) All staff personnel using chemical disinfectants shall have received training on their use.

(k) Performance records.

(1) Performance records for all sterilizers shall be maintained for each cycle. These records shall be retained and available for review for a minimum of five years.

(2) Each sterilizer shall be monitored continuously during operation for pressure, temperature, and time at desired temperature and pressure. A record shall be maintained and shall include:

(A) the sterilizer identification;

(B) sterilization date;

(C) cycle number;

(D) contents of each load;

(E) duration and temperature of exposure phase (if not provided on sterilizer recording charts);

(F) identification of operator or operators;

(G) results of biological tests and dates performed;

(H) time-temperature recording charts from each sterilizer;

(I) gas concentration and relative humidity (if applicable); and

(J) any other test results.

(l) Storage of sterilized items.

(1) Sterilized items shall be transported to maintain cleanliness and sterility and to prevent physical damage.

(2) Sterilized items shall be stored in well-ventilated, limited access areas with controlled temperature and humidity.

(3) The facility shall adopt, implement, and enforce a policy that describes the mechanism used to determine the shelf life of sterilized packages.

(m) Qualified personnel shall perform preventive maintenance of all sterilizers according to adopted, implemented, and enforced policy on a scheduled basis, using the sterilizer manufacturer's service manual as a reference. A preventive maintenance record shall be maintained for each sterilizer. These records shall be retained at least two years and shall be available for review at the facility within two hours of request by HHSC.

§509.57. Linen and Laundry Services.

(a) The facility shall adopt, implement, and enforce policies to provide sufficient clean linen to ensure the comfort of the patient.

(b) For purposes of this subsection, contaminated linen is linen that has been soiled with blood or other potentially infectious materials or may contain sharps. Other potentially infectious materials means:

(1) the following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;

(2) any unfixed tissue or organ (other than intact skin) from a human (living or dead); and

(3) Human Immunodeficiency Virus (HIV)-containing cell or tissue cultures, organ cultures, and HIV or Hepatitis B Virus (HBV)-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

(c) The facility, whether it operates its own laundry or uses commercial service, shall ensure that employees of a facility involved in transporting, processing, or otherwise handling clean or soiled linen shall be given initial and follow-up in-service training to ensure a safe product for patients and to safeguard employees in their work.

(d) Employees who have contact with contaminated linen shall wear gloves and other appropriate personal protective equipment.

(e) Clean linen shall be handled, transported, and stored by methods that will ensure its cleanliness.

(f) Contaminated linen shall be handled as little as possible and with a minimum of agitation.

(1) Contaminated linen shall not be sorted or rinsed in patient care areas.

(2) Contaminated linen shall be bagged or put into carts at the location where it was used.

(3) Contaminated linen shall be placed and transported in bags or containers that are labeled or color-coded.

(4) Bags containing contaminated linen shall be closed before transport.

(5) Whenever contaminated linen is wet and presents a reasonable likelihood of soak-through or leakage from the bag or container, the linen shall be deposited and transported in bags that prevent leakage of fluids to the exterior.

(g) All linen placed in chutes shall be bagged.

(h) If chutes are not used to convey linen to a central receiving or sorting room, then adequate space shall be allocated in the facility for holding the bagged contaminated linen.

(i) Linen shall be processed in the following manner.

(1) If hot water is used, linen shall be washed with detergent in water with a temperature of at least 71 degrees Centigrade (160 degrees Fahrenheit) for 25 minutes.

(2) If low-temperature (less than or equal to 70 degrees Centigrade, 158 degrees Fahrenheit) laundry cycles are used, chemicals suitable for low-temperature washing at proper use concentration shall be used.

(3) Fabrics soiled with blood may be commercially dry cleaned (because dry cleaning eliminates the risk of pathogen transmission).

(4) Flammable liquids shall not be used to process laundry but may be used for equipment maintenance.

§509.58. Waste and Waste Disposal.

(a) Special waste and liquid or sewage waste management.

(1) Facilities shall comply with the requirements set forth by the Texas Commission on Environmental Quality (TCEQ) in 30 TAC, Chapter 326 (relating to Medical Waste Management).

(2) All sewage and liquid wastes shall be disposed of in a municipal sewerage system or a septic tank system permitted by the TCEQ in accordance with 30 TAC, Chapter 285 (relating to On-Site Sewage Facilities).

(3) Facilities shall comply with the requirements set forth in 25 TAC Chapter 1, Subchapter K (relating to Definition, Treatment, and Disposition of Special Waste from Health Care-Related Facilities).

(b) Waste receptacles.

(1) Waste receptacles shall be conveniently available in all toilet rooms, patient areas, staff work areas, and waiting rooms. Receptacles shall be routinely emptied of their contents at a central location into closed containers.

(2) Waste receptacles shall be properly cleaned with soap and hot water, followed by treatment of inside surfaces of the receptacles with a germicidal agent.

(3) All containers for other municipal solid waste shall be leak-resistant, have tight-fitting covers, and be rodent-proof.

(4) Non-reusable containers shall be of suitable strength to minimize animal scavenging or rupture during collection operations.

§509.59. Patient Rights.

(a) Patients shall be treated with respect, consideration, and dignity.

(b) Patients shall be provided appropriate privacy.

(c) Patient records shall be treated confidentially. Patients shall be given the opportunity to approve or refuse release of patient records, except when release of the records is authorized by law.

(d) Patients shall be provided, to the degree known, appropriate information concerning their diagnosis, treatment, and prognosis. When it is medically inadvisable to give such information to a patient, the information shall be provided to a person designated by the patient or to a legally authorized person.

(e) Patients shall be given the opportunity to participate in decisions involving their health care, except when the patient's participation is contraindicated for medical reasons.

(f) Information shall be available to patients and staff concerning:

(1) patient rights, including those specified in subsections (a) - (e) of this section;

(2) patient conduct and responsibilities;

(3) services available at the facility;

(4) provisions for after-hours and emergency care, as applicable;

(5) fees for services provided;

(6) payment policies; and

(7) methods for expressing complaints and suggestions to the facility.

(g) Marketing or advertising shall not be misleading to patients.

(h) A facility shall post a notice of fees in accordance with Texas Health and Safety Code §254.155.

(i) A facility shall provide to a patient or a patient’s legally authorized representative a written disclosure statement, detailing the facility’s fees and health benefit plans, in accordance with Texas Health and Safety Code §254.156.

(j) a facility shall comply with HSC Chapter 324, Subchapter C.

§509.60. Abuse and Neglect.

(a) The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Abuse--The negligent or willful infliction of injury, unreasonable confinement, intimidation, or cruel punishment, including pain or sexual abuse, that adversely affects the physical, mental, or emotional welfare of a patient.

(2) Exploitation--The use of a patient's resources for monetary or personal benefit, profit, or gain without the informed consent of the patient.

(3) Illegal conduct--Conduct prohibited by law.

(4) Neglect--The failure to provide goods or services that are necessary to avoid adversely affecting the physical, mental, or emotional welfare of a patient.

(5) Unethical conduct--Conduct prohibited by the ethical standards adopted by state or national professional organizations for their respective professions or by rules established by the state licensing agency for the respective profession.

(6) Unprofessional conduct--Conduct prohibited under rules adopted by the state licensing agency for the respective profession.

(b) Incidents of abuse, neglect, exploitation, illegal conduct, unethical conduct, or unprofessional conduct shall be reported to the Texas Health and Human Services Commission (HHSC) or to the appropriate regulatory agency.

(c) A person associated with a facility, including an employee, volunteer, health care professional, or other person, who reasonably believes or knows of information that would reasonably cause a person to believe that an incident of abuse, neglect, or exploitation perpetrated by any person has, is, or will occur shall report the incident as soon as possible to HHSC or to the appropriate regulatory agency.

(d) A person associated with a facility, including an employee, volunteer, health care professional, or other person, who reasonably believes or who knows of information that would reasonably cause a person to believe that the facility or an employee or health care professional associated with the facility, has, is, or will be engaged in conduct that is or might be illegal, unprofessional, or unethical and that relates to the operation of the facility shall as report the information soon as possible to HHSC, or to the appropriate regulatory agency.

(e) A facility shall prominently and conspicuously post for display a statement of the duty to report abuse, neglect, exploitation, illegal conduct, unethical conduct, or unprofessional conduct. The display shall be posted in a public area of the facility and shall be readily visible to patients, residents, volunteers, employees, and visitors. The statement shall be in English and in a second language as appropriate to the demographic makeup of the community served. The statement shall contain the contact information for HHSC Complaint and Incident Intake.

(f) A facility shall comply with the requirements in 25 TAC Chapter 1, Subchapter Q (relating to Investigations of Abuse, Neglect, or Exploitation of Children or Elderly or Disabled Persons).

§509.61. Reporting Requirements.

(a) A facility shall report the following incidents to the Texas Health and Human Services Commission (HHSC):

(1) the death of a patient while under the care of the facility;

(2) a patient stay exceeding 23 hours; and

(3) 9-1-1 activation.

(b) Reports under subsection (a) shall be on a form provided by HHSC. The report shall contain a written explanation of the incident and the name of the individual responsible. The report shall be submitted online or through a telephone call to HHSC Complaint and Incident Intake not later than the 10th business day after the incident.

(c) A facility shall report any abuse, theft, or diversion of controlled drugs in accordance with applicable federal and state laws and shall report the incident to the chief executive officer of the facility.

(d) A facility shall report occurrences of fires in the facility as specified under Chapter 520 of this title (relating to Guidelines for Design, Construction, and Fire Safety in Health Care Facilities).

§509.62. Quality Assessment and Performance Improvement.

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

(b) The program shall reflect the complexity of the facility's organization and services involved. All facility services (including those services furnished under contract or arrangement) shall focus on indicators related to improved health outcomes and the prevention and reduction of medical errors.

(c) The program shall include an ongoing program that achieves measurable improvement in health outcomes and reduction of medical errors by using indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors.

(d) The facility shall demonstrate that facility staff, including the medical, nursing, and pharmacy staff, evaluate the provision of emergency care and patient services, set treatment goals, identify opportunities for improvement, develop and implement improvement plans, and evaluate the implementation until resolution is achieved. The facility shall measure, analyze, and track quality indicators, or other aspects of performance that the facility adopts or develops, that reflect processes of care and facility operations. Evidence shall support that aggregate patient data, including identification and tracking of patient infections, is continuously reviewed for trends.

(e) Core staff members, including the medical, nursing, and pharmacy staff, shall actively participate in the QAPI activities and monthly meetings.

(f) Core staff members, including the medical, nursing, and pharmacy staff, shall actively participate in QAPI meetings more often, as necessary to identify or correct problems. The QAPI meetings shall be documented.

(g) The facility's QAPI program shall include:

(1) an ongoing review of key elements of care using comparative and trend data to include aggregate patient data;

(2) identification of areas where performance measures or outcomes indicate an opportunity for improvement;

(3) appointment of interdisciplinary improvement teams to:

(A) identify, measure, analyze, and track indicators for variation from desired outcomes;

(B) create and implement improvement plans;

(C) evaluate the implementation of the improvement plans; and

(D) continue monitoring and improvement activities until resolution of the improvement plan;

(4) establishment and monitoring of quality indicators related to improved health outcomes. For each quality assessment indicator, the facility shall establish and monitor a level of performance consistent with current professional knowledge. These performance components shall influence or relate to the desired outcomes themselves. At a minimum, the following indicators shall be measured, analyzed, and tracked monthly:

(A) infection control (staff and patient screening; standard precautions);

(B) adverse events;

(C) mortality (review of each death and monitoring modality specific mortality rates);

(D) complaints and suggestions (from patients, family, or staff);

(E) staffing to include orientation, training, delegation, licensing and certification, and non-adherence to policies and procedures by facility staff;

(F) safety (fire and disaster preparedness, use of a Texas Health and Human Services Commission (HHSC) approved reporting system, and disposal of special waste); and

(G) clinical records review to include treatment errors and medication errors; and

(5) the facility shall continuously monitor performance, take actions that result in performance improvement, and track performance to ensure that improvements are sustained over time. The facility shall immediately correct any identified problems that threaten the health and safety of patients.

(h) HHSC may review a facility's QAPI activities to determine compliance with this section.

(1) A HHSC inspector shall verify that the facility has a QAPI program which addresses concerns relating to quality of care provided to its patients and that the core staff members have knowledge of and the ability to access the facility's QAPI program.

(2) HHSC may not require disclosure of QAPI program records, except when disclosure is necessary for HHSC to determine compliance with this section.

§509.63. Safety and Preparedness.

(a) A facility shall be in accordance with Chapter 520 of this title (relating to Guidelines for Design, Construction, and Fire Safety in Health Care Facilities).

(b) The facility shall maintain information on the HHSC approved reporting system to be updated online monthly.

§509.64. Patient Transfer Policy.

(a) General.

(1) The governing body of each facility shall adopt, implement, and enforce a policy relating to patient transfers that is consistent with this section and contains each of the requirements in subsection (b) of this section. The policies shall identify facility staff that has authority to represent the facility and the physician regarding transfers from the facility.

(2) The transfer policy shall be adopted by the governing body of the facility after consultation with the medical staff and shall apply to transfers to hospitals licensed under Texas Health and Safety Code Chapters 241 and 577, as well as transfers to hospitals that are exempt from licensing.

(3) The policy shall govern transfers not covered by a transfer agreement.

(4) The facility's transfer policy shall include a written operational plan to provide for patient transfer transportation services if the facility does not provide its own patient transfer transportation services.

(5) Each governing body, after consultation with the medical staff, shall implement its transfer policy by adopting transfer agreements with hospitals in accordance with §509.67 of this subchapter (relating to Patient Transfer Agreements).

(6) The facility's policy shall recognize and comply with the requirements of the Indigent Health Care and Treatment Act, Texas Health and Safety Code §§61.030 - 61.032 and §§61.057 - 61.059.

(7) The facility's policy shall acknowledge contractual obligations and comply with statutory or regulatory obligations which may exist concerning a patient and a designated provider.

(8) The facility's policy shall require that all reasonable steps are taken to secure the written informed consent of a patient, or of a person acting on a patient's behalf, when refusing a transfer or related examination and treatment. Reasonable steps include:

(A) a factual explanation of the increased medical risks to the patient reasonably expected from not being transferred, examined, or treated at the transferring hospital;

(B) a factual explanation of any increased risks to the patient from not effecting the transfer;

(C) a factual explanation of the medical benefits reasonably expected from the provision of appropriate treatment at another hospital; and

(D) The informed refusal of a patient, or of a person acting on a patient's behalf, to examination, evaluation or transfer shall be documented and signed if possible by the patient or by a person acting on the patient's behalf, dated and witnessed by the attending physician or facility employee, and placed in the patient's medical record.

(9) The facility's policy shall recognize the right of an individual to request a transfer into the care of a physician and a hospital of the individual's own choosing.

(b) Requirements for transfer of patients from facilities to hospitals.

(1) The facility policy shall provide that the transfer of a patient may not be predicated upon arbitrary, capricious, or unreasonable discrimination based upon race, religion, national origin, age, sex, physical condition, economic status, insurance status or ability to pay.

(2) The facility's policy shall recognize the right of an individual to request transfer into the care of a physician and a hospital of his own choosing; however, if a patient requests or consents to transfer for economic reasons and the patient's choice is predicated upon or influenced by representations made by the transferring physician or facility administration regarding the availability of medical care and hospital services at a reduced cost or no cost to the patient, the physician or facility administration shall fully disclose to the patient the eligibility requirements established by the patient's chosen physician or hospital.

(3) The facility's policy shall provide that each patient who arrives at the facility is:

(A) evaluated by a physician at the time the patient presents; and

(B) personally examined and evaluated by the physician before an attempt to transfer is made.

(4) The policy of the transferring facility and receiving hospital shall provide that licensed nurses and other qualified personnel are available and on duty to assist with patient transfers. The policy shall provide that written protocols or standing delegation orders are in place to guide facility personnel when a patient requires transfer to another hospital.

(5) Special requirements related to the transfer of patients who have emergency medical conditions.

(A) If a patient at a facility has an emergency medical condition that has not been stabilized, or when stabilization of the patient's vital signs is not possible because the facility does not have the appropriate equipment or personnel to correct the underlying process, the facility shall evaluate and treat the patient and shall transfer the patient as quickly as possible.

(B) The facility's transfer policy shall provide that the facility may not transfer a patient with an emergency medical condition that has not been stabilized unless:

(i) the individual or the individual’s legally authorized representative, after being informed of the facility's obligations under this section and of the risk of transfer, requests the transfer, in writing, and indicates the reasons for the request, as well as that he or she is aware of the risks and benefits of the transfer;

(ii) a physician has signed a certification, which includes a summary of the risks and benefits, that, based on the information available at the time of transfer, the medical benefits reasonably expected from the provision of appropriate medical treatment at another hospital outweigh the increased risks to the patient and, in the case of labor, to the unborn child from effecting the transfer; or

(C) Except as is specifically provided in subsection (a)(6) and (7) of this section, the facility's policy shall provide that the transfer of patients who have emergency medical conditions, as determined by a physician, shall be undertaken for medical reasons only. The facility must provide medical treatment within its capacity that minimizes the risks to the individual's health and, in the case of a woman in labor, the health of the unborn child.

(6) Physician's duties and standard of care.

(A) The policy shall provide that the transferring physician shall determine and order life support measures that are medically appropriate to stabilize the patient before transfer and to sustain the patient during transfer.

(B) The policy shall provide that the transferring physician shall determine and order the utilization of appropriate personnel and equipment for the transfer.

(C) The policy shall provide that in determining the use of medically appropriate life support measures, personnel, and equipment, the transferring physician shall exercise that degree of care which a reasonable and prudent physician exercising ordinary care in the same or similar locality would use for the transfer.

(D) The policy shall provide that, except as allowed under paragraph (5)(B) of this subsection, before each patient transfer, the physician who authorizes the transfer shall personally examine and evaluate the patient to determine the patient's medical needs and to ensure that the proper transfer procedures are used.

(E) The policy shall provide that before transfer, the transferring physician shall ensure that a receiving hospital and physician that are appropriate to the medical needs of the patient have accepted responsibility for the patient's medical treatment and hospital care.

(7) The facility's policy shall provide that the facility's medical staff review appropriate records of patients transferred from the facility to determine that the appropriate standard of care has been met.

(8) Medical record.

(A) The facility's policy shall provide that a copy of those portions of the patient's medical record that are available and relevant to the transfer and to the continuing care of the patient be forwarded to the receiving physician and receiving hospital with the patient. If all necessary medical records for the continued care of the patient are not available at the time the patient is transferred, the records shall be forwarded to the receiving physician and hospital as soon as possible.

(B) The medical record shall contain at a minimum:

(i) a brief description of the patient's medical history and physical examination;

(ii) a working diagnosis and recorded observations of physical assessment of the patient's condition at the time of transfer;

(iii) the reason for the transfer;

(iv) the results of all diagnostic tests, such as laboratory tests;

(v) pertinent radiological films and reports; and

(vi) any other pertinent information.

(9) Memorandum of transfer.

(A) The facility's policy shall provide that a memorandum of transfer be completed for every patient who is transferred.

(B) The memorandum shall contain the following information:

(i) patient's full name, if known;

(ii) patient's race, religion, national origin, age, sex, physical handicap, if known;

(iii) patient's address and next of kin, address, and phone number, if known;

(iv) names, telephone numbers, and addresses of the transferring and receiving physicians;

(v) names, addresses, and telephone numbers of the transferring facility and receiving hospital;

(vi) time and date on which the patient first presented or was presented to the transferring physician and transferring facility;

(vii) time and date on which the transferring physician secured a receiving physician;

(viii) name, date, and time hospital administration was contacted in the receiving hospital;

(ix) signature, time, and title of the transferring facility administration who contacted the receiving hospital;

(x) certification required by paragraph (5)(B)(ii) of this subsection, if applicable (the certification may be part of the memorandum of transfer form or may be on a separate form attached to the memorandum of transfer form);

(xi) time and date on which the receiving physician assumed responsibility for the patient;

(xii) time and date on which the patient arrived at the receiving hospital;

(xiii) signature and date of receiving hospital administration;

(xiv) type of vehicle and company used;

(xv) type of equipment and personnel needed in transfers;

(xvi) name and city of hospital to which patient was transported;

(xvii) diagnosis by transferring physician; and

(xviii) attachments by transferring hospital.

(C) A copy of the memorandum of transfer shall be retained by the transferring facility. The memorandum shall be filed separately from the patient's medical record and in a manner that will facilitate its inspection by the Texas Health and Human Services Commission (HHSC). All memorandum of transfer forms filed separately shall be retained for five years.

(c) A facility violates the Act and this section if:

(1) the facility fails to comply with the requirements of this section; or

(2) the governing body fails or refuses to:

(A) adopt a transfer policy that is consistent with this section and contains each of the requirements in subsection (b) of this section;

(B) adopt a memorandum of transfer form that meets the minimum requirements for content contained in this section; or

(C) enforce its transfer policy and the use of the memorandum of transfer.

§509.65. Patient Transfer Agreements.

(a) General provisions.

(1) Patient transfer agreements between a facility and hospitals are mandatory.

(2) The facility shall submit the transfer agreement to the Texas Health and Human Services Commission (HHSC) for review to determine if the agreement meets the requirements of subsection (b) of this section.

(3) Multiple transfer agreements may be entered into by a facility based upon the type or level of medical services available at other hospitals.

(b) Minimum requirements for patient transfer agreements. Patient transfer agreements shall include specific language that is consistent with the following:

(1) the Indigent Health Care Treatment Act, in accordance with §509.64(a)(6) of this subchapter (relating to Patient Transfer Policy);

(2) discrimination, in accordance with §509.64(b)(1) of this subchapter;

(3) patient's right to request transfer, in accordance with §509.64(b)(2) of this subchapter;

(4) transfer of patients with emergency medical conditions, in accordance with §509.64(b)(5) of this subchapter;

(5) physician's duties and standard of care, in accordance with §509.64(b)(6) of this chapter;

(6) medical records, in accordance with §509.64(b)(8) of this subchapter; and

(7) memorandum of transfer, in accordance with §509.64(b)(9) of this chapter.

(c) Review of transfer agreements.

(1) In order that HHSC may review the transfer agreements for compliance with the minimum requirements, the facility shall submit the following documents to HHSC:

(A) a copy of the current or proposed agreement signed by the representatives of the facility and the hospital;

(B) the date of the adoption of the agreement; and

(C) the effective date of the agreement.

(2) HHSC may waive the submittal of the documents required under paragraph (1) of this subsection to avoid the repetitious submission of required documentation and approved agreements.

(3) If a governing body or a governing body's designee executes a transfer agreement and the entire text of that agreement consists of the entire text of an agreement that has been previously approved by HHSC, the governing body or the governing body's designee is not required to submit the later agreement for review. On the date the later agreement is fully executed and before the later agreement is implemented, the governing body or the governing body's designee must give adequate notice to HHSC that the later agreement has been executed.

(4) HHSC shall review the agreement not later than 30 calendar days after the date HHSC receives the agreement to determine if the agreement is consistent with the requirements of this section.

(5) After HHSC review of the agreement, if HHSC determines that the agreement is consistent with the requirements contained in this section, HHSC shall notify the facility administration that the agreement has been approved.

(6) If HHSC determines that the agreement is not consistent with the requirements contained in this section, HHSC shall give notice to the facility administration that the agreement is deficient and provide recommendations for correction.

(7) A transfer agreement will be considered in compliance if it is consistent with the rules that were in effect at the time the transfer agreement was executed and approved by HHSC.

(d) Amendments to an agreement.

(1) The governing body of a facility or governing body's designee may adopt proposed amendments to a transfer agreement that has been approved by HHSC. Before the facility implements the amendments, the governing body or the governing body's designee shall submit the proposed amendments to HHSC for review in the same manner as the agreement to be amended was submitted.

(2) HHSC shall review the amendments and shall approve or reject them in the same manner as provided for the review of the agreement to be amended.

(e) Complaints. Complaints alleging a violation of a transfer agreement shall be treated in the same manner as complaints alleging violations of the Act or this chapter.

§509.66. Miscellaneous Policies and Protocol.

The facility shall adopt, implement, and enforce protocols to be used in determining death and for filing autopsy reports that comply with Texas Health and Safety Code, Chapter 671, Determination of Death and Autopsy Reports.

TITLE 26 HEALTH AND HUMAN SERVICES

PART 1 HEALTH AND HUMAN SERVICES COMMISSION

CHAPTER 509 FREESTANDING EMERGENCY MEDICAL CARE FACILITIES

SUBCHAPTER D INSPECTION AND INVESTIGATION PROCEDURES

§509.81. Inspections.

(a) The Health and Human Services Commission (HHSC) may conduct an unannounced, on-site inspection of a facility at any reasonable time, including when treatment services are provided, to inspect, investigate, or evaluate:

(1) compliance with any applicable statute or rule;

(2) a facility’s plan of correction;

(3) an order of the commissioner or the commissioner’s designee;

(4) a court order granting injunctive relief; or

(5) for other purposes relating to regulation of the facility.

(b) An applicant or licensee, by applying for or holding a license, consents to entry and inspection of any of its facilities by HHSC.

(c) HHSC inspections to evaluate a facility’s compliance may include:

(1) initial, change of ownership, or relocation inspections for the issuance of a new license;

(2) inspections related to changes in status, such as new construction or changes in services, designs, or bed numbers;

(3) routine inspections, which may be conducted without notice and at HHSC’s discretion, or prior to renewal;

(4) follow-up on-site inspections, conducted to evaluate implementation of a plan of correction for previously cited deficiencies;

(5) inspections to determine if an unlicensed facility is offering or providing, or purporting to offer or provide, treatment; and

(6) entry in conjunction with any other federal, state, or local agency’s entry.

(d) A facility shall cooperate with any HHSC inspection and shall permit HHSC to examine the facility’s grounds, buildings, books, records, and other documents and information maintained by or on behalf of the facility.

(e) A facility shall permit HHSC access to interview members of the governing body, personnel, and patients. Members of the governing body and personnel shall provide a written statement upon request from HHSC.

(f) A facility shall permit HHSC to inspect and copy any requested information. If it is necessary for HHSC to remove documents or other records from the facility, HHSC will provide a written description of the information being removed and when it is expected to be returned. HHSC will make a reasonable effort, consistent with the circumstances, to return any records removed in a timely manner.

(g) Upon entry, HHSC will hold an entrance conference with the facility’s designated representative to explain the nature, scope, and estimated duration of the inspection.

(h) During the inspection, the HHSC representative will give the facility an opportunity to submit information and evidence relevant to matters of compliance being evaluated.

(i) When an inspection is complete, HHSC will hold an exit conference with the facility representative to inform the facility representative of any preliminary findings of the inspection. The facility may provide any final documentation regarding compliance during the exit conference.

§509.82. Complaint Investigations.

(a) A facility shall provide each client and applicable consenter at the time of admission with a written statement identifying the Texas Health and Human Services Commission (HHSC) as the agency responsible for investigating complaints against the facility.

(1) The statement shall inform persons that they may direct a complaint to HHSC Complaint and Incident Intake (CII) and include current CII contact information, as specified by HHSC.

(2) The facility shall prominently and conspicuously post this information in patient common areas and in visitor’s areas and waiting rooms so that it is readily visible to patients, employees, and visitors. The information shall be in English and in a second language appropriate to the demographic makeup of the community served.

(b) HHSC will evaluate all complaints. A complaint must be submitted using HHSC’s current CII contact information for that purpose, as described in subsection (a) of this section.

(c) HHSC will document, evaluate, and prioritize complaints based on the seriousness of the alleged violation and the level of risk to patients, personnel, and the public.

(1) Allegations determined to be within HHSC’s regulatory jurisdiction relating to health care facilities may be investigated under this chapter.

(2) Complaints outside HHSC’s jurisdiction may be referred to an appropriate agency, as applicable.

(d) Investigations to evaluate a facility’s compliance shall be conducted following a complaint of abuse, neglect, or exploitation; or a complaint related to the health and safety of patients.

(e) HHSC may conduct an unannounced, on-site investigation of a facility at any reasonable time, including when treatment services are provided, to inspect, investigate, or evaluate:

(1) a facility’s compliance with any applicable statute or rule;

(2) a facility’s plan of correction;

(3) a facility’s compliance with an order of the commissioner or the commissioner’s designee;

(4) a facility’s compliance with a court order granting injunctive relief; or

(5) for other purposes relating to regulation of the facility.

(f) An applicant or licensee, by applying for or holding a license, consents to entry and investigation of any of its facilities by HHSC.

(g) A facility shall cooperate with any HHSC investigation and shall permit HHSC to examine the facility’s grounds, buildings, books, records, and other documents and information maintained by, or on behalf of, the facility.

(h) A facility shall permit HHSC access to interview members of the governing body, personnel, and patients. Members of the governing body and personnel shall provide a written statement upon request from HHSC.

(i) A facility shall permit HHSC to inspect and copy any requested information. If it is necessary for HHSC to remove documents or other records from the facility, HHSC will provide a written description of the information being removed and when it is expected to be returned. HHSC will make a reasonable effort, consistent with the circumstances, to return any records removed in a timely manner.

(j) Upon entry, HHSC will hold an entrance conference with the facility’s designated representative to explain the nature, scope, and estimated duration of the investigation.

(k) Once an investigation is complete, HHSC will review the evidence from the investigation to evaluate whether there is a preponderance of evidence supporting the allegations contained in the complaint.

§509.83. Notice.

(a) A facility is deemed to have received any Texas Health and Human Services Commission (HHSC) correspondence on the date of receipt, or three business days after mailing through the United States Postal Service, whichever is earlier.

(b) When deficiencies are found:

(1) HHSC will provide the facility with a written Statement of Deficiencies (SOD) within 10 business days of the exit conference via mail or email.

(2) Within 10 calendar days of the facility’s receipt of the SOD, the facility shall return a written Plan of Correction (POC) to HHSC that addresses each cited deficiency, including timeframes for corrections, together with any additional evidence of compliance.

(A) HHSC will determine if a POC and proposed timeframes are acceptable, and, if accepted, notify the facility in writing.

(B) If the POC is not accepted by HHSC, HHSC will notify the facility in writing no later than 10 business days after notification and request a modified POC and any additional evidence.

(C) The facility shall correct the identified deficiencies and submit evidence to HHSC verifying implementation of corrective action within the timeframes set forth in the POC, or as otherwise specified by HHSC.

(3) Regardless of the facility’s compliance with this subsection or HHSC’s acceptance of a facility’s POC, HHSC may, at any time, propose to take enforcement action as appropriate under this chapter.

§509.84. Professional Conduct.

In addition to any enforcement action under this chapter, the Texas Health and Human Services Commission (HHSC) will report in writing to the appropriate licensing board any issue or complaint relating to the conduct of a licensed professional, intern, or applicant for professional licensure.

§509.85. Complaint Against a HHSC Representative.

(a) A facility may register a complaint against a Texas Health and Human Services Commission (HHSC) representative who conducts an inspection or investigation in accordance with Subchapter D of this chapter (relating to Inspection and Investigation Procedures).

(b) A complaint against an HHSC representative shall be registered with the HHSC Health Facility Compliance Manager.

# TITLE 26 HEALTH AND HUMAN SERVICES

# PART 1 HEALTH AND HUMAN SERVICES COMMISSION

# CHAPTER 509 FREESTANDING EMERGENCY MEDICAL CARE FACILITIES

# SUBCHAPTER E ENFORCEMENT

§509.101. Enforcement Actions.

(a) The Texas Health and Human Services Commission (HHSC) has jurisdiction to enforce the Texas Health and Safety Code, Chapter 254, titled Freestanding Emergency Medical Care Facilities (Act) and the rules in this chapter.

(b) Denial, suspension, or revocation of a license. HHSC has jurisdiction to enforce violations of the Acts or the rules adopted under this chapter. HHSC may deny, suspend, or revoke a license or impose an administrative penalty for the following reasons:

(1) failure to comply with any provision of Health and Safety Code (HSC) Chapter 254;

(2) failure to comply with any provision of this chapter (Texas Administrative Code Title 26, Chapter 509) or any other applicable laws;

(3) the facility, or any of its employees, commits an act which causes actual harm or risk of harm to the health or safety of a patient;

(4) the facility, or any of its employees, materially alters any license issued by HHSC;

(5) failure to comply with minimum standards for licensure;

(6) failure to provide an adequate licensure application or renewal information;

(7) failure to comply with an order of the commissioner or another enforcement procedure under HSC Chapter 254;

(8) a history of failure to comply with the applicable rules relating to patient environment, health, safety, and rights;

(9) the facility, or any of its employees, has aided, committed, abetted, or permitted the commission of an illegal act;

(10) the facility, or any of its employees, commits fraud, misrepresentation, or concealment of a material fact on any documents required to be submitted to HHSC or required to be maintained by the facility pursuant to HSC Chapter 254 and the provisions of this chapter;

(12) failure to timely pay an assessed administrative penalty as required by HHSC;

(13) failure to submit an acceptable plan of correction for cited deficiencies within the timeframe required by HHSC;

(14) failure to timely implement plans of corrections to deficiencies cited by HHSC within the dates designated in the plan of correction; or

(15) failure to comply with applicable requirements within a designated probation period.

(d) The denial, suspension, or revocation of a license by HHSC and the appeal from that action are governed by the procedures for a contested case hearing under Texas Government Code, Chapter 2001.

§509.102. Denial of a License.

The Texas Health and Human Services Commission (HHSC) may deny a license if the applicant:

(1) fails to provide timely and sufficient information that is required by HHSC and that is directly related to the application; or

(2) has had the following actions taken against the applicant within the two-year period preceding the application:

(A) decertification or cancellation of its contract under the Medicare or Medicaid program in any state;

(B) federal Medicare or state Medicaid sanctions or penalties;

(C) unsatisfied federal or state tax liens;

(D) unsatisfied final judgments;

(E) eviction involving any property or space used as a health care facility in any state;

(F) unresolved state Medicaid or federal Medicare audit exceptions;

(G) denial, suspension, or revocation of a license for any health care facility in any state;

(H) a court injunction prohibiting ownership or operation of any health care facility; and

(I) a documented history of reportable conduct under Texas Health and Safety Code, Chapter 253 (relating to Employee Misconduct Registry).

§509.103. Suspension; Revocation.

(a) The Texas Health and Human Services Commission (HHSC) may suspend or revoke an existing valid license or disqualify a person from receiving a license because of a person's conviction of a felony or misdemeanor, if the crime directly relates to the duties and responsibilities of the ownership or operation of a health care facility.

(b) In determining whether a criminal conviction directly relates, HHSC shall consider the provisions of Texas Occupations Code, Chapter 53, Subchapter B (relating to Ineligibility for License).

(c) The following felonies and misdemeanors directly relate because these criminal offenses indicate an ability or a tendency for the person to be unable to own or operate a health care facility:

(1) a misdemeanor violation of the Texas Health and Safety Code, Chapter 254, titled Freestanding Emergency Medical Care Facilities (Act);

(2) a misdemeanor or felony involving moral turpitude;

(3) a conviction relating to deceptive business practices;

(4) a misdemeanor of practicing any health-related profession without a required license;

(5) a conviction under any federal or state law relating to drugs, dangerous drugs, or controlled substances;

(6) an offense under Texas Penal Code, Title 5, involving a patient or a client of any health care facility, a home and community support services agency, or a health care professional;

(7) a misdemeanor or felony offense under Texas Penal Code, as follows:

(A) Title 4 concerning offenses of attempting or conspiring to commit any of the offenses in this subsection;

(B) Title 5 concerning offenses against the person;

(C) Title 7 concerning offenses against property;

(D) Title 9 concerning offenses against public order and decency; or

(E) Title 10 concerning offenses against public health, safety, and morals; and

(8) other misdemeanors and felonies that indicate an inability or tendency for the person to be unable to own or operate a facility.

(d) Upon a licensee's felony conviction, felony probation revocation, revocation of parole, or revocation of mandatory supervision, the license shall be revoked.

§509.104. Emergency Suspension.

(a) The Texas Health and Human Services Commission (HHSC) may issue an emergency order to suspend a facility's license if HHSC has reasonable cause to believe that the conduct of a license holder creates an immediate danger to the public health and safety.

(b) An emergency suspension under this section is effective immediately without a hearing or notice to the license holder.

(c) On written request of the license holder, HHSC shall conduct a hearing not earlier than the 10th day or later than the 30th day after the date the hearing request is received to determine if the emergency suspension is to be continued, modified, or rescinded.

(d) A hearing and any appeal under this section are governed by HHSC rules for a contested case hearing and Texas Government Code, Chapter 2001.

§509.105. Probation.

(a) If the Texas Health and Human Services Commission (HHSC) finds that a facility is in repeated noncompliance with Texas Health and Safety Code Chapter 254, Freestanding Emergency Medical Care Facilities (Act) or this chapter but that the noncompliance does not endanger public health and safety, HHSC may schedule the facility for probation rather than suspending or revoking the facility's license.

(b) HHSC shall provide notice to the facility of the probation and of the violations not later than the 10th day before the date the probation period begins. The notice shall include the violations that resulted in placing the facility on probation.

(c) HHSC shall designate a period of not less than 30 days during which the facility remains under probation.

(d) During the probation period, the facility shall correct the violations and provide a written report that describes the corrective actions taken to HHSC for approval.

(e) HHSC may verify the corrective actions through an on-site inspection.

(f) HHSC may suspend or revoke the license of a facility that does not correct violations or that violates the Act or this chapter within the applicable probation period.

§509.106. Injunction.

(a) The Texas Health and Human Services Commission (HHSC) may petition a district court for a temporary restraining order to restrain a continuing violation if HHSC finds that the violation creates an immediate threat to the health and safety of the patients of a facility.

(b) A district court, on petition of HHSC and on a finding by the court that a person is violating the standards or licensing requirements provided under Texas Health and Safety Code Chapter 254, Freestanding Emergency Medical Care Facilities (Act), may by injunction:

(1) prohibit a person from continuing a violation;

(2) restrain or prevent the establishment or operation of a facility without a license issued under the Act; or

(3) grant any other injunctive relief warranted by the facts.

(c) The attorney general shall institute and conduct a suit authorized by this section at the request of HHSC.

(d) Venue for a suit brought under this section is in the county in which the facility is located or in Travis County.

§509.107. Criminal Penalty.

(a) A person commits an offense if the person violates Texas Health and Safety Code §254.051.

(b) An offense under this section is a Class C misdemeanor.

(c) Each day of a continuing violation constitutes a separate offense.

§509.108. Administrative Penalty.

(a) The Texas Health and Human Services Commission (HHSC) may impose an administrative penalty on a person licensed under the Texas Health and Safety Code, Chapter 254, Freestanding Emergency Medical Care Facilities (Act) who violates the Act, this chapter, or an order adopted under this chapter. A penalty collected under this section or §509.109 of this chapter (relating to Payment and Collection of Administrative Penalty; Judicial Review) shall be deposited in the state treasury in the general revenue fund.

(b) A proceeding to impose the penalty is a contested case under Texas Government Code, Chapter 2001.

(c) The amount of the penalty may not exceed $1,000 for each violation. Each day a violation continues or occurs is a separate violation for purposes of imposing a penalty.

(d) The amount shall be based on:

(1) the seriousness of the violation, including the nature, circumstances, extent, and gravity of the violation;

(2) the threat to health or safety caused by the violation;

(3) the history of previous violations;

(4) the amount necessary to deter a future violation;

(5) whether the violator demonstrated good faith efforts to come into compliance; and

(6) any other matter that justice may require.

(e) If HHSC initially determines that a violation occurred, HHSC shall give written notice of the report by certified mail to the person.

(f) The notice under subsection (e) of this section must:

(1) include a brief summary of the alleged violation;

(2) state the amount of the recommended penalty; and

(3) inform the person of the person's right to a hearing on the occurrence of the violation, the amount of the penalty, or both.

(g) Not later than the 20th day after the date the person receives the notice under subsection (e) of this section, the person in writing may:

(1) accept the determination and recommended penalty of HHSC; or

(2) make a request for a hearing on the occurrence of the violation, the amount of the penalty, or both.

(h) If the person accepts the determination and recommended penalty or if the person fails to respond to the notice, the executive commissioner or designee of HHSC by order shall approve the determination and impose the recommended penalty.

(i) If the person requests a hearing, HHSC shall refer the matter to the State Office of Administrative Hearings, which shall promptly set a hearing date and give written notice of the time and place of the hearing to the person. An administrative law judge of the State Office of Administrative Hearings shall conduct the hearing.

(j) The administrative law judge shall make findings of fact and conclusions of law and promptly issue to the executive commissioner of HHSC a proposal for a decision about the occurrence of the violation and the amount of a proposed penalty.

(k) Based on the findings of fact, conclusions of law, and proposal for a decision, the executive commissioner of HHSC by order may:

(1) find that a violation occurred and impose a penalty; or

(2) find that a violation did not occur.

(l) The notice of the order under subsection (k) of this section that is sent to the person in accordance with Texas Government Code, Chapter 2001, must include a statement of the right of the person to judicial review of the order.

§509.109. Payment and Collection of Administrative Penalty; Judicial Review.

(a) Not later than the 30th day after the date an order imposing an administrative penalty becomes final, the person shall:

(1) pay the penalty; or

(2) file a petition for judicial review of the executive commissioner's order contesting the occurrence of the violation, the amount of the penalty, or both.

(b) A person who files a petition for judicial review under subsection (a) of this section may:

(1) stay enforcement of the penalty by:

(A) paying the penalty to the court for placement in an escrow account; or

(B) giving the court a supersedeas bond approved by the court that:

(i) is for the amount of the penalty; and

(ii) is effective until all judicial review of the executive commissioner's order is final; or

(2) request the court to stay enforcement of the penalty by:

(A) filing with the court an affidavit of the person stating that the person is financially unable to pay the penalty and is financially unable to give the supersedeas bond; and

(B) sending a copy of the affidavit to the executive commissioner by certified mail.

(c) If the Texas Health and Human Services Commission (HHSC) receives a copy of an affidavit requesting a court to stay enforcement of a penalty, the executive commissioner may file with the court, not later than the fifth business day after the date the copy is received, a contest to the affidavit. The court shall hold a hearing on the facts alleged in the affidavit as soon as practicable and shall stay the enforcement of the penalty on finding that the alleged facts are true. The person who files an affidavit has the burden of proving that the person is financially unable to pay the penalty or to give a supersedeas bond.

(d) If the person does not pay the penalty and the enforcement of the penalty is not stayed, the penalty may be collected. The attorney general may sue to collect the penalty.

(e) If the court sustains the finding that a violation occurred, the court may uphold or reduce the amount of the penalty and order the person to pay the full or reduced amount of the penalty.

(f) If the court does not sustain the finding that a violation occurred, the court shall order that a penalty is not owed.

(g) If the person paid the penalty and if the amount of the penalty is reduced or the penalty is not upheld by the court, the court shall order, when the court's judgment becomes final, that the appropriate amount plus accrued interest be remitted to the person not later than the 30th day after the date that the judgment of the court becomes final. The interest accrues at the rate charged on loans to depository institutions by the New York Federal Reserve Bank. The interest shall be paid for the period beginning on the date the penalty is paid and ending on the date the penalty is remitted.

(h) If the person gave a supersedeas bond and the penalty is not upheld by the court, the court shall order, when the court's judgment becomes final, the release of the bond. If the person gave a supersedeas bond and the amount of the penalty is reduced, the court shall order the release of the bond after the person pays the reduced amount.