Proposed rules include new rules, amendments to existing rules, and repeals of existing rules. A state agency shall give at least 30 days' notice of its intention to adopt a rule before it adopts the rule. A state agency shall give all interested persons a reasonable opportunity to submit data, views, or arguments, orally or in writing (Government Code, Chapter 2001).

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

TITLE 1. ADMINISTRATION

PART 12. COMMISSION ON STATE EMERGENCY COMMUNICATIONS

CHAPTER 252. ADMINISTRATION

1 TAC §252.8

The Commission on State Emergency Communications (CSEC) proposes amendments to §252.8, concerning CSEC's Emergency Communications Advisory Committee.

BACKGROUND AND PURPOSE

CSEC proposes amendments to §252.8 (Title 1, Part 12, Chapter 252 of the Texas Administrative Code) relating to its Emergency Communications Advisory Committee (ECAC). Health and Safety Code §771.0511(b) authorizes CSEC to establish ECAC to assist in the "development, implementation, and management of an interconnected, state-level emergency services Internet Protocol network (State-level ESInet)." Section 252.8 establishes and governs ECAC in accordance with Government Code Chapter 2110, *State Agency Advisory Committees.* ECAC is abolished by §252.8 on September 1, 2023, if that date is not revised.

As required by the rule and statute, CSEC has completed its review of ECAC's work, usefulness, and costs and determined that it is in CSEC's best interests to continue receiving advice and assistance from ECAC regarding the State-level ESInet.

SECTION-BY-SECTION EXPLANATION

Section 252.8(p) is amended to replace the current year ECAC is abolished (2023) with a new abolishment year (2029).

FISCAL NOTE

Kelli Merriweather, CSEC's executive director, has determined that for each year of the first five fiscal years (FY) that amended §252.8 is in effect there will be no foreseeable cost or revenue implications to the state or local governments, including as a result of enforcing or administering the amended section.

PUBLIC BENEFITS AND COSTS

Ms. Merriweather has determined that for each year of the first five years the amended section is in effect, the public benefits will come from having a committee composed of representatives from the Texas 9-1-1 Entities whose purpose is to advise and make policy recommendations to CSEC on transitioning to Next Generation 9-1-1 service. Ms. Merriweather has also determined that for each year of the first five years the proposed section is in effect there are no probable economic costs to persons required to comply with the section, except for the unreimbursed costs of ECAC members who are not part of CSEC staff.

LOCAL EMPLOYMENT IMPACT STATEMENT

CSEC has determined that this proposal does not directly affect a local economy and therefore has not drafted a local employment impact statement as would otherwise be required under Government Code §2001.022.

COSTS TO REGULATED PERSONS

Government Code §2001.0045 precludes a state agency from adopting a proposed rule if the fiscal note states that the rule imposes a cost on regulated persons, including another state agency, a special district, or a local government, unless the state agency: (a) repeals a rule that imposes a total cost on regulated persons that is equal to or greater than the total cost imposed on regulated persons by the proposed rule; or (b) amends a rule to decrease the total cost imposed on regulated persons by an amount that is equal to or greater than the cost imposed on the persons by the rule. There are exceptions for certain types of rules under §2001.0045(c).

Section §2001.0045(b) applies to the proposed amended rule and no exceptions are applicable. The proposed amended rule fiscal note does not impose or increase costs on regulated persons, including another state agency, a special district, or a local government. Accordingly, no repeal or amendment of another rule to offset costs is required.

GOVERNMENT GROWTH IMPACT STATEMENT

Per Government Code § 2001.0221, CSEC has determined that during the first five years the proposed rule would be in effect it does not: (1) create or eliminate a government program; (2) require the creation of new employee positions or the elimination of existing employee positions; (3) require an increase or decrease in future legislative appropriations to the agency; (4) require an increase or decrease in fees paid to the agency; (5) does not create a new regulation; (6) expand, limit, or repeal an existing regulation; (7) increase or decrease the number of individuals subject to the rule's applicability; and (8) positively or adversely affect this state's economy.

REGULATORY ANALYSIS OF MAJOR ENVIRONMENTAL RULES

CSEC has determined that this proposal is not a "major environmental rule" as defined by Government Code §2001.0225(g)(3).

SMALL, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYSIS

In accordance with Government Code §2006.002, CSEC has determined that there will be no adverse economic effect on small businesses and micro-businesses as the rule being amended affects only the relationship between CSEC and Texas 9-1-1 Entities, all of whom are governmental bodies. Accordingly, CSEC has not prepared an economic impact statement or regulatory

flexibility analysis, nor has it contacted legislators in any rural communities regarding this proposal.

TAKINGS IMPACT ASSESSMENT:

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

PUBLIC COMMENT

Comments on the proposal may be submitted in writing to Patrick Tyler, Commission on State Emergency Communications, 1801 Congress Avenue, Suite 11.100, Austin, Texas 78701, by facsimile to (512) 305-6937, or by email to patrick.tyler@csec.texas.gov. Please include "Rulemaking Comments" in the subject line of your letter, fax, or email. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register.*

STATEMENT OF AUTHORITY

The amended section is authorized by Texas Health and Safety Code §771.051(a)(1), (2), (4), (7), (8), (9), (10), §771.0511, and §771.052; and Government Code Chapter 2110.

No other statutes, articles or codes are affected by the proposed amendment.

§252.8. Emergency Communications Advisory Committee.

(a) Purpose. The purpose of this rule is to establish an Emergency Communications Advisory Committee (Committee) to assist the Commission in coordinating the development, implementation, interoperability, and internetworking of interconnected emergency services Internet Protocol networks (ESInets). Interconnected, interoperable ESInets providing Next Generation Core Services covering all of Texas constitute the State-level ESInet. As defined in Health and Safety Code §771.0511(a)(2), the State-level ESInet is used for communications between and among public safety answering points (PSAPs) and other entities that support or are supported by PSAPs in providing emergency call handling and response, and will be a part of the Texas Next Generation Emergency Communications System.

(b) Policy. It is Commission policy that the development, implementation, interoperability, interconnection, and internetworking of ESInets be done on a cooperative basis with the state's 9-1-1 Entities. It is Commission policy that the Committee:

(1) advise the Commission on matters regarding the interoperability and interconnection of ESInets, specifically including but not limited to Statewide Interoperability & Standards development for planning for interconnectivity, interoperability, and internetworking of ESInets as reflected in the Commission's Next Generation 9-1-1 Master Plan (Appendix 1 to the Commission Strategic Plan for Statewide 9-1-1 Service for Fiscal Years 20xx-20xx); and

(2) provide for 9-1-1 Entity collaboration on issues regarding ESInets, particularly regarding interoperability and interconnection of ESInets, to ensure that the requirements of the state's 9-1-1 Entities are met.

(c) Composition of Committee. Each Committee member must have appropriate training, experience, and knowledge of Next Generation 9-1-1 technology and services and/or emergency services other than 9-1-1 services to effectively advise the Commission.

(1) the Committee is appointed by the Commission and includes, at a minimum, the following members:

(A) The Executive Director of the Commission or designee as an ex-officio, non-voting member;

(B) two representatives from the Regional Planning Commissions (RPCs);

(C) two representatives from the Emergency Communication Districts (ECDs), as that term is defined in Health and Safety Code §771.001(3)(A); and

(D) two representatives from the ECDs, as that term is defined in Health and Safety Code §771.001(3)(B).

(2) No two Committee members may be from the same state 9-1-1 Entity.

(3) The Commission may add to the composition of the Committee including members representing emergency services other than 9-1-1 service.

(4) In appointing members to the Committee except under paragraph (3) of this subsection, the Commission shall consult with the RPCs and ECDs. RPCs may designate responsibility for consulting with the Commission to the Texas Association of Regional Councils. ECDs defined in Health and Safety Code §771.001(3)(A) and (B) may designate responsibility for consulting with the Commission to the Municipal Emergency Communication Districts Association and the Texas 9-1-1 Alliance, respectively.

(d) Bylaws. Draft bylaws for approval by the Commission. The bylaws shall, at a minimum, provide for the following:

(1) selection from among the members a presiding officer and an assistant presiding officer whose terms may not exceed two years; and

(2) establish standing committees.

(e) Terms of Office for Voting Members. Each member shall be appointed for a term of 3 years, except for the initial member terms under paragraph (4) of this subsection.

(1) Member terms begin on January 1st.

(2) Members shall continue to serve after the expiration of their term until a replacement member is appointed by the Commission.

(3) If a vacancy occurs, a person shall be appointed by the Commission to serve the unexpired portion of the vacating member's term.

(4) Members serve staggered terms. Initial member terms are as follows:

(A) one member from each 9-1-1 Entity represented on the Committee expires on December 31, 2013; and

(B) one member from each 9-1-1 Entity represented on the Committee expires on December 31, 2014.

(f) Committee Meeting Attendance. Members shall attend scheduled Committee meetings.

(1) A member shall notify the presiding officer or Commission staff if the member is unable to attend a scheduled meeting.

(2) The Commission may remove a member if it determines that a member cannot discharge the member's duties for a substantial part of the member's appointed term because of illness or disability, is absent from more than half of the Committee meetings during a fiscal year, or is absent from at least three consecutive Committee meetings. The validity of an action of the Committee is not affected by the fact that it is taken when a ground for removal of a member exists.

(g) Committee Roles and Responsibilities. The Committee is to assist the Commission in coordinating the development, implementation, and management of interoperable and interconnected ESInets. The Committee will seek state 9-1-1 Entity input and collaboration regarding the interoperability and interconnection of ESInets, specifically including but not limited to Statewide Interoperability & Standards development for planning for interconnectivity, interoperability, and internetworking of ESInets as reflected in the Commission's Next Generation 9-1-1 Master Plan (Appendix 1 to the Commission Strategic Plan for Statewide 9-1-1 Service for Fiscal Years 20xx-20xx).

(h) Reporting to the Commission. The Committee, through its presiding officer, will submit by September 1 of each year, or according to the schedule established by the commission, written reports advising the Commission. The reports shall include the following:

(1) an update on the Committee's work, including:

(A) Committee and sub- or standing-committee meeting dates;

(B) member attendance records;

(C) description of actions taken by the Committee;

(D) description of how the Committee has accomplished or addressed the tasks and objectives of this section and any other issues assigned to the Committee by the Commission; and

(E) anticipated future activities of the Committee;

(2) description of the usefulness of the Committee's work; and

(3) statement of costs related to the Committee, including the cost of Commission staff time spent in support of the Committee.

(i) Statement by a Member.

(1) The Commission and the Committee shall not be bound in any way by any statement or action by a member except when the statement or action is in pursuit of specific instructions from the Commission.

(2) The Committee and its members may not participate in legislative activity in the name of the Commission or the Committee without Commission approval.

(j) Advisory Committee. The Committee is an advisory committee in that it does not supervise or control public business or policy. As an advisory committee, the Committee is not subject to the Open Meetings Act (Government Code, Chapter 551).

(k) Reimbursement for Expenses.

(1) In accordance with the requirements in Government Code, Chapter 2110, a Committee member may receive reimbursement for the member's expenses incurred for each day the member engages in official Committee business if authorized by the General Appropriations Act or budget execution process.

(2) No compensatory per diem shall be paid to Committee members unless required by law.

(3) A Committee member who is an employee of a state agency, other than the Commission, may not receive reimbursement for expenses from the Commission.

(4) A nonmember of the Committee who is appointed to serve on a committee may not receive reimbursement for expenses from the Commission.

(5) Each Committee member whose expenses are reimbursed under this section shall submit to Commission staff the member's receipts for expenses and any required official forms no later than 14 days after conclusion of the member's engagement in official Committee business.

(6) Requests for reimbursement of expenses shall be made on official state travel vouchers.

(l) Commission Staff. Support for the Committee will be provided by Commission staff.

(m) Applicable law. The Committee is subject to Government Code, Chapter 2110, concerning state agency advisory committees.

(n) Commission Evaluation. The Commission shall annually evaluate the Committee's work, usefulness, and the costs related to the Committee, including the cost of Commission staff time spent supporting the Committee's activities.

(o) Report to the Legislative Budget Board. The Commission shall report to the Legislative Budget Board the information developed in subsection (n) of this section on a biennial basis as part of the Commission's request for appropriations.

(p) Review and Duration. On or before September 1, 2029 [~~2023~~], the Commission will initiate and complete a review of the Committee to determine whether the Committee should be continued or abolished. If the Committee is not continued, it shall be automatically abolished on September 1, 2029 [~~2023~~].

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

Filed with the Office of the Secretary of State on June 1, 2023.

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Patrick Tyler
General Counsel
Commission on State Emergency Communications
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For further information, please call: (512) 305-6915

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CHAPTER 254. REGIONAL POISON CONTROL CENTERS

1 TAC §254.2

The Commission on State Emergency Communications (CSEC) proposes the repeal of rule §254.2, concerning CSEC's Poison Control Coordinating Committee (PCCC).

BACKGROUND AND PURPOSE

CSEC proposes to repeal §254.2 (Title 1, Part 12, Chapter 254 of the Texas Administrative Code) relating to its PCCC. Health and Safety Code § 777.008 authorizes a coordinating committee to "coordinate the activities of the regional poison control centers designated under Section 777.001(a) and advise the [CSEC]." Section 254.2, establishing the Poison Control Coordinating Committee (PCCC) was established by §254.2, was proposed and adopted in accordance with Government Code Chapter 2110, *State Agency Advisory Committees.* If not extended by rule, the PCCC is abolished on September 1, 2023. Per §254.2(o), CSEC conducted a review of the rule and voted to propose repealing the rule at its May 31, 2023, open meeting.

CSEC has determined that the PCCC would best serve the coordinating interests of the CSEC Poison Control Program as a

standing working group created per CSEC's bylaws. CSEC's approach mirrors that of the Department of State Health Services which established the PCCC as an advisory committee from 1995 - 2003. In 2003 DSHS repealed its PCCC rule stating in the preamble: "Issues relating to the type of advice previously provided by the committee are better addressed through the establishment of ad hoc workgroups." CSEC's proposed repeal was presented to and considered by the PCCC whose members voted in favor of repealing the rule.

SECTION-BY-SECTION EXPLANATION

Section 254.2 is proposed to be repealed and replaced by a standing CSEC working group.

FISCAL NOTE

Kelli Merriweather, CSEC's executive director, has determined that for each year of the first five fiscal years (FY) that repealed §254.2 is in effect there will be no foreseeable cost or revenue implications to the state or local governments, including as a result of enforcing or administering the amended section.

PUBLIC BENEFITS AND COSTS

Ms. Merriweather has determined that for each year of the first five years the repealed section is in effect, the public benefits will come from having a PCCC working group coordinating the activities of the CSEC Poison Control Program, including the delivery of poison control services to the public and health care professionals. Ms. Merriweather has also determined that for each year of the first five years the repealed section is in effect there will be no economic costs to persons required to comply with the section as the section is being repealed. Costs of complying with the rule have been borne by CSEC directly through staff time spent supporting the PCCC's activities and indirectly through grants to each Regional Poison Control Center comprising the PCCC; and by PCCC members volunteering their time.

LOCAL EMPLOYMENT IMPACT STATEMENT

CSEC has determined that this proposal does not directly affect a local economy and therefore has not drafted a local employment impact statement as would otherwise be required under Government Code §2001.022.

COSTS TO REGULATED PERSONS

Under Government Code §2001.0045, a state agency may not adopt a proposed rule if the fiscal note states that the rule imposes a cost on regulated persons, including another state agency, a special district, or a local government, unless the state agency: (a) repeals a rule that imposes a total cost on regulated persons that is equal to or greater than the total cost imposed on regulated persons by the proposed rule; or (b) amends a rule to decrease the total cost imposed on regulated persons by an amount that is equal to or greater than the cost imposed on the persons by the rule. There are exceptions for certain types of rules under §2001.0045(c).

Section §2001.0045(b) applies to the proposed repeal and no exceptions are applicable. The proposed repeal fiscal note does not impose or increase costs on regulated persons, including another state agency, a special district, or a local government. Accordingly, no (additional) repeal or amendment of another rule to offset costs is required.

GOVERNMENT GROWTH IMPACT STATEMENT

Per Government Code § 2001.0221, CSEC has determined that during the first five years the proposed repeal of the rule would be in effect it does not: (1) create or eliminate a government program; (2) require the creation of new employee positions or the elimination of existing employee positions; (3) require an increase or decrease in future legislative appropriations to the agency; (4) require an increase or decrease in fees paid to the agency; (5) does not create a new regulation; (6) expand, limit, or repeal an existing regulation; (7) increase or decrease the number of individuals subject to the rule's applicability; and (8) positively or adversely affect this state's economy.

REGULATORY ANALYSIS OF MAJOR ENVIRONMENTAL RULES

CSEC has determined that this proposal is not a "major environmental rule" as defined by Government Code §2001.0225(g)(3).

SMALL, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT ANALYSIS

In accordance with Government Code §2006.002, CSEC has determined that there will be no adverse economic effect on small businesses, micro-businesses, or rural communities as the rule being proposed for repeal affects only the relationship between CSEC, its PCCC, and the CSEC Poison Control Program. Accordingly, CSEC has not prepared an economic impact statement or regulatory flexibility analysis, nor has it contacted legislators in any rural communities regarding this proposal.

TAKINGS IMPACT ASSESSMENT

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

PUBLIC COMMENT

Comments on the proposal may be submitted in writing to Patrick Tyler, Commission on State Emergency Communications, 1801 Congress Avenue, Suite 11.100, Austin, Texas 78701, by facsimile to (512) 305-6937, or by email to patrick.tyler@csec.texas.gov. Please include "Rulemaking Comments" in the subject line of your letter, fax, or email. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register.*

STATEMENT OF AUTHORITY

The proposed repeal of the section is proposed under Health and Safety Code §777.008 and Government Code Chapter 2110. The former establishes the PCCC, the latter requires state agencies to prescribe by rule an advisory committee's purpose and tasks, the manner in which the advisory committee reports to CSEC, and the duration of the advisory committee.

No other statutes, articles, or codes are affected by the proposal.

§254.2. Poison Control Coordinating Committee.

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

Filed with the Office of the Secretary of State on June 1, 2023.

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Patrick Tyler
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Commission on State Emergency Communications
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TITLE 13. CULTURAL RESOURCES

PART 1. TEXAS STATE LIBRARY AND ARCHIVES COMMISSION

CHAPTER 3. STATE PUBLICATIONS DEPOSITORY PROGRAM

13 TAC §3.5, §3.6

The Texas State Library and Archives Commission (commission) proposes amendments to §3.5, Standard Exemptions for State Publications in All Formats, and §3.6, Special Exemptions.

BACKGROUND. Section 441.104 of the Government Code establishes the commission's duties under the State Publications Depository Program (program), under which the commission acquires, organizes, retains, and provides access to state publications. Under section 441.103 of the Government Code, state agencies are required to designate one or more staff persons as agency publications liaisons, who are required to maintain a record of the agency's state publications. State agencies must furnish copies of their state publications to the commission in the number specified by commission rules. Section 441.105 of the Government Code authorizes the state librarian to specifically exempt a publication or distribution format from the requirements of the program.

The proposed amendments are necessary to exempt additional types of publications not appropriate for retention in the program. Exempting these types of publications will ensure the program includes the types of publications that document the operations of state agencies while easing state agencies' duties by reducing the number of publications they are required to submit. In addition, exempting items that are not appropriate for inclusion in the program will allow the commission to maximize its use of record storage space.

ANALYSIS OF PROPOSED AMENDMENTS. Proposed amendments to §3.5 clarify the introductory language and make the following proposed changes:

A proposed amendment to §3.5(11) adds course materials to the existing exemption for course schedules. This exemption covers university course schedules and courses offered by state agencies. The commission proposes to add "materials" to this item, as course materials are also inappropriate for the program.

Proposed new §3.5(26) adds non-fiction university press publications not aligned with the commission's collection development policy. One of the primary goals of the program is to capture all publications documenting the operation of a state agency. Non-fiction university press publications take up a considerable amount of space. If the commission were to accept all non-fiction publications, additional offsite storage would likely be necessary. Further, these titles are typically widely available at other libraries, particularly at the universities whose presses produce them. Exempting non-fiction university press publications that are not aligned with the commission's collection development priorities will ensure consistent application of the policy and that the program documents the university press function focusing on publications relating to Texas-related history and government.

A proposed amendment to §3.5(37) adds a clarifying date to the exemption. The proposed new exemption will read "rules and regulations after 1976 (as compendia)." The State Law Library holds the complete collection of historic Texas Administrative Code (TAC) publications. The TAC from 1999 to present is available on the Secretary of State's website. Researching rules and regulations prior to 1976 can be more challenging as centralized resources such as the Register and the TAC do not exist. Locating rules prior to 1976 may require archival research in the minutes or other records of a particular agency if published compendia are not available. If an agency did not include rule language in minutes or did not maintain or transfer records containing the text of adopted rules, there may be no other way to locate this information. For this reason, published collections of rules predating 1976 are important to the program to provide greater access to this information. However, rules and regulations after 1976 are not appropriate for the program.

Proposed new §3.5(42) adds training materials. As with course materials, training materials that are distributed publicly do not typically document the operation of a state agency. For example, the State Bar of Texas produces course materials as part of their Continuing Legal Education programming. While these publications have historically been provided to the commission under the program, less than 1% of these publications have been requested since at least the year 2000. According to the commission's research, several other libraries maintain these materials, including the State Law Library, Legislative Reference Library, and at least five Texas law school libraries. Because these types of materials are readily available from multiple other sources and are not necessary for the program, the commission proposes to add "training materials" to the list of exempted items as §3.5(42).

Finally, proposed amendments to §3.5 renumber the paragraphs to maintain the list in alphabetical order.

Proposed amendments to §3.6 clarify that special exemptions are for types of publications not listed in §3.5.

FISCAL IMPACT. Jelain Chubb, State Archivist and Director, Archives and Information Services, has determined that for each of the first five years the proposed amendments are in effect, there are no reasonably foreseeable fiscal implications for the state or local governments as a result of enforcing or administering the amended rules, as proposed. At most, some state agencies may have fewer publications to furnish the program, thereby potentially resulting in a minimal cost savings to the agencies.

PUBLIC BENEFIT AND COSTS. Ms. Chubb has determined that for each of the first five years the proposed amendments are in effect, the anticipated public benefit will be a streamlined focus on the commission's ability to acquire, organize, retain, and provide access to state publications. There are no anticipated economic costs to persons required to comply with the proposed amendments.

LOCAL EMPLOYMENT IMPACT STATEMENT. The proposal has no impact on local economy; therefore, no local employment impact statement under Government Code, §2001.022 is required.

SMALL BUSINESS, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT STATEMENT. There will be no adverse economic effect on small businesses, micro-businesses, or rural communities; therefore, a regulatory flexibility analysis under Government Code, §2006.002 is not required.

COST INCREASE TO REGULATED PERSONS. The proposed amendments do not impose or increase a cost on regulated per-

sons, including another state agency, a special district, or a local government. Therefore, the commission is not required to take any further action under Government Code, §2001.0045.

GOVERNMENT GROWTH IMPACT STATEMENT. In compliance with Government Code, §2001.0221, the commission provides the following government growth impact statement. For each year of the first five years the proposed amendments will be in effect, the commission has determined the following:

1. The proposed amendments will not create or eliminate a government program;

2. Implementation of the proposed amendments will not require the creation of new employee positions or the elimination of existing employee positions;

3. Implementation of the proposed amendments will not require an increase or decrease in future legislative appropriations to the commission;

4. The proposed amendments will not require an increase or decrease in fees paid to the commission;

5. The proposal will not create a new regulation;

6. The proposed amendments will not expand or repeal an existing regulation, but they will limit an existing regulation by narrowing its scope of applicability;

7. The proposed amendments will not increase the number of individuals subject to the proposal's applicability; and

8. The proposed amendments will not positively or adversely affect this state's economy.

TAKINGS IMPACT ASSESSMENT. No private real property interests are affected by this proposal, and the proposal does not restrict or limit an owner's right to their property that would otherwise exist in the absence of government action. Therefore, the proposed amendments to not constitute a taking under Government Code, §2007.043.

REQUEST FOR PUBLIC COMMENT. Written comments on the proposed amendments may be submitted to Jelain Chubb, State Archivist and Director, Archives and Information Services, Texas State Library and Archives Commission, P.O. Box 12927, Austin, Texas 78711, or via email at rules@tsl.texas.gov. To be considered, a written comment must be received no later than 30 days from the date of publication in the *Texas Register.*

STATUTORY AUTHORITY. The amendments are proposed under Government Code, §441.102, which requires the commission by rule to establish procedures for the distribution of state publications to depository libraries and for the retention of those publications; Government Code, §441.103, which requires a state agency to furnish copies of its state publications that exist in a physical format to the Texas State Library in the number specified by commission rules; Government Code, §441.104, which directs the commission to establish a program for the preservation and management of state publications; and Government Code, §441.105, which authorizes the commission to specifically exempt a publication or a distribution format from this subchapter.

CROSS REFERENCE TO STATUTE. Government Code, Chapter 441.

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

§3.5. Standard Exemptions for State Publications in All Formats.

The following publications are exempt from the State Publications Depository Program and shall not be provided to the commission: [~~The Director and Librarian has exempted from deposit requirements certain kinds of state publications. A state agency is not required to deposit or provide access to these state publications:~~]

(1) agendas;

(2) advertisements;

(3) alumni materials;

(4) announcements;

(5) artwork (graphical representations without textual information);

(6) calendars;

(7) codes (as compendia);

(8) complex relational databases;

(9) contracts;

(10) correspondence;

(11) course schedules and materials;

(12) curriculum catalogs (departmental only);

(13) drafts of plans, reports;

(14) fiction;

(15) forms and instruction manuals for their completion;

(16) fund raising materials;

(17) grant proposals, bids;

(18) hearings (transcripts of);

(19) job listings;

(20) laws (as compendia);

(21) literary criticisms;

(22) memorabilia;

(23) memoranda (including e-mail);

(24) news or press releases;

(25) newsletters and subscriber lists meant only for employee, faculty or student use;

(26) non-fiction university press publications not aligned with the commission's collection development policy;

(27) [~~(26)~~] notices of sale;

(28) [~~(27)~~] opinions and orders issued by state courts;

(29) [~~(28)~~] daily or weekly periodicals (that are summarized in monthly or quarterly publications);

(30) [~~(29)~~] personnel manuals;

(31) [~~(30)~~] photographs;

(32) [~~(31)~~] poetry;

(33) [~~(32)~~] policy handbooks intended only for internal use;

(34) [~~(33)~~] programs (announcements of events, training sessions);

(35) [~~(34)~~] recruitment materials;

(36) [~~(35)~~] reprints (reissued without change);

(37) [~~(36)~~] rules and regulations after 1976 (as compendia);

(38) [~~(37)~~] standards (as compendia);

(39) [~~(38)~~] stationery;

(40) [~~(39)~~] student publications (those produced by students);

(41) [~~(40)~~] telephone directories meant only for employee, faculty, or student use;

(42) training materials;

(43) [~~(41)~~] unedited compilations of data or information submitted via forms or other means from individuals or entities under the regulation of a state agency; and

(44) [~~(42)~~] volunteer newsletters.

§3.6. Special Exemptions.

Upon written application, the Director and Librarian may exempt other [~~specific kinds of~~] state publications and information formats not listed in §3.5 of this title (relating to Standard Exemptions for State Publications in All Formats) from deposit requirements.

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

Filed with the Office of the Secretary of State on June 2, 2023.

TRD-202302058
Sarah Swanson
General Counsel
Texas State Library and Archives Commission
Earliest possible date of adoption: July 16, 2023
For further information, please call: (512) 463-5460

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CHAPTER 10. ARCHIVES AND HISTORICAL RESOURCES

13 TAC §10.1, §10.5

The Texas State Library and Archives Commission (commission) proposes an amendment to §10.1, Definitions, and new §10.5, Transfer of State Agency Records to the State Archives.

Section 441.181 of the Government Code requires the commission to take legal custody of and preserve archival state records in the state archives. Among other duties, the statute directs the state archivist to identify and designate archival state records and coordinate their transfer to the custody of the commission in accordance with Government Code, §441.186; arrange, describe, and preserve archival state records according to accepted archival practices; and prepare inventories, indexes, catalogs, or other research aids to state archival records held by the program.

Under Government Code, §441.186, the state archivist is authorized to identify and designate state records as archival state records or subject to archival review prior to their destruction. The statute further requires state agency records management officers to submit to the state archivist any information concerning a state record that the state archivist considers necessary to determine the archival value of a record. Unless the commission cannot accept immediate custody of an archival state record, state agencies generally must transfer all archival state records to the custody of the commission when they are no longer needed for the administration of the state agency, unless state law requires that the records remain in the custody of the agency. Once archival state records are transferred to the state archives, the commission becomes the legal owner of the records, preserves the records, and makes them available to the public.

Proposed new §10.5 will facilitate and streamline state agency transfers of archival state records to the commission and ensure the state archivist has the information necessary to properly identify, arrange, describe, catalog, preserve, and provide access to the archival state records in accordance with state statutes. The proposed new rule will benefit state agencies by establishing a systemic approach with key requirements clearly specified to improve state agencies' ability to verify they are transferring only those records that should be transferred to the state archives. The proposed new rule will also ensure more efficient use of the commission's resources needed for managing the appraisal, accession, processing, and cataloging of incoming state agency records.

ANALYSIS OF PROPOSED NEW SECTION. New subsection (a) restates the purpose of the new rule as authorized by statute. New subsections (b) and (c) provide that a state agency must use the forms and procedures available on the commission's website or on request to initiate a transfer of archival state records. Subsection (b) applies to archival state records in the physical possession of the agency and subsection (c) applies to archival state records stored in the State Records Center. Both subsections clarify that submission of the forms constitutes a formal request to transfer archival state records to the state archives. The form will require information such as quantity of records, record series number based on the state agency's approved records retention schedule, date span of records, and any known exceptions to disclosure under the Public Information Act that may apply to the records. The procedure will involve creating an inventory for the records, flagging restricted records, and instructions on how to properly pack and label boxes. New subsection (d) requires that archival state records be appropriately identified, packaged, and transferred according to the procedures available on the commission's website. New subsection (e) requires that all transfers be accompanied by an inventory. New subsection (f) provides that records storage equipment received with transfers of records will be retained or disposed of at the discretion of the State Archives unless the transferring agency requests the equipment's return. Examples of storage equipment that may be received with transfer of records include external drives and filing cabinets.

The proposed amendment to §10.1 adds a definition for "state archives" to ensure clarity in proposed new §10.5.

FISCAL IMPACT. Jelain Chubb, State Archivist and Director, Archives and Information Services, has determined that for each of the first five years the proposed amendment and new rule are in effect, there are no reasonably foreseeable fiscal implications for the state or local governments as a result of enforcing or administering the amended and new rule, as proposed. State agencies are already required to transfer materials to the state archives according to the state records retention schedule adopted under 13 Tex. Admin. Code §6.10 (archival records must be transferred to the Archives and Information Services Division of the Texas State Library and Archives Commission for

archival management). The proposed new rule will streamline and standardize the transfer process.

PUBLIC BENEFIT AND COSTS. Ms. Chubb has determined that for each of the first five years the proposed amendment and new rule are in effect, the anticipated public benefit will be improved organization and description of state archival records and an ability for the commission to make them available for public access more expediently. There are no anticipated economic costs to persons required to comply with the proposed amendment or new rule.

LOCAL EMPLOYMENT IMPACT STATEMENT. The proposal has no impact on local economy; therefore, no local employment impact statement under Government Code, §2001.022 is required.

SMALL BUSINESS, MICRO-BUSINESS, AND RURAL COMMUNITY IMPACT STATEMENT. There will be no adverse economic effect on small businesses, micro-businesses, or rural communities; therefore, a regulatory flexibility analysis under Government Code, §2006.002 is not required.

COST INCREASE TO REGULATED PERSONS. The proposed amendment and new rule do not impose or increase a cost on regulated persons, including another state agency, a special district, or a local government. Therefore, the commission is not required to take any further action under Government Code, §2001.0045.

GOVERNMENT GROWTH IMPACT STATEMENT. In compliance with Government Code, §2001.0221, the commission provides the following government growth impact statement. For each year of the first five years the proposed new rule will be in effect, the commission has determined the following:

1. The proposed amendment and rule will not create or eliminate a government program;

2. Implementation of the proposed amendment and rule will not require the creation of new employee positions or the elimination of existing employee positions;

3. Implementation of the proposed amendment and rule will not require an increase or decrease in future legislative appropriations to the commission;

4. The proposed amendment and rule will not require an increase or decrease in fees paid to the commission;

5. The proposed rule will create a new regulation;

6. The proposed amendment and rule will not expand, limit, or repeal an existing regulation;

7. The proposed amendment and rule will not increase the number of individuals subject to the proposed rule's applicability; and

8. The proposed amendment and rule will not positively or adversely affect this state's economy.

TAKINGS IMPACT ASSESSMENT. No private real property interests are affected by this proposal, and the proposal does not restrict or limit an owner's right to their property that would otherwise exist in the absence of government action. Therefore, the proposed new rule does not constitute a taking under Government Code, §2007.043.

REQUEST FOR PUBLIC COMMENT. Written comments on the proposed amendment and new rule may be submitted to Jelain Chubb, State Archivist and Director, Archives and Information Services, Texas State Library and Archives Commission, P.O. Box 12927, Austin, Texas, 78711, or via email at rules@tsl.texas.gov. To be considered, a written comment must be received no later than 30 days from the date of publication in the *Texas Register.*

STATUTORY AUTHORITY. The amendment and new rule are proposed under Government Code, §441.190, which authorizes the commission to adopt rules establishing standards and procedures for the protection, maintenance, and storage of state records. The statute further directs the commission to pay particular attention to the maintenance and storage of archival and vital state records and authorizes the commission to adopt rules as it considers necessary to protect those records. In addition, the amendment and new rule are proposed under Government Code, §441.199, which authorizes the commission to adopt rules it determines necessary for cost reduction and efficiency of recordkeeping by state agencies and for the state's management and preservation of records.

CROSS REFERENCE TO STATUTE. Government Code, Chapter 441.

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

§10.1. Definitions.

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

(1) Accession--means the formal acceptance of an item or collection into the holdings of the State Archives and generally includes a transfer of title.

(2) Agency--means the Texas State Library and Archives Commission as an agency of the state of Texas, including the staff, collections, archives, operations, programs, and property of the Texas State Library and Archives Commission.

(3) Commission--means the seven-member governing body of the Texas State Library and Archives Commission.

(4) Deaccession--means the permanent removal of an item or collection of items from the holdings of the State Archives.

(5) Disposal--means the final disposition of an item or collection of items from the State Archives which may include transfer to another repository, sale, or destruction of the item or collection.

(6) Item--means archival material, historical item, artifact, or museum piece in the custody of the State Archives, including the Sam Houston Regional Library and Research Center.

(7) Reappraisal--means the review of items that have been previously appraised, which may result in the identification of materials that no longer merit permanent preservation and that are candidates for deaccessioning.

(8) State archives--means the program of the Archives and Information Services Division of the Texas State Library and Archives Commission for the continued preservation of archival state records and historical resources.

§10.5. Transfer of State Agency Records to the State Archives.

(a) Archival state records shall be transferred to the state archives when the records are no longer needed for the administration of the state agency. Records designated as archival on the state

agency's approved records retention schedule must be transferred to the state archives. For records designated for archival review on the state agency's approved records retention schedule, the state agency's records management officer must contact the state archives for an archival review before disposition.

(b) To initiate a transfer of archival state records, the transferring state agency shall notify the state archives using the forms and procedures prescribed by the state archives and available at www.tsl.texas.gov. Submission of these forms shall constitute a formal request from the state agency for the state archives to accept legal and physical custody of the records.

(c) For archival state records stored temporarily in the State Records Center, on notification that the records have met retention requirements and are eligible for archival review or transfer, the state agency records management officer must notify the state archives using the forms and procedures prescribed by the state archives and available at www.tsl.texas.gov. Submission of these forms shall constitute a formal request from the state agency for the state archives to accept legal and physical custody of the records.

(d) Archival state records approved for transfer to the state archives must be identified, packaged, and transferred according to the procedures prescribed by the state archives and available at www.tsl.texas.gov.

(e) All transfers must be accompanied by an inventory as prescribed by the state archives and available at www.tsl.texas.gov.

(f) Records storage equipment received with transfers of records to the state archives will be retained or disposed of at the discretion of the state archives unless the transferring state agency requests the equipment's return.

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

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Sarah Swanson
General Counsel
Texas State Library and Archives Commission
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For further information, please call: (512) 463-5460

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TITLE 19. EDUCATION

PART 1. TEXAS HIGHER EDUCATION COORDINATING BOARD

CHAPTER 4. RULES APPLYING TO ALL PUBLIC INSTITUTIONS OF HIGHER EDUCATION IN TEXAS

SUBCHAPTER D. DUAL CREDIT PARTNERSHIPS BETWEEN SECONDARY SCHOOLS AND TEXAS PUBLIC COLLEGES

19 TAC §4.86

The Texas Higher Education Coordinating Board (Coordinating Board) proposes new rules in Texas Administrative Code, Title 19, Part 1, Chapter 4, Subchapter D, §4.86, concerning the establishment of College Connect Courses, an optional program for institutions of higher education to offer high school students. Specifically, this new section will clarify and assure institutions' ability to offer innovatively designed dual credit or dual enrollment programs within the scope of existing law.

The Coordinating Board proposes the establishment of the College Connect Courses rule framework to provide an optional foundation for public institutions of higher education to deliver innovatively designed courses integrating college-level content for secondary-level students. Institutions have the option to deliver courses in one of two modalities already in use: dual credit or dual enrollment.

These courses will interweave standard college-level coursework in the institution's core curriculum with supportive integrated skills curriculum designed to give high school students tools to take on college-level work. Institutions already have legal authority to offer college-level coursework to students (Texas Education Code §28.009); this rule provides more detailed guidance on an optional framework built on that existing authority.

Subsection 4.86(a) states the authority for these rules, which are promulgated under Texas Education Code (TEC) §§28.009(b), 130.001(b)(3)-(4), and 130.008.

Subsection 4.86(b) states the purpose of this new rule, which is to provide an optional foundation to encourage public institutions of higher education to offer these innovatively designed courses, giving secondary students exposure to both college-level content and supportive college readiness skills.

Subsection 4.86(c) lists criteria for student eligibility to enroll in these classes. Students must either demonstrate having met college readiness standards in accordance with TEC chapter 51, subchapter. F-1, or they must show exemption from that statute as non-degree-seeking or non-certificate-seeking students under TEC §51.338(a).

Subsection 4.86(d) pertains to the course content of College Connect Courses. The rule encourages institutions to offer College Connect Courses from their core curriculum catalog, as those courses must transfer across public institutions of higher education in Texas (TEC §61.822). In addition, this rule stipulates that, for students who have not yet demonstrated readiness under proposed subsection 4.86(c)(2), institutions should provide supplemental instructional content to support these students through a method at their discretion.

Subsection 4.86(e) provides that Coordinating Board staff may provide technical assistance upon request. The Coordinating Board has existing plans and authorization to develop course material that may be of assistance to institutions seeking to offer College Connect Courses.

Subsection 4.86(f) contains additional academic policies. This subsection states that students enrolled in these courses must finish with two grades, with the college-level grade determined according to a method determined by the institution. Institutions must also enter into institutional agreements to offer College Connect Courses, in accordance with TEC §28.009(b-2). This subsection encourages institutions to adopt academic policies that provide a maximum latitude to drop the college-level component, currently a matter of institutional policy. College Connect Course hours do not count against the excess semester credit hour limit for funding, in accordance with TEC §61.0595(d)(5).

Subsection 4.86(g) contains funding and tuition policies specifically for College Connect Courses offered through the dual credit option. This subsection restates current statute related to funding and tuition, including that dual credit courses may receive formula funding under TEC §61.059 and that institutions may waive tuition for dual credit courses under TEC §54.216.

Dr. Jennielle Strother, Assistant Commissioner for Student Success, has determined that for each of the first five years the sections are in effect there would be no fiscal implications for state or local governments as a result of enforcing or administering the rules. There are no estimated reductions in costs to the state and to local governments as a result of enforcing or administering the rule. There are no estimated losses or increases in revenue to the state or to local governments as a result of enforcing or administering the rule.

There is no impact on small businesses, micro businesses, and rural communities. There is no anticipated impact on local employment.

Dr. Jennielle Strother, Assistant Commissioner for Student Success, has also determined that for each year of the first five years the section is in effect, the public benefit anticipated as a result of administering the section will be providing a foundation for institutions of higher education to offer innovatively designed, supportive college-level coursework for secondary-level students. There are no anticipated economic costs to persons who are required to comply with the sections as proposed.

Government Growth Impact Statement

(1) the rules will not create or eliminate a government program;

(2) implementation of the rules will not require the creation or elimination of employee positions;

(3) implementation of the rules will not require an increase or decrease in future legislative appropriations to the agency;

(4) the rules will not require an increase or decrease in fees paid to the agency;

(5) the rules will not create a new rule;

(6) the rules will not limit an existing rule;

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

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

Comments on the proposal may be submitted to Dr. Jennielle Strother, Assistant Commissioner for Student Success, P.O. Box 12788, Austin, Texas 78711-2788, or via email at CRI@highered.texas.gov. Comments will be accepted for 30 days following publication of the proposal in the *Texas Register.*

The new section is proposed under Texas Education Code, Sections 28.009(b), which provides the Coordinating Board with existing authority to adopt rules as necessary concerning dual credit programs, and 130.008(a-3), which gives the Coordinating Board existing authority to adopt rules regarding existing courses for joint high school and junior college credit.

The proposed new section affects Texas Education Code, Sections 28.009, 130.001(b), and 130.008, and Texas Administrative Code, chapter 4, subchapter D, sections 4.83(7) and (8).

§4.86. Optional Dual Credit or Dual Enrollment Program: College Connect Courses.

(a) Authority. These rules are authorized by Texas Education Code §§28.009(b), 130.001(b)(3) - (4), and 130.008.

(b) Purpose. The purpose of this rule is to encourage and authorize public institutions of higher education to deliver innovatively designed dual credit or dual enrollment courses that integrate both college-level content in the core curriculum of the institution alongside college-readiness content and skills instruction. These innovatively designed courses will allow students the maximum flexibility to obtain college credit and provide integrated college readiness skills to students who are on the continuum of college readiness and will benefit from exposure to college-level content.

(c) Student eligibility. An eligible student must be enrolled in a public school district or open-enrollment charter as defined in Texas Education Code §5.001(6). An institution of higher education may offer College Connect Courses to:

(1) A student who has met the college readiness standards set forth in subchapter C, §4.57 of this chapter (relating to College Ready Standards); or

(2) A student who has not yet demonstrated college readiness by achieving minimum passing standards set forth in §4.57 of this chapter, if the student is:

(A) a non-degree-seeking or non-certificate seeking student under Texas Education Code §51.338(a); and

(B) has earned not more than 14 semester credit hours of college credits at an institution of higher education; or

(C) a student who is otherwise exempt from the Texas Success Initiative, as set forth in subchapter C, §4.54 of this chapter (relating to Exemptions, Exceptions, and Waivers).

(d) Course content. The following standards apply to delivery of College Connect Courses offered under this rule:

(1) An institution of higher education may offer College Connect Courses within the institution's core curriculum in accordance with subchapter B, §4.28 of this chapter (relating to Core Curriculum).

(2) An institution of higher education must also incorporate supplemental college readiness content to support students who have not yet demonstrated college readiness as defined in §4.57 of this chapter within these courses. An institution may deliver this supplemental instruction through a method at their discretion, including through embedded course content, supplemental corequisite coursework, or other method.

(e) Coordinating Board staff may provide technical assistance to public institutions of higher education and secondary schools and districts in developing and providing these courses.

(f) Additional Academic Policies.

(1) College Connect Courses offered through dual credit or dual enrollment must confer both a college-level grade and a secondary-level grade upon a students' successful completion of the course. A grade conferred for the college-level course may be different from the secondary-level grade, to reflect whether a student has appropriately demonstrated college-level knowledge and skills as well as secondary-level knowledge and skills. An institution may determine how a student enrolled in this course may earn college credit, whether through college-level course completion or successful completion of a recognized college-level assessment.

(2) An institution of higher education must enter into an institutional agreement with the secondary school according to §4.84

of this chapter (relating to Institutional Agreements) to offer College Connect Courses.

(3) An institution of higher education is strongly encouraged to provide the maximum latitude possible for a student to drop the college-level course component beyond the census date, while still giving the student an opportunity to earn credit toward high school graduation requirements.

(4) Hours earned through this program before the student graduates from high school that are used to satisfy high school graduation requirements do not count against the limitation on formula funding for excess semester credit hours under chapter 13, subchapter F, §13.104 of this title (relating to Exemptions for Excess Hours).

(g) Funding and Tuition. For College Connect Courses offered through dual credit under this option:

(1) An institution of higher education may receive formula funding for College Connect Course semester credit hours in accordance with Texas Education Code §61.059 and chapter 130, subchapter A, and any Coordinating Board rules that authorize funding for courses offered under this section.

(2) An institution of higher education may waive a student's tuition for College Connect Courses in accordance with Texas Education Code §§54.216 and 28.0095.

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

Filed with the Office of the Secretary of State on June 1, 2023.

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Nichole Bunker-Henderson
General Counsel
Texas Higher Education Coordinating Board
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For further information, please call: (512) 427-6537

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PART 2. TEXAS EDUCATION AGENCY

CHAPTER 129. STUDENT ATTENDANCE
SUBCHAPTER AA. COMMISSIONER'S RULES

19 TAC §129.1025

The Texas Education Agency (TEA) proposes an amendment to §129.1025, concerning the student attendance accounting handbook. The proposed amendment would adopt by reference the *2023-2024 Student Attendance Accounting Handbook.* The handbook provides student attendance accounting rules for school districts and charter schools.

BACKGROUND INFORMATION AND JUSTIFICATION: TEA has adopted its student attendance accounting handbook in rule since 2000. Attendance accounting evolves from year to year, so the intention is to annually update §129.1025 to refer to the most recently published student attendance accounting handbook.

Each annual student attendance accounting handbook provides school districts and charter schools with the Foundation School Program (FSP) eligibility requirements of all students, prescribes the minimum requirements of all student attendance accounting systems, lists the documentation requirements for attendance audit purposes, and details the responsibilities of all district personnel involved in student attendance accounting. TEA distributes FSP resources under the procedures specified in each current student attendance accounting handbook. The final version of the student attendance accounting handbook is published on the TEA website. A supplement, if necessary, is also published on the TEA website.

The proposed amendment to §129.1025 would adopt by reference the student attendance accounting handbook for the 2023-2024 school year. The proposed handbook is available on the TEA website at https://tea.texas.gov/finance-and-grants/financial-compliance/student-attendance-accounting-handbook.

Significant changes to the *2023-2024 Student Attendance Accounting Handbook* would include the following.

Section 1, Overview

Texas Education Code (TEC), Chapter 48, specifically §48.008, establishes the requirements for adopting an attendance accounting system and reporting attendance accounting data through the Texas Student Data System (TSDS) Public Education Information Management System (PEIMS). The following changes implement reporting requirements for attendance and funding.

Language would be deleted that references reporting attendance through TSDS PEIMS, the term "minutes" being interchangeable with "days," school days being converted to minutes, the repeal of the seven-hour school day requirement, and early release waivers being rescinded.

Language referring to the footnote would be revised to show §129.1025.

Language referring to the electronic Word version of the handbook would be deleted.

Section 3, General Attendance Requirements

TEC, §25.081, and Chapter 48, specifically §48.005, establish the general parameters for attendance and school operation. The following changes would implement reporting requirements for attendance and funding.

Language would be revised to state that Code 0 will be used for a nonresident student who is charged tuition for the purpose of reducing local revenue.

Language would be revised to state that the time spent in a course for which the student has already received credit does not count as instructional time for purposes of the two-through-four-hour-rule.

Language would be revised to state that a homeless student is entitled to enroll in any public school that non-homeless students who live in the attendance area in which the child or youth is actually living are eligible to attend.

Language would be revised to state that school districts can learn more on the responsibilities associated with homeless students on the Texas Education for Homeless Children and Youth (TEHCY) Program webpage.

Language would be revised to state that information on secondary school completion and dropouts in Texas public schools is available on the TEA Completion, Graduation and Dropout webpage for the current definition of "dropout."

Language would be revised to state that once withdrawn, a student in Grade 7-12 must be reported as a school leaver on the 40203 School Leaver Extension and could be considered a dropout according to the C162 Leaver Reason Code table of the Texas Education Data Standards (TEDS).

The footnote showing 19 TAC §129.21(i)(1) would be deleted.

Language would be added to state that Section 504 regulations and Individual with Disabilities Education Act (IDEA) protect the rights of students with disabilities. Absences should be monitored, and Section 504 committee meetings and admission, review, and dismissal (ARD) committee meetings should be convened, as needed, to proactively prevent truancy and possibly revise Section 504 plans. The footnote was revised to show 19 TAC §129.1043.

Language would be revised to include psychological reasons as a criterion for a student to be served through the general education homebound (GEH) program. A referral under Section 504 should be considered to determine eligibility for homebound students with a suspected disability. If the student is already eligible under Section 504, a Section 504 meeting must be held to discuss potential homebound eligibility.

Language would be revised to state that Section 504 policies and procedures for committee membership must be followed for Section 504 eligible students and that the GEH committee/Section 504 committee reviews the necessity for, types of, and duration of instruction based on information from the student's licensed physician.

Language would be revised to include the Section 504 committee in documentation responsibilities.

Language would be revised to include the Section 504 committee in determining the transition process from GEH to the classroom setting.

Language would be revised to state that TEDS is the reference point for information on number of school days in the calendar.

Language would be revised to state that low attendance day waivers requested for the district or campus must include the prior year's attendance report showing the overall attendance rate. For a new campus or a campus that existed as two separate campuses the prior year, the overall average attendance rate for the district as a whole must be used.

Language would be revised to show that information on missed school day or low attendance day waivers can be found on http://tealprod.tea.state.tx.us/waiversreports/tea.waiversreports.web.

Language in the table showing situations leading to school closures due to bad weather or student health and safety would be revised to state that a charter school's student attendance accounting software calendar must be adjusted according to TEA policy listed in the table prior to generating and submitting the Six-Week District Summary Attendance report in the FSP System.

Language in the table showing situations leading to school closures due to bad weather or student health and safety would be revised to state that a local educational agency (LEA) should locally track the minutes that it actually served students on a non-instructional day for auditing purposes.

Language would be revised to state that for the purposes of calculating state funding, the state funding calendar year begins the fourth Monday in August unless a district is designated as a year-round system or is a district of innovation that changes its start date.

Language relating to summer school and state funding would be deleted.

Language would be revised to state that districts with year-round programs with tracks ending later than June 20, 2024, may delay PEIMS submission until August 15, 2024, or two weeks after the latest year-round track, but resubmissions made after August 15 will not be processed. Corrections made after August 15, 2024, will be addressed by the State Funding Division.

Language would be revised in examples relating to prekindergarten (pre-K) programs to include that the ARD committee identifies that the student has special needs and places the student in a self-contained early childhood special education (ECSE) classroom for a three-hour afternoon session.

Language would be revised in an example relating to a student who is auditorily impaired attending a regional day school program for the deaf (RDSPD) in a neighboring school district. The average daily attendance (ADA) eligibility code for this student is 3 - Eligible Transfer Student Full-Day. The student would also be reported as a transfer student on the 40110 Student School Association Extension.

Language would be revised in an example to state that if a district provides less than 2,100 waiver minutes for actual staff development, the instructional track will need to contain additional minutes of operation and that if a charter school provides less than five waiver days for actual staff development, the instructional track will need to contain additional days of operation.

Section 4, Special Education

TEC, Chapter 48, specifically §48.102, authorizes funding for special education in certain circumstances. TEC, §48.004, authorizes the commissioner to require reports that may be necessary to implement and administer the FSP. The following changes would implement reporting for special education to account for attendance and funding.

Language would be revised to state that the term "special education services" includes related services.

Language would be revised to state that when a student moves from one district to another within the state in the same school year and either the parent or previous district verifies that the student had an individualized education program (IEP) that was in effect, the district must meet the requirements of 34 CFR, §300.323, regarding the provision of special education services.

Language would be revised to state that the admission, review, and dismissal (ARD) committee's verification process means the new district has received a copy of the student's IEP that was in effect in the previous district.

Language would be revised to state that when a student transfers from a school district in another state in the same school year and the parent or previous district verifies that the student had an IEP that was in effect in the previous district, the new school district must meet the requirements of 34 CFR, §300.323(f).

Language would be revised to state that, if the parents or in- or out-of-state district verifies before the new school year begins that the student had an IEP that was in effect in the previous district, the new school district must implement the IEP from the

previous school district in full on the first day of class of the new school year.

Language would be added to state that if the student's eligibility for special education and related services cannot be verified before the start of the new school year, then the timelines for a student who transfers during the school year from an in-state or out-of-state district will be applicable to the location of the student's previous district.

Language would be revised to state that if the new district wishes to convene an ARD meeting to consider revision to the student's IEP before the beginning of the school year, the new district must determine whether the parents will agree to waive the five-school-day notice. If the parents agree, the new district must make every reasonable effort to hold the ARD meeting prior to the first day of the new school year. Verification means the new district has received a copy of the student's IEP that was in effect in the previous district.

Language would be revised to state if an ARD committee determines that a private or home school student three or four years of age is eligible for special education and related services, the parent may enroll the student in public school, "dual enroll" the student, or decline to have the student enroll in public school.

Language would be revised to state that if an ARD committee determines that a private or home school student 5 through 21 years of age is eligible for special education and related services, the parent may enroll the student full time in public school.

Language would be revised to state that to be placed in the special education homebound instructional setting with a code 0, the student must have a medical or psychological condition that is documented by a physician licensed to practice in the United States.

Language would be revised to state that the teacher serving a student ("homebound teacher") while the student is in the special education homebound setting must be a certified special education teacher.

Language would be revised to state that TEA will phase out references to Program for Children with Disabilities (PPCD) in this and other TEA publications beginning with the 2024-2025 school year. Instead, children aged three through five who qualify for special education and related services will receive services through ECSE.

Language would be revised to state that to receive ECSE services, a child aged three through five years must meet the same eligibility requirements as other students receiving special education services.

Language would be revised to state that a student who is not eligible for free pre-K may be served in the pre-K classroom if the ARD committee determines that this is the appropriate setting based on the student's IEP.

Language would be revised in the coding chart to include eligibility and ineligibility for free pre-K.

Language would be revised in the coding chart for ESCE services to state that an eligible student must be provided special education services beginning on the third birthday of the student.

Language would be revised to state that if an ARD committee determines that a private or home school student aged three or four years is eligible for special education and related services, the parent may enroll the student only in the public school, "dual enroll" the student, or decline to have the student enroll in public school.

Language was revised to state that only a district that operates an early childhood intervention (ECI) program through a contract with the Texas Health and Human Services Commission may code an infant with this instructional setting code.

Language would be revised to state that the Texas Health and Human Services Commission will operate an ECI program that provides early intervention services for infants through age two and code an infant with an ECI instruction setting code.

Language was revised to state that a district will be funded for any extended school year services it provides for students receiving special education services beyond the regular school year during a period such as winter, spring, or summer break.

Language would be revised to state that the federal term "highly qualified teacher status" no longer applies.

Language would be revised in examples relating to students who receive special education and related services and medical or psychological conditions that prevent the student from attending school.

Language would be revised to state that a four-year-old student with a disability who is eligible for the free pre-K program and ECSE services receives special education and related services, including speech therapy, in the pre-K classroom for three hours five days a week.

Language would be revised to state that a student on an elementary campus spends 145 minutes out of 300 instructional minutes in the special education classroom and receives 30 minutes a week (an average of six minutes/day) of speech (or any related service).

Language would be revised in an example to include students receiving special education services.

Language would be revised in an example relating to speech therapy Indicator Code 1 to state that the student is ineligible for free pre-K but is eligible for the special education services the student receives.

Language referring to an example on excess contact hours would be revised to state that a student attends six career and technical education (CTE) classes that have been determined to meet CTE code V1 (see 5.5 CTE (Contact Hour) Codes) and speech therapy (0.25 contact hour multiplier) for a total of 6.25 contact hours a day.

Language referring to the calculation of excess contact hours example would be deleted.

Section 5, Career and Technical Education (CTE)

TEC, Chapter 48, including §48.106, authorizes funding for CTE in certain circumstances. TEC, Chapter 29, Subchapter F, establishes general parameters for CTE programs. TEC, §48.004, authorizes the commissioner to require reports as may be necessary to implement and administer the FSP. The following changes would implement reporting for CTE to account for attendance and funding.

Language would be revised to state that campuses report the students enrolled on the TEA-designated Pathways in Technology Early College High School (P-TECH) campus in TSDS PEIMS submissions 1 and 3 using the data element P-TECH-INDICATOR-CODE (E1612). Campuses report the

students enrolled on New Tech Network campus in TSDS PEIMS submissions 1 and 3 using the data element NEW-TECH-INDICATOR-CODE (E1647).

Language would be revised to state that appropriate staff members need to review students' schedules as courses are added or dropped in the enrollment of CTE courses.

Language would be revised to state that a student enrolled in a CTE course should be reported on the TSDS PEIMS 42401 Special Programs Reporting Period Attendance Extension with the CTE SERVICE-ID and the eligible days.

Language would be revised to state that to receive CTE weighted funding, course periods are required to be a minimum of 45 minutes in length. Three contact hours (V3) is the maximum an LEA may claim for a single course.

Language would be revised to state that a student who is auditing a CTE course and taking no other CTE courses for credit should not have CTE eligible days present on the 42401 Special Programs Reporting Period Attendance Extension.

Language would be revised to state that to receive CTE weighted funding, course periods are required to average a minimum of 45 minutes in length.

Language would be revised to state that when computing the Campus Summary Report (2.3.2 Campus Summary Reports), LEA personnel must determine the CTE V-code to assign to a student's CTE course separately based on the CTE course's average minutes per eligible school day.

Language would be revised to state that eligible CTE days are the number of student instructional days in an LEA's calendar. The number of eligible CTE days varies among districts.

Language would be revised to state that class periods are required to be a minimum of 45 minutes in length.

Language would be revised to state that practicum courses and other two-credit or three-credit courses may be used as laboratory-based, paid, or unpaid work experience for students. Class periods are required to be a minimum of 45 minutes in length.

Language would be added to state that class periods are required to be a minimum of 45 minutes in length.

Language would be revised to state that for students who do not complete the course, the LEA will still receive contact hours for the days the student was enrolled and present. The LEA should report the 42410 Special Programs Reporting Period Attendance Extension with eligible days present for the time the student was in the course.

Language in examples citing different situations would be revised to show the CTE course service-ID with a note to refer to the table on CTE (contact hour) codes for average CTE minutes per day.

Section 6, Bilingual/English as a Second Language (ESL)

TEC, Chapter 48, specifically §48.105, authorizes funding for bilingual or special language programs in certain circumstances. TEC, Chapter 29, Subchapter B, establishes general parameters for bilingual and special language programs. TEC, §48.004, authorizes the commissioner to require reports as may be necessary to implement and administer the FSP. The following changes would implement reporting for bilingual and special language programs to account for attendance and funding.

Language would be revised to state that if students are served by multiple programs, the provisions of each applicable program should be reviewed and applied.

Language would be revised to state that in PEIMS, the terms "emergent bilingual (EB)" and "English learner (EL)" are bridged as EB/EL.

Language would be revised to state that the term "district" includes all school districts, public open-enrollment charter schools, and districts of innovation.

Language would be revised to state that a student will be identified as EB if the student is not English proficient or the student's disabilities are so severe that the English language proficiency assessment cannot be administered.

Language would be revised to state that the district personnel must not assign the student a bilingual or English as a second language (ESL) program type code in the attendance accounting system until parental consent is received.

Language would be revised to state that the language proficiency assessment committee (LPAC) convenes to analyze the student records from the sending district, determine whether the student was previously identified as EB, recommend continuation of program services, as appropriate, and ensure that documented parental approval for current program participation has been obtained.

Language referring to the heading of a section would be revised to read Initial Program Placement/Eligibility.

Language would be revised to state that EB students and non-EB students participating in a dual language immersion one-way and served through an alternative language program do not generate the additional 0.05 weighted funding.

Language would be revised to state that funding is generated when a student is identified as an EB student and is being served in a bilingual or ESL program with parental approval.

Language in the chart showing teacher certification requirements would be revised to include the term bilingual education.

Language would be revised to note that EB students served through an alternative language program do generate bilingual education allotment funds at the basic allotment for EB students (0.1).

Language would be revised to state that district personnel, while reporting eligible days present, must identify each student who is participating in a bilingual education program, an ESL program, or an alternative language program (ALP) and who is eligible for funding with the appropriate bilingual, ESL, or ALP type code in the attendance accounting system.

Language would be revised to state that the Emergent Bilingual Student Reclassification Criteria Chart can be located on the TEA Bilingual and English as a Second Language Education Programs web page.

Language would be revised to state that, in alignment with the goals of dual language immersion programs, the LPAC will likely recommend that the English proficient student continue in the dual language immersion program with parental approval.

Language would be revised to state that the EB indicator codes of F and S are used to reflect the first and second years of monitoring.

Language relating to the footnote would be revised to show that to find the appropriate code to use, district personnel should consult the program type code tables available at https://www.texasstudentdatasystem.org/TSDS/TEDS/Texas_Education_Data_Standards, then search for the C175 code table for bilingual program type codes and the C176 code table for ESL program type codes.

Language would be revised to note that the LPAC records retention schedule is cessation of services (ending at reclassification) plus five years (including the two years of monitoring).

Section 7, Prekindergarten (Pre-K)

TEC, Chapter 29, Subchapter E, establishes special general parameters for pre-K programs. TEC, Chapter 48, including §48.005, establishes ADA requirements and authorizes funding for certain circumstances. TEC, §48.004, authorizes the commissioner to require reports that may be necessary to implement and administer the FSP. The following changes would implement reporting for prekindergarten to account for attendance and funding.

Language would be revised to include the term home language survey (HLS). The HLS is administered in English and the home language. For students of other language groups, the HLS is translated into the home language whenever possible.

Language would be revised to state that a child who is considered a migratory child is automatically eligible for pre-K based on being educationally disadvantaged.

Language would be added to state that a student is eligible on the basis of homelessness if the district's local McKinney-Vento liaison identifies the student as homeless, regardless of the residence of the child, of either parent of the child, or of the child's guardian or other person having lawful control of the child.

Section 9, Pregnancy-Related Services (PRS)

TEC, Chapter 48, including §48.104, authorizes funding for students who are pregnant under certain circumstances. TEC, §48.004, authorizes the commissioner to adopt reports that may be necessary to implement and administer the FSP. The following changes would implement reporting for pregnancy-related services (PRS) to account for attendance and funding.

Language would be revised to note that students may also be eligible for Section 504 services (regardless of the LEA having a PRS program) due to a suspected disability relating to pregnancy such as having gestational diabetes.

Language would be revised that for a baby recovery period, a note from a medical practitioner stating the infant's need for hospital confinement is needed.

Language would be revised to state that the time spent on campus receiving temporary, limited support services or taking required state assessments must not count as any part of the number of hours served as compensatory education home instruction (CEHI) for eligible days present.

Language would be revised to state that if a district has a PRS program, it must provide access to the services offered through the PRS program to students who already receive special education and related services and who become pregnant.

Language would be revised to state that a pregnant student's ARD committee must meet as necessary to address any changes in the student's needs, and a student receiving special education services who qualifies for PRS may also receive homebound instruction on campus if the district has an approved on-campus instruction waiver. A certified teacher, nurse, counselor, or social worker must provide the additional hours of PRS support services for a student who receives special education services.

Language would be revised to state that a student being administered standardized, six-weeks, semester, or final exams or required state assessments while at home is limited to earning one day present for a minimum of one hour or more of testing in one calendar day.

Language would be revised to show that a student receiving CEHI who returns to her campus to take required state assessments may need to have a medical release from a licensed medical practitioner. Language would also state that more information is provided in Section 9.11, Returning to Campus for Support Services or Testing.

Language would be revised to state that when the break-in-service option is used, documentation by a licensed medical professional stating that the infant needs to remain in the hospital and information collected by campus officials is required.

Language would be revised to state that when a student who receives special education services is served through the PRS program, both PRS and special education documentation is required.

Language would be revised to state that when serving a student who receives special education services, the district is not required to maintain the special education and PRS records in the same file.

Language in an example would be revised to include students who receive special education services.

Section 10, Audit Requirements

TEC, Chapter 48, specifically §48.270, establishes the requirements for violation of presenting reports that contain false information. TEC, §48.004, authorizes the commissioner to adopt reports that may be necessary to implement and administer the FSP. TEC, §44.010, allows for the review of budget, fiscal, and audit reports to determine whether all legal requirements have been met. The following changes would implement reporting for audit requirements to account for attendance and funding.

Language would be revised to state that regardless of the setting in which a student is served, the student's attendance must be reported according to the traditional rules of the standardized attendance accounting system required by the TEDS.

Language would be revised to state that the TEDS must be referred to for information on how a district should handle disciplinary removals and report disciplinary-removal information.

Language would be added to note that a partial day of out-of-school suspension is counted as a full day when reported in TSDS PEIMS.

Section 11, Nontraditional Programs

TEC, Chapter 29, Subchapter A, establishes special general parameters for nontraditional programs. TEC, Chapter 48, including §48.005, establishes ADA requirements and authorizes funding for certain circumstances. TEC, §48.004, authorizes the commissioner to require reports that may be necessary to implement and administer the FSP. The following changes would implement reporting for nontraditional programs to account for attendance and funding.

Language from the college credit program table referring to the ECHS row and other considerations column would be deleted.

Language would be revised to state that a public junior college, college, or university may offer a course in which a high school student may enroll and for which the student may receive both high school and college credit.

Language would be revised to note that TAC rules for ECHS and P-TECH programs prohibit requiring a student enrolled in an ECHS course for high school graduation credit to pay for tuition, fees, or required textbooks.

Language would be revised to state the student eligibility requirements specific to academic dual credit courses for high school students.

Language would be revised to state that a high school student is eligible to enroll in a dual credit course if he or she demonstrates college readiness by achieving the minimum passing standards and is exempt under the provisions of the Texas Success Initiative.

Language stated in the table on student eligibility for dual credit courses would be deleted.

Language would be revised to show the footnote referring to 19 TAC §4.85.

Language related to minimum passing standards would be revised in the table on student eligibility for dual credit courses to demonstrate dual credit eligibility.

Language would be revised to state that a high school student is eligible to enroll in workforce education dual credit courses contained in a postsecondary Level 1 certificate program or a program leading to a credential of less than a Level 1 certificate at a public junior college or public technical institute and is not required to provide demonstration of college readiness or dual credit enrollment eligibility.

Language would be revised to state that a high school student is eligible to enroll in workforce education dual credit courses contained in a postsecondary Level 2 certificate or applied associate degree program under the conditions stated in 19 TAC §4.85.

Language would be revised to state that a student enrolled in a TEA-designated ECHS or P-TECH program may enroll in dual credit courses if the student demonstrates college readiness by achieving the minimum passing standard(s) on a qualifying assessment instrument or has demonstrated dual credit eligibility.

Language would be revised to state that beginning in the 2023-2024 school year, participating campuses are eligible for up to five days of Additional Days School Year (ADSY) waivers for missed instructional days throughout the year due to weather, health, or safety reasons. LEAs that wish to request one or more ADSY waiver days must submit that request through the TEA waiver system under the ADSY waiver. If an LEA applies for and receives a missed school day waiver, the day(s) will count toward the 180-day total.

Language would be revised to state that each campus participating in ADSY must indicate their intent in the TSDS PEIMS Summer submission (due in June) along with their calendar reporting to ensure the campus meets the 180-day requirement.

Language would be revised to state that a child of a military family who moves to a district from another member state and satisfactorily completed a particular grade level in a public school in the sending state is entitled to enroll in the next highest grade level.

Section 12, Virtual, Remote, and Electronic Instruction

TEC, Chapter 30A, establishes the general parameters for the Texas Virtual School Network (TXVSN). TEC, §30A.153, authorizes funding for the TXVSN for the FSP under certain circumstances. TEC, §48.004, authorizes the commissioner to adopt reports that may be necessary to implement and administer the FSP. The following changes would implement reporting for the TXVSN to account for attendance and funding.

Language would be revised in the additional TXVSN requirements and information to state that a student is not entitled to any rights, privileges, activities, or services available to a student enrolled in a public school, other than the right to receive the appropriate unit of credit for completing an electronic course.

Language would be revised in an example to state that a student who is scheduled for and receiving instruction in traditional classes for 55 minutes each day and is enrolled in two TXVSN courses for Grades 9-12 is reported with an ADA eligibility code of 2.

Language would be revised to state that to meet a requirement of remote conferencing, a student is unable to attend school because of a temporary medical or psychological condition.

Language would be revised to state that to meet a requirement of remote conferencing, a student's temporary medical or psychological condition is documented by a physician licensed to practice in the United States.

Language would be revised to state that a waiver request must be submitted for an extension of remote conferencing beyond the allowable cumulative 20 instructional day period if the documented temporary medical or psychological condition persists.

Language would be revised to state that if the school district provides instruction through remote conferencing to a student who is eligible for special education and related services for all or part of the school day, the district may count that instruction as classroom time for FSP funding purposes, including in the calculation of contact hours.

Language would be revised to state that if a remote conferencing waiver is approved, funding for days extended beyond the 20 days may be retroactively claimed beginning on the 21st day, and proof of an approved waiver must be available for audit for students receiving special education and related services.

Language would be revised to state that if the waiver is granted, funding may be claimed beginning on the date remote homebound services began for regular education students. These waivers will only be granted in extremely severe medical or psychological circumstances, and a waiver must be submitted for each individual student.

Language would be revised to state that if the waiver is approved, funding may be claimed beginning on the date the ARD committee determined that remote homebound services began for students receiving special education and related services. These waivers will only be granted in extremely severe medical or psychological circumstances, and a waiver must be submitted for each individual student.

Note: Section 12.6, Virtual Instruction (Local Remote Learning Programs under the TEC, §29.9091, or as Modified by the TEC,

§48.007(c)) is subject to revision or even removal depending on legislative actions taken by the 88th Texas Legislature, 2023.

Section 13, Appendix: Average Daily Attendance (ADA) and Funding

Language would be revised to state that days in attendance are the total number of days that a student was in attendance (present at the designated attendance-taking time or absent for a purpose described by 19 TAC §129.1025) during a specific period (for example, a 180-day school year) while that student was eligible to generate funding (in membership).

Language would be revised to state that a student who receives special education and related services is assigned one of 12 special education instructional settings, each with a varying weight (from 1.15 to 5.0) that is based on the duration of the daily service provided and the location of the instruction.

Language would be revised to state that each CTE course must be reviewed separately to determine the average minutes per day students attend that course. To receive CTE weighted funding, course periods are required to be a minimum of 45 minutes in length for a total of 8,100 minutes per school year. Three contact hours is the maximum an LEA may claim for a single course.

Glossary

Language would be revised to note that career cluster refers to one of the 14 career clusters around which CTE programs of study are organized.

Language would be revised to state that center-based instruction is a setting code for a student who is provided early intervention services though the ECI program operated through the Texas Health and Human Services Commission.

Language would be revised to state that an English proficient student is a student who was previously identified as an EB student, has met reclassification criteria, and is no longer identified as an EB student.

Language would be revised to state that GEH students must be confined for medical or psychological reasons only and be expected to be confined for a minimum of four weeks (which need not be consecutive).

Language would be revised to state that home-based instruction is the setting for providing early intervention services through ECI programs operated through the Texas Health and Human Services Commission in the home of the client.

Language would be added to state that a migratory child is a child or youth who made a qualifying move in the preceding 36 months. Qualifying moves are stated as a migratory agricultural worker or a migratory fisher or with, or to join, a parent or spouse who is a migratory agricultural worker or a migratory fisher.

Language would be revised to state that the original entry date refers to the initial date that a student is physically present at the official attendance time.

Language would be revised to state that the reentry date refers to the initial date a student physically returns and is counted present at the official attendance time after a prior withdrawal. The reentry date applies to both regular school and special programs.

FISCAL IMPACT: James Terry, associate commissioner for school finance, has determined that for the first five-year period the proposal is in effect, there are no additional costs to state or local government, including school districts and open-enrollment charter schools, required to comply with the proposal.

LOCAL EMPLOYMENT IMPACT: The proposal has no effect on local economy; therefore, no local employment impact statement is required under Texas Government Code, §2001.022.

SMALL BUSINESS, MICROBUSINESS, AND RURAL COMMUNITY IMPACT: The proposal has no direct adverse economic impact for small businesses, microbusinesses, or rural communities; therefore, no regulatory flexibility analysis, specified in Texas Government Code, §2006.002, is required.

COST INCREASE TO REGULATED PERSONS: The proposal does not impose a cost on regulated persons, another state agency, a special district, or a local government and, therefore, is not subject to Texas Government Code, §2001.0045.

TAKINGS IMPACT ASSESSMENT: The proposal does not impose a burden on private real property and, therefore, does not constitute a taking under Texas Government Code, §2007.043.

GOVERNMENT GROWTH IMPACT: TEA staff prepared a Government Growth Impact Statement assessment for this proposed rulemaking. During the first five years the proposed rulemaking would be in effect, it would expand and limit an existing regulation. The proposed changes to the *2023-2024 Student Attendance Accounting Handbook* would amend requirements and provide clarity regarding student attendance accounting procedures. In some instances, the proposed changes would add information, and in some instances, information would be removed.

The proposed rulemaking would not create or eliminate a government program; would not require the creation of new employee positions or elimination of existing employee positions; would not require an increase or decrease in future legislative appropriations to the agency; would not require an increase or decrease in fees paid to the agency; would not create a new regulation; would not repeal an existing regulation; would not increase or decrease the number of individuals subject to its applicability; and would not positively or adversely affect the state's economy.

PUBLIC BENEFIT AND COST TO PERSONS: Mr. Terry has determined that for each year of the first five years the proposal is in effect, the public benefit anticipated as a result of enforcing the proposal would be continuing to inform the public of the existence of annual publications specifying attendance accounting procedures for school districts and charter schools. There is no anticipated economic cost to persons who are required to comply with the proposal

DATA AND REPORTING IMPACT: The proposal would have no data and reporting impact.

PRINCIPAL AND CLASSROOM TEACHER PAPERWORK REQUIREMENTS: TEA has determined that the proposal would not require a written report or other paperwork to be completed by a principal or classroom teacher.

PUBLIC COMMENTS: The public comment period on the proposal begins June 16, 2023, and ends July 17, 2023. A request for a public hearing on the proposal submitted under the Administrative Procedure Act must be received by the commissioner of education not more than 14 calendar days after notice of the proposal has been published in the *Texas Register* on June 16, 2023. A form for submitting public comments is available on the TEA website

at https://tea.texas.gov/About_TEA/Laws_and_Rules/Commissioner_Rules_(TAC)/Proposed_Commissioner_of_Education_Rules/.

STATUTORY AUTHORITY. The amendment is proposed under Texas Education Code (TEC), §7.055(b)(35), which states that the commissioner shall perform duties in connection with the Foundation School Program (FSP) as prescribed by the TEC, Chapter 48; TEC, §25.081, which states that for each school year, each school district must operate so that the district provides for at least 75,600 minutes, including time allocated for instruction, intermissions, and recesses, for students. TEC, §25.081(d), authorizes the commissioner to adopt rules to implement the section. TEC, §25.081(g), states that a school district may not provide student instruction on Memorial Day but that if a school district would be required to provide student instruction on Memorial Day to compensate for minutes of instruction lost because of school closures caused by disaster, flood, extreme weather conditions, fuel curtailment, or another calamity, the commissioner shall approve the instruction of students for fewer than the number of minutes required under TEC, §25.081(a); TEC, §25.0812, which states that school districts may not schedule the last day of school for students before May 15; TEC, §25.087, which provides purposes for which a school district shall excuse a student from attending school; TEC, §29.0822, which enables a school district to provide a program under this section that meets the needs of students described by TEC, §29.0822(a), for a school district that meets application requirements, including allowing a student to enroll in a dropout recovery program in which courses are conducted online. TEC, §29.0822, authorizes the commissioner to adopt rules for the administration of the section; TEC, §30A.153, which states that, subject to the limitation imposed under the TEC, §30A.153(a-1), a school district or open-enrollment charter school in which a student is enrolled is entitled to funding under the TEC, Chapter 48, or in accordance with the terms of a charter granted under the TEC, §12.101, for the student's enrollment in an electronic course offered through the state virtual school network in the same manner that the district or school is entitled to funding for the student's enrollment in courses provided in a traditional classroom setting, provided that the student successfully completes the electronic course. TEC, §30A.153(d), authorizes the commissioner to adopt rules necessary to implement the section, including rules regarding student attendance accounting; TEC, §48.004, which states that the commissioner shall adopt rules, take action, and require reports consistent with the TEC, Chapter 48, as necessary to implement and administer the FSP; TEC, §48.005, which states that average daily attendance (ADA) is the quotient of the sum of attendance for each day of the minimum number of days of instruction as described under the TEC, §25.081(a), divided by the minimum number of days of instruction. TEC, §48.005(m), authorizes the commissioner to adopt rules necessary to implement the section. Subsections (m-1) and (m-2) address virtual or remote instruction-related funding; TEC, §48.102, which states that for each student in average daily attendance in a special education program under the TEC, Chapter 29, Subchapter A, in a mainstream instructional arrangement, a school district is entitled to an annual allotment equal to the adjusted basic allotment multiplied by 1.15. For each full-time equivalent student in average daily attendance in a special education program under the TEC, Chapter 29, Subchapter A, in an instructional arrangement other than a mainstream instructional arrangement, a district is entitled to an annual allotment equal to the adjusted basic allotment multiplied by a weight determined according to its instructional arrangement; TEC, §48.103, which states that for each student that a district serves who has been identified as having dyslexia or a related disorder, the district is entitled to an annual allotment equal to the basic allotment multiplied by 0.1 or a greater amount provided by appropriation; TEC, §48.104, which states that for each student who does not have a disability and resides in a residential placement facility in a district in which the student's parent or legal guardian does not reside, a district is entitled to an annual allotment equal to the basic allotment multiplied by 0.2 or, if the student is educationally disadvantaged, 0.275. For each full-time equivalent student who is in a remedial and support program under TEC, §29.081, because the student is pregnant, a district is entitled to an annual allotment equal to the basic allotment multiplied 2.41; TEC, §48.105, which states that for each student in average daily attendance in a bilingual education or special language program under the TEC, Chapter 29, Subchapter B, a district is entitled to an annual allotment equal to the adjusted basic allotment multiplied by 0.1 or 0.15 if the student is in a bilingual education program using a dual language immersion/one-way or two-way program model, and for students not described in subdivision (1), 0.05 if the student is in bilingual education program using a dual language immersion/two-way program model; TEC, §48.106, which states that for each full-time equivalent student in average daily attendance in an approved career and technology education program in Grades 7-12 or in career and technology education programs, a district is entitled to an annual allotment equal to the basic allotment multiplied by a weight of 1.35 and $50 for each student that is enrolled in two or more advanced career and technology classes for a total of three or more credits; a campus designated as a Pathways in Technology Early College High School (P-TECH) school under TEC, §29.556; or a campus that is a member of the New Tech Network (NTN) and that focuses on project-based learning and work-based education; and TEC, §48.108, which states that for each student in average daily attendance in Kindergarten-Grade 3, a district is entitled to an annual allotment equal to the basic allotment multiplied by 0.1 if the student is educationally disadvantaged or a student of limited English proficiency, as defined by TEC, §29.052, and in bilingual education or special language program under TEC, Chapter 29, Subchapter B

CROSS REFERENCE TO STATUTE. The amendment implements Texas Education Code, §§7.055(b)(35), 25.081, 25.0812, 25.087, 29.0822, 30A.153, 48.004, 48.005, 48.102, 48.103, 48.104, 48.105, 48.106, and 48.108.

§129.1025. Adoption by Reference: Student Attendance Accounting Handbook.

(a) The student attendance accounting guidelines and procedures established by the commissioner of education under §129.21 of this title (relating to Requirements for Student Attendance Accounting for State Funding Purposes) and the Texas Education Code, §48.004, to be used by school districts and charter schools to maintain records and make reports on student attendance and student participation in special programs will be published annually.

(b) The standard procedures that school districts and charter schools must use to maintain records and make reports on student attendance and student participation in special programs for school year 2023-2024 [~~2022-2023~~] are described in the official Texas Education Agency (TEA) publication 2023-2024 [~~2022-2023~~] Student Attendance Accounting Handbook[~~, dated September 2022~~], which is adopted by this reference as the agency's official rule. A copy of the 2023-2024 [~~2022-2023~~] Student Attendance Accounting Handbook[~~, dated September 2022,~~] is available on the TEA website with informa-

tion related to financial compliance. The commissioner will amend the 2023-2024 [~~2022-2023~~] Student Attendance Accounting Handbook[~~, dated September 2022,~~] and this subsection adopting it by reference, as needed.

(c) Data from previous school years will continue to be subject to the student attendance accounting handbook as the handbook existed in those years.

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

Filed with the Office of the Secretary of State on June 5, 2023.

TRD-202302062
Cristina De La Fuente-Valadez
Director, Rulemaking
Texas Education Agency
Earliest possible date of adoption: July 16, 2023
For further information, please call: (512) 475-1497

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TITLE 22. EXAMINING BOARDS

PART 6. TEXAS BOARD OF PROFESSIONAL ENGINEERS AND LAND SURVEYORS

CHAPTER 134. LICENSING, REGISTRATION, AND CERTIFICATION FOR SURVEYORS

The Texas Board of Professional Engineers and Land Surveyors (Board) proposes amendments to 22 Texas Administrative Code, Chapter 134, regarding the licensing of registered professional land surveyors, and specifically §134.23, relating to Applications From Standard Registration Holders, and §134.101, relating to Proposed Actions on Applications. These proposed changes are referred to as "proposed rules."

BACKGROUND AND SUMMARY

The rules under 22 Texas Administrative Code, Chapter 134 implement Texas Occupations Code, Chapter 1001, the Texas Engineering Practice Act and Texas Occupations Code Chapter 1071, the Professional Land Surveying Practices Act. The proposed rules address the Board's ability to consider previous enforcement actions should a previous registration holder reapply for a new registration and they update an incorrect rule reference.

SECTION-BY-SECTION SUMMARY

The proposed rules amend §134.23 to clearly state that the Board may consider previous enforcement actions against a previous registration holder who allowed his or her registration to expire and become non-renewable if and when that registration holder reapplies for a new registration. In addition the title of §134.23 is being amended to make clear this rule applies to former registration holders. Identical amendments were adopted in July 2022, but were inadvertently repealed as part of a separate rule package that became effective in March 2023. The amendments restore the changes that were originally adopted in July 2022.

The proposed rules also amend §134.101 to correct an erroneous statutory citation.

FISCAL IMPACT ON STATE AND LOCAL GOVERNMENT

Mr. Michael Sims, P.E., Director of Compliance and Enforcement for the Board, has determined that for each year of the first five years the proposed rules are in effect, there are no estimated additional costs or reductions in costs to state or local government as a result of enforcing or administering the proposed rule.

Mr. Sims has determined that for each year of the first five years the proposed rules are in effect, there is no estimated increase or loss in revenue to the state or local government as a result of enforcing or administering the proposed rule.

LOCAL EMPLOYMENT IMPACT STATEMENT

Mr. Sims has determined that the proposed rules will not affect the local economy, so the agency is not required to prepare a local employment impact statement under Government Code §2001.022.

PUBLIC BENEFITS

Mr. Sims has determined that for each year of the first five-year period the proposed rules are in effect, the public benefit will be clarification of rules, removing unneeded procedural steps for applicants, and improved efficiency of Board operations.

PROBABLE ECONOMIC COSTS TO PERSONS REQUIRED TO COMPLY WITH PROPOSAL

Mr. Sims has determined that for each year of the first five-year period the proposed rules are in effect, there are no anticipated economic costs to persons who are required to comply with the proposed rules because no new requirements are part of the proposed rules.

FISCAL IMPACT ON SMALL BUSINESSES, MICRO-BUSINESSES, AND RURAL COMMUNITIES

There will be no adverse effect on small businesses, micro-businesses, or rural communities as a result of the proposed rules. Since the agency has determined that the proposed rules will have no adverse economic effect on small businesses, micro-businesses, or rural communities, preparation of an Economic Impact Statement and a Regulatory Flexibility Analysis, as detailed under Texas Government Code §2006.002, is not required.

ONE-FOR-ONE REQUIREMENT FOR RULES WITH A FISCAL IMPACT

The proposed rules are not subject to the requirements of Government Code §2001.0045 because the Board is a self-directed, semi-independent agency. Additionally, the proposed rules do not impose a cost on regulated persons, including another state agency, a special district, or a local government. Therefore, the agency is not required to take any further action under Government Code §2001.0045.

GOVERNMENT GROWTH IMPACT STATEMENT

Pursuant to Government Code §2001.0221, the agency provides the following Government Growth Impact Statement for the proposed rules. For each year of the first five years the proposed rules are in effect, the agency has determined the following:

1. The proposed rules do not create or eliminate a government program.

2. Implementation of the proposed rules do not require the creation of new employee positions or the elimination of existing employee positions.

3. Implementation of the proposed rules do not require an increase or decrease in future legislative appropriations to the agency.

4. The proposed rules do not require an increase or decrease in fees paid to the agency.

5. The proposed rules do not create a new regulation.

6. The proposed rule does not expand an existing regulation but does remove the requirement that new licensees submit a copy of their seal to the board.

7. The proposed rules do not increase the number of individuals subject to the rule's applicability.

8. The proposed rules do not positively or adversely affect this state's economy.

TAKINGS IMPACT ASSESSMENT

The Board has determined that no private real property interests are affected by the proposed rules and the proposed rules do not restrict, limit, or impose a burden on an owner's rights to his or her private real property that would otherwise exist in the absence of government action. As a result, the proposed rules do not constitute a taking or require a takings impact assessment under Government Code §2007.043.

ENVIRONMENTAL RULE ANALYSIS

The Board has determined that the proposed rules are not brought with the specific intent to protect the environment or reduce risks to human health from environmental exposure; thus, the Board asserts the proposed rules are not a "major environmental rule," as defined by Government Code §2001.0225. As a result, the Board asserts preparation of an environmental impact analysis, as provided by §2001.0225, is not required.

PUBLIC COMMENTS

Any comments or request for a public hearing may be submitted, no later than 30 days after the publication of this notice, to Lance Kinney, Ph.D., P.E., Executive Director, Texas Board of Professional Engineers and Land Surveyors, via email to rules@pels.texas.gov; via mail to 1917 S. Interstate 35, Austin, Texas 78741, or faxed to his attention at (512) 440-0417.

SUBCHAPTER C. LAND SURVEYOR APPLICATION REQUIREMENTS

22 TAC §134.23

STATUTORY AUTHORITY

The proposed rule is proposed pursuant to Texas Occupations Code §§1001.201 and 1001.202, which authorize the Board to regulate engineering and land surveying and make and enforce all rules and regulations and bylaws consistent with the Texas Engineering Practice Act and the Professional Land Surveying Practices as necessary for the performance of its duties, the governance of its own proceedings, and the regulation of the practices of engineering and land surveying in this state.

SECTIONS AFFECTED

The proposed rule implements the following sections of the law: Texas Occupations Code §§1071.251 - 1071.262.

§134.23. Application from Former Standard Registration Holders.

(a) - (e) (No change.)

(f) Any enforcement action taken against an expired registration or license holder in accordance with §139.31 of this title (relating to Enforcement Actions for Violations of the Act or Board Rules) or pending enforcement action at which time the registration or license became expired for two or more years may be considered in the evaluation of an application for a new registration or license.

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

Filed with the Office of the Secretary of State on June 1, 2023.

TRD-202302025
Lance Kinney
Executive Director
Texas Board of Professional Engineers and Land Surveyors
Earliest possible date of adoption: July 16, 2023
For further information, please call: (512) 440-7723

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SUBCHAPTER H. REVIEW PROCESS OF APPLICATIONS AND REGISTRATION ISSUANCE

22 TAC §134.101

STATUTORY AUTHORITY

The proposed rule is proposed pursuant to Texas Occupations Code §§1001.201 and 1001.202, which authorize the Board to regulate engineering and land surveying and make and enforce all rules and regulations and bylaws consistent with the Texas Engineering Practice Act and the Professional Land Surveying Practices as necessary for the performance of its duties, the governance of its own proceedings, and the regulation of the practices of engineering and land surveying in this state.

SECTIONS AFFECTED

The proposed rule implements the following sections of the law: Texas Occupations Code §§1071.251 - 1071.262.

§134.101. Proposed Actions on Applications.

The following is a table of suggested actions the board may impose against applicants for specific circumstances related to an application. The action may be less than or greater than the suggested actions shown in the following table.

Figure: 22 TAC §134.101

[~~Figure: 22 TAC §134.101~~]

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

Filed with the Office of the Secretary of State on June 1, 2023.

TRD-202302026
Lance Kinney
Executive Director
Texas Board of Professional Engineers and Land Surveyors
Earliest possible date of adoption: July 16, 2023
For further information, please call: (512) 440-7723

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PART 15. TEXAS STATE BOARD OF PHARMACY

CHAPTER 283. LICENSING REQUIREMENTS FOR PHARMACISTS

22 TAC §283.4

The Texas State Board of Pharmacy proposes amendments to §283.4, concerning Internship Requirements. The amendments, if adopted, extend the period that internship hours may be used for licensure from two years to three years from the date the internship is completed.

Julie Spier, R.Ph., President, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Ms. Spier has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be to provide clearer and more efficient requirements for pharmacist licensure. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendments will be in effect, Ms. Spier has determined the following:

(1) The proposed amendments do not create or eliminate a government program;

(2) Implementation of the proposed amendments does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed amendments does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed amendments do not require an increase or decrease in fees paid to the agency;

(5) The proposed amendments do not create a new regulation;

(6) The proposed amendments do limit an existing regulation by relaxing a requirement for licensure as a pharmacist;

(7) The proposed amendments do not increase or decrease the number of individuals subject to the rule's applicability; and

(8) The proposed amendments do not positively or adversely affect this state's economy.

Written comments on the amendments may be submitted to Eamon D. Briggs, Deputy General Counsel, Texas State Board of Pharmacy, 1801 Congress Avenue, Suite 13.100, Austin, Texas 78701-1319, FAX (512) 305-8061. Comments must be received by 5:00 p.m., July 24, 2023.

The amendments are proposed under §§551.002 and 554.051 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§283.4. Internship Requirements.

(a) Goals and competency objectives of internship.

(1) The goal of internship is for the pharmacist-intern to attain the knowledge, skills, and abilities to safely, efficiently, and effectively provide pharmacist-delivered patient care to a diverse patient population and practice pharmacy under the laws and regulations of the State of Texas.

(2) The following competency objectives are necessary to accomplish the goal of internship in paragraph (1) of this subsection:

(A) Provides drug products. The pharmacist-intern shall demonstrate competence in determining the appropriateness of prescription drug orders and medication orders; evaluating and selecting products; and assuring the accuracy of the product/prescription dispensing process.

(B) Communicates with patients and patients' agents about prescription drugs. The pharmacist-intern shall demonstrate competence in interviewing and counseling patients and patients' agents on drug usage, dosage, packaging, routes of administration, intended drug use, and storage; discussing drug cautions, adverse effects, and patient conditions; explaining policies on fees and services; relating to patients in a professional manner; and interacting to confirm patient understanding.

(C) Communicates with patients and patients' agents about nonprescription products, devices, dietary supplements, diet, nutrition, traditional nondrug therapies, complementary and alternative therapies, and diagnostic aids. The pharmacist-intern shall demonstrate competence in interviewing and counseling patients and patients' agents on conditions, intended drug use, and adverse effects; assisting in and recommending drug selection; triaging and assessing the need for treatment or referral, including referral for a patient seeking pharmacist-guided self-care; providing information on medical/surgical devices and home diagnostic products; and providing poison control treatment information and referral.

(D) Communicates with healthcare professionals, patients, and patients' agents. The pharmacist-intern shall demonstrate competence in obtaining and providing accurate and concise information in a professional manner and using appropriate oral, written, and nonverbal language.

(E) Practices as a member of the patient's interdisciplinary healthcare team. The pharmacist-intern shall demonstrate competence in collaborating with physicians, other healthcare professionals, patients, and patients' agents to formulate a therapeutic plan. The pharmacist-intern shall demonstrate competence in establishing and interpreting databases, identifying drug-related problems and recommending appropriate pharmacotherapy specific to patient needs, monitoring and evaluating patient outcomes, and devising follow-up plans.

(F) Maintains professional-ethical standards. The pharmacist-intern is required to comply with laws and regulations pertaining to pharmacy practice; to apply professional judgment; to exhibit reliability and credibility in dealing with others; to deal professionally and ethically with colleagues and patients; to demonstrate sensitivity and empathy for patients/care givers; and to maintain confidentiality.

(G) Compounds. The pharmacist-intern shall demonstrate competence in using acceptable professional procedures; selecting appropriate equipment and containers; appropriately preparing compounded non-sterile and sterile preparations; and documenting calculations and procedures. Pharmacist-interns engaged in compounding non-sterile preparations shall meet the training requirements for pharmacists specified in §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations). Pharmacist-interns

engaged in compounding sterile preparations shall meet the training requirements for pharmacists specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

(H) Retrieves and evaluates drug information. The pharmacist-intern shall demonstrate competence in retrieving, evaluating, managing, and using the best available clinical and scientific publications for answering a drug-related request in a timely fashion and assessing, evaluating, and applying evidence based information to promote optimal health care. The pharmacist-intern shall perform investigations on relevant topics in order to promote inquiry and problem-solving with dissemination of findings to the healthcare community and the public.

(I) Manages general pharmacy operations. The pharmacist-intern shall develop a general understanding of planning, personnel and fiscal management, leadership skills, and policy development. The pharmacist-intern shall have an understanding of drug security, storage and control procedures and the regulatory requirements associated with these procedures, and maintaining quality assurance and performance improvement. The pharmacist-intern shall observe and document discrepancies and irregularities, keep accurate records, and document actions. The pharmacist-intern shall attend meetings requiring pharmacy representation.

(J) Participates in public health, community service, or professional activities. The pharmacist-intern shall develop basic knowledge and skills needed to become an effective healthcare educator and a responsible participant in civic and professional organizations.

(K) Demonstrates scientific inquiry. The pharmacist-intern shall develop skills to expand and refine knowledge in the areas of pharmaceutical and medical sciences or pharmaceutical services. This may include data analysis of scientific, clinical, sociological, or economic impacts of pharmaceuticals (including investigational drugs), pharmaceutical care, and patient behaviors, with dissemination of findings to the scientific community and the public.

(b) Hours requirement.

(1) The board requires the number of hours of internship required by ACPE for licensure. These hours may be obtained through one or more of the following methods:

(A) in a board-approved student internship program, as specified in subsection (c) of this section;

(B) in a board-approved extended-internship program, as specified in subsection (d) of this section;

(C) graduation from a college/school of pharmacy. Persons graduating from such programs shall be credited the number of hours obtained and reported by the college; or

(D) internship hours approved and certified to the board by another state board of pharmacy.

(2) Pharmacist-interns participating in an internship may be credited no more than 50 hours per week of internship experience.

(3) Internship hours may be used for the purpose of licensure for no longer than three [~~two~~] years from the date the internship is completed.

(c) College-/School-Based Internship Programs.

(1) Internship experience acquired by student-interns.

(A) An individual may be designated a student-intern provided he/she:

(i) submits an application to the board that includes the following information:

(I) name;

(II) addresses, phone numbers, date of birth, and social security number;

(III) college of pharmacy and expected graduation date; and

(IV) any other information requested on the application;

(ii) is enrolled in the professional sequence of a college/school of pharmacy; and

(iii) has met all requirements necessary for the board to access the criminal history records information, including submitting fingerprint information and being responsible for all associated costs.

(B) The terms of the student internship shall be as follows.

(i) The student internship shall be gained concurrent with college attendance, which may include:

(I) partial semester breaks such as spring breaks;

(II) between semester breaks; and

(III) whole semester breaks, provided the student-intern attended the college/school in the immediately preceding semester and is scheduled with the college/school to attend in the immediate subsequent semester.

(ii) The student internship shall be obtained in pharmacies licensed by the board, federal government pharmacies, or in a board-approved program.

(iii) The student internship shall be in the presence of and under the supervision of a healthcare professional preceptor or a pharmacist preceptor.

(C) None of the internship hours acquired outside of a school-based program may be substituted for any of the hours required in a college/school of pharmacy internship program.

(2) Expiration date for student-intern designation.

(A) The student-internship expires if:

(i) the student-intern voluntarily or involuntarily ceases enrollment, including suspension, in a college/school of pharmacy;

(ii) the student-intern fails more than once either the NAPLEX or Texas Pharmacy Jurisprudence Examination specified in this section; or

(iii) the student-intern fails to take either the NAPLEX or Texas Pharmacy Jurisprudence Examination or both within six calendar months after graduation.

(B) The executive director of the board, in his/her discretion, may extend the term of the student internship if administration of the NAPLEX or Texas Pharmacy Jurisprudence Examination is suspended or delayed.

(3) Texas colleges/schools of pharmacy internship programs.

(A) Student-interns completing a board-approved Texas college/school-based structured internship shall be credited the

number of hours actually obtained and reported by the college. No credit shall be awarded for didactic experience.

(B) No more than 600 hours of the required number of hours may be obtained under a healthcare professional preceptor except when a pharmacist-intern is working in a federal government pharmacy.

(d) Extended-internship program.

(1) A person may be designated an extended-intern provided he/she has met one of the following requirements:

(A) passed the NAPLEX and Texas Pharmacy Jurisprudence Examination but lacks the required number of internship hours for licensure;

(B) applied to the board to take the NAPLEX and Texas Pharmacy Jurisprudence Examination within six calendar months after graduation and has:

(i) graduated and received a professional degree from a college/school of pharmacy; or

(ii) completed all of the requirements for graduation and receipt of a professional degree from a college/school of pharmacy.

(C) applied to the board to take the NAPLEX and Texas Pharmacy Jurisprudence Examination within six calendar months after obtaining full certification from the Foreign Pharmacy Graduate Equivalency Commission;

(D) applied to the board for re-issuance of a pharmacist license which has expired for more than two years but less than ten years and has successfully passed the Texas Pharmacy Jurisprudence Examination, but lacks the required number of hours of internship or continuing education required for licensure;

(E) is a resident in a residency program in the state of Texas and has not previously failed more than once either the NAPLEX or Texas Pharmacy Jurisprudence Examination; or

(F) been ordered by the Board to complete an internship.

(2) In addition to meeting one of the requirements in paragraph (1) of this subsection, an applicant for an extended-internship must:

(A) submit an application to the board that includes the following information:

(i) name;

(ii) addresses, phone numbers, date of birth, and social security number; and

(iii) any other information requested on the application; and

(B) meet all requirements necessary for the board to access the criminal history records information, including submitting fingerprint information and being responsible for all associated costs.

(3) The terms of the extended-internship shall be as follows.

(A) The extended-internship shall be board-approved and gained in a pharmacy licensed by the board, or a federal government pharmacy participating in a board-approved internship program.

(B) The extended-internship shall be in the presence of and under the direct supervision of a pharmacist preceptor.

(4) The extended internship remains in effect for two years. However, the internship expires immediately upon:

(A) the failure of the extended-intern to take the NAPLEX and Texas Pharmacy Jurisprudence Examination within six calendar months after graduation or FPGEC certification;

(B) the extended-intern failing more than once either the NAPLEX or Texas Pharmacy Jurisprudence Examination specified in this section;

(C) termination of the residency program; or

(D) obtaining a Texas pharmacist license.

(5) The executive director of the board, in his/her discretion, may extend the term of the extended internship if administration of the NAPLEX or Texas Pharmacy Jurisprudence Examination is suspended or delayed.

(6) An applicant for licensure who has completed less than 500 hours of internship at the time of application shall complete the remainder of the required number of hours of internship and have the preceptor certify that the applicant has met the objectives listed in subsection (a) of this section.

(e) Pharmacist-intern identification.

(1) Pharmacist-interns shall keep documentation of designation as a pharmacist-intern with them at all times they are serving as a pharmacist-intern and make it available for inspection by board agents.

(2) All pharmacist-interns shall wear an identification tag or badge which bears the person's name and identifies him or her as a pharmacist-intern.

(f) Change of address or name.

(1) Change of address. A pharmacist-intern shall notify the board electronically or in writing within 10 days of a change of address, giving the old and new address.

(2) Change of name. A pharmacist-intern shall notify the board in writing within 10 days of a change of name by sending a copy of the official document reflecting the name change (e.g., marriage certificate, divorce decree).

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

Filed with the Office of the Secretary of State on May 31, 2023.

TRD-202302006
Julie Spier, R.Ph.
President
Texas State Board of Pharmacy
Earliest possible date of adoption: July 16, 2023
For further information, please call: (512) 305-8026

22 TAC §283.6

The Texas State Board of Pharmacy proposes amendments to §283.6, concerning Preceptor Requirements and Ratio of Preceptors to Pharmacist-Interns. The amendments, if adopted, remove the condition that a pharmacist preceptor must have six months of residency training if the pharmacist-intern's residency program is accredited by the American Society of Health System Pharmacists.

Julie Spier, R.Ph., President, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Ms. Spier has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be to remove an unnecessary distinction between residency programs in relation to pharmacist preceptor requirements. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendments will be in effect, Ms. Spier has determined the following:

(1) The proposed amendments do not create or eliminate a government program;

(2) Implementation of the proposed amendments does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed amendments does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed amendments do not require an increase or decrease in fees paid to the agency;

(5) The proposed amendments do not create a new regulation;

(6) The proposed amendments do expand an existing regulation by removing a condition on which residency programs implicate the regulation;

(7) The proposed amendments do not increase or decrease the number of individuals subject to the rule's applicability; and

(8) The proposed amendments do not positively or adversely affect this state's economy.

Written comments on the amendments may be submitted to Eamon D. Briggs, Deputy General Counsel, Texas State Board of Pharmacy, 1801 Congress Avenue, Suite 13.100, Austin, Texas 78701-1319, FAX (512) 305-8061. Comments must be received by 5:00 p.m., July 24, 2023.

The amendments are proposed under §§551.002 and 554.051 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§283.6. Preceptor Requirements and Ratio of Preceptors to Pharmacist-Interns.

(a) Preceptor requirements.

(1) Preceptors shall be:

(A) a pharmacist whose license to practice pharmacy in Texas is current and not on inactive status with the board; or

(B) a healthcare professional preceptor.

(2) To be recognized as a pharmacist preceptor, a pharmacist must:

(A) have at least:

(i) one year of experience as a licensed pharmacist; or

(ii) six months of residency training if the pharmacy resident is completing a residency program [~~pharmacy resident is in a program accredited by the American Society of Health-System Pharmacists~~];

(B) have completed:

(i) for initial certification, three hours of pharmacist preceptor training provided by an ACPE approved provider within the previous two years. Such training shall be:

(I) developed by a Texas college/school of pharmacy; or

(II) approved by:

(-a-) a committee comprised of the Texas college/schools of pharmacy; or

(-b-) the board; or

(ii) to continue certification, three hours of pharmacist preceptor training provided by an ACPE approved provider within the pharmacist's current license renewal period. Such training shall be:

(I) developed by a Texas college/school of pharmacy; or

(II) approved by:

(-a-) a committee comprised of the Texas college/schools of pharmacy; or

(-b-) the board; and

(C) meet the requirements of subsection (c) of this section.

(3) A pharmacist preceptor must be certified by the board.

(b) Ratio of preceptors to pharmacist-interns.

(1) A preceptor may supervise only one pharmacist-intern at any given time (1:1 ratio) except as provided in paragraph (2) of this subsection.

(2) The following is applicable to Texas college/school of pharmacy internship programs only.

(A) Supervision. Supervision of a pharmacist-intern shall be:

(i) direct supervision when the student-intern is engaged in functions associated with the preparation and delivery of prescription or medication drug orders; and

(ii) general supervision when the student-intern is engaged in functions not associated with the preparation and delivery of prescription or medication drug orders.

(B) Exceptions to the 1:1 ratio. There is no ratio requirement for preceptors supervising student-interns as a part of a Texas college/school of pharmacy program.

(c) No pharmacist may serve as a pharmacist preceptor if his or her license to practice pharmacy has been the subject of an order of the board imposing any penalty set out in §565.051 of the Act during the period he or she is serving as a pharmacist preceptor or within the three-year period immediately preceding application for approval as a pharmacist preceptor. Provided, however, a pharmacist who has been the subject of such an order of the board may petition the board, in writing, for approval to act as a pharmacist preceptor. The board may

consider the following items in approving a pharmacist's petition to act as a pharmacist preceptor:

(1) the type and gravity of the offense for which the pharmacist's license was disciplined;

(2) the length of time since the action that caused the order;

(3) the length of time the pharmacist has previously served as a preceptor;

(4) the availability of other preceptors in the area;

(5) the reason(s) the pharmacist believes he/she should serve as a preceptor;

(6) a letter of recommendation from a Texas college/school of pharmacy if the pharmacist will be serving as a pharmacist preceptor for a Texas college/school of pharmacy; and

(7) any other factor presented by the pharmacist demonstrating good cause why the pharmacist should be allowed to act as a pharmacist preceptor.

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

Filed with the Office of the Secretary of State on May 31, 2023.

TRD-202302007
Julie Spier, R.Ph.
President
Texas State Board of Pharmacy
Earliest possible date of adoption: July 16, 2023
For further information, please call: (512) 305-8026

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CHAPTER 291. PHARMACIES
SUBCHAPTER A. ALL CLASSES OF PHARMACIES

22 TAC §291.12

The Texas State Board of Pharmacy proposes a new rule §291.12, concerning Delivery of Prescription Drugs. The new rule, if adopted, specifies requirements for the delivery of prescription drugs to a patient or patient's agent.

Julie Spier, R.Ph., President, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Ms. Spier has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the proposed rule will be to improve the health, safety, and welfare of patients by ensuring the safety and efficacy of prescription drugs that are delivered to a patient or patient's agent by Class A, Class A-S, Class E, and Class E-S pharmacies. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed rule will be in effect, Ms. Spier has determined the following:

(1) The proposed rule does not create or eliminate a government program;

(2) Implementation of the proposed rule does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed rule does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed rule does not require an increase or decrease in fees paid to the agency;

(5) The proposed rule does create a new regulation concerning the delivery of prescription drugs;

(6) The proposed rule does not limit or expand an existing regulation;

(7) The proposed rule does not increase or decrease the number of individuals subject to the rule's applicability; and

(8) The proposed rule does not positively or adversely affect this state's economy.

Written comments on the proposed rule may be submitted to Eamon D. Briggs, Deputy General Counsel, Texas State Board of Pharmacy, 1801 Congress Avenue, Suite 13.100, Austin, Texas 78701-1319, FAX (512) 305-8061. Comments must be received by 5:00 p.m., July 24, 2023.

The new rule is proposed under §§551.002 and 554.051 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by the proposed rule: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§291.12. Delivery of Prescription Drugs.

(a) Applicability. This section applies to the delivery of prescription drugs by a pharmacy licensed by the board as a Class A, Class A-S, Class E, or Class E-S pharmacy.

(b) Delivery by mail. A pharmacy may deliver prescription drugs by use of a common carrier or the U.S. Mail as provided in §291.9 of this title (relating to Prescription Pick Up Locations) on request of the patient or patient's agent.

(1) Standards. The pharmacy shall ensure that all prescription drugs are delivered to the patient or patient's agent in accordance with standards of the manufacturer or the United States Pharmacopeia.

(2) Packaging. The pharmacy shall ensure that prescription drugs are packaged in tamper proof and tamper evident mailers that are resistant to tearing and moisture.

(3) Temperature. The pharmacy shall ensure the integrity of any prescription drug requiring temperature control other than "room temperature" storage as defined in §291.15 of this title (relating to Storage of Drugs) that is delivered by mail. The pharmacy shall use temperature tags, time temperature strips, insulated packaging, gel ice packs, or a combination of these as necessary.

(4) Irregularity in delivery. The pharmacy shall provide a method by which a patient or patient's agent can notify the pharmacy as to any irregularity in the delivery of the patient's prescription, to include, but not be limited to:

(A) timeliness of delivery;

(B) condition of the prescription drug upon delivery; and

(C) failure to receive the proper prescription drug.

(5) Replacement. If a prescription drug is in any way compromised during delivery, the pharmacy shall replace the drug or arrange for the drug to be replaced, either by promptly delivering a replacement to the patient or by promptly contacting the prescriber to arrange for the drug to be dispensed to the patient by a pharmacy of the patient's or patient's agent's choice.

(6) Refusal to deliver. The pharmacy shall refuse to deliver by mail a prescription drug which in the professional opinion of a pharmacist may be clinically compromised by delivery by mail.

(c) Delivery by pharmacy employee. A pharmacy may deliver prescription drugs by means of its employee as provided in §291.9 of this title on request of the patient or patient's agent.

(1) Standards. The pharmacy is responsible for any problems in the delivery of the prescription drug. The delivery shall be on a continuous route from the pharmacy to the patient or patient's agent.

(2) Temperature. The prescription drug shall be maintained within the temperature range recommended by the manufacturer until the delivery has been completed.

(d) All deliveries. A pharmacy that delivers prescription drugs by mail or by pharmacy employee shall also comply with the following:

(1) Counseling information. The pharmacy shall comply with the requirements of §291.33(c)(1)(F) of this title (relating to Operational Standards).

(2) Notification of delivery. The pharmacy shall notify the patient or patient's agent of the delivery of a prescription drug. The notification shall provide information to the patient or patient's agent about the timeliness in addressing the proper storage of the prescription drug. The pharmacy shall document and maintain a record of the notification.

(3) Required signature. The pharmacy shall require the patient or patient's agent to sign for delivery if the prescription drug is reasonably likely to be compromised if left unattended. If the drug cannot be delivered with a signature, the package may not be left unattended and shall be returned to be held for pickup or redelivered on the request of the patient or patient's agent.

(4) Compromised delivery. The pharmacy shall include with the delivery the procedures for the patient or patient's agent to follow if the prescription drug does not arrive in a timely manner or if the integrity of the packaging or prescription drug has been compromised during delivery.

(5) Records. The pharmacy shall maintain records for two years on the following events:

(A) when a prescription drug was sent to the patient or patient's agent;

(B) patient complaints and audits regarding the timeliness of deliveries;

(C) prescription drugs that were compromised in delivery; and

(D) the failure of a patient to receive a prescription drug delivery.

(6) Controlled substances. A pharmacy shall comply with all state and federal laws and rules relating to the delivery of controlled substances.

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

Filed with the Office of the Secretary of State on May 31, 2023.

TRD-202302009
Julie Spier, R.Ph.
President
Texas State Board of Pharmacy
Earliest possible date of adoption: July 16, 2023
For further information, please call: (512) 305-8026

22 TAC §291.24

The Texas State Board of Pharmacy proposes the repeal of §291.24, concerning Pharmacy Residency Programs. The proposed repeal, if adopted, removes standards for a statutory program that no longer exists.

Julie Spier, R.Ph., President, has determined that, for the first five-year period the repeal is in effect, there will be no fiscal implications for state or local government as a result of repealing the rule. Ms. Spier has determined that, for each year of the first five-year period the repeal will be in effect, the public benefit anticipated as a result of the repeal will be clearer and more concise agency regulations. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed repeal will be in effect, Ms. Spier has determined the following:

(1) The proposed repeal does not create or eliminate a government program;

(2) Implementation of the proposed repeal does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed repeal does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed repeal does not require an increase or decrease in fees paid to the agency;

(5) The proposed repeal does not create a new regulation;

(6) The proposed repeal does limit an existing regulation by eliminating requirements that are no longer necessary;

(7) The proposed repeal does decrease the number of individuals subject to the rule's applicability by eliminating the requirements of the rule; and

(8) The proposed repeal does not positively or adversely affect this state's economy.

Written comments on the proposed repeal may be submitted to Eamon D. Briggs, Deputy General Counsel, Texas State Board of Pharmacy, 1801 Congress Avenue, Suite 13.100, Austin, Texas 78701-1319, FAX (512) 305-8061. Comments must be received by 5:00 p.m., July 24, 2023.

The repeal is proposed under §§551.002 and 554.051 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency

to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by the proposed repeal: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§291.24. Pharmacy Residency Programs.

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

Filed with the Office of the Secretary of State on May 31, 2023.

TRD-202302008
Julie Spier, R.Ph.
President
Texas State Board of Pharmacy
Earliest possible date of adoption: July 16, 2023
For further information, please call: (512) 305-8026

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22 TAC §291.27

The Texas State Board of Pharmacy proposes amendments to §291.27, concerning Confidentiality. The amendments, if adopted, correct a misspelled word.

Julie Spier, R.Ph., President, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Ms. Spier has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be clear and correct regulations. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendments will be in effect, Ms. Spier has determined the following:

(1) The proposed amendments do not create or eliminate a government program;

(2) Implementation of the proposed amendments does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed amendments does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed amendments do not require an increase or decrease in fees paid to the agency;

(5) The proposed amendments do not create a new regulation;

(6) The proposed amendments do not limit or expand an existing regulation;

(7) The proposed amendments do not increase or decrease the number of individuals subject to the rule's applicability; and

(8) The proposed amendments do not positively or adversely affect this state's economy.

Written comments on the amendments may be submitted to Eamon D. Briggs, Deputy General Counsel, Texas State Board of Pharmacy, 1801 Congress Avenue, Suite 13.100, Austin, Texas 78701-1319, FAX (512) 305-8061. Comments must be received by 5:00 p.m., July 24, 2023.

The amendments are proposed under §§551.002 and 554.051 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§291.27. Confidentiality.

(a) A pharmacist shall provide adequate security of prescription drug orders, medication orders, and patient medication records to prevent indiscriminate or unauthorized access to confidential health information. If prescription drug orders, requests for refill authorization, or other confidential health information are not transmitted directly between a pharmacy and a physician but are transmitted through a data communication device, confidential health information may not be accessed or maintained by the operator of the data communication device unless specifically authorized to obtain the confidential information by this section.

(b) Confidential records are privileged and may be released only to:

(1) the patient or the patient's agent;

(2) a practitioner or another pharmacist if, in the pharmacist's professional judgement, the release is necessary to protect the patient's health and well being;

(3) the board or to a person or another state or federal agency authorized by law to receive the confidential record;

(4) a law enforcement agency engaged in investigation of a suspected violation of Chapter 481 or 483, Health and Safety Code, or the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. Section 801 et seq.);

(5) a person employed by a state agency that licenses a practitioner, if the person is performing the person's official duties; or

(6) an insurance carrier or other third party payor authorized by a patient to receive such information.

(c) A pharmacy shall provide written policies [~~polices~~] and procedures to prohibit the unauthorized disclosure of confidential records.

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

Filed with the Office of the Secretary of State on May 31, 2023.

TRD-202302010
Julie Spier, R.Ph.
President
Texas State Board of Pharmacy
Earliest possible date of adoption: July 16, 2023
For further information, please call: (512) 305-8026

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SUBCHAPTER G. SERVICES PROVIDED BY PHARMACIES

22 TAC §291.121

The Texas State Board of Pharmacy proposes amendments to §291.121, concerning Remote Pharmacy Services. The amendments, if adopted, allow remote pharmacy services to be provided using an automated pharmacy system to be provided at healthcare facilities regulated under Chapter 534, Health and Safety Code.

Julie Spier, R.Ph., President, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Ms. Spier has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will to improve public access to pharmacy services by allowing remote pharmacy services to be provided at more types of healthcare facilities. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendments will be in effect, Ms. Spier has determined the following:

(1) The proposed amendments do not create or eliminate a government program;

(2) Implementation of the proposed amendments does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed amendments does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed amendments do not require an increase or decrease in fees paid to the agency;

(5) The proposed amendments do not create a new regulation;

(6) The proposed amendments do limit an existing regulation by allowing an additional type of healthcare facility to provide remote pharmacy services using an automated pharmacy system;

(7) The proposed amendments do not increase or decrease the number of individuals subject to the rule's applicability; and

(8) The proposed amendments do not positively or adversely affect this state's economy.

Written comments on the amendments may be submitted to Eamon D. Briggs, Deputy General Counsel, Texas State Board of Pharmacy, 1801 Congress Avenue, Suite 13.100, Austin, Texas 78701-1319, FAX (512) 305-8061. Comments must be received by 5:00 p.m., July 24, 2023.

The amendments are proposed under §§551.002 and 554.051 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§291.121. Remote Pharmacy Services.

(a) Remote pharmacy services using automated pharmacy systems.

(1) Purpose. The purpose of this section is to provide standards for the provision of pharmacy services by a Class A or Class C pharmacy in a facility that is not at the same location as the Class A or Class C pharmacy through an automated pharmacy system as outlined in §562.109 of the Texas Pharmacy Act.

(2) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. All other words and terms shall have the meanings defined in the Act.

(A) Automated pharmacy system--A mechanical system that dispenses prescription drugs and maintains related transaction information.

(B) Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original commercial container, or quantities of unit dosed drugs, into another cartridge or container for dispensing by a pharmacist using an automated pharmacy system.

(C) Provider pharmacy--The community pharmacy (Class A) or the institutional pharmacy (Class C) providing remote pharmacy services.

(D) Remote pharmacy service--The provision of pharmacy services, including the storage and dispensing of prescription drugs, in remote sites.

(E) Remote site--A facility not located at the same location as a Class A or Class C pharmacy, at which remote pharmacy services are provided using an automated pharmacy dispensing system.

(F) Unit dose--An amount of a drug packaged in a dosage form ready for administration to a particular patient, by the prescribed route at the prescribed time, and properly labeled with name, strength, and expiration date of the drug.

(3) General requirements.

(A) A provider pharmacy may provide remote pharmacy services using an automated pharmacy system to a jail or prison operated by or for the State of Texas, a jail or prison operated by local government or a healthcare facility regulated under Chapter 142, 241, 242, 247, 252, 464, 534, or 577, Health and Safety Code, provided drugs are administered by a licensed healthcare professional working in the jail, prison, or healthcare facility.

(B) A provider pharmacy may provide remote pharmacy services at more than one remote site.

(C) Before providing remote pharmacy services, the automated pharmacy system at the remote site must be tested by the provider pharmacy and found to dispense accurately. The provider pharmacy shall make the results of such testing available to the board upon request.

(D) A provider pharmacy which is licensed as an institutional (Class C) pharmacy is required to comply with the provisions of §§291.31 - 291.34 of this title (relating to Definitions, Personnel, Operational Standards, and Records, respectively) and this section.

(E) The pharmacist-in-charge of the provider pharmacy is responsible for all pharmacy operations involving the automated pharmacy system located at the remote site including supervision of the automated pharmacy system and compliance with this section.

(F) A pharmacist from the provider pharmacy shall be accessible at all times to respond to patients' or other health professionals' questions and needs pertaining to drugs dispensed through the use of the automated pharmacy system. Such access may be through a 24 hour pager service or telephone which is answered 24 hours a day.

(4) Operational standards.

(A) Application for permission to provide pharmacy services using an automated pharmacy system.

(i) A Class A or Class C Pharmacy shall file a completed application containing all information required by the board to provide remote pharmacy services using an automated pharmacy system.

(ii) Such application shall be resubmitted every two years in conjunction with the application for renewal of the provider pharmacy's license.

(iii) Upon approval of the application, the provider pharmacy will be sent a certificate which must be displayed at the remote site.

(B) Notification requirements.

(i) A provider pharmacy shall notify the board in writing within ten days of a discontinuance of service, or closure of:

(I) a remote site where an automated pharmacy system is operated by the pharmacy; or

(II) a remote pharmacy service at a remote site.

(ii) A provider pharmacy shall comply with appropriate federal and state controlled substance registrations for each remote site if controlled substances are maintained within an automated pharmacy system at the facility.

(iii) A provider pharmacy shall file a change of location and/or name of a remote site as specified in §291.3 of this title (relating to Notifications).

(C) Environment/Security.

(i) A provider pharmacy shall only store drugs at a remote site within an automated pharmacy system which is locked by key, combination or other mechanical or electronic means so as to prohibit access by unauthorized personnel.

(ii) An automated pharmacy system shall be under the continuous supervision of a provider pharmacy pharmacist. To qualify as continuous supervision, the pharmacist is not required to be physically present at the site of the automated pharmacy system if the system is supervised electronically by a pharmacist.

(iii) Automated pharmacy systems shall have adequate security and procedures to:

(I) comply with federal and state laws and regulations; and

(II) maintain patient confidentiality.

(iv) Access to the automated pharmacy system shall be limited to pharmacists or personnel who:

(I) are designated in writing by the pharmacist-in-charge; and

(II) have completed documented training concerning their duties associated with the automated pharmacy system.

(v) Drugs shall be stored in compliance with the provisions of §291.15 of this title (relating to Storage of Drugs) and §291.33(f)(2) of this title including the requirements for temperature and handling of outdated drugs.

(D) Prescription dispensing and delivery.

(i) Drugs shall only be dispensed at a remote site through an automated pharmacy system after receipt of an original prescription drug order by a pharmacist at the provider pharmacy in a manner authorized by §291.34(b) of this title.

(ii) A pharmacist at the provider pharmacy shall control all operations of the automated pharmacy system and approve the release of the initial dose of a prescription drug order. Subsequent doses from an approved prescription drug order may be removed from the automated medication system after this initial approval. Any change made in the prescription drug order shall require a new approval by a pharmacist to release the drug.

(iii) A pharmacist at the provider pharmacy shall conduct a drug regimen review as specified in §291.33(c) of this title prior to releasing a prescription drug order to the automated pharmacy system.

(iv) Drugs dispensed by the provider pharmacy through an automated pharmacy system shall comply with the labeling or labeling alternatives specified in §291.33(c) of this title.

(v) An automated pharmacy system used to meet the emergency medication needs for residents of a remote site must comply with the requirements for emergency medication kits in subsection (b) of this section.

(E) Drugs.

(i) Drugs for use in an automated pharmacy system shall be packaged in the original manufacturer's container or be prepackaged in the provider pharmacy and labeled in compliance with the board's prepackaging requirements for the class of pharmacy.

(ii) Drugs dispensed from the automated pharmacy system may be returned to the pharmacy for reuse provided the drugs are in sealed, tamper evident packaging which has not been opened.

(F) Stocking an automated pharmacy system.

(i) Stocking of drugs in an automated pharmacy system shall be completed by a pharmacist, pharmacy technician, or pharmacy technician trainee under the direct supervision of a pharmacist, except as provided in clause (ii) of this subparagraph.

(ii) If the automated pharmacy system uses removable cartridges or containers to hold drugs, the prepackaging of the cartridges or containers shall occur at the provider pharmacy unless provided by an FDA approved repackager. The prepackaged cartridges or containers may be sent to the remote site to be loaded into the machine by personnel designated by the pharmacist-in-charge provided:

(I) a pharmacist verifies the cartridge or container has been properly filled and labeled;

(II) the individual cartridges or containers are transported to the remote site in a secure, tamper-evident container; and

(III) the automated pharmacy system uses barcoding, microchip, or other technologies to ensure that the containers are accurately loaded in the automated pharmacy system.

(iii) All drugs to be stocked in the automated pharmacy system shall be delivered to the remote site by the provider pharmacy.

(G) Quality assurance program. A pharmacy that provides pharmacy services through an automated pharmacy system at a remote site shall operate according to a written program for quality assurance of the automated pharmacy system which:

(i) requires continuous supervision of the automated pharmacy system; and

(ii) establishes mechanisms and procedures to routinely test the accuracy of the automated pharmacy system at a minimum of every six months and whenever any upgrade or change is made to the system and documents each such activity.

(H) Policies and procedures of operation.

(i) A pharmacy that provides pharmacy services through an automated pharmacy system at a remote site shall operate according to written policies and procedures. The policy and procedure manual shall include, but not be limited to, the following:

(I) a current list of the name and address of the pharmacist-in-charge and personnel designated by the pharmacist-in-charge to have access to the drugs stored in the automated pharmacy system;

(II) duties which may only be performed by a pharmacist;

(III) a copy of the portion of the written contract or agreement between the pharmacy and the facility which outlines the services to be provided and the responsibilities and accountabilities of each party relating to the operation of the automated pharmacy system in fulfilling the terms of the contract in compliance with federal and state laws and regulations;

(IV) date of last review/revision of the policy and procedure manual; and

(V) policies and procedures for:

(-a-) security;

(-b-) operation of the automated pharmacy system;

(-c-) preventative maintenance of the automated pharmacy system;

(-d-) sanitation;

(-e-) storage of drugs;

(-f-) dispensing;

(-g-) supervision;

(-h-) drug procurement;

(-i-) receiving of drugs;

(-j-) delivery of drugs; and

(-k-) recordkeeping.

(ii) A pharmacy that provides pharmacy services through an automated pharmacy system at a remote site shall, at least annually, review its written policies and procedures, revise them if necessary, and document the review.

(iii) A pharmacy providing remote pharmacy services using an automated pharmacy system shall maintain a written plan for recovery from an event which interrupts the ability of the automated pharmacy system to dispense prescription drugs. The written plan for recovery shall include:

(I) planning and preparation for maintaining pharmacy services when an automated pharmacy system is experiencing downtime;

(II) procedures for response when an automated pharmacy system is experiencing downtime; and

(III) procedures for the maintenance and testing of the written plan for recovery.

(5) Records.

(A) Maintenance of records.

(i) Every record required under this section must be:

(I) kept by the provider pharmacy and be available, for at least two years for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and

(II) supplied by the provider pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(ii) The provider pharmacy shall maintain original prescription drug orders for drugs dispensed from an automated pharmacy system in compliance with §291.34(b) of this title.

(iii) if prescription drug records are maintained in a data processing system, the system shall have a workable (electronic) data retention system which can produce a separate audit trail of drug usage by the provider pharmacy and each remote site for the preceding two years as specified in §291.34(e) of this title.

(B) Prescriptions. Prescription drug orders shall meet the requirements of §291.34(b) of this title.

(C) Records of dispensing. Dispensing records for a prescription drug order shall be maintained by the provider pharmacy in the manner required by §291.34(d) or (e) of this title.

(D) Transaction information.

(i) The automated pharmacy system shall electronically record all transactions involving drugs stored in, removed, or dispensed from the system.

(ii) Records of dispensing from an automated pharmacy system for a patient shall be maintained by the providing pharmacy and include the:

(I) identity of the system accessed;

(II) identification of the individual accessing the system;

(III) date of transaction;

(IV) name, strength, dosage form, and quantity of drug accessed; and

(V) name of the patient for whom the drug was accessed.

(iii) Records of stocking or removal from an automated pharmacy system shall be maintained by the pharmacy and include the:

(I) date;

(II) name, strength, dosage form, and quantity of drug stocked or removed;

(III) name, initials, or identification code of the person stocking or removing drugs from the system; and

(IV) name, initials, or identification code of the pharmacist who checks and verifies that the system has been accurately filled.

(E) Patient medication records. Patient medication records shall be created and maintained by the provider pharmacy in the manner required by §291.34(c) of this title.

(F) Inventory.

(i) A provider pharmacy shall:

(I) keep a record of all drugs sent to and returned from a remote site separate from the records of the provider pharmacy and from any other remote site's records; and

(II) keep a perpetual inventory of controlled substances and other drugs required to be inventoried under §291.17 of this title (relating to Inventory Requirements) that are received and dispensed or distributed from each remote site.

(ii) As specified in §291.17 of this title, a provider pharmacy shall conduct an inventory at each remote site. The following is applicable to this inventory.

(I) The inventory of each remote site and the provider pharmacy shall be taken on the same day.

(II) The inventory of each remote site shall be included with, but listed separately from, the drugs of other remote sites and separately from the drugs of the provider pharmacy.

(b) Remote pharmacy services using emergency medication kits.

(1) Purpose. The purpose of this section is to provide standards for the provision of pharmacy services by a Class A or Class C pharmacy in a facility that is not at the same location as the Class A or Class C pharmacy through an emergency medication kit as outlined in §562.108 of the Texas Pharmacy Act.

(2) Definitions. The following words and terms, when used in this subsection, shall have the following meanings, unless the context clearly indicates otherwise. All other words and terms shall have the meanings defined in the Act or §291.31 of this title.

(A) Automated pharmacy system--A mechanical system that dispenses prescription drugs and maintains related transaction information.

(B) Emergency medication kits--Controlled substances and dangerous drugs maintained by a provider pharmacy to meet the emergency medication needs of a resident:

(i) at an institution licensed under Chapter 242 or 252, Health and Safety Code; or

(ii) at an institution licensed under Chapter 242, Health and Safety Code and that is a veterans home as defined by the §164.002, Natural Resources Code, if the provider pharmacy is a United States Department of Veterans Affairs pharmacy or another federally operated pharmacy.

(C) Prepackaging--The act of repackaging and relabeling quantities of drug products from a manufacturer's original commercial container, or quantities of unit dosed drugs, into another cartridge or container for dispensing by a pharmacist using an emergency medication kit.

(D) Provider pharmacy--The community pharmacy (Class A), the institutional pharmacy (Class C), the non-resident pharmacy (Class E) located not more than 20 miles from an institution licensed under Chapter 242 or 252, Health and Safety Code, or the United States Department of Veterans Affairs pharmacy or another federally operated pharmacy providing remote pharmacy services.

(E) Remote pharmacy service--The provision of pharmacy services, including the storage and dispensing of prescription drugs, in remote sites.

(F) Remote site--A facility not located at the same location as a Class A, Class C, Class E pharmacy or a United States Department of Veterans Affairs pharmacy or another federally operated pharmacy, at which remote pharmacy services are provided using an emergency medication kit.

(3) General requirements.

(A) A provider pharmacy may provide remote pharmacy services using an emergency medication kit to an institution regulated under Chapter 242, or 252, Health and Safety Code.

(B) A provider pharmacy may provide remote pharmacy services at more than one remote site.

(C) A provider pharmacy shall not place an emergency medication kit in a remote site which already has a kit from another provider pharmacy except as provided by paragraph (4)(B)(iii) of this subsection.

(D) A provider pharmacy which is licensed as an institutional (Class C) or a non-resident (Class E) pharmacy is required to comply with the provisions of §§291.31 - 291.34 of this title and this section.

(E) The pharmacist-in-charge of the provider pharmacy is responsible for all pharmacy operations involving the emergency medication kit located at the remote site including supervision of the emergency medication kit and compliance with this section.

(4) Operational standards.

(A) Application for permission to provide pharmacy services using an emergency medication kit.

(i) A Class A, Class C, or Class E pharmacy shall file a completed application containing all information required by the board to provide remote pharmacy services using an emergency medication kit.

(ii) Such application shall be resubmitted every two years in conjunction with the application for renewal of the provider pharmacy's license.

(iii) Upon approval of the application, the provider pharmacy will be sent a certificate which must be displayed at the remote site.

(B) Notification requirements.

(i) A provider pharmacy shall notify the board in writing within ten days of a discontinuance of service, or closure of:

(I) a remote site where an emergency medication kit is operated by the pharmacy; or

(II) a remote pharmacy service at a remote site.

(ii) A provider pharmacy shall comply with appropriate federal and state controlled substance registrations for each remote site if controlled substances are maintained within an emergency medication kit at the facility.

(iii) If more than one provider pharmacy provides an emergency kit to a remote site, the provider pharmacies must enter into a written agreement as to the emergency medications supplied by each pharmacy. The written agreement shall include reasons why an addi-

tional pharmacy is required to meet the emergency medication needs of the residents of the institution.

(iv) A provider pharmacy shall file a change of location and/or name of a remote site as specified in §291.3 of this title.

(C) Environment/Security.

(i) Emergency medication kits shall have adequate security and procedures to:

(I) prohibit unauthorized access;

(II) comply with federal and state laws and regulations; and

(III) maintain patient confidentiality.

(ii) Access to the emergency medication kit shall be limited to pharmacists and licensed healthcare personnel employed by the facility.

(iii) Drugs shall be stored in compliance with the provisions of §291.15 and §291.33(f)(2) of this title including the requirements for temperature and handling outdated drugs.

(D) Prescription dispensing and delivery.

(i) Drugs in the emergency medication kit shall be accessed for administration to meet the emergency medication needs of a resident of the remote site pursuant to an order from a practitioner. The prescription drug order for the drugs used from the emergency medication kit shall be forwarded to the provider pharmacy in a manner authorized by §291.34(b) of this title.

(ii) The remote site shall notify the provider pharmacy of each entry into an emergency medication kit. Such notification shall meet the requirements of paragraph (5)(D)(ii) of this subsection.

(E) Drugs.

(i) The contents of an emergency medication kit:

(I) may consist of dangerous drugs and controlled substances; and

(II) shall be determined by the consultant pharmacist, pharmacist-in-charge of the provider pharmacy, medical director, and the director of nurses and limited to those drugs necessary to meet the resident's emergency medication needs. For the purpose of this subsection, this shall mean a situation in which a drug cannot be supplied by a pharmacy within a reasonable time period.

(ii) When deciding on the drugs to be placed in the emergency medication kit, the consultant pharmacist, pharmacist-in-charge of the provider pharmacy, medical director, and the director of nurses must determine, select, and record a prudent number of drugs for potential emergency incidents based on:

(I) clinical criteria applicable to each facility's demographics;

(II) the facility's census; and

(III) the facility's healthcare environment.

(iii) A current list of the drugs stored in each remote site's emergency medication kit shall be maintained by the provider pharmacy and a copy kept with the emergency medication kit.

(iv) An automated pharmacy system may be used as an emergency medication kit provided the system limits emergency access to only those drugs approved for the emergency medication kit.

(v) Drugs for use in an emergency medication kit shall be packaged in the original manufacturer's container or prepackaged in the provider pharmacy and labeled in compliance with the board's prepackaging requirements for the class of pharmacy.

(F) Stocking emergency medication kits.

(i) Stocking of drugs in an emergency medication kit shall be completed at the provider pharmacy or remote site by a pharmacist, pharmacy technician, or pharmacy technician trainee under the direct supervision of a pharmacist, except as provided in clause (ii) of this subparagraph.

(ii) If the emergency medication kit is an automated pharmacy system which uses bar-coding, microchip, or other technologies to ensure that the containers or unit dose drugs are accurately loaded, the prepackaging of the containers or unit dose drugs shall occur at the provider pharmacy unless provided by an FDA approved repackager. The prepackaged containers or unit dose drugs may be sent to the remote site to be loaded into the machine by personnel designated by the pharmacist-in-charge provided:

(I) a pharmacist verifies the container or unit dose drug has been properly filled and labeled;

(II) the individual containers or unit dose drugs are transported to the remote site in a secure, tamper-evident container; and

(III) the automated pharmacy system uses bar-coding, microchip, or other technologies to ensure that the containers or unit dose drugs are accurately loaded in the automated pharmacy system.

(iii) All drugs to be stocked in the emergency medication kit shall be delivered to the remote site by the provider pharmacy.

(G) Policies and procedures of operation.

(i) A provider pharmacy that provides pharmacy services through an emergency medication kit at a remote site shall operate according to written policies and procedures. The policy and procedure manual shall include, but not be limited to, the following:

(I) duties which may only be performed by a pharmacist;

(II) a copy of the written contract or agreement between the pharmacy and the facility which outlines the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract in compliance with federal and state laws and regulations;

(III) date of last review/revision of the policy and procedure manual; and

(IV) policies and procedures for:

(-a-) security;

(-b-) operation of the emergency medication kit;

(-c-) preventative maintenance of the automated pharmacy system if the emergency medication kit is an automated pharmacy system;

(-d-) sanitation;

(-e-) storage of drugs;

(-f-) dispensing;

(-g-) supervision;

(-h-) drug procurement;

(-i-) receiving of drugs;

(-j-) delivery of drugs; and

(-k-) recordkeeping.

(ii) A pharmacy that provides pharmacy services through an emergency medication kit at a remote site shall, at least annually, review its written policies and procedures, revise them if necessary, and document the review.

(iii) A pharmacy providing remote pharmacy services using an emergency medication kit which is an automated pharmacy system shall maintain a written plan for recovery from an event which interrupts the ability of the automated pharmacy system to provide emergency medications. The written plan for recovery shall include:

(I) planning and preparation for maintaining pharmacy services when an automated pharmacy system is experiencing downtime;

(II) procedures for response when an automated pharmacy system is experiencing downtime; and

(III) procedures for the maintenance and testing of the written plan for recovery.

(5) Records.

(A) Maintenance of records.

(i) Every record required under this section must be:

(I) kept by the provider pharmacy and be available, for at least two years, for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and

(II) supplied by the provider pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(ii) The provider pharmacy shall maintain original prescription drug orders for drugs dispensed from an emergency medication kit in compliance with §291.34(b) of this title.

(B) Prescriptions. Prescription drug orders shall meet the requirements of §291.34(b) of this title.

(C) Records of dispensing. Dispensing records for a prescription drug order shall be maintained by the provider pharmacy in the manner required by §291.34(d) or (e) of this title.

(D) Transaction information.

(i) A prescription drug order shall be maintained by the provider pharmacy as the record of removal of a drug from an emergency medication kit for administration to a patient.

(ii) The remote site shall notify the provider pharmacy electronically or in writing of each entry into an emergency medication kit. Such notification may be included on the prescription drug order or a separate document and shall include the name, strength, and quantity of the drug removed, the time of removal, and the name of the person removing the drug.

(iii) A separate record of stocking, removal, or dispensing for administration from an emergency medication kit shall be maintained by the pharmacy and include the:

(I) date;

(II) name, strength, dosage form, and quantity of drug stocked, removed, or dispensed for administration;

(III) name, initials, or identification code of the person stocking, removing, or dispensing for administration, drugs from the system;

(IV) name, initials, or identification code of the pharmacist who checks and verifies that the system has been accurately filled; and

(V) unique prescription number assigned to the prescription drug order when the drug is administered to the patient.

(E) Inventory.

(i) A provider pharmacy shall:

(I) keep a record of all drugs sent to and returned from a remote site separate from the records of the provider pharmacy and from any other remote site's records; and

(II) keep a perpetual inventory of controlled substances and other drugs required to be inventoried under §291.17 of this title, that are received and dispensed or distributed from each remote site.

(ii) As specified in §291.17 of this title, a provider pharmacy shall conduct an inventory at each remote site. The following is applicable to this inventory.

(I) The inventory of each remote site and the provider pharmacy shall be taken on the same day.

(II) The inventory of each remote site shall be included with, but listed separately from, the drugs of other remote sites and separately from the drugs of the provider pharmacy.

(c) Remote pharmacy services using telepharmacy systems.

(1) Purpose. The purpose of this section is to provide standards for the provision of pharmacy services by a Class A or Class C pharmacy in a healthcare facility that is not at the same location as a Class A or Class C pharmacy through a telepharmacy system as outlined in §562.110 of the Texas Pharmacy Act.

(2) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. All other words and terms shall have the meanings defined in the Act or §291.31 of this title.

(A) Provider pharmacy--

(i) a Class A pharmacy that provides pharmacy services through a telepharmacy system at a remote dispensing site or at a healthcare facility that is regulated by this state or the United States; or

(ii) a Class C pharmacy that provides pharmacy services though a telepharmacy system at a healthcare facility that is regulated by this state or the United States.

(B) Remote dispensing site--a location licensed as a telepharmacy that is authorized by a provider pharmacy through a telepharmacy system to store and dispense prescription drugs and devices, including dangerous drugs and controlled substances.

(C) Remote healthcare site--a healthcare facility regulated by this state or the United States that is a:

(i) rural health clinic regulated under 42 U.S.C. Section 1395x(aa);

(ii) health center as defined by 42 U.S.C. Section 254b;

(iii) healthcare facility located in a medically underserved area as determined by the United States Department of Health and Human Services;

(iv) healthcare facility located in a health professional shortage area as determined by the United States Department of Health and Human Services; or

(v) a federally qualified health center as defined by 42 U.S.C. Section 1396d(I)(2)(B).

(D) Remote pharmacy service--The provision of pharmacy services, including the storage and dispensing of prescription drugs, drug regimen review, and patient counseling, at a remote site.

(E) Remote site--a remote healthcare site or a remote dispensing site.

(F) Still image capture--A specific image captured electronically from a video or other image capture device.

(G) Store and forward--A video or still image record which is saved electronically for future review.

(H) Telepharmacy system--A system that monitors the dispensing of prescription drugs and provides for related drug use review and patient counseling services by an electronic method which shall include the use of the following types of technology:

(i) audio and video;

(ii) still image capture; and

(iii) store and forward.

(3) General requirements.

(A) A provider pharmacy may provide remote pharmacy services using a telepharmacy system at a:

(i) remote healthcare site; or

(ii) remote dispensing site.

(B) A provider pharmacy may not provide remote pharmacy services at a remote healthcare site if a Class A or Class C pharmacy that dispenses prescription drug orders to out-patients is located in the same community, unless the remote healthcare site is a federally qualified health center as defined by 42 U.S.C. Section 1396d(I)(2)(B). For the purposes of this subsection a community is defined as:

(i) the census tract in which the remote site is located, if the remote site is located in a Metropolitan Statistical Area (MSA) as defined by the United States Census Bureau in the most recent U.S. Census; or

(ii) within 10 miles of the remote site, if the remote site is not located in an MSA.

(C) A provider pharmacy may not provide remote pharmacy services at a remote dispensing site if a Class A pharmacy is located within 22 miles by road of the remote dispensing site.

(D) If a Class A or Class C pharmacy is established in a community in which a remote healthcare site has been located, the remote healthcare site may continue to operate.

(E) If a Class A pharmacy is established within 22 miles by road of a remote dispensing site that is currently operating, the remote dispensing site may continue to operate at that location.

(F) Before providing remote pharmacy services, the telepharmacy system at the remote site must be tested by the provider pharmacy and found to operate properly. The provider pharmacy shall make the results of such testing available to the board upon request.

(G) A provider pharmacy which is licensed as a Class C pharmacy is required to comply with the provisions of §§291.31 - 291.34 of this title and this section.

(H) A provider pharmacy can only provide pharmacy services at no more than two remote dispensing sites.

(4) Personnel.

(A) The pharmacist-in-charge of the provider pharmacy is responsible for all operations at the remote site including supervision of the telepharmacy system and compliance with this section.

(B) The provider pharmacy shall have sufficient pharmacists on duty such that each pharmacist may supervise no more than two remote sites that are simultaneously open to provide services.

(C) The following duties shall be performed only by a pharmacist at the provider pharmacy:

(i) receiving an oral prescription drug order for a controlled substance;

(ii) interpreting the prescription drug order;

(iii) verifying the accuracy of prescription data entry;

(iv) selecting the drug product to be stored and dispensed at the remote site;

(v) interpreting the patient's medication record and conducting a drug regimen review;

(vi) authorizing the telepharmacy system to print a prescription label at the remote site;

(vii) performing the final check of the dispensed prescription to ensure that the prescription drug order has been dispensed accurately as prescribed; and

(viii) counseling the patient.

(D) A pharmacy technician at the remote site may receive an oral prescription drug order for a dangerous drug.

(5) Operational standards.

(A) Application to provide remote pharmacy services using a telepharmacy system.

(i) A Class A or Class C pharmacy shall file a completed application containing all information required by the board to provide remote pharmacy services using a telepharmacy system.

(ii) Such application shall be resubmitted every two years in conjunction with the renewal of the provider pharmacy's license.

(iii) On approval of the application, the provider pharmacy will be sent a license for the remote site, which must be displayed at the remote site.

(iv) If the average number of prescriptions dispensed each day at a remote dispensing site is open for business is more than 125 prescriptions, as calculated each calendar year, the remote dispensing site shall apply for a Class A pharmacy license as specified in §291.1 of this title (relating to Pharmacy License Application).

(B) Notification requirements.

(i) A provider pharmacy shall notify the board in writing within ten days of a discontinuance of service, or closure of a remote site where a telepharmacy system is operated by the pharmacy.

(ii) A provider pharmacy shall comply with appropriate federal and state controlled substance registrations for each remote site, if controlled substances are maintained.

(iii) A provider pharmacy shall file a change of location and/or name of a remote site as specified in §291.3 of this title.

(C) Environment/Security.

(i) A remote site shall be under the continuous supervision of a provider pharmacy pharmacist at all times the site is open to provide pharmacy services. To qualify as continuous supervision, the pharmacist is not required to be physically present at the remote site and shall supervise electronically through the use of the following types of technology:

(I) audio and video;

(II) still image capture; and

(III) store and forward.

(ii) Drugs shall be stored in compliance with the provisions of §291.15 and §291.33(f)(2) of this title including the requirements for temperature and handling of outdated drugs.

(iii) Drugs for use in the telepharmacy system at a remote healthcare site shall be stored in an area that is:

(I) separate from any other drugs used by the healthcare facility; and

(II) locked by key, combination or other mechanical or electronic means, so as to prohibit access by unauthorized personnel.

(iv) Drugs for use in the telepharmacy system at a remote dispensing site shall be stored in an area that is locked by key, combination, or other mechanical or electronic means, so as to prohibit access by unauthorized personnel.

(v) Access to the area where drugs are stored at the remote site and operation of the telepharmacy system shall be limited to:

(I) pharmacists employed by the provider pharmacy;

(II) licensed healthcare providers, if the remote site is a remote healthcare site; and

(III) pharmacy technicians;

(vi) Individuals authorized to access the remote site and operate the telepharmacy system shall:

(I) be designated in writing by the pharmacist-in-charge; and

(II) have completed documented training concerning their duties associated with the telepharmacy pharmacy system.

(vii) Remote sites shall have adequate security and procedures to:

(I) comply with federal and state laws and regulations; and

(II) maintain patient confidentiality.

(D) Prescription dispensing and delivery.

(i) A pharmacist at the provider pharmacy shall conduct a drug regimen review as specified in §291.33(c) of this title prior to delivery of the dispensed prescription to the patient or patient's agent.

(ii) The dispensed prescription shall be labeled at the remote site with the information specified in §291.33(c) of this title.

(iii) A pharmacist at the provider pharmacy shall perform the final check of the dispensed prescription before delivery to the patient to ensure that the prescription has been dispensed accurately as prescribed. This final check shall be accomplished through a visual check using electronic methods.

(iv) A pharmacist at the provider pharmacy shall counsel the patient or patient's agent as specified in §291.33(c) of this title. This counseling may be performed using electronic methods. Non-pharmacist personnel may not ask questions of a patient or patient's agent which are intended to screen and/or limit interaction with the pharmacist.

(v) If the remote site has direct access to the provider pharmacy's data processing system, only a pharmacist or pharmacy technician may enter prescription information into the data processing system.

(vi) Drugs which require reconstitution through the addition of a specified amount of water may be dispensed by the remote site only if a pharmacy technician, pharmacy technician trainee, or licensed healthcare provider reconstitutes the product.

(vii) A telepharmacy system located at a remote dispensing site may not dispense a schedule II controlled substance.

(viii) Drugs dispensed at the remote site through a telepharmacy system shall only be delivered to the patient or patient's agent at the remote site.

(E) Quality assurance program. A pharmacy that provides remote pharmacy services through a telepharmacy system at a remote site shall operate according to a written program for quality assurance of the telepharmacy system which:

(i) requires continuous supervision of the telepharmacy system at all times the site is open to provide remote pharmacy services; and

(ii) establishes mechanisms and procedures to routinely test the operation of the telepharmacy system at a minimum of every six months and whenever any upgrade or change is made to the system and documents each such activity.

(F) Policies and procedures.

(i) A pharmacy that provides pharmacy services through a telepharmacy system at a remote site shall operate according to written policies and procedures. The policy and procedure manual shall include, but not be limited to, the following:

(I) a current list of the name and address of the pharmacist-in-charge and personnel designated by the pharmacist-in-charge to have:

(-a-) access to the area where drugs are stored at the remote site; and

(-b-) operate the telepharmacy system;

(II) duties which may only be performed by a pharmacist;

(III) if the remote site is located at a remote healthcare site, a copy of the written contact or agreement between the provider pharmacy and the healthcare facility which outlines the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract or agreement in compliance with federal and state laws and regulations;

(IV) date of last review/revision of policy and procedure manual; and

(V) policies and procedures for:

(-a-) security;
(-b-) operation of the telepharmacy system;
(-c-) sanitation;
(-d-) storage of drugs;
(-e-) dispensing;
(-f-) supervision;
(-g-) drug and/or device procurement;
(-h-) receiving of drugs and/or devices;
(-i-) delivery of drugs and/or devices; and
(-j-) recordkeeping.

(ii) A pharmacy that provides remote pharmacy services through a telepharmacy system at a remote site shall, at least annually, review its written policies and procedures, revise them if necessary, and document the review.

(iii) A pharmacy providing remote pharmacy services through a telepharmacy system shall maintain a written plan for recovery from an event which interrupts the ability of a pharmacist to electronically supervise the telepharmacy system and the dispensing of prescription drugs at the remote site. The written plan for recovery shall include:

(I) a statement that prescription drugs shall not be dispensed at the remote site, if a pharmacist is not able to electronically supervise the telepharmacy system and the dispensing of prescription drugs;

(II) procedures for response when a telepharmacy system is experiencing downtime; and

(III) procedures for the maintenance and testing of the written plan for recovery.

(6) Additional operational standards for remote dispensing sites.

(A) A pharmacist employed by a provider pharmacy shall make at least monthly on-site visits to a remote site. The remote site shall maintain documentation of the visit.

(B) A pharmacist employed by a provider pharmacy shall be physically present at a remote dispensing site when the pharmacist is providing services requiring the physical presence of the pharmacist, including immunizations.

(C) A remote dispensing site shall be staffed by an on-site pharmacy technician who is under the continuous supervision of a pharmacist employed by the provider pharmacy.

(D) All pharmacy technicians at a remote dispensing site shall be counted for the purpose of establishing the pharmacist-pharmacy technician ratio of the provider pharmacy which, notwithstanding Section 568.006 of the Act, may not exceed three pharmacy technicians for each pharmacist providing supervision.

(E) A pharmacy technician working at a remote dispensing site must:

(i) have worked at least one year at a retail pharmacy during the three years preceding the date the pharmacy technician begins working at the remote dispensing site; and

(ii) have completed a training program on the proper use of a telepharmacy system.

(F) A pharmacy technician at a remote dispensing site may not perform sterile or nonsterile compounding. However, a pharmacy technician may prepare commercially available medications for dispensing, including the reconstitution of orally administered powder antibiotics.

(7) Records.

(A) Maintenance of records.

(i) Every record required under this section must be:

(I) accessible by the provider pharmacy and be available, for at least two years for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and

(II) supplied by the provider pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(ii) The remote site shall maintain original prescription drug orders for medications dispensed from a remote site using a telepharmacy system in the manner required by §291.34(b) of this title and the provider pharmacy shall have electronic access to all prescription records.

(iii) If prescription drug records are maintained in a data processing system, the system shall have a workable (electronic) data retention system which can produce a separate audit trail of drug usage by the provider pharmacy and by each remote site for the preceding two years as specified in §291.34(e) of this title.

(B) Prescriptions. Prescription drug orders shall meet the requirements of §291.34(b) of this title.

(C) Patient medication records. Patient medication records shall be created and maintained at the remote site or provider pharmacy in the manner required by §291.34(c) of this title. If such records are maintained at the remote site, the provider pharmacy shall have electronic access to those records.

(D) Inventory.

(i) A provider pharmacy shall:

(I) keep a record of all drugs ordered and dispensed by a remote site separate from the records of the provider pharmacy and from any other remote site's records;

(II) keep a perpetual inventory of all controlled substances that are received and dispensed or distributed from each remote site. The perpetual inventory shall be reconciled, by a pharmacist employed by the provider pharmacy, at least monthly.

(ii) As specified in §291.17 of this title, a provider pharmacy shall conduct an inventory at each remote site. The following is applicable to this inventory.

(I) The inventory of each remote site and the provider pharmacy shall be taken on the same day.

(II) The inventory of each remote site shall be included with, but listed separately from, the drugs of other remote sites and separately from the drugs at the provider pharmacy.

(III) A copy of the inventory of the remote site shall be maintained at the remote site.

(d) Remote pharmacy services using automated dispensing and delivery systems.

(1) Purpose. The purpose of this section is to provide standards for the provision of pharmacy services by a Class A or Class C pharmacy in a facility that is not at the same location as the Class A or Class C pharmacy through an automated dispensing and delivery system.

(2) Definitions. The following words and terms, when used in this section, shall have the following meanings, unless the context clearly indicates otherwise. All other words and terms shall have the meanings defined in the Act.

(A) Automated dispensing and delivery system--A mechanical system that dispenses and delivers prescription drugs to patients at a remote delivery site and maintains related transaction information.

(B) Deliver or delivery--The actual, constructive, or attempted transfer of a prescription drug or device or controlled substance from one person to another, whether or not for a consideration.

(C) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug or device in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner.

(D) Provider pharmacy--The community pharmacy (Class A) or the institutional pharmacy (Class C) providing remote pharmacy services.

(E) Remote delivery site--A location at which remote pharmacy services are provided using an automated dispensing and delivery system.

(F) Remote pharmacy service--The provision of pharmacy services, including the dispensing and delivery of prescription drugs, in remote delivery sites.

(3) General requirements for a provider pharmacy to provide remote pharmacy services using an automated dispensing and delivery system to dispense and deliver a prescription that is verified by the provider pharmacy to a patient or patient's agent.

(A) The pharmacist-in-charge of the provider pharmacy is responsible for all pharmacy operations involving the automated dispensing and delivery system located at the remote delivery site including supervision of the automated dispensing and delivery system and compliance with this section.

(B) The patient or patient's agent shall receive counseling via a direct link to audio or video communication by a Texas licensed pharmacist who has access to the complete patient medication record (patient profile) maintained by the provider pharmacy prior to the release of any new prescription released from the system.

(C) A pharmacist shall be accessible at all times to respond to patients' or other health professionals' questions and needs pertaining to drugs delivered through the use of the automated dispensing and delivery system. Such access may be through a 24 hour pager service or telephone which is answered 24 hours a day.

(D) The patient or patient's agent shall be given the option whether to use the system.

(E) An electronic notice shall be provided to the patient or patient's agent at the remote delivery site with the following information:

(i) the name and address of the pharmacy that verified the prescription; and

(ii) a statement that a pharmacist is available 24 hours a day, 7 days a week through the use of telephonic communication.

(F) Drugs stored in the automated dispensing and distribution system shall be stored at proper temperatures, as defined in the USP/NF and §291.15 of this title.

(G) A provider pharmacy may only provide remote pharmacy services using an automated dispensing and delivery system to patients at a board-approved remote delivery site.

(H) A provider pharmacy may provide remote pharmacy services at more than one remote delivery site.

(I) Before providing remote pharmacy services, the automated dispensing and delivery system at the remote delivery site must be tested by the provider pharmacy and found to dispense and deliver accurately. The provider pharmacy shall make the results of such testing available to the board upon request.

(J) A provider pharmacy which is licensed as an institutional (Class C) pharmacy is required to comply with the provisions of §§291.31 - 291.34 of this title and this section.

(4) Operational standards.

(A) Application to provide remote pharmacy services using an automated dispensing and delivery system.

(i) A community (Class A) or institutional (Class C) pharmacy shall file a completed application containing all information required by the board to provide remote pharmacy services using an automated dispensing and delivery system.

(ii) Such application shall be resubmitted every two years in conjunction with the application for renewal of the provider pharmacy's license.

(iii) Upon approval of the application, the provider pharmacy will be sent a certificate which must be displayed at the provider pharmacy.

(B) Notification requirements.

(i) A provider pharmacy shall notify the board in writing within ten days of a discontinuance of service.

(ii) A provider pharmacy shall comply with appropriate controlled substance registrations for each remote delivery site if dispensed controlled substances are maintained within an automated dispensing and delivery system at the facility.

(iii) A provider pharmacy shall file an application for change of location and/or name of a remote delivery site as specified in §291.3 of this title.

(C) Environment/Security.

(i) A provider pharmacy shall only store prescription drugs at a remote delivery site within an automated dispensing and delivery system which is locked by key, combination or other mechanical or electronic means so as to prohibit access by unauthorized personnel.

(ii) Access to the automated dispensing and delivery system shall be limited to pharmacists and pharmacy technicians or pharmacy technician trainees under the direct supervision of a pharmacist who:

(I) are designated in writing by the pharmacist-in-charge; and

(II) have completed documented training concerning their duties associated with the automated dispensing and delivery system.

(iii) Drugs shall be stored in compliance with the provisions of §291.15 of this title and §291.33(c)(8) of this title, including the requirements for temperature and the return of undelivered medication to stock.

(iv) the automated dispensing and delivery system must have an adequate security system, including security camera(s), to prevent unauthorized access and to maintain patient confidentiality.

(D) Stocking an automated dispensing and delivery system. Stocking of prescription drugs in an automated dispensing and delivery system shall be completed under the supervision of a pharmacist.

(E) Quality assurance program. A pharmacy that provides pharmacy services through an automated dispensing and delivery system at a remote delivery site shall operate according to a written program for quality assurance of the automated dispensing and delivery system which:

(i) requires continuous supervision of the automated dispensing and delivery system; and

(ii) establishes mechanisms and procedures to routinely test the accuracy of the automated dispensing and delivery system at a minimum of every six months and whenever any upgrade or change is made to the system and documents each such activity.

(F) Policies and procedures of operation.

(i) A pharmacy that provides pharmacy services through an automated dispensing and delivery system at a remote delivery site shall operate according to written policies and procedures. The policy and procedure manual shall include, but not be limited to, the following:

(I) a current list of the names and addresses of the pharmacist-in-charge and all personnel designated by the pharmacist-in-charge to have access to the prescription drugs stored in the automated dispensing and delivery system;

(II) duties which may only be performed by a pharmacist;

(III) a copy of the portion of the written contract or lease agreement between the pharmacy and the remote delivery site location which outlines the services to be provided and the responsibilities and accountabilities of each party relating to the operation of the automated dispensing and delivery system in fulfilling the terms of the contract in compliance with federal and state laws and regulations;

(IV) date of last review/revision of the policy and procedure manual; and

(V) policies and procedures for:

(-a-) security;

(-b-) operation of the automated dispensing and delivery system;

(-c-) preventative maintenance of the automated dispensing and delivery system;

(-d-) sanitation;

(-e-) storage of prescription drugs;

(-f-) supervision;

(-g-) delivery of prescription drugs; and

(-h-) recordkeeping.

(ii) A pharmacy that provides pharmacy services through an automated dispensing and delivery system at a remote delivery site shall, at least annually, review its written policies and procedures, revise them if necessary, and document the review.

(iii) A pharmacy providing remote pharmacy services using an automated dispensing and delivery system shall maintain a written plan for recovery from an event which interrupts the ability of the automated dispensing and delivery system to dispense and deliver prescription drugs. The written plan for recovery shall include:

(I) planning and preparation for maintaining pharmacy services when an automated dispensing and delivery system is experiencing downtime;

(II) procedures for response when an automated dispensing and delivery system is experiencing downtime; and

(III) procedures for the maintenance and testing of the written plan for recovery.

(5) Records.

(A) Maintenance of records.

(i) Every record required under this section must be:

(I) kept by the provider pharmacy and be available, for at least two years for inspecting and copying by the board or its representative and to other authorized local, state, or federal law enforcement agencies; and

(II) supplied by the provider pharmacy within 72 hours, if requested by an authorized agent of the Texas State Board of Pharmacy. If the pharmacy maintains the records in an electronic format, the requested records must be provided in an electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this section, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(ii) The provider pharmacy shall have a workable (electronic) data retention system which can produce a separate audit trail of drug delivery and retrieval transactions at each remote delivery site for the preceding two years.

(B) Transaction information.

(i) The automated dispensing and delivery system shall electronically record all transactions involving drugs stored in, removed, or delivered from the system.

(ii) Records of delivery from an automated dispensing and delivery system for a patient shall be maintained by the provider pharmacy and include the:

(I) identity of the system accessed;

(II) identification of the individual accessing the system;

(III) date of transaction;

(IV) prescription number, drug name, strength, dosage form;

(V) number of prescriptions retrieved;

(VI) name of the patient for whom the prescription was retrieved;

(VII) name of prescribing practitioner; and

(VIII) name of pharmacist responsible for consultation with the patient, if required, and documentation that the consultation was performed.

(iii) Records of stocking or removal from an automated dispensing and delivery system shall be maintained by the pharmacy and include the:

(I) count of bulk prescription drugs stored or removed;

(II) number of dispensed prescription packages removed;

(III) name, initials, or identification code of the person stocking or removing prescription drugs from the system; and

(IV) name, initials, or identification code of the pharmacist who checks and verifies that the system has been accurately filled.

(C) The pharmacy shall make the automated dispensing and delivery system and any records of the system, including testing records, available for inspection by the board.

(D) The automated dispensing and delivery system records a digital image of the individual accessing the system to pick-up a prescription and such record is maintained by the pharmacy for two years.

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

Filed with the Office of the Secretary of State on May 31, 2023.

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Julie Spier, R.Ph.
President
Texas State Board of Pharmacy
Earliest possible date of adoption: July 16, 2023
For further information, please call: (512) 305-8026

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SUBCHAPTER H. OTHER CLASSES OF PHARMACY

22 TAC §291.151

The Texas State Board of Pharmacy proposes amendments to §291.151, concerning Pharmacies Located in a Freestanding Emergency Medical Care Facility (Class F). The amendments, if adopted, clarify that a pharmacist must verify the completeness and reconciliation of the perpetual inventory of controlled substances for an FEMCF pharmacy.

Julie Spier, R.Ph., President, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Ms. Spier has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be clear and grammatically correct regulations. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendments will be in effect, Ms. Spier has determined the following:

(1) The proposed amendments do not create or eliminate a government program;

(2) Implementation of the proposed amendments does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed amendments does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed amendments do not require an increase or decrease in fees paid to the agency;

(5) The proposed amendments do not create a new regulation;

(6) The proposed amendments do not limit or expand an existing regulation;

(7) The proposed amendments do not increase or decrease the number of individuals subject to the rule's applicability because the rule continues to apply to all pharmacies located in a freestanding emergency medical care facility; and

(8) The proposed amendments do not positively or adversely affect this state's economy.

Written comments on the amendments may be submitted to Eamon D. Briggs, Deputy General Counsel, Texas State Board of Pharmacy, 1801 Congress Avenue, Suite 13.100, Austin, Texas 78701-1319, FAX (512) 305-8061. Comments must be received by 5:00 p.m., July 24, 2023.

The amendments are proposed under §§551.002 and 554.051 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§291.151. Pharmacies Located in a Freestanding Emergency Medical Care Facility (Class F).

(a) Purpose. The purpose of this section is to provide standards in the conduct, practice activities, and operation of a pharmacy located in a freestanding emergency medical care facility that is licensed by the Texas Department of State Health Services or in a freestanding emergency medical care facility operated by a hospital that is exempt from registration as provided by §254.052, Health and Safety Code. Class F pharmacies located in a freestanding emergency medical care facility shall comply with this section.

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

(1) Act--The Texas Pharmacy Act, Occupations Code, Subtitle J, as amended.

(2) Administer--The direct application of a prescription drug by injection, inhalation, ingestion, or any other means to the body of a patient by:

(A) a practitioner, an authorized agent under his supervision, or other person authorized by law; or

(B) the patient at the direction of a practitioner.

(3) Automated medication supply system--A mechanical system that performs operations or activities relative to the storage and distribution of medications for administration and which collects, controls, and maintains all transaction information.

(4) Board--The Texas State Board of Pharmacy.

(5) Consultant pharmacist--A pharmacist retained by a facility on a routine basis to consult with the FEMCF in areas that pertain to the practice of pharmacy.

(6) Controlled substance--A drug, immediate precursor, or other substance listed in Schedules I - V or Penalty Groups 1 - 4 of the Texas Controlled Substances Act, as amended, or a drug immediate precursor, or other substance included in Schedules I - V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended (Public Law 91-513).

(7) Dispense--Preparing, packaging, compounding, or labeling for delivery a prescription drug or device in the course of professional practice to an ultimate user or his agent by or pursuant to the lawful order of a practitioner.

(8) Distribute--The delivery of a prescription drug or device other than by administering or dispensing.

(9) Downtime--Period of time during which a data processing system is not operable.

(10) Electronic signature--A unique security code or other identifier which specifically identifies the person entering information into a data processing system. A facility which utilizes electronic signatures must:

(A) maintain a permanent list of the unique security codes assigned to persons authorized to use the data processing system; and

(B) have an ongoing security program which is capable of identifying misuse and/or unauthorized use of electronic signatures.

(11) Floor stock--Prescription drugs or devices not labeled for a specific patient and maintained at a nursing station or other FEMCF department (excluding the pharmacy) for the purpose of administration to a patient of the FEMCF.

(12) Formulary--List of drugs approved for use in the FEMCF by an appropriate committee of the FEMCF.

(13) Freestanding emergency medical care facility (FEMCF)--A freestanding facility that is licensed by the Texas Department of State Health Services pursuant to Chapter 254, Health and Safety Code, to provide emergency care to patients.

(14) Hard copy--A physical document that is readable without the use of a special device (i.e., data processing system, computer, etc.).

(15) Investigational new drug--New drug intended for investigational use by experts qualified to evaluate the safety and effectiveness of the drug as authorized by the federal Food and Drug Administration.

(16) Medication order--An order from a practitioner or his authorized agent for administration of a drug or device.

(17) Pharmacist-in-charge--Pharmacist designated on a pharmacy license as the pharmacist who has the authority or responsibility for a pharmacy's compliance with laws and rules pertaining to the practice of pharmacy.

(18) Pharmacy--Area or areas in a facility, separate from patient care areas, where drugs are stored, bulk compounded, delivered, compounded, dispensed, and/or distributed to other areas or departments of the FEMCF, or dispensed to an ultimate user or his or her agent.

(19) Prescription drug--

(A) A substance for which federal or state law requires a prescription before it may be legally dispensed to the public;

(B) A drug or device that under federal law is required, prior to being dispensed or delivered, to be labeled with either of the following statements:

(i) Caution: federal law prohibits dispensing without prescription or "Rx only" or another legend that complies with federal law; or

(ii) Caution: federal law restricts this drug to use by or on order of a licensed veterinarian; or

(C) A drug or device that is required by any applicable federal or state law or regulation to be dispensed on prescription only or is restricted to use by a practitioner only.

(20) Prescription drug order--

(A) An order from a practitioner or his authorized agent to a pharmacist for a drug or device to be dispensed; or

(B) An order pursuant to Subtitle B, Chapter 157, Occupations Code.

(21) Full-time pharmacist--A pharmacist who works in a pharmacy from 30 to 40 hours per week or if the pharmacy is open less than 60 hours per week, one-half of the time the pharmacy is open.

(22) Part-time pharmacist--A pharmacist who works less than full-time.

(23) Pharmacy technician--An individual who is registered with the board as a pharmacy technician and whose responsibility in a pharmacy is to provide technical services that do not require professional judgment regarding preparing and distributing drugs and who works under the direct supervision of and is responsible to a pharmacist.

(24) Pharmacy technician trainee--An individual who is registered with the board as a pharmacy technician trainee and is authorized to participate in a pharmacy's technician training program.

(25) Texas Controlled Substances Act--The Texas Controlled Substances Act, Health and Safety Code, Chapter 481, as amended.

(c) Personnel.

(1) Pharmacist-in-charge.

(A) General. Each FEMCF shall have one pharmacist-in-charge who is employed or under contract, at least on a consulting or part-time basis, but may be employed on a full-time basis.

(B) Responsibilities. The pharmacist-in-charge shall have the responsibility for, at a minimum, the following:

(i) establishing specifications for procurement and storage of all materials, including drugs, chemicals, and biologicals;

(ii) participating in the development of a formulary for the FEMCF, subject to approval of the appropriate committee of the FEMCF;

(iii) distributing drugs to be administered to patients pursuant to the practitioner's medication order;

(iv) filling and labeling all containers from which drugs are to be distributed or dispensed;

(v) maintaining and making available a sufficient inventory of antidotes and other emergency drugs, both in the pharmacy and patient care areas, as well as current antidote information, telephone numbers of regional poison control center and other emergency assistance organizations, and such other materials and information as may be deemed necessary by the appropriate committee of the FEMCF;

(vi) maintaining records of all transactions of the FEMCF pharmacy as may be required by applicable state and federal law, and as may be necessary to maintain accurate control over and accountability for all pharmaceutical materials;

(vii) participating in those aspects of the FEMCF's patient care evaluation program which relate to pharmaceutical material utilization and effectiveness;

(viii) participating in teaching and/or research programs in the FEMCF;

(ix) implementing the policies and decisions of the appropriate committee(s) relating to pharmaceutical services of the FEMCF;

(x) providing effective and efficient messenger and delivery service to connect the FEMCF pharmacy with appropriate areas of the FEMCF on a regular basis throughout the normal workday of the FEMCF;

(xi) labeling, storing, and distributing investigational new drugs, including maintaining information in the pharmacy and nursing station where such drugs are being administered, concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interactions, and symptoms of toxicity of investigational new drugs;

(xii) meeting all inspection and other requirements of the Texas Pharmacy Act and this section; and

(xiii) maintaining records in a data processing system such that the data processing system is in compliance with the requirements for an FEMCF; and

(xiv) ensuring that a pharmacist visits the FEMCF at least once each calendar week that the facility is open.

(2) Consultant pharmacist.

(A) The consultant pharmacist may be the pharmacist-in-charge.

(B) A written contract shall exist between the FEMCF and any consultant pharmacist, and a copy of the written contract shall be made available to the board upon request.

(3) Pharmacists.

(A) General.

(i) The pharmacist-in-charge shall be assisted by a sufficient number of additional licensed pharmacists as may be required to operate the FEMCF pharmacy competently, safely, and adequately to meet the needs of the patients of the facility.

(ii) All pharmacists shall assist the pharmacist-in-charge in meeting the responsibilities as outlined in paragraph (1)(B) of this subsection and in ordering, administering, and accounting for pharmaceutical materials.

(iii) All pharmacists shall be responsible for any delegated act performed by pharmacy technicians or pharmacy technician trainees under his or her supervision.

(iv) All pharmacists while on duty shall be responsible for complying with all state and federal laws or rules governing the practice of pharmacy.

(B) Duties. Duties of the pharmacist-in-charge and all other pharmacists shall include, but need not be limited to, the following:

(i) receiving and interpreting prescription drug orders and oral medication orders and reducing these orders to writing either manually or electronically;

(ii) selecting prescription drugs and/or devices and/or suppliers; and

(iii) interpreting patient profiles.

(C) Special requirements for compounding non-sterile preparations. All pharmacists engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

(4) Pharmacy technicians and pharmacy technician trainees.

(A) General. All pharmacy technicians and pharmacy technician trainees shall meet the training requirements specified in §297.6 of this title (relating to Pharmacy Technician and Pharmacy Technician Trainee Training).

(B) Duties. Pharmacy technicians and pharmacy technician trainees may not perform any of the duties listed in paragraph (3)(B) of this subsection. Duties may include, but need not be limited to, the following functions, under the direct supervision of a pharmacist:

(i) prepacking and labeling unit and multiple dose packages, provided a pharmacist supervises and conducts a final check and affixes his or her name, initials, or electronic signature to the appropriate quality control records prior to distribution;

(ii) preparing, packaging, compounding, or labeling prescription drugs pursuant to medication orders, provided a pharmacist supervises and checks the preparation;

(iii) compounding non-sterile preparations pursuant to medication orders provided the pharmacy technicians or pharmacy technician trainees have completed the training specified in §291.131 of this title;

(iv) bulk compounding, provided a pharmacist supervises and conducts in-process and final checks and affixes his or her name, initials, or electronic signature to the appropriate quality control records prior to distribution;

(v) distributing routine orders for stock supplies to patient care areas;

(vi) entering medication order and drug distribution information into a data processing system, provided judgmental decisions are not required and a pharmacist checks the accuracy of the information entered into the system prior to releasing the order or in compliance with the absence of pharmacist requirements contained in subsection (d)(6)(D) and (E) of this section;

(vii) maintaining inventories of drug supplies;

(viii) maintaining pharmacy records; and

(ix) loading drugs into an automated medication supply system. For the purpose of this clause, direct supervision may be accomplished by physically present supervision or electronic monitoring by a pharmacist.

(C) Procedures.

(i) Pharmacy technicians and pharmacy technician trainees shall handle medication orders in accordance with standard written procedures and guidelines.

(ii) Pharmacy technicians and pharmacy technician trainees shall handle prescription drug orders in the same manner as pharmacy technicians or pharmacy technician trainees working in a Class A pharmacy.

(D) Special requirements for compounding non-sterile preparations. All pharmacy technicians and pharmacy technician trainees engaged in compounding non-sterile preparations shall meet the training requirements specified in §291.131 of this title.

(5) Owner. The owner of an FEMCF pharmacy shall have responsibility for all administrative and operational functions of the pharmacy. The pharmacist-in-charge may advise the owner on administrative and operational concerns. The owner shall have responsibility for, at a minimum, the following, and if the owner is not a Texas licensed pharmacist, the owner shall consult with the pharmacist-in-charge or another Texas licensed pharmacist:

(A) establishing policies for procurement of prescription drugs and devices and other products dispensed from the FEMCF pharmacy;

(B) establishing and maintaining effective controls against the theft or diversion of prescription drugs;

(C) if the pharmacy uses an automated medication supply system, reviewing and approving all policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality, prevention of unauthorized access, and malfunction;

(D) providing the pharmacy with the necessary equipment and resources commensurate with its level and type of practice; and

(E) establishing policies and procedures regarding maintenance, storage, and retrieval of records in a data processing system such that the system is in compliance with state and federal requirements.

(6) Identification of pharmacy personnel. All pharmacy personnel shall be identified as follows:

(A) Pharmacy technicians. All pharmacy technicians shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacy technician.

(B) Pharmacy technician trainees. All pharmacy technician trainees shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacy technician trainee.

(C) Pharmacist interns. All pharmacist interns shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacist intern.

(D) Pharmacists. All pharmacists shall wear an identification tag or badge that bears the person's name and identifies him or her as a pharmacist.

(d) Operational standards.

(1) Licensing requirements.

(A) An FEMCF pharmacy shall register annually or biennially with the board on a pharmacy license application provided by the board, following the procedures specified in §291.1 of this title (relating to Pharmacy License Application).

(B) An FEMCF pharmacy which changes ownership shall notify the board within 10 days of the change of ownership and apply for a new and separate license as specified in §291.3 of this title (relating to Required Notifications).

(C) An FEMCF pharmacy which changes location and/or name shall notify the board of the change within 10 days and file for an amended license as specified in §291.3 of this title.

(D) A pharmacy owned by a partnership or corporation which changes managing officers shall notify the board in writing of the names of the new managing officers within 10 days of the change, following the procedures in §291.3 of this title.

(E) An FEMCF pharmacy shall notify the board in writing within 10 days of closing, following the procedures in §291.5 of this title (relating to Closing a Pharmacy).

(F) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for issuance and renewal of a license and the issuance of an amended license.

(G) A separate license is required for each principal place of business and only one pharmacy license may be issued to a specific location.

(H) An FEMCF pharmacy, which also operates another type of pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(1), concerning community pharmacy (Class A), is not required to secure a license for the other type of pharmacy; provided, however, such license is required to comply with the provisions of §291.31 of this title (relating to Definitions), §291.32 of this title (relating to Personnel), §291.33 of this title (relating to Operational Standards), §291.34 of this title (relating to Records), and §291.35 of this title (relating to Official Prescription Requirements), to the extent such sections are applicable to the operation of the pharmacy.

(I) An FEMCF pharmacy engaged in the compounding of non-sterile preparations shall comply with the provisions of §291.131 of this title.

(2) Environment.

(A) General requirements.

(i) Each FEMCF shall have a designated work area separate from patient areas, and which shall have space adequate for the size and scope of pharmaceutical services and shall have adequate space and security for the storage of drugs.

(ii) The FEMCF pharmacy shall be arranged in an orderly fashion and shall be kept clean. All required equipment shall be clean and in good operating condition.

(B) Special requirements.

(i) The FEMCF pharmacy shall have locked storage for Schedule II controlled substances and other controlled drugs requiring additional security.

(ii) The FEMCF pharmacy shall have a designated area for the storage of poisons and externals separate from drug storage areas.

(C) Security.

(i) The pharmacy and storage areas for prescription drugs and/or devices shall be enclosed and capable of being locked by

key, combination, or other mechanical or electronic means, so as to prohibit access by unauthorized individuals. Only individuals authorized by the pharmacist-in-charge may enter the pharmacy or have access to storage areas for prescription drugs and/or devices.

(ii) The pharmacist-in-charge shall consult with FEMCF personnel with respect to security of the drug storage areas, including provisions for adequate safeguards against theft or diversion of dangerous drugs, controlled substances, and records for such drugs.

(iii) The pharmacy shall have locked storage for Schedule II controlled substances and other drugs requiring additional security.

(3) Equipment and supplies. FEMCFs supplying drugs for outpatient use shall have the following equipment and supplies:

(A) data processing system including a printer or comparable equipment;

(B) adequate supply of child-resistant, moisture-proof, and light-proof containers; and

(C) adequate supply of prescription labels and other applicable identification labels.

(4) Library. A reference library shall be maintained that includes the following in hard copy or electronic format and that pharmacy personnel shall be capable of accessing at all times:

(A) current copies of the following:

(i) Texas Pharmacy Act and rules;

(ii) Texas Dangerous Drug Act and rules;

(iii) Texas Controlled Substances Act and rules; and

(iv) Federal Controlled Substances Act and rules or official publication describing the requirements of the Federal Controlled Substances Act and rules;

(B) at least one current or updated general drug information reference which is required to contain drug interaction information including information needed to determine severity or significance of the interaction and appropriate recommendations or actions to be taken; and

(C) basic antidote information and the telephone number of the nearest regional poison control center.

(5) Drugs.

(A) Procurement, preparation, and storage.

(i) The pharmacist-in-charge shall have the responsibility for the procurement and storage of drugs, but may receive input from other appropriate staff of the facility, relative to such responsibility.

(ii) The pharmacist-in-charge shall have the responsibility for determining specifications of all drugs procured by the facility.

(iii) FEMCF pharmacies may not sell, purchase, trade, or possess prescription drug samples, unless the pharmacy meets the requirements as specified in §291.16 of this title (relating to Samples).

(iv) All drugs shall be stored at the proper temperatures, as defined in the USP/NF and in §291.15 of this title (relating to Storage of Drugs).

(v) Any drug bearing an expiration date may not be dispensed or distributed beyond the expiration date of the drug.

(vi) Outdated drugs shall be removed from dispensing stock and shall be quarantined together until such drugs are disposed of.

(B) Formulary.

(i) A formulary may be developed by an appropriate committee of the FEMCF.

(ii) The pharmacist-in-charge, consultant pharmacist, or designee shall be a full voting member of any committee which involves pharmaceutical services.

(iii) A practitioner may grant approval for pharmacists at the FEMCF to interchange, in accordance with the facility's formulary, for the drugs on the practitioner's medication orders provided:

(I) a formulary has been developed;

(II) the formulary has been approved by the medical staff of the FEMCF;

(III) there is a reasonable method for the practitioner to override any interchange; and

(IV) the practitioner authorizes a pharmacist in the FEMCF to interchange on his/her medication orders in accordance with the facility's formulary through his/her written agreement to abide by the policies and procedures of the medical staff and facility.

(C) Prepackaging and loading drugs into automated medication supply system.

(i) Prepackaging of drugs.

(I) Drugs may be prepackaged in quantities suitable for internal distribution only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist.

(II) The label of a prepackaged unit shall indicate:

(-a-) brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor;

(-b-) facility's lot number;

(-c-) expiration date; and

(-d-) quantity of the drug, if quantity is greater than one.

(III) Records of prepackaging shall be maintained to show:

(-a-) the name of the drug, strength, and dosage form;

(-b-) facility's lot number;

(-c-) manufacturer or distributor;

(-d-) manufacturer's lot number;

(-e-) expiration date;

(-f-) quantity per prepackaged unit;

(-g-) number of prepackaged units;

(-h-) date packaged;

(-i-) name, initials, or electronic signature of the prepacker; and

(-j-) signature or electronic signature of the responsible pharmacist.

(IV) Stock packages, repackaged units, and control records shall be quarantined together until checked/released by the pharmacist.

(ii) Loading bulk unit of use drugs into automated medication supply systems. Automated medication supply systems

may be loaded with bulk unit of use drugs only by a pharmacist, by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist, or by a licensed nurse who is authorized by the pharmacist to perform the loading of the automated medication supply system. For the purpose of this clause, direct supervision may be accomplished by physically present supervision or electronic monitoring by a pharmacist. In order for the pharmacist to electronically monitor, the medication supply system must allow for bar code scanning to verify the loading of drugs, and a record of the loading must be maintained by the system and accessible for electronic review by the pharmacist.

(6) Medication orders.

(A) Drugs may be administered to patients in FEMCFs only on the order of a practitioner. No change in the order for drugs may be made without the approval of a practitioner except as authorized by the practitioner in compliance with paragraph (5)(B) of this subsection.

(B) Drugs may be distributed only pursuant to the copy of the practitioner's medication order.

(C) FEMCF pharmacies shall be exempt from the labeling provisions and patient notification requirements of §562.006 and §562.009 of the Act, as respects drugs distributed pursuant to medication orders.

(D) In FEMCFs with a full-time pharmacist, if a practitioner orders a drug for administration to a bona fide patient of the facility when the pharmacy is closed, the following is applicable:

(i) prescription drugs and devices only in sufficient quantities for immediate therapeutic needs of a patient may be removed from the FEMCF pharmacy;

(ii) only a designated licensed nurse or practitioner may remove such drugs and devices;

(iii) a record shall be made at the time of withdrawal by the authorized person removing the drugs and devices. The record shall contain the following information:

(I) name of the patient;

(II) name of device or drug, strength, and dosage form;

(III) dose prescribed;

(IV) quantity withdrawn;

(V) time and date; and

(VI) signature or electronic signature of the person making the withdrawal;

(iv) the medication order in the patient's chart may substitute for such record, provided the medication order meets all the requirements of clause (iii) of this subparagraph;

(v) the pharmacist shall verify the withdrawal of a controlled substance as soon as practical, but in no event more than 72 hours from the time of such withdrawal; and

(vi) the pharmacist shall verify the withdrawal of a dangerous drug at a reasonable interval, but such verification must occur at least once in every calendar week.

(E) In FEMCFs with a part-time or consultant pharmacist, if a practitioner orders a drug for administration to a bona fide patient of the FEMCF when the pharmacist is not on duty, or when the pharmacy is closed, the following is applicable:

(i) prescription drugs and devices only in sufficient quantities for therapeutic needs may be removed from the FEMCF pharmacy;

(ii) only a designated licensed nurse or practitioner may remove such drugs and devices;

(iii) a record shall be made at the time of withdrawal by the authorized person removing the drug or device as described in clauses (6)(D)(iii) and (iv) of this subsection; and

(iv) the pharmacist shall verify withdrawals at a reasonable interval, but such verification must occur at least once in every calendar week that the pharmacy is open.

(7) Floor stock. In facilities using a floor stock method of drug distribution, the pharmacy shall establish designated floor stock areas outside of the central pharmacy where drugs may be stored, in accordance with the pharmacy's policies and procedures. The following is applicable for removing drugs or devices in the absence of a pharmacist:

(A) prescription drugs and devices may be removed from the pharmacy only in the original manufacturer's container or prepackaged container;

(B) only a designated licensed nurse or practitioner may remove such drugs and devices;

(C) a record shall be made at the time of withdrawal by the authorized person removing the drug or device and the record shall contain the following information:

(i) name of the drug, strength, and dosage form;

(ii) quantity removed;

(iii) location of floor stock;

(iv) date and time; and

(v) signature or electronic signature of person making the withdrawal;

(D) the medication order in the patient's chart may substitute for the record required in subparagraph (C) of this paragraph, provided the medication order meets all the requirements of subparagraph (C) of this paragraph; and

(E) if a stored drug or device is returned to the pharmacy from floor stock areas, a record shall be made by the authorized person returning the drug or device. The record shall contain the following information:

(i) drug name, strength, and dosage form, or device name;

(ii) quantity returned;

(iii) previous floor stock location for the drug or device;

(iv) date and time; and

(v) signature or electronic signature of person returning the drug or device.

(8) Policies and procedures. Written policies and procedures for a drug distribution system, appropriate for the freestanding emergency medical facility, shall be developed and implemented by the pharmacist-in-charge with the advice of the appropriate committee. The written policies and procedures for the drug distribution system shall include, but not be limited to, procedures regarding the following:

(A) controlled substances;

(B) investigational drugs;

(C) prepackaging and manufacturing;

(D) medication errors;

(E) orders of physician or other practitioner;

(F) floor stocks;

(G) adverse drug reactions;

(H) drugs brought into the facility by the patient;

(I) self-administration;

(J) emergency drug tray;

(K) formulary, if applicable;

(L) drug storage areas;

(M) drug samples;

(N) drug product defect reports;

(O) drug recalls;

(P) outdated drugs;

(Q) preparation and distribution of IV admixtures;

(R) procedures for supplying drugs for postoperative use, if applicable;

(S) use of automated medication supply systems;

(T) use of data processing systems; and

(U) drug regimen review.

(9) Drugs supplied for outpatient use. Drugs provided to patients for take home use shall be supplied according to the following procedures.

(A) Drugs may only be supplied to patients who have been admitted to the FEMCF.

(B) Drugs may only be supplied in accordance with the system of control and accountability established for drugs supplied from the FEMCF; such system shall be developed and supervised by the pharmacist-in-charge or staff pharmacist designated by the pharmacist-in-charge.

(C) Only drugs listed on the approved outpatient drug list may be supplied; such list shall be developed by the pharmacist-in-charge and the medical staff and shall consist of drugs of the nature and type to meet the immediate postoperative needs of the FEMCF patient.

(D) Drugs may only be supplied in prepackaged quantities not to exceed a 72-hour supply in suitable containers and appropriately prelabeled (including name, address, and phone number of the facility and necessary auxiliary labels) by the pharmacy, provided, however that topicals and ophthalmics in original manufacturer's containers may be supplied in a quantity exceeding a 72-hour supply.

(E) At the time of delivery of the drug, the practitioner shall complete the label, such that the prescription container bears a label with at least the following information:

(i) date supplied;

(ii) name of practitioner;

(iii) name of patient;

(iv) directions for use;

(v) brand name and strength of the drug; or if no brand name, then the generic name of the drug dispensed, strength, and the name of the manufacturer or distributor of the drug; and

(vi) unique identification number.

(F) After the drug has been labeled, the practitioner or a licensed nurse under the supervision of the practitioner shall give the appropriately labeled, prepackaged medication to the patient.

(G) A perpetual record of drugs which are supplied from the FEMCF shall be maintained which includes:

(i) name, address, and phone number of the facility;

(ii) date supplied;

(iii) name of practitioner;

(iv) name of patient;

(v) directions for use;

(vi) brand name and strength of the drug; or if no brand name, then the generic name of the drug dispensed, strength, and the name of the manufacturer or distributor of the drug; and

(vii) unique identification number.

(H) The pharmacist-in-charge, or a pharmacist designated by the pharmacist-in-charge, shall review the records at least once in every calendar week that the pharmacy is open.

(10) Drug regimen review.

(A) A pharmacist shall evaluate medication orders and patient medication records for:

(i) known allergies;

(ii) rational therapy--contraindications;

(iii) reasonable dose and route of administration;

(iv) reasonable directions for use;

(v) duplication of therapy;

(vi) drug-drug interactions;

(vii) drug-food interactions;

(viii) drug-disease interactions;

(ix) adverse drug reactions;

(x) proper utilization, including overutilization or underutilization; and

(xi) clinical laboratory or clinical monitoring methods to monitor and evaluate drug effectiveness, side effects, toxicity, or adverse effects, and appropriateness to continued use of the drug in its current regimen.

(B) A retrospective, random drug regimen review as specified in the pharmacy's policies and procedures shall be conducted on a periodic basis to verify proper usage of drugs not to exceed 31 days between such reviews.

(C) Any questions regarding the order must be resolved with the prescriber and a written notation of these discussions made and maintained.

(e) Records.

(1) Maintenance of records.

(A) Every inventory or other record required to be kept under the provisions of this section (relating to Pharmacies Located in a Freestanding Emergency Medical Care Facility (Class F) shall be:

(i) kept by the pharmacy and be available, for at least two years from the date of such inventory or record, for inspecting and copying by the board or its representative, and other authorized local, state, or federal law enforcement agencies; and

(ii) supplied by the pharmacy within 72 hours, if requested by an authorized agent of the board. If the pharmacy maintains the records in an electronic format, the requested records must be provided in a mutually agreeable electronic format if specifically requested by the board or its representative. Failure to provide the records set out in this subsection, either on site or within 72 hours, constitutes prima facie evidence of failure to keep and maintain records in violation of the Act.

(B) Records of controlled substances listed in Schedule II shall be maintained separately and readily retrievable from all other records of the pharmacy.

(C) Records of controlled substances listed in Schedules III - V shall be maintained separately or readily retrievable from all other records of the pharmacy. For purposes of this subparagraph, "readily retrievable" means that the controlled substances shall be asterisked, redlined, or in some other manner readily identifiable apart from all other items appearing on the record.

(D) Records, except when specifically required to be maintained in original or hard copy form, may be maintained in an alternative data retention system, such as a data processing or direct imaging system, provided:

(i) the records in the alternative data retention system contain all of the information required on the manual record; and

(ii) the alternative data retention system is capable of producing a hard copy of the record upon the request of the board, its representative, or other authorized local, state, or federal law enforcement or regulatory agencies.

(E) Controlled substance records shall be maintained in a manner to establish receipt and distribution of all controlled substances.

(F) An FEMCF pharmacy shall maintain a perpetual inventory of controlled substances listed in Schedules II - V which shall be verified by a pharmacist for completeness and reconciled at least once in every calendar week that the pharmacy is open.

(G) Distribution records for controlled substances, listed in Schedules II - V, shall include the following information:

(i) patient's name;

(ii) practitioner's name who ordered the drug;

(iii) name of drug, dosage form, and strength;

(iv) time and date of administration to patient and quantity administered;

(v) signature or electronic signature of individual administering the controlled substance;

(vi) returns to the pharmacy; and

(vii) waste (waste is required to be witnessed and cosigned, manually or electronically, by another individual).

(H) The record required by subparagraph (G) of this paragraph shall be maintained separately from patient records.

(I) A pharmacist shall conduct an audit by randomly comparing the distribution records required by subparagraph (G) of this paragraph with the medication orders in the patient record on a periodic basis to verify proper administration of drugs not to exceed 30 days between such reviews.

(2) Patient records.

(A) Each medication order or set of orders issued together shall bear the following information:

(i) patient name;

(ii) drug name, strength, and dosage form;

(iii) directions for use;

(iv) date; and

(v) signature or electronic signature of the practitioner or that of his or her authorized agent, defined as a licensed nurse employee or consultant/full or part-time pharmacist of the FEMCF.

(B) Medication orders shall be maintained with the medication administration record in the medical records of the patient.

(3) General requirements for records maintained in a data processing system.

(A) If an FEMCF pharmacy's data processing system is not in compliance with the board's requirements, the pharmacy must maintain a manual recordkeeping system.

(B) The facility shall maintain a backup copy of information stored in the data processing system using disk, tape, or other electronic backup system and update this backup copy on a regular basis to assure that data is not lost due to system failure.

(C) A pharmacy that changes or discontinues use of a data processing system must:

(i) transfer the records to the new data processing system; or

(ii) purge the records to a printout which contains:

(I) all of the information required on the original document; or

(II) for records of distribution and return for all controlled substances, the same information as required on the audit trail printout as specified in subparagraph (F) of this paragraph. The information on the printout shall be sorted and printed by drug name and list all distributions and returns chronologically.

(D) Information purged from a data processing system must be maintained by the pharmacy for two years from the date of initial entry into the data processing system.

(E) The pharmacist-in-charge shall report to the board in writing any significant loss of information from the data processing system within 10 days of discovery of the loss.

(F) The data processing system shall have the capacity to produce a hard copy printout of an audit trail of drug distribution and return for any strength and dosage form of a drug (by either brand or generic name or both) during a specified time period. This printout shall contain the following information:

(i) patient's name or patient's facility identification number;

(ii) prescribing or attending practitioner's name;

(iii) name, strength, and dosage form of the drug product actually distributed;

(iv) total quantity distributed from and returned to the pharmacy;

(v) if not immediately retrievable via electronic image, the following shall also be included on the printout:

(I) prescribing or attending practitioner's address; and

(II) practitioner's DEA registration number, if the medication order is for a controlled substance.

(G) An audit trail printout for each strength and dosage form of the drugs distributed during the preceding month shall be produced at least monthly and shall be maintained in a separate file at the facility. The information on this printout shall be sorted by drug name and list all distributions/returns for that drug chronologically.

(H) The pharmacy may elect not to produce the monthly audit trail printout if the data processing system has a workable (electronic) data retention system which can produce an audit trail of drug distribution and returns for the preceding two years. The audit trail required in this clause shall be supplied by the pharmacy within 72 hours, if requested by an authorized agent of the board, or other authorized local, state, or federal law enforcement or regulatory agencies.

(I) In the event that an FEMCF pharmacy which uses a data processing system experiences system downtime, the pharmacy must have an auxiliary procedure which will ensure that all data is retained for online data entry as soon as the system is available for use again.

(4) Distribution of controlled substances to another registrant. A pharmacy may distribute controlled substances to a practitioner, another pharmacy, or other registrant, without being registered to distribute, under the following conditions.

(A) The registrant to whom the controlled substance is to be distributed is registered under the Controlled Substances Act to possess that controlled substance.

(B) The total number of dosage units of controlled substances distributed by a pharmacy may not exceed 5.0% of all controlled substances dispensed by the pharmacy during the 12-month period in which the pharmacy is registered; if at any time it does exceed 5.0%, the pharmacy is required to obtain an additional registration to distribute controlled substances.

(C) If the distribution is for a Schedule III, IV, or V controlled substance, a record shall be maintained which indicates:

(i) the actual date of distribution;

(ii) the name, strength, and quantity of controlled substances distributed;

(iii) the name, address, and DEA registration number of the distributing pharmacy; and

(iv) the name, address, and DEA registration number of the pharmacy, practitioner, or other registrant to whom the controlled substances are distributed.

(D) A pharmacy shall comply with 21 CFR 1305 regarding the DEA order form (DEA 222) requirements when distributing a Schedule II controlled substance.

(5) Other records. Other records to be maintained by the pharmacy include:

(A) a permanent log of the initials or identification codes which identifies each pharmacist by name. The initials or identification code shall be unique to ensure that each pharmacist can be identified, i.e., identical initials or identification codes cannot be used;

(B) suppliers' invoices of dangerous drugs and controlled substances dated and initialed or signed by the person receiving the drugs;

(i) a pharmacist shall verify that the controlled substances listed on the invoices were added to the pharmacy's perpetual inventory by clearly recording his/her initials and the date of review of the perpetual inventory; and

(ii) for controlled substances, the documents retained must contain the name, strength and quantity of controlled substances distributed, and the name, address and DEA number of both registrants; the supplier and the receiving pharmacy;

(C) supplier's credit memos for controlled substances and dangerous drugs;

(D) a copy of inventories required by §291.17 of this title (relating to Inventory Requirements) except that a perpetual inventory of controlled substances listed in Schedule II may be kept in a data processing system if the data processing system is capable of producing a hard copy of the perpetual inventory on site;

(E) reports of surrender or destruction of controlled substances and/or dangerous drugs to an appropriate state or federal agency or reverse distributor;

(F) records of distribution of controlled substances and/or dangerous drugs to other pharmacies, practitioners, or registrants; and

(G) a copy of any notification required by the Texas Pharmacy Act or these rules, including, but not limited to, the following:

(i) reports of theft or significant loss of controlled substances to DEA and the board;

(ii) notification of a change in pharmacist-in-charge of a pharmacy; and

(iii) reports of a fire or other disaster which may affect the strength, purity, or labeling of drugs, medications, devices, or other materials used in the diagnosis or treatment of injury, illness, and disease.

(6) Permission to maintain central records. Any pharmacy that uses a centralized recordkeeping system for invoices and financial data shall comply with the following procedures.

(A) Controlled substance records. Invoices and financial data for controlled substances may be maintained at a central location provided the following conditions are met:

(i) Prior to the initiation of central recordkeeping, the pharmacy submits written notification by registered or certified mail to the divisional director of DEA as required by the Code of Federal Regulations, Title 21, §1304(a), and submits a copy of this written notification to the board. Unless the registrant is informed by the divisional director of DEA that permission to keep central records is denied, the pharmacy may maintain central records commencing 14 days after receipt of notification by the divisional director;

(ii) The pharmacy maintains a copy of the notification required in this subparagraph; and

(iii) The records to be maintained at the central record location shall not include executed DEA order forms, prescription drug orders, or controlled substance inventories, which shall be maintained at the pharmacy.

(B) Dangerous drug records. Invoices and financial data for dangerous drugs may be maintained at a central location.

(C) Access to records. If the records are kept on microfilm, computer media, or in any form requiring special equipment to render the records easily readable, the pharmacy shall provide access to such equipment with the records.

(D) Delivery of records. The pharmacy agrees to deliver all or any part of such records to the pharmacy location within two business days of written request of a board agent or any other authorized official.

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

Filed with the Office of the Secretary of State on May 31, 2023.

TRD-202302012
Julie Spier, R.Ph.
President
Texas State Board of Pharmacy
Earliest possible date of adoption: July 16, 2023
For further information, please call: (512) 305-8026

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PART 16. TEXAS BOARD OF PHYSICAL THERAPY EXAMINERS

CHAPTER 343. CONTESTED CASE PROCEDURE

22 TAC §§343.5, 343.6, 343.8, 343.9, 343.21, 343.22, 343.36, 343.40, 343.41

The Texas Board of Physical Therapy Examiners (board) proposes amending Chapter 343. Contested Case Procedures, Occupations Code. Specifically, the Board proposes amendments to §343.5. Licensure of Persons with a History of Substance Abuse, §343.6. Other Grounds for Denial of a License or Discipline of a Licensee, §343.8. Licensure of Persons with a History of Voluntary or Involuntary Psychiatric Hospitalization, §343.9. Licensure of Persons with Criminal Convictions, §343.21. Witness Fees and Expenses, §343.22. Service of Notice, §343.36. Filing and Receipt of Complaints, §343.40. Informal Conference, and §343.41. Agreed Orders.

The amendments are proposed in order to provide clarity to the procedures for contested cases, to correct inaccurate and outdated references, and to conform the rules with the physical therapy provisions in Chapter 453, Occupations Code; with the administrative procedures in Chapter 2001, Government Code; and with the consequences of criminal conviction in Chapter 53, Occupations Code.

Section-by-Section Summary

Section 343.5. Licensure of Persons with a History of Substance Abuse would be amended to conform with Section 453.351(a)(2), Occupations Code which provides that the board can discipline a license holder who has used drugs or intoxicating liquors to an extent that affects the license holder's or applicant's professional competence, but does not permit the board to consider history of substance abuse. Also, the amendment would eliminate the need for letters of recommendation to be notarized.

Section 343.6. Other Grounds for Denial of a License or Discipline of a Licensee would be amended to correct an outdated reference to the Act.

Section 343.8. Licensure of Persons with a History of Voluntary or Involuntary Psychiatric Hospitalization would be amended to eliminate the need for letters of recommendation to be notarized.

Section 343.9. Licensure of Persons with Criminal Convictions would be amended to conform the considerations of whether a crime relates to physical therapy with the provisions in Chapter 53, Occupations Code section 53.022(5), and to conform the considerations in determining the respondent's/applicant's present fitness to practice physical therapy with the factors in Chapter 53, Occupations Code section 53.023(a)(1)-(7).

Section 343.21. Witness Fees and Expenses would be amended to correct an outdated reference for witness reimbursement of expenses.

Section 343.22. Service of Notice would be amended to conform the service of notice of a hearing in accordance with Texas Government Code, §2001.051 and §2001.052.

Section 343.36. Filing and Receipt of Complaints would be amended correct an inaccurate reference to the Government Code.

Section 343.40. Informal Conference would be amended to eliminate the requirement of complaints having to be sworn; to provide consistency with the use of "informal settlement conference" throughout the section; adding staff authorization to decide on time, date, and place of an informal settlement conference and to cancel an informal settlement conference upon notice of non-attendance by the licensee of applicant; to eliminate the requirement for certified mail/return receipt and allowing for sending notices electronically or by mail; to require waiver of 10-day notice to be submitted in writing by applicant or licensee; to clarify that committee refers to the investigation committee and attorney refers to the board's attorney; to update the reference for access to the board's investigative files; and to reword disposition of complaint for clarification.

Section 343.41. Agreed Orders would be amended to clarify that an agreed order is proposed until adopted by the board; to eliminate the executive director's authority to approve agreed orders; to allow for methods of service of an Agreed Order in accordance with Government Code §2001.142; to eliminate the need for notarization of agreed orders; to authorize the board chair to sign an approved agreed order on behalf of the board; to eliminate the requirement to send a copy of the agreed order to the licensee's employer and facility administrator; to eliminate the prohibition of board member who participated in the investigation of a complaint or formulation of the agreed order to participate in the board review of the agreed order; and to clarify the disposition of an order that the board does not approve.

Fiscal Note

Ralph A. Harper, Executive Director of the Executive Council of Physical Therapy & Occupational Therapy Examiners, has determined that for the first five-year period the amendments are in effect there would be no loss of revenue, and there would be

no fiscal implication to units of local government as a result of enforcing or administering the rules.

Public Benefits and Costs

Mr. Harper has determined that for the first five-year period these amendments are in effect, the public benefit will be providing increased clarity of the procedures for a contested case. Additionally, there will be no cost to the public.

Local Employment Economic Impact Statement

The amendments are not anticipated to impact a local economy, so a local employment economic impact statement is not required.

Small and Micro-Businesses and Rural Communities Impact

Mr. Harper has determined that there will be no costs or adverse economic effects to small or micro-businesses or rural communities; therefore, an economic impact statement or regulatory flexibility analysis is not required.

Government Growth Impact Statement

During the first five-year period these amendments are in effect, the impact on government growth is as follows:

(1) The proposed rule amendments will neither create nor eliminate a government program.

(2) The proposed rule amendments will neither create new employee positions nor eliminate existing employee positions.

(3) The proposed rule amendments will neither increase nor decrease future legislative appropriations to the agency.

(4) The proposed rule amendments will neither require an increase nor a decrease in fees paid to the agency.

(5) The proposed rule amendments revise the language to existing regulation but does not create a new regulation.

(6) The proposed rule amendments will neither repeal nor limit an existing regulation.

(7) The proposed rule amendments will neither increase nor decrease the number of individuals subject to the rule's applicability.

(8) The proposed rule amendment will neither positively nor adversely affect this state's economy.

Takings Impact Assessment The proposed rule amendment will not impact private real property as defined by Tex. Gov't Code §2007.003, so a takings impact assessment under Tex. Gov't Code §2001.043 is not required.

Requirement for Rule Increasing Costs to Regulated Persons

Tex. Gov't Code §2001.0045, Requirement for Rule Increasing Costs to Regulated Persons, does not apply to this proposed rule because the amendments will not increase costs to regulated persons.

Public Comment

Comments on the proposed amendments may be submitted to Karen Gordon, PT Coordinator, Texas Board of Physical Therapy Examiners, 1801 Congress Ave, Suite 10.900, Austin, Texas 78701; email: karen@ptot.texas.gov. Comments must be received no later than 30 days from the date this proposed amendment is published in the *Texas Register.*

Statutory Authority

The amendments are proposed under Texas Occupation Code §453.102, which authorizes the board to adopt rules necessary to implement chapter 453.

Cross-reference to Statute

The proposed amendment implements provisions in Chapter 453, Subchapter H, Occupations Code that pertains to disciplinary action and procedure. No other statutes, articles, or codes are affected by the proposed amendments.

§343.5. Licensure of Persons with [~~a History of~~] Substance Abuse or Addiction.

(a) The board may deny a license to or discipline an applicant/respondent who used drugs or intoxicating liquors to an extent that affects the license holder's or applicant's professional competence. [~~has been found to have a history of substance abuse.~~]

(b) In review of a complaint alleging intemperate use of drugs or alcohol by a respondent/applicant, the board shall consider the following evidence in determining the respondent's/applicant's present fitness to practice physical therapy:

(1) - (4) (No change.)

(5) [~~notarized~~] letters of recommendation.

(c) - (d) (No change.)

§343.6. Other Grounds for Denial of a License or Discipline of a Licensee.

(a) Grounds for the board to deny a license to or discipline an applicant/respondent may include the following:

(1) - (2) (No change.)

(3) failure to meet the qualifications for licensure as set forth in the Act, §453.203 [~~§§8, 9, or 10~~], as applicable, and/or to any other rules or procedures set forth by the board relating to these sections;

(4) (No change.)

(b) (No change.)

§343.8. Licensure of Persons with a History of Voluntary or Involuntary Psychiatric Hospitalization.

(a) (No change.)

(b) In review of a complaint alleging that the respondent/applicant has a history of voluntary or involuntary psychiatric hospitalization, the board shall consider the following evidence in determining the respondent's/applicant's present fitness to practice physical therapy:

(1) - (3) (No change.)

(4) [~~notarized~~] letters of recommendation.

(c) (No change.)

§343.9. Licensure of Persons with Criminal Convictions.

(a) The board may revoke or suspend an existing valid license, disqualify a person from receiving or renewing a license, or deny to a person the opportunity to be examined for a license because of a person's conviction of a felony or misdemeanor if the crime directly relates to the practice of physical therapy. Those crimes which the board considers to be directly related to the duties and responsibilities of a licensed physical therapist or physical therapist assistant shall include, but are not limited to:

(1) (No change.)

(2) any criminal violation of the [~~Physical Therapy Practice~~] Act or other statutes regulating or pertaining to physical therapy or the medical profession;

(3) - (16) (No change.)

(b) In determining whether a crime not listed previously relates to physical therapy, the board will consider:

(1) - (2) (No change.)

(3) the extent to which a license might offer opportunities to engage in further criminal activity of the same type as that in which the person was previously engaged; [~~and~~]

(4) the relationship of the crime to the ability, capacity, or fitness required to perform the duties and to discharge the responsibilities of a physical therapist or physical therapist assistant; and[~~.~~]

(5) any correlation between the elements of the crime and the duties and responsibilities of a physical therapist or physical therapist assistant.

(c) In review of a complaint alleging that the respondent/applicant has been convicted of a crime which directly relates to the duties and responsibilities of a physical therapist or physical therapist assistant, the board shall consider the following evidence in determining the respondent's/applicant's present fitness to practice physical therapy:

(1) - (2) (No change.)

(3) the amount of time that has elapsed since the person's last criminal activity;

(4) [~~(3)~~] the conduct and work activity of the person before [~~prior to~~] and after the criminal activity;

(5) [~~(4)~~] evidence of the person's rehabilitation or rehabilitative effort while incarcerated or after [~~following~~] release;

(6) [~~(5)~~] evidence of the person's compliance with any condition of community supervision, parole, or mandatory supervision, including [~~notarized~~] letters of recommendation from prosecution, law enforcement, and correctional officers who prosecuted, arrested, or had custodial responsibility for the person; letters from the sheriff or chief of police where the person resides; and other persons having contact with the convicted person; and

(7) [~~(6)~~] other evidence of the person's fitness, including letters of recommendation, records of steady employment, provision for dependents, payment of all court costs, supervision fees, fines, and restitution if ordered as a result of the person's conviction.

(d) - (e) (No change.)

§343.21. Witness Fees and Expenses.

A witness who is not a party to the proceeding and who is subpoenaed to appear at a deposition or hearing or to produce documents, records, or other tangible things, shall receive reimbursement for expenses incurred in complying with the subpoena. Reimbursement shall be in accordance with Government Code, §2001.103 [~~be based on the minimum set forth in the Administrative Procedure and Texas Register Act (APTRA) or the State of Texas Travel Allowance Guide issued by the Comptroller of Public Accounts, whichever is greater~~]. Said amount shall be paid by the party at whose request the witness is subpoenaed.

§343.22. Service of Notice.

Service of notice of hearing [~~or investigation~~] on the respondent/applicant shall be complete and effective in accordance with Texas Government Code, §2001.051 and §2001.052. [~~if the document to be served is sent by registered or certified mail to the respondent/applicant at his or her most recent address as shown in the records of the board. Service by mail shall be complete upon deposit of the paper enclosed in a post paid properly addressed wrapper in a post office or official depository under the care and custody of the United States Postal Service.~~]

§343.36. Filing and Receipt of Complaints.

(a) - (b) (No change.)

(c) Prior to commencing disciplinary proceedings, the staff shall serve the respondent with written notice in accordance with [~~the Texas~~] Government Code, §2001.054(c) [~~§2001.54(c)~~].

(1) - (2) (No change.)

§343.40. Informal Settlement Conference.

(a) At any time after the filing of a [~~sworn~~] complaint, an informal settlement conference may be held prior to the contested case hearing for the purpose of:

(1) - (5) (No change.)

(b) (No change.)

(c) Participation in an informal settlement conference shall not be mandatory for the licensee or applicant, nor is it a prerequisite to a formal hearing.

(d) The executive director or staff shall decide upon the time, date, and place of the informal settlement conference and provide written notice to the licensee or applicant of the same. Notice shall be provided no less than 10 days prior to the date of the informal settlement conference [~~by certified mail, return receipt requested,~~] to the last known address of the licensee or applicant. The 10 days shall begin on the date [~~of~~] the notice [~~mailing~~] is sent electronically or deposited into the mail. The licensee or applicant may waive the 10-day notice requirement in writing.

(1) The notice shall inform the licensee or applicant of the following:

(A) - (G) (No change.)

(H) that the informal settlement conference shall be cancelled if the licensee or applicant notifies the executive director or staff that he or she will not attend.

(2) A copy of the board's rules [~~concerning informal disposition~~] may [~~shall~~] be referenced [~~enclosed~~] with the notice of the informal settlement conference.

(e) The notice of the informal settlement conference shall be sent [~~by certified mail, return receipt requested,~~] to the complainant at his or her last known address. The complainant shall be informed that he or she may appear and testify or may submit a written statement for consideration at the informal settlement conference. The complainant shall be notified if the conference is cancelled.

(f) Participants in the informal settlement conference may include board members, agency staff, the complainant, the licensee or applicant, attorneys representing any of the participants, and any other persons determined by the investigation committee or the executive director or board's designee to be necessary for proper conduct of the conference. All other persons shall be excluded.

(g) The informal settlement conference [~~shall be informal and~~] shall not follow the procedures established in this chapter for contested cases and formal hearings.

(h) The licensee, the licensee's attorney, investigation committee members, and board staff may question witnesses, make relevant statements, present statements of persons not in attendance, and present such other evidence as may be appropriate.

(i) The board's attorney [~~An attorney~~] from the office of the attorney general shall attend [~~each~~] the informal settlement conferences [~~conference~~] to advise the[~~. The~~] board members, [~~or~~] executive director, and staff. [~~may call upon the attorney at any time for assistance in the settlement conference.~~]

(j) (No change.)

(k) Access to the board's investigative file may be prohibited or limited in accordance with [~~Texas Civil Statutes, Article 6252-13a, and~~] the Administrative Procedure Act (APA) and Texas Register Act (TRA) [~~(APTRA)~~].

(l) No formal recording of the informal settlement conference shall be made.

(m) At the conclusion of the informal settlement conference, the investigation committee members, [~~or~~] the executive director, or staff may propose an informal disposition of a complaint or contested case to the respondent subject to the board's approval [~~make recommendations for informal disposition of the complaint or contested case~~]. The informal disposition [~~recommendations~~] may include any disciplinary action authorized by the [~~Physical Therapy Practice~~] Act and rules. The investigation committee, [~~or~~] the executive director, or staff may also close the complaint investigation because [~~conclude that~~] the board lacks jurisdiction, [~~that~~] a violation of the act or rules was [~~this chapter has~~] not [~~been~~] established, or determine [~~order that the investigation be closed, or refer the matter for~~] further investigation is required.

§343.41. Agreed Orders.

(a) A proposed [~~An~~] agreed order may be negotiated with any person under the jurisdiction of the board, the terms of which shall be approved by the investigation committee [~~or by the executive director~~].

(b) The proposed agreed order will be sent to the respondent by a method of service in accordance with Government Code, §2001.142 [~~certified mail~~]. To accept the agreed order, the respondent must sign it [~~in the presence of a notary~~] and return it to the board staff within 10 days after receipt. Inaction by the respondent constitutes rejection. If the respondent rejects the proposed settlement, the matter shall be referred to the investigation committee, [~~or~~] the executive director, or staff for appropriate action.

(c) The proposed agreed order with the [~~notarized~~] signature of the respondent will be presented to the board. The proposed agreed order shall have no effect until such time as the board may, at a regularly scheduled meeting, take action approving the agreed order. If approved by the board, the chair of the board is authorized to sign the agreed order on behalf of the board. When the board has approved and signed [~~ratified~~] an agreed order, the board order will be sent to the licensee, [~~the licensee will reimburse the board for all the investigation expenses. The investigation expenses will be included as a condition of the order. A copy of the agreed order will be sent to the licensee's employer, and facility administrator.~~]

(d) (No change.)

(e) Consideration by the board.

[~~(1) Any board member who participated in the investigation of the complaint or formulation of the proposed agreed order may not participate in the board review of the agreed order.~~]

(1) [~~(2)~~] The name and license number of the licensee or the name of the applicant will not be made available to the board until after the board has reviewed and made a decision on the agreed order.

(2) [~~(3)~~] Upon an affirmative majority vote, the board shall approve [~~authorize~~] the agreed order, and the chairperson of the board will sign it on behalf of the board. The final board order [~~board-approved agreed order~~] will be provided to the respondent.

(3) [~~(4)~~] If the board does not approve the agreed order, the matter may [~~will~~] be referred to the investigation committee, [~~or~~] the executive director, or designee for other appropriate action. The respondent and the complainant shall be so informed.

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

Filed with the Office of the Secretary of State on June 2, 2023.

TRD-202302047
Ralph Harper
Executive Director
Texas Board of Physical Therapy Examiners
Earliest possible date of adoption: July 16, 2023
For further information, please call: (512) 305-6900

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CHAPTER 346. PRACTICE SETTINGS FOR PHYSICAL THERAPY

22 TAC §346.3

The Texas Board of Physical Therapy Examiners proposes amending §346.3. Early Childhood Intervention (ECI) Setting. relating to the provision of physical therapy services to infants and toddlers in an early childhood setting.

The amendment is proposed in order to update a Code of Federal Regulations reference, to eliminate the requirement for the completion of an evaluation and reevaluation to be done on-site allowing for provision via telehealth if indicated, to align the 60-day review of the plan of care (POC) to the requirement in other settings prior to continuation of treatment by a physical therapist assistant, and to report recommendations following a review of the POC to the ECI Interdisciplinary Team.

Fiscal Note

Ralph A. Harper, Executive Director of the Executive Council of Physical Therapy and Occupational Therapy Examiners, has determined that for the first five-year period the amendment is in effect there would be no loss of revenue, and there would be no fiscal implication to units of local government as a result of enforcing or administering the rules.

Public Benefits and Costs

Mr. Harper has determined that for the first five-year period this amendment is in effect, the public benefit will be providing increased clarity of requirements for licensees working in an early childhood intervention within both state and federal guidelines. Additionally, there will be no cost to the public.

Local Employment Economic Impact Statement

The amendment is not anticipated to impact a local economy, so a local employment economic impact statement is not required.

Small and Micro-Businesses and Rural Communities Impact

Mr. Harper has determined that there will be no costs or adverse economic effects to small or micro-businesses or rural communities; therefore, an economic impact statement or regulatory flexibility analysis is not required.

Government Growth Impact Statement

During the first five-year period this amendment is in effect, the impact on government growth is as follows:

The proposed rule amendment will neither create nor eliminate a government program.

(2) The proposed rule amendment will neither create new employee positions nor eliminate existing employee positions.

(3) The proposed rule amendment will neither increase nor decrease future legislative appropriations to the agency.

(4) The proposed rule amendment will neither require an increase nor a decrease in fees paid to the agency.

(5) The proposed rule amendment revises the language to an existing regulation but does not create a new regulation.

(6) The proposed rule amendment will neither repeal nor limit an existing regulation.

(7) The proposed rule amendment will neither increase nor decrease the number of individuals subject to the rule's applicability.

(8) The proposed rule amendment will neither positively nor adversely affect this state's economy.

Takings Impact Assessment The proposed rule amendment will not impact private real property as defined by Tex. Gov't Code §2007.003, so a takings impact assessment under Tex. Gov't Code §2001.043 is not required.

Requirement for Rule Increasing Costs to Regulated Persons

Tex. Gov't Code §2001.0045, Requirement for Rule Increasing Costs to Regulated Persons, does not apply to this proposed rule because the amendments will not increase costs to regulated persons.

Public Comment

Comments on the proposed amendments may be submitted to Karen Gordon, PT Coordinator, Texas Board of Physical Therapy Examiners, 1801 Congress Ave, Suite 10.900, Austin, Texas 78701; email: karen@ptot.texas.gov. Comments must be received no later than 30 days from the date this proposed amendment is published in the *Texas Register.*

Statutory Authority

The amendment is proposed under Texas Occupation Code §453.102, which authorizes the board to adopt rules necessary to implement chapter 453.

Cross-reference to Statute

The proposed amendment implements provisions in Sec. 453.005, Occupations Code that pertains to the practice of physical therapy.

§346.3. Early Childhood Intervention (ECI) Setting.

(a) - (d) (No change.)

(e) Evaluation and reevaluation in the early childhood intervention setting will be conducted in accordance with the Early Intervention Program for Infants and Toddlers with Disabilities, 34 CFR Subtitle B, Chapter III, Part 303.321 [~~federal mandates under Part C of the Individuals with Disabilities Education Act (IDEA), 20 USC §1436, or when warranted by a change in the child's condition,~~] and must include direct physical therapist-to-child interaction [~~onsite reexamination of the child~~].

(f) The Plan of Care (Individual Family Service Plan) must be reviewed by the PT at least every 60 days, or concurrent with every visit if the child is seen at intervals greater than 60 days, prior to continuation of treatment by a PTA [~~to determine if revisions are necessary~~]. Any modification or revision of physical therapy services identified during the review should be recommended to the Interdisciplinary Team.

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

Filed with the Office of the Secretary of State on June 2, 2023.

TRD-202302046
Ralph Harper
Executive Director
Texas Board of Physical Therapy Examiners
Earliest possible date of adoption: July 16, 2023
For further information, please call: (512) 305-6900

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TITLE 26. HEALTH AND HUMAN SERVICES

PART 1. HEALTH AND HUMAN SERVICES COMMISSION

CHAPTER 511. LIMITED SERVICES RURAL HOSPITALS

The Executive Commissioner of the Texas Health and Human Services Commission (HHSC) proposes new Chapter 511, concerning Limited Services Rural Hospitals, comprising of §§511.1 - 511.3, 511.11 - 511.17, 511.41 - 511.78, 511.111 - 511.116, 511.121, 511.141 - 511.143, and 511.161 - 511.169 in Texas Administrative Code Title 26.

BACKGROUND AND PURPOSE

The proposal is necessary to implement Senate Bill (S.B.) 1621, 86th Legislature, Regular Session, 2019, relating to certain rural medical facilities; requiring a license; authorizing fees and taxes, which amends Texas Health and Safety Code (HSC) Chapter 241 by adding Subchapter K, relating to Limited Services Rural Hospital.

HSC §241.302(b), as added by S.B. 1621, requires HHSC to adopt rules to establish the minimum standards for limited services rural hospitals (LSRHs) and to implement licensing standards for LSRHs under HSC §241.302 if the United States Congress enacts a bill creating a payment program for LSRHs or similarly designated hospitals that becomes law.

The federal Consolidated Appropriations Act, 2021, became law on December 27, 2020, and required the Centers for Medicare and Medicaid Services (CMS) to establish a federal rural emergency hospital (REH) designation. CMS adopted federal Conditions of Participation for REHs effective January 1, 2023, and now HHSC must adopt rules as required by HSC Section 241.302(b).

Pursuant to Texas Government Code §2005.003, HHSC proposes a 45-day processing timeline for applications to maintain consistency processing timeframes for other acute health care facilities. HHSC is unable to provide the maximum, minimum, and median time frames required by §2005.003(d)(1) because

the LSRH licenses are a new licensure type and HHSC currently lacks the data to estimate these statistics.

SECTION-BY-SECTION SUMMARY

Proposed new §511.1, Purpose, describes the purpose, statutory authority, and general requirements of Chapter 511.

Proposed new §511.2, Definitions, describes the definitions for words and terms that have meanings specific to this chapter.

Proposed new §511.3, Waiver Provisions, describes the process an LSRH must use when requesting a waiver of a particular provision of HSC Chapter 241 or this chapter, except for fire safety requirements, and the process HHSC uses to determine whether to grant a waiver request.

Proposed new §511.11, General, describes the general license requirements for an entity to obtain an LSRH license.

Proposed new §511.12, Application and Issuance of Initial License, describes the initial application requirements for an applicant seeking a license to operate as an LSRH within the state of Texas.

Proposed new §511.13, Application and Issuance of Renewal License, describes the requirements for an applicant to renew their previously issued license to operate an LSRH.

Proposed new §511.14, Inactive Status and Closure, describes the requirements and process for placing an LSRH on inactive status and the procedures required if an LSRH closes.

Proposed new §511.15, Change of Ownership, describes the license requirements for an LSRH that changes ownership.

Proposed new §511.16, Time Periods for Processing and Issuing Limited Services Rural Hospital Licenses, describes the time period for HHSC to process applications, causes for exceeding this time period, and information on reimbursement.

Proposed new §511.17, Fees, describes the fees for LSRH initial and renewal application and construction plan reviews.

Proposed new §511.41, Governing Body Organization, describes the standards the LSRHs must meet and maintain in organizing the governing body.

Proposed new §511.42, Governing Body Responsibilities, describes the responsibilities of an LSRH's governing body.

Proposed new §511.43, Administration, describes the administrative standards an LSRH must meet and maintain to ensure the orderly and efficient management of the LSRH.

Proposed new §511.44, Emergency Services, describes the standards which an LSRH must meet and maintain to deliver emergency services.

Proposed new §511.45, Laboratory Services, describes the standards an LSRH must meet and maintain to deliver laboratory services.

Proposed new §511.46, Radiological Services, describes the standards that an LSRH must meet and maintain when conducting radiological services.

Proposed new §511.47, Pharmaceutical Services, describes the standards an LSRH must meet and maintain when providing pharmaceutical and related services.

Proposed new §511.48, Abuse and Neglect Issues, describes issues relating to abuse and neglect and the process HHSC uses to investigate abuse, neglect, and exploitation allegations.

Proposed new §511.49, Medical Director, describes the standards an LSRH must meet and maintain for the medical director position.

Proposed new §511.50, Medical Staff, describes the standards an LSRH must meet and maintain for medical staff.

Proposed new §511.51, Provision of Services, describes the professional standards an LSRH must meet and maintain when providing services.

Proposed new §511.52, Surgical Services within the Scope of the Practice of Emergency Medicine, describes the standards an LSRHs must meet and maintain when performing limited surgical procedures as an emergency procedure.

Proposed new §511.53, Dietary Services, describes the standards an LSRH must meet and maintain when providing food to patients, including standards associated with contracted food management services and other related services.

Proposed new §511.54, General Outpatient Requirements, describes the general standards an LSRH must meet and maintain when the LSRH offers outpatient services.

Proposed new §511.55, Surgical Services, describes the standards an LSRH must meet and maintain when providing surgical services.

Proposed new §511.56, Anesthesia Services, describes the standards an LSRH must meet and maintain when providing anesthesia services.

Proposed new §511.57, Therapy Services, describes the standards an LSRH must meet and maintain when providing therapeutic services.

Proposed new §511.58, Renal Dialysis Services, describes the standards an LSRH must meet and maintain when providing renal dialysis services.

Proposed new §511.59, Infection Prevention and Control and Antibiotic Stewardship Programs, describes the standards an LSRH must meet and maintain to prevent and control infection and form an antibiotic stewardship program.

Proposed new §511.60, Staffing and Staff Responsibilities, describes the standards and responsibilities an LSRH must meet and maintain to properly staff the facility.

Proposed new §511.61, Nursing Services, describes the standards and responsibilities an LSRH must meet and maintain when providing nursing services.

Proposed new §511.62, Discharge Planning, describes the standards and responsibilities an LSRH must meet and maintain when discharging patients.

Proposed new §511.63, Patient's Rights, describes standards an LSRH must meet and maintain to protect and promote patient rights.

Proposed new §511.64, Quality Assessment and Performance Improvement Program, describes the standards an LSRH must meet and maintain when forming and operating the required quality assessment and performance improvement program.

Proposed new §511.65, Patient Transfer Policy, describes the standards an LSRH must meet and maintain when patient transfers occur with hospitals not currently in a patient transfer agreement.

Proposed new §511.66, Patient Transfer Agreements, describes the standards an LSRH must meet and maintain when forming and holding patient transfer agreements with qualified general hospitals.

Proposed new §511.67, Medical Records, describes the standards an LSRH must meet and maintain regarding documenting, storing, and providing access to patient medical records.

Proposed new §511.68, Emergency Preparedness, describes the standards an LSRH must meet and maintain for proper emergency preparedness.

Proposed new §511.69, Skilled Nursing Facility as a Distinct Unit, describes the standards an LSRH must meet and maintain when providing a skilled nursing facility, which includes complying with the separate licensing requirements under Texas Health and Safety Code Chapter 242 and federal regulations.

Proposed new §511.70, Respiratory Care Services, describes the standards an LSRH must meet and maintain if the LSRH decides to provide respiratory care services.

Proposed new §511.71, Waste and Waste Disposal, describes the standards an LSRH must meet and maintain when handling waste and conducting waste disposal services.

Proposed new §511.72, Linen and Laundry Services, describes the standards an LSRH must meet and maintain when caring for linens and conducting laundry services.

Proposed new §511.73, Sterilization, describes the standards an LSRH must meet and maintain when sterilizing equipment and associated actions.

Proposed new §511.74, Sanitary Conditions and Hygienic Practices, describes the standards an LSRH must meet and maintain for sanitary conditions and to prevent disease transmission.

Proposed new §511.75, Limited Services Rural Hospital Billing, describes the standards LSRHs must meet and maintain when billing and conducting billing related actions, including complying with state law and Texas Department of Insurance rules regarding balance billing.

Proposed new §511.76, Patient Visitation, requires an LSRH to adopt patient visitation policies and procedures, requires an LSRH to inform patients of their visitation rights, and describes the standards an LSRH must meet and maintain to ensure in-person visitation during a public health emergency or disaster.

Proposed new §511.77, Hospital Price Transparency Reporting and Enforcement, describes the requirements for price transparency reporting under HSC Chapter 327 and the enforcement procedures and administrative penalties HHSC may assess for violations of HSC Chapter 327.

Proposed new §511.78, Restraint and Seclusion, describes restraint and seclusion requirements an LSRH must meet and maintain.

Proposed new §511.111, Integrity of Inspections and Investigations, places limits on an LSRH's authority to record HHSC interviews and internal discussions.

Proposed new §511.112, Inspections, describes the requirements of the HHSC inspection process for an LSRH.

Proposed new §511.113, Complaint Investigations, describes the requirements of the HHSC investigation process after receiving a complaint against and LSRH.

Proposed new §511.114, Notice, informs an LSRH of the required timeframes regarding responding to deficiencies, plans of correction, and the provision of additional evidence.

Proposed new §511.115, Professional Conduct, notifies an LSRH that HHSC will report enforcement actions to appropriate licensing authorities.

Proposed new §511.116, Complaint Against an HHSC Representative, informs an LSRH about registering a complaint against an HHSC representative.

Proposed new §511.121, Enforcement, describes enforcement procedures HHSC may take when an LSRH commits a violation of statute or rule.

Proposed new §511.141, Fire Prevention and Protection, describes the standards LSRHs must meet and maintain for fire prevention and protection, including requirements for fire inspections, reporting, protection, smoking rules, extinguishing systems, evacuation and protection plans, drills, alarm systems, and fire department protection.

Proposed new §511.142, General Safety, describes the standards an LSRH must meet and maintain for general safety, including requirements for a safety committee, safety manual, and emergency communication system.

Proposed new §511.143, Handling and Storage of Gases, Anesthetics, and Flammable Liquids, describes the standards an LSRH must meet and maintain when it comes to handling and storing gases, anesthetics, and flammable liquids.

Proposed new §511.161, Requirements for Buildings in Which Existing Licensed Hospitals are Located, describes the standards an LSRH must meet and maintain for the building in which existing general or special hospitals licensed by HHSC are located. This includes fire safety, construction, and remodeling requirements.

Proposed new §511.162, General Construction Requirements, describes the general construction standards an LSRH must meet and maintain. This includes physical conditions, environmental considerations, and on-site conditions.

Proposed new §511.163, Spatial Requirements, describes the spatial standards an LSRH must meet and maintain for different unit and sections of the LSRH.

Proposed new §511.164, Elevators, Escalators, and Conveyors, describes the standards an LSRH must meet and maintain for any elevators, escalators, and conveyors used in the building.

Proposed new §511.165, Building with Multiple Occupancies, describes the standards an LSRH located in a building with multiple occupancies must meet and maintain.

Proposed new §511.166, Mobile, Transportable, and Relocatable Units, describes the standards an LSRH must meet and maintain when the LSRH uses a mobile, transportable, or relocatable unit to provide patient treatment services.

Proposed new §511.167, Preparation, Submittal, Review and Approval of Plans, and Retention of Records, describes the standards and processes an LSRH must meet and maintain for construction plans. This applies to new buildings, additions to or renovations or conversions of existing buildings.

Proposed new §511.168, Construction, Inspections, and Approval of Project, describes the construction standards and processes to obtain HHSC approval on construction projects.

Proposed new §511.169, Tables, describes the standards an LSRH must meet and maintain for flame spread and smoke production, ventilation, and hot water use.

FISCAL NOTE

Trey Wood, HHSC Chief Financial Officer, has determined that for each year of the first five years that the rules will be in effect, there could be an estimated decrease of revenue to state government as a result of enforcing and administering the rules as proposed. Additionally, there is a onetime IT cost to update the Regulatory Automation System (RAS) portal for the new licensure type, but HHSC will absorb the cost using existing resources.

Most entities eligible for licensure as an LSRH are currently licensed general or special hospitals. The LSRH fee is a flat $350 fee for the two-year license term versus the general and special hospital fee of $39 per licensed bed per two-year term. This is likely to cause a decrease in revenue. HHSC lacks the ability to estimate this decrease as HHSC is unable to predict how many eligible qualified hospitals will seek licensure as an LSRH.

Enforcing or administering the rules does not have foreseeable implications relating to costs or revenues of local government because it is optional for an eligible rural hospital owned or operated by a hospital district, county, or municipality to seek licensure as an LSRH.

GOVERNMENT GROWTH IMPACT STATEMENT

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

(1) the proposed rules will not create or eliminate a government program;

(2) implementation of the proposed rules will not affect the number of HHSC employee positions;

(3) implementation of the proposed rules will result in no assumed change in future legislative appropriations;

(4) the proposed rules will require a decrease in fees paid to HHSC;

(5) the proposed rules will create a new rule;

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

(7) the proposed rules will increase the number of individuals subject to the rules; and

(8) HHSC has insufficient information to determine the proposed rules' effect on the state's economy.

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

Trey Wood has also determined that there will be no adverse economic effect on small businesses, micro-businesses, or rural communities because it is optional for a qualified rural hospital to seek licensure as an LSRH.

LOCAL EMPLOYMENT IMPACT

The proposed rules will not affect a local economy.

COSTS TO REGULATED PERSONS

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

PUBLIC BENEFIT AND COSTS

Stephen Pahl, Deputy Executive Commissioner for Regulatory Services, has determined that for each year of the first five years the rules are in effect, the public benefit will be ensuring continued access to health care services in rural communities.

Trey Wood has also determined that for the first five years the rules are in effect, persons who are required to comply with the proposed rules may incur economic costs because a qualified hospital who seeks to become an LSRH must pay a licensing fee of $350 for the two-year licensing term. However, HHSC does not have sufficient information to determine cost to comply because participation is optional.

TAKINGS IMPACT ASSESSMENT

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

PUBLIC COMMENT

Written comments on the proposal may be submitted to Rules Coordination Office, P.O. Box 13247, Mail Code 4102, Austin, Texas 78711-3247, or street address 701 W. 51st Street, Austin, Texas 78751; or emailed to HCR_PRU@hhs.texas.gov.

To be considered, comments must be submitted no later than 31 days after the date of this issue of the *Texas Register.* Comments must be (1) postmarked or shipped before the last day of the comment period; (2) hand-delivered before 5:00 p.m. on the last working day of the comment period; or (3) emailed before midnight on the last day of the comment period. If last day to submit comments falls on a holiday, comments must be postmarked, shipped, or emailed before midnight on the following business day to be accepted. When emailing comments, please indicate "Comments on Proposed Rule 23R017" in the subject line.

SUBCHAPTER A. GENERAL PROVISIONS

26 TAC §§511.1 - 511.3

STATUTORY AUTHORITY

The new sections are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies, and Texas Health and Safety Code §241.302(b), which provides that the Executive Commissioner of HHSC shall adopt rules to implement that section and establish minimum standards for LSRHs.

The new sections implement Texas Government Code §531.0055 and Texas Health and Safety Code §241.302.

§511.1. Purpose.

(a) The purpose of this chapter is to implement Texas Health and Safety Code Chapter 241, Subchapter K for Limited Services Rural Hospitals licensed by the Texas Health and Human Services Commission.

(b) This chapter provides:

(1) procedures for obtaining a limited services rural hospital (LSRH) license;

(2) standards for LSRH functions and services;

(3) patient rights;

(4) discrimination or retaliation prohibitions;

(5) patient transfer and other policy and protocol requirements;

(6) reporting, posting, and training requirements relating to abuse and neglect;

(7) standards for voluntary agreements;

(8) inspection and investigation procedures;

(9) enforcement standards;

(10) fire prevention and protection requirements;

(11) general safety standards;

(12) physical plant and construction requirements; and

(13) standards for the preparation, submittal, review, and approval of construction documents.

(c) An LSRH shall comply with the Conditions of Participation for Rural Emergency Hospitals at Code of Federal Regulations Title 42 Part 485, Subpart E (relating to Conditions of Participation: Rural Emergency Hospitals (REHs). To the extent the conditions of participation conflict with Texas law and this chapter, Texas law and this chapter shall prevail.

(d) 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 requirements.

§511.2. Definitions.

The following words and terms, when used in this chapter, shall have the following meanings.

(1) Act--The Texas Hospital Licensing Law, Texas Health and Safety Code (HSC), Chapter 241.

(2) Actual harm--A negative outcome that compromises a patient's physical, mental, or emotional well-being.

(3) Advance directive--a directive, as that term is defined by HSC §166.031 (relating to Definitions), an out-of-hospital do not resuscitate (DNR) order as that term is defined by HSC §166.081 (relating to Definitions), or a medical power of attorney under HSC Chapter 166, Subchapter D (relating to Medical Power of Attorney).

(4) Advanced practice registered nurse (APRN)--A registered nurse authorized 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 limited services rural hospital (LSRH) license from the Texas Health and Human Services Commission (HHSC) and is legally responsible for the operation of the LSRH, whether by lease or ownership.

(7) Attending physician--A physician selected by or assigned to a patient who has primary responsibility for a patient's treatment and care.

(8) Available--When referring to on-site personnel, on the premises and able to rapidly perform hands-on care in an emergency situation.

(9) Biological indicators--Commercially available microorganisms (e.g., United States Food and Drug Administration approved strips or vials of Bacillus species endospores).

(10) Cardiopulmonary resuscitation--Any medical intervention used to restore circulatory or respiratory function that has ceased.

(11) Chemical dependency services--A planned, structured, and organized program designed to initiate and promote a person's chemical-free status or to maintain the person free of illegal drugs. It includes the application of planned procedures to identify and change patterns of behavior related to or resulting from chemical dependency that are maladaptive, destructive, or injurious to health, or to restore appropriate levels of physical, psychological, or social functioning lost due to chemical dependency.

(12) Competent--Possessing the ability, based on reasonable medical judgment, to understand and appreciate the nature and consequences of a treatment decision, including the significant benefits and harms of and reasonable alternatives to a proposed treatment decision.

(13) Comprehensive medical rehabilitation--The provision of rehabilitation services that are designed to improve or minimize a person's physical or cognitive disabilities, maximize a person's functional ability, or restore a person's lost functional capacity through close coordination of services, communication, interaction, and integration among several professions that share responsibility to achieve team treatment goals for the person.

(14) Contaminated linen--Linen that has been soiled with blood or other potentially infectious materials or may contain sharps.

(15) Dentist--A person licensed to practice dentistry by the Texas State Board of Dental Examiners. This includes a doctor of dental surgery or a doctor of dental medicine.

(16) Dietitian--A person who is currently licensed by the Texas Department of Licensing and Regulation as a licensed dietitian or provisional licensed dietitian, or who is a registered dietitian with the Academy of Nutrition and Dietetics.

(17) Do not resuscitate (DNR) order--An order issued under HSC Chapter 166, Subchapter E (relating to Health Care Facility Do-Not-Resuscitate Orders), instructing a health care professional not to attempt cardiopulmonary resuscitation on a patient whose circulatory or respiratory function ceases.

(18) Emergency medical condition--A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain, psychiatric disturbances or symptoms of substance abuse) such that the absence of immediate medical attention could reasonably be expected to result in one or all of the following:

(A) placing the health of the individual (or with respect to a pregnant individual, the health of the pregnant individual or her unborn child) in serious jeopardy;

(B) serious impairment to bodily functions;

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

(D) with respect to a pregnant individual who is having contractions:

(i) that there is inadequate time to safely transfer to another hospital before delivery; or

(ii) that transfer may pose a threat to the health or safety of the pregnant individual or the unborn child.

(19) General hospital--An establishment that:

(A) offers services, facilities, and beds for use for more than 24 hours for two or more unrelated individuals requiring diagnosis, treatment, or care for illness, injury, deformity, abnormality, or pregnancy; and

(B) regularly maintains, at a minimum, clinical laboratory services, diagnostic X-ray services, treatment facilities, including surgery or obstetrical care or both, and other definitive medical or surgical treatment of similar extent.

(20) Governing body--The governing authority of an LSRH that is responsible for the LSRH's organization, management, control, and operation, including appointment of medical staff. This term includes the owner or partners for an LSRH owned or operated by an individual or partners.

(21) Governmental unit--A political subdivision of the state, including a hospital district, county, or municipality, and any department, division, board, or other agency of a political subdivision.

(22) Incompetent--Lacking the ability, based on reasonable medical judgment, to understand and appreciate the nature and consequences of a treatment decision, including the significant benefits and harms of and reasonable alternatives to a proposed treatment decision.

(23) Inpatient--An individual admitted to a facility for an intended length of stay of 24 hours or greater.

(24) Inpatient services--Services provided to an individual admitted to an LSRH for an intended length of stay of 24 hours or greater.

(25) Licensed vocational nurse (LVN)--A person who is currently licensed by the Texas Board of Nursing as a licensed vocational nurse or who holds a valid vocational nursing license with multi-state licensure privilege from another compact state.

(26) Licensee--The person or governmental unit named in the application for issuance of an LSRH license.

(27) Limited services rural hospital (LSRH)--A general or special hospital that is or was licensed under HSC Chapter 241 and that:

(A) is:

(i) located in a rural area, as defined by:

(I) Texas Health and Human Services Commission rule; or

(II) 42 U.S.C. Section 1395ww(d)(2)(D); or

(ii) designated by the Centers for Medicare & Medicaid Services as a critical access hospital, rural referral center, or sole community hospital; and

(B) otherwise meets the requirements to be designated as to be designated as a rural emergency hospital under Code of Federal Regulations Title 42 (42 CFR) Part 485, Subpart E.

(28) Limited services rural hospital (LSRH) administration--Administrative body of an LSRH headed by an individual who has the authority to represent the LSRH and who is responsible for the operation of the LSRH according to the policies and procedures of the LSRH's governing body.

(29) Medical staff--A physician or group of physicians and a podiatrist or group of podiatrists who by action of the governing body of an LSRH are privileged to work in and use the facilities of an LSRH for or in connection with the observation, care, diagnosis, or treatment of an individual who is, or may be, suffering from a mental or physical disease or disorder or a physical deformity or injury.

(30) Mental health services--All services concerned with research, prevention, and detection of mental disorders and disabilities and all services necessary to treat, care for, supervise, and rehabilitate persons who have a mental illness.

(31) Nurse--A registered, vocational, or advanced practice registered nurse licensed by the Texas Board of Nursing or entitled to practice in this state under Texas Occupations Code Title 3, Subtitle E.

(32) Other potentially infectious materials--Any of the following materials.

(A) The following human body fluids:

(i) semen;

(ii) vaginal secretions;

(iii) cerebrospinal fluid;

(iv) synovial fluid;

(v) pleural fluid;

(vi) pericardial fluid;

(vii) peritoneal fluid;

(viii) amniotic fluid;

(ix) saliva in dental procedures;

(x) any body fluid that is visibly contaminated with blood; and

(xi) all body fluids in situations where it is difficult or impossible to differentiate between body fluids;

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

(C) 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.

(33) Outpatient--An individual who presents for diagnostic or treatment services for an intended length of stay of less than 24 hours. An individual who requires continued observation may be considered as an outpatient for up to 48 hours.

(34) Outpatient services--Services provided to patients whose medical needs can be met in less than 24 hours and are provided within the LSRH. Services that require continued observation may be considered as outpatient services for up to 48 hours.

(35) Owner--One of the following persons or governmental unit which will hold or does hold a license issued under the statute 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.

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

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

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

(39) Physician assistant--A person licensed as a physician assistant by the Texas Physician Assistant Board.

(40) Podiatrist--A podiatrist licensed by the Texas Department of Licensing and Regulation.

(41) Practitioner--A health care professional licensed in the state of Texas, other than a physician, podiatrist, or dentist.

(42) Prelicensure 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 prior to the on-site licensure inspection.

(43) Premises--A building where patients receive LSRH services.

(44) Prominent location--A size and font at least as large as that of surrounding text, links, or buttons, distinct from the background of the website, immediately viewable upon accessing the home page of the hospital's publicly accessible website without having to scroll.

(45) Prominently displayed--Refer to "prominent location."

(46) Public health emergency--A state of disaster or local disaster declared under Texas Government Code Chapter 418 or a public health disaster as defined by HSC §81.003.

(47) Qualified rural hospital--A general or special hospital licensed under HSC Chapter 241 (relating to Hospitals) on December 27, 2020, that meets the requirements to be designated as a rural emergency hospital under 42 CFR §485.502 (relating to Definitions), and §485.506 (relating to Designation and Certification of REHs) and is:

(A) located in a rural area, as defined by 42 United States Code §1395ww(d)(2)(D); or

(B) designated by the Centers for Medicare & Medicaid Services as a critical access hospital, rural referral center, or sole community hospital.

(48) Qualifying official disaster order--An order, proclamation, or other instrument issued by the Governor, another official of this state, or the governing body or an official of a political subdivision of this state declaring a disaster that has infectious disease as the basis for the declared disaster.

(49) Qualifying period of disaster--The period of time the area in which a LSRH is located is declared to be a disaster area by a qualifying official disaster order.

(50) Quality improvement--A method of evaluating and improving processes of patient care that emphasizes a multidisciplinary approach to problem solving, and focuses not on individuals, but systems of patient care which might be the cause of variations.

(51) Quality improvement organization--An organization that has a contract with the Centers for Medicare & Medicaid Services, under Title XI Part B of the Social Security Act, to perform utilization and quality control review of the health care furnished, or to be furnished, to Medicare beneficiaries.

(52) Religious counselor--An individual acting substantially in a pastoral or religious capacity to provide spiritual counsel to other individuals.

(53) Registered nurse (RN)--A person who is currently licensed by the Texas Board of Nursing as a registered nurse or who holds a valid registered nursing license with multi-state licensure privilege from another compact state.

(54) Restraint--A restraint is:

(A) any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move their arms, legs, body, or head freely; or

(B) a drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition and does not include:

(i) devices such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests; or

(ii) devices to protect the patient from falling out of bed, off of a stretcher, or out of a chair, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).

(55) Seclusion--The involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving.

(56) Special hospital--An establishment that:

(A) offers services, facilities, and beds for use for more than 24 hours for two or more unrelated individuals who are regularly admitted, treated, and discharged and who require services more intensive than room, board, personal services, and general nursing care;

(B) has clinical laboratory facilities, diagnostic X-ray facilities, treatment facilities, or other definitive medical treatment;

(C) has a medical staff in regular attendance; and

(D) maintains records of the clinical work performed for each patient.

(57) Stabilize--With respect to an emergency medical condition, to provide such medical treatment of the condition necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility, or that the woman has delivered the child and the placenta.

(58) Surgical technologist--A person who practices surgical technology as defined in HSC Chapter 259.

(59) Telemedicine--A health care service that is initiated by a physician or provided by a licensed health professional acting under appropriate physician delegation and supervision that is provided for purposes of client assessment by a health professional, diagnosis or consultation by a physician, or treatment, or for the transfer of medical data, and that requires the use of advanced telecommunications technology, other than telephone or facsimile technology, including:

(A) compressed digital interactive video, audio, or data transmission;

(B) clinical data transmission using computer imaging by way of still-image capture and store and forward; and

(C) other technology that facilitates access to health care services or medical specialty expertise.

(60) Transfer--The movement (including the discharge) of an individual outside an LSRH's facilities at the direction of any person employed by (or affiliated or associated, directly or indirectly, with) the LSRH, but does not include such a movement of an individual who has been declared dead, or leaves the facility without the permission of any such person.

(61) 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 the CDC that are designed to reduce the risk of transmission of blood borne and other pathogens in hospitals.

(62) Violation--Failure to comply with the licensing statute, a rule or standard, special license provision, or an order issued by the HHSC executive commissioner (executive commissioner) or the executive commissioner's designee, adopted or enforced under the licensing statute. Each day a violation continues or occurs is a separate violation for purposes of imposing a penalty.

§511.3. Waiver Provisions.

(a) A limited services rural hospital (LSRH) may submit a written request to the Texas Health and Human Services Commission (HHSC) for a waiver or modification of a particular provision of Texas Health and Safety Code (HSC) Chapter 241 (relating to Hospitals) or a standard in this chapter, except fire safety requirements. The written request shall specify the section or sections of HSC Chapter 241 or this chapter for which the LSRH is requesting a waiver.

(b) In requesting the waiver, the LSRH must address each of the following requirements and provide documentation as necessary to support its position. The LSRH must:

(1) provide evidence to support why the requested waiver will not adversely affect the health and safety of the hospital patients, employees, or the general public;

(2) indicate how the LSRH determined that granting the waiver would not adversely impact the LSRH's participation in the federal Medicare program or accreditation by a Centers for Medicare & Medicaid Services-approved organization;

(3) describe how not granting the waiver would impose an unreasonable hardship on the LSRH in providing adequate care for patients;

(4) describe how the waiver would facilitate creating or operating the LSRH; and

(5) explain why the waiver would be appropriate when balanced against the best interests of the individuals served or to be served by the LSRH.

(c) The LSRH must submit supporting documentation with the waiver request. HHSC may request additional written documentation from the LSRH to support the waiver or modification.

(d) In accordance with HSC §241.302(f) (relating to License Required), HHSC may grant a waiver under this section if HHSC determines the waiver or modification will facilitate creating or operating the LSRH and that the waiver or modification is in the best interests of the individuals served or to be served by the LSRH.

(e) The HHSC Health Care Regulation licensing director ("licensing director") shall submit a written recommendation for granting or denying the waiver to the HHSC executive commissioner or designee.

(f) If the licensing director recommends that the waiver or modification be granted, the executive commissioner may issue a written order granting the waiver or modification.

(g) If the licensing director recommends that the waiver or modification be denied, the executive commissioner may issue a written order denying the waiver or modification.

(h) The LSRH's licensing file maintained by HHSC shall contain a copy of the request, any supporting documents the LSRH provided, and the order. The LSRH shall maintain the original order in their permanent records.

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

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Health and Human Services Commission
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SUBCHAPTER B. LICENSING REQUIREMENTS

26 TAC §§511.11 - 511.17

STATUTORY AUTHORITY

The new sections are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies, and Texas Health and Safety Code §241.302(b), which provides that the Executive Commissioner of HHSC shall adopt rules to implement that section and establish minimum standards for LSRHs.

The new sections implement Texas Government Code §531.0055 and Texas Health and Safety Code §241.302.

§511.11. General.

(a) A limited services rural hospital (LSRH) shall obtain a license before admitting patients.

(b) An applicant for an LSRH license shall submit a license application to the Texas Health and Human Services Commission (HHSC) in a form and manner prescribed by HHSC.

(c) An applicant shall submit a license application in accordance with §511.12 of this subchapter (relating to Application and Issuance of Initial License). The applicant shall retain copies of all application documents submitted to HHSC.

(d) An LSRH shall comply with the other provisions of Texas Health and Safety Code Chapter 241 (relating to Hospitals), to the extent they do not conflict with Subchapter K (relating to Limited Services Rural Hospitals), and Code of Federal Regulations Title 42 Part 485 Subpart E (relating to Conditions of Participation: Rural Emergency Hospitals (REHs)) and this chapter during the licensing period.

(e) HHSC issues an LSRH license for the premises and person named in the application.

(1) An LSRH license shall not include off-site outpatient facilities.

(2) An LSRH may share a building with other licensed facilities.

(A) The LSRH must be licensed separately from the other licensed facilities.

(B) No identifiable part of the building may be dually licensed by more than one facility.

(C) Each licensed facility in the building shall comply with the requirements of §511.165 of this chapter (relating to Building with Multiple Occupancies).

(3) A licensed LSRH shall not hold or pursue dual licensure as any other facility type.

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

(g) An LSRH shall not alter the LSRH license.

(h) An LSRH license is nontransferable. The LSRH shall comply with the provisions of §511.15 of this subchapter (relating to Change of Ownership) in the event of a change in the ownership of an LSRH.

(i) An LSRH shall notify HHSC in writing and in accordance with HHSC instructions, of any changes affecting the LSRH's license before the change occurs. Changes may include:

(1) addition or deletion of services indicated on the license application; or

(2) any construction, renovation, or modification of the hospital buildings.

(j) An LSRH shall notify HHSC, in writing and in accordance with HHSC instructions, at the time of the occurrence of any of the following:

(1) cessation of operation of the LSRH, whether temporary or permanent;

(2) change in certification or accreditation status;

(3) change in the LSRH name, telephone number, or administrator; or

(4) change in the emergency contact name or emergency contact phone number.

(k) A written notice of cessation of operation under subsection (j)(1) of this section shall include the location where the LSRH will store medical records and the identity and telephone number of the custodian of the medical records.

§511.12. Application and Issuance of Initial License.

(a) An applicant who meets the definition of a qualified rural hospital under §511.2(47) of this chapter (relating to Definitions) and is seeking a limited services rural hospital (LSRH) license shall submit the following documents to the Texas Health and Human Services Commission (HHSC) within 60 calendar days before the projected opening date of the LSRH:

(1) an accurate and complete application form;

(2) a copy of the LSRH's patient transfer policy, developed in accordance with §511.65 of this chapter (relating to Patient Transfer Policy) and signed by both the chairman and secretary of the LSRH's governing body attesting to the date the governing body adopted the policy and the policy's effective date;

(3) a copy of the LSRH's memorandum of transfer form that contains at least the information described in §511.65 of this chapter;

(4) a copy of a patient transfer agreement entered into between the LSRH and at least one hospital certified by the Centers for Medicare & Medicaid Services that is designated as a level I or level II trauma center in accordance with §511.66 of this chapter (relating to Patient Transfer Agreements);

(5) a copy of a fire inspection approved by an individual certified by the Texas Commission on Fire Protection that is dated no earlier than one year before the LSRH's opening date; and

(6) the appropriate license fee as required in §511.17 of this subchapter (relating to Fees).

(b) In addition to the document submittal requirements in subsection (a) of this section, the applicant must complete the following before HHSC will issue an LSRH license.

(1) If applicable, per HHSC instructions, submit written approval from HHSC confirming compliance with Subchapters F and G of this chapter (relating to Fire Prevention and Safety and Physical Plant and Construction Requirements, respectively). HHSC requires an architectural inspection when a qualifying rural hospital that has closed subsequently applies for an LSRH license. HHSC will waive the architectural inspection for a currently operating qualifying rural hospital that applies for an LSRH license.

(2) If the applicant intends to add on any new services as an LSRH that the applicant did not offer while licensed as a general or special hospital, the applicant must comply with Subchapter G of this chapter as applicable.

(3) The applicant or the applicant's representative shall attend a prelicensure conference conducted by the HHSC. HHSC may waive the prelicensure conference requirement at its discretion.

(c) Subject to subsection (g) of this section, when HHSC determines the applicant has complied with subsections (a) and (b) of this section, HHSC shall issue the LSRH license to the applicant.

(1) The license is effective on the issue date.

(2) The license expires on the last day of the month two years after the issue date.

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

(e) If the applicant does not complete all requirements of subsections (a) and (b) of this section within six months after the date HHSC receives the application and payment, HHSC may deny the application.

(f) Any fee paid for a withdrawn application under subsection (d) or (e) of this section is nonrefundable, as indicated by §511.17(a) of this subchapter.

(g) Denial of a license shall be governed by §511.121 of this chapter (relating to Enforcement).

(h) Once the LSRH is operational and providing services, HHSC shall conduct an inspection of the LSRH to ascertain compliance with the provisions of Texas Health and Safety Code Chapter 241 to the extent it does not conflict with Subchapter K and this chapter. This inspection may be conducted at the same time as the inspection to determine compliance with Code of Federal Regulations Title 42, Part 482 (relating to Conditions of Participation for Hospitals).

(i) An LSRH seeking relocation shall comply with all requirements of this section, except the prelicensure conference required under subsection (b)(3) of this section. An initial license for the relocated facility is effective on the issue date. The previous license is void on the date the previous location closes. The facility must notify HHSC once the previous location has closed.

§511.13. Application and Issuance of Renewal License.

(a) The Texas Health and Human Services Commission (HHSC) shall send written notice of license expiration to a limited services rural hospital (LSRH) at least 60 calendar days before the expiration date of the license. If the LSRH has not received notice, it is the LSRH's duty to notify HHSC and request a renewal notice.

(b) The LSRH shall submit the following to HHSC before the license expiration date:

(1) a complete and accurate application;

(2) a copy of two fire inspections that are conducted and approved by an individual certified by the Texas Commission on Fire Protection to conduct fire inspections and meet the requirements of §511.141 of this chapter (relating to Fire Prevention and Protection), one from within the last 12 months and one from the year before, as the LSRH must obtain an approved fire inspection annually;

(3) the renewal license fee; and

(4) if the applicant is accredited by a Centers for Medicare & Medicaid Services-approved organization, a copy of documentation from the accrediting body showing the current accreditation status of the hospital.

(c) HHSC may conduct an inspection before issuing a renewal license in accordance with §511.112 of this chapter (relating to Inspections).

(d) Subject to subsection (g) of this section, HHSC shall issue a renewal license to an LSRH that meets the requirements for a license.

(e) Renewal licenses will be valid for two years from the previous expiration date.

(f) If an LSRH fails to submit the application, documents, and fee by the expiration date of the LSRH's license, HHSC may notify the LSRH that it must cease operation and immediately return the license to HHSC. If the LSRH intends to provide services after the expiration date of the license, HHSC may require the LSRH to apply for a license under §511.12 of this subchapter (relating to Application and Issuance of Initial License).

(g) Denial of a renewal license shall be governed by §511.121 of this chapter (relating to Enforcement).

§511.14. Inactive Status and Closure.

(a) A limited services rural hospital (LSRH) that is not offering services under its license shall immediately inform the Texas Health and Human Services Commission (HHSC). HHSC may automatically close an LSRH facility if the facility does not offer services for more than 60 days, unless the facility sends a written request to place the license on inactive status.

(1) To be eligible for inactive status, an LSRH must be in good standing with no pending enforcement action or investigation.

(2) The licensee is 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 without an approved extension from HHSC.

(4) To reactivate the license, the LSRH must inform HHSC no later than 60 calendar days after the LSRH stopped offering services under its license.

(5) An LSRH that does not reactivate its license by the 60th calendar day may request an extension of the inactive status from HHSC through a written request.

(6) If by the 60th calendar day after it stopped offering services, the LSRH does not reactivate its license or request an extension for inactive status, HHSC may consider the facility closed.

(b) An LSRH shall notify HHSC, in writing in accordance with HHSC instructions, before closure of the facility.

(1) The LSRH shall dispose of medical records in accordance with §511.67 of this chapter (relating to Medical Records).

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

(3) A license becomes invalid when an LSRH closes. The facility shall return the licensure certificate to HHSC immediately after the LSRH closes.

(c) An LSRH 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.

§511.15. Change of Ownership.

(a) A change of ownership of a limited services rural hospital (LSRH) occurs when there is a change in the person or governmental entity legally responsible for the operation of the LSRH, whether by lease or by ownership.

(1) If a licensee amends its articles of incorporation to revise its name and the tax identification number does not change, this section does not apply, except that the corporation must notify the Texas Health and Human Services Commission (HHSC) within 10 calendar days after the effective date of the name change.

(2) The sale of stock of a licensee does not cause this section to apply.

(b) The new owner shall submit a license application to HHSC before the date of the change of ownership or not later than 10 calendar days after the date of a change of ownership. The application shall be in accordance with §511.12 of this subchapter (relating to the Application and Issuance of Initial License) except the applicant does not need to submit any transfer agreements previously approved by HHSC if the current applicant affirmatively indicates adoption of the HHSC-approved transfer agreement. In addition to the documents required in §511.12 of this subchapter, the applicant shall include a legal document reflecting the change of ownership, such as a copy of the signed bill of sale, or lease agreement, that reflects the effective date of the sale or lease and has been executed by both parties.

(c) HHSC may waive the on-site construction and health inspections required by §511.12 of this subchapter.

(d) When HHSC determines the new owner has complied with the provisions of §511.12 of this subchapter, HHSC shall issue a new license which shall be effective the date of the change of ownership.

(e) The expiration date of the license shall be in accordance with §511.12 of this subchapter.

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

§511.16. Time Periods for Processing and Issuing Limited Services Rural Hospital Licenses.

(a) The application receipt date for an initial license or a renewal license is the date the Texas Health and Human Services Commission (HHSC) receives the application and fee.

(b) An initial license application is complete when HHSC receives, reviews, and finds acceptable the information described in §511.12(a) - (b) of this subchapter (relating to Application and Issuance of Initial License).

(c) A renewal license application is complete when HHSC receives, reviews, and finds acceptable the information described in §511.13(b) of this subchapter (relating to Application and Issuance of Renewal License).

(d) HHSC shall process a limited services rural hospital (LSRH) initial or renewal license in accordance with the following time periods.

(1) The first time period begins on the date HHSC receives the application and supporting documents and ends on the date HHSC issues the LSRH license. If HHSC receives an incomplete application, the time period ends on the date HHSC issues a written notice to the applicant that the application is incomplete. The written notice shall describe the specific documents or information required to complete the application. The first time period is 45 calendar days.

(2) For incomplete applications, the second time period begins on the date HHSC determines the application is complete and ends on the date HHSC issues the LSRH license. The second time period is 45 calendar days.

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

(f) The following circumstances are good cause for HHSC exceeding the established time period:

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

(2) another public or private entity utilized in the application process caused the delay; or

(3) other conditions existed which gave good cause for exceeding the established time periods.

(g) If HHSC denies the request for full reimbursement authorized by subsection (e) of this section, the applicant may then appeal to the HHSC executive commissioner for a resolution of the dispute. The applicant shall give written notice to the executive commissioner requesting full reimbursement of all filing fees paid because HHSC did not process the application within the adopted 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. The executive commissioner shall make the final decision and provide written notification of the decision to the applicant and HHSC.

§511.17. Fees.

(a) All fees paid to the Texas Health and Human Services Commission (HHSC) are nonrefundable with the exception of inspection fees for inspections that were not conducted.

(b) All fees shall be paid by check or money order made payable to HHSC.

(c) The license application fee for an initial license or a renewal license is $350.00.

(d) A limited services rural hospital (LSRH) shall submit a license fee regardless of the number of months remaining in the license period.

(e) An LSRH will not receive a refund of previously submitted fees should the LSRH's design capacity decrease as a result of an approved construction project.

(f) This subsection outlines the fees that must accompany the application for plan review and all proposed plans and specifications covering the alterations to existing buildings which the LSRH must submit for review and approval by HHSC in accordance with §511.167 of this chapter (relating to Preparation, Submittal, Review, and Approval of Plans, and Retention of Records).

(1) HHSC will not review or approve construction plans until HHSC receives the required fee and an application for plan review.

(2) HHSC bases plan review fees on the estimated construction project costs that are the total expenditures required for a proposed project from initiation to completion, including at least the following items.

(A) Construction project costs shall include expenditures for physical assets, such as:

(i) site acquisition;

(ii) soil tests and site preparation;

(iii) construction and improvements required as a result of the project;

(iv) building, structure, or office space acquisition;

(v) renovation;

(vi) fixed equipment; and

(vii) energy provisions and alternatives.

(B) Construction project costs shall include expenditures for professional services, including:

(i) planning consultants;

(ii) architectural fees;

(iii) fees for cost estimation;

(iv) legal fees;

(v) management fees; and

(vi) feasibility study.

(C) Construction project costs shall include expenditures or costs associated with financing, excluding long-term interest, but including:

(i) financial advisor;

(ii) fund-raising expenses;

(iii) lender's or investment banker's fee; and

(iv) interest on interim financing.

(D) Construction project costs shall include expenditure allowances for contingencies, including:

(i) inflation;

(ii) inaccurate estimates;

(iii) unforeseen fluctuations in the money market; and

(iv) other unforeseen expenditures.

(3) Regarding purchases, donations, gifts, transfers, and other comparable arrangements whereby the acquisition is to be made for no consideration or at less than the fair market value, HHSC shall determine project cost by the fair market value of the item to be acquired as a result of the purchase, donation, gift, transfer, or other comparable arrangement.

(A) The plan review fee schedule based on cost of construction is:

(i) $100,000 or less--$300;

(ii) $100,001 to $600,000--$850;

(iii) $600,001 to $2,000,000--$2,000;

(iv) $2,000,001 to $5,000,000--$3,000;

(v) $5,000,001 to $10,000,000--$4,000; and

(vi) $10,000,001 and over--$5,000.

(B) If an estimated construction cost cannot be established, the estimated cost shall be based on $225 per square foot. No construction project shall be increased in size, scope, or cost unless the LSRH submits appropriate fees with the proposed changes.

(g) An LSRH shall submit a fee of $500 and a construction inspection application for each inspection to HHSC at least three weeks before the anticipated inspection date. HHSC will not conduct construction inspections until HHSC receives all required fees. If the LSRH requests additional construction inspections of the proposed project, the LSRH shall submit appropriate additional fees before HHSC conducts any inspections. When HHSC performs follow-up construction inspections to verify plans of correction, the LSRH shall submit the fee when HHSC completes the inspection.

(h) HHSC collects 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 (relating to Use of State Electronic Internet Portal Project) and §2054.252 (State Electronic Internet Portal Project).

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

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Karen Ray
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SUBCHAPTER C. OPERATIONAL REQUIREMENTS

26 TAC §§511.41 - 511.78

STATUTORY AUTHORITY

The new sections are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies, and Texas Health and Safety Code §241.302(b), which provides that the Executive Commissioner of HHSC shall adopt rules to implement that section and establish minimum standards for LSRHs.

The new sections implement Texas Government Code §531.0055 and Texas Health and Safety Code §241.302.

§511.41. Governing Body Organization.

(a) A limited services rural hospital (LSRH) shall have an identified governing body responsible for the LSRH's organization, management, control, and operation, including the appointment of the LSRH's medical staff. For LSRHs owned and operated by an individual or by partners, the individual or partners are the governing body.

(b) An LSRH shall formally organize its governing body in accordance with a written constitution and bylaws, which clearly set forth the organizational structure and responsibilities.

§511.42. Governing Body Responsibilities.

(a) A limited services rural hospital's (LSRH's) governing body shall address and is fully responsible, either directly or by appropriate professional delegation, for the operation and performance of the LSRH.

(b) The governing body is responsible for all services furnished in the LSRH, whether furnished directly or under contract. The governing body shall ensure:

(1) services, including any contracted services, are provided in a safe and effective manner that permits the LSRH to comply with all applicable rules and standards, including the federal conditions of participation at Code of Federal Regulations Title 42 (42 CFR) Part 485, Subchapter E and this chapter;

(2) the LSRH maintains a list of all contracted services, including the scope and nature of the services provided;

(3) the medical staff is accountable to the governing body for the quality of care provided to patients as required by 42 CFR §485.510; and

(4) the provision of education to students and postgraduate trainees if the LSRH participates in such programs.

(c) An LSRH's governing body shall adopt, implement, and enforce written policies and procedures for the total operation and all services the LSRH provides. The policies and procedures shall include at least the following:

(1) bylaws or similar rules and regulations for the orderly development and management of the LSRH;

(2) policies or procedures necessary for the orderly conduct of the LSRH;

(3) policies or procedures related to emergency planning and disaster preparedness that shall require the governing body to review the LSRH's disaster preparedness plan at least annually;

(4) policies for the provision of the following services:

(A) emergency services;

(B) radiological services;

(C) laboratory services;

(D) pharmacy services; and

(E) any outpatient services the LSRH provides;

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

(6) policy on the rights of patients and complying with all state and federal patient rights requirements;

(7) 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 LSRH, including a transfer agreement with a hospital licensed in this state as defined in §511.66 of this subchapter (relating to Patient Transfer Agreements);

(8) policies for all individuals that arrive at the LSRH to ensure they are provided an appropriate medical screening examination within the capability of the LSRH, including:

(A) ancillary services routinely available to determine whether or not the individual needs emergency care as defined in §511.2 of this chapter (relating to Definitions); and

(B) if emergency care is determined to be needed, the LSRH shall provide any necessary stabilizing treatment or arrange an appropriate transfer for the individual as defined in §511.65 of this subchapter (relating to Patient Transfer Policy);

(9) a policy that complies with the requirements under Texas Health and Safety Code §241.009 to require employees, physicians, contracted employees, and individuals in training who provide direct patient care at the LSRH to wear a photo identification badge during all patient encounters, unless precluded by adopted isolation or sterilization protocols; and

(10) policies to ensure compliance with applicable state and federal laws.

(d) The governing body's responsibilities shall include:

(1) determining the LSRH's mission, goals, and objectives;

(2) ensuring that facilities and personnel are sufficient and appropriate to carry out the LSRH's mission;

(3) determining, in accordance with state law, which categories of practitioners are eligible candidates for appointment to the medical staff;

(4) appointing members of the medical staff after considering the recommendations of the existing members of the medical staff;

(5) ensuring that the medical staff is accountable to the governing body for the quality of care provided to patients;

(6) ensuring the criteria for selection are individual character, competence, training, experience, and judgment;

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

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

(9) reviewing and approving the LSRH's training program for staff;

(10) ensuring all equipment utilized by LSRH staff or by patients is properly used and maintained per manufacturer recommendations;

(11) ensuring there is a quality assessment and performance improvement (QAPI) program to evaluate the provision of patient care;

(12) reviewing and monitoring QAPI activities quarterly;

(13) consulting directly at least periodically throughout the fiscal or calendar with medical director or their designee, and include discussion of matters related to the quality of medical care provided to patients of the LSRH;

(14) consulting directly with the individual responsible for the organized medical staff (or their designee) of each hospital or LSRH within its system as applicable for a multi-facility system, including a multi-hospital or multi-LSRH system, using a single governing body;

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

(16) ensuring that under no circumstances is the accordance of staff membership or professional privileges in the LSRH dependent solely upon certification, fellowship, or membership in a specialty body or society;

(17) maintaining effective communication throughout the LSRH;

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

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

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

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

(22) developing a system of risk management appropriate to the LSRH, including:

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

(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;

(23) ensuring that when telemedicine services are furnished to the LSRH's patients through an agreement with a distant-site hospital, the agreement meets the requirements of 42 CFR §485.510; and

(24) ensuring that when telemedicine services are furnished the services meet all federal and state laws, rules, and regulations.

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

(f) The governing body shall approve medical staff bylaws and other medical staff rules and regulations.

(g) The governing body, with input from the medical staff, shall periodically review the scope of procedures performed in the LSRH and amend as appropriate.

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

(i) The governing body shall meet at least annually and maintain minutes or other records necessary for the orderly conduct of the LSRH. Meetings the LSRH's governing body holds shall be separate meetings with separate minutes from any other governing body meeting.

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

(k) 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.

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

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

(n) The governing body shall review patient satisfaction with services and environment at least annually.

§511.43. Administration.

(a) A limited services rural hospital (LSRH) shall adopt, implement, and enforce administrative policies and procedures to ensure the orderly and efficient management of the LSRH. An LSRH's administrative policies and procedures shall include the following administrative responsibilities:

(1) enforcing policies delegated by the governing body;

(2) employing qualified management personnel;

(3) long-range and short-range planning for the LSRH's needs, as determined by the governing body;

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

(5) controlling the purchase, maintenance, and distribution of the LSRH's equipment, materials, and facilities;

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

(7) establishing controls relating to the custody of the LSRH's official documents; and

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

(b) The LSRH shall adopt, implement, and enforce personnel policies to facilitate the LSRH attaining its mission, goals, and objectives. The LSRH's personnel policies shall:

(1) define and delineate functional responsibilities and authority;

(2) require LSRH personnel to have qualifications commensurate with their job responsibilities and authority, including appropriate licensure or certification;

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

(4) specify employment responsibilities and privileges;

(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 LSRH's policies, procedures, equipment, and facilities.

(c) An LSRH shall include all employee categories in personnel policies and shall develop appropriate job descriptions for each position.

§511.44. Emergency Services.

(a) A limited services rural hospital (LSRH) shall provide the emergency care necessary to meet the needs of its patients in accordance with acceptable standards of practice.

(b) An LSRH 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 hospital, to determine whether an emergency medical condition exists and shall provide any necessary stabilizing treatment.

(c) An LSRH shall have an emergency suite that complies with §511.163(e) of this chapter (relating to Spatial Requirements).

(d) The organization of the LSRH's emergency services must be appropriate to the scope of the services offered.

(e) Emergency services must be organized under the direction of a qualified physician member of the LSRH's medical staff who is the medical director or clinical director.

(f) Emergency services must be integrated with other LSRH departments.

(g) The LSRH must 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.

(h) The policies and procedures governing medical care provided in the emergency suite must be established by and must be a continued responsibility of the medical staff.

(i) There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the LSRH.

(j) There must be on-duty and on-site 24 hours a day, seven days a week 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. This individual or individuals must be able to receive patients and activate the appropriate medical resources to meet the care needed by the patient.

(k) Qualified personnel must be physically present in the emergency treatment area at all times.

(l) An LSRH must maintain schedules, names, and phone numbers of all physicians and others on emergency call duty, including alternates. The LSRH must maintain the schedules for at least one year.

(m) In accordance with Code of Federal Regulations Title 42 (42 CFR) §485.516(c)(4), there must be a physician, a physician assistant, or an advanced nurse practitioner, with training or experience in emergency care, on call and immediately available by telephone or radio contact, and available on-site at the LSRH within 30 minutes, on a 24-hour a day basis, if the LSRH is located in an area other than an area described in 42 CFR §485.618(d)(1)(ii).

(n) Emergency services must be available 24-hours per day.

(o) An LSRH shall keep adequate age-appropriate equipment, supplies, and medication used in treating emergency cases and make this equipment, supplies, and medication readily available for treating emergency cases.

(p) The age-appropriate emergency equipment and supplies available at the LSRH shall include at least the following:

(1) emergency call system;

(2) oxygen;

(3) mechanical ventilatory assistance equipment, including airways, manual breathing bag, endotracheal tubes, ambu bag/valve/mask;

(4) cardiac defibrillator;

(5) cardiac monitoring equipment;

(6) laryngoscopes and endotracheal tubes;

(7) suction equipment;

(8) stabilization devices for cervical injuries;

(9) blood pressure monitoring equipment;

(10) pulse oximeter or similar medical device to measure blood oxygenation;

(11) tourniquets;

(12) immobilization devices;

(13) nasogastric tubes;

(14) splints;

(15) Intravenous (IV) therapy supplies;

(16) suction machine;

(17) chest tubes;

(18) indwelling urinary catheters; and

(19) drugs and biologicals commonly used in life-saving procedures as specified by the medical staff, which shall include:

(A) analgesics,

(B) local anesthetics,

(C) antibiotics,

(D) anticonvulsants,

(E) antidotes and emetics,

(F) serums and toxoids,

(G) antiarrhythmics,

(H) cardiac glycosides,

(I) antihypertensives,

(J) diuretics, and

(K) electrolytes and replacement solutions.

(q) Equipment and supplies must be available at the LSRH for administering intravenous medications as well as facilities for bleeding control and emergency splinting of fractures.

(r) The LSRH shall periodically test emergency equipment according to the LSRH's adopted policy.

(s) An LSRH shall provide, either directly or under arrangements, services for the procurement, safekeeping, and transfusion of blood, including the availability of blood products needed for emergencies on a 24-hour a day basis.

(t) Provision for the storage of blood and blood products must be made as needed. If blood banking services are provided under an arrangement, the arrangement is approved by the LSRH's medical staff and by the persons directly responsible for the operation of the LSRH. An LSRH shall ensure all blood and blood components are stored in accordance with §511.45(h) of this subchapter (relating to Laboratory Services).

(u) An LSRH shall, in coordination with emergency response systems in the area, establish procedures under which a physician is immediately available by telephone or radio contact on a 24-hour a day basis to receive emergency calls, provide information on treatment of emergency patients, and refer patients to the LSRH or other appropriate locations for treatment.

§511.45. Laboratory Services.

(a) A limited services rural hospital (LSRH) shall provide basic laboratory services essential to the immediate diagnosis and treatment of the patient consistent with nationally recognized standards of care for emergency services, patient population, and services offered.

(b) The LSRH must ensure laboratory services are available, either directly or through a contractual agreement with a certified laboratory that complies with the Clinical Laboratory Improvement Amendments of 1988 (CLIA 1988) in accordance with the requirements specified in Code of Federal Regulations Title 42 (42 CFR) Part 493 (relating to Laboratory Requirements). CLIA 1988 applies to all hospitals with laboratories that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

(c) The LSRH 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, including at least the following:

(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 LSRH shall have written procedures readily available containing directions on

how to maintain the blood and blood components within permissible temperatures and include instructions to follow in the event of a power failure or other disruption of refrigeration.

(1) Blood transfusions shall be prescribed in accordance with LSRH 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) A label or tray with the recipient's first and last names and identification number, donor unit number and interpretation of compatibility, if performed, shall be attached securely to the blood container.

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

(4) 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.

(5) LSRH 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 as defined in the LSRH's blood transfusion policy.

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

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

(i) The LSRH 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.

(j) An LSRH 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 that may occur during the normal course of job performance.

(k) Pathology and clinical laboratory services shall include at least the following:

(1) conducting laboratory procedures that are appropriate to the needs of the patients;

(2) performing tests in a timely manner;

(3) distributing test results within 24 hours after completion of a test and maintaining a copy of the results in the laboratory; and

(4) performing and documenting appropriate quality assurance procedures, including calibrating equipment periodically and validating test results through use of standardized control specimens or laboratories.

(l) Preoperative laboratory procedures may be required as follows.

(1) It shall be at the discretion of the governing body upon the recommendation of the medical staff to require preoperative laboratory orders.

(2) If specific preoperative laboratory work is required, the medical staff shall approve them in accordance with the medical staff bylaws. Other laboratory work shall be performed only on the order of a physician, podiatrist, dentist, or advanced practice registered nurse and written on the patient's chart.

(3) These services shall be provided either directly within or through an effective contract arrangement with a Medicare-approved reference laboratory.

(4) The contractual agreement with the Medicare-approved reference laboratory shall provide for routine and stat work to include pathology, clinical, and blood bank services, if blood is authorized by the LSRH, and shall be available for review.

§511.46. Radiological Services.

(a) A limited services rural hospital (LSRH) shall maintain, or have available, diagnostic radiologic services according to needs of the patients. All radiology equipment, including X-ray equipment, mammography equipment and laser equipment, shall be licensed and registered as required under Texas Administrative Code Title 25 (25 TAC) Chapter 289 (relating to Radiation Control). When therapeutic services are also provided, the services, as well as the diagnostic services, shall meet professionally approved standards for safety and personnel qualifications as required in 25 TAC §§289.227, 289.229, 289.230, and 289.231 (relating to Use of Radiation Machines in the Healing Arts; Radiation Safety Requirements for Accelerators, Therapeutic Radiation Machines, Simulators, and Electronic Brachytherapy Devices; Certification of Mammography Systems and Mammography Machines Used for Interventional Breast Radiography; and General Provisions and Standards for Protection Against Machine-Produced Radiation, respectively). Portable X-ray equipment may be acceptable as a minimum requirement.

(b) An LSRH shall adopt, implement, and enforce policies and procedures describing the radiology services provided in the LSRH and how the LSRH maintains employee and patient safety.

(c) LSRH policies shall address the quality aspects of radiology services by:

(1) performing radiology services only upon the written order of a physician, advanced practice registered nurse, or other authorized practitioner and 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.

(d) An LSRH shall minimize hazards to patients and personnel when providing radiology services, particularly ionizing radiology procedures.

(e) An LSRH shall adopt, implement, and enforce policies and procedures to 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 (DSHS);

(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, including requiring monitoring devices be worn by all personnel in any area with a radiation hazard;

(5) personnel monitoring dosimeters for nuclear medicine workers to measure their radiation exposure;

(6) maintenance of radiation exposure records on personnel;

(7) authenticated dated reports of all examinations performed shall be made a part of the patient's medical record;

(8) inspection of equipment shall be made by or under the supervision of a licensed medical physicist in accordance with 25 TAC §289.227(o) (relating to Use of Radiation Machines in the Healing Arts). Defective equipment shall be promptly repaired or replaced; and

(9) exposure reports and documentation shall be available for review.

(f) Only personnel designated as qualified by the medical staff shall use the radiology equipment and administer procedures.

(g) LSRH personnel shall provide radiology services only on the order of individuals granted privileges by the medical staff.

(h) A qualified full-time, part-time, or consulting radiologist shall supervise the ionizing radiology services and shall interpret only those radiology tests that are determined by the medical staff to require a radiologist's specialized knowledge. For purposes of this section a radiologist is a physician who is qualified by education and experience in radiology in accordance with medical staff bylaws.

(i) An LSRH shall maintain records of radiology services. The radiologist or other individuals in accordance with subsections (f) and (h) of this section shall sign reports of their interpretations.

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

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

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

(m) When the LSRH provides nuclear medicine services, these services shall meet the needs of the patients in accordance with acceptable standards of practice and be licensed in accordance with 25 TAC §289.256 (relating to Medical and Veterinary Use of Radioactive Material).

(1) The LSRH shall adopt, implement, and enforce policies and procedures describing the LSRH's nuclear medicine services and how the LSRH maintains employee and patient safety with regard to these services.

(2) The organization of the nuclear medicine services shall be appropriate to the scope and complexity of the services offered.

(3) The LSRH shall have a medical director or clinical director who is a physician qualified in nuclear medicine.

(4) The medical director or clinical director shall specify the qualifications, training, functions, and responsibilities of nuclear medicine personnel and the medical staff shall approve them.

(5) Radioactive materials shall be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice and in accordance with 25 TAC §289.256.

(6) In-house preparation of radiopharmaceuticals shall be by, or under, the direct supervision of an appropriately trained licensed pharmacist or physician.

(7) There shall be proper storage and disposal of radioactive materials.

(8) When nuclear medicine services staff perform clinical laboratory tests, the nuclear medicine staff shall comply with CLIA 1988 in accordance with the requirements specified in 42 CFR Part 493.

(9) Equipment and supplies shall be appropriate for the types of nuclear medicine services offered and shall be maintained for safe and efficient performance. Qualified personnel shall inspect, test, and calibrate the equipment at least annually.

(10) The LSRH shall maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures.

(11) The physician approved by the medical staff to interpret diagnostic procedures shall sign and date the interpretations of these tests.

(12) The LSRH shall maintain records of the receipt and disposition of radiopharmaceuticals until disposal is authorized by DSHS in accordance with 25 TAC §289.256.

(13) Only an individual whose scope of state licensure and whose defined staff privileges allow referrals to nuclear medicine services shall order such services.

§511.47. Pharmaceutical Services.

(a) A limited services rural hospital (LSRH) shall provide pharmaceutical services that meet the needs of the patients. The LSRH shall provide a pharmacy that is licensed, as required, by the Texas State Board of Pharmacy. Pharmacy services shall comply with all applicable statutes and rules.

(b) The LSRH pharmacy shall be directed by a licensed pharmacist.

(c) The LSRH medical staff shall develop policies and procedures that minimize drug errors. This function may be delegated to the LSRH's organized pharmaceutical services.

(d) The LSRH pharmacy or drug storage area shall be administered in accordance with accepted professional principles.

(e) Standards of practice as defined by state law shall be followed regarding the provision of pharmacy services.

(f) The pharmaceutical services shall have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.

(1) The staff shall be sufficient in number and training to respond to the pharmaceutical needs of the patient population being served. There shall be an arrangement for emergency services.

(2) Employees shall provide pharmaceutical services within the scope of their license and education.

(g) Drugs and biologicals shall be properly stored to ensure ventilation, light, security, and temperature controls.

(h) Records shall have sufficient detail to follow the flow of drugs from entry through dispensation.

(i) There shall be adequate controls over all drugs and medications, including the floor stock. Drug storage areas shall be approved by the pharmacist, and floor stock lists shall be established.

(j) Inspections of drug storage areas shall be conducted throughout the LSRH under pharmacist supervision.

(k) The LSRH shall have a drug recall procedure.

(l) A full-time, part-time, or consulting pharmacist shall be responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

(1) Direction of pharmaceutical services may not require on-premises supervision but may be accomplished through regularly scheduled visits in accordance with state law.

(2) A job description or other written agreement shall clearly define the responsibilities of the pharmacist.

(m) The LSRH shall keep current and accurate records of the receipt and disposition of all scheduled drugs.

(1) There shall be a record system in place that provides the information on controlled substances in a readily retrievable manner that is separate from the patient record.

(2) Records shall trace the movement of scheduled drugs throughout the services, documenting utilization or wastage.

(3) The pharmacist shall be responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled with written orders.

(n) In order to provide patient safety, drugs and biologicals shall be controlled and distributed in accordance with applicable standards of practice, consistent with federal and state laws.

(o) All compounding, packaging, and dispensing of drugs and biologicals shall be under the supervision of a pharmacist and performed consistent with federal and state laws.

(p) All drugs and biologicals shall be kept in a secure area and locked when appropriate.

(1) The LSRH shall adopt, implement, and enforce a policy to ensure the safeguarding, transferring, and availability of keys to the locked storage area.

(2) Drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. 91-513, 84 Stat. 1236 (21 USC Ch. 13 § 801 et seq.), shall be kept locked within a secure area.

(q) Outdated, mislabeled, or otherwise unusable drugs and biologicals shall not be available for patient use.

(r) When a pharmacist is not available, drugs and biologicals shall be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with federal and state laws.

(1) There shall be a current list of individuals identified by name and qualifications who are designated to remove drugs from the pharmacy.

(2) Only amounts sufficient for immediate therapeutic needs shall be removed.

(s) Drugs and biologicals not specifically prescribed as to time or number of doses shall automatically be stopped after a reasonable time that is predetermined by the medical staff.

(1) Stop order policies and procedures shall be consistent with those of the nursing staff and the medical staff rules and regulations.

(2) A protocol shall be established by the medical staff for the implementation of the stop order policy, in order that drugs shall be reviewed and renewed, or automatically stopped.

(3) A system shall be in place to determine compliance with the stop order policy.

(t) Drug administration errors, adverse drug reactions, and incompatibilities shall be immediately reported to the attending physician and, if appropriate, to the LSRH-wide quality assessment and performance improvement program. There shall be a mechanism in place for capturing, reviewing, and tracking medication errors and adverse drug reactions.

(u) Abuses and losses of controlled substances shall be reported, in accordance with applicable federal and state laws, to the individual responsible for the pharmaceutical services, and to the chief executive officer, as appropriate.

(v) Information relating to drug interactions and information on drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration shall be immediately available to the professional staff.

(1) A pharmacist shall be readily accessible by telephone or other means to discuss drug therapy, interactions, side effects, dosage, assist in drug selection, and assist in the identification of drug induced problems.

(2) There shall be staff development programs on drug therapy available to facility staff to cover such topics as new drugs added to the formulary, how to resolve drug therapy problems, and other general information as the need arises.

(3) The medical staff shall establish a formulary system to ensure quality pharmaceuticals at reasonable costs.

(w) Blood transfusions, blood products, and intravenous medications must be administered in accordance with state law and approved medical staff policies and procedures.

(x) Orders given orally for drugs and biologicals must be followed by a written order, signed by the prescribing physician or other authorized prescriber.

(y) The LSRH shall have a procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

§511.48. Abuse and Neglect Issues.

(a) A limited services rural hospital (LSRH) shall report to the Texas Health and Human Services Commission (HHSC) incidents of abuse, neglect, exploitation, or illegal, unethical, or unprofessional conduct as those terms are defined in subsection (b) of this section.

(b) The following definitions apply only to this subsection.

(1) Abuse of a child--includes the following acts or omissions by any person:

(A) mental or emotional injury to a child that results in an observable and material impairment in the child's growth, development, or psychological functioning;

(B) causing or permitting the child to be in a situation in which the child sustains a mental or emotional injury that results in an observable and material impairment in the child's growth, development, or psychological functioning;

(C) physical injury that results in substantial harm to the child, or the genuine threat of substantial harm from physical injury to the child, including an injury that is at variance with the history or explanation given and excluding an accident (an unforeseen event that causes or threatens physical injury despite prudent efforts to avoid the risk of injury) or reasonable discipline (correction of behavior that does not result in or risk substantial harm from physical injury) by a parent, guardian, or managing or possessory conservator that does not expose the child to a substantial risk of harm;

(D) failure to make a reasonable effort to prevent an action (effort that an ordinary and prudent person would take to stop an action from occurring) by another person that results in physical injury that results in substantial harm to the child;

(E) sexual conduct harmful to a child's mental, emotional, or physical welfare;

(F) failure to make a reasonable effort to prevent sexual conduct harmful to a child;

(G) compelling or encouraging the child to engage in sexual conduct as defined by the Texas Penal Code §43.01 (this is met whether the child actually engages in sexual conduct or simply faces a substantial risk of doing so);

(H) causing, permitting, encouraging, engaging in, or allowing the photographing, filming, or depicting of the child if the person knew or should have known that the resulting photograph, film, or depiction of the child is obscene (as defined by the Texas Penal Code) or pornographic (this is met whether or not the child voluntarily participates);

(I) the current use by a person of a controlled substance as defined by the Texas Health and Safety Code (HSC) Chapter 481, in a manner or to the extent that the use results in physical, mental, or emotional injury to a child; or

(J) causing, expressly permitting, or encouraging a child to use a controlled substance as defined by HSC Chapter 481.

(2) Abuse of an elderly or disabled person--means:

(A) the negligent or willful infliction of injury, unreasonable confinement, intimidation, or cruel punishment with resulting physical or emotional harm or pain by the person's caretaker, family member, or other individual who has an ongoing relationship with the person; or

(B) sexual abuse by the persons, caretaker, family member, or other individual who has an ongoing relationship with the person, but does not include:

(i) the proper use of restraints or seclusion in accordance with federal or state laws or regulations or court order;

(ii) other actions taken in accordance with federal or state laws or regulations or court order;

(iii) actions an employee may reasonably believe to be immediately necessary to avoid imminent harm to self, patients or clients, or other individuals if such actions are limited only to those actions reasonably believed to be necessary under the existing circumstances. Such actions do not include acts of unnecessary force or the inappropriate use of restraints or seclusion; or

(iv) complaints related to the daily administrative operations of a facility (e.g., staffing ratios).

(3) Abuse of an individual with mental illness--Has the following meanings:

(A) In accordance with 42 United States Code (USC) §10802(1) (relating to Definitions), any act or failure to act by an employee of a facility rendering care or treatment that was performed, or that was failed to be performed, knowingly, recklessly, or intentionally, and that caused, or may have caused, injury or death to an individual with mental illness, and includes acts such as:

(i) the rape or sexual assault of an individual with mental illness;

(ii) the striking of an individual with mental illness;

(iii) the use of excessive force when placing an individual with mental illness in bodily restraints; and

(iv) the use of bodily or chemical restraints on an individual with mental illness that is not in compliance with federal and state laws and regulations.

(B) In accordance with HSC §161.132(j) (relating to Reports of Abuse and Neglect or of Illegal, Unprofessional, or Unethical Conduct), abuse also includes coercive or restrictive actions that are illegal or not justified by the patient's condition and that are in response to the patient's request for discharge or refusal of medication, therapy, or treatment.

(4) Exploitation of an elderly or disabled person--means the illegal or improper act or process of a caretaker, family member, or other individual who has an ongoing relationship with the elderly or disabled person using the resources of an elderly or disabled person for monetary or personal benefit, profit, or gain without the informed consent of the elderly or disabled person.

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

(6) Neglect of a child--includes:

(A) the leaving of a child in a situation where the child would be exposed to a substantial risk of physical or mental harm, without arranging for necessary care for the child, and a demonstration of an intent not to return by a parent, guardian, or managing or possessory conservator of a child;

(B) the following acts or omissions by any person:

(i) placing the child in or failing to remove the child from a situation that a reasonable person would realize requires judgment or actions beyond the child's level of maturity, physical condition, or mental abilities and that results in bodily injury or a substantial risk of immediate harm to the child;

(ii) the failure to seek, obtain, or follow through with medical care for the child, with the failure resulting in or presenting a substantial risk of death, disfigurement, or bodily injury or with the failure resulting in an observable and material impairment to the growth, development, or functioning of the child;

(iii) the failure to provide the child with food, clothing, or shelter necessary to sustain the life or health of the child (if the failure results in an observable and material impairment to the child's growth, development, or functioning or in a substantial risk of such an observable or material impairment), excluding failure caused primarily by financial inability unless relief services had been offered and refused; or

(iv) placing a child in or failing to remove the child from a situation in which the child would be exposed to a substantial risk of sexual conduct harmful to the child; or

(C) the failure by the person responsible for a child's care, custody, or welfare to permit the child to return to the child's home without arranging for the necessary care for the child after the child has been absent from the home for any reason, including having been in residential placement or having run away.

(7) Neglect of an elderly or disabled person--means the failure to provide for one's self the goods or services, including medical services, which are necessary to avoid physical or emotional harm or pain or the failure of a caretaker to provide such goods or services.

(8) Neglect of an individual with mental illness--In accordance with 42 USC §10802(5), a negligent act or omission by any individual responsible for providing services in a facility rendering care or treatment that:

(A) caused or may have caused injury or death to an individual with mental illness, or

(B) placed an individual with mental illness at risk of injury or death, and includes an act or omission such as the failure to:

(i) establish or carry out an appropriate individual program plan or treatment plan for an individual with mental illness,

(ii) provide adequate nutrition, clothing, or health care to an individual with mental illness, or

(iii) provide a safe environment for an individual with mental illness, including the failure to maintain adequate numbers of appropriately trained staff.

(9) 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.

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

(c) An LSRH shall prominently and conspicuously post for display in a public area that is readily visible to patients, residents, volunteers, employees, and visitors a statement of the duty to report abuse and neglect, or illegal, unethical or unprofessional conduct in accordance with HSC §161.132(e). The statement shall be in English and in a second language appropriate to the demographic makeup of the community served and contain the current HHSC patient information and complaint line phone number. The LSRH shall ensure the following individuals are aware of the reporting requirements required under HSC §161.132.

(1) In accordance with HSC §161.132(a), a person, including an employee, volunteer, or other person associated with the LSRH who reasonably believes or who knows of information that would reasonably cause a person to believe that the physical or mental health or welfare of a patient of the facility who is receiving mental health or chemical dependency services has been, is, or will be adversely affected by abuse or neglect (as those terms are defined in subsection (b) of this section) by any person, shall as soon as possible report the information supporting the belief to HHSC or to the appropriate state health care regulatory agency.

(2) In accordance with HSC §161.132(b), an LSRH employee or other person associated with the LSRH, including a health care professional, who reasonably believes or who knows of information that would reasonably cause a person to believe the LSRH, an employee, or health care professional associated with the LSRH, 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 LSRH or mental health or chemical dependency services provided in the LSRH, shall as soon as possible report the information supporting the belief to HHSC or to the appropriate state health care regulatory agency.

(d) In accordance with HSC §161.133 (relating to Inservice Training), an LSRH providing comprehensive medical rehabilitation, mental health or substance use services shall annually provide, as a condition of continued licensure, a minimum of eight hours of in-service training designed to assist employees and health care professionals associated with the facility in identifying patient abuse or neglect and illegal, unprofessional, or unethical conduct by or in the LSRH and establish a means for monitoring compliance with the requirement.

(e) A health care professional who fails to report abuse and neglect or illegal, unprofessional, or unethical conduct as required by subsection (c)(2) of this section shall be referred by HHSC to the individual's licensing board for appropriate disciplinary action.

(f) In addition to the reporting requirements described in subsection (c)(2) of this section, a mental health services provider must report suspected sexual exploitation in accordance with Texas Civil Practice and Remedies Code §81.006 (relating to Duty to Report).

§511.49. Medical Director.

(a) The medical director shall be on-site at the limited services rural hospital (LSRH) when necessary to fulfill the responsibilities of the position, as described by this chapter and the LSRH's governing body.

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

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

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

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

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

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

§511.50. Medical Staff.

(a) A limited services rural hospital (LSRH) shall have an organized medical staff that operates under bylaws approved by the LSRH's governing body, and which is responsible for the quality of medical care provided to patients by the LSRH.

(b) The medical staff shall be composed of physicians and may also include podiatrists, dentists, and other practitioners appointed by the LSRH's governing body.

(c) The medical staff shall be well-organized, in a manner approved by the LSRH's governing body, and accountable to the governing body for the quality of the medical care provided to patients.

(d) The responsibility for organization and conduct of the medical staff must be assigned to a physician or podiatrist.

(e) When an LSRH is part of a system consisting of multiple separately certified hospitals, critical access hospitals, or LSRHs, and the system elects to have a unified and integrated medical staff, each separately certified LSRH must demonstrate:

(1) the decision to have a unified and integrated medical staff is in accordance with all applicable state and local laws;

(2) the medical staff members of each separately certified LSRH in the system (that is, all medical staff members who hold specific privileges to practice at that LSRH) have voted by majority, in accordance with medical staff bylaws, either to accept a unified and integrated medical staff structure or to opt out of such a structure and to maintain a separate and distinct medical staff for their respective LSRH;

(3) the unified and integrated medical staff has bylaws, rules, and requirements describing:

(A) its processes for self-governance, appointment, credentialing, privileging, and oversight;

(B) as well as its peer review policies and due process rights guarantees; and

(C) a process to advise the members of the medical staff of each separately certified LSRH (that is, all medical staff members who hold specific privileges to practice at that LSRH) of their right to opt out of the unified and integrated medical staff structure in accordance with paragraph (2) of this subsection;

(4) the unified and integrated medical staff is established in a manner that considers each member LSRH's unique circumstances and any significant differences in patient populations and services offered in each hospital, critical access hospital (CAH), and LSRH;

(5) the unified and integrated medical staff establishes and implements policies and procedures to ensure that the needs and concerns expressed by members of the medical staff, at each of its separately certified hospitals, CAHs, and LSRHs, regardless of practice or location, are given due consideration; and

(6) the unified and integrated medical staff has mechanisms in place to ensure that issues localized to particular hospitals, CAHs, and LSRHs are duly considered and addressed.

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

(g) The medical staff shall examine credentials of a candidate for medical staff membership and make a recommendation to the LSRH's governing body on the candidate's appointment.

(h) When the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.

(i) An LSRH shall maintain records of medical staff meetings.

(j) The medical staff shall adopt, implement, and enforce written bylaws, 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 (for example, active, courtesy, etc.);

(3) describe the organization of the medical staff;

(4) describe the candidate qualifications needed for the medical staff to recommend the candidate's appointment by the governing body; and

(5) include criteria for granting privileges to individual practitioners and a procedure for applying the criteria to individuals requesting privileges. For distant-site physicians and practitioners requesting privileges to provide telemedicine services under an agreement with the LSRH, the criteria for determining privileges and the procedure for applying the criteria are also subject to the requirements in the Code of Federal Regulations Title 42 (42 CFR) §485.510(a)(8) and §485.512(a)(9).

(k) To be privileged as an emergency room practitioner, a physician shall be currently board certified in emergency medicine or have a minimum of one year experience in emergency services and have current certification in advanced cardiac life support, pediatric advanced life support, and advanced trauma life support.

(l) The LSRH shall comply with applicable telemedicine requirements in 42 CFR §485.512.

§511.51. Provision of Services.

(a) The limited services rural hospital (LSRH) shall adopt, implement, train, and enforce written policies to ensure all provided services are consistent with accepted professional standards and practice and compliance in accordance with applicable federal and state law.

(b) The LSRH must develop policies with the advice of members of the LSRH's professional health care staff, including:

(1) one or more physicians; and

(2) one or more of the following if they are on staff under the provisions of Code of Federal Regulations Title 42 (42 CFR) §485.528(b)(1):

(A) physician assistants; or

(B) advanced practice nurse practitioners.

(c) The policies must include:

(1) a description of the services the LSRH provides, including those provided through agreement or arrangement;

(2) policies and procedures for emergency medical services;

(3) guidelines for the medical management of health problems, including:

(A) conditions requiring medical consultation or patient referral;

(B) maintenance of health care records; and

(C) procedures for the periodic review and evaluation of LSRH services; and

(4) policies and procedures that address the post-acute care needs of patients receiving services in the LSRH.

(d) The group of professional personnel described in subsection (b) of this section must review and update the policies as necessary, but at least biennially.

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

(a) A limited services rural hospital (LSRH) shall limit the surgical procedures performed at the LSRH to procedures the governing body approved upon the medical staff's recommendation.

(b) Adequate supervision of surgical procedures conducted in the LSRH shall be:

(1) a responsibility of the governing body;

(2) recommended by medical staff; and

(3) provided by appropriate medical staff.

(c) An LSRH shall only perform surgical procedures when:

(1) a physician or practitioner licensed to perform surgical procedures in Texas performs the procedure;

(2) the governing body granted privileges to the physician or practitioner to perform surgical procedures;

(3) the LSRH's medical staff recommended the surgical procedure; and

(4) the governing body has medically reviewed the physician's or practitioner's documented education, training, experience, and current competence.

(d) An LSRH shall periodically review surgical procedures to be performed in the LSRH as part of the peer review portion of the LSRH's quality assessment and performance improvement program by physically observing planned surgical procedures.

(e) An LSRH shall incorporate an appropriate patient history, physical examination, and pertinent preoperative diagnostic studies into the patient's medical record before surgical procedures.

(f) Unless otherwise provided by law, the LSRH shall discuss the proposed surgical procedure's necessity or appropriateness, as well as any available alternative treatment techniques, with the patient or the patient's legally authorized representative, as applicable, before the surgical procedure.

(g) Unless otherwise provided by law, the LSRH shall obtain the informed consent of the patient or, if applicable, of the patient's legally authorized representative before a surgical procedure is performed. When the LSRH is unable to obtain informed consent before an emergency surgery, the LSRH shall document in the patient's medical record the reason or reasons why the LSRH was unable to obtain the informed consent.

(h) With the exception of those tissues exempted by the governing body after medical review, a pathologist shall examine tissues removed and sign or authenticate the report of the examination for the patient's medical record.

(i) 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.

(j) The LSRH shall allow patients who have received anesthesia, other than solely topical anesthesia, 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.

§511.53. Dietary Services.

(a) A limited services rural hospital (LSRH) shall have organized dietary services that are directed and staffed by adequate qualified personnel.

(1) An LSRH that has a contract with an outside food management company or an arrangement with another hospital may meet this requirement if the food management company or other hospital:

(A) has a dietitian who serves the LSRH on a full-time, part-time, or consultant basis;

(B) maintains at least the minimum requirements specified in this section; and

(C) provides for the frequent and systematic liaison with the LSRH medical staff for recommendations of dietetic policies affecting patient treatment.

(2) The LSRH shall ensure that there are sufficient personnel to respond to the dietary needs of the patient population being served.

(b) The LSRH shall employ a full-time staff who is qualified by experience or training to serve as director of the food and dietetic service and is responsible for the daily management of the dietary services. The director shall:

(1) comply with a job-specific position description;

(2) clearly delineate responsibility and authority;

(3) participate in conferences with administration and department heads;

(4) establish, implement, and enforce policies and procedures for the overall operational components of the LSRH's dietary department that include:

(A) integration of the food and dietetic service into the LSRH-wide quality assessment and performance improvement program and infection control program;

(B) the frequency of meals served;

(C) nonroutine occurrences; and

(D) identification of patient trays; and

(5) maintain authority and responsibility for at least the following:

(A) providing orientation and training;

(B) evaluating staff performance;

(C) providing work assignments;

(D) supervising work and food handling techniques including kitchen sanitation and acceptable hygiene practices of food service personnel;

(E) procuring food, paper, chemical, and other supplies, including implementing a first-in first-out rotation system for all food items;

(F) ensuring there is a four-day food supply on hand at all times;

(G) planning the menu; and

(H) ensuring compliance with Texas Administrative Code Title 25 Chapter 228 (relating to Retail Food Establishments).

(c) The LSRH shall employ a qualified dietitian who works full-time, part-time, or on a consultant basis. If the LSRH chooses to employ the dietician on a consultant basis, such services shall occur at least once per month for not less than eight hours. The dietitian shall:

(1) be currently licensed under the laws of this state to use the titles of licensed dietitian or provisional licensed dietitian, or be a registered dietitian;

(2) maintain professional practice standards;

(3) supervise the nutritional aspects of patient care;

(4) assess the nutritional status and nutritional regimen adequacy, as appropriate;

(5) provide diet counseling and teaching, as appropriate;

(6) document nutritional status and pertinent information in patient medical records, as appropriate;

(7) approve menus; and

(8) approve menu substitutions.

(d) The LSRH shall employ administrative and technical personnel competent in their respective duties. The administrative and technical personnel shall:

(1) participate in established departmental or LSRH training pertinent to assigned duties;

(2) conform to food handling techniques in accordance with subsection (b)(5)(D) of this section;

(3) adhere to clearly defined work schedules and assignment sheets; and

(4) comply with job-specific position descriptions.

(e) An LSRH shall ensure menus meet the needs of the patients.

(f) A physician responsible for the care of the patients shall prescribe therapeutic diets. The LSRH's dietary department shall:

(1) establish procedures for processing therapeutic diets, including:

(A) accurate patient identification;

(B) transcription from nursing to dietary services;

(C) diet planning by a dietitian;

(D) regular review and updating of diet when necessary; and

(E) written and verbal instruction to patient and family, which shall be in the patient's primary language, if practicable, prior to discharge;

(2) ensure a qualified dietitian plans therapeutic diets in writing;

(3) ensure a qualified dietitian approves menu substitutions;

(4) document pertinent information about the patient's response to a therapeutic diet in the patient's medical record; and

(5) evaluate therapeutic diets for nutritional adequacy.

(g) An LSRH shall meet patient nutritional needs in accordance with recognized dietary practices and in accordance with orders of a physician or appropriately credentialed practitioner responsible for the care of the patients. The LSRH shall meet the following requirements.

(1) Menus shall provide a sufficient variety of foods served in adequate amounts at each meal according to the guidance provided in the Recommended Dietary Allowances (RDA), as published by the National Research Council.

(2) The LSRH shall not exceed 15 hours between providing the last meal of the day (i.e., dinner) and the breakfast meal, unless a substantial snack is provided. The LSRH shall adopt, implement, and enforce a policy on the definition of "substantial" to meet each patient's varied nutritional needs.

(h) An LSRH shall have a current therapeutic diet manual approved by the dietitian and medical staff readily available to all medical, nursing, and food service personnel. The LSRH shall:

(1) revise the therapeutic manual as needed and at least every five years;

(2) ensure the therapeutic manual:

(A) is appropriate for the diets routinely ordered in the LSRH;

(B) has standards in compliance with the RDA; and

(C) contains specific diets which are not in compliance with RDA; and

(3) ensure staff use the therapeutic manual as a guide for ordering and serving diets.

§511.54. General Outpatient Requirements.

(a) In addition to providing emergency services and observation care, a limited services rural hospital (LSRH) may provide outpatient and medical health diagnostic and therapeutic items and services that are commonly furnished in a physician's office or at another entry point into the health care delivery system that include: radiology, laboratory, outpatient rehabilitation, surgical, maternal health, and behavioral health services. If an LSRH provides additional outpatient and medical health diagnostic and therapeutic items and services, the LSRH shall comply with the requirements of this section.

(b) The outpatient and medical health diagnostic and therapeutic items and services the LSRH provides shall:

(1) align with the health needs of the community served by the LSRH; and

(2) be appropriately organized and meet the needs of the patients in accordance with acceptable standards of practice.

(c) The LSRH shall:

(1) provide items and services based on nationally recognized guidelines and standards of practice;

(2) have a system in place for referral from the LSRH to different levels of care, including follow-up care, as appropriate;

(3) have effective communication systems in place between the LSRH and the patient (or responsible individual) and their family, ensuring that the LSRH is responsive to their needs and preferences;

(4) have established relationships with hospitals that have the resources and capacity available to deliver care that is beyond the scope of care delivered at the LSRH; and

(5) have personnel providing these services who meet the requirements in subsection (d) of this section.

(d) The LSRH shall meet the following personnel requirements for outpatient services.

(1) The LSRH shall assign one or more individuals to be responsible for outpatient services.

(2) The LSRH shall have appropriate professional and nonprofessional personnel available at each location where outpatient services are offered, based on the scope and complexity of outpatient services.

(3) For any specialty services offered at the LSRH, the LSRH shall have a physician, advanced practice nurse practitioner, or physician assistant providing services with experience and training in the specialty service area and in accordance with their scope of practice.

(e) Outpatient medical and health services shall be ordered by a practitioner who is:

(1) responsible for the care of the patient for whom the practitioner is ordering the services;

(2) licensed in the state of Texas;

(3) acting within their scope of practice under state law;

(4) authorized, in accordance with state law and policies adopted by the medical staff; and

(5) approved by the governing body, to order the applicable outpatient services and either:

(A) appointed to the LSRH's medical staff and who have been granted privileges to order the applicable outpatient services; or

(B) not appointed to the medical staff, but who satisfy the requirements for authorization by the medical staff and the LSRH for ordering the applicable outpatient services for their patients.

§511.55. Surgical Services.

(a) If a limited services rural hospital (LSRH) performs outpatient surgical services, emergency surgical services, or both, the LSRH shall comply with this section.

(b) The LSRH's governing body, on recommendation of the LSRH's medical staff, shall approve surgical procedures performed in the LSRH.

(c) Surgical services shall be well-organized and provided in accordance with acceptable standards of practice.

(d) An LSRH 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.

(e) The organization of the surgical services shall be appropriate for the scope of the services offered.

(f) The LSRH shall periodically review surgical procedures performed in the LSRH as part of the LSRH's quality assessment and performance improvement program.

(g) Appropriate medical staff shall provide adequate supervision of surgical procedures conducted in the LSRH under the recommendation of medical staff and approval of the governing body.

(h) The LSRH shall establish a written procedure for observation and care of the patient during and after surgical procedures.

(i) The LSRH shall establish written protocols for instructing patients in self-care after surgical procedures, including written instructions to be given to patients who receive conscious sedation, regional anesthesia, or both.

(j) The LSRH shall develop an effective written procedure for the immediate transfer to a hospital of patients requiring emergency care beyond the capabilities of the LSRH. The LSRH shall have a written transfer agreement with a hospital as set forth in §511.65 of this subchapter (relating to Patient Transfer Policy).

(k) Surgical procedures shall be performed only by a physician or practitioner who:

(1) is licensed to perform surgical procedures in Texas; and

(2) has 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.

(l) The LSRH shall designate the practitioners who are allowed to perform surgery for LSRH patients, in accordance with its approved policies and procedures, and with state scope of practice laws.

(m) The LSRH shall provide adequate staff during surgical procedures.

(1) The operating rooms shall be supervised by an experienced RN or physician.

(2) Licensed vocational nurses (LVNs) and surgical technologists (operating room technicians) may serve as scrub nurses or technologists only under the supervision of an RN.

(3) Circulating duties in the operating room must be performed by qualified RNs. In accordance with approved medical staff policies and procedures, LVNs and surgical technologists may assist in circulatory duties only under the direct supervision of a qualified RN circulator.

(4) The LSRH shall delineate surgical privileges for all physicians, podiatrists, and dentists performing surgery in accordance with the competencies of each. The surgical services department shall maintain a roster specifying the surgical privileges of each.

(5) If the LSRH employs surgical technologists, the LSRH shall adopt, implement, and enforce policies and procedures to comply with Texas Health and Safety Code Chapter 259 (relating to Surgical Technologists at Health Care Facilities).

(6) 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.

(n) Preoperative laboratory procedures may be required as follows.

(1) It shall be at the discretion of the governing body and the medical staff to require preoperative laboratory orders.

(2) If specific preoperative laboratory work is required, the medical staff shall approve them in accordance with the medical staff bylaws. Specific preoperative laboratory work shall be performed only on the order of a physician, podiatrist, dentist, or advanced practice registered nurse and written on the patient's chart.

(3) These services shall be provided either directly within or through an effective contract arrangement with a Medicare-approved reference laboratory.

(4) The contractual agreement with the Medicare-approved reference laboratory shall provide for routine and stat work to include pathology, clinical, and blood bank services, and shall be available for review.

(o) Surgical services shall be consistent with needs and resources. Written policies governing surgical care that are designed to ensure the achievement and maintenance of high standards of medical practice and patient care shall be adopted, implemented, and enforced.

(p) There shall be a complete medical history and physical examination, as required under subsections (s) and (t) of this section, in the medical record of every patient prior to surgery, except in emergencies. If this has been dictated verbally, but not yet transcribed in the patient's medical record, there shall be a statement to that effect and an admission note in the record by the individual who admitted the patient.

(q) A properly executed informed consent form for the operation shall be in the patient's medical record before surgery, except in emergencies.

(r) A "time out" shall be conducted before starting the procedure to confirm that the correct patient, site, and procedure have been identified, and that all required documents and equipment are available and ready for use.

(s) A qualified practitioner, as specified in subsection (k) of this section, must examine the patient immediately before surgery to evaluate the risk of the procedure to be performed.

(t) A qualified practitioner, as specified in subsection (k) of this section, must examine each patient before surgery to evaluate the risk of anesthesia.

(u) All persons shall use acceptable aseptic techniques in accordance with the LSRH's chosen infection control standards.

(v) 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.

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

(x) Written policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies shall be adopted, implemented, and enforced as described in §511.73 of this subchapter (relating to Sterilization).

(1) Performance records for all sterilizers shall be maintained for a period of six months.

(2) The LSRH shall maintain appropriate supplies to prevent immediate use sterilization.

(3) Preventive maintenance of all sterilizers shall be completed according to manufacturer's recommendations on a scheduled basis. A preventive maintenance record shall be maintained for each sterilizer. An LSRH shall retain these records for at least one year and shall ensure their availability for review at the facility within two hours of HHSC's request.

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

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

(aa) The following equipment shall be available in the operating room suites:

(1) communication system;

(2) cardiac monitor;

(3) resuscitator;

(4) defibrillator;

(5) aspirator; and

(6) tracheotomy set.

(bb) If flammable agents are present in a treatment/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.

(cc) If nonflammable agents are present in a treatment/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.

(dd) There shall be adequate provisions for immediate postoperative care.

(ee) The operating room register shall be complete and up-to-date. The register shall contain, but not be limited to, the following:

(1) patient's name and hospital identification number;

(2) date of operation;

(3) operation performed;

(4) operating surgeon and assistant(s);

(5) type of anesthesia used and name of person administering it;

(6) time operation began and ended;

(7) time anesthesia began and ended;

(8) disposition of specimens;

(9) names of scrub and circulating personnel;

(10) unusual occurrences; and

(11) disposition of the patient.

(ff) An operative report describing techniques, findings, and tissue removed or altered shall be written or dictated immediately following surgery and signed by the surgeon.

(gg) Before discharge from the LSRH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in subsection (k) of this section, as applicable.

(hh) All patients are discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure.

§511.56. Anesthesia Services.

(a) The anesthesia services must be provided:

(1) in a well-organized manner;

(2) under the direction of a qualified physician approved by the governing body; and

(3) in accordance with Texas Occupations Code Title 3, Subtitle B (relating to Physicians) and Texas Occupations Code Chapter 301 (relating to Nurses).

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

(c) The organization of anesthesia services shall be appropriate to the scope of the services offered.

(d) Only personnel who have been approved by the LSRH 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 subsection, the LSRH 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.

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

(f) 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 stan-

dards 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.

(g) Anesthesia services shall be consistent with needs and resources. Policies on anesthesia procedures shall include the delineation of pre-anesthesia and post-anesthesia responsibilities. The policies shall ensure that the following are provided for each patient.

(1) A pre-anesthesia evaluation by an individual qualified to administer anesthesia under subsection (e) of this section shall be performed within 48 hours before surgery.

(2) An intraoperative anesthesia record shall be provided. The record shall include any complications or problems occurring during the anesthesia, including time, description of symptoms, review of affected systems, and treatments rendered. The record shall correlate with the controlled substance administration record.

(3) A post-anesthesia follow-up report shall be written by the person administering the anesthesia before transferring the patient from the post-anesthesia care unit and shall include evaluation for recovery from anesthesia, level of activity, respiration, blood pressure, level of consciousness, and patient's oxygen saturation level.

(4) Immediately prior to discharge, a post-anesthesia evaluation for proper anesthesia recovery shall be performed by the person administering the anesthesia, RN, or physician in accordance with policies and procedures approved by the medical staff and using criteria written in the medical staff bylaws for postoperative monitoring of anesthesia.

(h) Anesthesia services provided in the LSRH 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.)

(i) 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.

(j) 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.

(k) Emergency equipment and supplies appropriate for the type of anesthesia services provided shall be maintained and accessible to staff at all times. Functioning equipment and supplies that are required for all LSRHs include the following:

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

(2) 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 (l) of this section, an LSRH that provides moderate sedation/analgesia, deep sedation/analgesia, or regional analgesia shall provide the following:

(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.

(m) The advanced practice registered nurse, the anesthesiologist, or the operating surgeon shall be available until the surgeon's patients operated on that day have been discharged from the postanesthesia care unit.

(n) Patients who have received anesthesia shall be evaluated for proper anesthesia recovery by the operating surgeon or the person administering the anesthesia prior to discharge from the postanesthesia care unit using criteria approved by the medical staff.

(o) Patients who remain in the facility for extended observation following discharge from the postanesthesia care unit shall be evaluated immediately prior to leaving the facility by a physician, the person administering the anesthesia, or a registered nurse acting in accordance with physician's orders and written policies, procedures, and criteria developed by the medical staff.

(p) A physician shall be on call and able to respond physically or by telephone within 30 minutes until all patients have been discharged from the LSRH.

§511.57. Therapy Services.

(a) If a limited services rural hospital (LSRH) provides physical therapy, occupational therapy, audiology, or speech pathology services as outpatient services, the services shall be organized and staffed to ensure the health and safety of patients.

(b) The organization of the services shall be appropriate to the scope of the services offered.

(c) The director of the services shall have the necessary knowledge, experience, and capabilities to properly supervise and administer the services.

(d) Physical therapy, occupational therapy, speech therapy, or audiology services, if provided, shall be provided by staff who meet the qualifications specified by the medical staff, consistent with state law.

(e) Services shall be furnished in accordance with a written plan of treatment. Services to be provided shall be consistent with applicable state laws and regulations, and in accordance with orders of the physician, podiatrist, dentist, or other licensed practitioner who is authorized by the medical staff to order the services. Therapy orders shall be incorporated in the patient's medical record.

§511.58. Renal Dialysis Services.

(a) A limited services rural hospital (LSRH) may provide dialysis services as a patient medical service in an emergency or to stabilize a patient without an additional license under Texas Health and Safety Code (HSC) Chapter 251. An LSRH may not provide outpatient dialysis services or seek licensure under HSC Chapter 251 except if providing services during a state of disaster as allowed by HSC §251.012(2)(B) (relating to Exemptions from Licensing Requirement) and subsection (b) of this section.

(b) An LSRH may provide outpatient dialysis services when the governor declares a state of disaster or the president of the United States declares a federal disaster in this state or another state. The LSRH may provide outpatient dialysis only during the term of the disaster declaration.

(c) All equipment used in the process for providing dialysis, including backup equipment, shall be operated within manufacturer's specifications, and maintained free of defects that could be a potential hazard to patients, staff, or visitors. Maintenance and repair of all equipment shall be performed by qualified staff or contract personnel.

(d) Staff shall be able to identify malfunctioning equipment used in the process for providing dialysis and report such equipment to the appropriate staff for immediate repair.

(e) Medical equipment used in the process for providing dialysis that malfunctions must be clearly labeled and immediately removed from service until the malfunction is identified and corrected. Written evidence of all maintenance and repairs shall be maintained.

(f) After repairs or alterations are made to any equipment or system used in the process for providing dialysis, the equipment or system shall be thoroughly tested for proper operation before returning to service. This testing must be documented.

(g) An LSRH shall comply with the federal Food, Drug, and Cosmetic Act, 21 United States Code (USC), §360i(b), relating to reporting when a medical device as defined in 21 USC §321(h) has or may have caused or contributed to the injury or death of a patient of the facility.

(h) An LSRH shall develop, implement, and enforce a written preventive maintenance program to ensure patient care related equipment used in a facility receives electrical safety inspections, if appropriate, and maintenance at least annually or more frequently as recommended by the manufacturer. The preventive maintenance may be provided by LSRH staff or by contract.

(i) At least one complete dialysis machine shall be available on site as backup for every 10 dialysis machines in use. At least one of these backup machines must be completely operational during hours of treatment. Machines not in use during a patient shift may be counted as backup except at the time of an initial or an expansion survey.

(j) An LSRH shall have emergency equipment and supplies immediately accessible in the treatment area. The emergency equipment and supplies shall include at least the following:

(1) oxygen;

(2) mechanical ventilatory assistance equipment, to include airways, manual breathing bag, and mask;

(3) suction equipment;

(4) supplies specified by the medical director;

(5) electrocardiograph; and

(6) automated external defibrillator or defibrillator.

(k) If pediatric patients are treated, the LSRH shall have the appropriate type and size emergency equipment and supplies listed in subsection (j) of this section for this special population.

(l) If pediatric patients are treated, an LSRH shall use equipment and supplies, to include blood pressure cuffs, dialyzers, and blood tubing, appropriate for this special population.

(m) An LSRH shall establish, implement, and enforce a policy for the periodic testing and maintenance of the emergency equipment. Staff shall properly maintain and test the emergency equipment and supplies and document the testing and maintenance.

(n) A transducer protector shall be replaced when wetted during a dialysis treatment and shall be used for one treatment only.

(o) Water treatment and dialysate supply systems shall meet the requirements of this subsection. An LSRH may follow more stringent requirements than the standards required by this subsection.

(1) The LSRH administrator and medical director shall each demonstrate responsibility for the water treatment and dialysate supply systems to protect hemodialysis patients from adverse effects arising from known chemical and microbial contaminates that may be found in improperly prepared dialysate, to ensure that the dialysate is correctly formulated and meets the requirements of all applicable quality standards.

(2) The LSRH administrator and medical director must assure that policies and procedures related to water treatment and dialysate are understandable and accessible to the operator and that the training program includes quality testing, risks and hazards of improperly prepared concentrate and bacterial issues.

(3) The LSRH administrator and medical director must be informed before any alteration of, or any device being added to, the water system.

(4) These requirements apply to water intended for use in the delivery of hemodialysis, including the preparation of concentrates from powder at a dialysis facility and dialysate.

(5) The design for the water treatment system in an LSRH shall be based on considerations of the source water for the LSRH and designed by a water quality professional with education, training, or experience in dialysis system design.

(6) When an LSRH does not use a public water system supply, the LSRH shall test the source water at monthly intervals in the same manner as a public water system as described in Texas Administrative Code Title 30 §290.104 (relating to Summary of Maximum Contaminant Levels, Maximum Residual Disinfectant Levels, Treatment Techniques, and Action Levels), and §290.109 (relating to Microbial Contaminants) as adopted by the Texas Commission on Environmental Quality (TCEQ).

(7) The physical space in which the water treatment system is located must be adequate to allow for maintenance, testing, and repair of equipment. If mixing of dialysate is performed in the same area, the physical space must also be adequate to house and allow for the maintenance, testing, and repair of the mixing equipment and for performing the mixing procedure.

(8) The water treatment system components shall be arranged and maintained so that bacterial and chemical contaminant levels in the product water do not exceed the standards for hemodialysis water quality described in §4.2.1 (relating to Water Bacteriology) and §4.2.2 (relating to Maximum Level of Chemical Contaminants) of the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition, published by the Association for the Advancement of Medical Instrumentation (AAMI).

(9) Written policies and procedures for the operation of the water treatment system must be developed and implemented. Parameters for the operation of each component of the water treatment system must be developed, in writing, and known to the operator. Each major water system component shall be labeled in a manner that identifies the device, describes its function, how performance is verified and actions to take in the event performance is not within an acceptable range.

(10) The materials of any components of water treatment systems (including piping, storage, filters and distribution systems) that contact the purified water shall not interact chemically or physically so as to affect the purity or quality of the product water adversely. Such components shall be fabricated from unreactive materials (e.g., plastics) or appropriate stainless steel. The use of materials that are known to cause toxicity in hemodialysis, such as copper, brass, galvanized material, or aluminum, is prohibited.

(11) Chemicals infused into the water such as iodine, acid, flocculants, and complexing agents shall be shown to be nondialyzable or shall be adequately removed from product water. Monitors or specific test procedures to verify removal of additives shall be provided and documented.

(12) Each water treatment system shall include reverse osmosis (RO) membranes or deionization (DI) tanks and a minimum of two carbon tanks in series. If the source water is from a private supply that does not use chlorine/chloramine, the water treatment system shall include RO membranes or deionization tanks and a minimum of one carbon tank.

(13) Reverse osmosis membranes, if used, shall meet the standards in §4.3.7 (relating to Reverse Osmosis) of the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition, published by the AAMI.

(14) Deionization systems, if used, shall be monitored continuously to produce water of one megohm-centimeter (cm) or greater specific resistivity (or conductivity of one microsiemen/cm or less) at 25 degrees Centigrade. An audible and visual alarm shall be activated when the product water resistivity falls below this level and the product water stream shall be prevented from reaching any point of use.

(15) Patients shall not be dialyzed on deionized water with a resistivity less than 1.0 megohm-cm measured at the output of the deionizer.

(16) A minimum of two DI tanks in series shall be used with resistivity monitors including audible and visual alarms placed pre and post the final DI tank in the system. The alarms must be audible in the patient care area.

(17) Feed water for deionization systems shall be pretreated with activated carbon adsorption, or a comparable alternative, to prevent nitrosamine formation.

(18) If a deionization system is the last process in a water treatment system, it shall be followed by an ultrafilter or other bacteria and endotoxin reducing device.

(19) The carbon tanks must contain acid washed carbon, 30-mesh or smaller with a minimum iodine number of 900.

(20) A minimum of two carbon adsorption beds shall be installed in a series configuration.

(21) The total empty bed contact time (EBCT) shall be at least 10 minutes, with the final tank providing at least five minutes EBCT. Carbon adsorption systems used to prepare water for portable dialysis systems are exempt from the requirement for the second carbon and a 10-minute EBCT if removal of chloramines to below 0.1 milligram (mg)/1 is verified before each treatment.

(22) A means shall be provided to sample the product water immediately prior to the final bed(s). Water from this port(s) must be tested for chlorine/chloramine levels immediately prior to each patient shift.

(23) All samples for chlorine/chloramine testing must be drawn when the water treatment system has been operating for at least 15 minutes.

(24) Tests for total chlorine, which include both free and combined forms of chlorine, may be used as a single analysis with the maximum allowable concentration of 0.1 mg/liter (L). Test results of greater than 0.5 parts per million (ppm) for chlorine or 0.1 ppm for chloramine from the port between the initial tank(s) and final tank(s) shall require testing to be performed at the final exit and replacement of the initial tank(s).

(25) In a system without a holding tank, if test results at the exit of the final tank(s) are greater than the parameters for chlorine or chloramine described in this subclause, dialysis treatment shall be immediately terminated to protect patients from exposure to chlorine/chloramine and the medical director shall be notified. In systems with holding tanks, if the holding tank tests <1 mg/L for total chlorine, the RO may be turned off and the product water in the holding tank may be used to finish treatments in process. The medical director shall be notified.

(26) If means other than granulated carbon are used to remove chlorine/chloramine, the facility's governing body must approve such use, in writing, after review of the safety of the intended method for use in hemodialysis applications. If such methods include the use of additives, there must be evidence the product water does not contain unsafe levels of these additives.

(27) Water softeners, if used, shall be tested at the end of the treatment day to verify their capacity to treat a sufficient volume of water to supply the facility for the entire treatment day and shall be fitted with a mechanism to prevent water containing the high concen-

trations of sodium chloride used during regeneration from entering the product water line during regeneration.

(28) If used, the face(s) of timer(s) used to control any component of the water treatment or dialysate delivery system shall be visible to the operator at all times. Written evidence that timers are checked for operation and accuracy each day of operation must be maintained.

(29) Filter housings, if used during disinfectant procedures, shall include a means to clear the lower portion of the housing of the disinfecting agents. Filter housings shall be opaque.

(30) Ultrafilters, or other bacterial reducing filters, if used, shall be fitted with pressure gauges on the inlet and outlet water lines to monitor the pressure drop across the membrane. Ultrafilters shall be included in routine disinfection procedures.

(31) If used, storage tanks shall have a conical or bowl-shaped base and shall drain from the lowest point of the base. Storage tanks shall have a tight-fitting lid and be vented through a hydrophobic 0.2 micron air filter. Means shall be provided to effectively disinfect any storage tank installed in a water distribution system.

(32) Ultraviolet (UV) lights, if used, shall be monitored at the frequency recommended by the manufacturer. A log sheet shall be used to record monitoring.

(33) Water treatment system piping shall be labeled to indicate the contents of the pipe and direction of flow.

(34) The water treatment system must be continuously monitored during patient treatment and be guarded by audible and visual alarms that can be seen and heard in the dialysis treatment area should water quality drop below specific parameters. Quality monitor sensing cells shall be located as the last component of the water treatment system and at the beginning of the distribution system. No water treatment components that could affect the quality of the product water as measured by this device shall be located after the sensing cell.

(35) When deionization tanks do not follow an RO system, parameters for the rejection rate of the membranes must assure that the lowest rate accepted would provide product water in compliance with §4.2.2 (relating to Maximum Level of Chemical Contaminants) of the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition published by the AAMI.

(36) An LSRH shall maintain written logs of the operation of the water treatment system for each treatment day. The log book shall include each component's operating parameter and the action taken when a component is not within the facility's set parameters.

(37) Microbiological testing of product water shall be conducted.

(A) Microbiological testing shall be conducted monthly and following any repair or change to the water treatment system. For a newly installed water distribution system, or when a change has been made to an existing system, weekly testing shall be conducted for one month to verify that bacteria and endotoxin levels are consistently within the allowed limits.

(B) At a minimum, sample sites chosen for the testing shall include the beginning of the distribution piping, at any site of dialysate mixing, and the end of the distribution piping.

(C) Samples shall be collected immediately before sanitization/disinfection of the water treatment system and dialysis machines. Water testing results shall be routinely trended and reviewed by the medical director in order to determine if results seem questionable or if there is an opportunity for improvement. The medical director shall determine if there is a need for retesting. Repeated results of "no growth" shall be validated via an outside laboratory. A calibrated loop may not be used in microbiological testing of water samples. Colonies shall be counted using a magnifying device.

(38) Product water used to prepare dialysate, concentrates from powder, or to reprocess dialyzers for multiple use, shall contain a total viable microbial count less than 200 colony forming units (CFU)/millimeter (ml) and an endotoxin concentration less than 2 endotoxin units (EU)/ml. The action level for the total viable microbial count in the product water shall be 50 CFU/ml and the action level for the endotoxin concentration shall be 1 EU/ml.

(39) Required action for unacceptable results. If the action levels described at paragraph (6) of this subsection are observed in the product water, corrective measures shall be taken promptly to reduce the levels into an acceptable range.

(40) All bacteria and endotoxin results shall be recorded on a log sheet in order to identify trends that may indicate the need for corrective action.

(41) If ozone generators are used to disinfect any portion of the water or dialysate delivery system, testing based on the manufacturer's direction shall be used to measure the ozone concentration each time disinfection is performed, to include testing for safe levels of residual ozone at the end of the disinfection cycle. Testing for ozone in the ambient air shall be conducted on a periodic basis as recommended by the manufacturer. Records of all testing must be maintained in a log.

(42) If used, hot water disinfection systems shall be monitored for temperature and time of exposure to hot water as specified by the manufacturer. Temperature of the water shall be recorded at a point furthest from the water heater, where the lowest water temperature is likely to occur. The water temperature shall be measured each time a disinfection cycle is performed. A record that verifies successful completion of the heat disinfection shall be maintained.

(43) After chemical disinfection, means shall be provided to restore the equipment and the system in which it is installed to a safe condition relative to residual disinfectant prior to the product water being used for dialysis applications.

(44) Samples of product water must be submitted for chemical analysis every six months and must demonstrate that the quality of the product water used to prepare dialysate or concentrates from powder, meets §4.2.2 (relating to Maximum Level of Chemical Contaminants) of the American National Standard, Water Treatment Equipment for Hemodialysis Applications, August 2001 Edition, published by the AAMI.

(45) Samples for chemical analysis shall be collected at the end of the water treatment components and at the most distal point in each water distribution loop, if applicable. All other outlets from the distribution loops shall be inspected to ensure that the outlets are fabricated from compatible materials. Appropriate containers and pH adjustments shall be used to ensure accurate determinations. New LSRHs or LSRHs that add or change the configuration of the water distribution system must draw samples at the most distal point for each water distribution loop, if applicable, on a one time basis.

(46) Additional chemical analysis shall be submitted if substantial changes are made to the water treatment system or if the percent rejection of an RO system decreased 5.0% or more from the percent rejection measured at the time the water sample for the preceding chemical analysis was taken.

(47) LSRH records must include all test results and evidence that the medical director has reviewed the results of the water quality testing and directed corrective action when indicated.

(48) Only persons qualified by the education or experience may operate, repair, or replace components of the water treatment system.

(49) Quality control procedures shall be established to ensure ongoing conformance to policies and procedures regarding dialysate quality.

(p) Each LSRH shall set all hemodialysis machines to use only one family of concentrates. When new machines are put into service or the concentrate family or concentrate manufacturer is changed, samples shall be sent to a laboratory for verification.

(q) Prior to each patient treatment, LSRH staff shall verify the dialysate conductivity and pH of each machine with an independent device.

(r) The LSRH shall conduct bacteriological testing.

(s) Responsible LSRH staff shall develop a schedule to ensure each hemodialysis machine is tested quarterly for bacterial growth and the presence of endotoxins. Hemodialysis machines of home patients shall be cultured monthly until results not exceeding 200 CFU/ml are obtained for three consecutive months, then quarterly samples shall be cultured.

(t) Dialysate shall contain less than 200 CFU/ml and an endotoxin concentration of less than 2 EU/ml. The action level for total viable microbial count shall be 50 CFU/ml and the action level for endotoxin concentration shall be 1 EU/ml.

(u) Disinfection and retesting shall be done when bacterial or endotoxin counts exceed the action levels. Additional samples shall be collected when there is a clinical indication of a pyrogenic reaction and/or septicemia.

(v) Only a licensed nurse may use an additive to increase concentrations of specific electrolytes in the acid concentrate. Mixing procedures shall be followed as specified by the additive manufacturer. When additives are prescribed for a specific patient, the container holding the prescribed acid concentrate shall be labeled with the name of the patient, the final concentration of the added electrolyte, the date the prescribed concentrate was made, and the name of the person who mixed the additive.

(w) All components used in concentrate preparation systems (including mixing and storage tanks, pumps, valves, and piping) shall be fabricated from materials (e.g., plastics or appropriate stainless steel) that do not interact chemically or physically with the concentrate so as to affect its purity, or with the germicides used to disinfect the equipment. The use of materials that are known to cause toxicity in hemodialysis such as copper, brass, galvanized material, and aluminum is prohibited.

(x) LSRH policies shall address means to protect stored acid concentrates from tampering or from degeneration due to exposure to extreme heat or cold.

(y) Procedures to control the transfer of acid concentrates from the delivery container to the storage tank and prevent the inadvertent mixing of different concentrate formulations shall be developed, implemented, and enforced. The storage tanks shall be clearly labeled.

(z) Concentrate mixing systems shall include a purified water source, a suitable drain, and a ground fault-protected electrical outlet.

(aa) Operators of mixing systems shall use personal protective equipment as specified by the manufacturer during all mixing processes.

(bb) The manufacturer's instructions for use of a concentrate mixing system shall be followed, including instructions for mixing the powder with the correct amount of water. The number of bags or weight of powder added shall be determined and recorded.

(1) The mixing tank shall be clearly labeled to indicate the fill and final volumes required to correctly dilute the powder.

(2) Systems for preparing either bicarbonate or acid concentrate from powder shall be monitored according to the manufacturer's instructions.

(3) Concentrates shall not be used, or transferred to holding tanks or distribution systems, until all tests are completed.

(4) If an LSRH designs its own system for mixing concentrates, procedures shall be developed and validated using an independent laboratory to ensure proper mixing.

(5) Acid concentrate mixing tanks shall be designed to allow the inside of the tank to be rinsed when changing concentrate formulas.

(6) Acid mixing systems shall be designed and maintained to prevent rust and corrosion.

(7) Acid concentrate mixing tanks shall be emptied completely and rinsed with product water before mixing another batch of concentrate to prevent cross contamination between different batches.

(8) Acid concentrate mixing equipment shall be disinfected as specified by the equipment manufacturer or in the case where no specifications are given, as defined by LSRH policy.

(9) Records of disinfection and rinsing of disinfectants to safe residual levels shall be maintained.

(10) Bicarbonate concentrate mixing tanks shall have conical or bowl-shaped bottoms and shall drain from the lowest point of the base. The tank design shall allow all internal surfaces to be disinfected and rinsed.

(11) Bicarbonate concentrate mixing tanks shall not be prefilled the night before use.

(12) If disinfectant remains in the mixing tank overnight, this solution must be completely drained and the tank must be rinsed and tested for residual disinfectant prior to preparing the first batch of that day of bicarbonate concentrate.

(13) Unused portions of bicarbonate concentrate shall not be mixed with fresh concentrate.

(14) At a minimum, bicarbonate distribution systems shall be disinfected weekly. More frequent disinfection shall be done if required by the manufacturer, or if dialysate culture results are above the action level.

(15) If jugs are reused to deliver bicarbonate concentrate to individual hemodialysis machines:

(A) jugs shall be emptied of concentrate, rinsed, and inverted to drain at the end of each treatment day;

(B) at a minimum, jugs shall be disinfected weekly, and more frequent disinfection shall be considered by the medical director if dialysate culture results are above the action level; and

(C) following disinfection, jugs shall be drained, rinsed free of residual disinfectant, and inverted to dry. Testing for residual disinfectant shall be done and documented.

(16) All mixing tanks, bulk storage tanks, dispensing tanks, and containers for single hemodialysis treatments shall be labeled as to the contents.

(17) Prior to batch preparation, a label shall be affixed to the mixing tank that includes the date of preparation and the chemical composition or formulation of the concentrate being prepared. This labeling shall remain on the mixing tank until the tank has been emptied.

(18) Mixing tanks shall be permanently labeled to identify the chemical composition or formulation of their contents.

(19) At a minimum, single machine containers shall be labeled with sufficient information to differentiate the contents from other concentrate formulations used in the LSRH and permit positive identification by users of container contents.

(20) Permanent records of batches produced shall be maintained to include the concentrate formula produced, the volume of the batch, lot number(s) of powdered concentrate packages, the manufacturer of the powdered concentrate, date and time of mixing, test results, person performing mixing, and expiration date (if applicable).

(21) If dialysate concentrates are prepared in the facility, the manufacturers' recommendations shall be followed regarding any preventive maintenance. Records shall be maintained indicating the date, time, person performing the procedure, and the results (if applicable).

(cc) With the advice and consent of a patient's attending nephrologist, facility staff shall make the hepatitis B vaccine available to a patient who is susceptible to hepatitis B, provided that the patient has coverage or is willing to pay for vaccination.

(dd) The LSRH shall make available to patients literature describing the risks and benefits of the hepatitis B vaccination.

(ee) A patient new to dialysis shall have been screened for hepatitis B surface antigen (HBsAg) within one month before or at the time of admission to the facility or have a known hepatitis B surface antibody (anti-HBs) status of at least 10 milli-international units per milliliter no more than 12 months prior to admission. The LSRH shall document how this screening requirement is met.

(1) Repeated serologic screening shall be based on the antigen or antibody status of the patient.

(2) Monthly screening for HBsAg is required for patients whose previous test results are negative for HBsAg.

(3) Screening of HBsAg-positive or anti-HBs-positive patients may be performed on a less frequent basis, provided that the LSRH's policy on this subject remains congruent with Appendices i and ii of the National Surveillance of Dialysis Associated Disease in the United States, 2000, published by the United States Department of Health and Human Services.

(ff) The LSRH shall treat patients positive for HBsAg in a segregated treatment area that includes a hand washing sink, a work area, patient care supplies and equipment, and sufficient space to prevent cross-contamination to other patients.

(1) A patient who tests positive for HBsAg shall be dialyzed on equipment reserved and maintained for the HBsAg-positive patient's use only.

(2) When a caregiver is assigned to both HBsAg-negative and HBsAg-positive patients, the HBsAg-negative patients assigned to this grouping must be hepatitis B antibody positive. Hepatitis B antibody positive patients are to be seated at the treatment stations nearest the isolation station and be assigned to the same staff member who is caring for the HBsAg-positive patient.

(3) If an HBsAg-positive patient is discharged, the equipment that had been reserved for that patient shall be given intermediate level disinfection prior to use for a patient testing negative for HBsAg.

(4) In the case of patients new to dialysis, if these patients are admitted for treatment before results of HBsAg or anti-HBs testing are known, these patients shall undergo treatment as if the HBsAg test results were potentially positive, except that they shall not be treated in the HBsAg isolation room, area, or machine.

(A) The LSRH shall treat potentially HBsAg-positive patients in a location in the treatment area that is outside of traffic patterns until the HBsAg test results are known.

(B) The dialysis machine used by this patient shall be given intermediate level disinfection prior to its use by another patient.

(C) The LSRH shall obtain HBsAg status results of the patient no later than three days from admission.

§511.59. Infection Prevention and Control and Antibiotic Stewardship Programs.

(a) A limited services rural hospital (LSRH) shall have an infection prevention and control and antibiotic stewardship program that complies with Code of Federal Regulations Title 42 §485.528 to the extent it does not conflict with this chapter and state law.

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

§511.60. Staffing and Staff Responsibilities.

(a) The LSRH must have a professional health care staff that includes one or more physicians, and may include one or more physician assistants, or advanced practice nurse practitioners.

(b) Any ancillary personnel are supervised by the professional staff.

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

(d) The LSRH shall maintain documentation of evidence that all personnel are trained prior to treatment of services.

(e) The staff shall be sufficient to provide the services essential to the operation of the LSRH.

(f) A registered nurse, clinical nurse specialist, or licensed vocational nurse shall be on duty whenever the LSRH has one or more patients receiving emergency care or observation care.

(g) If the LSRH provides outpatient services, the services shall meet the needs of the patients in accordance with acceptable standards of practice.

(1) The LSRH shall assign an individual to be responsible for outpatient services.

(2) The LSRH shall have appropriate physicians on staff and other professional and nonprofessional personnel available.

(3) The physician must:

(A) provide medical direction for the LSRH's health care activities and consultation for, and medical supervision of, the health care staff;

(B) participate, in conjunction with any physician assistant or nurse practitioner members, in developing, executing, and

periodically reviewing the LSRH's written policies governing the services it furnishes;

(C) review periodically, in conjunction with any physician assistant or nurse practitioner members, the LSRH patient records, provide medical orders, and provide medical care services to the patients of the LSRH; and

(D) review periodically and sign a sample of outpatient records of patients cared for by advanced practice nurse practitioners or physician assistants only to the extent where state law requires record reviews or co-signatures, or both, by a collaborating physician.

(h) A physician must be present for sufficient periods of time to provide medical direction, consultation, and supervision for the services provided in the LSRH, and is available through direct radio or telephone communication or electronic communication for consultation, assistance with medical emergencies, or patient referral.

(i) The physician assistant, the nurse practitioner, or clinical nurse specialist members of the LSRH staff shall:

(1) participate in the development, execution and periodic review of the written policies governing the services the LSRH furnishes; and

(2) participate with a physician in a periodic review of the patients' health records.

(j) The physician assistant, nurse practitioner, or clinical nurse specialist shall perform the following functions to the extent they are not being performed by a physician:

(1) provides services in accordance with the LSRH's policies; and

(2) arranges for, or refers patients to, needed services that cannot be furnished at the LSRH, and assures that adequate patient health records are maintained and transferred as required when patients are referred.

(k) Whenever a patient is placed in observation care at the LSRH by a nurse practitioner, physician assistant, or clinical nurse specialist, a physician on the staff of the LSRH is notified of the patient's status.

(l) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists, and physician assistants at the LSRH must be evaluated by a member of the LSRH staff who is a physician or by another physician under contract with the LSRH.

(m) The quality and appropriateness of the diagnosis and treatment provided by a physician at the LSRH must be evaluated by one of the following:

(1) One Quality Improvement Organization (QIO) or equivalent entity;

(2) in the case of distant-site physicians and practitioners providing telemedicine services to the LSRH's patient under an agreement between the LSRH and a distant-site hospital, the distant-site hospital; or

(3) in the case of distant-site physicians and practitioners providing telemedicine services to the LSRH's patients under a written agreement between the LSRH and a distant-site telemedicine entity, one QIO or equivalent entity.

(n) The LSRH staff shall consider the findings of the evaluation and make the necessary changes as specified in Code of Federal Regulations Title 42 §485.528 (b) - (d) (relating to Condition of participation: Staffing and staff responsibilities).

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

(p) 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 service shall include nursing care rendered to patients preoperatively, intraoperatively, and postoperatively.

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

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

(3) Surgical technicians and licensed vocational nurses may be permitted to serve in the scrub nurse role under the direct supervision of an RN; they shall not be permitted to function as circulating nurses in the operating rooms. Licensed vocational nurses and surgical technicians may assist in circulatory duties under the direct supervision of a qualified RN.

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

(5) The LSRH shall adopt, implement and enforce policies and procedures to comply with Texas Health and Safety Code Chapter 259 (relating to Surgical Technologists at Health Care Facilities).

(6) There shall be an adequate number of RNs on duty to meet the following minimum staff requirements: director of the department (or designee), and supervisory and staff personnel for each service area to assure the immediate availability of an RN for emergency care or for any patient when needed.

(7) 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.

(8) There shall be other nursing personnel in sufficient numbers to provide nursing care not requiring the service of an RN.

(9) An RN qualified, at a minimum, with current certification in advanced cardiac life support and pediatric advanced life support shall be on duty and on the premises at all times whenever patients are present in the LSRH.

(q) All direct patient care staff must have current certification in basic cardiac life support.

(r) In addition to meeting the requirements for nursing staff under subsections (p) and (q) of this section, LSRHs shall comply with the following staffing requirements.

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

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

(A) a second individual on duty on the premises 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, if surgery is performed on pediatric patients, pediatric advanced life support shall be available until all patients have been discharged from the postanesthesia care unit.

(s) LSRHs that provide deep sedation/analgesia, general anesthesia, or regional anesthesia shall have the following additional staff:

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

(2) an individual who is trained and currently certified in advanced cardiac life support and, if surgery is performed on pediatric patients, pediatric advanced life support shall be on duty on the premises and sufficiently free of other duties to enable the individual to respond rapidly to emergency situations until all patients have been discharged from the postanesthesia care unit.

(t) As applicable, the LSRH shall establish a nursing peer review committee to conduct nursing peer review, as required by Texas Occupations Code Chapter 303 (relating to Nursing Peer Review).

§511.61. Nursing Services.

(a) A limited services rural hospital (LSRH) shall have a well-organized nursing service with a plan of administrative authority and delineation of responsibilities for patient care and provides 24-hour nursing services as needed.

(b) An LSRH shall provide nursing services in accordance with current recognized standards or recommended practices.

(c) Nursing services shall be under the administrative authority of a chief nursing officer (CNO) who is a registered nurse (RN).

(1) The CNO shall be responsible for the operation of nursing services, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the LSRH.

(2) The CNO shall report directly to the individual who has authority to represent the LSRH and who is responsible for the operation of the LSRH according to the policies and procedures of the LSRH's governing board.

(3) The CNO shall participate with the governing body, medical staff, and clinical areas, in planning, promoting and conducting performance improvement activities.

(d) An LSRH shall adopt, implement and enforce a procedure to verify nursing personnel for whom licensure is required have valid and current licensure.

(e) An LSRH shall comply with the following nursing staff requirements.

(1) The LSRH shall have adequate numbers of RNs, licensed vocational nurses (LVNs), and other personnel to provide nursing care to all patients as needed in accordance with subsection (f) of this section.

(2) The LSRH shall have an adequate number of RNs on duty to meet the LSRH's minimum staff requirements in accordance with subsection (f)(2) of this section to include supervisory and staff RNs to ensure the immediate availability of an RN for emergency care or for any patient when needed.

(3) The nursing staff shall develop and keep current a nursing plan of care for each patient which addresses the patient's needs.

(4) The LSRH shall establish a nurse staffing committee as a standing committee of the LSRH. The committee shall be established in accordance with Texas Health and Safety Code (HSC) Chapter 161, Subchapter D (relating to Medical Committees, Medical Peer Review Committees, and Compliance Officers), to be responsible for soliciting and receiving input from nurses on the development, ongoing monitoring, and evaluation of the staffing plan. As used in this section, "committee" or "staffing committee" means a nurse staffing committee established under this paragraph.

(f) An LSRH shall adopt, implement, and enforce a written official nurse services staffing plan. As used in this subsection, "patient care unit" means a unit or area of an LSRH in which registered nurses provide patient care.

(1) The official nurse services staffing plan and policies shall:

(A) require significant consideration to be given to the nurse staffing plan recommended by the LSRH's nurse staffing committee and the committee's evaluation of any existing plan;

(B) be based on the needs of each patient care unit and shift and on evidence relating to patient care needs;

(C) require use of the official nurse services staffing plan as a component in setting the nurse staffing budget;

(D) encourage nurses to provide input to the nurse staffing committee relating to nurse staffing concerns;

(E) protect from retaliation nurses who provide input to the nurse staffing committee;

(F) reflect current standards established by private accreditation organizations, governmental entities, national nursing professional associations, and other health professional organizations and should be developed based upon a review of the codes of ethics developed by the nursing profession through national nursing organizations; and

(G) comply with this section.

(2) The plan shall set minimum staffing levels for patient care units that are:

(A) based on multiple nurse and patient considerations including:

(i) patient characteristics and number of patients for whom care is being provided, including number of admissions, discharges, and transfers on a unit;

(ii) intensity of patient care being provided and variability of patient care across a nursing unit;

(iii) scope of services provided;

(iv) context within which care is provided, including architecture and geography of the environment, and the availability of technology; and

(v) nursing staff characteristics, including staff consistency and tenure, preparation and experience, and the number and competencies of clinical and non-clinical support staff the nurse must collaborate with or supervise;

(B) determined by the nursing assessment and in accordance with evidence-based safe nursing standards; and

(C) recalculated at least annually, or as necessary.

(3) The plan shall include:

(A) a method for adjusting the staffing plan shift to shift for each patient care unit based on factors, such as, the intensity of patient care to provide staffing flexibility to meet patient needs;

(B) a contingency plan when patient care needs unexpectedly exceed direct patient care staff resources;

(C) how on-call time will be used;

(D) a mechanism for evaluating the effectiveness of the official nurse services staffing plan based on patient needs, nursing sensitive quality indicators, nurse satisfaction measures collected by the LSRH, and evidence-based nurse staffing standards, which must include at least one from each of the following three types of outcomes shall be correlated to the adequacy of staffing:

(i) nurse-sensitive patient outcomes selected by the nurse staffing committee, such as, patient falls, adverse drug events, injuries to patients, skin breakdown, pneumonia, infection rates, upper gastrointestinal bleeding, shock, cardiac arrest, length of stay, or patient readmissions;

(ii) operational outcomes, such as, work-related injury or illness, vacancy and turnover rates, nursing care hours per patient day, on-call use, or overtime rates; and

(iii) substantiated patient complaints related to staffing levels;

(E) a process that facilitates the timely and effective identification of concerns about the adequacy of the staffing plan by the nurse staffing committee, which includes:

(i) a prohibition on retaliation for reporting concerns;

(ii) a requirement that nurses report concerns timely through appropriate channels within the LSRH;

(iii) orientation of nurses on how to report concerns and to whom;

(iv) encouraging nurses to provide input to the committee relating to nurse staffing concerns;

(v) review, assessment, and response by the committee to staffing concerns expressed to the committee;

(vi) a process for providing feedback during the committee meeting on how concerns are addressed by the committee; and

(vii) use of the nurse safe harbor peer review process pursuant to Texas Occupations Code §303.005 (relating to Request for Peer Review Committee Determination); and

(F) policies and procedures that require:

(i) orientation of nurses and other personnel who provide nursing care to all patient care units to which they are assigned on either a temporary or permanent basis;

(ii) the orientation of nurses and other personnel and the competency to perform nursing services is documented in accordance with LSRH policy; and

(iii) nursing assignments be congruent with documented competency.

(g) The LSRH shall use the staffing plan required under subsection (f) of this section as a component in setting the nurse staffing budget and guiding the LSRH in assigning nurses LSRH wide.

(h) The LSRH shall make readily available to nurses on each patient care unit at the beginning of each shift the official nurse services staffing plan levels and current staffing levels for that unit and that shift.

(i) There shall be a semiannual evaluation by the staffing committee of the effectiveness of the official nurse services staffing plan and variations between the staffing plan and actual staffing.

(1) The evaluation shall consider the outcomes and nursing-sensitive indicators as set out in subsection (f)(3)(D)(i) of this section, patient needs, nurse satisfaction measures collected by the LSRH, and evidence-based nurse staffing standards.

(2) The evaluation shall be documented in the minutes of the committee and presented to the LSRH governing body.

(3) The LSRH may determine whether the evaluation is done on a unit or facility level basis.

(4) To assist the committee with the semiannual evaluation, the LSRH shall report to the committee the variations between the staffing plan and actual staffing. This report of variations shall be confidential.

(j) The LSRH shall retain each staffing plan for a period of two years.

(k) Nonemployee licensed nurses who are working in the LSRH shall adhere to the LSRH's policies and procedures. The LSRH's CNO shall provide for the adequate orientation, supervision, and evaluation of the clinical activities of nonemployee nursing personnel that occur within the responsibility of the nursing services.

(l) The LSRH shall annually report to the Texas Health and Human Services Commission on:

(1) whether the LSRH governing body has adopted a nurse staffing policy;

(2) whether the LSRH has established a nurse staffing committee that meets the requirements of subsection (e)(4) of this section;

(3) whether the nurse staffing committee has evaluated the LSRH official nurse services staffing plan and has reported the results of the evaluation to the LSRH's governing body; and

(4) the nurse-sensitive outcome measures the committee adopted for use in evaluating the LSRH official nurse services staffing plan.

(m) The LSRH shall adopt, implement and enforce policies on use of mandatory overtime. The policies shall comply with the following requirements.

(1) As used in this subsection:

(A) "on-call time" means time spent by a nurse who is not working but who is compensated for availability; and

(B) "mandatory overtime" means a requirement that a nurse work hours or days that are in addition to the hours or days scheduled, regardless of the length of a scheduled shift or the number of scheduled shifts each week. Mandatory overtime does not include prescheduled on-call time or time immediately before or after a scheduled shift necessary to document or communicate patient status to ensure patient safety.

(2) An LSRH may not require a nurse to work mandatory overtime, and a nurse may refuse to work mandatory overtime.

(3) This subsection does not prohibit a nurse from volunteering to work overtime.

(4) An LSRH may not use on-call time as a substitute for mandatory overtime.

(5) The prohibitions on mandatory overtime do not apply if:

(A) a health care disaster, such as a natural or other type of disaster that increases the need for health care personnel, unexpectedly affects the county in which the nurse is employed or affects a contiguous county;

(B) a federal, state, or county declaration of emergency is in effect in the county in which the nurse is employed or is in effect in a contiguous county;

(C) there is an emergency or unforeseen event of a kind that:

(i) does not regularly occur;

(ii) increases the need for health care personnel at the LSRH to provide safe patient care; and

(iii) could not prudently be anticipated by the LSRH; or

(D) the nurse is actively engaged in an ongoing medical or surgical procedure and the continued presence of the nurse through the completion of the procedure is necessary to ensure the health and safety of the patient. The nurse staffing committee shall ensure that scheduling a nurse for a procedure that could be anticipated to require the nurse to stay beyond the end of his or her scheduled shift does not constitute mandatory overtime.

(6) If an LSRH determines that an exception exists under paragraph (5) of this subsection, the LSRH shall, to the extent possible, make and document a good faith effort to meet the staffing need through voluntary overtime, including calling per diems and agency nurses, assigning floats, or requesting an additional day of work from off-duty employees.

(7) An LSRH may not suspend, terminate, or otherwise discipline or discriminate against a nurse who refuses to work mandatory overtime.

(n) Drugs and biologicals shall be prepared and administered in accordance with federal and state laws, the orders of the individuals granted privileges by the medical staff, and accepted standards of practice.

(o) All drugs and biologicals shall be administered by, or under supervision of, nursing or other personnel in accordance with federal and state laws and regulations, including applicable licensing rules, and in accordance with the approved medical staff policies and procedures.

(p) All orders for drugs and biologicals shall be in writing, dated, timed, and signed by the individual responsible for the care of the patient as specified under §511.46(x) of this subchapter (relating to Radiological Services). When telephone or verbal orders must be used, they shall be:

(1) accepted only by personnel who are authorized to do so by the medical staff policies and procedures, consistent with federal and state laws;

(2) dated, timed, and authenticated within 96 hours by the prescriber or another practitioner who is responsible for the care of the patient and has been credentialed by the medical staff and granted privileges that are consistent with the written orders; and

(3) used infrequently.

(q) There shall be an LSRH procedure for immediately reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs to the attending physician and, if appropriate, to the LSRH-wide quality assessment and performance improvement program.

(r) Blood transfusions shall be prescribed in accordance with LSRH 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.

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

(t) 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.

(u) Nursing staff shall observe and monitor the patient during blood and blood component transfusions and for an appropriate time thereafter as required by the LSRH's blood transfusion policy for suspected adverse reactions.

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

(w) When warming of blood is indicated, this shall be accomplished during its passage through the transfusion set. The warming system shall be equipped with a visible thermometer and may have an audible warning system. Blood shall not be warmed above 42 degrees Centigrade.

(x) Drugs or medications, including those intended for intravenous use, shall not be added to blood or blood components. A 0.9% sodium chloride injection, United States Pharmacopeia, may be added to blood or blood components. Other solutions intended for intravenous use may be used in an administration set or added to blood or blood components under either of the following conditions:

(1) they have been approved for this use by the U.S. Food and Drug Administration; or

(2) there is documentation available to show that addition to the component involved is safe and efficacious.

(y) There shall be a system for detection, reporting, and evaluation of suspected complications of transfusion. Any adverse event experienced by a patient in association with a transfusion is to be regarded as a suspected transfusion complication. In the event of a suspected transfusion complication, the personnel attending the patient shall notify immediately a responsible physician and the transfusion service and document the complication in the patient's medical record. All suspected transfusion complications shall be evaluated promptly according to an established procedure.

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

(aa) An LSRH shall adopt, implement, and enforce a policy to ensure the LSRH complies with Texas Occupations Code Chapter 301, Subchapter I (relating to Reporting Violations and Patient Care Concerns), and Chapter 303 (relating to Nursing Peer Review), and with the rules adopted by the Texas Board of Nursing in Texas Administrative Code Title 22 §217.16 (relating to Minor Incidents), §217.19 (relating to Incident-Based Nursing Peer Review and Whistleblower Protections), and §217.20 (relating to Safe Harbor Peer Review for Nurses and Whistleblower Protections).

(bb) The LSRH shall adopt, implement, and enforce policies and procedures related to the work environment for nurses which:

(1) improve workplace safety and reduce the risk of injury, occupational illness, and violence; and

(2) increase the use of ergonomic principles and ergonomically designed devices to reduce injury and fatigue.

(cc) The policies and procedures adopted under subsection (bb) of this section must address at least the following:

(1) evaluating new products and technology that incorporate ergonomic principles;

(2) educating nurses in the application of ergonomic practices;

(3) conducting workplace audits to identify areas of risk of injury, occupational illness, or violence and recommending ways to reduce those risks;

(4) controlling access to those areas identified as having a high risk of violence; and

(5) promptly reporting crimes committed against nurses to appropriate law enforcement agencies.

(dd) The LSRH shall adopt, implement and enforce policies and procedures to identify, assess, and develop strategies to control risk of injury to patients and nurses associated with the lifting, transferring, repositioning, or movement of a patient. The policies and procedures shall establish a process that includes at least the following:

(1) analysis of the risk of injury to both patients and nurses posed by the patient handling needs of the patient populations served by the LSRH and the physical environment in which patient handling and movement occurs;

(2) education of nurses in the identification, assessment, and control of risks of injury to patients and nurses during patient handling;

(3) evaluation of alternative ways to reduce risks associated with patient handling, including evaluation of equipment and the environment;

(4) restriction, to the extent feasible with existing equipment and aids, of manual patient handling or movement of all or most of a patient's weight to emergency, life-threatening, or otherwise exceptional circumstances;

(5) collaboration with and annual report to the nurse staffing committee;

(6) procedures for nurses to refuse to perform or be involved in patient handling or movement that the nurse believes in good faith will expose a patient or a nurse to an unacceptable risk of injury;

(7) submission of an annual report to the governing body on activities related to the identification, assessment, and development of strategies to control risk of injury to patients and nurses associated with the lifting, transferring, repositioning, or movement of a patient; and

(8) development of architectural plans for constructing or remodeling a LSRH or a unit of an LSRH in which patient handling and movement occurs, with consideration of the feasibility of incorporating patient handling equipment or the physical space and construction design needed to incorporate that equipment at a later date.

§511.62. Discharge Planning.

(a) A limited services rural hospital (LSRH) shall have an effective, ongoing, discharge planning process that facilitates the provision of follow-up care and focuses on the patient's goals and treatment preferences and includes the patient and their caregivers or support persons as active partners in the discharge planning for post-discharge care.

(b) The discharge planning process and the discharge plan shall be consistent with the patient's goals for care and their treatment preferences, ensure an effective transition of the patient from the LSRH to post-discharge care, and reduce the factors leading to preventable LSRH admissions or readmissions.

(c) An LSRH's discharge planning process shall identify, at an early stage of the provision of services, those patients who are likely to suffer adverse health consequences on discharge in the absence of adequate discharge planning and must provide a discharge planning evaluation for those patients so identified as well as for other patients upon the request of the patient, patient's legally authorized representative, or patient's physician.

(d) Any discharge planning evaluation must be made on a timely basis to ensure appropriate arrangements for post-LSRH care will be made before discharge and to avoid unnecessary delays in discharge.

(e) A discharge planning evaluation must include:

(1) an evaluation of a patient's likely need for appropriate services following those furnished by the LSRH, including:

(A) hospice care services;

(B) post-LSRH extended care services;

(C) home health services;

(D) non-health care services; and

(E) community-based care providers;

(2) a determination of the availability of the appropriate services; and

(3) a determination of the patient's access to those services.

(f) The discharge planning evaluation must be included in the patient's medical record for use in establishing an appropriate discharge plan and the results of the evaluation must be discussed with the patient (or the patient's legally authorized representative).

(g) On the request of a patient's physician, the LSRH must arrange for the development and initial implementation of a discharge plan for the patient.

(h) Any discharge planning evaluation or discharge plan required under this section must be developed by, or under the supervision of, a registered nurse, social worker, or other appropriately qualified personnel.

(i) The LSRH's discharge planning process must require regular re-evaluation of the patient's condition to identify changes that require modification of the discharge plan. The discharge plan must be updated, as needed, to reflect these changes.

(j) The LSRH must assess its discharge planning process on a regular basis. The assessment must include ongoing periodic review of a representative sample of discharge plans.

(k) The LSRH must assist patients, their families, or the patient's legally authorized representative in selecting a post-acute care provider by using and sharing data that includes, but is not limited to, home health agency, skilled nursing facility (SNF), inpatient rehabilitation facility, or long-term care hospital data on quality measures and data on resource use measures. The LSRH must ensure that the

post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences.

(l) The LSRH must discharge the patient, and also transfer or refer the patient where applicable, along with all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, at the time of discharge, to the appropriate post-acute care service providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners responsible for the patient's follow-up or ancillary care.

§511.63. Patient's Rights.

(a) A limited services rural hospital (LSRH) shall protect and promote each patient's rights.

(b) An LSRH shall adopt, implement, and enforce a policy to ensure patients' rights. The LSRH's written patient's rights policy shall include the following:

(1) the right to participate in the development and implementation of their plan of care;

(2) the right to make informed decisions regarding their care, including being informed of their health status, and being able to request or refuse treatment;

(3) the right to formulate advance directives and to have LSRH staff and practitioners who provide care in the LSRH comply with these directives, in accordance with Code of Federal Regulations Title 42 (42 CFR) §§489.100 (relating to Definitions), 489.102 (relating to Requirement for Providers), and 489.104 (relating to Effective Dates) and Texas Health and Safety Code Chapter 166 (relating to Advance Directives);

(4) the right to have personal privacy;

(5) the right to receive medical standard of care in a safe setting;

(6) the right to be free from all forms of abuse, neglect, exploitation, and harassment;

(7) the right to have confidentiality of their medical records;

(8) the right to access their medical records, including current medical records, on an oral or written request;

(9) the right to the LSRH's reasonable response to the patient's requests and needs for treatment or service, within the LSRH's capacity, stated mission, and applicable law and regulation;

(10) the right to considerate and respectful care, which includes:

(A) the care of the patient includes consideration of the psychosocial, spiritual, and cultural variables that influence perceptions of illness; and

(B) the care of a dying patient optimizes the comfort and dignity of the patient through;

(i) treating primary and secondary symptoms that respond to treatment as desired by the patient or surrogate decision maker;

(ii) effectively managing pain; and

(iii) acknowledging the psychosocial and spiritual concerns of the patient and the family regarding dying and the expression of grief by the patient and family;

(11) the right to, in collaboration with their physician, make decisions involving their health care, including:

(A) the right to accept medical care or to refuse treatment to the extent permitted by law and to be informed of the medical consequences of such refusal; and

(B) the right to formulate advance directives and to appoint a surrogate to make health care decisions on their behalf to the extent permitted by law;

(12) a mechanism to ascertain the existence of, and, as appropriate, assist in the development of advance directives at the time of the patient's admission;

(13) the right to not have the provision of care conditioned on the existence of an advance directive;

(14) the right of a patient to the information necessary to enable them to make treatment decisions reflecting their wishes;

(15) the right of a patient to receive at the time of admission information about the LSRH's patient rights policy or policies and the mechanism for the initiation, review, and, when possible, resolution of patient complaints concerning the quality of care;

(16) the right to receive information about the patient's rights in advance of receiving or discontinuing patient care whenever possible;

(17) the right of the patient or the patient's legally authorized representative to participate in the consideration of ethical issues that arise in the care of a patient;

(18) a mechanism for the consideration of ethical issues arising in the care of patients and to provide education to care givers and patients on ethical issues in health care;

(19) the right of the patient to be informed of any human experimentation or other research or educational projects affecting their care or treatment;

(20) the right of the patient or the patient's legally authorized representative to access the information contained in the patient's medical record, within the limits of the law; and

(21) the right of the patient's guardian, next of kin, or legally authorized responsible person to exercise, to the extent permitted by law, the rights delineated on behalf of the patient if the patient:

(A) has been adjudicated incompetent in accordance with the law;

(B) is found by their physician to be medically incapable of understanding the proposed treatment or procedure;

(C) is unable to communicate their wishes regarding treatment; or

(D) is a minor.

(c) An LSRH must post the patient bill of rights prominently and conspicuously for display in a public area of the LSRH that is readily available to patients, residents, employees, and visitors.

(1) In addition to these patient bill of rights requirements, an LSRH that provides chemical dependency services shall comply with this section and Texas Administrative Code Title 25 (25 TAC) §448.701 (relating to Client Bill of Rights) applicable to patients who receive such services.

(2) In addition to these patient bill of rights requirements, an LSRH that provides mental health services shall comply with this section and 25 TAC Chapter 404, Subchapter E (relating to Rights of

Persons Receiving Mental Health Services) applicable to patients who receive such services.

(3) The patient bill of rights posted for display shall be in English and in a second language appropriate to the demographic makeup of the community served.

(d) An LSRH's medical staff and governing body shall adopt, implement, and enforce a policy on informed decision making that is consistent with any legal requirements.

(e) An LSRH shall establish a process for prompt resolution of patient grievances and inform each patient whom to contact to file a grievance. The LSRH's governing body or responsible individual shall approve and be responsible for the effective operation of the grievance process and shall review and resolve grievances, unless it delegates the responsibility, in writing, to a grievance committee. The grievance process shall include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization.

(1) The LSRH shall establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the LSRH.

(2) The grievance process shall specify timeframes for review of the grievance and the provision of a response.

(3) In its resolution of the grievance, the LSRH shall provide the patient with written notice of its decision that contains the name of the LSRH contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

(f) Notwithstanding subsection (b) of this section, an LSRH may deny treatment or services deemed medically unnecessary or inappropriate.

§511.64. Quality Assessment and Performance Improvement Program.

(a) A limited services rural hospital (LSRH) shall develop, implement, and maintain an effective, ongoing, LSRH-wide, data-driven quality assessment and performance improvement (QAPI) program.

(b) An LSRH's governing body shall ensure the QAPI program is individualized to ensure the LSRH complies with the requirements of this section, reflects the complexity of the LSRH's organization and services, involves all LSRH departments and services (including those services furnished under contract or arrangement), and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The LSRH must maintain and demonstrate evidence of its QAPI program.

(c) The LSRH shall measure, analyze, and track quality indicators, including adverse patient events, staffing, and other aspects of performance to evaluate processes of care, including LSRH service and operations.

(d) The QAPI program shall:

(1) include an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors;

(2) incorporate quality indicator data, including patient care data, and other relevant data, to achieve the goals of the QAPI program;

(3) evaluate all LSRH departments and services, including services furnished under contract or arrangement;

(4) evaluate health care associated infections;

(5) evaluate medication therapy;

(6) evaluate all medical and surgical services performed in the LSRH as they relate to appropriateness of diagnosis and treatment;

(7) measure, analyze, and track quality indicators, including adverse patients' events, and other aspects of performance that assess processes of care, LSRH services, and operations; and

(8) use the data collected to monitor the effectiveness and safety of service and quality of care, and to identify opportunities for changes that will lead to improvement.

(e) For each quality assessment indicator, the LSRH shall establish and monitor a level of performance consistent with current professional knowledge. These performance components shall influence or relate to the desired outcomes. The LSRH shall measure, analyze, and track at least the following indicators on a monthly basis:

(1) infection control, including staff and patient screening and standard precautions;

(2) adverse events;

(3) mortality, including review of each death and monitoring modality specific mortality rate;

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

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

(6) safety, including fire and disaster preparedness, use of a Texas Health and Human Services Commission-required reporting system, and disposal of special waste; and

(7) clinical records review, including treatment errors and medication errors.

(f) The LSRH shall establish priorities for performance improvement activities that focus on high-risk, high-volume, or problem-prone areas; consider the incidence, prevalence, and severity of problems in those areas; and affect health outcomes, patient safety, and quality of care. Performance improvement activities shall:

(1) track medical errors and adverse patient events;

(2) analyze their causes; and

(3) implement preventive actions and mechanisms that include feedback and learning throughout the LSRH.

(g) The LSRH shall measure the success of actions implemented resulting from performance improvement activities and track ongoing performance to ensure sustained improvements.

(h) The LSRH shall ensure staff, including the medical, nursing, and pharmacy staff, complete the following activities:

(1) evaluate the provision of emergency care and patient services;

(2) set treatment goals;

(3) identify opportunities for improvement;

(4) develop and implement improvement plans; and

(5) evaluate the implementation until resolution is achieved.

(i) The LSRH shall measure, analyze, and track quality indicators or other aspects of performance the LSRH adopts or develops that reflect processes of care and LSRH operations. The LSRH shall

document evidence demonstrating the LSRH continuously reviews aggregate patient data, including identifying and tracking patient infections trends.

(j) The LSRH shall hold QAPI meetings as necessary, but not less than quarterly. Core staff members, including the medical, nursing, and pharmacy staff, shall actively participate in QAPI activities and meetings to identify or correct problems. The LSRH shall document QAPI meetings.

(k) The LSRH's governing body, medical staff, and administrative officials are responsible and accountable for ensuring:

(1) the LSRH defines, implements, and maintains an ongoing quality improvement and patient safety program, including the reduction of medical errors;

(2) the LSRH-wide QAPI efforts address priorities for improved quality of care and patient safety, and evaluates all improvement actions;

(3) the LSRH establishes clear expectations for safety; and

(4) the LSRH allocates adequate resources for measuring, assessing, improving, and sustaining the LSRH's performance and reducing risk to patients.

(l) The LSRH shall have an ongoing plan, consistent with available community and LSRH resources, to provide or make available social work, psychological, and educational services to meet the medically related needs of its patients.

(m) When an LSRH is part of a system consisting of multiple separately certified hospitals, critical access hospitals (CAHs), or LSRHs using a system governing body that is legally responsible for the conduct of two or more hospitals, CAHs, or LSRHs, the system governing body can elect to have a unified and integrated QAPI program for all of its member facilities after determining that such a decision is in accordance with all applicable state and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified LSRHs meets all of the requirements of this section. Each separately certified LSRH subject to the system governing body must demonstrate:

(1) the unified and integrated QAPI program is established in a manner that takes into account each member LSRH's unique circumstances and any significant differences in patient populations and services offered in each LSRH; and

(2) the unified and integrated QAPI program establishes and implements policies and procedures to ensure that the needs and concerns of each of its separately certified LSRHs, regardless of practice or location, are given due consideration, and the unified and integrated QAPI program has mechanisms in place to ensure that issues localized to particular LSRHs are duly considered and addressed.

§511.65. Patient Transfer Policy.

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

(b) The LSRH's governing body shall adopt the transfer policy after consultation with the medical staff. The policy shall apply to patient transfers to general and special hospitals licensed under Texas Health and Safety Code (HSC) Chapter 241 (relating to Hospitals) and private psychiatric hospitals licensed under HSC Chapter 577 (relating to Private Mental Hospitals and Other Mental Health Facilities), as well as transfers to general, special, and private psychiatric hospitals that are exempt from licensing.

(c) The LSRH's transfer policy shall govern transfers not covered by a transfer agreement.

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

(e) The LSRH's governing body, after consultation with the medical staff, shall implement its transfer policy by adopting transfer agreements with hospitals in accordance with this section.

(f) The LSRH's transfer policy shall recognize and comply with the requirements HSC Chapter 61 §§61.030 - 61.032 and §§61.057 - 61.059 (relating to Indigent Health Care and Treatment Act).

(g) The LSRH's transfer policy shall acknowledge contractual obligations and comply with statutory or regulatory obligations that may exist concerning a patient and a designated provider.

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

(1) providing a factual explanation regarding:

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

(B) any increased risks to the patient from not effecting the transfer; and

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

(2) documenting the informed refusal of a patient, or of a person acting on a patient's behalf, to examination, evaluation, or transfer and obtaining, if possible, the signature of the patient or the person acting on the patient's behalf, regarding the refusal that is dated and witnessed by the attending physician or facility employee, and placed in the patient's medical record.

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

(j) The LSRH's transfer policy shall prohibit a patient transfer from being 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.

(k) The LSRH's transfer policy shall require, when a patient requests or consents to transfer for economic reasons and the patient's choice is based on or influenced by representations made by the transferring physician or LSRH 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 to fully disclose to the patient the eligibility requirements established by the patient's chosen physician or hospital.

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

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

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

(m) The transfer policies of the transferring LSRH and receiving general or special hospital shall require the facilities to have licensed nurses and other qualified personnel available and on duty to assist with patient transfers. The policies shall require written protocols or standing delegation orders to be in place to guide facility personnel when a patient requires transfer to another hospital.

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

(o) The LSRH's transfer policy shall prohibit the LSRH from transferring a patient with an emergency medical condition that has not been stabilized unless:

(1) the individual (or a legally responsible person acting on the individual's behalf), after being informed of the LSRH's obligations under this section and of the risk of transfer, requests the transfer in writing, indicates the reasons for the request, and states the individual is aware of the risks and benefits of the transfer; or

(2) a physician signs a certification, which includes a summary of the risks and benefits 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.

(p) except as specifically provided in subsection (o) of this section, the LSRH'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 LSRH 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.

(q) The LSRH's transfer policy shall include the following information related to physicians' duties and standard of care. The policy shall require:

(1) the transferring physician to determine and order life support measures that are medically appropriate to stabilize the patient before transfer and to sustain the patient during transfer;

(2) the transferring physician to determine and order the utilization of appropriate personnel and equipment for the transfer;

(3) the transferring physician, in determining the use of medically appropriate life support measures, personnel, and equipment, to 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;

(4) except as allowed under subsection (o) of this section, before each patient transfer, the physician who authorizes the transfer to personally examine and evaluate the patient to determine the patient's medical needs and to ensure that the proper transfer procedures are used;

(5) before each patient transfer, the transferring physician to ensure the receiving general or special hospital and physician are appropriate to the patient's medical needs and have accepted responsibility for the patient's medical treatment and hospital care; and

(6) the LSRH's medical staff review appropriate records of patients transferred from the LSRH to determine that the appropriate standard of care has been met.

(r) The LSRH's transfer policy shall comply with the following requirements related to medical records.

(1) The policy shall require the LSRH to forward a copy of the portions of the patient's medical record, which are available and relevant to the transfer and to the continuing care of the patient, to the receiving physician and receiving hospital with the patient. When all necessary medical records for the continued care of the patient are not available at the time the patient is transferred, the transferring LSRH shall forward the records to the receiving physician and hospital as soon as possible.

(2) The patient's medical record shall contain at least the following:

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

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

(C) the reason for the transfer;

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

(E) relevant radiological films and reports; and

(F) any other relevant information.

(s) The LSRH's transfer policy shall require the LSRH to complete a memorandum of transfer for every transferred patient.

(1) The memorandum shall contain the following information:

(A) if known, the patient's:

(i) full name;

(ii) race, religion, national origin, age, sex, disability status;

(iii) address and phone number; and

(iv) next of kin address and phone number;

(B) the transferring and receiving physicians' names, telephone numbers, and addresses;

(C) the transferring LSRH's and receiving general or special hospital's names, addresses, and telephone numbers;

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

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

(F) the name of the hospital contact and date and time hospital administration was contacted in the receiving general or special hospital;

(G) the transferring LSRH administrator's signature and title and time the administrator contacted the receiving hospital;

(H) certification required by subsection (o)(2) of this section, 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);

(I) the time and date the receiving physician assumed responsibility for the patient;

(J) the time and date the patient arrived at the receiving general or special hospital;

(K) the signature and date of receiving hospital administration;

(L) the type of vehicle and company used to transport the patient;

(M) the type of equipment and personnel needed in transfers;

(N) the name and city of hospital where the patient was transported;

(O) the patient's diagnosis by the transferring physician; and

(P) the attachments by the transferring LSRH.

(2) The transferring LSRH shall retain a copy of the memorandum of transfer for five years and file the memorandum separately from the patient's medical record and in a manner facilitating its inspection by the Texas Health and Human Services Commission.

(t) An LSRH violates HSC Chapter 241 and this section if:

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

(2) the LSRH's governing body fails or refuses to:

(A) adopt a transfer policy that complies with this section and contains all requirements listed in this section;

(B) adopt a memorandum of transfer form that complies with the content requirements contained in this section; or

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

§511.66. Patient Transfer Agreements.

(a) A limited services rural hospital (LSRH) shall have in effect an agreement with at least one general hospital that is a level I or level II trauma center as designated by the Texas Department of State Health Services (DSHS), certified by the Centers for Medicare & Medicaid Services for the referral and transfer of patients requiring emergency medical care beyond the capabilities of the LSRH, and is:

(1) licensed under Texas Health and Safety Code (HSC) Chapter 241;

(2) maintained or operated by the state or an agency of the federal government and exempt from licensure under HSC Chapter 241; or

(3) maintained or operated by the federal government or an agency of the federal government and exempt from licensure under HSC Chapter 241.

(b) An LSRH shall submit the transfer agreement to the Texas Health and Human Services Commission (HHSC) for review to determine whether the agreement meets the requirements of subsection (a) of this section.

(c) An LSRH may enter into multiple transfer agreements based on the type or level of medical services available at other hospitals.

(d) A patient transfer agreement shall include specific language that is consistent with the following.

(1) HSC Chapter 61 (relating to Indigent Health Care Treatment Act) in accordance with §511.65(f) of this subchapter (relating to Patient Transfer Policy);

(2) discrimination in accordance with §511.65(j) of this subchapter;

(3) patient's right to request a transfer in accordance with §511.65(k) of this subchapter;

(4) transfer of patients with emergency medical conditions in accordance with §511.65(n) and (o) of this subchapter;

(5) physician's duties and standard of care in accordance with §511.65(q) of this subchapter;

(6) medical records in accordance with §511.65(r) of this subchapter; and

(7) memorandum of transfer in accordance with §511.65(s) of this subchapter.

(e) In order for HHSC to review the transfer agreements to determine compliance with the requirements of this section, an LSRH shall submit the following documents to HHSC:

(1) a copy of the current or proposed agreement signed by the representatives of the LSRH and the general or special hospital subject to the agreement;

(2) the agreement's adoption date; and

(3) the agreement's effective date.

(f) HHSC may waive the document submission requirements under subsection (e) of this section at its sole discretion to avoid the repetitious submission of required documentation and approved agreements.

(g) When an LSRH's governing body or governing body's designee executes a transfer agreement and the text of that agreement is the same text of a previously HHSC-approved agreement, the governing body or the governing body's designee is not required to submit the later agreement for review.

(h) HHSC shall review the patient transfer agreement not later than 45 calendar days after the date HHSC receives the agreement to determine whether the agreement complies with the requirements of this section.

(1) After HHSC's review of the agreement, if HHSC determines the agreement complies with the requirements contained in this section, HHSC shall notify the LSRH's administration that HHSC has approved the agreement.

(2) If after reviewing the agreement, HHSC determines the agreement is not consistent with the requirements contained in this section, HHSC shall give notice to the LSRH's administration that the agreement is deficient and provide recommendations for correction.

(i) HHSC considers a transfer agreement in compliance with this section if the agreement complies with the rules in effect at the time the LSRH executed the transfer agreement and HHSC approved the agreement.

(j) HHSC shall treat complaints alleging a transfer agreement violation in the same manner as complaints alleging violations of HSC Chapter 241, Subchapter K (relating to Limited Services Rural Hospitals) or this chapter.

§511.67. Medical Records.

(a) A limited services rural hospital (LSRH) shall maintain a medical records system in accordance with the LSRH's written policies and procedures, which must:

(1) contain procedures for collecting, processing, maintaining, storing, retrieving, authenticating, and distributing patient medical records; and

(2) require the medical records to be:

(A) legible;

(B) completely and accurately documented, dated, and timed;

(C) authenticated by the person responsible for providing or evaluating the service provided no later than 48 hours after the patient's discharge;

(D) systematically organized according to a predetermined and uniform medical record format;

(E) confidential, secure, and safely stored; and

(F) readily accessible, including that all a patient's relevant clinical information is readily available to physicians or practitioners involved in that patient's care, and an individual's records are timely retrievable upon request.

(b) An LSRH shall designate a member of the LSRH's professional staff who is responsible for maintaining the records and for ensuring the records comply with the LSRH's written policies and procedures under subsection (a) of this section.

(c) An LSRH shall maintain a uniformly formatted and organized medical record for each patient receiving health care services at the LSRH. The record shall include the following, as applicable:

(1) complete patient identification and social data, as described in Code of Federal Regulations Title 42 §485.540(a)(4)(i) (relating to Conditions of Participation: Medical Records);

(2) date, time, and means of the patient's arrival and discharge;

(3) evidence of properly executed informed consent forms;

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

(5) relevant medical history;

(6) the patient's advance directive;

(7) assessment of the patient's health status and health care needs;

(8) a brief summary of the episode, any care given to the patient before the patient's arrival to the LSRH, the patient's disposition, and instructions given to the patient;

(9) a complete detailed description of treatment and procedures performed in the LSRH;

(10) clinical observations, diagnostic impression, and consultative findings, including results of:

(A) physical examinations, including vital signs;

(B) diagnostic and laboratory tests, including clinical laboratory services; and

(C) treatment provided and procedures performed;

(11) a pre-anesthesia evaluation by an individual qualified to administer anesthesia before and LSRH administers anesthesia to a patient;

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

(13) for a patient with a length of stay greater than eight hours, an evaluation of nutritional needs and evidence of how the LSRH met the patient's identified needs;

(14) all orders of physicians or other practitioners;

(15) all reports of treatments and medications, including 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;

(16) nursing notes and documentation of complications;

(17) other relevant information necessary to monitor the patient's progress, such as temperature graphics and progress notes describing the patient's response to treatment;

(18) evidence of the patient's evaluation by a physician or advanced practice registered nurse before dismissal;

(19) conclusion at the termination of evaluation and 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;

(20) medical advice given to a patient by telephone; and

(21) dated signatures of the physician or other health care professional.

(d) Except when otherwise required or permitted by law, an LSRH shall maintain the strict confidentiality of patient record information, including any record that contains clinical, social, financial, or other data on a patient, and provide safeguards against loss, tampering, altering, improper destruction, unauthorized use, or inadvertent disclosure.

(e) An LSRH shall have written policies and procedures governing the use and removal of records from the LSRH and the conditions for the release of information. The written policies and procedures shall include all the following requirements.

(1) An LSRH shall obtain a patient's written consent before releasing information not required by law.

(2) An LSRH shall retain medical records until at least the 10th anniversary of the last entry date when the patient was last treated in the LSRH except as required in subparagraphs (A) and (B) of this paragraph.

(A) If a patient was younger than 18 years of age when the LSRH last treated the patient, the LSRH shall retain the patient's medical records until on or after the date of the patient's 20th birthday or on or after the 10th anniversary of the last entry date when the LSRH last treated the patient, whichever date is later.

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

(3) If an LSRH plans to close, the LSRH shall arrange for disposition of the medical records in accordance with applicable law. The LSRH 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.

(f) An LSRH shall provide written notice to a patient, or a patient's legally authorized representative as defined in Texas Health and Safety Code §241.151, that the LSRH, unless the exception in subsection (e)(2)(B) of this section applies, may authorize the disposal of

medical records relating to the patient on or after the periods specified in this section.

(1) The LSRH shall provide the notice to the patient or the patient's legally authorized representative not later than the date on which the patient who is or will be the subject of a medical record is treated, except in an emergency treatment situation.

(2) In an emergency treatment situation, the LSRH shall provide the notice to the patient or the patient's legally authorized representative as soon as is reasonably practicable following the emergency treatment situation.

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

(h) When the LSRH utilizes an electronic medical records system or other electronic administrative system, which is conformant with the content exchange standard at Code of Federal Regulations Title 45 §170.205(d)(2) (relating to Content Exchange Standards and Implementation Specifications for Exchanging Electronic Health Information), then the LSRH must demonstrate:

(1) the system's notification capacity is fully operational and the LSRH uses it in accordance with all state and federal laws and regulations applicable to the LSRH's exchange of patient health information;

(2) the system sends notifications that must include at least patient name, treating practitioner name, and sending institution name;

(3) to the extent permissible under applicable federal and state law and regulations, and not inconsistent with the patient's expressed privacy preferences, the system sends notifications directly, or through an intermediary that facilitates exchange of health information, at the time of the patient's registration in the LSRH's emergency department;

(4) to the extent permissible under applicable federal and state law and regulations, and not inconsistent with the patient's expressed privacy preferences, the system sends notifications directly, or through an intermediary that facilitates exchange of health information, either immediately prior to, or at the time the patient's discharge or transfer from the LSRH's emergency department; and

(5) the LSRH has made a reasonable effort to ensure the system sends the notifications to all applicable post-acute care services providers and suppliers, as well as to any of the following practitioners and entities, which need to receive notification of the patient's status for treatment, care coordination, or quality improvement purposes:

(A) the patient's established primary care practitioner;

(B) the patient's established primary care practice group or entity; or

(C) other practitioner, or other practice group or entity, identified by the patient as the practitioner, or practice group or entity, primarily responsible for their care.

(i) An LSRH shall provide medical records in the form and format requested by the individual, if it is readily producible in such form and format. This includes in an electronic form or format when such medical records are maintained electronically or if not, in a readable hard copy form or such other form and format as agreed to by the LSRH and the individual.

(j) An LSRH shall provide records within a reasonable timeframe. The LSRH must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.

§511.68. Emergency Preparedness.

(a) A limited services rural hospital (LSRH) shall develop, adopt, implement, enforce, and maintain a written emergency preparedness plan. The LSRH shall review and update the plan at least every two years. The plan shall:

(1) be based on and include a documented, facility-based and community-based risk assessment, using an all-hazards approach;

(2) include strategies for addressing emergency events identified by the risk assessment;

(3) identify the services the LSRH has the ability to provide in an emergency and include strategies for addressing and serving the patient population;

(4) include the use of a Texas Health and Human Services Commission (HHSC)-approved process to update patient station availability as requested by HHSC during a public health emergency or state-declared disaster;

(5) include continuity of operations, including delegations of authority and succession plans;

(6) include a process for cooperation and collaboration with local, tribal, regional, state, and federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation; and

(7) incorporate applicable information listed in subsection (e) of this section and the State of Texas Emergency Management Plan. Information regarding the State of Texas Emergency Management Plan is available from the city or county emergency management coordinator.

(b) An LSRH shall send the plan, which may be subject to review and approval by HHSC, to the local disaster management authority.

(c) The LSRH shall develop the plan through a joint effort of the LSRH governing body, administration, medical staff, LSRH personnel, and emergency medical services partners.

(d) An LSRH shall have an effective procedure for obtaining emergency laboratory, radiology, and pharmaceutical services when these services are not immediately available due to system failure.

(e) An LSRH shall develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in subsection (a) of this section, risk assessment at subsection (a)(1) of this section, and the communication plan at subsection (f) of this section. The LSRH shall review and update the policies and procedures at least every two years. The policies and procedures shall at least address the following:

(1) reception, treatment, and disposition of casualties that can be used if a disaster situation requires the LSRH to accept multiple patients;

(2) the process, developed in conjunction with appropriate agencies, for allowing essential health care workers and personnel to safely access their delivery care sites;

(3) providing subsistence needs throughout the duration of the response for staff, volunteers, and patients, whether they evacuate or shelter in place, including:

(A) food, water, medical and pharmaceutical supplies, personal protection equipment, and appropriate immunizations;

(B) alternate sources of power to maintain:

(i) temperatures to protect patient health and safety and for the safe and sanitary storage of provisions;

(ii) emergency lighting;

(iii) fire detection, extinguishing, and alarm systems; and

(iv) sewage and waste disposal; and

(C) a system to track the location of on-duty staff and sheltered patients in the LSRH's care during an emergency, which also requires the LSRH to document the specific name and location of the receiving facility or other location when on-duty staff or sheltered patients are relocated during the emergency;

(4) safe evacuation from the LSRH, which includes the following:

(A) activation procedures, including who makes the decision to activate and how it is activated;

(B) consideration of care and treatment needs of evacuees;

(C) staff responsibilities;

(D) plan for the order of removal of patients and planned route of movement;

(E) transportation of staff, volunteers, and patients;

(F) records and supplies transportation, including:

(i) the protocol for transferring patient-specific medications and records to the receiving facility, which requires records to include at a minimum, the patient's most recent physician's assessment, order sheet, medication administration record (MAR), and patient history with physical documentation; and

(ii) A weather-proof patient identification wrist band (or equivalent identification) must be intact on all patients;

(G) identification of any evacuation locations and destinations, including protocol to ensure the patient destination is compatible to patient acuity and health care needs; and

(H) primary and alternate means of communication with external sources of assistance;

(5) a means to shelter in place for patients, staff, and volunteers who remain in the LSRH;

(6) a system of medical documentation that does the following:

(A) preserves patient information;

(B) protects confidentiality of patient information; and

(C) secures and maintains the availability of records;

(7) the use of volunteers in an emergency and other staffing strategies, including the process and role for integration of state and federally designated health care professionals to address surge needs during an emergency; and

(8) An LSRH's emergency preparedness policies and procedures shall include the LSRH's role in providing care and treatment at an alternate care site identified by federal and local emergency management officials, in the event of a declared disaster or national emergency in accordance with federal rules, regulations, and associated waivers.

(f) An LSRH must develop and maintain an emergency preparedness communication plan that complies with federal, state, and local laws. The LSRH shall review and update the communication plan at least every two years. The communication plan shall include:

(1) names and contact information for:

(A) staff;

(B) entities providing services under arrangement;

(C) patients' physicians; and

(D) volunteers;

(2) contact information for:

(A) federal, state, tribal, regional, and local emergency preparedness staff, including the city and county emergency management officers;

(B) the LSRH water supplier; and

(C) other sources of assistance;

(3) primary and alternate means for communicating with:

(A) LSRH staff; and

(B) federal, state, tribal, regional, and local emergency management agencies;

(4) procedures for notifying each of the following entities, as soon as practicable, regarding the closure or reduction in hours of operation of the LSRH due to an emergency:

(A) HHSC;

(B) each hospital with which the facility has a transfer agreement in accordance with §511.66 of this subchapter (relating to Patient Transfer Agreements);

(C) the trauma service area regional advisory council that serves the geographic area in which the facility is located; and

(D) each applicable local emergency management agency;

(5) a method for sharing information and medical documentation for patients under the LSRH's care, as necessary, with other health care providers to maintain the continuity of care;

(6) a means, in the event of an evacuation, to notify a patient's emergency contact or contacts of an evacuation and the patient's destination and release patient information as permitted under Code of Federal Regulations Title 45 (45 CFR) §164.510(b)(1)(ii) (relating to Uses and Disclosures Requiring an Opportunity for the Individual to Agree or to Object);

(7) a means of providing information about the general condition and location of patients under the LSRH's care as permitted under 45 CFR §164.510(b)(4);

(8) a means of providing information about the LSRH's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee; and

(9) evidence that the LSRH has communicated prospectively with the local utility and phone companies regarding the need for the LSRH to be given priority for the restoration of utility and phone services and a process for testing internal and external communications systems regularly.

(g) An LSRH shall post a phone number listing specific to the LSRH equipment and locale to assist staff in contacting mechanical and technical support in the event of an emergency.

(h) An LSRH must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in subsection (a) of this section, risk assessment in subsection (a)(1) of this section, policies and procedures in subsection (E) of this section, and the communication plan in subsection (f) of this section. The LSRH shall review and update the training and testing program at least every two years.

(1) The LSRH shall:

(A) provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, and volunteers, consistent with their expected roles;

(B) provide emergency preparedness training at least every two years;

(C) maintain documentation of all emergency preparedness training;

(D) demonstrate staff knowledge of emergency procedures; and

(E) conduct training on the updated policies and procedures if the LSRH significantly updates the emergency preparedness policies and procedures.

(2) The LSRH shall conduct exercises to test the emergency plan at least annually. The LSRH shall comply with all of the following requirements.

(A) The LSRH shall participate in a full-scale exercise that is community-based every two years.

(i) When a community-based exercise is not accessible, the LSRH shall conduct an LSRH-based functional exercise every two years; or

(ii) If the LSRH experiences an actual natural or man-made emergency that requires activation of the emergency plan, the LSRH is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the emergency event.

(B) The LSRH shall conduct an additional exercise at least every two years, opposite the year the LSRH conducts the full-scale or functional exercise under subparagraph (A) of this paragraph, that may include the following:

(i) a second full-scale exercise that is community-based, or an individual, facility-based functional exercise;

(ii) a mock disaster drill; or

(iii) a tabletop exercise or workshop that is led by a facilitator and includes a group discussion using a narrated, clinically relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(C) The LSRH shall analyze the LSRH's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the LSRH's emergency plan, as needed.

(3) An LSRH participating in an exercise or responding to a real-life event shall develop an after-action report (AAR) within 60 days after the exercise or event. The LSRH shall retain an AAR for at least three years and be available for review by the local emergency management authority and HHSC. The LSRH shall revise the LSRH's emergency plan, as needed, in response to the AAR.

(i) An LSRH must implement emergency and standby power systems based on the emergency plan set forth in subsection (a) of this section.

(1) The generator shall be located in accordance with the location requirements found in the Health Care Facilities Code (National Fire Protection Association (NFPA) 99 and Tentative Interim Amendments (TIA) 12-2, TIA 12-3, TIA 12-4, TIA 12-5, and TIA 12-6), Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4), and NFPA 110, when a new structure is built or when an existing structure or building is renovated.

(2) The LSRH shall implement emergency power system inspection and testing requirements found in the Health Care Facilities Code, NFPA 110, and the Life Safety Code.

(3) An LSRH that maintains an onsite fuel source to power emergency generators must have a plan for how it will keep emergency power systems operational during the emergency unless it evacuates.

(j) When an LSRH is part of a health care system consisting of multiple separately certified health care facilities that elects to have a unified and integrated emergency preparedness program, the LSRH may choose to participate in the health care system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program shall:

(1) demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program;

(2) be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered;

(3) demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance;

(4) include a unified and integrated emergency plan that meets the requirements of this section and include the following:

(A) a documented community-based risk assessment, utilizing an all-hazards approach; and

(B) a documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach; and

(5) include integrated policies and procedures that meet the requirements set forth in subsection (e) of this section, and a coordinated communication plan and training and testing programs that meet the requirements of subsections (f) and (h) of this section, respectively.

(k) The following material listed in this subsection is incorporated by reference into this section.

(1) NFPA 99, Health Care Facilities Code, 2012 edition, issued August 11, 2011.

(2) TIA 12-2 to NFPA 99, issued August 11, 2011.

(3) TIA 12-3 to NFPA 99, issued August 9, 2012.

(4) TIA 12-4 to NFPA 99, issued March 7, 2013.

(5) TIA 12-5 to NFPA 99, issued August 1, 2013.

(6) TIA 12-6 to NFPA 99, issued March 3, 2014.

(7) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011.

(8) TIA 12-1 to NFPA 101, issued August 11, 2011.

(9) TIA 12-2 to NFPA 101, issued October 30, 2012.

(10) TIA 12-3 to NFPA 101, issued October 22, 2013.

(11) TIA 12-4 to NFPA 101, issued October 22, 2013.

(12) NFPA 110, Standard for Emergency and Standby Power Systems, 2010 edition, including TIAs to chapter 7, issued August 6, 2009.

§511.69. Skilled Nursing Facility as a Distinct Unit.

When a limited services rural hospital provides skilled nursing facility services, the services shall be provided in a unit that is in a distinct part, according to Code of Federal Regulations Title 42 §485.546 (Relating to Skilled Nursing Facility Distinct Part Unit), that is separately licensed as a nursing facility under Texas Health and Safety Code Chapter 242 (relating to Convalescent and Nursing Facilities and Related Institutions), certified by the Centers for Medicaid & Medicare Services, and comply with the requirements of participation for long-term care facilities specified in the Code of Federal Regulations Title 42 Part 483, Subpart B (relating to Requirements for Long Term Care Facilities).

§511.70. Respiratory Care Services.

(a) If a limited services rural hospital (LSRH) provides respiratory care as an outpatient service, the services shall meet the needs of the patients in accordance with acceptable standards of practice and shall comply with this section.

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

(c) The LSRH shall provide respiratory care services only on, and in accordance with, a physician's orders.

(d) The LSRH shall organize respiratory care services to ensure they are appropriate to the scope and complexity of the services offered.

(e) The LSRH shall have a medical director or clinical director of respiratory care services who is a physician with the knowledge, experience, and capabilities to supervise and administer the services properly. The medical director or clinical director may serve on either a full-time or part-time basis.

(f) The LSRH shall ensure the LSRH has an adequate number of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with state law.

(g) The LSRH shall designate, in writing, personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures.

(h) When respiratory care services staff perform blood gases or other clinical laboratory tests, the respiratory care staff shall comply with the Clinical Laboratory Improvement Amendments of 1988 (CLIA 1988) and the CLIA 1988 regulations at Code of Federal Regulations Title 42 CFR Part 493 (relating to Laboratory Requirements).

§511.71. Waste and Waste Disposal.

(a) A limited services rural hospital (LSRH) shall comply with the requirements set forth by the Texas Commission on Environmental Quality (TCEQ) in Texas Administrative Code Title 30 (30 TAC) Chapter 326 (relating to Medical Waste Management).

(b) An LSRH shall dispose of all sewage and liquid wastes in a municipal sewerage system or a septic tank system permitted by TCEQ in accordance with 30 TAC Chapter 285 (relating to On-Site Sewage Facilities).

(c) An LSRH shall comply with 25 TAC Chapter 1, Subchapter K (relating to the Definition, Treatment, and Disposition of Special Waste from Health Care-Related Facilities).

(d) An LSRH shall make waste receptacles conveniently available in all toilet rooms, patient areas, staff work areas, and waiting rooms. The LSRH shall ensure receptacles are routinely emptied of their contents at a central location or locations into closed containers.

(e) An LSRH shall properly clean waste receptacles with soap and hot water, followed by treatment of inside surfaces of the receptacles with a germicidal agent.

(f) An LSRH shall ensure all containers for other municipal solid waste are leak-resistant, have tight-fitting covers, and are rodent-proof.

(g) An LSRH shall ensure non-reusable containers are of suitable strength to minimize animal scavenging or rupture during collection operations.

§511.72. Linen and Laundry Services.

(a) A limited services rural hospital (LSRH) shall provide sufficient clean linen to ensure the patient's comfort.

(b) An LSRH, whether it operates its own laundry or uses commercial service, shall ensure the following.

(1) LSRH employees involved in transporting, processing, or otherwise handling clean or soiled linen are given initial and follow-up in-service training to ensure a safe product for patients and to safeguard employees in their work.

(2) Clean linen is handled, transported, and stored by methods that will ensure its cleanliness.

(3) All contaminated linen is placed and transported in bags or containers labeled or color-coded.

(4) LSRH employees who have contact with contaminated linen wear gloves and other appropriate personal protective equipment.

(5) Contaminated linen is handled as little as possible and with a minimum of agitation and is not sorted or rinsed in patient care areas.

(6) All contaminated linen is bagged or put into carts at the location where it was used.

(A) Bags containing contaminated linen are closed before transport to the laundry.

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

(C) All linen placed in chutes is bagged.

(D) If chutes are not used to convey linen to a central receiving or sorting room, then adequate space is allocated on the various nursing units for holding the bagged contaminated linen.

(7) Linen is processed as follows.

(A) When using hot water, the LSRH shall wash the linen with detergent in the water with a temperature of at least 71 degrees Centigrade (160 degrees Fahrenheit) for 25 minutes. The LSRH shall meet the hot water requirements specified in Table 5 of §511.169(e) of this chapter (relating to Tables).

(B) When using low-temperature (less than or equal to 70 degrees Centigrade) (158 degrees Fahrenheit) laundry cycles, the LSRH shall use chemicals suitable for low-temperature washing at proper use concentration.

(C) Commercial dry cleaning of fabrics soiled with blood also renders these items free of the risk of pathogen transmission.

(D) The LSRH shall not use flammable liquids to process laundry, but may use flammable liquids for equipment maintenance.

§511.73. Sterilization.

(a) A limited services rural hospital (LSRH) staff qualified by education, training, and experience shall supervise all supplies and equipment sterilization in an LSRH. An LSRH shall ensure:

(1) staff responsible for sterilizing supplies and equipment participate in a documented continuing education program;

(2) new employees receive initial orientation and on-the-job training; and

(3) staff using chemical disinfectants received training on their use.

(b) An LSRH shall adopt, implement, and enforce written policies and procedures for performing decontamination and sterilization activities.

(1) Policies shall include the receiving, cleaning, decontaminating, disinfecting, preparing, and sterilizing of reusable items, as well as the assembly, wrapping, storage, distribution, and quality control of sterile items and equipment.

(2) The infection control program shall review and approve the written policies at least every other year.

(c) An LSRH shall provide equipment adequate for supplies and equipment sterilization as needed. The LSRH shall maintain and operate sterilization equipment to accurately sterilize the various materials required for sterilization.

(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. An LSRH shall provide hand-washing facilities and a separate sink for safe disposal of liquid waste.

(e) An LSRH shall clearly label all containers for solutions, drugs, flammable solvents, ether, alcohol, and medicated supplies to indicate contents.

(1) Containers sterilized by the LSRH shall be labeled to be identifiable before and after sterilization.

(2) Sterilized items shall have a load control identification that indicates the sterilizer used, the cycle or load number, and the date of sterilization.

(f) An LSRH shall ensure staff use the appropriate sterilizer, as indicated in the following paragraphs, when sterilizing materials and items. An LSRH shall use:

(1) steam sterilizers (saturated steam under pressure) to sterilize heat-and moisture-stable items according to the manufacturer's written instructions;

(2) ethylene oxide (EO) sterilizers for processing heat and moisture sensitive items (the LSRH shall use and vent EO sterilizers and aerators according to the manufacturer's written instructions); and

(3) flash sterilizers only for emergency sterilization of clean, unwrapped instruments approved by the manufacturer for flash sterilization and according to the manufacturer's written instructions.

(g) Before sterilization, an LSRH shall reduce the bioburden by:

(1) thoroughly cleaning, decontaminating, and preparing all items in a clean, controlled environment;

(2) arranging all articles in preparation for sterilization so all surfaces will be directly exposed to the sterilizing agent for the prescribed time and temperature; and

(3) packaging all wrapped articles in preparation for sterilization in materials recommended for the specific type of sterilizer and material to be sterilized.

(h) An LSRH shall use external chemical indicators, also known as sterilization process indicators, on each package in preparation for sterilization, including items being flash sterilized to indicate that items have been exposed to the sterilization process.

(1) The LSRH shall interpret indicator results according to manufacturer's written instructions and indicator reaction specifications.

(2) The LSRH shall maintain a log with the load identification, indicator results, and identification of the contents of the load.

(i) An LSRH shall use biological indicators to verify the performance of waste treatment equipment and processes (or sterilization equipment and processes). The LSRH shall:

(1) monitor the sterilizing process efficacy using reliable biological indicators appropriate for the type of sterilizer used;

(2) include biological indicators 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) include biological indicators in every load that contains implantable objects;

(4) maintain a log with the load identification, biological indicator results, and identification of the contents of the load; and

(5) take a sterilizer out of service immediately if a test is positive and shall:

(A) recall and reprocess implantable items if a biological indicator test (spore test) is positive;

(B) recall and reprocess all available items when a sterilizer malfunction is found and submit a list of those items not retrieved in the recall to infection control; and

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

(j) An LSRH shall adopt, implement, and enforce written policies, approved by the infection control program, for the use of chemical disinfectants. The LSRH:

(1) shall follow the manufacturer's written instructions for the use of disinfectants;

(2) shall mark an expiration date, determined according to manufacturer's written recommendations, on the container of disinfection solution currently in use;

(3) shall keep disinfectant solutions covered and used in well-ventilated areas;

(4) may use chemical germicides that are registered with the United States Environmental Protection Agency as "sterilants" either for sterilization or high-level disinfection; and

(5) shall provide training to all staff and personnel who use chemical disinfectants on their use.

(k) The LSRH shall maintain performance records for all sterilizers for each cycle. The LSRH must retain and have these records available for review for at least five years.

(l) The LSRH shall continuously monitor each sterilizer during operation for pressure, temperature, and time at desired temperature and pressure. A record shall be maintained and shall include:

(1) the sterilizer identification;

(2) sterilization date;

(3) cycle number;

(4) contents of each load;

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

(6) identification of operators;

(7) results of biological tests and dates performed;

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

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

(10) any other test results.

(m) An LSRH shall comply with the following requirements for storing sterilized items.

(1) The LSRH shall transport sterilized items so as to maintain cleanliness and sterility and to prevent physical damage.

(2) The LSRH shall store sterilized items in well-ventilated, limited access areas with controlled temperature and humidity.

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

(n) 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. An LSRH shall:

(1) maintain a preventive maintenance record for each sterilizer,

(2) retain these records for at least two years, and

(3) ensure their availability for review at the facility within two hours of request by HHSC.

§511.74. Sanitary Conditions and Hygienic Practices.

(a) A limited services rural hospital (LSRH) shall follow universal precautions for all patient care activities in accordance with Code of Federal Regulations Title 29 §1910.1030(d)(1) - (3) (relating to Bloodborne Pathogens) and Texas Health and Safety Code Chapter 85, Subchapter I (relating to Prevention of Transmission of HIV and Hepatitis B Virus by Infected Health Care Workers).

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

(1) The LSRH shall clean blood spills immediately or as soon as is practical with a disposable cloth and an appropriate chemical disinfectant.

(2) 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.

(3) When 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.

(4) The LSRH shall use dedicated cleaning supplies (i.e., mop, bucket) for the cleaning of blood spills.

§511.75. Limited Services Rural Hospital Billing.

(a) A limited services rural hospital (LSRH) shall adopt, implement, and enforce a policy to ensure that the hospital complies with the Texas Health and Safety Code (HSC) §311.002 (relating to Itemized Statement of Billed Services).

(b) An LSRH shall adopt, implement, and enforce a policy to ensure that the LSRH complies with HSC §311.0025 (relating to Audits of Billing).

(c) An LSRH may not violate a law that prohibits the hospital from billing a patient who is an insured, participant, or enrollee in a managed care plan an amount greater than an applicable copayment, coinsurance, and deductible under the insured's, participant's, or enrollee's managed care plan or that imposes a requirement related to that prohibition.

(d) An LSRH shall comply with Senate Bill 1264, 86th Legislature, Regular Session, 2019, and with related Texas Department of Insurance rules at 28 Texas Administrative Code (TAC) Chapter 21, Subchapter OO (relating to Disclosures by Out-of-Network Providers) to the extent that subchapter applies to the LSRH.

(e) A complaint submitted to the Texas Health and Human Services Commission's (HHSC's) Complaint and Incident Intake relating to billing must specify the patient for whom the bill was submitted.

(1) Upon receiving a complaint warranting an investigation, HHSC shall send the complaint to the LSRH and request the LSRH to conduct an internal investigation. Within 30 days of the LSRH's receipt of the complaint, the LSRH shall submit to HHSC:

(A) a report outlining the LSRH's investigative process;

(B) the resolution or conclusions reached by the LSRH with the patient, third party payor, or complainant; and

(C) corrections, if any, in the LSRH's policies or protocols that were made as a result of its investigative findings.

(2) In addition to the LSRH's internal investigation, HHSC may also conduct an investigation to audit any billing and patient records of the LSRH.

(3) HHSC shall inform, in writing, a complainant who identifies him or herself by name and address:

(A) of the receipt of the complaint;

(B) if the complainant's allegations are potential violations of the Act or this chapter warranting an investigation;

(C) whether the complaint will be investigated by HHSC;

(D) if the complaint was referred to the LSRH for internal investigation;

(E) whether and to whom the complaint will be referred;

(F) of the results of the LSRH's investigation and the LSRH's resolution with the complainant; and

(G) of HHSC's findings if an on-site audit investigation was conducted.

(4) HHSC shall refer investigative reports of billing by health care professionals who have provided improper, unreasonable, or medically or clinically unnecessary treatments or billed for treatments that were not provided to the appropriate licensing agency.

§511.76. Patient Visitation.

(a) A limited services rural hospital (LSRH) shall adopt, implement, and enforce written policies and procedures regarding patient visitation rights, including those setting forth any clinically necessary or reasonable restriction or limitation that the LSRH may need to place on such rights and the reasons for the clinical restriction or limitation.

(b) An LSRH shall:

(1) inform each patient (or support person, where appropriate) of their visitation rights, including any clinical restriction or limitation on such rights, when they are informed of their other rights under this section;

(2) inform each patient (or support person, where appropriate) of the right, subject to their consent, to receive the visitors whom they designate, including a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and their right to withdraw or deny such consent at any time;

(3) not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability; and

(4) ensure all visitors enjoy full and equal visitation privileges consistent with patient preferences.

(c) In accordance with Texas Health and Safety Code (HSC) §260C.002 (relating to In-Person Visitation with Religious Counselor), except as provided by subsections (d) and (e) of this section, an LSRH may not prohibit a patient from receiving in-person visitation with a religious counselor during a public health emergency upon the request of the patient or, if the patient is incapacitated, upon the request of the patient's legally authorized representative, including a family member of the patient.

(d) An LSRH may prohibit in-person visitation with a religious counselor during a public health emergency if federal law or a federal agency requires the LSRH to prohibit in-person visitation during that period.

(e) To the extent that an LSRH establishes policies and procedures for in-person religious counselor visitation during a public health emergency, these policies and procedures shall comply with the following.

(1) The policies and procedures shall establish minimum health and safety requirements for in-person visitation with religious counselors consistent with:

(A) state, local, and federal directives and guidance regarding the public health emergency;

(B) public health emergency and disaster preparedness plans; and

(C) other policies adopted by the LSRH, including the LSRH's general visitation policy and infection control policy.

(2) The policies and procedures shall address considerations for patients who are receiving end-of-life care.

(3) The policies and procedures may contain reasonable time, place, and manner restrictions on in-person visitation with religious counselors to mitigate the spread of a communicable disease or address a patient's medical condition.

(4) The policies and procedures may condition in-person visitation with religious counselors on the counselor's compliance with guidelines, policies, and procedures established under this subsection.

(f) In accordance with HSC §241.012 (relating to In-Person Hospital Visitation During Period of Disaster), an LSRH may not, during a qualifying period of disaster prohibit in-person visitation with a patient receiving care or treatment at the LSRH unless federal law or a federal agency requires the LSRH to prohibit in-person visitation during that period.

(g) Notwithstanding subsection (f) of this section, an LSRH may, during a qualifying period of disaster:

(1) restrict the number of visitors a patient receiving care or treatment at the LSRH may receive to not fewer than one, except for religious counselors visiting under subsection (b) of this section; and

(2) require a visitor, including a religious counselor visiting under subsection (c) of this section, to:

(A) complete a health screening before entering the LSRH;

(B) wear personal protective equipment at all times while visiting a patient at the LSRH; and

(C) deny entry to or remove from the LSRH's premises a visitor, including a religious counselor visiting under subsection (c) of this section, who fails or refuses to:

(i) submit to or meet the requirements of a health screening administered by the LSRH; or

(ii) wear personal protective equipment that meets the LSRH's infection control and safety requirements in the manner prescribed by the LSRH.

(h) A health screening administered by an LSRH under this section must be conducted in a manner that, at a minimum, complies with:

(1) LSRH policy; and

(2) if applicable, guidance or directives issued by the Texas Health and Human Services Commission, the Centers for Medicare & Medicaid Services, or another agency with regulatory authority over the LSRH.

(i) This section does not require an LSRH to:

(1) provide a specific type of personal protective equipment to a visitor, including a religious counselor visiting under subsection (c) of this section; or

(2) except for a religious counselor visiting under subsection (c) of this section, allow in-person visitation with a patient receiving care or treatment at the LSRH if an attending physician determines and documents in the patient's medical record that in-person visitation

with that patient may lead to the transmission of an infectious agent that poses a serious community health risk.

(j) A determination made by an attending physician under subsection (h) of this section is valid for not more than five days after the date the determination is made unless renewed by an attending physician.

(k) When a visitor to an LSRH is denied in-person visitation with a patient receiving care or treatment at a LSRH because of a determination made by an attending physician under subsection (i) of this section, the LSRH shall:

(1) provide each day a written or oral update of the patient's condition to the visitor if the visitor:

(A) is authorized by the patient to receive relevant health information regarding the patient;

(B) has authority to receive the patient's health information under an advance directive or medical power of attorney; or

(C) is otherwise the patient's surrogate decision-maker regarding the patient's health care needs under LSRH policy and other applicable law; and

(2) notify the person who receives the daily update required under paragraph (1) of this subsection of the estimated date and time at which the patient will be discharged from the LSRH.

§511.77. Hospital Price Transparency Reporting and Enforcement.

(a) A limited services rural hospital (LSRH) shall comply with the disclosure and reporting requirements of Texas Health and Safety Code (HSC) Chapter 327 (relating to Disclosure of Prices) as described in this section.

(b) An LSRH shall make the information required by HSC Chapter 327 available in a prominent location on the home page of its publicly accessible website or accessible by selecting a dedicated link that is prominently displayed on the home page of its publicly accessible website. If the LSRH operates multiple locations and maintains a single website, the homepage must contain a link to the list containing the links to each location the LSRH operates in a manner that clearly associates the list with the applicable location of the LSRH.

(c) Each time an LSRH updates a list as required by HSC §327.003 and §327.004, it shall submit the updated list to the Texas Health and Human Services Commission (HHSC) in the manner specified by HHSC on its website.

(d) HHSC has jurisdiction to impose an administrative penalty against a hospital licensed under this chapter for violations of HSC Chapter 327 and this section. An administrative penalty imposed under this section shall be in accordance with the provisions of HSC §327.008.

(e) In determining the amount of any penalty sought pursuant to HSC §327.008, HHSC shall consider:

(1) previous violations by the hospital's operator;

(2) the seriousness of the violation;

(3) the demonstrated good faith of the hospital's operator; and

(4) any other matters that justice may require.

(f) For purposes of calculating any penalty sought pursuant to HSC §327.008, the penalty imposed by HHSC for an LSRH with one of the following total gross revenues, as reported to the Centers for Medicare and Medicaid Services, in the year preceding the year in which a penalty is imposed, may not exceed:

(1) $10 for each day the hospital violated HSC Chapter 327, if the hospital's total gross revenue is less than $10,000,000;

(2) $100 for each day the hospital violated HSC Chapter 327, if the hospital's total gross revenue is $10,000,000 or more and less than $100,000,000; and

(3) $1,000 for each day the hospital violated HSC Chapter 327, if the hospital's total gross revenue is $100,000,000 or more.

(g) Each day a violation continues is considered a separate violation.

(1) The administrative penalties for each day of a continuing violation cease on the date the violation is corrected. A violation that is the subject of a penalty is presumed to continue on each successive day until it is corrected. The date of correction alleged by the hospital in its written plan of correction or corrective action plan will be presumed to be the actual date of correction, unless HHSC later determines that the correction was not made by that date or was not satisfactory.

(2) For continuing violations pursuant to HSC Chapter 327, penalties are cumulative as demonstrated in Figure: 26 TAC §511.77(g)(2)(B). The penalty amount is multiplied by the number of days the violation continues. The penalty amount for each day of the continuing violation is then added to the running total of the previous day's penalties according to the formula in subparagraph (A) of this paragraph.

(A) Cumulative administrative penalty = [penalty for each day of violation + (penalty for each day of violation x number of days of violation)]/2 x (number of days of violation).

(B) The cumulative amounts are not subject to the per day penalty cap in subsection (f) of this section.
Figure: 26 TAC §511.77(g)(2)(B)

§511.78. Restraint and Seclusion.

(a) All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.

(b) A limited services rural hospital (LSRH) may only use restraint or seclusion when less restrictive interventions have been determined to be ineffective to protect the patient, a staff member, or others from harm.

(c) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.

(d) The LSRH shall have written policies and procedures regarding the use of restraint and seclusion that are consistent with current standards of practice.

(e) An LSRH may only seclude a patient for the management of violent or self-destructive behavior.

(f) The patient has the right to safe implementation of restraint or seclusion by trained staff.

(1) The LSRH shall provide patient-centered competency-based training and education on the use of restraint and seclusion to LSRH personnel and staff, including medical staff and, as applicable, personnel providing contracted services in the LSRH.

(2) The training must include alternatives to the use of restraint or seclusion.

(g) An LSRH shall comply with the restraint and seclusion documentation and reporting requirements under Code of Federal Regulations Title 42 §485.534(g)

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

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For further information, please call: (512) 834-4591

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SUBCHAPTER D. INSPECTIONS AND INVESTIGATIONS

26 TAC §§511.111 - 511.116

STATUTORY AUTHORITY

The new sections are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies, and Texas Health and Safety Code §241.302(b), which provides that the Executive Commissioner of HHSC shall adopt rules to implement that section and establish minimum standards for LSRHs.

The new sections implement Texas Government Code §531.0055 and Texas Health and Safety Code §241.302.

§511.111. Integrity of Inspections and Investigations.

(a) To preserve the integrity of the Texas Health and Human Services Commission's (HHSC's) inspection and investigation process, a limited services rural hospital (LSRH):

(1) shall not record, listen to, or eavesdrop on any HHSC interview with LSRH staff or patients unless HHSC has granted permission; or

(2) shall not record, listen to, or eavesdrop on any internal discussion by or among HHSC staff unless it first informs HHSC staff that it will do so and obtains HHSC's written approval before beginning to record, listen to, or eavesdrop on the discussion.

(b) An LSRH shall inform HHSC when security cameras or other existing recording devices in the LSRH are in operation during any internal discussion by or among HHSC staff.

(c) This section does not prohibit an individual from recording an HHSC interview with the individual.

§511.112. Inspections.

(a) The Texas Health and Human Services Commission (HHSC) may inspect a limited services rural hospital (LSRH) before issuing or renewing an LSRH license.

(1) An LSRH is not subject to additional annual licensing inspections after HHSC issues the initial license while the LSRH maintains:

(A) certification under Title XVIII of the Social Security Act, 42 United States Code (USC), §§1395 et seq; or

(B) accreditation from The Joint Commission, the American Osteopathic Association, or other national accreditation organization for the offered services.

(2) HHSC may inspect an LSRH that is exempt from an annual licensing inspection under paragraph (1) of this subsection before issuing a renewal license to the LSRH if the certification or accreditation body has not conducted an on-site inspection of the LSRH in the preceding three years and HHSC determines an inspection of the LSRH by the certification or accreditation body is not scheduled within 60 days of the license expiration date.

(b) HHSC may conduct an unannounced, on-site inspection of an LSRH at any reasonable time, including when treatment services are provided, to inspect, investigate, or evaluate compliance with or prevent a violation of:

(1) any applicable statute or rule;

(2) an LSRH's plan of correction;

(3) an order or special order of the executive commissioner or the executive commissioner's designee;

(4) a court order granting injunctive relief; or

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

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

(d) HHSC inspections to evaluate an LSRH's compliance may include:

(1) initial, change of ownership, or relocation inspections, which HHSC may conduct when issuing a new license;

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

(3) routine inspections, which HHSC may conduct without notice and at HHSC's discretion, or before HHSC renews an LSRH license;

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

(5) inspections to determine whether an unlicensed LSRH is offering or providing, or purporting to offer or provide, treatment or services; and

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

(e) An LSRH shall cooperate with any HHSC inspection and shall permit HHSC to examine the LSRH's grounds, buildings, books, records, video surveillance, and other documents and information maintained by or on behalf of the LSRH.

(f) An LSRH shall permit HHSC access to interview members of the governing body, personnel, and patients, including the opportunity to request a written statement.

(g) An LSRH shall permit HHSC to inspect and copy any requested information, unless prohibited by law.

(h) HHSC shall maintain the confidentiality of LSRH records as applicable under state or federal law. All information and materials obtained or compiled by HHSC in connection with an inspection are confidential and not subject to disclosure under Texas Government Code Chapter 552 (relating to Public Information), and not subject to disclosure, discovery, subpoena, or other means of legal compulsion for their release to anyone other than HHSC or its employees or agents

involved in the enforcement action except that this information may be disclosed to:

(1) persons involved with HHSC in the enforcement action against the LSRH;

(2) the LSRH that is the subject of the enforcement action, or the LSRH's authorized representative;

(3) appropriate state or federal agencies that are authorized to inspect, survey, or investigate LSRH services;

(4) law enforcement agencies; and

(5) persons engaged in bona fide research, if all individual-identifying and LSRH-identifying information has been deleted.

(i) The following information is subject to disclosure in accordance with Texas Government Code Chapter 552:

(1) a notice of alleged violation against the LSRH, which notice shall include the provisions of law that the LSRH is alleged to have violated, and a general statement of the nature of the alleged violation;

(2) the pleadings in the administrative proceeding;

(3) a final decision or order by HHSC; and

(4) any other information required by law to be disclosed under public information request laws.

§511.113. Complaint Investigations.

(a) A limited services rural hospital (LSRH) shall provide each patient 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 LSRH.

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

(2) The LSRH shall prominently and conspicuously post this information in each patient common area, visitor area, and waiting room 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 evaluates all complaints. A person must submit a complaint using HHSC's current CII contact information for complaint submission, as described in subsection (a) of this section.

(c) HHSC documents, evaluates, and prioritizes complaints based on the seriousness of the alleged violation and the level of risk to patients, personnel, and the public.

(1) HHSC may investigate allegations determined to be within HHSC's regulatory jurisdiction relating to LSRH's under this chapter.

(2) HHSC may refer complaints outside HHSC's jurisdiction to an appropriate agency, as applicable.

(d) HHSC shall conduct an investigation to evaluate an LSRH's compliance following a complaint of abuse, neglect, or exploitation; or a complaint related to the health and safety of patients. HHSC may coordinate complaint investigations with the federal Centers for Medicare & Medicaid Services and its agents responsible for surveying LSRHs to determine compliance with the conditions of participation under Title XVIII of the Social Security Act, (42 USC, §§1395 et seq), to avoid duplicate investigations.

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

(1) an LSRH's compliance with any applicable statute or rule;

(2) an LSRH's plan of correction;

(3) an LSRH's compliance with an order of the executive commissioner or the executive commissioner's designee;

(4) an LSRH's compliance with a court order granting injunctive relief; or

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

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

(g) An LSRH shall cooperate with any HHSC investigation and shall permit HHSC to examine the LSRH's grounds, buildings, books, records, video surveillance, and other documents and information maintained by, or on behalf of, the LSRH.

(h) An LSRH shall permit HHSC access to interview members of the governing body, personnel, and patients, including the opportunity to request a written statement.

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

(j) HHSC shall maintain the confidentiality of LSRH records as applicable under state or federal law. All information and materials obtained or compiled by HHSC in connection with an investigation are confidential and not subject to disclosure under Texas Government Code Chapter 552 (relating to Public Information), and not subject to disclosure, discovery, subpoena, or other means of legal compulsion for their release to anyone other than HHSC or its employees or agents involved in the enforcement action except that this information may be disclosed to:

(1) persons involved with HHSC in the enforcement action against the LSRH;

(2) the LSRH that is the subject of the enforcement action, or the LSRH's authorized representative;

(3) appropriate state or federal agencies that are authorized to inspect, survey, or investigate LSRH services;

(4) law enforcement agencies; and

(5) persons engaged in bona fide research, if all individual-identifying and LSRH-identifying information has been deleted.

(k) The following information is subject to disclosure in accordance with Texas Government Code Chapter 552:

(1) a notice of alleged violation against the LSRH, which notice shall include the provisions of law that the LSRH is alleged to have violated, and a general statement of the nature of the alleged violation;

(2) the pleadings in the administrative proceeding;

(3) a final decision or order by HHSC; and

(4) any other information required by law to be disclosed under public information request laws.

(l) On entry, HHSC holds an entrance conference with the LSRH's designated representative to explain the nature, scope, and estimated duration of the investigation.

(m) HHSC holds an exit conference with the LSRH representative to inform the LSRH representative of any preliminary findings of the investigation. The LSRH may provide any final documentation regarding compliance during the exit conference.

(n) Once HHSC completes an investigation, HHSC reviews the evidence from the investigation to evaluate whether there is a preponderance of evidence supporting the allegations contained in the complaint.

§511.114. Notice.

(a) A limited service rural hospital (LSRH) is deemed to have received any Texas Health and Human Services Commission (HHSC) correspondence on the date of receipt, or three business days after sending, whichever is earlier.

(b) When deficiencies are found:

(1) HHSC sends the LSRH a written Statement of Deficiencies (SOD) within 10 business days after the exit conference by U.S. Postal Service or electronic mail.

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

(A) HHSC determines if a POC and proposed timeframes are acceptable, and, if accepted, notifies the LSRH in writing.

(B) If HHSC does not accept the POC, HHSC notifies the LSRH, in writing, and requests the LSRH submit a modified POC and any additional evidence no later than 10 business days after HHSC notifies the LSRH in writing.

(C) The LSRH shall correct the identified deficiencies and submit evidence to HHSC verifying the LSRH implemented all corrective actions within the timeframes set forth in the POC, or as otherwise specified by HHSC.

(3) Regardless of the LSRH's compliance with this subsection or HHSC's acceptance of an LSRH's POC, HHSC may, at any time, propose to take enforcement action as appropriate under this chapter in accordance with §511.121 of this chapter (relating Enforcement).

§511.115. Professional Conduct.

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

§511.116. Complaint Against an HHSC Representative.

(a) A limited services rural hospital (LSRH) may register a complaint against a Texas Health and Human Services Commission (HHSC) representative who conducts an inspection or investigation under this subchapter by contacting the HHSC Health Facility Compliance Regional Director for the region in which the LSRH is located.

(b) HHSC shall register all complaints against an HHSC representative with HHSC leadership.

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

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Karen Ray
Chief Counsel
Health and Human Services Commission
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SUBCHAPTER E. ENFORCEMENT

26 TAC §511.121

STATUTORY AUTHORITY

The new sections are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies, and Texas Health and Safety Code §241.302(b), which provides that the Executive Commissioner of HHSC shall adopt rules to implement that section and establish minimum standards for LSRHs.

The new sections implement Texas Government Code §531.0055 and Texas Health and Safety Code §241.302.

§511.121. Enforcement.

(a) Enforcement is a process by which a sanction is proposed, and if warranted, imposed on an applicant or licensee regulated by the Texas Health and Human Services Commission (HHSC) for failure to comply with applicable statutes, rules, or orders.

(b) HHSC has jurisdiction to enforce violations of Texas Health and Safety Code (HSC) Chapter 241 (relating to Hospitals) and this chapter. HHSC may deny, suspend, or revoke a license or impose an administrative penalty on a limited services rural hospital (LSRH) for the following reasons:

(1) failure to comply with any applicable provision of the HSC, including Chapters 241, 311 (relating to Powers and Duties of Hospitals), and 327 (relating to Disclosure of Prices);

(2) failure to comply with any provision of this chapter or any other applicable laws;

(3) the LSRH, 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 LSRH, 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 a complete license application;

(7) failure to comply with an order of the executive commissioner or another enforcement procedure under HSC Chapters 241, 311, or 327;

(8) a history of failure to comply with the applicable rules relating to patient environment, health, safety, and rights that reflects more than nominal noncompliance;

(9) the LSRH has aided, committed, abetted or permitted the commission of an illegal act;

(10) the LSRH, or any of its employees, commits fraud, misrepresentation, or concealment of a material fact on any documents

an LSRH is required to submit to HHSC or required to maintain pursuant to HSC Chapter 241, 311, or 327, and the provisions of this chapter;

(11) failure to comply with other state and federal laws affecting the health, safety, and rights of LSRH patients;

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

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

(14) failure to timely implement POCs for deficiencies cited by HHSC within the dates designated in the POC;

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

(16) if the LSRH is participating under Title XVIII and the Centers for Medicare & Medicaid Services terminates the LSRH's Medicare provider agreement.

(c) HHSC has jurisdiction to enforce violations of HSC Chapters 241, 311, and 327 and this chapter. HHSC may deny a license if the applicant:

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

(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 an LSRH or health care facility in any state;

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

(G) denial, suspension, or revocation of an LSRH license, a private psychiatric hospital license, or a license for any health care facility in any state; or

(H) a court injunction prohibiting ownership or operation of an LSRH.

(d) Following notice and opportunity for hearing, the executive commissioner of HHSC or a person designated by the executive commissioner may issue an emergency order in relation to the operation of an LSRH licensed under this chapter if the executive commissioner or the executive commissioner's designee determines that the LSRH is violating this chapter, a rule adopted pursuant to this chapter, a special license provision, injunctive relief, an order of the executive commissioner or the executive commissioner's designee, or another enforcement procedure permitted under this chapter and the provision, rule, license provision, injunctive relief, order, or enforcement procedure relates to the health or safety of the LSRH's patients.

(1) HHSC shall send written notice of the hearing and shall include within the notice the time and place of the hearing. The hearing must be held within 10 days after the date of the LSRH's receipt of the notice.

(2) The hearing shall be held in accordance with HHSC's informal hearing rules.

(3) The order shall be effective on delivery to the LSRH or at a later date specified in the order.

(e) In lieu of denying, suspending, or revoking the license, HHSC may place the LSRH on probation for a period of not less than 30 days, if the LSRH is found in repeated noncompliance with these rules or HSC Chapter 241 and the LSRH's noncompliance does not endanger the health and safety of the public.

(1) HHSC shall provide notice to the LSRH of the probation and of the items of noncompliance not later than the 10th day before the probation period begins.

(2) During the probation period, the LSRH must correct the items that were in noncompliance and report the corrections to HHSC for approval.

(3) HHSC has jurisdiction to impose an administrative penalty against an LSRH licensed or regulated under this chapter for violations of HSC Chapters 241, 311, and 327 and this chapter. The imposition of an administrative penalty shall be in accordance with the provisions of HSC §241.059 (relating to Administrative Penalty), §241.060 (relating to Administrative Penalty for Mental Health, Chemical Dependency, or Rehabilitation Services), and §327.008 (relating to Administrative Penalty).

(f) HHSC may deny a person or entity a license or suspend or revoke an existing license on the grounds that the person or entity has been convicted of a felony or misdemeanor that directly relates to the duties and responsibilities of the ownership or operation of an LSRH. HHSC shall apply the requirements of Texas Occupations Code Chapter 53 (relating to Consequences of Criminal Conviction).

(1) HHSC is entitled under Texas Government Code Chapter 411 (relating to Department of Public Safety of the State of Texas) to obtain criminal history information maintained by the Texas Department of Public Safety, the Federal Bureau of Investigation, or any other law enforcement agency to investigate the eligibility of an applicant for an initial or renewal license and to investigate the continued eligibility of a licensee.

(2) The following felonies and misdemeanors directly relate because these criminal offenses indicate an inability or a tendency for the person to be unable to own or operate an LSRH:

(A) a misdemeanor violation of HSC Chapter 241;

(B) a misdemeanor or felony involving moral turpitude;

(C) a misdemeanor or felony relating to deceptive business practices;

(D) a misdemeanor or felony of practicing any health-related profession without a required license;

(E) a misdemeanor or felony under any federal or state law relating to drugs, dangerous drugs, or controlled substances;

(F) a misdemeanor or felony under the Texas Penal Code (TPC) 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; or

(G) a misdemeanor or felony under the TPC:

(i) Title 4, relating to offenses of attempting or conspiring to commit any of the offenses in this clause;

(ii) Title 5, relating to offenses against the person;

(iii) Title 7, relating to offenses against property;

(iv) Title 8, relating to offenses against public administration;

(v) Title 9, relating to offenses against public order and decency;

(vi) Title 10, relating to offenses against public health, safety and morals; or

(vii) Title 11, relating to offenses involving organized crime.

(g) Offenses listed in subsection (f)(2) of this section are not exclusive in that HHSC may consider similar criminal convictions from other state, federal, foreign, or military jurisdictions that indicate an inability or tendency for the person or entity to be unable to own or operate an LSRH.

(h) HHSC shall revoke a license on the licensee's conviction of a felony or revocation of community supervision.

(i) If HHSC proposes to deny, suspend or revoke a license, place on probation, or impose an administrative penalty, HHSC shall send a notice of the proposed action by certified mail, return receipt requested, at the address shown in the current records of HHSC. The notice to deny, suspend, or revoke a license, place on probation, or impose an administrative penalty, shall state the alleged facts or conduct to warrant the proposed action, provide an opportunity to demonstrate or achieve compliance, and shall state that the applicant or license holder has an opportunity for a hearing before taking the action.

(j) Within 20 calendar days after receipt of the notice, the applicant or licensee may notify HHSC, in writing, of acceptance of HHSC's determination or request a hearing. Receipt of the notice is presumed to occur on the third day after the date the notice is mailed by HHSC to the last known address of the applicant or licensee.

(k) A hearing shall be conducted pursuant to Texas Government Code Chapter 2001 and Texas Administrative Code Title 1 Chapter 357, Subchapter I (relating to Hearings under the Administrative Procedure Act).

(l) If the applicant or licensee fails to timely respond to the notice or does not request a hearing, in writing, within 30 calendar days after receipt of the notice, HHSC shall refer the matter to the State Office of Administrative Hearings.

(m) HHSC shall send the licensee or applicant a copy of HHSC's decision for denial, suspension, or revocation of license or imposition of an administrative penalty by certified mail, which shall include the findings of fact and conclusions of law on which HHSC based its decision.

(n) On HHSC's determination to suspend or revoke a license, the license holder may not admit new patients until the license is reissued.

(o) When HHSC's decision to suspend or revoke a license is final, the licensee shall immediately cease operation, unless a stay of such action is issued by the district court.

(p) On suspension, revocation, or non-renewal of the license, the original license shall be returned to HHSC within 30 calendar days of HHSC's notification.

(q) One year after HHSC's decision to deny or revoke, or the voluntary surrender of a license by an LSRH while enforcement action is pending, an LSRH may petition HHSC, in writing, for a license. Expiration of a license prior to HHSC's decision becoming final shall not affect the one-year waiting period required before a petition may be submitted.

(1) HHSC may allow a reapplication for licensure if there is proof that the reasons for the original action no longer exist.

(2) HHSC may deny reapplication for licensure if HHSC determines that:

(A) the reasons for the original action continues;

(B) the petitioner has failed to offer sufficient proof that conditions have changed; or

(C) the petitioner has demonstrated a repeated history of failure to provide patients a safe environment or has violated patient rights.

(3) If HHSC allows a reapplication for licensure, the petitioner shall be required to meet the requirements as described in §511.12 of this chapter (relating to Application and Issuance of Initial License).

(r) An LSRH whose license expires during a suspension period may not reapply for license renewal until the end of the suspension period.

(s) In the event that enforcement, as defined in this subsection, is pending or reasonably imminent, the surrender of an LSRH license shall not deprive HHSC of jurisdiction in regard to enforcement against the LSRH.

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

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Health and Human Services Commission
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SUBCHAPTER F. FIRE PREVENTION AND SAFETY

26 TAC §§511.141 - 511.143

STATUTORY AUTHORITY

The new sections are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies, and Texas Health and Safety Code §241.302(b), which provides that the Executive Commissioner of HHSC shall adopt rules to implement that section and establish minimum standards for LSRHs.

The new sections implement Texas Government Code §531.0055 and Texas Health and Safety Code §241.302.

§511.141. Fire Prevention and Protection.

(a) Fire inspections.

(1) Annual inspection. A limited services rural hospital (LSRH) shall obtain approval of the fire protection of the LSRH by an individual certified by the Texas Commission on Fire Protection as a prerequisite for licensure.

(2) Hazardous or dangerous conditions or materials. Whenever any of the officers, members, or inspectors of the Texas Commission on Fire Protection find in any building or upon any premises dangerous or hazardous conditions or materials, removal or remedy of dangerous conditions or materials shall be carried out in a manner specified by the head of the local fire department.

(3) Access for inspection. At all reasonable hours, the LSRH shall allow the chief of the fire department, the chief of the bureau of fire prevention, or any of the fire inspectors to enter any LSRH building or premises for the purpose of making an inspection or investigation that may be deemed necessary under the provisions of these rules.

(b) Fire reporting. All occurrences of fire shall be reported, in writing, to the Texas Health and Human Services Commission (HHSC) as soon as possible but not later than 10 calendar days after the occurrence.

(c) Fire protection. Fire protection shall be provided in accordance with the requirements of National Fire Protection Association 101, Life Safety Code, 2012 edition (NFPA 101), §18.7, §511.161(a)(1) of this chapter (relating to Requirements for Buildings in Which Existing Licensed Hospitals are Located), and §511.162(a)(1) and (d) of this chapter (relating to General Construction Requirements). Sprinkler systems for exterior fire exposures shall comply with NFPA 80A, Recommended Practice for Protection of Buildings from Exterior Fire Exposures, 2001 edition.

(d) Smoking rules. Each LSRH shall adopt, implement, and enforce a smoking policy. The policy shall include the minimal provisions of NFPA 101 §18.7.4.

(e) Fire extinguishing systems. An LSRH shall conduct inspection, testing, and maintenance of fire-fighting equipment.

(1) Water-based fire protection systems. All fire sprinkler systems, fire pumps, fire standpipe and hose systems, water storage tanks and valves, and fire department connections shall be inspected, tested, and maintained in accordance with NFPA 25, Standard for the Inspection, Testing and Maintenance of Water-Based Fire Protection Systems, 2011 edition.

(2) Range hood extinguishers. Fire extinguishing systems for commercial cooking equipment, such as at range hoods, shall be inspected and maintained in accordance with NFPA 96, Standard for Ventilation Control and Fire Protection of Cooking Operations, 2011 edition.

(3) Portable fire extinguishers. Every portable fire extinguisher located in an LSRH or on LSRH property shall be installed, tagged, and maintained in accordance with NFPA 10, Standard for Portable Fire Extinguishers, 2010 edition.

(f) Fire protection and evacuation plan. A plan for the protection of patients in the event of fire and their evacuation from the building when necessary shall be formulated according to NFPA 101, §18.7. Copies of the plan shall be available to all staff.

(1) Posting requirements. An evacuation floor plan shall be prominently and conspicuously posted for display throughout the LSRH in public areas that are readily visible to patients, residents, employees, and visitors.

(2) Annual training. The LSRH shall conduct an annual training program for instruction of all personnel in the LSRH location and use of fire-fighting equipment. All employees shall be instructed regarding their duties under the fire protection and evacuation plan.

(g) Fire drills. An LSRH shall conduct at least 12 fire drills each year, one fire drill per shift per quarter, which shall include communication of alarms, simulation of evacuation of patients and other occupants, and use of fire-fighting equipment.

(h) Fire alarm system. Every LSRH and building used for patient care shall have an approved fire alarm system. Each fire alarm system shall be installed and tested in accordance with §511.161(a)(1)(A) of this chapter for existing hospitals, and §511.162(d)(5)(N) of this chapter for new construction.

(i) System for communicating an alarm of fire. A reliable communication system shall be provided as a means of reporting a fire to the fire department. This is in addition to the automatic alarm transmission to the fire department required by NFPA 101, §18.3.4.3.2.

(j) Fire department access. As an aid to fire department services, an LSRH shall provide the following.

(1) Driveways. The LSRH shall maintain driveways, free from all obstructions, to main buildings for fire department apparatus use.

(2) Submission of plans. Upon request, the LSRH shall submit a copy of the floor plans of the building to the local fire department officials.

(3) Outside identification. The LSRH shall place proper identification on the outside of the main building showing the locations of siamese connections and standpipes as required by the local fire department services.

(k) Fire department protection. When an LSRH is located outside of the service area or range of the public fire protection, arrangements shall be made to have the nearest fire department respond in case of a fire.

§511.142. General Safety.

(a) Safety committee. A limited services rural hospital (LSRH) shall have a multidisciplinary safety committee. The LSRH chief executive officer (CEO) shall appoint the chairman and members of the safety committee.

(1) Safety officer. The CEO shall appoint a safety officer who is knowledgeable in safety practices in health care facilities. The safety officer shall be a member of the safety committee, and shall carry out the functions of the safety program.

(2) Safety committee meetings. The safety committee shall meet as required by the chairman, but not less than quarterly. The committee shall retain written minutes for each meeting for at least one year.

(3) Safety activities.

(A) Incident reports. The safety committee shall establish an incident reporting system that includes a mechanism to ensure that all incidents recorded in safety committee minutes are evaluated, and documentation is provided to show follow-up and corrective actions.

(B) Safety policies and procedures. Safety policies and procedures for each department or service shall be developed, implemented, and enforced.

(C) Safety training and continuing education. Safety training shall be established as part of new employee orientation and in the continuing education of all employees.

(4) Written authority. The authority of the safety committee to take action when conditions exist that are a possible threat to life, health, or building damage, shall be defined, in writing, and approved by the governing body.

(b) Safety manual. Each department or service shall have a safety policy and procedure manual within their own area that becomes a part of the overall facility safety manual.

(c) Emergency communication system. An emergency communication system shall be provided in each facility. The system shall be self-sufficient and capable of operating without reliance on the building's service or emergency power supply. Such system shall have the capability of communicating with the available community or state emergency networks, including police and fire departments.

§511.143. Handling and Storage of Gases, Anesthetics, and Flammable Liquids.

(a) Flammable germicides. If flammable germicides, including alcohol-based products, are used for preoperative surgical skin preparation in a limited services rural hospital (LSRH), the LSRH must:

(1) use only self-contained, single-use, pre-measured applicators to apply the surgical skin preparations;

(2) follow all manufacturer product safety warnings and guidelines;

(3) develop, implement, and enforce written policies and procedures outlining the safety precautions required related to the use of the products, which, at a minimum, must include minimum drying times, prevention and management of product pooling, parameters related to draping and the use of ignition sources, staff responsibilities related to ensuring safe use of the product, and documentation requirements sufficient to evaluate compliance with the written policies and procedures;

(4) ensure that all staff working in the surgical environment where flammable surgical skin preparation products are in use have received training on product safety and the facility policies and procedures related to the use of the product;

(5) develop, implement, and enforce an interdisciplinary team process for the investigation and analysis of all surgical suite fires and alleged violations of the policies; and

(6) report all occurrences of surgical suite fires to the Texas Health and Human Services Commission as soon as possible but not later than 10 calendar days after the occurrence, and complete an investigation of the occurrence and develop and implement a corrective action plan within 30 days after a surgical suite fire.

(b) Flammable and nonflammable gases and liquids. Flammability of liquids and gases shall be determined by National Fire Protection Association (NFPA) 329, Recommended Practice for Handling Releases of Flammable and Combustible Liquids and Gases, 2010 edition.

(1) Nonflammable gases (examples including oxygen and nitrous oxide) shall be stored and distributed in accordance with Chapter 5 of the NFPA 99, Standard for Health Care Facilities, 2012 edition.

(A) Medical gases and liquefied medical gases shall be handled in accordance with the requirements of NFPA 99 Chapter 9.

(B) Oxygen shall be administered in accordance with NFPA 99 §9.6.

(2) Piped flammable gas systems intended for use in laboratories and piping systems for fuel gases shall comply with requirements of NFPA 99 §11.11.

(3) Flammable gases shall be stored in accordance with NFPA 99 §11.10.

(4) Flammable and combustible liquids used in laboratories shall be handled and stored in accordance with NFPA 99 §11.7, and National Fire Protection Association 101, Life Safety Code, 2012 edition, §18.3.2.2.

(5) Other flammable agents shall be stored in accordance with NFPA 99 Chapter 7.

(c) Gasoline and gasoline powered equipment. No motor vehicles including gasoline powered standby generators or any amount of gasoline shall be located within the LSRH building. Other devices that may cause or communicate fire, and that are not necessary for patient treatment or care, shall not be stored within the LSRH building. All such devices and materials when necessary shall be used within the building only with precautions ensuring a reasonable degree of safety from fire.

(d) Gas-fired appliances. The installation, use, and maintenance of gas-fired appliances and gas piping installations shall comply with the National Fire Protection Association 54, National Fuel Gas Code, 2012 edition. The use of portable gas heaters and unvented open flame heaters is specifically prohibited.

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

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Karen Ray
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Health and Human Services Commission
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SUBCHAPTER G. PHYSICAL PLANT AND CONSTRUCTION REQUIREMENTS

26 TAC §§511.161 - 511.169

STATUTORY AUTHORITY

The new sections are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies, and Texas Health and Safety Code §241.302(b), which provides that the Executive Commissioner of HHSC shall adopt rules to implement that section and establish minimum standards for LSRHs.

The new sections implement Texas Government Code §531.0055 and Texas Health and Safety Code §241.302.

§511.161. Requirements for Buildings in Which Existing Licensed Hospitals Are Located.

(a) Compliance. All buildings in which existing hospitals licensed by the Texas Health and Human Services Commission (HHSC) are located shall comply with this subsection. This chapter shall not be applied retroactively to an operating hospital holding an active HHSC facility license before the effective date of this chapter that complies with the occupancy requirements in National Fire Protection Association 101, Life Safety Code, (NFPA 101), the Hospital Licensing Standards/Rules (1969, 1985, or 1998 editions as amended), and the hospital licensing rules under which the buildings or sections of buildings were constructed.

(1) Minimum fire safety and construction requirements.

(A) Code requirements. A limited services rural hospital (LSRH) shall meet the requirements for health care occupancies contained in the 1967, 1973, 1981, 1985, 1991, 1997, 2000, 2003, or 2010 editions of the NFPA 101, Life Safety Code, the Hospital Licensing Standards/Rules (1969, 1985, or 1998 editions as amended), and the hospital licensing rules under which the buildings or sections of buildings were constructed.

(B) Existing construction requirements. Existing LSRHs or portions of existing LSRHs constructed before the adoption of any of the editions of NFPA 101, the Hospital Licensing Standards, and the hospital licensing rules listed in subparagraph (A) of this paragraph, shall comply with this section and Chapter 19, NFPA 101, 2012 edition.

(2) Remodeling. All requirements listed in this chapter are applicable to renovations, additions and alterations unless stated otherwise.

(A) Alteration or installation of new equipment. Any alteration or any installation of new equipment shall be accomplished as nearly as practicable with the subchapter requirements, except that when existing conditions make changes impractical to accomplish, minor deviations from functional requirements may be permitted if the intent of the requirements is met and if the care and safety of patients will not be jeopardized.

(B) Installation, alteration, or extension approval. No new system of mechanical, electrical, plumbing, fire protection, or piped medical gas system may be installed or any such existing system may be replaced, materially altered or extended, until complete plans and specifications for the replacement, installation, alteration, or extension have been submitted to HHSC, reviewed and approved in accordance with §511.167 of this subchapter (relating to Preparation, Submittal, Review, and Approval of Plans, and Retention of Records).

(C) Minor remodeling or alterations. All remodeling or alterations that do not involve alterations to load bearing members or partitions, change functional operation, affect fire safety (e.g., modifications to the fire, smoke, and corridor walls), add or subtract services for which the LSRH is licensed, and do not involve changes listed in subparagraph (B) of this paragraph, shall be submitted for approval without submitting contract documents. Such approval shall be requested in writing, with a brief description of the proposed changes in accordance with §511.167(f)(3) of this subchapter.

(D) Major remodeling or alterations. Plans shall be submitted in accordance with §511.167 of this subchapter for all major remodeling or alterations. All remodeling or alterations that involve alterations to load bearing members or partitions, change functional operation, affect fire safety (e.g., modifications to the fire, smoke, and corridor walls), or add services over those for which the LSRH is licensed are considered as major remodeling and alterations.

(E) Phasing of construction in existing facilities.

(i) Projects involving alterations of and additions to existing buildings shall be programmed and phased so that on-site construction will minimize disruptions of existing functions.

(ii) Access, exit access, and fire protection shall be maintained so that the safety of the occupants will not be jeopardized during construction.

(iii) A noncombustible or limited combustible dust and vapor barrier shall be provided to separate areas undergoing demolition and construction from occupied areas. When a fire retardant plastic material is used for temporary daily usage, it shall be removed at the end of each day.

(iv) The air inside the construction area shall be protected by mechanical filtration that recirculates inside the space or is exhausted directly to the exterior.

(v) The area shall be properly ventilated and maintained. The area under construction shall have a negative air pressure differential to the adjoining areas and shall continue to operate as long as construction dust and odors are present.

(vi) Temporary sound barriers shall be provided where intense prolonged construction noises will disturb patients or staff in the occupied portions of the building.

(F) Nonconforming conditions. When doing renovation work, if it is found to be infeasible to correct all of the nonconforming conditions in the existing LSRH in accordance with these rules, HHSC may grant a conditional approval if the operation of the LSRH, Americans with Disabilities Act accessibility requirements, and safety of the patients are not jeopardized by the nonconforming condition.

(b) Previously licensed hospitals. Buildings that have been licensed previously as general hospitals, special hospitals, or LSRHs but have been vacated or used for purposes other than as general hospitals, special hospitals, or LSRHs and that are not in compliance with the 1967, 1973, 1981, 1985, 1991, 1997, 2000, 2003, or 2010 editions of the NFPA 101, the Hospital Licensing Standards/Rules (1969, 1985, or 1998 editions as amended), and hospital licensing rules under which the building or sections of buildings were constructed shall comply with the requirements of §511.162 of this subchapter (relating to General Construction Requirements), §511.163 of this subchapter (relating to Spatial Requirements), §511.165 of this subchapter (relating to Building with Multiple Occupancies), §511.167 of this subchapter, and §511.168 of this subchapter (relating to Construction, Inspections, and Approval of Project).

(c) Service removal. Where removal of a patient care service occurs in a patient care bedroom, patient treatment room, patient diagnostic room, patient therapy room, or any other similar location where patient services are provided and the area does not hold an Architectural Review Unit application number, the following systems and furnishing shall be removed from that room, rooms, or unit affected:

(1) access to the nurse call system equipment, including nurse call activation devises, and dome lights;

(2) access to the medical gases;

(3) access to cubicle curtains and cubicle curtain tracks; and

(4) access to patient reading lights.

§511.162. General Construction Requirements.

(a) Location. Any proposed limited services rural hospital (LSRH) shall be easily accessible to the community and to service vehicles such as delivery trucks, ambulances, and fire protection apparatus. No building may be converted for use as an LSRH which, because of its location, physical condition, state of repair, or arrangement of facilities, would be hazardous to the health and safety of the patients.

(1) Hazardous locations.

(A) Underground and above ground hazards. New LSRHs or additions to existing LSRHs shall not be constructed within 150 feet of easement boundaries or setbacks of hazardous underground locations including liquid butane or propane, liquid petroleum or

natural gas transmission lines, high pressure lines, and not within the easement of high voltage electrical lines.

(B) Fire hazards. New LSRHs and additions to existing LSRHs shall not be built within 300 feet of above ground or underground storage tanks containing liquid petroleum or other flammable liquids used in connection with a bulk plant, marine terminal, aircraft refueling, bottling plant of a liquefied petroleum gas installation, or near other hazardous or hazard producing plants.

(2) Undesirable locations.

(A) Nuisance producing sites. New LSRHs shall not be located near nuisance producing industrial sites, feed lots, sanitary landfills, or manufacturing plants producing excessive noise or air pollution.

(B) Cemeteries. New LSRHs shall not be located near a cemetery in a manner that allows direct view of the cemetery from patient windows.

(C) Flood plains.

(i) Previously licensed eligible general or special hospital. An existing building or a portion of an existing building located in a designated 100-year flood plain that was previously licensed as a general or special hospital but has been vacated or used for purposes other than a hospital, will not be licensed as an LSRH.

(ii) Existing LSRH. Access and required functional LSRH components shall be constructed above the designated flood plain in a new addition to an existing LSRH located in a designated 100-year flood plain.

(D) Airports. Construction of new LSRHs shall be avoided in close proximity to airports. When LSRHs are proposed to be located near airports, recommendations of the Texas Aviation Authority and the Federal Aviation Authority shall apply. An LSRH may not be constructed within a rectangular area formed by lines perpendicular to and two miles (10,560 feet) from each end of any runway and by lines parallel to and one-half mile (2,640 feet) from each side of any runway.

(b) Environmental considerations. Development of an LSRH site and LSRH construction shall be governed by state and local regulations and requirements with respect to the effect of noise and traffic on the community and the environmental impact on air and water.

(c) LSRH site.

(1) Paved roads and walkways. Paved roads shall be provided within the lot lines to provide access from public roads to the main entrance, emergency entrance, entrances serving community activities, and to service entrances, including loading and unloading docks for delivery trucks.

(A) Emergency entrance. An LSRH shall have its emergency entrance well-marked to facilitate entry from the public roads or streets serving the site.

(B) Access to emergency department. Access to the emergency entrance shall not conflict with other vehicular traffic or pedestrian traffic and shall be located so as not to be compromised by floods.

(C) Pedestrian traffic. Finished surface walkways shall be provided for pedestrians.

(2) Parking. Off-street parking shall be available for visitors, employees, and staff. Parking structures directly accessible from an LSRH shall be separated with two-hour fire rated noncombustible construction. When used as required means of egress for LSRH occupants, parking structures shall comply with National Fire Protection Association (NFPA) 88A, Standard for Parking Structures, 2011 edition. This requirement does not apply to freestanding parking structures.

(A) Number of parking places. In the absence of a formal parking study, one parking space shall be provided for each day shift employee plus one space for each patient station. This ratio may be reduced in an area convenient to a public transportation system or to public parking facilities on the basis of a formal parking study. Parking facilities shall be increased accordingly when the size of existing facilities is increased.

(B) Additional parking. Additional parking shall be required to accommodate medical staff, outpatient and other services when such services are provided.

(C) Emergency and delivery parking. Separate parking facilities shall be provided for ambulances and delivery vehicles.

(d) Building design and construction requirements. Every building and every portion thereof shall be designed and constructed to sustain all dead and live loads in accordance with accepted engineering practices and standards and the local governing building codes. Where there is no local governing building code, the LSRH shall be constructed in accordance with the International Building Code, 2003 edition.

(1) General architectural requirements. All new construction, including conversion of an existing building to an LSRH, and establishing a separately licensed LSRH in a building with an existing licensed LSRH, shall comply with Chapter 18 of the NFPA 101, Life Safety Code, 2012 edition (NFPA 101), Subchapter F of this chapter (relating to Fire Prevention and Safety), and this subchapter. An LSRH shall submit construction documents to the Texas Health and Human Services Commission (HHSC) in accordance with §511.167 of this subchapter (relating to Preparation, Submittal, Review, and Approval of Plans, and Retention of Records).

(A) Physical environment. A physical environment that protects the health and safety of patients, personnel, and the public shall be provided in each LSRH. The physical premises of the LSRH and those areas of the LSRH's physical structure that are used by the patients (including all stairwells, corridors, and passageways) shall meet the local building and fire safety codes, Subchapter F of this chapter, and this subchapter.

(B) Construction type. An LSRH may occupy an entire building or a portion of a building, provided the LSRH portion of the building is separated from the rest of the building in accordance with subparagraph (C) of this paragraph and the entire building or the LSRH portion of the building complies with this subchapter's requirements (type of construction permitted for hospitals by NFPA 101 §18.1.6.2), and the entire building is protected with a fire sprinkler system conforming with requirements of NFPA 13, Standard for the Installation of Sprinkler Systems, 2010 edition.

(C) Separate buildings. Portions of a building divided horizontally with two-hour fire rated walls that are continuous (without offsets) from the foundation to above the roof shall be considered as a separate building. Communicating openings in the two-hour wall shall be limited to public spaces such as lobbies and corridors. All such openings shall be protected with self-closing one and one-half hour, Class B fire door assemblies.

(D) Design for the accessibility. Special considerations benefiting staff, visitors, and patients with disabilities shall be provided. An LSRH shall comply with the Americans with Disabilities Act (ADA) of 1990, Public Law 101-336, 42 United States Code,

Chapter 126, and Title 36 Code of Federal Regulations, Part 1191, Appendix A (relating to Accessibility Guidelines for Buildings and Facilities) or 16 TAC Chapter 68 (relating to Elimination of Architectural Barriers), Texas Accessibility Standards (TAS), April 1, 1994 edition, issued by the Texas Department of Licensing and Regulation, under Texas Government Code Chapter 469 (relating to Elimination of Architectural Barriers).

(E) Patient safety. In developing construction documents for submission to HHSC in accordance with §511.167 of this subchapter, the owner shall comply with the requirements of Texas Health and Safety Code Chapter 256 (relating to Safe Patient Handling and Movement Practices). Texas Health and Safety Code §256.002(b)(8) requires an LSRH's governing body to consider the feasibility of incorporating patient handling equipment or the physical space and construction design needed to incorporate that equipment at a later date.

(F) Other regulations. The more stringent standard, code or requirement shall apply when a difference in requirements for construction exists.

(G) Exceeding minimum requirements. Nothing in this subchapter shall be construed to prohibit a better type of building construction, more exits, or otherwise safer conditions than the minimum requirements specified in this subchapter.

(H) Equivalency. Nothing in this subchapter is intended to prevent the use of systems, methods, or devices of equivalent or superior quality, strength, fire resistance, effectiveness, durability, and safety to those prescribed by this subchapter, providing technical documentation that demonstrates equivalency is submitted to HHSC for approval.

(I) Freestanding buildings (not for patient use). Separate freestanding buildings for nonpatient use such as the heating plant, boiler plant, laundry, repair workshops, or general storage may be of unprotected noncombustible construction, protected noncombustible construction, or fire-resistive construction and be designed in accordance with other occupancy classifications requirements listed in NFPA 101.

(J) Energy conservation. In new construction and in major alterations and additions to existing buildings and in new buildings, electrical and mechanical components shall be selected for efficient utilization of energy. LSRH construction shall be in accordance with the provisions of Texas Health and Safety Code Chapter 388 (relating to Texas Building Energy Performance Standards).

(K) Heliports. Heliports located on LSRH buildings or land used or intended to be used for landing and takeoff of helicopters shall comply with National Fire Protection Association 418, Standard for Heliports, 2011 edition.

(2) General detail and finish requirements. Details and finishes in new construction projects, including additions and alterations, shall be in compliance with this paragraph, with NFPA 101, Chapter 18, with local building codes, and with any specific detail and finish requirements for the particular unit as contained in §511.163 of this subchapter (relating to Spatial Requirements).

(A) General detail requirements.

(i) Fire safety. Fire safety features, including compartmentation, means of egress, automatic extinguishing systems, inspections, smoking regulations, and other details relating to fire prevention and fire protection shall comply with §511.161 of this subchapter (relating to Requirements for Buildings in Which Existing Licensed Hospitals Are Located), and NFPA 101, Chapter 18 requirements for hospitals. The Fire Safety Evaluation System for Health Care Occupancies contained in the NFPA 101A, Alternative Approaches to Life Safety, 2010 edition, Chapter 3, shall not be used in new building construction, renovations, or additions to existing LSRHs.

(ii) Access to exits. Corridors providing access to all patient, diagnostic, treatment, and patient therapy rooms and exits shall be at least eight feet in clear and unobstructed width, not less than seven feet six inches in height, and constructed in accordance with requirements listed in NFPA 101 §18.3.6.

(iii) Corridors in other occupancies. Public corridors in administrative and service areas that are designed to requirements other than LSRH requirements and are the required means of egress from the LSRH shall be not less than five feet in width.

(iv) Encroachment into the means of egress. Items such as drinking fountains, telephone booths or stations, and vending machines shall be so located as to not project into and restrict exit corridor traffic or reduce the exit corridor width below the required minimum. Portable equipment shall not be stored so as to project into and restrict exit corridor traffic or reduce the exit corridor width below the required minimum.

(v) Doors in means of egress. All door leaves in the means of egress shall be not less than 44 inches wide or as otherwise permitted for hospitals by NFPA 101 §18.2.3.6.

(vi) Sliding doors. Horizontal sliding doors serving an occupant load of fewer than 10 shall be permitted. The area served by the door has no high hazard contents. The door is readily operable from either side without special knowledge or effort. The force required to operate the door in the direction of door travel is not more than 30 pounds per foot to set the door in motion and is not more than 15 pounds per foot to close the door or open in the minimum required width. The door assembly complies with any required fire protection rating, and, where rated, is self-closing or automatic closing. The sliding doors opening to the egress corridor doors shall have a latch or other mechanism that ensures that the doors will not rebound into a partially open position if forcefully closed. The sliding doors may have breakaway provisions and shall be installed to resist passage of smoke. The latching sliding panel shall have a minimum clear opening of 41.5 inches in the fully open position. The fixed panels may have recessed tracks.

(vii) Control doors. Designs that include cross-corridor control doors should be avoided. When unavoidable, cross-corridor control doors shall consist of two 44-inch wide leaves that swing in a direction opposite from the other, or of the double acting type. Each door leaf shall be provided with a view window.

(viii) Emergency access. Rooms containing bathtubs, showers, and water closets, intended for patient use shall be provided with at least one door having hardware that will permit access from the outside in any emergency. Door leaf width of such doors shall not be less than 36 inches.

(ix) Obstruction of corridors. All doors that swing towards the corridor must be recessed. Corridor doors to rooms not subject to occupancy (any room that you can walk into and close the door behind you is considered occupiable) may swing into the corridor, provided that such doors comply with the requirements of NFPA 101 §7.2.1.4.4.

(x) Stair landing. Doors shall not open immediately onto a stair without a landing. The landing shall be 44 inches deep or have a depth at least equal to the door width, whichever is greater.

(xi) Doors to rooms subject to occupancy. All doors to rooms subject to occupancy shall be of the swing type except that horizontal sliding doors complying with the requirements of NFPA 101 §18.2.2.2.9 are permitted. Door leaves to rooms subject to occupancy shall not be less than 36 inches wide.

(xii) Operable windows and exterior doors. Windows that can be opened without tools or keys and outer doors without automatic closing devices shall be provided with insect screens.

(xiii) Glazing. Glass doors, lights, sidelights, borrowed lights, and windows located within 12 inches of a door jamb or with a bottom-frame height of less than 18 inches and a top-frame height of more than 36 inches above the finished floor that may be broken accidentally by pedestrian traffic shall be glazed with safety glass or plastic glazing material that will resist breaking and will not create dangerous cutting edges when broken. Similar materials shall be used for wall openings in activity areas such as recreation and exercise rooms, unless otherwise required for fire safety. Safety glass, tempered, or plastic glazing materials shall be used for shower doors and bath enclosures, interior windows and doors. Plastic and similar materials used for glazing shall comply with the flame spread ratings of NFPA 101 §18.3.3.

(xiv) Fire doors. All fire doors shall be listed by an independent testing laboratory and shall meet the construction requirements for fire doors in NFPA 80, Standard for Fire Doors and Fire Windows, 2010 edition. Reference to a labeled door shall be construed to include labeled frame and hardware.

(xv) Grab bars. Grab bars shall be provided at patient toilets, showers and tubs. The bars shall be one and one-half inches in diameter, shall have either one and one-fourth or one and one-half inches clearance to walls, and shall have sufficient strength and anchorage to sustain a concentrated vertical or horizontal load of 250 pounds. Grab bars are not permitted at bathing and toilet fixtures in mental health and chemical dependency units unless designed and installed to eliminate the possibility of patients harming themselves. Grab bars intended for use by the disabled shall also comply with Americans with Disabilities Act of 1990 (ADA) requirements.

(xvi) Soap dishes. Soap dishes shall be provided at all showers and bathtubs.

(xvii) Hand washing facilities. Location and arrangement of fittings for hand washing facilities shall permit their proper use and operation. Hand washing fixtures with hands-free operable controls shall be provided within each workroom, examination, and treatment room. Hands-free includes blade-type handles, and foot, knee, or sensor operated controls. Particular care shall be given to the clearances required for blade-type operating handles. Lavatories and hand washing facilities shall be securely anchored to withstand an applied vertical load of not less than 250 pounds on the front of the fixture. In addition to the specific areas noted, hand washing facilities shall be provided and conveniently located for staff use throughout the LSRH where patient care contact occurs and services are provided.

(xviii) Soap dispensers. A liquid or foam soap dispenser shall be located at each hand washing facility.

(xix) Alcohol-based hand rubs. Alcohol-based hand rubs (ABHRs) are considered flammable. When used, ABHRs shall meet the following requirements.

(I) The dispensers may be installed in a corridor so long as the corridor width is six feet or greater. The dispensers shall be installed at least four feet apart.

(II) The maximum individual dispenser fluid capacity is 1.2 liters for dispensers in rooms, corridors, and areas open to corridors, and 2.0 liters for dispensers in suites of rooms.

(III) The dispensers shall not be installed over or directly adjacent to electrical outlets and switches.

(IV) Dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments.

(V) Each smoke compartment may contain a maximum aggregate of 10 gallons of ABHR solution in dispensers and a maximum of five gallons in storage.

(xx) Hand drying. Provisions for hand drying shall be included at all hand washing facilities except scrub sinks. There shall be hot air dryers or individual paper or cloth units enclosed in such a way as to provide protection against dust or soil and ensure single-unit dispensing.

(xxi) Mirrors. Mirrors shall not be installed at hand washing fixtures where asepsis control and sanitation requirements would be lessened by hair combing. Mirrors may be installed in patient toilet rooms, lockers, and public toilet rooms.

(xxii) Ceiling heights. The minimum ceiling height shall be seven feet six inches with the following exceptions.

(I) Boiler rooms. Boiler rooms shall have ceiling clearances not less than two feet six inches above the main boiler header and connecting piping.

(II) Rooms with ceiling-mounted equipment. Rooms containing ceiling-mounted equipment shall have the ceiling height clearance increased to accommodate the equipment or fixtures.

(III) Overhead clearance. Suspended tracks, rails, pipes, signs, lights, door closers, exit signs, and other fixtures that protrude into the path of normal traffic shall not be less than six feet eight inches above the finished floor.

(xxiii) Areas producing impact noises. Recreation rooms, exercise rooms, and similar spaces where impact noises may be generated shall not be located directly over patient bed area or operating rooms unless special provisions are made to minimize noise.

(xxiv) Noise reduction. Noise reduction criteria in accordance with the Table 1 in §511.169(a) of this subchapter (relating to Tables) shall apply to partitions, floor, and ceiling construction in patient areas.

(xxv) Rooms with heat-producing equipment. Rooms containing heat-producing equipment such as heater rooms, laundries, etc. shall be insulated and ventilated to prevent any occupied floor surface above from exceeding a temperature differential of 10 degrees Fahrenheit above the ambient room temperature.

(xxvi) Chutes. Linen and refuse chutes shall comply with the requirements of NFPA 82, Standard on Incinerators, Waste and Linen Handling Systems and Equipment, 2009 edition, and NFPA 101 §18.5.4.

(xxvii) Thresholds and expansion joint covers. Thresholds and expansion joint covers shall be flush or not more than one-half inch above the floor surface to facilitate the use of wheelchairs and carts. Expansion and seismic joints shall be constructed to restrict the passage of smoke and fire and shall be listed by a nationally recognized testing laboratory.

(xxviii) Housekeeping room.

(I) In addition to any housekeeping rooms required in certain departments, sufficient housekeeping rooms shall be provided throughout the LSRH as required to maintain a clean and sanitary environment.

(II) Each housekeeping room shall contain a floor receptor or service sink and storage space for housekeeping equipment and supplies.

(B) General finish requirements.

(i) Cubicle curtains and draperies.

(I) Cubicle curtains, draperies, and other hanging fabrics shall be noncombustible or flame retardant and shall pass both the small scale and the large-scale tests of NFPA 701, Standard Methods of Fire Tests for Flame-Resistant Textiles and Films, 2010 edition. Copies of laboratory test reports for installed materials shall be submitted to HHSC at the time of the final construction inspection.

(II) Cubicle curtains shall be provided to assure patient privacy.

(ii) Flame spread, smoke development, and noxious gases. Flame spread and smoke developed limitations of interior finishes shall comply with Table 2 of §511.169(b) of this subchapter and NFPA 101 §10.2. The use of materials known to produce large or concentrated amounts of noxious or toxic gases shall not be used in exit accesses or in patient areas. Copies of laboratory test reports for installed materials tested in accordance with NFPA 255, Standard Method of Test of Surface Burning Characteristics of Building Materials, 2000 edition, and NFPA 258, Standard Research Test Method for Determining Smoke Generation of Solid Materials, 2001 edition, shall be provided.

(iii) Floor finishes. Flooring shall be easy to clean and have wear resistance appropriate for the location involved. Floors that are subject to traffic while wet (such as shower and bath areas, kitchens, and similar work areas) shall have a nonslip surface. In all areas frequently subject to wet cleaning methods, floor materials shall not be physically affected by germicidal and cleaning solutions. The following are acceptable floor finishes:

(I) painted concrete;

(II) vinyl and vinyl composition tiles and sheets;

(III) monolithic or seamless flooring. Where required, seamless flooring shall be impervious to water, coved and installed integral with the base, tightly sealed to the wall, and without voids that can harbor insects or retain dirt particles. The base shall not be less than six inches in height. Welded joint flooring is acceptable;

(IV) ceramic and quarry tile;

(V) wood floors. Wood floors subject to frequent cleaning methods shall be avoided. When wood floors are used, the floor shall be tightly sealed, without voids and the joints shall be impervious to water;

(VI) carpet flooring. Carpeting installed in patient care areas shall be treated to prevent bacterial and fungal growth;

(VII) terrazzo; and

(VIII) poured in place floors.

(iv) Wall finishes. Wall finishes shall be smooth, washable, moisture resistant, and cleanable by standard housekeeping practices. Wall finishes shall comply with requirements contained in Table 2 of §511.169(b) of this subchapter, and NFPA 101 §18.3.3.

(I) Wall finishes shall be water-resistant in the immediate area of plumbing fixtures.

(II) Wall finishes subject to frequent wet cleaning methods shall be impervious to water, tightly sealed, and without voids.

(v) Floor, wall, and ceiling penetrations. Floor, wall, and ceiling penetrations by pipes, ducts, and conduits or any direct openings shall be tightly sealed to minimize entry of dirt particles, rodents, and insects. Joints of structural elements shall be similarly sealed.

(vi) Ceiling types. Ceilings that are a part of a rated roof/ceiling assembly or a floor/ceiling assembly shall be constructed of listed components and installed in accordance with the listing. The following subclauses describe three types of ceilings that are required in various areas of the LSRH.

(I) Ordinary ceilings. Ceilings such as acoustical tiles installed in a metal grid that are dry cleanable with equipment used in daily housekeeping activities such as dusters and vacuum cleaners.

(II) Washable ceilings. Ceilings that are made of washable, smooth, moisture impervious materials such as painted lay-in gypsum wallboard or vinyl faced acoustic tile in a metal grid.

(III) Monolithic ceilings. Ceilings that are monolithic from wall to wall (painted solid gypsum wallboard), smooth and without fissures, open joints, or crevices and with a washable and moisture impervious finish.

(vii) Special construction. Special conditions may require special wall and ceiling construction for security in areas such as storage of controlled substances and areas where patients are likely to attempt suicide or escape.

(viii) Flammable anesthetizing locations. Flammable anesthetic locations in which flammable anesthetic agents are stored or administered shall comply with Annex E of NFPA 99, Health Facilities Code, 2012 edition.

(ix) Materials finishes. Materials known to produce noxious gases when burned shall not be used for mattresses, upholstery, and wall finishes.

(x) Signage. A sign shall be posted at the entrance to each toilet or restroom to identify the facility for public, staff, or patient use. A sign is not required for patient room bathrooms.

(3) General mechanical requirements. This paragraph contains common requirements for mechanical systems; steam and hot and cold water systems; air conditioning, heating and ventilating systems; plumbing fixtures; piping systems; and thermal and acoustical insulation. An LSRH shall comply with the requirements of this paragraph and any specific mechanical requirements for the particular unit of the LSRH as described in §511.163 of this subchapter.

(A) Equipment location. When mechanical equipment is exposed to weather, it shall be weather protected or protected by weatherproof construction.

(B) Vibration isolation. Mechanical equipment shall be mounted on vibration isolators as required to prevent unacceptable structure-borne vibration. Ducts, pipes, etc. connected to mechanical equipment that is a source of vibration shall be isolated from the equipment with vibration isolators.

(C) Performance and acceptance. Before completion and acceptance of the facility, all mechanical systems shall be tested, balanced, and operated to demonstrate to the design engineer or their

representative that the installation and performance of these systems conform to the requirements of the plans and specifications.

(i) Material lists. On completion of the contract, the owner shall be provided with parts lists and procurement information with numbers and description for each piece of equipment.

(ii) Instructions. On completion of the contract, the owner shall be provided with instructions in the operational use of systems and equipment as required.

(D) Heating, ventilating and air conditioning (HVAC) systems. All HVAC systems shall comply with and shall be installed in accordance with the requirements of NFPA 90A, Standard for the Installation of Air Conditioning and Ventilating Systems, 2012 edition, NFPA 99, Chapter 6, the requirements contained in this subparagraph, and the specific requirements for a particular unit in accordance with §511.163 of this subchapter.

(i) General ventilation requirements. All rooms and areas in the LSRH listed in Table 3 of §511.169(c) of this subchapter shall have provision for positive ventilation. Fans serving exhaust systems shall be located at the discharge end and shall be conveniently accessible for service. Exhaust systems may be combined, unless otherwise noted, for efficient use of recovery devices required for energy conservation. The ventilation rates shown in Table 3 of §511.169(c) of this subchapter shall be used only as minimum requirements since they do not preclude the use of higher rates that may be appropriate. Supply air to the building and exhaust air from the building shall be regulated to provide a positive pressure within the building with respect to the exterior.

(I) Cost reduction methods. To reduce utility costs, facility design may utilize energy conserving procedures including recovery devices, variable air volume, load shedding, systems shutdown or reduction of ventilation rates (when specifically permitted) in certain areas when unoccupied. In no case shall patient care be jeopardized.

(II) Economizer cycle. Mechanical systems shall be arranged to take advantage of outside air conditions by using an economizer cycle when appropriate to reduce heating and cooling systems loads. An LSRH may present to HHSC for consideration an innovative design that provides for additional energy conservation while meeting the intent of this section for acceptable patient care.

(III) Outside air intake locations. Outside air intakes shall be located at least 25 feet from exhaust outlets of ventilating systems, combustion equipment stacks, medical-surgical vacuum systems, plumbing vents, or areas that may collect vehicular exhaust or other noxious fumes. (Prevailing winds and proximity to other structures may require more stringent requirements). Plumbing and vacuum vents that terminate five feet above the level of the top of the air intake may be located as close as 10 feet.

(IV) Low air intake location limit. The bottom of outside air intakes serving central systems shall be located as high as practical but at least six feet above ground level, or if installed above the roof, three feet above the roof level.

(V) Contaminated air exhaust outlets. Exhaust outlets from areas (kitchen hoods, etc.) that exhaust contaminated air shall be above the roof and be arranged to exhaust upward unless the air has been treated by an appropriate means where sidewall exhaust will be allowed. Ethylene oxide sterilizers shall be terminated above the roof and be arranged to exhaust upward. Each patient room bathroom shall be exhausted continuously to the exterior in accordance with Table 3 of §511.169(c) of this subchapter.

(VI) Directional air flow. Ventilation systems shall be designed and balanced to provide directional flow as shown in Table 3 of §511.169(c) of this subchapter. For reductions and shutdown of ventilation systems when a room is unoccupied, the provisions in Note 4 of Table 3 of §511.169(c) of this subchapter shall be followed.

(VII) Areas requiring fully ducted systems. Fully ducted supply, return and exhaust air for HVAC systems shall be provided for all critical care areas, sensitive care areas, all patient care areas, all areas requiring a sterile regimen, storage rooms, food preparation areas, and where required for fire safety purposes. Combination systems, utilizing both ducts and plenums for movement of air in these areas shall not be permitted.

(VIII) Ventilation start-up requirements. Air handling systems shall not be started or operated without the filters installed in place. This includes the 90 percent and 99.97 percent efficiency filters where required. Ducts shall be cleaned thoroughly and throughout by a certified air duct cleaning contractor when the air handling systems have been operating without the required filters in place. When ducts are determined to be dirty or dusty, HHSC will require a written report assuring cleanliness of duct and clean air quality.

(IX) Humidifier location. When duct humidifiers are located upstream of the final filters, they shall be located at least 15 feet from the filters. Ductwork with duct-mounted humidifiers shall be provided with a means of removing water accumulation. An adjustable high-limit humidistat shall be located downstream of the humidifier to reduce the potential of condensation inside the duct. All duct take-offs should be sufficiently downstream of the humidifier to ensure complete moisture absorption. Reservoir-type water spray or evaporative pan humidifiers shall not be used.

(ii) Filtration requirements. All central air handling systems serving patient care areas, including corridors, shall be equipped with filters having efficiencies equal to, or greater than, those specified in Table 4 of §511.169(d) of this subchapter. Filter efficiencies shall be average efficiencies tested in accordance with American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE), Inc., Standard 52.2, 1999 edition, Method of Testing General Ventilation Air-Cleaning Devices for Removal Efficiency by Particle Size. All joints between filter segments, and between filter segments and the enclosing ductwork, shall have gaskets and seals to provide a positive seal against air leakage. Air handlers serving more than one room shall be considered as central air handlers.

(I) Filtration requirements for air handling units serving single rooms requiring asepsis control. Dedicated air handlers serving only one room where asepsis control is required, including operating rooms and special procedure rooms shall be equipped with filters having efficiencies equal to, or greater than, those specified for patient care areas in Table 4 of §511.169(d) of this subchapter.

(II) Filtration requirements for air handling units serving other single rooms. Dedicated air handlers serving all other single rooms shall be equipped with nominal filters installed at the return air system.

(III) Location of multiple filters. Where two filter beds are required by Table 4 of §511.169(d) of this subchapter, filter bed number one shall be located upstream of the air conditioning equipment, and filter bed number two shall be downstream of the supply air blowers and cooling and heating coils.

(IV) Location of single filters. Where only one filter bed is required by Table 4 of §511.169(d) of this subchapter, it

shall be located upstream of the supply fan. Filter frames shall be durable and constructed to provide an airtight fit with the enclosing ductwork.

(V) Pressure monitoring devices. A manometer or draft gauge shall be installed across each filter bed having a required efficiency of 75 percent or more including hoods requiring high efficiency particulate air (HEPA) filters.

(iii) Thermal and acoustical insulation for air handling systems. Asbestos insulation shall not be used.

(I) Thermal duct insulation. Air ducts and casings with outside surface temperature below ambient dew point or temperature above 80 degrees Fahrenheit shall be provided with thermal insulation.

(II) Insulation in air plenums and ducts. Linings in air ducts and equipment shall meet the Erosion Test Method described in Underwriters Laboratories (UL), Inc., Standard Number 181 (relating to Factory-Made Duct Materials and Air Duct Connectors), April 4, 1996 edition.

(III) Insulation flame spread and smoke developed ratings. Interior and exterior insulation, including finishes and adhesives on the exterior surfaces of ducts and equipment, shall have a flame spread rating of 25 or less and a smoke developed rating of 50 or less as required by NFPA 90A Chapters 4 and 5.

(IV) Linings and acoustical traps. Duct lining and acoustical traps exposed to air movement shall not be used in ducts serving critical care areas. This requirement shall not apply to mixing boxes and acoustical traps that have approved nonabrasive coverings over such linings.

(V) Frangible insulation. Insulation of soft and spray-on types shall not be used where it is subject to air currents or mechanical erosion or where loose particles may create a maintenance problem.

(VI) Existing duct linings. Internal linings shall not be used in ducts, terminal boxes, or other air system components supplying operating rooms, delivery rooms, birthing rooms, labor rooms, recovery rooms, nurseries, trauma rooms, isolation rooms, and intensive care units unless terminal filters of at least 90 percent efficiency are installed downstream of linings.

(iv) Ventilation for anesthetizing locations. Ventilation for anesthetizing locations, as defined in NFPA 99 §3.3, shall comply with NFPA 99 §13.4.1.2, and any specific ventilation requirements for the particular unit in accordance with §511.163 of this subchapter.

(I) Smoke removal systems for windowless anesthetizing locations. Smoke removal systems shall be provided in all windowless anesthetizing locations in accordance with NFPA 99 §6.4.1.2.

(II) Smoke removal systems for surgical suites. Smoke removal systems shall be provided in all surgical suites in accordance with NFPA 99 §6.4.1.3.

(III) Smoke exhaust grilles. Exhaust grilles for smoke evacuation systems shall be ceiling-mounted or wall-mounted within 12 inches of the ceiling.

(v) Location of return and exhaust air devices. The bottoms of wall-mounted return and exhaust air openings shall be at least four inches above the floor. Return air openings located less than six inches above the floor shall be provided with nominal filters. All exhaust air openings and return air openings located higher than six inches but less than seven feet above the floor shall be protected with grilles or screens having openings through which a one-half inch sphere will not pass.

(vi) Ray protection. Ducts that penetrate construction intended for X-ray or other ray protection shall not impair the effectiveness of the protection.

(vii) Fire damper requirements. Fire dampers shall be located and installed in all ducts at the point of penetration of a required two-hour or higher fire rated wall or floor in accordance with the requirements of NFPA 101 §18.5.2.

(viii) Smoke damper requirements. Smoke dampers shall be located and installed in accordance with the requirements of NFPA 101 §18.3.7.3 and NFPA 90A Chapter 5.

(I) Fail-safe installation. Smoke dampers shall close on activation of the fire alarm system by smoke detectors installed and located as required by NFPA 72, National Fire Alarm Code, 2010 edition, Chapter 8; NFPA 90A Chapter 6; and NFPA 101 §18.3.7; the fire sprinkler system; and on loss of power. Smoke dampers shall not close by fan shutdown alone unless it is a part of an engineered smoke removal system.

(II) Interconnection of air handling fans and smoke dampers. Air handling fans and smoke damper controls may be interconnected so that closing of smoke dampers will not damage the ducts.

(III) Frangible devices. Use of frangible devices for shutting smoke dampers is not permitted.

(ix) Acceptable damper assemblies. Only fire damper and smoke damper assemblies integral with sleeves and listed for the intended purpose is acceptable.

(x) Duct access doors. Unobstructed access to duct openings in accordance with NFPA 90A §4.3.4 shall be provided in ducts within reach and sight of every fire damper, smoke damper, and smoke detector. Each opening shall be protected by an internally insulated door that shall be labeled externally to indicate the fire protection device located within.

(xi) Restarting controls. Controls for restarting fans may be installed for convenient fire department use to assist in evacuation of smoke after a fire is controlled, provided provisions are made to avoid possible damage to the system because of closed dampers. To accomplish this, smoke dampers shall be equipped with remote control devices.

(xii) Make-up air. If air supply requirements in Table 3 of §511.169(c) of this subchapter do not provide sufficient air for use by exhaust hoods and safety cabinets, filtered make-up air shall be ducted to maintain the required air flow direction in that room. Make-up systems for hoods shall be arranged to minimize short circuiting of air and to avoid reduction in air velocity at the point of contaminant capture.

(xiii) Isolation room exhaust. An isolation room exhaust shall be a dedicated system that exhausts all air continuously to the exterior in accordance with Table 3 of §511.169(c) of this subchapter. Multiple isolation rooms may be interconnected to the same exhaust system.

(4) General piping systems and plumbing fixture requirements. All piping systems and plumbing fixtures shall be designed and installed in accordance with the requirements of the National Standard Plumbing Code Illustrated published by the National Association of Plumbing-Heating-Cooling Contractors (PHCC), 2003 edition, and this paragraph.

(A) Piping systems.

(i) Water supply systems. Water service pipe to point of entrance to the building shall be brass pipe, copper tube (not less than type M when buried directly), copper pipe, cast iron water pipe, galvanized steel pipe, or approved plastic pipe. Domestic water distribution system piping within buildings shall be brass pipe, copper pipe, copper tube, or galvanized steel pipe. Piping systems shall be designed to supply water at sufficient pressure to operate all fixtures and equipment during maximum demand.

(I) Valves. Each water service main, branch main, riser, and branch to a group of fixtures shall be equipped with accessible and readily identifiable shutoff valves. Stop valves shall be provided at each fixture.

(II) Backflow preventers. Backflow preventers (vacuum breakers) shall be installed on hose bibbs, laboratory sinks, janitor sinks, bedpan-flushing attachments, autopsy tables, and on all other fixtures to which hoses or tubing can be attached.

(III) Flushing valves. Flush valves installed on plumbing fixtures shall be of a quiet operating type, equipped with silencers.

(IV) Capacity of water heating equipment. Water heating equipment shall have sufficient capacity to supply water for clinical, dietary and laundry use at the temperatures and amounts specified in Table 5 of §511.169(e) of this subchapter.

(V) Water temperature measurements. Water temperatures shall be measured at hot water point of use or at the inlet to processing equipment.

(VI) Water storage tanks. Any domestic water storage tanks shall be fabricated of corrosion-resistant metal or lined with noncorrosive material. When potable water storage tanks (hot and cold) are used, the water shall be used and replenished. Water shall not be stored in tanks for future use unless the water is tested weekly for contaminates and bacteria.

(VII) Hot water distribution. Water distribution systems shall be arranged to provide hot water at each hot water outlet at all times.

(VIII) Purified water supply system. Purified water distribution system piping shall be task specific and include Polypropylene (PP), Polyvinylidene fluoride (PVDF) or Polyvinyl Chloride (PVC) pipe. Final installed purified water system piping assemblies shall be UL approved and fully comply with applicable American Society for Testing and Materials (ASTM) Fire Resistant/Smoke Density requirements.

(IX) Dead-end piping. Dead-end piping (risers with no flow, branches with no fixture) shall not be installed. In any renovation work, dead-end piping shall be removed. Empty risers, mains and branches installed for future use are permitted.

(ii) Fire sprinkler systems. Fire sprinkler systems shall be provided in an LSRH as required by NFPA 101 §18.3.5. All fire sprinkler systems shall be designed, installed, and maintained in accordance with the requirements of NFPA 13, and shall be certified as required by §511.168(c)(1)(C) of this subchapter (relating to Construction, Inspections, and Approval of Project).

(iii) Nonflammable medical gas and clinical vacuum systems. Nonflammable medical gas and clinical vacuum system installations shall be designed, installed, and certified in accordance with the requirements of NFPA 99 §5.1 for Level I systems and the requirements of this clause.

(I) Outlets. Nonflammable medical gas and clinical vacuum outlets shall be provided in accordance with Table 6 of §511.169(f) of this subchapter.

(II) Installer qualifications. All installations of the medical gas piping systems shall be done only by, or under the direct supervision of, a holder of a master plumber license or a journeyman plumber license with a medical gas piping installation endorsement issued by the Texas State Board of Plumbing Examiners.

(III) Installer tests. Prior to closing of walls, the installer shall perform an initial pressure test, a blowdown test, a secondary pressure test, a cross-connection test, and a purge of the piping system as required by NFPA 99.

(IV) Qualifications for conducting verification tests and inspections. Verification testing shall be performed and inspected by a party, other than the installer, installing contractor, or material vendor. Testing shall be conducted by a registered medical gas system verifier and technically competent and experienced in the field of medical gas and vacuum pipeline testing and meeting the requirements of the American Society of Safety Engineers (ASSE) Personnel Standard 6030, Professional Qualifications Standard for Medical Gas Systems.

(V) Verification tests. On completion of the installer inspections and tests and after closing of walls, verification tests of the medical gas piping systems, the warning system, and the gas supply source shall be conducted. The verification tests shall include a cross-connection test, valve test, flow test, piping purge test, piping purity test, final tie-in test, operational pressure tests, and medical gas concentration test.

(VI) Verification test requirements. Verification tests of the medical gas piping system and the warning system shall be performed on all new piped medical gas systems, additions, renovations, or repaired portions of an existing system. All systems that are breached and components that are added, renovated, or replaced shall be inspected and appropriately tested. The breached portions of the systems subject to inspection and testing shall be all of the new and existing components in the immediate zone or area located upstream of the point or area of intrusion and downstream to the end of the system or a properly installed isolation valve.

(VII) Warning system verification tests. Verification tests of piped medical gas systems shall include tests of the source alarms and monitoring safeguards, master alarm systems, and the area alarm systems.

(VIII) Source equipment verification tests. Source equipment verification tests shall include medical gas supply sources (bulk and manifold) and the compressed air source systems (compressors, dryers, filters, and regulators).

(IX) LSRH responsibility. Before new piped medical gas systems, additions, renovations, or repaired portions of an existing system are put into use, the LSRH is responsible for ensuring the gas delivered at the outlet is the gas shown on the outlet label and the proper connecting fittings are checked against their labels.

(X) Written certification. On successful completion of all verification tests, written certification for affected piped medical gas systems and piped medical vacuum systems including the supply sources and warning systems shall be provided by a party technically competent and experienced in the field of medical gas pipeline testing stating the provisions of NFPA 99 have been adhered to and systems integrity has been achieved. The written certification shall be submitted directly to the LSRH and the installer. The LSRH shall forward a copy to HHSC.

(XI) Documentation of medical gas and clinical vacuum outlets. The same party certifying the piped medical gas systems shall submit to HHSC documentation of the installed, modified, extended or repaired medical gas piping system. The number and type of medical gas outlets (oxygen, vacuum, medical air, nitrogen, nitrous oxide, etc.) shall be documented and arranged tabularly by room numbers and room types.

(iv) Medical gas storage facilities. Main storage of medical gases may be outside or inside the LSRH in accordance with NFPA 99 §5.1. Provision shall be made for additional separate storage of reserve gas cylinders necessary to complete at least one day's procedures.

(v) Multiple gas outlets on one medical gas outlet. Y-connections, "twinning," or other similar devices shall not be used on any medical gas outlet.

(vi) Waste anesthetic gas disposal (WAGD) systems. Each space routinely used for administering inhalation anesthesia shall be provided with a WAGD system as required by NFPA 99 §5.1.3.7.

(vii) Steam and hot water systems.

(I) Boilers. Boilers shall have the capacity, based on the net ratings as published in the I-B-R Ratings Book for Boilers, Baseboard Radiation and Finned Tube (commercial) by the Hydronics Institute Division of Gas Appliance Manufacturers Association, to supply the normal requirements of all systems and equipment. The number and arrangement of boilers shall be such that, when one boiler breaks down or routine maintenance requires that one boiler be temporarily taken out of service, the capacity of the remaining boiler or boilers shall be sufficient to provide hot water service for clinical, dietary, and patient use, steam for sterilization and dietary purposes, and heating for operating, emergency, recovery, treatment, and general patient care rooms. However, reserve capacity for space heating of noncritical care areas (e.g., general patient care rooms and administrative areas) is not required in geographical areas where a design dry bulb temperature equals 25 degrees Fahrenheit or higher as based on the 99 percent design value shown in the Handbook of Fundamentals, 2005 edition, published by ASHRAE, Inc.

(II) Boiler accessories. Boiler feed pumps, heating circulating pumps, condensate return pumps, and fuel oil pumps shall be connected and installed to provide normal and standby service.

(III) Valves. Supply and return mains and risers of cooling, heating, and process steam systems shall be valved to isolate the various sections of each system. Each piece of equipment shall be valved at the supply and return ends except that vacuum condensate returns need not be valved at each piece of equipment.

(IV) Hot water distribution systems. Hot water distribution systems for patient care areas shall be under constant recirculation to provide continuous hot water at each hot water outlet. Nonrecirculated fixtures branch piping shall not exceed 25 feet in length. Water temperature is measured at the point of use or inlet to the equipment. Tankless water system may be used at point of use.

(V) Domestic hot water system. The domestic hot water system shall make provisions to limit the amount of Legionella bacteria and opportunistic waterborne pathogens.

(viii) Drainage systems.

(I) Above ground piping. Soil stacks, drains, vents, waste lines, and leaders installed above ground within buildings shall be drain-waste-vent (DWV) weight or heavier and shall be copper pipe, copper tube, cast iron pipe, or galvanized iron pipe.

(II) Underground piping. All underground building drains shall be cast iron soil pipe, hard temper copper tube (DWV or heavier), acrylonitrile-butodiene-styrene (ABS) plastic pipe (DWV Schedule 40 or heavier), polyvinyl chloride (PVC) plastic pipe (DWV Schedule 40 or heavier), or extra strength vitrified clay pipe (VCP) with compression joints or couplings with at least 12 inches of earth cover.

(III) Drains for chemical wastes. Separate drainage systems for chemical wastes (acids and other corrosive materials) shall be provided. Materials acceptable for chemical waste drainage systems shall include chemically resistant glass pipe, high silicone content cast iron pipe, VCP, plastic pipe, or plastic lined pipe.

(ix) Thermal insulation for piping systems and equipment. Insulation shall be provided for the following:

(I) boilers, smoke breeching, and stacks;

(II) steam supply and condensate return piping;

(III) hot water piping and all hot water heaters, generators, converters, and storage tanks;

(IV) chilled water, refrigerant, other process piping, equipment operating with fluid temperatures below ambient dew point, and water supply and drainage piping on which condensation may occur. Insulation on cold surfaces shall include an exterior vapor barrier; and

(V) other piping, ducts, and equipment as necessary to maintain the efficiency of the system.

(x) Pipe and equipment insulation rating. Flame spread shall not exceed 25 and smoke development rating shall not exceed 150 for pipe insulation as determined by an independent testing laboratory in accordance with NFPA 255, Standard Method of Test of Surface Burning Characteristics of Building Materials, 2000 edition. Smoke development rating for pipe insulation located in environmental air areas shall not exceed 50.

(xi) Asbestos insulation. Asbestos insulation shall not be used.

(B) Plumbing fixtures. Plumbing fixtures shall be made of nonabsorptive acid-resistant materials and shall comply with the recommendations of the National Standard Plumbing Code and this paragraph.

(i) Sink and lavatory controls. All fixtures used by medical and nursing staff and all lavatories used by patients and food handlers shall be trimmed with valves that can be operated without the use of hands. Blade handles used for this purpose shall not be less than four inches in length. Single lever or wrist blade devices may be used.

(ii) Clinical sink traps. Clinical sinks shall have an integral trap in which the upper portion of a visible trap seal provides a water surface.

(iii) Sinks for disposal of plaster of paris. Sinks used for the disposal of plaster of paris shall have a plaster trap.

(iv) Back-flow or siphoning. All plumbing fixtures and equipment shall be designed and installed to prevent the back-flow or back-siphonage of any material into the water supply. The over-the-rim type water inlet shall be used wherever possible. Vacuum-breaking devices shall be properly installed when an over-the-rim type water inlet cannot be utilized.

(v) Drinking fountain. Each drinking fountain shall be designed so that the water issues at an angle from the vertical, the end of the water orifice is above the rim of the bowl, and a guard is located over the orifice to protect it from lip contamination.

(vi) Sterilizing equipment. All sterilizing equipment shall be designed and installed to prevent not only the contamination of the water supply but also the entrance of contaminating materials into the sterilizing units.

(vii) Hose attachment. No hose shall be affixed to any faucet if the end of the hose can become submerged in contaminated liquid unless the faucet is equipped with an approved, properly installed vacuum breaker.

(viii) Bedpan washers and sterilizers. Bedpan washers and sterilizers shall be designed and installed so that both hot and cold water inlets shall be protected against back-siphonage at maximum water level.

(ix) Flood level rim clearance. The water supply spout for lavatories and sinks required in patient care areas shall be mounted so that its discharge point is a minimum of five inches above the rim of the fixture.

(x) Scrub sink controls. Scrub sinks and lavatories used for scrubbing in procedure rooms shall be trimmed with foot, knee, or ultrasonic controls. Single lever wrist blades are not acceptable at scrub sinks.

(xi) Floor drains or floor sinks. Where floor drains or floor sinks are installed, they shall be of a type that can be easily cleaned by removal of the cover. Removable stainless steel mesh shall be provided in addition to grilled drain cover to prevent entry of large particles of waste that might cause stoppages.

(xii) Under-counter piping. Under-counter piping and above floor drains shall be arranged (raised) so as not to interfere with cleaning of floor below the equipment.

(xiii) Ice machines. All ice-making machines used for human consumption shall be of the self-dispensing type. Copper tubing shall be provided for supply connections to ice machines.

(xiv) Food disposal units. A food disposal unit shall only be permitted in the dietary department in accordance with §511.163(d) of this subchapter.

(5) General electrical requirements. This paragraph contains common electrical requirements. The LSRH shall comply with the requirements of this paragraph and with any specific electrical requirements for the particular unit of the LSRH in accordance with §511.163 of this subchapter.

(A) Electrical installations. All new electrical material and equipment, including conductors, controls, and signaling devices, shall be installed in compliance with applicable sections of NFPA 70, National Electrical Code, 2011 edition, and NFPA 99 and as necessary to provide a complete electrical system. Electrical systems and components shall be listed by nationally recognized listing agencies as complying with available standards and shall be installed in accordance with the listings and manufacturers' instructions.

(i) All fixtures, switches, sockets, and other pieces of apparatus shall be maintained in a safe and working condition.

(ii) Extension cords and cables shall not be used for permanent wiring.

(iii) All electrical heating devices shall be equipped with a pilot light to indicate when the device is in service, unless equipped with a temperature limiting device integral with the heater.

(iv) All equipment, fixtures, and appliances shall be properly grounded in accordance with NFPA 70.

(v) Under-counter receptacles and conduits shall be arranged (raised) to not interfere with cleaning of floor below the equipment.

(B) Installation testing and certification.

(i) Installation testing. The electrical installations, including alarm, nurses calling system and communication systems, shall be tested to demonstrate that equipment installation and operation is appropriate and functional.

(ii) Grounding system testing. The grounding system shall be tested as described in NFPA 99 4.3.3, for patient care areas in new or renovated work. A qualified electrician or their qualified electrical testing agent shall perform the testing. The electrical contractor shall provide a letter stating the grounding system has been tested in accordance with NFPA 99, the testing device use complies with NFPA 99, and whether the grounding system passed the test. The qualified electrical contractor or their designated qualified electrical testing agent shall sign the letter, certifying the system has been tested and the results of the test are indicated.

(C) Electrical safeguards. Shielded isolation transformers, voltage regulators, filters, surge suppressors, and other safeguards shall be provided as required where power line disturbances are likely to affect fire alarm components, data processing, equipment used for treatment, and automated laboratory diagnostic equipment.

(D) Services and switchboards. Electrical service and switchboards serving the required LSRH components shall be installed above the designated 100-year flood plain. Main switchboards shall be located in separate rooms, separated from adjacent areas with one-hour fire rated enclosures containing only electrical switchgear and distribution panels and shall be accessible to authorized persons only. These rooms shall be ventilated to provide an environment free of corrosive or explosive fumes and gases, or any flammable and combustible materials. Switchboards shall be located convenient for use and readily accessible for maintenance as required by NFPA 70 Article 384. Overload protective devices shall operate properly in ambient temperatures.

(E) Panelboards. Panelboards serving normal lighting and appliance circuits shall be located on the same floor as the circuits they serve. Panelboards serving critical branch emergency circuits shall be located on each floor that has major users (operating rooms, emergency department, etc.) and may also serve the floor above and the floor below. Panelboards serving life safety branch circuits may serve three floors, the floor where the panelboard is located and the floors above and below.

(F) Wiring. All conductors for controls, equipment, lighting and power operating at 100 volts or higher shall be installed in accordance with the requirements of NFPA 70 Article 517. All surface mounted wiring operating at less than 100 volts shall be protected from mechanical injury with metal raceways to a height of seven feet above the floor. Conduits and cables shall be supported in accordance with NFPA 70 Article 300.

(G) Lighting.

(i) Lighting intensity for staff and patient needs shall comply with guidelines for health care facilities set forth in the Illuminating Engineering Society of North America (IESNA) Handbook, 2000 edition, published by the IESNA.

(I) Consideration should be given to controlling intensity and wavelength to prevent harm to the patient's eyes (i.e., cataracts due to ultraviolet light).

(II) Approaches to buildings and parking lots shall be illuminated. All rooms including storerooms, electrical and

mechanical equipment rooms, and all attics shall have sufficient artificial lighting so all parts of these spaces are clearly visible.

(III) Consideration should be given to the special needs of the elderly. Excessive contrast in lighting levels that makes effective sight adaptation difficult shall be minimized.

(ii) Means of egress and exit sign lighting intensity shall comply with NFPA 101 §§7.8 - 7.10.

(iii) Electric lamps that may be subject to breakage or that are installed in fixtures in confined locations when near woodwork, paper, clothing, or other combustible materials, shall be protected by wire guards, or plastic shields.

(iv) Ceiling-mounted surgical and examination light fixtures shall be suspended from rigid support structures mounted above the ceiling.

(H) Receptacles. Only listed hospital grade single-grounding or duplex-grounding receptacles shall be used in all patient care areas. This does not apply to special purpose receptacles.

(i) Installations of multiple-ganged receptacles shall not be permitted in patient care areas.

(ii) Electrical outlets powered from the critical branch shall be provided in all patient care, procedure and treatment locations in accordance with NFPA 99 §4.4.2.2.2.3. At least one receptacle at each patient treatment or procedure location shall be powered from the normal power panel.

(iii) Replacement of malfunctioning receptacles and installation of new receptacles powered from the critical branch in existing facilities shall be accomplished with receptacles of the same distinct color as the existing receptacles.

(iv) In locations where mobile X-ray or other equipment requiring special electrical configuration is used, the additional receptacles shall be distinctively marked for the special use.

(v) Each receptacle shall be grounded to the reference grounding point by means of a green insulated copper equipment grounding conductor.

(vi) All critical care area receptacles shall be identified. The face plate for the receptacle or receptacles shall have a nonremovable label or be engraved indicating the panel and circuit number.

(I) Equipment.

(i) Equipment required for safe operation of the LSRH shall be powered from the equipment system in accordance with the requirements contained in NFPA 99 §4.4.2.2.3.

(ii) Boiler accessories including feed pumps, heat-circulating pumps, condensate return pumps, fuel oil pumps, and waste heat boilers shall be connected and installed to provide both normal and standby service.

(iii) Laser equipment shall be installed according to manufacturer recommendations and shall be registered with the Texas Department of State Health Services Radiation Control Program.

(J) Ground fault circuit interrupters (GFCI). GFCI receptacles shall be provided for all general use receptacles located within three feet of a wash basin or sink. When GFCI receptacles are used, they shall be connected to not affect other devices connected to the circuit in the event of a trip. Receptacles connected to the critical branch that may be used for equipment that should not be interrupted do not have to be GFCI protected. Receptacles in wet locations, as defined by NFPA 70 §517.20 and §517.21, shall be GFCI protected regardless of the branch of the electrical system serving the receptacle.

(K) Grounding requirements. In areas such as a critical care unit where a patient may be treated with an internal probe or catheter connected to the heart, the ground system shall comply with applicable sections of NFPA 99 and NFPA 70.

(L) Nurses calling systems. Three different types of nurses calling systems are required to be installed in an LSRH: a nurses regular calling system; a nurses emergency calling system; and a staff emergency assistance calling system. The LSRH shall comply with the requirements of this subparagraph in addition to any specific requirements for nurses calling systems for the particular unit of the LSRH in accordance with §511.163 and Table 7 of §511.169(g) of this subchapter. When required in this subparagraph, when a colored dome light lamp or particular combination of colored lamps is used for only one type of call, a distinct visible signal shall be (used or provided). Different flash rates do not meet this requirement.

(i) A nurses regular calling system is intended for routine communication between each patient and the nursing staff. Activation of the system at a patient's regular calling station will sound a repeating (every 20 seconds or less) distinct audible signal at the nurse station, indicate type and location of call on the system monitor, and activate a distinct visible signal in the corridor at the patient suites door. In multi-corridor nursing units, additional visible signals shall be installed at corridor intersections. The audible signal shall be canceled and two-way voice communication between the patient room and the nursing staff shall be established at the unit's nursing station when the call is answered by the nursing staff. The visible signal or signals in the corridor shall be canceled upon termination of the call. Calls shall activate visible signals in accordance with Table 7 of §511.169(g) of this subchapter. An alarm shall activate at the nurse station when the call cable is unplugged.

(ii) A nurses emergency calling system shall be installed in all toilets used by patients to summon nursing staff in an emergency. Activation of the system shall sound a repeating (every 5 seconds or less) a distinct audible signal at the nurse station, indicate type and location of call on the system monitor, and activate a distinct visible signal in the corridor at the patient suites door. In multi-corridor nursing units, additional visible signals shall be installed at corridor intersections. The visible and audible signals shall be cancelable only at the patient calling station. Calls shall activate visible signals in accordance with Table 7 of §511.169(g) of this subchapter. When conveniently located and accessible from both the bathing and toilet fixtures, one emergency call station may serve one bathroom. A nurses emergency call system shall be accessible to a collapsed patient lying on the floor. Inclusion of a pull cord extending to within six inches of the floor will satisfy this requirement.

(iii) A staff emergency assistance calling system (code blue) is intended to be used by staff to summon additional help in an emergency. In open suites, an emergency assistant call system device shall be located at the head of each patient station and in each individual room. The emergency assistance calling device can be shared between two patient stations if conveniently located. Activation of the system will sound a distinct audible signal at the nursing unit's nurse station or at a staffed control station of a suite, department or unit, indicate type and location of call on the system monitor and activate a distinct visible signal in the corridor at the patient suites door. In multi-corridor nursing units, additional visible signals shall be installed at corridor intersections. Calls shall activate audible and visible signals in accordance with Table 7 of §511.169(g) of this subchapter. A visible system shall clearly define the alarm location to a continuously staffed back up area (other than the nurse station or an

administrative center) from which assistance can be summoned. Alternatively, back up may be provided by automatic annunciation from the staff emergency assistance calling system through wireless phones or pagers. The system shall have voice communication capability so that the type of emergency or help required may be specified between the point of alarm and the unit's nurse station.

(M) Emergency electric service. A type I essential electrical system shall be provided in each LSRH in accordance with requirements of NFPA 99; NFPA 101; and NFPA 110, Standard for Emergency and Standby Power Systems, 2010 edition.

(i) When the emergency and standby power systems require a fuel source with tank, the fuel storage capacity tank shall have enough fuel for a 24-hour period.

(ii) When a vapor liquefied petroleum gas (LPG) systems (natural gas) system is used, the 24-hour fuel capacity on-site is not required. The vapor withdrawal LPG system shall require a dedicated fuel supply.

(iii) When the emergency generator or generators and electrical transformer or transformers are located within the same area, they shall be located at least 10 feet apart.

(N) Fire alarm system. A fire alarm system that complies with NFPA 101 §18.3.4, and with NFPA 72 Chapter 6 requirements shall be provided in each LSRH. The required fire alarm system components are as follows.

(i) A fire alarm control panel (FACP) shall be installed at a continuously attended (24 hour) location. A remote fire alarm annunciator listed for fire alarm service and installed at a continuously attended location and is capable of indicating both visual and audible alarm, trouble and supervisory signals in accordance with the requirements of NFPA 72 may be substituted for the FACP.

(ii) Manual fire alarm pull stations shall be installed in accordance with NFPA 101 §18.3.4.

(iii) Smoke detectors for door release service shall be installed on the ceiling at each door opening in the smoke partition in accordance with NFPA 72 §6.15.6, where the doors are held open with electromagnetic devices conforming with NFPA 101 §18.2.2.6.

(iv) Ceiling-mounted smoke detector or detectors shall be installed in room containing the FACP when this room is not attended continuously by staff as required by NFPA 72 §4.4.5.

(v) Smoke detectors shall be installed in air ducts in accordance with NFPA 72 §5.14.4.2 and §5.14.5 and NFPA 90A §6.4.2.

(vi) Smoke detectors shall be installed in return air ducts in accordance with requirements of NFPA 72 §5.14.4.2.2 and §5.14.5 and NFPA 90A §6.4.2.2.

(vii) Fire sprinkler system water flow switches shall be installed in accordance with requirements of NFPA 101 §9.6.2; NFPA 13 §6.9; and NFPA 72 §8.5.3.3.3.4.

(viii) Sprinkler system valve supervisory switches shall be installed in accordance with the requirements of NFPA 72 §6.8.5.5.

(ix) Audible alarm indicating devices shall be installed in accordance with the requirements of NFPA 101 §18.3.4 and NFPA 72 §7.4.

(x) Visual fire alarm indicating devices that comply with the requirements of paragraph (1)(D) of this subsection and NFPA 72 §7.5 shall be provided.

(xi) Devices for transmitting alarm for alerting the local fire brigade or municipal fire department of fire or other emergency shall be provided. The devices shall be listed for the fire alarm service by a nationally recognized laboratory, and be installed in accordance with such listing and the requirements of NFPA 72.

(xii) A smoke detection system for spaces open to a corridor shall be provided when required by NFPA 101 §18.3.6.1.

(xiii) A fire alarm signal notification that complies with NFPA 101 §9.6.3 shall be provided to alert occupants of fire or other emergency.

(xiv) Wiring for fire alarm detection circuits and fire alarm notification circuits shall comply with requirements of NFPA 70 Article 760.

(xv) A smoke detection system for elevator recall shall be located in elevator lobbies, elevator machine rooms and at the top of elevator hoist ways as required by NFPA 72 §6.15.3.10.

(I) The elevator recall smoke detection system in new construction shall comply with requirements of American Society of Mechanical Engineers/American National Standards Institute (ASME/ANSI) A17.1, Safety Code for Elevators and Escalators, 2000 edition.

(II) The elevator recall smoke detection system in existing hospitals shall comply with requirements of ASME/ANSI A17.3, Safety Code for Existing Elevators and Escalators, 2002 edition.

(xvi) Smoke detectors for initiating smoke removal from windowless anesthetizing areas shall be provided in accordance with NFPA 99 §6.4.1.2.

(xvii) Smoke detectors for initiating smoke removal from surgical suites shall be provided in accordance with NFPA 99 §6.4.1.3.

(xviii) A smoke detection system for initiating smoke removal from atriums shall be located above the highest floor level of the atrium and at return intakes from the atrium in accordance with NFPA 92B, Guide for Smoke Management Systems in Malls, Atria, and Large Areas, 2000 edition.

(xix) A smoke detector or detectors for shutdown of air handling units shall be provided. The detectors shall be installed in accordance with NFPA 90A §6.4.3.

(O) Telecommunications and information systems. Telecommunications and information systems central equipment shall be installed in a separate location designed for the intended purpose. Special air conditioning and voltage regulation shall be provided as recommended by the manufacturer.

(P) Lightning protection systems. When installed, lightning protection systems shall comply with NFPA 780, Standard for the Installation of Lightning Protection Systems, 2000 edition.

(6) General design requirements. Services that the LSRH provides to patients under the LSRH license shall be within the LSRH. The services may be provided throughout the LSRH within identifiable suites, departments or units within the LSRH however all required units in this chapter shall be in one identifiable contiguous location. To be included in the LSRH license, a required patient care unit or support areas shall be physically connected to the LSRH and become contiguous to the LSRH. In no case may one leave the LSRH, traverse the other occupancies, and then reenter the LSRH to access the remaining portion of the LSRH. An LSRH may not occupy two or more noncontiguous

areas of non-LSRH occupancies that contain intervening space of the non-LSRH occupancies even if on the same floor or other floors.

§511.163. Spatial Requirements.

(a) Administration and public suite.

(1) Architectural requirements. The following rooms or areas shall be provided.

(A) Primary entrance. An entrance at grade level shall be accessible and protected from inclement weather with a drive under canopy for loading and unloading passengers.

(B) Lobby. A main lobby shall be located at the primary entrance and shall include a reception and information counter or desk, waiting space, public toilet facilities, public telephones, drinking fountain, and storage room or alcove for wheelchairs.

(C) Admissions area. An admissions area shall include a waiting area, work counters or desk, private interview spaces, and storage room or alcove for wheelchairs. The waiting area and wheelchair storage may be shared with similar areas located in the main lobby.

(D) General or individual offices. Office space shall be provided for business transactions, medical and financial records, and administrative and professional staffs.

(E) Multipurpose rooms. A multipurpose room or rooms shall be provided for conferences, meetings, and health education purposes including provisions for showing visual aids.

(F) Storage. Storage for office equipment and supplies shall be provided. The construction protection for the storage room or area shall be in accordance with National Fire Protection Association 101, Life Safety Code, 2012 edition (NFPA 101) §18.3.2.

(2) Details and finishes. Details and finishes shall comply with §511.162(d)(2) of this subchapter (relating to General Construction Requirements).

(3) Mechanical requirements. Mechanical requirements shall comply with §511.162(d)(3) of this subchapter.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall comply with §511.162(d)(4) of this subchapter.

(5) Electrical requirements. Electrical requirements shall comply with §511.162(d)(5) of this subchapter.

(b) Cart cleaning and sanitizing unit.

(1) Architectural requirements.

(A) Facilities. Cart cleaning, sanitizing, and storage facilities shall be provided for carts serving central services, dietary services, and linen services.

(B) Location. Cart facilities may be provided for each service or be centrally located.

(C) Hand washing fixtures. Hand washing fixtures shall be provided in cart cleaning, sanitizing, and storage areas.

(2) Details and finishes. When interior cart cleaning facilities are provided, details and finishes shall comply with §511.162(d)(2) of this subchapter and this paragraph.

(A) Flooring. Flooring in the cart cleaning and sanitizing unit shall be of the seamless type, or ceramic or quarry tile as required by §511.162(d)(2)(B)(iii)(III) or (IV) of this subchapter.

(B) Ceilings. Ceilings in the cart cleaning and sanitizing unit shall be the monolithic type as required by §511.162(d)(2)(B)(vi)(III) of this subchapter.

(3) Mechanical requirements. Mechanical requirements shall comply with §511.162(d)(3) of this subchapter.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall comply with §511.162(d)(4) of this subchapter and this paragraph.

(A) Hand washing fixtures. Hand washing fixtures shall be provided with hot and cold water. Hot and cold water fixtures shall be provided in cart cleaning and sanitizing locations regardless of whether they are interior or exterior.

(B) Floor drains and floor sinks. Where floor drains or floor sinks are installed, they shall be of a type that can be easily cleaned by removal of the cover. Removable stainless steel mesh shall be provided in addition to a grilled drain cover to prevent entry of large particles of waste that might cause stoppages. Floor drains and floor sinks shall be located to avoid conditions where removal of covers for cleaning is difficult.

(5) Electrical requirements. Electrical requirements shall be in accordance with §511.162(d)(5) of this subchapter.

(c) Central sterile supply suite.

(1) Architectural requirements.

(A) General. When surgical services are provided, the following rooms or areas shall be provided.

(i) Decontamination room. This room shall be physically separated from all other areas of the suite. The room shall include work counters or tables, flush type utility sink, equipment for initial disinfection, and hand washing facilities with hands-free operable controls. Materials shall be transferred from the decontamination room to the clean assembly room by way of pass-through doors, windows, or washer equipment. The dirty side of the decontamination room may be combined with a soiled utility room if all functions for each space are provided within the room.

(ii) Clean and assembly room. The room shall include counters or tables, equipment for sterilizing, and hand washing facilities with hands-free operable controls. Clean and soiled work areas shall be physically separated.

(iii) Breakdown storage room. A storage room for breakdown of supplies shall be provided. The storage room shall have adequate areas and counters for breakdown of prepackaged supplies.

(iv) Sterile and clean supply room. A sterile and clean supply room shall be provided. Storage of sterile and clean supplies shall not occur within the breakdown room.

(v) Equipment storage. An equipment storage room shall be provided.

(vi) Cart storage room. The storage room for distribution carts shall be adjacent to clean and sterile storage and close to main distribution points.

(vii) Multipurpose room. The equipment storage and cart storage room may be combined into a multipurpose room.

(B) Service areas. The central supply suite shall provide the following service areas.

(i) Office space. Office space for director of central services.

(ii) Staff toilets. Facilities may be outside the unit but must be convenient for staff use and shall contain hand washing fixtures with hands-free operable controls.

(iii) Locker room. When provided, the locker room for staff shall include lockers, toilets, lavatories, showers, and male and female dressing rooms or cubicles. A central changing locker room may be shared and made available within the immediate area of the central sterile supply suite.

(iv) Housekeeping room. A housekeeping room shall be provided and contain a floor receptor or service sink and storage space for housekeeping supplies and equipment. The housekeeping room shall be located on the decontamination or soiled side of the central sterile supply suite.

(2) Details and finishes. Details and finishes shall comply with §511.162(d)(2) of this subchapter and this paragraph.

(A) Details. Mirrors shall not be installed at hand washing fixtures in clean and sterile supply areas.

(B) Finishes.

(i) Flooring. Flooring used in the decontamination room and the clean assembly room shall be of the seamless type as required by §511.162(d)(2)(B)(iii)(III) of this subchapter.

(ii) Ceilings. Ceilings in the decontamination room, clean assembly room, and supply storage room shall be the monolithic type as required by §511.162(d)(2)(B)(vi)(III) of this subchapter.

(3) Mechanical Requirements. Mechanical requirements shall comply with §511.162(d)(3) of this subchapter and this paragraph.

(A) Ventilation, humidity, and temperature control. The sterile supply room and the clean and assembly room shall include provisions for ventilation, humidity, and temperature control.

(B) Ethylene oxide (EO) sterilizers. When provided, installations of EO sterilizers shall comply with the requirements of 30 TAC §106.417 (relating to Ethylene Oxide Sterilizers) administered by the Texas Commission on Environmental Quality (TCEQ), and the following requirements.

(i) EO sterilizer requirements. All source areas shall be exhausted, including the sterilizer equipment room, service and aeration areas, over sterilizer door, and the aerator. If the EO cylinders are not located in a well-ventilated unoccupied equipment space, an exhaust hood shall be provided over the cylinders. The relief valve shall be terminated in a well-ventilated, unoccupied equipment space, or outside the building.

(ii) Airflow. General airflow shall be away from sterilizer operators and towards the sterilizers.

(iii) Exhaust. A dedicated exhaust fan and an exhaust duct system shall be provided for EO sterilizers. The exhaust outlet to the atmosphere shall be located on the highest roof, directed upward, and not less than 25 feet from any air intake. A legible warning sign shall be provided to identify the exhaust stack on the roof.

(iv) Alarm. An audible and visual alarm located in sterilizer work area and a 24-hour staffed location shall be activated upon loss of airflow in the exhaust system.

(C) Filtration. Filtration requirements for air handling units serving the central sterile supply suite shall be equipped with filters having efficiencies equal to, or greater than specified in Table 4 of §511.169(d) of this subchapter (relating to Tables).

(D) Ducts. Duct linings exposed to air movement shall not be used in ducts serving the central sterile supply suite unless terminal filters of at least 90 percent efficiency are installed downstream of linings. This requirement shall not apply to mixing boxes and acoustical traps that have special coverings over such lining.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall comply with §511.162(d)(4) of this subchapter. When medical gas systems are provided, the systems shall comply with §511.162(d)(4) of this subchapter and this paragraph.

(A) Drainage and waste piping. Drainage and waste piping shall not be installed within the ceiling or installed in an exposed location in sterile areas unless precautions are taken to protect the space below from leakage and condensation from necessary overhead piping. Any required secondary protection shall be labeled, "code required secondary drain system" every 20 feet in a highly visible print or label.

(B) Plumbing lines. No plumbing lines may be exposed or on walls where possible leaks would create a potential of contamination of the sterile areas.

(C) Compressed air requirements. The compressed air required for the decontamination room shall not be connected to the medical air piping distribution system such as supporting breathable air for respiratory assistance needs, anesthesia machines, intermittent positive pressure breathing machine (IPPB), etc. A separate compressed air supply source shall be provided for maintenance and equipment needs for facility support use.

(5) Electrical requirements. Electrical requirements shall comply with §511.162(d)(5) of this subchapter and this paragraph. An electrical circuit or circuits to equipment in wet areas shall be provided with ground fault circuit interrupters (GFCIs).

(d) Dietary suite.

(1) Architectural requirements.

(A) General. Construction, equipment, and installation shall comply with all applicable local and state requirements for food safety and handling and food service.

(B) Food service facilities. Food services shall be provided by an on-site food preparation system or an off-site food service system or a combination of the two. The following minimum functional elements shall be provided on site regardless of the type of dietary services.

(i) Dining area. Provide dining space for ambulatory patients, staff, and visitors. These spaces shall be separate from the food preparation and distribution areas.

(ii) Receiving area. This receiving area shall have direct access to the outside for incoming dietary supplies or off-site food preparation service and shall be separate from the general receiving area. The receiving area shall contain a control station and an area for breakout for loading, unloading, uncrating, and weighing supplies. The entrance area to the receiving area shall be covered from the weather.

(iii) Storage spaces. Storage spaces shall be convenient to receiving area and food preparation area and shall be located to exclude traffic through the food preparation area. Regardless of the type of food services provided, the facility shall provide storage of food for emergency use for a minimum of four calendar days.

(I) Storage space. Storage space shall be provided for bulk, refrigerated, and frozen foods.

(II) Cleaning supply storage. This room or closet shall be used to store nonfood items that might contaminate edibles. This storage area may be combined with the housekeeping room.

(iv) Food preparation area. Counter space shall be provided for food preparation work, equipment, and an area to assemble trays for distribution for patient meals.

(v) Ice-making equipment. Ice-making equipment shall be provided for both drinks and food products (self-dispensing equipment) and for general use (storage-bin type equipment).

(vi) Hand washing. Hand washing fixtures with hands-free operable controls shall be conveniently located at all food preparation areas and serving areas.

(vii) Food service carts. When a cart distribution system is provided, space shall be provided for storage, loading, distribution, receiving, and sanitizing of the food service carts. The cart traffic shall be designed to eliminate any danger of cross-circulation between outgoing food carts and incoming soiled carts, and the cleaning and sanitizing process. Cart circulation shall not be through food processing areas.

(viii) Ware washing room. A ware washing room equipped with commercial type dishwasher equipment shall be located separate from the food preparation and serving areas. Space shall be provided for receiving, scraping, sorting, and stacking soiled tableware and for transferring clean tableware to the using areas. Hand washing facilities with hands-free operable controls shall be located within the soiled dish wash area. A physical separation to prevent cross-traffic between "dirty side" and "clean side" of the dish wash areas shall be provided.

(ix) Pot washing facilities. A three compartmented sink of adequate size for intended use shall be provided convenient to the food preparation area. Supplemental heat for hot water to clean pots and pans shall be by booster heater or by steam jet.

(x) Waste storage room. A food waste storage room shall be conveniently located to the food preparation and ware washing areas but not within the food preparation area. It shall have direct access to the LSRH's waste collection and disposal facilities.

(xi) Sanitizing facilities. Storage areas and sanitizing facilities for garbage or refuse cans, carts, and mobile tray conveyors shall be provided. All containers for trash storage shall have tight-fitting lids.

(xii) Housekeeping room. A housekeeping room shall be provided for the exclusive use of the dietary department. Where hot water or steam is used for general cleaning, additional space within the room shall be provided for the storage of hoses and nozzles.

(xiii) Office spaces. An office shall be provided for the use of the food service manager or the dietary service manager. In smaller LSRHs, a designated alcove may be located in an area that is part of the food preparation area.

(xiv) Toilets and locker spaces. A toilet room with at least one hand washing fixture with hands-free operable controls shall be provided for the exclusive use of the dietary staff. A toilet room shall not open directly into the food preparation areas, but must be in close proximity to them. For larger LSRHs, a locker room or space for lockers shall be provided for staff belongings.

(C) Additional service areas, rooms, and facilities. When an on-site food preparation system is used, in addition to the items required in subparagraph (B) of this paragraph, the following service areas, rooms and facilities shall be provided.

(i) Food preparation facilities. When food preparation systems are provided, there shall be space and equipment for preparing, cooking, and baking.

(ii) Tray assembly line. A patient tray assembly and distribution area shall be located within close proximity to the food preparation and distribution areas.

(iii) Food storage. When food is prepared on site, the storage room shall be adequate to accommodate food for a seven calendar day menu cycle.

(iv) Additional storage rooms. An additional room or rooms shall be provided for the storage of cooking wares, extra trays, flatware, plastic and paper products, and portable equipment.

(v) Drying storage area. Provisions shall be made for drying and storage of pots and pans from the pot washing room.

(D) Equipment. Equipment for use in the dietary suite shall meet the following requirements.

(i) Mechanical devices. Mechanical devices shall be heavy duty, suitable for the use intended, and easily cleaned. Where equipment is movable, provide heavy duty locking casters. Equipment with fixed utility connections shall not be equipped with casters.

(ii) Panels. Floor, wall, and top panels of walk-in coolers, refrigerators, and freezers shall be insulated. Coolers and refrigerators shall be capable of maintaining a temperature down to freezing. Freezers shall be capable of maintaining a temperature of 20 degrees below 0 degrees Fahrenheit. Coolers, refrigerators, and freezers shall be thermostatically controlled to maintain desired temperature settings in increments of two degrees or less. Interior temperatures shall be indicated digitally and visible from the exterior. Controls shall include audible and visible high and low-temperature alarm. The time of alarm shall be automatically recorded.

(iii) Walk-in units. Walk-in units may be lockable from the outside but must have a release mechanism for exit from inside at all times. The interior shall be lighted. All shelving shall be corrosion-resistant, easily cleaned, and constructed and anchored to support a load of at least 100 pounds per linear foot.

(iv) Cooking equipment. All cooking equipment shall be equipped with automatic shutoff devices to prevent excessive heat buildup.

(E) Vending services. When vending machines are provided, a dedicated room or an alcove shall be located so that access is available at all times.

(2) Details and finishes. Details and finishes shall comply with §511.162(d)(2) of this subchapter and this paragraph.

(A) Details.

(i) Food storage. Food storage shelves shall not be less than four inches above the finished floor and the space below the bottom shelf shall be closed in and sealed tight for ease of cleaning.

(ii) Windows. Operable windows and doors not equipped with automatic closing devices shall be equipped with insect screens.

(iii) Food processing areas. Food processing areas in the central dietary kitchen shall have ceiling heights not less than nine feet. Ceiling-mounted equipment shall be supported from rigid structures located above the finished ceiling.

(iv) Mirrors. Mirrors shall not be installed at hand washing fixtures in the food preparation areas.

(B) Finishes.

(i) Flooring. Floors in areas used for food preparation, food assembly, soiled and clean ware cleaning shall be water-resistant and grease-proof. Floor surfaces, including tile joints, shall be resistant to food acids.

(ii) Wall bases. Wall bases in food preparation, food assembly, soiled and clean ware cleaning, and other areas that are frequently subject to wet cleaning methods shall be made integral and coved with the floor, tightly sealed to the wall, constructed without voids that can harbor insects, retain dirt particles, and be impervious to water.

(iii) Wall construction, finishes, and trim. In the dietary and food preparation areas, the wall construction, finishes, and trim, including the joints between the walls and the floors, shall be free of voids, cracks, and crevices.

(iv) Food preparation and food assembly area ceiling. The ceiling in food preparation and food assembly areas shall be washable as required by §511.162(d)(2)(B)(vi)(II) of this subchapter.

(v) Soiled and clean ware cleaning area ceiling. The ceiling in the soiled and clean ware cleaning area shall be of the monolithic type as required by §511.162(d)(2)(B)(vi)(III) of this subchapter.

(3) Mechanical Requirements. Mechanical requirements shall comply with §511.162(d)(3) of this subchapter and this paragraph.

(A) Exhaust hood requirements. Exhaust hoods handling grease-laden vapors in food preparation centers shall comply with National Fire Protection Association 96, Standard for Ventilation Control and Fire Protection of Commercial Cooking Operations, 2011 edition. All hoods over cooking ranges shall be equipped with grease filters, fire extinguishing systems, and heat-actuated fan controls. Clean out openings shall be provided every 20 feet and at any changes in direction in the horizontal exhaust duct systems serving these hoods. (Horizontal runs of ducts serving range hoods should be kept to a minimum.)

(B) Air change standards. When air change standards in Table 3 of §511.169(c) of this subchapter do not provide sufficient air for proper operation of exhaust hoods (when in use), supplementary filtered make-up air shall be provided in these rooms to maintain the required airflow direction and exhaust velocity. Make-up systems for hoods shall be arranged to minimize "short circuiting" of air and to avoid reduction in air velocity at the point of contaminant capture.

(C) Air handling units. Air handling units serving the dietary suite shall be equipped with filters having efficiencies equal to, or greater than specified in Table 4 of §511.169(d) of this subchapter.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §511.162(d)(4) of this subchapter and this paragraph.

(A) Grease trap location. The kitchen grease traps shall be located and arranged to permit easy access without the need to enter food preparation or storage areas. Grease traps shall be of capacity required and shall be accessible from outside of the building without need to interrupt any services.

(B) Grease traps or grease interceptors. Grease traps or grease interceptors shall be located outside the food preparation area and shall comply with the requirements in the National Association of Plumbing-Heating-Cooling Contractors (PHCC), National Standard Plumbing Code, 2000 edition.

(C) Plumbing fixtures. The material used for plumbing fixtures shall be nonabsorptive and acid-resistant.

(D) Water spouts. Water spouts used at lavatories and sinks shall have clearances adequate to avoid contaminating utensils and containers.

(E) Food handler hand washing fixtures. Hand washing fixtures used by food handlers shall be trimmed with valves that can be operated without hands. Single lever or wrist blade devices may be used. Blade handles used for this purpose shall not be less than four inches in length.

(F) Drainage and waste piping. Drainage and waste piping shall not be installed within the ceiling or installed in an exposed location in food preparation centers, food serving facilities and food storage areas unless precautions are taken to protect the space below from leakage and condensation from necessary overhead piping. Any required secondary protection shall be labeled, "code required secondary drain system" every 20 feet in a highly visible print or label.

(G) Plumbing lines. No plumbing lines may be exposed overhead or on walls where possible leaks would create a potential for food contamination.

(5) Electrical requirements. Electrical requirements shall comply with §511.162(d)(5) of this subchapter and this paragraph.

(A) Exhaust hoods. Exhaust hoods shall have an indicator light indicating that the exhaust fan is in operation.

(B) Electrical circuits. The electrical circuit or circuits to equipment in wet areas shall be provided with five milliampere GFCI.

(e) Emergency suite. This subsection applies to all LSRHs included under the LSRH license.

(1) Architectural requirements.

(A) Emergency treatment area.

(i) Emergency treatment room. An LSRH shall provide at least one emergency treatment room and facilities to handle emergencies. The room and facilities shall meet the following requirements.

(I) Single patient room area requirements. The emergency treatment room for a single patient shall have a minimum clear floor area of 120 square feet exclusive of fixed and movable cabinets and shelves. The minimum clear room dimension exclusive of fixed cabinets and built-in shelves shall be 10 feet. The emergency treatment room shall contain cabinets, medication storage, work counter, examination light, and a hand washing fixture with hands-free operable controls.

(II) Multiple-patient room area requirements. When a multiple-patient station emergency treatment room is provided, the clearance between the side of a gurney and a wall or partition shall be a minimum of four feet. The clearance between the sides of gurneys shall be a minimum of six feet. The minimum distance at the foot of the gurney shall not be less than seven feet for single load area or room or ten feet for double load area or room. Four feet of the passage space at the foot of the gurney may be shared between two gurneys. The multiple-patient station emergency treatment room shall contain cabinets, medication storage, work counter, examination light, and a hand washing fixture with hands-free operable controls. The fixed and movable cabinets and shelves shall not encroach upon the gurney clear floor space or area.

(III) Hand washing fixtures. One hand washing fixture with hands-free operable controls shall be provided for each gurney location. One hand washing fixture may serve two gurneys if distributed appropriately between the two.

(IV) Storage space. Storage space shall be provided within the room or suite and be under staff control for general medical-surgical emergency supplies and medications. Adequate space shall be provided for emergency equipment such as emergency treatment trays, ventilator, defibrillator, splints, cardiac monitor, etc.

(V) Medication preparation storage. Locked storage space shall be provided for drugs and an area for preparation of medication with a work counter, refrigerator, and hand washing fixture with hands-free operable controls.

(VI) Stretcher and wheelchair storage. An alcove shall be provided for stretcher and wheelchair storage. The storage shall be located out of the line of traffic.

(VII) Patient toilet room. At least one patient toilet room shall be provided and shall be convenient to treatment rooms, examination rooms, and holding rooms, and a hand washing fixture with hands-free operable controls.

(VIII) Emergency entry signage. An emergency sign shall be provided at the entry from the public roads or streets serving the site. The emergency sign at the entry to the site shall be illuminated and connected to the emergency essential electrical system. Additional signs on-site may be required to direct patients to the emergency treatment area entrance when the emergency treatment area is not visible from the site entry. The letters on the entry sign shall be red with a contrasting background, all capitalized, at least eight inches in height, and an arrow indicating direction.

(IX) Entrances. Separate ambulance and pedestrian entrances at grade level shall be well-illuminated, identified by signs, and protected from inclement weather. The ambulance entry shall have a drive under canopy for protection from inclement weather. The emergency access to permit discharge of patients from automobile and ambulances shall be paved. Parking shall be provided near and convenient to the pedestrian entrance.

(X) Control station. A registration, reception, discharge or control station shall be located to permit staff observation and control of access to treatment rooms, pedestrian and ambulance entrances, and public waiting areas. When a dedicated triage space is provided, it shall include a counter with a hand washing fixture with hands-free operable controls.

(XI) Public waiting room. A public waiting room shall be provided.

(XII) Public facilities. Toilet facilities, public telephone, and drinking fountain shall be provided for the exclusive use of the waiting room.

(XIII) Diagnostic radiographic (X-ray) room. Imaging facilities for diagnostic services shall be readily available to the emergency suite. If a separate radiographic (X-ray) room is installed within the emergency suite, it shall comply with the requirements in subsection (j)(1)(A) of this section. When the diagnostic X-ray room is exclusively used for the emergency treatment area, the dressing rooms may be omitted.

(XIV) Laboratory unit. Laboratory services shall be made available to the emergency suite. If a separate laboratory workroom is installed within the emergency suite, it shall comply with the requirements in subsection (k)(1)(C)(i) of this section. All laboratory services provided on site or by contractual arrangement shall comply with §511.45 of this chapter (relating to Laboratory Services).

(XV) Medical staff work area and charting areas. A medical staff work area and charting area shall be provided. The area may be combined with the reception and control area.

(XVI) Clean storage room. A clean storage room shall be provided for clean supplies, linens, and medications as needed. A hand washing fixture shall be provided with hands-free operable controls.

(XVII) Soiled workroom. The workroom shall contain a work counter, a clinical sink or equivalent flushing type fixture, hand washing fixture with hands-free operable controls, waste receptacles, and soiled linen receptacles.

(XVIII) Housekeeping room. The housekeeping room shall contain a floor receptor or service sink, storage space for housekeeping supplies and equipment, and be located within the suite. When automatic film processors are used, a receptacle of adequate size with hot and cold water for cleaning the processor racks shall be provided.

(XIX) Staff toilets. Toilets may be outside the suite but shall be convenient for staff use and include hand washing fixtures with hands-free operable controls. When a department has four or more treatment or examination rooms, toilet facilities shall be in the suite.

(ii) Other rooms. If an LSRH provides one or more of the following rooms, the room shall meet the applicable requirements in this clause.

(I) Examination room. When provided, the examination room for a single patient shall have a minimum clear floor area of 100 square feet exclusive of fixed and movable cabinets and shelves. The minimum clear room dimension exclusive of fixed cabinets and built-in shelves shall be nine feet. The examination room shall contain cabinets, medication storage, work counter, examination light, and a hand washing fixture with hands-free operable controls.

(II) Multi-bed examination room. When a multiple-patient station examination room is provided, the clearance between the side of the gurney and a wall or partition shall be a minimum of three feet. The clearance between sides of the gurneys shall be a minimum of six feet. The minimum distance at the foot of the gurney shall not be less than seven feet for single load area or room or ten feet for double load area or room. Four feet of the passage space at the foot of the bed may be shared between two gurneys. The multiple-patient station examination room shall contain cabinets, work counters, and a hand washing fixture with hands-free operable controls. One hand washing fixture shall be provided for every four gurneys or fraction thereof. Fixtures shall be uniformly distributed. The fixed and moveable cabinets and shelves shall not encroach upon the gurney clear floor space or area.

(III) Isolation room. The need for an airborne infection isolation room in the emergency suite shall be determined by the LSRH and the infection risk assessment. When an LSRH provides treatment rooms to perform procedures on persons who are known or suspected of having an airborne infectious disease, these procedures shall be performed in a designated treatment room meeting airborne infection isolation ventilation requirements. The isolation room shall have functional space in accordance with clause (i)(I) of this subparagraph, and meet the ventilation requirements contained in Table 3 of §511.169(c) of this subchapter.

(IV) Secured holding room. When provided, this room shall be constructed to allow for security, patient and staff safety, patient observation, and sound mitigation. The secure holding room shall have a minimum clear floor area of 100 square feet exclusive of fixed cabinets. The minimum clear room dimension exclusive of fixed cabinets shall be 10 feet.

(V) Orthopedic and cast room. When provided, the room may be in a separate room or in the trauma room. The room shall contain a work counter, storage for splints and orthopedic supplies, traction hooks, medication storage, examination light, and a hand washing fixture with hands-free operable controls. When a cast room is provided it shall be equipped with hand washing facilities, plaster sink, storage, and other provisions required for cast procedures.

(VI) Film processing room. When a radiographic (X-ray) room is provided, a darkroom for processing film shall be provided unless the processing equipment does not require a darkroom for loading and transfer. When daylight processing is used, the darkroom may be minimal for emergency and special uses. Film processing shall be located convenient to the darkroom.

(VII) Decontamination room. When provided, a decontamination room shall have an exterior entry point and as far as practical from any other entry point to the emergency treatment area. The internal door from the decontamination room shall open directly to the corridor into the emergency treatment area. The door shall swing into the room and be lockable against ingress from the corridor. The room shall have a minimum clear floor area of at least 80 square feet and a hand washing fixture with hands-free operable controls.

(B) Holding or observation room area.

(i) Location. When a holding or observation room or area is provided within or adjacent to the emergency suite, it shall comply with the following.

(I) Single occupancy room area. A single occupancy holding or observation room shall have a minimum clear area of 100 square feet exclusive of fixed and movable cabinets and shelves. The holding or observation room shall contain a work counter and hand washing fixture with hands-free operable controls.

(II) Single occupancy room location. The single occupancy holding or observation room shall be near the nurse station and near a patient toilet room that contains a hand washing fixture with hands-free operable controls.

(III) Multiple occupancy room area. In a multiple occupancy holding or observation room or area, the clearance between the side of the gurney and a wall or partition shall be at least three feet. The clearance between sides of the gurneys shall be at least six feet. The minimum distance at the foot of the gurney shall not be less than seven feet for a single load area or room or ten feet for a double load area or room. Four feet of the passage space at the foot of the gurney may be shared between two gurneys. The multiple occupancy holding or observation room or area shall contain cabinets, work counters, and a hand washing fixture with hands-free operable controls. One hand washing fixture shall be provided for every four holding or observation gurneys or fraction thereof. Fixtures shall be uniformly distributed. The fixed and moveable cabinets and shelves shall not encroach upon the gurney clear floor space or area.

(IV) Toilet room. In a multiple occupancy holding or observation room or area, a patient toilet room with a hand washing fixture with hands-free operable controls shall be provided within the room or area.

(ii) Multiple occupancy room location. When a multiple occupancy holding or observation room is not within or adjacent to the emergency suite, the following additional spaces shall be provided:

(I) a stretcher and wheelchair storage alcove, that shall be located out of the line of traffic;

(II) a clean storage room for clean supplies, linen and medication as needed that is located within or adjacent to the holding or observation room and contains a hand washing fixture with hands-free operable controls;

(III) a soiled workroom located within or adjacent to the holding or observation room and contains a work counter, a clinical sink or equivalent flushing type fixture, hand washing fixture with hands-free operable controls, waste receptacles, and soiled linen receptacles; and

(IV) a housekeeping room located within or near the holding or observation room and contains a floor receptor or service sink and storage space for housekeeping supplies and equipment.

(C) Trauma center. When provided, a trauma center shall comply with subparagraph (B) of this paragraph and the following requirements.

(i) Trauma room. At least one trauma room shall be provided with 250 square feet of clear floor area exclusive of aisles and fixed and moveable cabinets and shelves. The minimum clear dimension between fixed cabinets and built-in shelves shall be 12 feet. The trauma room shall contain a work counter, cabinets, medication storage, and examination light.

(ii) Multiple-station trauma room. When multiple-patient stations are provided, the clearance between the head of the gurney to the wall or partition shall be at least three feet. The clearance between the side of a gurney and a wall or partition shall be at least six feet. The clearance between the sides of gurneys shall be at least twelve feet. The minimum distance at the foot of the gurney shall not be less than seven feet for a single load area or room or ten feet for a double load area or room. Four feet of the passage space at the foot of the gurney may be shared between two gurneys. The multiple-station trauma room shall contain cabinets, medication storage, work counter, examination light, and scrub sink with hands-free operable controls. The fixed and moveable cabinets and shelves shall not encroach upon the gurney clear floor space or area.

(iii) Scrub facilities. A scrub station shall be located at the entrance to each trauma room either inside or outside of the room. One scrub station may serve two trauma gurneys. Scrub facilities shall be arranged to minimize any incidental splatter on nearby personnel or supply carts. The scrub sinks shall be recessed out of the main line of traffic.

(iv) Doorways. All doorways openings from the ambulance entrance to the trauma room shall be at least five feet wide.

(D) Emergency clinic. When an emergency clinic (that may also be referred to as "urgent care," "fast track," "express care," "minor care," etc.) is provided, the clinic shall be separate and distinct from the emergency treatment area and trauma center and shall meet all the requirements of subparagraph (A) of this paragraph. All facilities required by subparagraph (A) of this paragraph may be shared with the emergency treatment area and trauma center except for the emergency treatment room. An emergency treatment room in the emergency clinic shall not be less than 100 square feet. An emergency exam room in the emergency clinic shall not be less than 80 square feet.

(2) Details and finishes. Details and finishes shall comply with §511.162(d)(2) of this subchapter and this paragraph.

(A) Details.

(i) Area. Trauma rooms shall have ceiling heights not less than nine feet.

(ii) Fixtures. The decontamination room shall be equipped with two hand-held showerheads with temperature controls and a dedicated holding tank with a floor drain.

(B) Finishes.

(i) Flooring. Flooring used in a trauma room, treatment room, examination room, holding area, and soiled workroom shall be of the seamless type as required by §511.162(d)(2)(B)(iii)(III) of this subchapter. Seamless type flooring is not required in the examination room in the emergency clinic.

(ii) Ceiling. Ceilings in soiled workrooms, isolation rooms, and trauma rooms shall be of the monolithic type as required by §511.162(d)(2)(B)(vi)(III) of this subchapter.

(iii) Surfaces. The decontamination room floor shall be self-coved to a height of six inches. The room shall have all smooth, nonporous, scrubbable, nonabsorbent and nonperforated surfaces.

(3) Mechanical requirements. Mechanical requirements shall comply with §511.162(d)(3) of this subchapter and this paragraph.

(A) Duct linings. Duct linings exposed to air movement shall not be used in ducts serving any trauma rooms, treatment rooms, examination rooms, holding areas, and clean room. This requirement shall not apply to mixing boxes and acoustical traps that have special coverings over such lining.

(B) Air supply. When a trauma room is provided under paragraph (1)(C)(i) of this subsection, the air supply for the trauma or surgical room shall be from ceiling outlets that are as near the work centers as possible, and a minimum of two low return inlets shall be located diagonally opposite from one another.

(C) Return air inlets. Return air inlets shall be not lower than four inches nor higher than 12 inches from floor level.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall comply with §511.162(d)(4) of this subchapter and this paragraph.

(A) Medical gas systems. Medical gas systems shall be provided in accordance with §511.162(d)(4)(A)(iii) of this subchapter.

(B) Ice machine. An ice machine shall be provided for therapeutic purposes and shall be located in the clean utility room. A self-dispensing ice machine shall be provided for ice for human consumption.

(5) Electrical requirements. Electrical requirements shall comply with §511.162(d)(5) of this subchapter and this paragraph.

(A) General.

(i) Examination room electrical receptacles. Each treatment and examination room in the emergency treatment area and trauma center shall have at least six duplex electrical receptacles located convenient to the head of each patient station.

(ii) Emergency clinic suite electrical receptacles. Each treatment and examination room in the emergency clinic suite shall have a minimum of four duplex electrical receptacles located convenient to the head of each patient station.

(iii) Work counter electrical receptacles. Each work counter and table shall have access to at least one duplex receptacle connected to the critical branch of the emergency electrical system.

(iv) Film illuminators. The LSRH shall provide X-ray film illuminators for handling at least four films simultaneously in all treatment, examination, and trauma rooms in the emergency treatment area. When the entire emergency treatment area is provided with digital imaging, at least two X-ray film illuminators shall be provided within a central location within the emergency treatment area.

(B) Nurses calling systems. The nurse call system shall comply with §511.162(d)(5)(L) of this subchapter and Table 7 of §511.169(g) of this subchapter.

(f) Employees suite.

(1) Architectural requirements.

(A) Compliance. Architectural requirements shall comply with §511.162(d)(1) of this subchapter and this paragraph.

(B) Lockers, lounges, toilets, and showers. Lockers, lounges, toilets, and showers shall be provided within the LSRH for employees and volunteers. These facilities are in addition to, and separate from, those required for the medical staff and the public.

(2) Details and finishes. Details and finishes shall comply with §511.162(d)(2) of this subchapter.

(3) Mechanical requirements. Mechanical requirements shall comply with §511.162(d)(3) of this subchapter.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall comply with §511.162(d)(4) of this chapter.

(5) Electrical requirements. Electrical requirements shall comply with §511.162(d)(5) of this subchapter.

(g) Engineering suite and equipment areas.

(1) Architectural requirements. Architectural requirements comply with §511.162(d)(1) of this subchapter and this paragraph.

(A) General. The following facilities shall be provided:

(i) an engineer's office with file space and provisions for protected storage of facility drawings, records, manuals, etc.;

(ii) a general maintenance shop or shops for repair and maintenance;

(iii) a separate room for building maintenance supplies and equipment, and storage of bulk solvents and flammable liquids shall be in a separate building and not within the LSRH building;

(iv) a medical equipment room that includes provisions for the storage, repair, and testing of electronic and other medical equipment;

(v) a separate room or building for yard maintenance equipment and supplies. When a separate room is within the physical plant the room shall be located so that equipment may be moved directly to the exterior. Yard equipment or vehicles using flammable liquid fuels shall not be stored or housed within the LSRH building; and

(vi) sufficient space in all mechanical and electrical equipment rooms for proper maintenance of equipment. Provisions shall also be made for removal and replacement of equipment.

(B) Additional areas or rooms. Additional areas or rooms for mechanical, and electrical equipment shall be provided within the physical plant or installed in separate buildings or weatherproof enclosures with the following exceptions.

(i) An area shall be provided for cooling towers and heat rejection equipment when such equipment is used.

(ii) An area for the medical gas park and equipment shall be provided. For smaller medical gas systems, the equipment

may be housed in a room within the physical plant in accordance with National Fire Protection Association 99, Standard for Health Care Facilities, 2012 edition (NFPA 99), Chapters 4 and 8.

(iii) When provided, compactors, dumpsters, and incinerators shall be located in an area remote from public entrances.

(2) Details and finishes. Details and finishes shall comply with §511.162(d)(2) of this subchapter.

(3) Mechanical requirements. Mechanical requirements shall comply with §511.162(d)(3) of this subchapter.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall comply with §511.162(d)(4) of this subchapter.

(5) Electrical requirements. Electrical requirements shall comply with §511.162(d)(5) of this subchapter.

(h) General storage. A general storage room shall be provided at least equal to five percent of the total area of the patient care units.

(i) Hyperbaric suite.

(1) Architectural requirements. When a hyperbaric suite is provided, it shall meet the requirements of NFPA 99 Chapter 20, and NFPA 101 Chapter 18.

(A) Hyperbaric chamber clearances. Multiple occupancy chambers (Class A) shall comply with NFPA 99 Chapter 20. The minimum clearances for individual (Class B) hyperbaric chambers and the side of a chamber and a wall or partition shall be at least three feet. The clearance between sides of chambers shall be at least six feet. The minimum distance at the chamber entry shall not be less than seven feet for a single load area or room or ten feet for a double load area or room. Four feet of the passage space at the chamber entry may be shared between two chambers. The chamber room shall contain cabinets, medication storage, work counter and a hand washing fixture with hands-free operable controls. The fixed and movable cabinets and shelves shall not encroach upon the chamber clear floor space or area.

(B) Service areas. The following minimum service areas and facilities shall be provided convenient to the hyperbaric chamber suite.

(i) Patient waiting area. The area shall be out of traffic, under staff control, and shall have seating capacity in accordance with the LSRH's functional program. Patient waiting areas are not required where two or fewer individual hyperbaric chamber units are provided.

(ii) Control desk and reception area. A control desk and reception area shall be provided.

(iii) Holding area. A holding area under staff control shall accommodate patients on stretchers or beds. Stretcher patients shall be out of the direct line of normal traffic. The patient holding area is not required where two or fewer individual hyperbaric chamber units are provided.

(iv) Patient toilet rooms. Toilet rooms shall be provided with hand washing fixtures with hands-free operable controls and with direct access from the hyperbaric suite.

(v) Patient dressing room. A dressing room for outpatients shall be provided and shall include a seat or bench, mirror, and provisions for hanging patients' clothing and for securing valuables. At least one dressing room shall be provided to accommodate wheelchair patients.

(vi) Staff facilities. Toilets with hand washing fixtures with hands-free operable controls may be outside the suite but shall be convenient for staff use. These facilities may be shared with an adjacent suite.

(vii) Consultation room. An appropriate consultation room for individual consultation with referring clinicians shall be provided for outpatients. This room may be shared with an adjacent suite.

(viii) Storage space. A clean storage space shall be provided for clean supplies and linens. The space shall contain a hand washing fixture with hands-free operable controls. The storage room may be shared with another department if convenient to both.

(ix) Soiled holding room. A soiled holding room shall be provided with waste receptacles and soiled linen receptacles. This room may be shared with an adjacent suite.

(x) Hand washing. A lavatory equipped for hand washing with hands-free operable controls shall be located in the room where the hyperbaric chambers are located.

(xi) Housekeeping room. The housekeeping room shall contain a floor receptor or service sink, storage space for housekeeping supplies and equipment, and be located nearby.

(2) Details and finishes. Details and finishes shall comply with §511.162(d)(2) of this subchapter.

(3) Mechanical requirements. Mechanical requirements shall comply with §511.162(d)(3) of this subchapter.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall comply with §511.162(d)(4) of this subchapter.

(5) Electrical requirements. Electrical requirements shall comply with §511.162(d)(5) of this subchapter and this paragraph.

(A) Grounding of hyperbaric chambers shall be connected only to the equipment ground in accordance with NFPA 99 §3-3.2.1.2, and National Fire Protection Association 70, National Electrical Code, 2011 edition (NFPA 70) Article 250 (A)-(C), and Article 517.

(B) Additional grounds such as earth or driven grounds shall not be permitted.

(C) The nurse call shall comply with §511.162(d)(5)(L) and Table 7 of §511.169(g) of this subchapter.

(j) Imaging suite.

(1) Architectural requirements.

(A) General. An LSRH shall have a diagnostic radiographic (X-ray) room convenient to emergency suites, and where provided surgery suites.

(i) Room size. All diagnostic imaging room sizes shall be in compliance with the manufacturer's recommendations for the specific equipment. Clearance and unobstructed space shall not be less than three feet around the diagnostic equipment.

(ii) Radiation protection. When radiation protection is required for any diagnostic imaging room, a medical physicist licensed under the Texas Occupations Code Chapter 602 (relating to Medical Physicists), shall specify the type, location, and amount of radiation protection to be installed for the layout and equipment selections.

(iii) Shielded control. Each room where radiation protection is required shall include a shielded control alcove. The control alcove shall be provided with a view window designed to permit full view of the examination table and the patient at all times.

(iv) Warning signs. Warning signs capable of indicating that the equipment is in use shall be provided.

(v) Ventilation requirements. Diagnostic and procedure room intended for patients with airborne infectious diseases shall meet the ventilation requirements as contained in Table 3 of §511.169(c) of this subchapter.

(B) Diagnostic X-ray and radiographic and fluoroscopy (R&F) rooms. X-ray and R&F rooms shall comply with the manufacturer's recommendations for the specific equipment. Clearance and unobstructed space shall not be less than three feet around the diagnostic equipment.

(i) Control alcove. A control alcove shall be provided with a view window designed to provide full view of the patient at all times.

(ii) Toilet room. A toilet room shall be provided including a hand washing fixture with hands-free operable controls and have direct access to each R&F room and a corridor.

(C) Noninvasive angiography imaging room. When noninvasive angiography imaging is provided, the room shall have a minimum clear floor area of 250 square feet exclusive of built-in shelves or cabinets. Clearance and unobstructed space shall not be less than three feet around the diagnostic equipment.

(i) Control alcove. A control alcove shall be provided with a view window designed to provide full view of the patient at all times.

(ii) Viewing room or area. A viewing room or area shall be provided and shall be at least 10 feet in length. The viewing room or area may be provided in combination with the control room.

(iii) Scrub sink. A scrub sink shall be near the entrance to each angiographic room and shall be recessed out of the main traffic areas or corridor. Scrub facilities shall be arranged to minimize any incidental splatter on nearby personnel or supply carts.

(iv) Storage space. Storage space for portable equipment and supplies shall be provided.

(D) Computerized tomography (CT) scanning. When CT services are provided, the CT room's size shall comply with the manufacturer's recommendations and shall contain the following.

(i) Control room. A control room shall be provided with a view window permitting view of the patient. The control room shall be located to allow convenient film processing.

(ii) Patient toilet room. A patient toilet shall be provided conveniently to the procedure room. When directly accessible to the scan room, the toilet shall be arranged so that a patient may leave the toilet room without having to reenter the scan room. The toilet room shall have a hand washing fixture with hands-free operable controls.

(E) Mammography. When mammography services are provided, the room shall have a minimum clear floor area of 100 square feet exclusive of built-in shelves or cabinets.

(i) Control alcove. A control alcove shall be provided with a view window designed to provide full view of the patient at all times.

(ii) Built-in shielding. When mammography machines with built-in shielding for the operator are provided, the alcove is not required when approved by a medical physicist licensed under Texas Occupations Code Chapter 602.

(F) Magnetic resonance imaging (MRI). When MRI services are provided, the room shall be of sufficient size to house equipment but no less than 325 square feet of clear floor area exclusive of built-in shelves or cabinets.

(i) Control alcove. A control alcove shall be provided with a view window designed to provide full view of the patient at all times.

(ii) Computer room. A separate computer room shall be provided to accommodate the equipment.

(iii) Cryogen storage requirements. When cryogen is provided, a storage room or closet shall have a minimum clear floor area of 50 square feet for two large dewars of cryogen. A storage room or closet is required in areas where service to replenish supplies is not readily available.

(iv) Darkroom. When a darkroom is provided, the room shall be located near the required control room and shall be outside the 10-gauss field.

(v) Spectroscopy. When spectroscopy is provided, caution should be exercised in locating it in relation to the magnetic fringe fields.

(vi) Magnetic shielding. Magnetic shielding may be required to restrict the magnetic field plot. Radio frequency shielding is required to attenuate stray radio frequencies.

(vii) Patient holding area. A patient holding area shall be provided and shall be located near the MRI unit and be large enough to accommodate stretchers.

(viii) Hand washing fixture. A hand washing fixture with hands-free controls shall be provided near the entrance to the MRI room and shall be recessed out of the main traffic areas or corridor.

(ix) 3T magnetic strength MRI. A 3T or larger magnetic strength MRI shall be secured behind locked doors. The patient and staff entrance to the MRI shall have a traffic pattern from the waiting, dressing, holding and work areas through a lockable control station before entering the MRI. At no time shall patients or nonpatients be allowed to enter this restricted area without MRI staff present when the magnet is active.

(G) Ultrasound room. When ultrasound services are provided, the room's size shall comply with the manufacturer's recommendations. A patient toilet room shall be provided convenient to the procedure room and a corridor. The toilet room shall have a hand washing fixture with hands-free operable controls.

(H) Cardiac catheterization laboratory. The cardiac catheterization laboratory is normally a separate suite, but may be within the imaging suite. If provided, a cardiac catheterization laboratory shall comply with the requirements of subsection (w)(1)(C) of this section.

(I) Service areas. The following common service areas shall be provided.

(i) Patient waiting area. The area shall be out of traffic and under direct staff visual control.

(ii) Control desk and reception area. A control desk and reception area shall be provided.

(iii) Holding area. The holding area shall be out of direct traffic patterns and under visual control by staff. At least one stretcher station shall be provided for each three diagnostic and procedure rooms or fraction thereof. The minimum clear floor space in the holding area shall be 80 square feet exclusive of aisles and fixed and moveable cabinets and shelves. The area shall contain cabinets, a work counter, and a hand washing fixture with hands-free operable controls. The holding area may be reduced to 50 square feet exclusive of aisles and fixed and moveable cabinets and shelves for mammography, bone density, and other similar procedures.

(iv) Post-procedure observation room. When invasive diagnostic X-ray services are provided with anesthesia, a room for extended post-procedure observation of patients shall be provided. The minimum clear floor space for the observation space shall be 100 square feet exclusive of aisles and fixed and moveable cabinets and shelves. The room shall contain cabinets, a work counter, and a hand washing fixture with hands-free operable controls.

(v) Patient toilet rooms. A toilet room with hand washing facilities shall be located convenient to the waiting area.

(vi) Patient dressing rooms or cubicles. Dressing rooms or cubicles shall be convenient to the waiting areas and X-ray rooms. Each room shall include a seat or bench, mirror, and provisions for hanging patients' clothing and for securing valuables. At least one dressing room shall be provided to accommodate wheelchair patients.

(vii) Hand washing facilities. A hand washing fixture with hands-free controls shall be provided in or near the entrance to each diagnostic and procedure room unless noted otherwise. When a hand washing fixture is provided in the room, the fixture shall be located near the entrance to the room or near the staff entrance. When a hand washing fixture is located outside the room, the fixture shall be recessed in the egress corridor and located within five feet of the entrance to the room. Hand washing facilities shall be arranged to minimize any incidental splatter on nearby personnel or equipment.

(viii) Staff facilities. Toilets may be outside the suite and may be shared with other departments but shall be convenient for staff use. When four or more diagnostic or procedure imaging rooms are provided, a staff toilet is required with a hand washing fixture with hands-free controls.

(ix) X-ray film illuminator viewers. When all the diagnostic and imaging procedures are provided with digital imaging, two mounted X-ray film illuminator viewers shall be provided in the central viewing area or room.

(x) Contrast media preparation. This room shall include a work counter, a sink with hands-free operable controls, and storage. One preparation room may serve any number of rooms. When prepared media is used, this area is not required, but storage shall be provided for the media.

(xi) Film processing room. A darkroom shall be provided for processing film unless the processing equipment normally used does not require a darkroom for loading and transfer. When daylight processing is used, the darkroom may be minimal for emergency and special uses. Film processing shall be located convenient to the procedure rooms and to the quality control area.

(xii) Quality control area or room. An area or room for film viewing shall be located near the film processor. All view boxes shall be illuminated to provide light of the same color value and intensity.

(xiii) Film storage (active). When X-ray film is used, it shall be stored in a room with a cabinet or shelves for filing patient film for immediate retrieval.

(xiv) Film storage (inactive). When X-ray film is used, a room for inactive film storage shall be provided. It may be outside the imaging suite, but must be under the administrative control of imaging suite personnel and be properly secured to protect films against loss or damage.

(xv) Storage for unexposed film. When X-ray film is used, storage facilities for unexposed film shall include protection of film against exposure or damage.

(xvi) Storage of cellulose nitrate film. When used, cellulose nitrate film shall be stored in accordance with the requirements of National Fire Protection Association 40, Standard for the Storage and Handling of Cellulose Nitrate Motion Picture Film, 2011 edition.

(xvii) Additional spaces. When four or more diagnostic or procedure rooms are provided in the LSRH, the following shall be required:

(I) an office for radiologists and assistants;

(II) clerical office spaces, as necessary for the functional program;

(III) consultation area or room;

(IV) medication station. Storage and preparation of medication shall be done from a room, alcove area, or from a self-contained dispensing unit but must be under visual control of nursing staff. A work counter, hand washing fixture with hands-free operable controls, refrigerator, and double-locked storage for controlled substances shall be provided. Standard cup-sinks are not acceptable for hand washing;

(V) clean storage room. Clean storage room shall be provided for clean supplies and linens. A hand washing fixture shall be provided with hands-free operable controls. When conveniently located, the clean storage room may be shared with another department; and

(VI) soiled workroom. The soiled workroom shall not have direct connection to the diagnostic and procedure rooms. The room shall contain a clinical sink or equivalent flushing type fixture, work counter, hand washing fixture with hands-free operable controls, waste receptacle, and soiled linen receptacle. When contaminated soiled material or fluid waste is not handled, only a soiled holding room shall be required.

(xviii) Housekeeping room. The room may serve multiple departments when conveniently located.

(2) Details and finishes. Details and finishes shall comply with §511.162(d)(2) of this subchapter and this paragraph.

(A) Details.

(i) Radiation protection. Radiation protection shall be designed, tested, and approved by a medical physicist licensed under Texas Occupations Code Chapter 602.

(I) Room shielding. Room shielding calculations for linear accelerators, teletherapy units and remote control brachytherapy units must be submitted to the Department of State Health Services Radiation Control Program (RC) for approval prior to use. Shielding in diagnostic radiographic rooms will be reviewed by RC inspectors, in the field, subsequent to use. Any changes in design

or shielding that affects radiation exposure levels adjacent to those rooms requires prior approval by RC.

(II) Facility design and environmental controls. Facility design and environmental controls associated with licensable quantities of radioactive material in laboratories, imaging rooms, or both shall be approved by RC prior to licensed authorizations.

(ii) Protected alcoves. Where protected alcoves with view windows are required, provide a minimum of one foot six inches from the edge where the glazing and the frame connect and the outside partition edge.

(iii) Ceilings. Imaging procedure rooms shall have ceiling heights not less than nine feet. Ceilings containing ceiling-mounted equipment shall be of sufficient height to accommodate the equipment of fixtures and their normal movement.

(B) Finishes.

(i) Flooring. Flooring used in contrast media preparation and soiled workroom shall be of the seamless type as required by §511.162(d)(2)(B)(iii)(III) of this subchapter.

(ii) Ceilings. A lay-in type ceiling is acceptable for the diagnostic and procedure rooms.

(3) Mechanical Requirements. Mechanical requirements shall comply with §511.162(d)(3) of this subchapter and this paragraph.

(A) Cryogen gas venting and exhaust. The cryogen gas venting from the MRI unit shall be exhausted to the exterior. When a cryogen storage room is provided to replenish supplies, the storage room shall be vented and exhausted to the exterior.

(B) Air conditioning. Self-contained air conditioning to supplement the cooling capacity in computer rooms is permitted.

(C) Air handling units. Air handling units serving the imaging suite shall be equipped with filters having efficiencies equal to, or greater than specified in Table 4 of §511.169(d) of this subchapter.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall comply with §511.162(d)(4) of this subchapter and this paragraph. When automatic film processors are used, a receptacle of adequate size with hot and cold water for cleaning the processor racks shall be provided.

(5) Electrical requirements. Electrical requirements shall comply with §511.162(d)(5) of this subchapter and this paragraph.

(A) General.

(i) Each imaging procedure room shall have at least four duplex electrical receptacles.

(ii) A special grounding system in areas such as imaging procedures rooms where a patient may be treated with an internal probe or catheter shall comply with NFPA 99 Chapter 9 and NFPA 70 Article 517.

(iii) General lighting with at least one light fixture powered from a normal circuit shall be provided in imaging procedures rooms in addition to special lighting units at the procedure or diagnostic tables.

(B) Nurses calling system. The nurse call shall comply with §511.162(d)(5)(L) and Table 7 of §511.169(g) of this subchapter.

(k) Laboratory suite.

(1) Architectural requirements.

(A) General.

(i) Laboratory facilities. Laboratory facilities and services shall be provided by the LSRH such as hematology, clinical chemistry, urinalysis, cytology, anatomic pathology, immunohematology, microbiology, bacteriology and others.

(ii) Code requirements. Each laboratory unit shall meet the requirements of NFPA 99 Chapter 11 (relating to Laboratories), and NFPA 101 Chapter 18 (relating to New Health Care Occupancies).

(B) Minimum laboratory facilities. When laboratory services are provided off site by contract, the following minimum facilities shall be provided within the LSRH.

(i) Laboratory work room. The laboratory workroom shall include a counter and a sink with hands-free operable controls.

(ii) General storage. Cabinets or closets shall be provided for supplies and equipment used in obtaining samples for testing. A refrigerator or other similar equipment shall be provided for specimen storage waiting for transfer to off-site testing.

(iii) Blood storage facilities. Refrigerated blood storage facilities for transfusions shall be provided. The blood storage refrigerator shall be equipped with temperature monitoring and alarm signals.

(iv) Specimen collection facilities. A blood collection area shall be provided with a counter, space for seating, and hand washing fixture with hands-free operable controls. A toilet and lavatory with hands-free operable controls shall be provided for specimen collection. This facility may be outside the laboratory suite if conveniently located.

(C) On-site laboratory facilities. When the LSRH provides on-site laboratory services, the following facilities shall be provided in addition to the requirements in subparagraphs (A) and (B) of this paragraph.

(i) Laboratory workroom. The laboratory work room shall include a counter, space appropriately designed for laboratory equipment and a sink with hands-free operable controls.

(ii) General storage. Storage, including refrigeration for reagents, standards, supplies, and stained specimen microscope slides, etc. shall be provided. Separate facilities shall be provided for such incompatible materials as acids and bases, and vented storage shall be provided for volatile solvents.

(iii) Chemical safety facilities. When chemical safety is a requirement, provisions shall be made for an emergency shower and eye flushing devices.

(iv) Flammable liquids. When flammable or combustible liquids are used, the liquids shall be stored in approved containers, in accordance with National Fire Protection Association 30, Flammable and Combustible Liquids Code, 2012 edition.

(v) Radioactive materials. When radioactive materials are employed, storage facilities shall be provided.

(D) Bone marrow laboratory. A cryopreservation laboratory and a human leukocyte antigen laboratory shall be provided in hospitals providing bone marrow transplantation services.

(E) Service areas and facilities. The following service areas and facilities shall be provided.

(i) Hand washing facilities. Each laboratory room or work area shall be provided with a hand washing fixture with hands-free operable controls.

(ii) Office spaces. The scope of laboratory services shall determine the size and quantity for administrative areas including offices as well as space for clerical work, filing, and record maintenance. At a minimum, an office space shall be provided for the use of the laboratory service director.

(iii) Staff facilities. Lounge, locker, and toilet facilities shall be conveniently located for male and female laboratory staff. These may be outside the laboratory area and shared with other departments.

(iv) Housekeeping room. A housekeeping room shall be located within the suite or conveniently located nearby.

(2) Details and finishes. Details and finishes shall comply with §511.162(d)(2) of this subchapter. Floors in laboratories shall comply with the requirements of §511.162(d)(2)(B)(iii) of this subchapter except that carpet flooring shall not be used.

(3) Mechanical requirements. Mechanical requirements shall comply with §511.162(d)(3) of this subchapter and this paragraph.

(A) Air recirculation. No air from the laboratory areas shall be recirculated to other parts of the LSRH. Recirculation of air within the laboratory suite is allowed.

(B) Laboratory hoods. When laboratory hoods are provided, they shall meet the following general requirements.

(i) Face velocity. The average face velocity of each exhaust hood shall be at least 75 feet per minute.

(ii) Exhaust system. The exhaust shall be connected to an exhaust system to the exterior that is separate from the building exhaust system. Biological safety cabinets with HEPA filters and alarms to alert staff do not have to be exhausted to the exterior. If the air changes for biological safety cabinets as provided in Table 3 of §511.169(c) of this subchapter do not provide sufficient air for proper operation of the safety cabinets (when in use), supplementary make-up air (filtered and preheated) shall be provided around these units to maintain the required airflow direction and exhaust velocity. Make-up air system for safety cabinets shall be arranged to minimize "short circuiting" of air and to avoid reduction in air velocity at the point of contaminant capture.

(iii) Exhaust fan. The exhaust fan shall be located at the discharge end of the system.

(iv) Exhaust duct system. The exhaust duct system shall be of noncombustible and corrosion- resistant material.

(v) Fume hoods. Where fume hoods are used, the design should consider the placement and types of air distribution devices to avoid the disturbance of a uniform velocity across the face of the hood.

(C) Special laboratory hoods. When special laboratory hoods are provided, they shall meet the following special standards for these types of hoods.

(i) Associated equipment. Fume hoods, and their associated equipment in the air stream, intended for use with perchloric acid and other strong oxidants, shall be constructed of stainless steel or other material consistent with special exposures, and be provided with a water wash and drain system to permit periodic flushing of duct and hood. Electrical equipment intended for installation within such ducts shall be designed and constructed to resist penetration by water. Duct systems serving these hoods shall be constructed of acid-resistant stainless steel for at least 10 feet from the hood. Lubricants and seals shall not contain organic materials. When perchloric acid or other strong oxidants are only transferred from one container to another, standard laboratory fume hoods and the associated equipment may be used in lieu of stainless steel construction.

(ii) Infectious or radioactive material laboratory hoods. Each laboratory hood used to process infectious or radioactive materials shall have a minimum face velocity of 90-110 feet per minute and be connected to an independent exhaust system, with suitable pressure-independent air modulating devices and alarms to alert staff of fan shutdown or loss of airflow. Each hood shall also have filters with a 99.97 percent efficiency (based on the dioctyl-phthalate (DOP) test method) in the exhaust stream, and be designed and equipped to permit the safe removal, disposal, and replacement of contaminated filters. Filters shall be as close to the hood as practical to minimize duct contamination.

(iii) Radioactive isotope hoods. Fume hoods intended for use with radioactive isotopes shall be constructed of stainless steel or other material suitable for the particular exposure and shall comply with National Fire Protection Association 801, Standard for Facilities Handling Radioactive Materials, 2003 edition and NFPA 99 §11.3.5.

(iv) Air modulating devices. Each laboratory hood shall have a suitable pressure-independent air modulating device and alarm to alert staff of fan shutdown or loss of airflow. The alarm shall be audible within the laboratory and at a 24-hour manned location.

(D) Filtration requirements. Filtration requirements for air handling units serving the laboratory suite shall be equipped with filters having efficiencies equal to, or greater than specified in Table 4 of §511.169(d) of this subchapter.

(E) Duct linings. Duct linings exposed to air movement shall not be used in ducts serving any laboratory room and clean room unless terminal filters of at least 80 percent efficiency are installed downstream of linings. This requirement shall not apply to mixing boxes and acoustical traps that have special coverings over such lining.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall comply with §511.162(d)(4) of this subchapter and this paragraph.

(A) General.

(i) Faucet spouts. Faucet spouts at lavatories and sinks shall have clearances adequate to avoid contaminating utensils and the contents of beakers, test tubes, etc.

(ii) Sink drain lines. Drain lines from sinks used for acid waste disposal shall be made of acid-resistant material.

(iii) Other drain lines. Drain lines serving some types of automatic blood-cell counters must be of carefully selected material that will eliminate potential for undesirable chemical reactions, explosions, or both between sodium azide wastes and copper, lead, brass, and solder, etc.

(B) Medical gas systems. When provided, medical gas systems shall comply with §511.162(d)(4)(A)(iii) and (iv) of this subchapter. The number of outlets in the laboratory for vacuum, gases, and air shall be determined by the LSRH's functional program requirements.

(5) Electrical requirements. Electrical requirements shall comply with §511.162(d)(5) of this subchapter.

(A) Blood storage refrigerator alarm. The blood storage refrigerator shall have an alarm device to indicate a temperature

increase or malfunction and indicate an audible warning at a 24-hour manned location.

(B) Blood storage refrigerator connection. The blood storage refrigerator shall be connected to the critical branch of the emergency essential electrical system.

(C) Exhaust hoods. All exhausts hoods shall be connected to the emergency essential electrical system.

(l) Laundry suite. Laundry facilities shall be provided on site or off site. On-site laundry services may be within the LSRH or in a separate building on-site. The laundry facilities shall be separated from a patient treatment room, patient examination room, and a patient diagnostic room, or areas of food preparation and storage, and areas in which clean supplies and equipment are stored.

(1) Architectural requirements.

(A) When laundry service is provided on site, it shall comply with the following.

(i) Soiled and clean linen processing room. Soiled and clean linen processing rooms shall be provided. When the soiled and clean linen processing are combined in a single room, each process shall be physically separated within the room.

(ii) Hand washing facilities. Adequate hand washing facilities shall be provided in both the soiled and clean processing areas.

(iii) Receiving, holding, and sorting room. A receiving, holding, and sorting room for control and distribution of soiled linen shall be provided. This area may be combined with the soiled linens processing room. Discharge from soiled linen chutes may be received in the soiled room or area or in a separate dedicated room.

(iv) Laundry processing room. A laundry processing room shall be provided with a commercial washer and dryer capable of processing at least a seven-day laundry supply within the regular scheduled work week.

(v) Clean linen processing room. A clean linen processing room or area shall be provided with folding counters or tables. This area shall have provisions for inspections, folding, packing, and mending of linen.

(vi) Storage room. A holding room or area for storage and issuing of clean linen shall be provided but may be combined with clean linen processing room.

(vii) Storage space. Storage space and cabinets for soaps, stain removers, and other laundry processing agents shall be located in the soiled and clean processing room or areas.

(viii) Laundry equipment. Laundry equipment shall be arranged so that the processing of laundry is an orderly work flow from soiled to clean operations. Cross-traffic shall be held to a minimum to prevent contamination.

(B) Off-site laundry. When laundry service is provided off site, the following minimum requirements shall be provided on site:

(i) a service entrance that shall have a drive under canopy for protection from inclement weather, for loading and unloading of linen;

(ii) a control station for pickup and receiving. This may be a room at the common loading dock, in the soiled linen holding room, or the central clean linen storage room;

(iii) a soiled linen holding room; and

(iv) a central clean linen storage and issuing room in addition to linen storage required at the individual patient units.

(C) Required areas or rooms. The following areas or rooms shall be provided regardless of delivery type of laundry service:

(i) office space for the director of laundry services;

(ii) cart storage rooms for clean and soiled linen. The cart storage areas may be provided within the clean and soiled rooms. Carts may not be parked or stored in the egress corridor;

(iii) cart sanitizing facilities that comply with subsection (b) of this section;

(iv) staff toilet in the laundry suite or convenient for staff use and with a hand washing fixture with hands-free operable controls;

(v) lockers for staff use may be in laundry suite or part of a central locker room when convenient to the laundry; and

(vi) housekeeping room within the laundry suite or available nearby.

(2) Details and finishes. Details and finishes shall comply with §511.162(d)(2) of this subchapter.

(3) Mechanical Requirements. Mechanical requirements shall comply with §511.162(d)(3) of this subchapter and this paragraph.

(A) Ventilation system. The ventilation system shall include adequate intake, filtration, exchange rate, and exhaust in accordance with Table 3 and Table 4 of §511.169(c) and (d) of this subchapter, respectively.

(B) Filtration. Filtration requirements for air handling units serving the laundry suite shall be equipped with filters having efficiencies equal to, or greater than specified in Table 4 of §511.169(d) of this subchapter.

(C) Air flow. Direction of air flow of the HVAC systems shall be from clean to soiled areas.

(D) Soiled processing ventilation. The ventilation system for soiled processing area shall have negative air pressure while the clean processing area shall have positive pressure.

(E) Lint interceptors. Lint interceptors shall be located outside the laundry area. Drainage piping that serves laundry equipment shall employ suds-control features.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall comply with §511.162(d)(4) of this subchapter.

(5) Electrical requirements. Electrical requirements shall comply with §511.162(d)(5) of this subchapter.

(m) Medical records suite.

(1) Architectural requirements. The following rooms, areas, or offices shall be provided in the medical records suite:

(A) medical records administrator or technician office;

(B) review and dictating rooms or spaces;

(C) work area that includes provisions for sorting, recording, scanning, or microfilming records; and

(D) file room. When nondigital files are stored on site, the room shall be considered as hazardous. The construction protection for the storage room or area shall comply with Chapter 18 of NFPA 101 §18.3.2.

(2) Details and finishes. Details and finishes shall comply with §511.162(d)(2) of this subchapter.

(3) Mechanical requirements. Mechanical requirements shall comply with §511.162(d)(3) of this subchapter.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall comply with §511.162(d)(4) of this subchapter.

(5) Electrical requirements. Electrical requirements shall comply with §511.162(d)(5) of this subchapter.

(n) Mental health and chemical dependency treatment.

(1) General requirements. Areas that a patient receiving mental health or chemical dependency services at the LSRH may occupy shall comply with the requirements in this subsection.

(2) Details and finishes.

(A) Details.

(i) Security. The type and degree of security and patient safety required in the suite shall be determined by LSRH administration and described in the LSRH's functional program narrative, unless stated otherwise within these rules.

(ii) Visibility. All areas where a person receiving mental health services is located in the LSRH, including entrances to patient care rooms, shall be visible from the nurse station. Observation by video cameras of seclusion rooms, entrances, hallways, and activity areas shall be acceptable.

(iii) Fasteners. All exposed and accessible fasteners shall be tamper-resistant.

(iv) Hardware. Suitable hardware shall be provided on doors to toilet rooms so that access to these rooms can be controlled by staff. Hardware shall be utilized that is appropriate to prevent patient injury.

(v) Breakaway fixtures. Only breakaway or collapsible clothes bars in wardrobes, lockers, and closets and shower curtain rods shall be permitted in areas that a patient receiving mental health or chemical dependency treatment services may occupy in the LSRH.

(vi) Hangers. Wire coat hangers shall not be permitted in the suite.

(vii) Special hardware. Special fixtures, hardware, and tamper-proof screws are required throughout the suite.

(viii) Grab bars. Horizontal grab bars shall be constructed to prevent looping or tying of cords, ropes, etc.

(ix) Safety glazing. Where glass fragments may create a hazard, safety glazing or other appropriate security features shall be incorporated.

(B) Finishes. Patient sleeping rooms, patient toilet rooms and seclusion rooms shall have monolithic ceilings and bonded walls for patient safety and security measures. The ceiling in the soiled workroom shall be monolithic type as required by §511.162(d)(2)(B)(vi)(III) of this subchapter.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with 25 TAC §133.163(t)(3) and this paragraph. Special consideration shall be given to the type of heating and cooling units, ventilation outlets, and appurtenance installed in patient-occupied areas of mental health nursing units. The following shall apply:

(A) All air grilles and diffusers shall be of a type that prevents the insertion of foreign objects.

(B) All convector or HVAC enclosures exposed in the room shall be constructed with rounded corners and shall have enclosures fastened with tamper-resistant fasteners.

(C) HVAC equipment shall be of a type that minimizes the need for maintenance within the room.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with 25 TAC §133.163(t)(4) and this paragraph.

(A) Piping systems.

(i) Medical gas. Piped medical gas systems are not required.

(ii) Sprinklers and showerheads. Only tamper-proof sprinkler and tamper-proof showerheads from which it is not possible to suspend any objects shall be installed.

(B) Plumbing fixtures.

(i) Faucet controls. Faucet controls shall not be equipped with handles that may be easily broken off.

(ii) Bedpan washers. Bedpan washers are not allowed in patient bathrooms or toilet rooms.

(5) Electrical requirements. Electrical requirements shall be in accordance with 25 TAC §133.163(t)(5) and this paragraph.

(A) Nurse call. A nurse call system shall comply with the requirements of §511.162(d)(5)(L) and Table 7 of §511.169(g) of this subchapter. Pull cords shall not exceed 18 inches in length, and provisions shall be made to permit removal of call buttons and use of blank plates as required for security.

(B) Each patient room shall have duplex grounded receptacles. There shall be one receptacle at each side of the head of each bed and one on every other wall. Receptacles in areas intended for mental health and chemical dependency patients of all ages shall be protected by GFCI breakers installed in distribution panel enclosures serving the unit.

(C) Fifteen-ampere and 20-ampere, 125-volt receptacles intended to supply patient care areas shall be tamper-resistant as permitted by NFPA 70, §517-18, or shall be protected by GFCI breakers. A tamper-resistant receptacle is one that is constructed to limit improper access to its energized contacts.

(o) Morgue.

(1) Architectural requirements.

(A) General. When a morgue or body-holding room is provided, it shall be located to avoid the need for transporting bodies of deceased patients through public areas. A body-holding room shall be provided.

(B) Autopsy performed within LSRH. When autopsies are performed within the LSRH, the following rooms, areas, and equipment shall be provided.

(i) Facilities. Refrigerated facilities shall be provided for body-holding.

(ii) Room requirements. The autopsy room shall contain work counters, hand washing facilities with hands-free operable controls, autopsy table and storage space for supplies, equipment and specimens.

(iii) Sink. A deep sink shall be provided for washing specimens.

(iv) Change area. A clothing change area shall be provided with shower, toilet, hand washing facilities and lockers.

(C) Service areas. The following service areas shall be provided:

(i) a pathologist office;

(ii) staff toilets may be outside the suite but be convenient for staff use with a hand washing fixture with hands-free operable controls; and

(iii) a housekeeping room that meets the requirements of §511.162(d)(2)(A)(xxviii) of this subchapter shall be provided for the exclusive use of the morgue when autopsies are performed.

(D) Minimum requirements. If autopsies are performed outside the LSRH, a well-ventilated, temperature-controlled, nonrefrigerated body-holding room shall be provided.

(2) Details and finishes. Details and finishes shall be in accordance with §511.162(d)(2) of this subchapter and this paragraph.

(A) Flooring used in the autopsy room shall be the seamless type as required by §511.162(d)(2)(B)(iii)(III) of this subchapter.

(B) Ceilings in the autopsy rooms shall be monolithic as required by §511.162(d)(2)(B)(vi)(III) of this subchapter.

(3) Mechanical requirements. Mechanical requirements shall be in accordance with §511.162(d)(3) of this subchapter and this paragraph.

(A) The autopsy room shall be equipped with low exhaust grilles.

(B) The body-holding room shall be ventilated in accordance with Table 3 of §511.169(c) of this subchapter.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall be in accordance with §511.162(d)(4) of this subchapter.

(5) Electrical requirements. Electrical requirements shall be in accordance with §511.162(d)(5) of this subchapter and this paragraph. Refrigerators for body-holding in the autopsy room shall be connected to the equipment branch of the essential electrical distribution system.

(p) Nuclear medicine suite.

(1) Architectural requirements.

(A) General. When nuclear medicine services are provided, the facilities may be in a separate suite or combined with an imaging suite.

(i) Radiation protection. When nuclear medicine requires radiation protection, a medical physicist licensed under Texas Occupations Code Chapter 602 shall specify the type, location, and amount of radiation protection to be installed for the layout, equipment selections and storage, handling and disposal of radioactive material.

(ii) Room size. The nuclear medicine room shall be sufficiently sized to house all fixed and moveable equipment and allow a minimum of three feet of clear and unobstructed working space on all sides of equipment accessible to staff and patient.

(B) Radioisotope room (Hot lab). When radiopharmaceutical preparation is performed on site, the room shall include sufficient space for equipment, storage of radionuclides, chemicals for preparation, dose calibrators, and record keeping. When preprepared materials are used, storage and calculation area may be smaller than for on-site preparation.

(i) Radiation shielding. The room and isotope handling areas within the room shall have appropriate radiation shielding.

(ii) Radioisotope storage. There shall be a shielded area or enclosed shielded cabinet for long-term storage of decaying radioisotopes.

(iii) Hood exhaust. When venting of radioactive gases is required, a hood shall exhaust to the exterior.

(C) Positron emission tomography (PET). When PET services are provided, scanner and cyclotron rooms shall be in compliance with the manufacturer's recommendations and provide a minimum of three feet of clear and unobstructed working space on all sides of equipment accessible to staff and patient.

(i) Control alcove. A control alcove shall be provided with a view window permitting view of the patient.

(ii) Equipment area. An equipment area large enough to contain necessary electronic and electrical gear shall be provided.

(iii) Dose administration room. A dose administration room with radiation shielding shall be located near the treatment room. Patients in route to procedure rooms shall not pass through public corridors and waiting rooms after injection with radioisotope.

(iv) Patient toilet. A patient toilet with radiation shielding shall be provided with or adjacent to the dose administration room. The patient toilet room shall contain a hand washing fixture with hands-free operable controls.

(D) Service areas.

(i) Patient waiting area. The area shall be out of traffic and under direct staff visual control.

(ii) Control desk and reception area. A control desk and reception area shall be provided.

(iii) Dictation and report preparation area. The dictation and report preparation area may be incorporated with the control station.

(iv) Holding area. The holding area shall be under direct staff control, out of the direct line of traffic, and have space for stretchers. The holding area shall accommodate two stretchers for the first procedure room with one additional station for each additional procedure room.

(v) Patient toilet facilities. A toilet room with a hand washing fixture with hands-free operable controls shall be provided convenient to the waiting room and procedure room.

(vi) Staff toilet facilities. Toilets and hand washing fixtures with hands-free operable controls may be outside the suite but shall be convenient for staff use.

(vii) Patient dressing rooms or cubicles. Dressing rooms or cubicles shall be provided convenient to the waiting areas and procedure rooms. Each room or cubicle shall include a seat or bench, mirror, and provisions for hanging patients' clothing and for securing valuables. At least one dressing room shall be provided to accommodate patients using wheelchairs.

(viii) Exam rooms. When examination rooms are provided, each room shall have a minimum of 100 square feet of clear floor area exclusive of built-in shelves or cabinets. Each exam room shall be equipped with a work counter and a hand washing fixture with hands-free operable controls.

(ix) Dose administration area. When a dose administration area is provided, the area shall be located near the preparation area and include visual privacy for the patients.

(x) Computer control area or room. Computer control area shall be located within or adjacent to the treatment room or rooms. When a centralized computer area is provided, it shall be a separate room with access terminals available within the treatment rooms.

(xi) Film processing room. A darkroom shall be provided for film processing unless the processing equipment normally used does not require a darkroom for loading and transfer. When daylight processing is used, the darkroom may be minimal for emergency and special uses. Film processing shall be located convenient to the treatment room or rooms and to the quality control area.

(xii) Quality control area or room. A quality control area shall include view boxes illuminated with light of the same color value and intensity.

(xiii) Film storage room (active). A room with cabinet or shelves for filing patient film for immediate retrieval shall be provided.

(xiv) Film storage room (inactive). A room for inactive film storage may be located outside the nuclear medicine suite, but must be under the administrative control of nuclear medicine personnel and properly secured to protect films against loss or damage.

(xv) Digital imaging. If digital imaging is utilized throughout the suite, the darkroom film processing area and film viewers is not required.

(xvi) Storage for unexposed film. Storage facilities for unexposed film shall include protection of film against exposure or damage.

(xvii) Offices for physicians, oncologist, physicists, and assistants. Offices shall include provisions for individual consultation, viewing, and charting of film.

(xviii) Clerical office spaces. Clerical office spaces shall be provided.

(xix) Consultation room. A consultation room shall be provided.

(xx) Clean storage room. A clean storage room shall be provided for clean supplies and linens. A hand washing fixture shall be provided with hands-free operable controls. When conveniently located, the clean storage room may be shared with another department.

(xxi) Soiled workroom. The soiled workroom shall not have direct connection to the nuclear medicine procedure or diagnostic rooms or sterile activity rooms. The room shall contain a clinical sink or equivalent flushing type fixture, work counter, hand washing fixture with hands-free operable controls, waste receptacle, and soiled linen receptacle. When contaminated soiled material or fluid waste is not handled, only a soiled holding room is required.

(xxii) Housekeeping room. The housekeeping room shall be located within the suite.

(2) Details and finishes. Details and finishes shall comply with §511.162(d)(2) of this subchapter and this paragraph.

(A) Details.

(i) Radiation protection. Radiation protection shall be designed, tested and approved by a medical physicist licensed under Texas Occupations Code Chapter 602.

(I) Room shielding. Room shielding calculations for the stipulated rooms within the nuclear medicine suite must be submitted to the Department of State Health Services Radiation Control Program (RC) for approval prior to use. Shielding in diagnostic radiographic rooms will be reviewed by RC inspectors, in the field, subsequent to use. Any changes in design or shielding that affects radiation exposure levels adjacent to those rooms requires prior approval by RC.

(II) Facility design and environmental controls associated with licensable quantities of radioactive material in laboratories or procedure rooms must be approved by RC prior to licensed authorizations.

(ii) The nuclear medicine treatment rooms shall have ceiling heights not less than nine feet. Ceilings containing ceiling-mounted equipment shall be of sufficient height to accommodate the equipment of fixtures and their normal movement.

(B) Finishes.

(i) Flooring. Flooring used in the nuclear medicine procedure room, any work or treatment areas where radioactive material is handled, and soiled workroom shall be of the seamless monolithic type as required by §511.162(d)(2)(B)(iii)(III) of this subchapter.

(ii) Ceiling. Ceilings in radiopharmacy, hot laboratory, and soiled workrooms shall be monolithic as required by §511.162(d)(2)(B)(vi)(III) of this subchapter.

(3) Mechanical requirements. Mechanical requirements shall comply with §511.162(d)(3) of this subchapter and this paragraph.

(A) Radiopharmaceutical preparations. When radiopharmaceutical preparations are performed, vents and traps for radioactive gases shall be provided.

(B) Direction of air flow of the HVAC system shall be from nonradioactive spaces into the radioactive spaces. A minimum of two return air inlets located diagonally opposite from one another and near floor level shall be provided.

(C) In the PET suite, special ventilation systems together with monitors, sensors, and alarm systems shall be required to vent gases and chemicals. The ventilation shall be directly to the exterior.

(D) Filtration requirements for air handling units serving the nuclear medicine suite shall be equipped with filters having efficiencies equal to, or greater than specified in Table 4 of §511.169(d) of this subchapter.

(E) Where fume hoods are used, the design should consider the placement and types of air distribution devices to avoid the disturbance of a uniform velocity across the face of the hood. Fume hoods shall be exhausted directly to the exterior.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall comply with §511.162(d)(4) of this subchapter.

(5) Electrical requirements. Electrical requirements shall comply with §511.162(d)(5) of this subchapter and this paragraph.

(A) General.

(i) Nuclear medicine procedure room. Each nuclear medicine procedure room shall have at least four duplex electrical hospital grade receptacles.

(ii) Nuclear medicine procedures rooms shall have general lighting in addition to that provided by special lighting units at the procedure tables.

(B) Nurses calling systems. The nurse call shall comply with §511.162(d)(5)(L) and Table 7 of §511.169(g) of this subchapter.

(q) Nursing unit. The requirements in this subsection apply to nursing units in LSRHs.

(1) Architectural requirements. Architectural requirements shall comply with §511.162(d)(1) of this subchapter and this paragraph.

(A) Accessibility requirements. At least 10 percent of each patient room type, isolation room, bathing units and toilets in medical/surgical, intermediate care, universal care, antepartum, postpartum, mental health, chemical dependency, and pediatric nursing units and all public and common use areas shall be designed and constructed to be Americans with Disabilities Act (ADA) accessible. These requirements shall apply in all new construction and when an existing nursing unit or a portion thereof is converted from one service to another (e.g., mental health care to medical or surgical nursing care).

(B) Patient room suites. A patient room suite shall consist of the patient room and a bathroom. Patient room suites shall comply with the following requirements.

(i) Maximum patient room capacity. The maximum patient room capacity shall be two patients. In existing facilities where renovation work is undertaken and the present capacity is more than two patients, the maximum room capacity shall be no more than the present capacity with a maximum of four patients.

(ii) Single-patient station room. In a single-patient station room, the minimum clear floor area shall be 120 square feet.

(iii) Multi (two)-patient station room. The clearance between the side of a station and a wall or partition shall be a minimum of three feet. The clearance between sides of stations shall be a minimum of five feet. The minimum distance at the foot of the station shall not be less than four feet for a single load area or room or seven feet for a double load area or room. Four feet of the passage space at the foot of the station may be shared between two stations.

(iv) Multi (two)-station accessible patient room. The clearance between the side of a station and a wall or partition shall be a minimum of five feet. The clearance between sides of stations shall be a minimum of four feet. The minimum distance at the foot of the station shall not be less than four feet for a single load area or room or seven feet for a double load area or room. Four feet of the passage space at the foot of the station may be shared between two stations.

(v) Arrangement of patient rooms. Minor encroachments including columns and wall hung lavatories that do not interfere with functions may be ignored when determining space requirements for patient rooms.

(I) Clear floor space. Required clear floor space in patient rooms shall be exclusive of toilet rooms, closets, lockers, built-in cabinets, wardrobes, alcoves, or vestibules.

(II) Visual privacy. Visual privacy shall be provided each patient in multi-station room. Design for privacy shall not restrict independent patient access to the corridor, lavatory, or bathroom.

(vi) Patient bathroom. Each patient shall have access to a bathroom without having to enter the general corridor area. Each bathroom shall contain a toilet with bed pan washers, hand washing fixture with hands-free operable controls, bathing facilities, and storage shelf or cabinet and serve not more than two patient rooms. Hand washing facilities shall be located in the patient room and in the patient bathroom. The hand washing fixture in the room shall be located outside of the patient's cubicle curtain in multi-station patient room.

(vii) Patient storage. Each patient shall have a separate wardrobe, locker, or closet that is suitable for hanging full-length garments and for storing personal effects. A minimum of 12 lineal inches of hanging space shall be provided per patient.

(C) Airborne infection isolation suites. Where provided, a minimum of one isolation room shall be designated for pediatric patient care. Each airborne infection isolation suite shall consist of a work area, a patient room, and a patient bathroom.

(i) The work area may be a separately enclosed anteroom or a vestibule that is open to and is located immediately inside the door to the patient room. It shall have facilities for hand washing, gowning, and storage of clean and soiled materials. One enclosed anteroom may serve multiple isolation rooms.

(ii) Each patient room shall have a clear floor area of 120 square feet exclusive of the work area and shall contain only one patient station. A patient bathroom shall be provided in accordance with subparagraph (B)(vi) of this paragraph.

(iii) At least one airborne infection isolation suite with an enclosed anteroom shall be provided.

(iv) A door from an anteroom to an airborne infection isolation room and a door from an egress corridor into an anteroom shall be provided with a self-closing device. When an isolation room does not have an anteroom, the door from the egress corridor into the isolation room shall be provided with a self-closing device. When sliding doors are used in isolation rooms and in surgical suite post-anesthesia care units, the self-closing device may not be required as long as assurances of negative air pressure are met when sliding doors are opened.

(v) Pressure differential monitors or air flow devices shall be installed outside the isolation room and anteroom. Devices shall be installed in corridors, passageways, etc.

(vi) Where a special assisted bathing facility is provided, it shall meet the requirements of this paragraph. including space for attendant, for patients on stretchers, carts, and wheelchairs. This may be on another floor if convenient for use. The central bathing room shall contain a bathtub that is accessible to a patient using a wheelchair or a shower that can accommodate a gurney. The room shall have space for drying and dressing and be provided with a hand washing fixture with hands-free operable controls and a toilet with three feet of clear space on sides and front of the water closet; The nurse call shall comply with §511.162(d)(5)(L) and Table 7 of §511.169(g) of this subchapter.

(r) LSRH-based outpatient suite.

(1) Architectural requirements.

(A) Site, administration and public areas. The following areas shall be provided.

(i) Public waiting area. Toilet facilities, public telephone, and drinking fountain shall be provided. When pediatric services are provided, pediatric and adult patients waiting areas shall be separate.

(ii) Control station. A control station shall be located to permit staff observation of waiting area and control of access to LSRH-based outpatient clinical rooms.

(iii) Wheelchair storage alcove. The alcove provided for wheelchair storage shall be located out of line of traffic.

(iv) Interview space. Interview spaces shall be provided for social services, credit, and admissions. Provisions shall be made for privacy and dignity of the patient during interview, LSRH-based outpatient clinical services.

(v) Office. At least one office shall be provided for business transaction, records, and administrative and professional staff.

(B) LSRH-based outpatient room. The room shall have a minimum clear floor area of 100 square feet exclusive of fixed cabinets and shelves. Each examination room shall contain a work counter, cabinets, examination light and hand washing fixture with hands-free operable controls. A clearance of three feet shall be provided at each side and the foot of the examination table.

(C) Service areas. The following service areas and facilities shall be provided within the outpatient suite unless noted otherwise.

(i) Nurse stations. The nurse station shall contain a work counter, communication system, space for supplies, and provisions for charting.

(ii) Hand washing fixtures. Hand washing fixtures with hands-free operable controls shall be available at all patient care areas.

(iii) Patient toilet rooms. A toilet room shall be conveniently located to treatment rooms, examination rooms, and diagnostic rooms and shall include hand washing fixtures with hands-free operable controls.

(iv) Staff toilet facilities. Toilet rooms equipped with hand washing fixtures with hands-free operable controls shall be provided for the exclusive staff use. Toilet facilities may be provided in conjunction with the staff lounge.

(v) Staff lounge. A staff lounge with separate male and female staff clothing change rooms and toilets with hand washing fixtures with hands-free operable controls shall be provided in an LSRH having a total of six or more LSRH-based outpatient clinical rooms.

(vi) Medication station. Storage and distribution of medication may be done from a medicine preparation room, medicine alcove area, or from a self-contained medicine dispensing unit but must be under visual control of nursing staff. A work counter, a hand washing fixture with hands-free operable controls, refrigerator, and double-locked storage for controlled substances shall be provided. Standard cup-sinks provided in many self-contained units are not acceptable for hand washing. The medication station may be shared with the clean workroom.

(vii) Dictation and report preparation area. This area may be accessible from the lounge.

(viii) Cast room. When a cast room is provided, it shall be equipped with hand washing facilities, plaster sink, storage, and other provisions required for cast procedures.

(ix) Wheelchair and stretcher storage. Wheelchair and stretcher storage space or alcove shall be provided and located out of direct line of traffic.

(x) Storage. Storage facilities shall be provided for office supplies, sterile supplies, pharmaceutical supplies, splints and other orthopedic supplies, and housekeeping supplies and equipment.

(xi) Ice machine. A self-dispensing ice machine shall be provided.

(xii) Clean workroom. A clean workroom or clean supply room shall be provided.

(xiii) Storage room. A storage room for the outpatient services shall be provided at least equal to five percent of the total area of the outpatient suite. This required storage room area may be combined with general stores.

(xiv) Soiled workroom. A soiled workroom shall be provided. It shall not have direct access to any patient treatment, examination, diagnostic rooms, or sterile rooms. The room shall contain a clinical sink or equivalent flushing rim fixture, work counter, hand washing fixture with hands-free operable controls, waste receptacle, and linen receptacle.

(xv) Housekeeping room. The housekeeping room shall be located within the suite.

(2) Details and finishes. Details and finishes shall comply with §511.162(d)(2) of this subchapter and this paragraph. Treatment rooms shall be provided with seamless flooring in accordance with requirements contained in §511.162(d)(2)(B)(iii)(III) of this subchapter.

(3) Mechanical requirements. Mechanical requirements shall comply with §511.162(d)(3) of this subchapter and this paragraph. Filtration requirements for air handling units serving the outpatient and surgical suite shall be equipped with filters having efficiencies equal to, or greater than specified for patient care areas in Table 4 of §511.169(d) of this subchapter.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall comply with §511.162(d)(4) of this subchapter and this paragraph. Sinks used for the disposal of plaster of paris shall have a plaster trap.

(5) Electrical requirements. Electrical requirements shall comply with §511.162(d)(5) of this subchapter and this paragraph. The nurse call shall comply with §511.162(d)(5)(L) and Table 7 of §511.169(g) of this subchapter.

(s) Pharmacy suite.

(1) Architectural requirements.

(A) General. The pharmacy room or suite shall be located for convenient access, staff control, and security for drugs and personnel.

(B) Dispensing area. The pharmacy room or suite shall include the following functional spaces and facilities:

(i) area for pickup, receiving, reviewing and recording;

(ii) extemporaneous compounding area with sufficient counter space for drug preparation and sink with hands-free operable controls;

(iii) work counter space for automated and manual dispensing activities;

(iv) storage or areas for temporary storage, exchange, and restocking of carts; and

(v) security provisions for drugs and personnel in the dispensing counter area.

(C) Manufacturing. The pharmacy room or suite shall provide the following functional spaces and facilities for the manufacturing area:

(i) bulk compounding area with work space and counters; and

(ii) area for packaging, labeling and quality control.

(D) Storage. The following spaces shall be provided in cabinets, shelves, or separate rooms or closets:

(i) space for bulk storage, active storage, and refrigerated storage;

(ii) storage in a fire safety cabinet or storage room that is constructed under the requirements for protection from hazardous areas in accordance with NFPA 101 Chapter 12, for alcohol or other volatile fluids, when used;

(iii) storage in a secure vault, safe, or double locking wall cabinet for narcotics and controlled drugs; and

(iv) storage space for general supplies and equipment not in use.

(E) Intravenous (IV) solutions area. When IV solutions are prepared in a pharmacy, a sterile work area shall be provided and be in compliance with 22 TAC §291.133 (relating to Pharmacies Compounding Sterile Preparations) and the United States Pharmacopeia Chapter 797, Pharmaceutical Compounding-Sterile Preparations.

(i) IV work area components. The IV work area shall consist of a preparation room, hood room and, if provided, a separate chemo-hood room. Access to the preparation room shall be through the pharmacy only, access to the hood room or chemo-hood room shall be through the preparation room only.

(ii) Preparation room components. The preparation room shall contain a work counter, gowning area, and shelving.

(iii) Hand washing fixtures. A hand washing fixture with hands-free operable controls shall be in the preparation room and within five feet of each entrance to the hood room or chemo-hood room. Hand washing fixtures and floor drains are not allowed inside the hood room or chemo-hood room.

(iv) Laminar-flow hoods/work stations. Laminar-flow hoods/work stations shall be located inside the hood room.

(F) Compounding aseptic isolator (CAI). When a CAI is used for compounding in lieu of the IV solutions area, it may be done within the pharmacy provided it complies with the following.

(i) CAI requirements. The CAI shall provide isolation from the room and maintain the International Organization for Standardization (ISO) Class 5 (100 particles greater than or equal to 0.5 microns per cubic foot) levels during dynamic operating conditions including transferring ingredients, components, and devices into and out of the isolator and during preparation of compounded sterile preparations.

(ii) Particle counts. The particle counts sampled shall be six to 12 inches upstream of the critical exposure site within the CAI and maintain ISO Class 5 levels during compounding operations.

(iii) CAI documentation. The pharmacy shall obtain documentation from the manufacturer that the CAI will meet this standard when located in worse than ISO Class 7 (10,000 particles greater than or equal to 0.5 microns per cubic foot environments).

(G) Administrative areas. The following functional spaces and facilities shall be included for the administrative areas:

(i) office area for the chief pharmacist and any other offices areas required for records, reports, accounting activities, and patients profiles;

(ii) poison control center with storage facilities for reaction data and drug information centers; and

(iii) a room or area for counseling and instruction when individual medication pick-up is available for inpatients or outpatients.

(H) Satellite pharmacy facilities. When provided, the room shall include a work counter, a sink with hands-free operable controls, storage facilities, and refrigerator for medications. As applicable, items required in subparagraphs (B) and (C) of this paragraph may be incorporated into the satellite pharmacy.

(I) Service areas and facilities. The following service areas and facilities shall be provided.

(i) Hand washing facilities. A hand washing fixture with hands-free operable controls shall be located in each room where open medication is handled except for IV prepared chemo-hood rooms.

(ii) Staff facilities. Toilet rooms with hand washing fixture with hands-free operable controls may be outside the suite but shall be convenient for staff use.

(2) Details and finishes. Details and finishes shall comply with §511.162(d)(2) of this subchapter and this paragraph.

(A) Flooring. Flooring in the IV solutions area for the preparation room, hood room and chemo-hood room shall be seamless and coved to the wall.

(B) Ceilings. IV solutions area ceiling and wall finishes for the preparation room, hood room and chemo-hood room shall be interlocking monolithic panels and sealed together or monolithic epoxy-painted gypsum board. The ceiling shall be coved to the wall.

(C) Sealing requirements. All penetrations in the walls and ceilings shall be sealed.

(D) Door requirements. The door from hood room shall swing into the preparation room. The door from preparation room shall swing into the chemo room. The door from preparation room shall swing into pharmacy.

(3) Mechanical Requirements. Mechanical requirements shall comply with §511.162(d)(3) of this subchapter and this paragraph.

(A) Laminar-flow system. When IV solutions are prepared, the required laminar-flow system shall include a nonhygroscopic filter rated at 99.97 percent (HEPA). A pressure gauge shall be installed for detection of filter leaks or defects.

(B) Fume hoods for chemotherapy. When fume hoods are used for chemotherapy, the air and fumes shall be exhausted directly to the exterior. The hood exhaust shall not use the building exhaust system. When more than one fume hood is in the same hood room and the work stations face each other, at least six feet must separate work area openings.

(C) General fume hood requirements. When fume hoods are used, the design should consider the placement and types of air distribution devices to avoid the disturbance of a uniform velocity across the face of the hood.

(D) Filtration. All air entering the IV solutions area for the preparation room, hood room and chemo-hood room shall be HEPA filtered.

(E) Air pressure. In the IV solutions area the air pressure in the preparation room shall be positive to the pharmacy, the hood room shall be positive to the preparation room, and the chemo-hood room shall be negative to the preparation room.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall comply with §511.162(d)(4) of this subchapter and this paragraph.

(A) Material used for plumbing fixtures shall be nonabsorptive and acid-resistant.

(B) Water spouts used at lavatories and sinks shall have clearances adequate to avoid contaminating utensils and the contents of carafes, etc.

(5) Electrical requirements. Electrical requirements shall comply with §511.162(d)(5) of this subchapter and this paragraph.

(A) Under-counter receptacles. Under-counter receptacles and conduits shall be arranged (raised) to not interfere with cleaning of the floor below or of the equipment.

(B) Exhaust hoods. Exhaust hoods shall have an indicator light indicating that the exhaust fan is in operation.

(C) Electrical circuits. Electrical circuits to equipment in wet areas shall be provided with five milliampere GFCI.

(t) Radiotherapy suite. When radiotherapy services are provided, the suite may contain equipment for electron beam therapy, radiation therapy, or both. The following facilities shall be provided.

(1) Architectural requirements.

(A) Radiation protection. Cobalt, linear accelerators, and simulation rooms require radiation protection. A medical physicist licensed under Texas Occupations Code Chapter 602, shall specify the type, location, and amount of radiation protection to be installed for the layout and equipment selections. Room layouts and construction shall prevent the escape of radioactive particles. Openings into the room, including doors, ductwork, vents, and electrical raceways and conduits, shall be baffled to prevent direct exposure to other areas of the facility.

(B) Room size. Cobalt, linear accelerator, and simulator rooms shall be sized in accordance with the installed equipment requirements, patient access on a stretcher, medical staff access to the equipment and patient, and access for servicing the equipment.

(C) Mold room. When a mold room is provided, it shall contain a ventilation hood exhausted to the exterior and a hand washing fixture with hands-free operable controls.

(D) Block room. A block room with storage for the linear accelerator may be combined with the mold room.

(E) Hot laboratory. A hot laboratory in support of cobalt therapy shall be provided.

(F) Service areas. The following service areas shall be provided unless these are accessible from other departments such as imaging or outpatient areas:

(i) a stretcher hold area adjacent to the treatment rooms, screened for privacy, and combined with a seating area for outpatients;

(ii) exam rooms for each treatment room shall be at least 100 square feet and shall be provided with hand washing facilities;

(iii) a patient gowning area with provisions for safe storage of valuables and clothing. At least one space shall be sized to allow for staff-assisted dressing;

(iv) convenient access to a housekeeping room;

(v) film file area;

(vi) film storage area for unprocessed film; and

(vii) a radioisotope decay room, that may be combined with the hot lab.

(2) Details and finishes. Details and finishes shall comply with §511.162(d)(2) of this subchapter and this paragraph.

(A) Details.

(i) Radiation protection. Radiation protection shall be designed, tested, and approved by a medical physicist licensed under the Texas Occupations Code Chapter 602.

(ii) Room shielding. Room shielding calculations for linear accelerators, cobalt, and simulation rooms shall be submitted to the Department of State Health Services Radiation Control Program (RC) for approval prior to use. Shielding in diagnostic radiographic rooms will be reviewed by inspectors, in the field, subsequent to use. Any changes in design or shielding that affects radiation exposure levels adjacent to those rooms requires prior approval by RC.

(iii) Ceiling heights. The cobalt, simulation, and linear accelerator rooms shall have ceiling heights not less than nine feet. Ceilings containing ceiling-mounted equipment shall be of sufficient height to accommodate the equipment of fixtures and their normal movement.

(iv) Ceiling-mounted equipment. Properly designed rigid support structures for ceiling-mounted equipment shall be located above the finished ceiling.

(B) Finishes.

(i) Flooring. Flooring in the soiled workroom and any work or treatment areas in the radiotherapy suite where radioactive materials are handled shall be of the seamless type as required by §511.162(d)(2)(B)(iii)(III) of this subchapter.

(ii) Walls. Walls shall be constructed of materials that are easily decontaminated from accidental radioactive spills and finished in accordance with §511.162(d)(2)(B)(iv) of this subchapter.

(iii) Ceilings. Ceilings in the hot laboratory and soiled workroom shall be monolithic as required by §511.162(d)(2)(B)(vi)(III) of this subchapter.

(3) Mechanical requirements. Mechanical requirements shall comply with §511.162(d)(3) of this subchapter and this paragraph.

(A) Fume hoods. Where fume hoods are used, the design should consider the placement and types of air distribution devices to avoid the disturbance of a uniform velocity across the face of the hood.

(B) Radioactive material fume hoods. Each hood used to process radioactive materials shall have a minimum face velocity of 90-110 feet per minute, be connected to an independent exhaust system, with suitable pressure-independent air modulating devices and alarms to alert staff of fan shutdown or loss of airflow. Each hood shall also have filters with a 99.97 percent efficiency (based on the dioctyl-phthalate (DOP) test method) in the exhaust stream, and be designed and equipped to permit the safe removal, disposal, and replacement of con-

taminated filters. Filters shall be as close to the hood as practical to minimize duct contamination.

(4) Plumbing fixtures and piping systems. Piping systems and plumbing fixtures shall comply with the requirements of §511.162(d)(4) of this subchapter.

(5) Electrical requirements. Each radiotherapy suite shall comply with the requirements of §511.162(d)(5) of this subchapter and this paragraph.

(A) Radiotherapy procedure room. Each radiotherapy procedure room shall have at least four electrical receptacles.

(B) Ground fault circuit. Ground fault circuit interrupters shall not be used in radiotherapy procedure rooms.

(C) Nurses calling system. The nurse call shall comply with §511.162(d)(5)(L) and Table 7 of §511.169(g) of this subchapter.

(u) Rehabilitation therapy suite. Rehabilitation therapy may include one or more categories of services. Where two or more rehabilitation services are provided, the services may share common areas when appropriate.

(1) Architectural requirements.

(A) Occupational therapy. When occupational therapy services are provided, the following rooms or areas shall be included:

(i) an activity area with work areas, counters and a hand washing fixture with hands-free operable controls. Work areas and counters shall be suitable for wheel chairs;

(ii) an area for teaching daily living activities with space for a bed, kitchen counter with appliances and sink, bathroom, and a table and chair. The daily living activities area may be combined with the activity area;

(iii) an office for the occupational therapist; and

(iv) a storage room for supplies and equipment.

(B) Physical therapy. When physical therapy services are provided, the following rooms or areas shall be included.

(i) Provisions shall be made for thermotherapy, diathermy, ultrasonics, and hydrotherapy when required by the LSRH's functional program.

(ii) Treatment areas shall be provided with at least 70 square feet of clear floor area for each patient station, exclusive of four foot aisle space. Privacy screens or curtains shall be provided at each treatment station.

(iii) A hand washing fixture with hands-free operable controls shall be provided in each treatment room or space. One hand washing fixture may serve up to four patient stations when cubicles or open room concepts are used and when the fixture is conveniently located.

(iv) An area shall be provided for exercise and may be combined with treatment areas in open plan concepts.

(v) An office shall be provided for the physical therapist.

(vi) Separate storage shall be provided for soiled linen, towels, and supplies.

(vii) A storage area or room for equipment, clean linen, and supplies shall be provided.

(viii) When outpatient physical therapy services are provided, the suite shall have as a minimum patient dressing areas, showers and lockers. These shall be accessible and usable by people with disabilities.

(C) Prosthetics and orthotics. When prosthetics and orthotics services are provided, the following rooms or areas shall be included:

(i) work space with counters and shelves for technicians;

(ii) a treatment space for evaluating and fitting with privacy screens or curtains; and

(iii) a storage area or room for equipment and supplies.

(D) Speech and hearing. When speech and hearing services are provided, the following rooms or areas shall be included:

(i) a space for evaluating and treatment with privacy screens or curtains; and

(ii) a storage area or room for equipment and supplies.

(E) Service areas. The following areas or items shall be provided in a rehabilitation therapy suite, but may be shared when multiple rehabilitation services are offered:

(i) patient waiting area out of traffic with space for wheelchairs;

(ii) patient toilet facilities containing hand washing fixtures, with hands-free operable controls;

(iii) reception and control stations shall be located to provide supervision of activities areas. The control station may be combined with office and clerical spaces;

(iv) office and clerical space;

(v) wheelchair and stretcher storage room or alcove that shall be in addition to other storage requirements;

(vi) lockable closets, lockers or cabinets for securing staff personal effects;

(vii) staff toilets may be outside the suite but shall be convenient for staff use and contain hand washing fixtures with hands-free operable controls;

(viii) soiled holding room; and

(ix) housekeeping room with service sink, conveniently accessible.

(2) Details and finishes.

(A) Details. Details shall comply with §511.162(d)(2)(A) of this subchapter.

(B) Finishes. Finishes shall comply with §511.162(d)(2)(B) of this subchapter and this paragraph.

(i) Flooring in a treatment room and soiled workroom shall be of the seamless type as required by §511.162(d)(2)(B)(iii)(III) of this subchapter.

(ii) Wall finishes shall comply with the requirements of §511.162(d)(2)(B)(iv) of this subchapter.

(3) Mechanical requirements. Mechanical requirements shall comply with §511.162(d)(3) of this subchapter and this paragraph. Air handling units serving the rehabilitation therapy suite shall be equipped with filters having efficiencies equal to, or greater

than specified for patient care areas in Table 4 of §511.169(d) of this subchapter.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall comply with §511.162(d)(4) of this subchapter.

(5) Electrical requirements. Electrical requirements shall comply with §511.162(d)(5) of this subchapter and this paragraph. The nurse call shall comply with §511.162(d)(5)(L) and Table 7 of §511.169(g) of this subchapter.

(v) Respiratory therapy suite. The type and extent of respiratory therapy services vary greatly in each LSRH.

(1) Architectural requirements.

(A) Respiratory therapy suite. When respiratory services are provided from a centralized area, the following rooms or areas shall be included:

(i) an office for the respiratory therapist;

(ii) office and clerical space with provision for filing and retrieval of patient records;

(iii) receiving/decontamination workroom with work counter or table, a deep sink, and a hand washing fixture with hands-free operable controls;

(iv) a storage room for clean and sterile supplies that is separate from the receiving/decontamination workroom;

(v) when a blood gas analyzer is provided, it shall be located in a room and contain a counter and hand washing sink;

(vi) when a portable blood gas analyzer is used, it may be used in rooms that have a work counter and hand washing facilities with hands-free operable controls and storage of the unit may occur in an alcove or equipment storage room;

(vii) patient waiting area with space for wheelchairs;

(viii) reception and control station with visual control of waiting and activities areas;

(ix) patient toilet facilities that include hand washing fixtures with hands-free operable controls;

(x) office and clerical space; and

(xi) consultation/education room.

(B) Cough-inducing and aerosol-generating procedures. All cough-inducing procedures performed on patients who may have infectious Mycobacterium tuberculosis shall be performed in rooms, booths or special enclosures using local exhaust ventilation devices with HEPA filters located at the discharge end and exhaust directly to the outside.

(C) Service areas. The following areas and facilities shall be provided for the respiratory therapy suite but may be shared with other departments when conveniently located:

(i) wheelchair and stretcher storage room or alcove that is in addition to other storage requirements;

(ii) lockable closets, lockers or cabinets for securing staff personal effects;

(iii) staff toilets that include a hand washing fixture with hands-free operable controls. Staff toilets may be located outside suite if location is near and convenient; and

(iv) the housekeeping room shall be located within the suite or nearby, and shall contain a service sink and storage space for housekeeping supplies and equipment.

(2) Details and finishes.

(A) Details. Details shall comply with §511.162(d)(2)(A) of this subchapter.

(B) Finishes. Finishes shall comply with §511.162(d)(2)(B) of this subchapter and this paragraph.

(i) Flooring. Flooring in a decontamination room shall be of the seamless type as required by §511.162(d)(2)(B)(iii)(III) of this subchapter.

(ii) Wall finishes. Wall finishes shall comply with the requirements of §511.162(d)(2)(B)(iv) of this subchapter.

(iii) Ceilings. Ceilings shall comply with §511.162(d)(2)(B)(vi)(III) of this subchapter.

(3) Mechanical requirements. Mechanical requirements shall comply with §511.162(d)(3) of this subchapter.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall comply with §511.162(d)(4) of this subchapter.

(5) Electrical requirements. Electrical requirements shall comply with §511.162(d)(5) of this subchapter.

(w) Special procedure suite.

(1) Architectural requirements.

(A) General. When special procedures such as endoscopy, bronchoscopy, and cardiac catheterization and other similar special procedures are provided, procedure rooms may be in a separate suite or may be part of the surgical suite.

(i) When special procedure rooms are part of the surgical suite and noninvasive procedures are performed, these rooms are not required to be part of the sterile environment.

(ii) Nonsurgical or noninvasive procedure rooms shall have a minimum clear floor area of 250 square feet, and a minimum clear dimension between fixed cabinets and built-in shelves shall be 14 feet.

(iii) A hand washing fixture or a scrub sink with hands-free controls shall be located within five feet of the entrance to each nonsurgical procedure room either in the room or outside. Hand washing facilities shall be arranged to minimize any incidental splatter on nearby personnel or supply carts and recessed out of the main traffic areas.

(iv) When general anesthesia or inhalation anesthetizing agents are used during special procedures, these rooms shall comply with the detail, finish, mechanical and electrical requirements for an operating room contained in subsection (x) of this section.

(B) Special procedure room. Special procedure rooms for surgical cystoscopic and other endourologic procedures.

(i) Room area. The procedure room shall have a minimum clear floor area of 350 square feet exclusive of fixed cabinets and shelves. The minimum clear dimension between fixed cabinets and built-in shelves shall be 15 feet.

(ii) Room design. Procedure rooms shall be designed for visual and acoustical privacy for the patient.

(iii) Scrub station. One scrub station shall be located within five feet of the outside entrance of each special procedure surgical room. Scrub facilities shall be arranged to minimize any incidental splatter on nearby personnel, medical equipment, or supply carts. The scrub sinks shall be recessed out of the main traffic areas. The scrub sink shall be located off the restricted areas of the special procedure surgical procedure rooms. Scrub sinks or sinks shall not be located inside the sterile area.

(iv) Changing rooms. Appropriately sized areas shall be provided for male and female changing rooms within the special procedure surgical suite. These areas shall contain lockers, showers, toilets, hand washing fixtures with hands-free operable controls, and space to change into scrub suits and boots. Separate locker or changing rooms shall be provided for male and female staff. The shower and toilet room may be unisex. These areas shall be arranged to provide a traffic pattern so that personnel entering from outside the special procedure surgical suite can shower, change, and move into the restricted portions of special procedure surgical suite.

(C) Catheterization laboratory. A catheterization procedure room may be in a separate suite, part of a special procedure suite, surgical suite, or in the imaging suite. The following items and facilities shall be provided.

(i) The room shall be located in an area restricted to authorized personnel.

(ii) The procedure room shall be a minimum of 400 square feet of clear floor area exclusive of fixed and movable cabinets and shelves. The minimum clear dimension between fixed cabinets and built-in shelves shall be 18 feet.

(iii) A control room shall have a view window that permits complete observation of the patient from the control console. The control room shall be large enough to contain the efficient functioning of the X-ray and image recording equipment.

(iv) An area for viewing images and film file room shall be provided. When digital imaging is provided throughout the suite, at least two X-ray film illuminators shall be provided within a central location within the catheterization laboratory and the film file room is not required.

(v) An equipment room large enough to contain X-ray transformers, power modules, and necessary electronics and electrical gear shall be provided.

(vi) Appropriately sized areas shall be provided for male and female changing rooms within the catheterization laboratory suite. These areas shall contain lockers, showers, toilets, hand washing fixtures with hands-free operable controls, and space to change into scrub suits and boots. Separate locker or changing rooms shall be provided for male and female staff. The shower and toilet rooms may be unisex. These areas shall be arranged to provide a traffic pattern so that personnel entering from outside the catheterization laboratory can shower, change, and move into the restricted portions of catheterization laboratory.

(vii) One scrub station shall be located within five feet of the outside entrance of each cardiac catheterization laboratory procedure room. Scrub facilities shall be arranged to minimize any incidental splatter on nearby personnel, medical equipment, or supply carts. The scrub sinks shall be recessed out of the main traffic areas. The scrub sink shall be located off the restricted areas of the cardiac catheterization laboratory. Scrub sinks or sinks shall not be located inside the sterile area.

(viii) Sterilizing facilities for immediate or emergency use shall be provided unless instruments are all disposable. A work space and hand washing fixture with hands-free operable controls shall be included.

(D) Patient holding and preparation area. In suites with two or more special procedure rooms, a patient holding and preparation area shall be provided to accommodate ambulatory and stretcher patients and meet the following requirements:

(i) two-stretcher stations shall be provided for first procedure room with one additional station for each additional procedure room;

(ii) the minimum clear floor space in a private holding and preparation room shall be 100 square feet exclusive of toilet room, built-in cabinets, work counter, alcove, or vestibules. A hand washing fixture with hands-free operable controls shall be provided. A minimum of 10 feet width shall be provided for the head wall;

(iii) in a multiple-station holding and preparation area, the clearance between the side of a gurney and a wall or partition shall be a minimum of three feet. The clearance between sides of gurneys shall be a minimum of six feet. The minimum distance at the foot of the gurney shall not be less than seven feet for single load area or room or ten feet for double load area or room. Four feet of the passage space at the foot of the gurney may be shared between two gurneys. The fixed and moveable cabinets and shelves shall not encroach upon the gurney clear floor space or area;

(iv) a control station and charting area arranged to permit staff visual observation of holding and preparation area;

(v) a work counter and a hand washing fixture with hands-free operable controls for every four gurneys located in the preparation area; and

(vi) cubicle curtains at each station for patient privacy.

(E) Recovery room or area. In suites with two or more special procedure rooms, a recovery room or area shall be provided to accommodate ambulatory and stretcher patients and meet the following requirements:

(i) a minimum of one patient recovery station shall be provided for each special procedure room;

(ii) in a single patient recovery room, there shall be a minimum clear area of 130 square feet exclusive of aisles and fixed and moveable cabinets and selves. A minimum of 10 feet width shall be provided for the head wall. The room shall contain cabinets, work counter, and a hand washing fixture with hands-free operable controls. The fixed and movable cabinets and shelves shall not encroach upon the gurney clear floor space or area;

(iii) when multiple-gurney recovery patient stations are provided, the clearance between side of gurney and a wall or partition shall be a minimum of four feet. The clearance between sides of gurneys shall be a minimum of six feet. The minimum distance at the foot of the gurneys shall not be less than eight feet for single load area or room or twelve feet for double load area or room. Four feet of passage space requirement at the foot of the gurney may be shared between two gurneys. The multiple-gurney recovery patient station shall contain cabinets, medication storage, and work counter. The fixed and movable cabinets and shelves shall not encroach upon the gurney clear floor space or area. One hand washing fixture with hands-free operable controls shall be provided for every four stations or fraction thereof;

(iv) a nurse station with a hand washing fixture with hands-free operable controls and charting area shall be provided and arranged to provide visual observation of recovery room area;

(v) a staff toilet room with a hand washing fixture with hands-free operable controls shall be provided and located within the working area to maintain staff availability to patients;

(vi) cubicle curtains shall be provided at each station for patient privacy; and

(vii) the recovery room or area may be within the patient holding area.

(F) Instrument processing room. When instruments and equipment are processed, cleaned and disinfected within the suite, dedicated rooms shall be provided. The room may serve multiple procedure rooms. The following rooms shall be included.

(i) A decontamination room shall be provided and equipped with work counters, two sinks remote from each other and a hand washing fixture with hands-free operable controls. One of the sinks shall be utility type.

(ii) A clean room shall be provided and the process of cleaning the instruments or equipment shall flow from the contaminated area to the clean area, and finally, to storage. The room shall include a work counter and a hand washing sink fixture with hands-free operable controls. Instruments and equipment shall be protected from contamination.

(iii) When endoscopy scope wash rooms are provided, cleaning, washing and drying may occur in the same room. The room shall contain two sinks.

(G) Service areas. The following services shall be provided for all types of special procedure rooms unless noted otherwise.

(i) Control station. In facilities with two or more special procedure rooms in a suite, a nurse station shall be provided and located to permit visual surveillance of all traffic that enters the special procedure rooms suite.

(ii) Dictation and report preparation area. This area may be incorporated with the control station.

(iii) Medication station. Provision shall be made for the storage and distribution of medication to be administered to patients. This may be done from a medicine preparation room, medicine alcove area or from a self-contained medicine dispensing unit. The medicine preparation room, medicine alcove area or self-contained medicine dispensing unit shall be under visual control of nursing staff. A work counter, hand washing fixture with hands-free operable controls, refrigerator, and double-locked storage for controlled substances shall be provided. Standard cup-sinks provided in many self-contained units are not acceptable for hand washing. The medication station may be shared with the clean work room.

(iv) Patient toilet room. A toilet room shall be conveniently located to special procedure rooms and patient changing areas and shall include hand washing fixtures with hands-free operable controls.

(v) Staff toilet facilities. Facilities shall be provided for exclusive staff use and include a hand washing fixture with hands-free operable controls. The toilet may be accessible from a staff lounge, when a staff lounge is provided.

(vi) Storage. A storage room shall be provided for equipment and supplies used in the special procedure suite. Each special procedure suite shall provide at least 150 square feet of storage area or 50 square feet per procedure room, whichever is greater.

(vii) Wheelchair and stretcher storage. A wheelchair and stretcher storage space or alcove shall be provided and located out of direct line of traffic.

(viii) Staff storage. Storage space for employees' personal effects shall be provided.

(ix) Ice machine. An ice machine shall be provided.

(x) Clean storage room. A clean storage room shall be provided for clean supplies and linens. A hand washing fixture shall be provided with hands-free operable controls.

(xi) Soiled workroom. The soiled workroom shall not have direct connection to the special procedure or diagnostic rooms or other sterile or clean activity rooms. The room shall contain a clinical sink or equivalent flushing type fixture, work counter, hand washing fixture with hands-free operable controls, waste receptacle, and linen receptacle.

(xii) Housekeeping room. A housekeeping room shall be provided for the exclusive use of the special procedure suite. It shall be directly accessible from the suite and shall contain a floor receptor or service sink and storage for supplies and housekeeping equipment.

(2) Details and finishes. Details and finishes shall comply with §511.162(d)(2) of this subchapter and this paragraph.

(A) Details. Special procedure rooms shall have ceiling heights not less than nine feet.

(B) Finishes.

(i) Flooring. Flooring used in special procedure rooms, decontamination room, and in the soiled workroom shall be of the seamless type as required by §511.162(d)(2)(B)(iii)(III) of this subchapter.

(ii) Ceilings. Ceiling finishes in special surgical procedure rooms and isolation rooms, soiled workroom and sterile processing rooms shall be monolithic as required by §511.162(d)(2)(B)(vi)(III) of this subchapter.

(iii) Nonsurgical special procedure room ceilings. A lay-in type ceiling is acceptable in nonsurgical special procedure rooms.

(iv) Nonsurgical or noninvasive cauterization lab ceilings. A nonsurgical or noninvasive catheterization lab shall have a washable ceiling.

(3) Mechanical Requirements. Mechanical requirements comply with §511.162(d)(3) of this subchapter and this paragraph.

(A) Air supply. Air supply for the special procedure rooms shall be from ceiling outlets that are as near the work centers as possible. At least two low return inlets shall be located diagonally opposite from one another.

(B) Return air inlets. Return air inlets shall be not lower than four inches nor higher than 12 inches from floor level.

(C) Smoke removal system. Smoke removal systems shall be provided in accordance with §511.162(d)(3)(D)(iv)(II) of this subchapter, for special procedure rooms that have piped-in nitrous oxide medical gas or where anesthesia is administered to patients.

(D) Ventilation. The decontamination room shall meet the ventilation requirements that are contained in Table 3 of §511.169(c) of this subchapter.

(E) Temperature and humidity indicating devices. Each special procedure room and recovery room shall have wall-mounted temperature and humidity indicating devices.

(F) Airborne infection ventilation. When patients with airborne infectious disease are treated, the room shall meet requirements for airborne infection ventilation for patient care areas in accordance with Table 3 of §511.169(c) of this subchapter.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall comply with §511.162(d)(4) of this subchapter and this paragraph.

(A) Drainage and waste piping shall not be installed within the ceiling or installed in an exposed location in special procedure rooms and sterile processing rooms unless precautions are taken to protect the space below from leakage and condensation from necessary overhead piping. Any required secondary protection shall be labeled, "code required secondary drain system" every 20 feet in a highly visible print or label.

(B) A medical gas system shall be provided in accordance with §511.162(d)(4)(A)(iii) and (iv), and Table 6 of §511.169(f) of this subchapter.

(5) Electrical requirements. Electrical requirements shall comply with §511.162(d)(5) of this subchapter and this paragraph.

(A) General.

(i) X-ray film illuminators. X-ray film illuminators for handling at least four films simultaneously shall be provided in a central location. When the entire special procedure suite is provided with digital imaging system capabilities, at least two X-ray film illuminators viewers shall be provided.

(ii) Electrical receptacles. Each special procedure room shall have at least six duplex electrical hospital grade receptacles.

(iii) Additional receptacles. In locations where mobile X-ray, laser, or other equipment requiring special electrical configuration is used, the additional receptacles shall be distinctively marked for the special use.

(iv) GFCIs. The electrical circuits to equipment in wet areas shall be provided with GFCIs. GFCI circuits shall not be used in special procedure rooms. When ground fault circuit interrupters are used in critical areas, provisions shall be made to ensure that other essential equipment is not affected by activation of one interrupter.

(v) Special grounding system. Special grounding system in areas such as special procedure rooms where a patient may be treated with an internal probe or catheter the ground system shall comply with NFPA 99 Chapter 10 and NFPA 70 Article 517.

(vi) Lighting. Special procedures rooms shall have general lighting in addition to that provided by special lighting units at the procedure tables.

(B) Nurses calling system. The nurse call shall comply with §511.162(d)(5)(L) and Table 7 of §511.169(g) of this subchapter.

(x) Surgical suite.

(1) Architectural requirements.

(A) General.

(i) Waiting room. A public waiting room shall be provided.

(ii) Toilet facilities. Toilet facilities, public telephone, and drinking fountains shall be provided within or nearby.

(iii) Unrelated traffic. The surgical suite shall be located and arranged to preclude unrelated traffic through the suite.

(B) General operating room. At least one operating room shall be provided and shall have a minimum clear floor area of 400 square feet exclusive of fixed and movable cabinets and shelves. The minimum clear dimension between fixed cabinets and built-in shelves shall be 20 feet. There shall be no direct access between operating rooms.

(C) Operating rooms for cardiovascular, orthopedic, neurological, and other special surgical procedures that require additional personnel and large equipment.

(i) When provided, these rooms shall have a minimum clear floor area of 600 square feet, with a minimum of 20 feet clear dimension exclusive of fixed or wall-mounted cabinets and built-in shelves.

(ii) An additional room shall be provided in the restricted area of the surgical suite, preferably adjoining this operating room, where extra corporeal pumps, supplies and accessories can be stored and serviced.

(iii) When complex orthopedic surgery and neurosurgery are performed, additional rooms shall be provided in the restricted area of the surgical suite, preferably adjoining the specialty operating rooms, for storage of equipment used during these procedures.

(D) Preoperative patient holding areas or rooms. In facilities with two or more operating rooms, a patient holding area or rooms shall be provided. The preoperative patient holding area may be used for secondary recovery. The area shall meet the following requirements.

(i) Clear floor space for private preoperative holding room. The minimum clear floor space in a private preoperative holding room shall be 100 square feet exclusive of aisles and fixed and moveable cabinets and selves. A minimum of nine feet width shall be provided for the head wall.

(ii) Clear floor space for multiple-patient station preoperative holding area. In a multiple-patient station preoperative holding area, the clearance between the side of a gurney and a wall or partition shall be a minimum of three feet. The clearance between sides of gurneys shall be a minimum of six feet. The minimum distance at the foot of the gurney shall not be less than seven feet for single load area or room or ten feet for double load area or room. Four feet of the passage space at the foot of the gurney may be shared between two gurneys. The fixed and moveable cabinets and shelves shall not encroach upon the gurney clear floor space or area.

(iii) Control station. A control station and charting area shall be provided and arranged to permit staff visual observation of holding and preparation area.

(iv) Work counter. A work counter with hand washing fixture with hands-free operable controls shall be provided and located in the preparation area.

(v) Cubicle curtains. Cubicle curtains shall be provided at each station for patient privacy.

(vi) Hand washing fixtures. One hand washing fixture with hands-free operable controls shall be provided for every four

preoperative holding beds or fraction thereof. Fixtures shall be uniformly distributed. One hand washing fixture with hands-free operable controls shall be provided within each single-bed preoperative holding room.

(E) Post-anesthesia care units.

(i) Post-anesthesia care units (PACU) requirements. PACUs for surgical patients shall contain a medication distribution station, nurse station with charting facilities, clinical sink provisions for bedpan cleaning, and storage space for stretchers, supplies, and equipment. The nurse station shall be arranged to permit the staff to have full visual control of the PACU area.

(ii) Patient station. At least one and a half patient stations per operating room shall be provided for post-anesthesia care or fraction thereof. At least two stations shall be provided when there is only one operating room.

(iii) Private recovery room clear floor area. The minimum clear floor space in a private recovery room shall be 130 square feet exclusive of aisles and fixed and moveable cabinets and selves. A minimum of 10 feet width shall be provided for the head wall. The room shall contain cabinets, work counter, and hand washing fixture with hands-free operable controls. The fixed and movable cabinets and shelves shall not encroach upon the gurney clear floor space or area.

(iv) Multiple-gurney recovery patient station area. In multiple-gurney recovery patient stations, the clearance between the side of gurney and a wall or partition shall be a minimum of five feet. The clearance between sides of gurneys shall be a minimum of six feet. The minimum distance at the foot of the gurney shall not be less than eight feet for single load area or room or twelve feet for double load area or room. Four feet of the passage space at the foot of the gurney may be shared between two gurneys. The multi-gurney recovery patient station shall contain cabinets, medication storage, and work counter. The fixed and movable cabinets and shelves shall not encroach upon the gurney clear floor space or area.

(v) Cubicle curtains. Cubicle curtains shall be provided for patient privacy.

(vi) Doors. At least one door to the PACU room shall be within the surgical suite.

(vii) Staff toilets. Staff toilet facilities and a hand washing fixture with hands-free operable controls shall be located within or immediately adjacent to the PACU.

(viii) One hand washing fixture shall be provided for every four recovery beds or fraction thereof in open wards. Fixtures shall be uniformly distributed. One hand washing fixture shall be provided within each single-bed recovery room.

(F) Separation of recovery patients. Provisions shall be made for separating all patients subject to general anesthesia from those who did not receive general anesthesia. This requirement may be satisfied by providing separate recovery rooms, cubicles, secondary recovery rooms, or scheduling of procedures.

(G) Service areas. Services, except for the enclosed soiled workroom and the housekeeping room, may be shared with the obstetrical facilities if the LSRH's functional program reflects this concept. Service areas, when shared with delivery rooms, shall be designed to avoid the passing of patients or staff between the operating room and the delivery room areas.

(i) Control station. A control station located to permit visual surveillance of all traffic entering the surgical suite shall be provided.

(ii) Office. A supervisor's office or station shall be provided.

(iii) Scrub facilities. Two scrub stations shall be located in the restricted corridor within five feet of the entrance of each operating room. Two scrub stations may serve two operating rooms if the scrub stations are located adjacent to the entrance of both operating rooms. Scrub facilities shall be arranged to minimize any incidental splatter on nearby personnel, medical equipment, or supply carts. Viewing panels shall be provided for observation of the surgical room interior. The scrub sinks shall be recessed out of the main traffic areas. The alcove shall be located within the restricted areas of the surgical suite. Scrub sinks shall not be located inside the sterile area.

(iv) Substerile facilities. Sterilizing facilities located conveniently to the operating rooms for immediate or emergency use with work counter shall be provided.

(v) Anesthesia workroom. The anesthesia workroom shall contain a work counter, sink with hands-free operable controls, and storage space for medical gas cylinders and other anesthesia equipment.

(vi) Medication station. Storage and distribution of medication may be done from a medicine preparation room, medicine alcove area, or from a self-contained medicine dispensing unit but must be under visual control of nursing staff. A work counter, hand washing fixture with hands-free operable controls, refrigerator, and double-locked storage for controlled substances shall be provided. Standard cup-sinks provided in many self-contained units are not acceptable for hand washing. The medication station may be shared with the clean work room.

(vii) General storage room. At least 50 square feet per operating room is required for general storage space. The minimum requirement for three operating rooms or less is 150 square feet. This storage room is exclusive of soiled holding, sterile supplies, clean storage, drug storage, locker rooms, and storage alcoves.

(viii) Orthopedic surgery storage. Splints and traction equipment shall be stored in an enclosed storage room. Storage shall be outside the operating room but must be conveniently located.

(ix) Storage alcove. An alcove or alcoves located out of the direct line of traffic shall be provided for the storage of stretchers, portable X-ray equipment, fracture tables, warming devices, auxiliary lamps, etc.

(x) Surgical suite staff clothing change rooms. Appropriately sized areas shall be provided for male and female personnel working within the surgical suite. These areas shall contain lockers, showers, toilets, hand washing fixtures with hands-free operable controls, and space to change into scrub suits and boots. Separate changing rooms shall be provided for male and female staff. The shower and toilet room or rooms may be unisex. These areas shall be arranged to provide a traffic pattern so that personnel entering from outside the surgical suite can shower, change, and move directly into the restricted areas of the surgical suite.

(xi) Lounge. A lounge shall be provided in an LSRH with three or more operating rooms. The lounge shall permit staff use without leaving the surgical suite and may be accessed from the clothing changing rooms. The lounge shall not have direct access from outside the surgical suite. When the lounge is remote from the clothing change rooms, toilet facilities and a hand washing fixture with

hands-free operable controls accessible from the lounge shall be provided.

(xii) Staff toilet facilities. Toilet facilities located in the surgical suite for exclusive staff use shall be provided and contain a hand washing fixture with hands-free operable controls. The toilet room may be accessible from a staff lounge, when provided.

(xiii) Dictation and report preparation area. This may be accessible from the lounge area.

(xiv) Cast room. When a cast room is provided, it shall be equipped with hand washing facilities, plaster sink, storage, and other provisions required for cast procedures. This room may be located in the emergency room.

(xv) Ice machines. An ice machine shall be provided for therapeutic purposes. A self-dispensing ice machine shall be provided for human consumption.

(xvi) Clean workroom or clean supply room. A clean workroom is required when clean materials are assembled within the surgical suite prior to use or following the decontamination cycle. It shall contain a work counter, a hand washing fixture with hands-free operable controls, storage facilities for clean supplies, and a space to package reusable items. The storage for sterile supplies must be in a separate room. When the room is used only for storage and holding as part of a system for distribution of clean and sterile supply materials, the work counter and hand washing fixture are not required.

(xvii) Sterile core. When a surgical suite contains a sterile core, it shall be free of any cross-traffic of staff and supplies from the soiled or decontaminated areas to the sterile or clean areas. The use of facilities outside the operating room for soiled or decontaminated processing, clean assembly and sterile processing shall be designed to move the flow of goods and personnel from dirty to clean without compromising universal precautions or aseptic techniques in both departments.

(xviii) Soiled workroom. The soiled workroom shall contain a clinical sink or equivalent flushing type fixture, work counter, hand washing fixture with hands-free operable controls, waste receptacle, and linen receptacle. The clinical sink and work counter may be eliminated if the room is used only for temporary holding of soiled material and cleaning of equipment and instruments and sterilization is provided outside the surgical suite. Provisions shall be made for the disposal of liquid waste. The soiled workroom shall be provided for the exclusive use of the surgical suite, shall be located in the restricted area of the surgical suite, and shall not have direct connection with operating rooms, delivery rooms, or other sterile activity rooms.

(xix) Housekeeping room. A housekeeping room containing a floor receptor or service sink and storage space for housekeeping supplies and equipment shall be provided for the exclusive use of the surgical suite and shall be directly accessible from the surgical suite.

(2) Details and finishes. Details and finishes shall comply with §511.162(d)(2) of this subchapter and this paragraph.

(A) Details.

(i) Ceiling height. Operating rooms shall have ceiling heights not less than nine feet.

(ii) Noise minimization. Recreation rooms, exercise rooms, equipment rooms, and similar spaces where impact noises may be generated shall not be located directly over operating suites, unless special provisions are made to minimize such noise.

(B) Finishes.

(i) Flooring. Flooring within operating rooms, soiled workrooms and sterile processing rooms shall be of the seamless type as required by §511.162(d)(2)(B)(iii)(III) of this subchapter.

(ii) Walls. Walls in operating rooms, special procedures rooms, and soiled workrooms shall comply with the requirements of §511.162(d)(2)(B)(iv)(II) of this subchapter.

(iii) Ceilings. Ceilings in operating rooms, isolation rooms, soiled workroom, and sterile processing rooms shall be monolithic as required by §511.162(d)(2)(B)(vi)(III) of this subchapter.

(3) Mechanical requirements. Mechanical requirements shall comply with §511.162(d)(3) of this subchapter and this paragraph.

(A) Air supply for the operating rooms shall be from ceiling outlets near the center of the work area to efficiently control air movement. At least two return air inlets located diagonally opposite from one another and near floor level shall be provided. Design should consider turbulence and other factors of air movement to minimize airborne particulate matter. Where extraordinary procedures require special designs, the installation shall be reviewed on a case-by-case basis.

(B) Smoke removal systems shall be provided in accordance with §511.162(d)(3)(D)(iv)(II) of this subchapter.

(C) The ventilation system for anesthesia storage rooms and medical gases storage shall conform to the requirements of Chapter 5, NFPA 99 §5.1.3.3.3.

(D) Each operating room, PACU, and recovery room shall be provided with conveniently mounted temperature and humidity indicating devices.

(4) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall comply with §511.162(d)(4) of this subchapter and this paragraph.

(A) General.

(i) Drainage and waste piping shall not be installed above or below ceilings in operating rooms, and sterile processing rooms unless precautions are taken to protect the space below from leakage and condensation from necessary overhead piping. Any required secondary protection shall be labeled, "code required secondary drain system" every 20 feet in a highly visible print or label.

(ii) Floor drains shall not be installed in operating rooms. Flushing rim type floor drains may be installed in cystoscopic operating rooms. If a floor drain is installed in cystoscopy, it shall contain a nonsplash, horizontal-flow flushing bowl beneath the drain plate.

(iii) Sinks used for the disposal of plaster of paris shall have plaster trap.

(B) Medical gas systems. Medical gas systems and outlets that comply with §511.162(d)(4)(A)(iii) and Table 6 of §511.169(f) of this subchapter shall be provided.

(5) Electrical requirements. Electrical requirements shall comply with §511.162(d)(5) of this subchapter and this paragraph.

(A) General.

(i) X-ray film illuminators for handling at least four films simultaneously shall be provided in each operating room. When the entire surgical suite is provided with digital imaging system capabilities, at least two X-ray film illuminator viewers shall be provided. The film illuminators shall be mounted within the central area of the suite.

(ii) Each operating room shall have at least eight duplex electrical hospital grade receptacles of which three shall be located convenient to the head of the procedure table. Each PACU recovery station shall have at least seven receptacles at the head of each patient station.

(iii) Special grounding system for critical care areas such as operating rooms, and special procedure rooms where patients are subjected to invasive procedures and connected to line-operated, electromedical devices shall comply with NFPA 99 Chapter 9 and NFPA 70 Article 517.

(iv) Operating rooms and special procedure rooms shall have general lighting in addition to that provided by special lighting units at the surgical tables. Each fixed special lighting unit at the operating or delivery table shall be connected to an independent circuit powered by the critical branch of the essential electrical system. Portable units may share circuits. At least one general lighting fixture shall be served from a normal branch panel.

(v) Operating rooms shall be provided with one or more battery-powered emergency lighting units as required by NFPA 99 §13.4.1.2.6(E).

(vi) Operating rooms shall be provided with at least one receptacle powered from a normal power panel. Receptacle shall be labeled, "Normal power receptacle, use only in the event of loss of critical system."

(B) Nurses calling system. The nurse call shall comply with §511.162(d)(5)(L) and Table 7 of §511.169(g) of this subchapter.

(y) Labor, Delivery, and Recovery (LDR).

(1) When provided, each LDR room shall have controlled access and shall be located so that a patient may be transported to the caesarean section operating room without the need to pass through other functional areas.

(2) Each LDR room shall be designed for single occupancy and have a minimum clear floor area of 200 square feet exclusive of the infant resuscitation area, built-in shelves or cabinets, alcove, vestibule or other adjoining rooms. The minimum clear room dimension shall not be less than 11 feet.

(3) A hand washing fixture with hands-free operable controls shall be provided in each LDR room.

(4) Each LDR shall have direct access to and exclusive use of a bathroom with a shower, or tub with shower, hand washing fixture with hands-free operable controls and a toilet.

§511.164. Elevators, Escalators, and Conveyors.

(a) General. All limited services rural hospitals (LSRHs) with two or more floor levels shall have at least one electrical or electrical hydraulic elevator. Elevators shall also give access to all building levels normally used by the public. Escalators and conveyors are not required but, when provided, shall comply with these requirements and the requirement of §18.3 of the National Fire Protection Association (NFPA) 101, Life Safety Code, 2012 edition.

(b) Requirements for new elevators, escalators, and conveyors. New elevators, escalators and conveyors shall be installed in accordance with the requirements of A17.1 Safety Code for Elevators and Escalators, 2012 edition, published by the American Society of Mechanical Engineers (ASME) and the American National Standards Institute (ANSI).

(1) Cars and doors.

(A) Cars of hospital type elevators for patient transport shall not be less than five feet eight inches wide and not less than eight feet six inches deep inside the cab.

(B) The car door opening shall not be less than four feet wide and seven feet high.

(C) Elevator doors shall be B-labeled one-hour fire protection rated doors in buildings less than four stories, and one and one-half hour fire protection rated doors in buildings four or more stories.

(2) Type of controls and alarms. Elevator cab lighting, control, communication, and signal systems shall be connected in accordance with NFPA 99 §4.4.2.2.2.2, 2012 edition.

(3) Location. Conveyors, elevators, dumbwaiters, and pneumatic conveyors serving various stories of a building shall not open to an exit.

(4) Elevator machine rooms. Elevator machine rooms that contain solid-state equipment for elevators having a travel distance of more than 50 feet above the level of exit discharge or more than 30 feet below the level of exit discharge shall be provided with independent ventilation or air conditioning systems required to maintain temperature during fire fighters' service operation for elevator operation. The operating temperature shall be established by the elevator equipment manufacturer's specifications and shall be posted in each such elevator machine room. When standby power is connected to the elevator, the machine room ventilation or air conditioning shall be connected to standby power.

(c) Requirements for existing elevators, escalators, and conveyors. Existing elevators, escalators, and conveyors shall comply with ASME/ANSI A17.3, Safety Code for Existing Elevators and Escalators, 2008 edition. All existing elevators having a travel distance of 25 feet or more above or below the level that best serves the needs of emergency personnel for fire-fighting or rescue purposes shall conform to Fire Fighters' Service Requirements of ASME/ANSI A17.3 as required by NFPA 101 §9.4.3.

(d) Testing. All elevators and escalators shall be subject to routine and periodic inspections and tests as specified in ASME/ANSI A17.1, Safety Code for Elevators and Escalators, 2007 edition. All elevators equipped with fire fighter service shall be subject to a monthly operation with a written record of the findings made and kept on the premises as required by NFPA 101 §9.4.6.

(e) Certification. A certificate of inspection evidencing that the elevators, escalators, and related equipment were inspected in accordance with the requirements in Texas Health and Safety Code (HSC) Chapter 754 (relating to Elevators, Escalators, and Related Equipment), and determined to be in compliance with the safety standards adopted under HSC §754.014 and administered by the Texas Department of Licensing and Regulation shall be on record in each LSRH.

(f) Where an LSRH has more than one floor, at least two elevators shall be provided.

§511.165. Building with Multiple Occupancies.

(a) Multiple hospitals located within one building.

(1) Identifiable location. Each hospital shall conform with all the requirements contained in Chapter 18 of the National Fire Protection Association 101, Life Safety Code, 2012 edition (NFPA 101), relating to New Health Care Occupancies.

(A) The guest hospital shall be in one separately contiguous location.

(B) In no case may a person leave the guest hospital, traverse the host hospital, and then reenter the guest hospital to access the remaining portion of the guest hospital.

(C) A connecting stair within the host hospital may be used to connect the vertical contiguous areas of the guest hospital.

(D) A guest hospital may not occupy two or more non-contiguous areas of a host hospital that contain intervening space of the host hospital even if on the same floor.

(E) Construction of the host hospital building shall conform to the requirements of NFPA 101 Chapter 18, and the building shall be fully sprinklered.

(2) Separate facilities. Each limited services rural hospital (LSRH) shall provide the following separate facilities:

(A) a nursing unit in accordance with the requirements of §511.163(q) of this subchapter (relating to Spatial Requirements);

(B) an administration office with an adjacent waiting room or waiting area;

(C) a medical records room that conforms with the requirements of §511.163(m) of this subchapter;

(D) a pharmacy suite that complies with §511.163(s) of this subchapter;

(E) employee locker facilities that comply with requirements of §511.163(f)(1) of this subchapter;

(F) a housekeeping room that complies with the requirements of §511.162(d)(2)(A)(xxviii) of this subchapter (relating to Construction Requirements);

(G) emergency facilities as required by §511.163(e)(1)(A) of this subchapter;

(H) imaging and other diagnostic services and facilities, in accordance with §511.46 of this chapter (relating to Radiological Services) and §511.163(j) of this subchapter respectively;

(I) laboratory services and a laboratory suite that comply with §511.163(k) of this subchapter, and §511.45 of this chapter (relating to Laboratory Services) of this chapter respectively;

(J) where surgical services are provided, a surgical suite in accordance with §511.163(x) of this subchapter;

(K) dietary services and dietary suite, including staff dining facilities, which comply with §511.53 of this chapter (relating to Dietary Services) and §511.163(d) of this subchapter respectively;

(L) external signage at the building entrance that identifies each hospital; and

(M) internal signage that provides directions to each hospital.

(3) Means of egress. Means of egress from the host or guest hospital shall not be through a psychiatric hospital or a crisis stabilization unit or other area subject to locking. Means of egress may traverse through a hospital that conforms with the requirements of §511.161 of this subchapter (relating to Requirements for Buildings in Which Existing Licensed Hospitals are Located) or §511.162 of this subchapter. Stairs must have guardrails from the floor of the guest hospital to the level of exit discharge in accordance with NFPA 101 §7.2.2.4.5.

(4) Additional services and facilities. Additional services and facilities when required in each licensed hospital may be provided by contractual agreement with the other hospital when the services and facilities comply with the specific requirements of Subchapter C of this chapter (relating to Operational Requirements) and §511.163 of this subchapter. Some services may be provided by contractual agreement with a commercial contractor; however, the following minimal facilities shall be provided on site by the host hospital and be located in one of the hospitals. If the host hospital fails to provide the facilities and services, the guest hospital shall describe to the Texas Health and Human Services Commission (HHSC) how it plans to provide services:

(A) cart cleaning and sanitizing services and facilities that comply with §511.163(b) of this subchapter;

(B) general storage services and facilities that comply with §511.163(h) of this subchapter;

(C) housekeeping rooms as required in §511.162(d)(2)(A)(xxviii) of this subchapter;

(D) parking facilities, in accordance with §511.162(c)(2) of this subchapter;

(E) physical therapy, occupational therapy services and facilities, or both in accordance with §511.57 of this chapter (relating to Therapy Services), and §511.163(u) of this subchapter respectively;

(F) patient activity facilities shall comply with the requirements for the specific service in accordance with §511.163 of this subchapter as follows: mental health and chemical dependency nursing units §511.163(n)(1) and rehabilitation therapy suite §511.163(u)(1)(A)(i) and (ii) of this subchapter;

(G) respiratory care services and respiratory therapy suite that comply with §511.70 of this chapter (relating to Respiratory Care Services) and §511.163(v) of this subchapter respectively;

(H) body-holding room that complies with §511.163(o)(1)(D) of this subchapter;

(I) central sterile supply that complies with §511.163(c) of this subchapter respectively;

(J) waste and waste disposal services and waste processing and storage units shall comply with §511.71 of this chapter (relating to Waste and Waste Disposal); and

(K) emergency water storage requirement in Texas Administrative Code Title 25 §133.162(d)(4)(A)(i)(VIII) shall be required for the LSRH and the hospital and be located in either the LSRH or other hospital.

(5) Building systems and equipment.

(A) The following systems shall be provided separately in each hospital at a 24-hour staffed location.

(i) Nurses calling systems shall be provided separately in each hospital in accordance with §511.162(d)(5)(L) and Table 7 in §511.169(g) of this subchapter (relating to Tables).

(ii) Medical gas alarms shall be provided in each hospital.

(iii) Fire alarm annunciator panels shall be provided in each hospital so that each hospital can monitor the other.

(iv) An emergency generator annunciator panel shall be provided in each hospital.

(B) Where applicable, the following systems may serve more than one hospital provided the systems meet the new construction requirements of §511.162 of this subchapter.

(i) Air conditioning, heating, and ventilating systems.

(ii) Drainage systems.

(iii) Elevators.

(iv) Fire sprinkler systems. The guest hospital may not be constructed in a host hospital when the host hospital is not fully sprinklered. The host and guest hospitals shall be fully sprinklered.

(v) Medical piping systems.

(vi) Stand pipe systems.

(vii) Steam systems.

(viii) Water supply systems, hot and cold (including emergency water storage).

(ix) Electrical service and equipment.

(I) Where applicable, the building electrical service, lighting, essential electrical system, and fire alarm system may be a part of or extension of those in the existing hospital, provided the existing systems meet these requirements. The host hospital shall be responsible for maintenance, testing and upkeep of the essential electrical system. Power and lighting distribution panels shall be within each hospital served and comply with the requirements of §511.162(d)(5)(E) of this subchapter. Electrical installation details shall conform with all requirements contained in §511.162(d)(5)(A) of this subchapter.

(II) When the existing essential electrical system is nonconforming, the following options are available:

(-a-) a separate conforming essential electrical system shall be provided in the guest hospital; or

(-b-) separate transfer switches connected to the existing on-site generator(s) shall be provided when adequate capacity is available and the host hospital existing nonconforming system shall be corrected. Corrections shall be made in accordance with a plan of correction approved by HHSC.

(b) LSRHs located in buildings with licensed health care facilities other than hospitals.

(1) Before an LSRH is licensed in a building containing other licensed health care facilities, all the requirements of this chapter and the following requirements shall be met.

(A) Construction of the building shall conform to the requirements of NFPA 101 Chapter 18 and the building shall be fully sprinklered.

(B) The LSRH shall be in one identifiable contiguous location and shall be separated (vertically and horizontally) with two-hour fire rated noncombustible construction from the other licensed health care facility and comply with the requirements of this chapter.

(i) In no case may a person leave the LSRH, traverse other licensed health care facilities, and then reenter the LSRH to access the remaining portion of the hospital.

(ii) A connecting stair and elevator within the building shall be provided to connect the vertical contiguous areas of the LSRH.

(iii) An LSRH may not occupy two or more noncontiguous areas of other licensed health care facilities that contain intervening space of the other licensed health care facilities even if on the same floor.

(iv) Access to the LSRH shall be directly from a main lobby or an elevator lobby, if on an upper floor. The required means of egress from the LSRH may be through the other licensed health care facility except not through a psychiatric hospital or a crisis stabilization unit or other area subject to locking.

(I) Each licensed facility shall be identified with external signage at the building entrance.

(II) Internal signage shall provide direction to the LSRH.

(v) The LSRH shall have services and facilities separate from the other licensed health care facility. The required facilities shall be located within the proposed LSRH proper.

(vi) Common use of facilities using time-sharing concepts may be permitted on a case-by-case basis when the other health care facilities comply with the requirements contained in NFPA 101 Chapter 18 and §511.163 of this subchapter, and provided this chapter and the other health care facility licensing regulations allow.

(C) The equipment and systems required in each new LSRH may be provided exclusively for the LSRH or by contractual agreement with a licensed health care facility. The equipment and systems shall comply with §511.162 of this subchapter.

(i) The following equipment and systems shall be provided for the exclusive use of the LSRH, except where noted otherwise.

(I) Where the LSRH is served by the building's normal electrical system, the breaker serving the LSRH shall originate in the main switchboard and shall be labeled, "Hospital Service - Contact Hospital Representative Prior to Opening Breaker".

(II) The LSRH distribution panel board shall be within the LSRH.

(III) An electrical room for the distribution of type I essential electrical system shall be provided separate from the building electrical room. The LSRH staff shall have access at all times to the essential electrical system room and the building's electrical room. The LSRH shall be responsible for maintenance, testing, and upkeep of the essential electrical system. When the existing essential electrical system owned and operated by the other licensed health care facility is nonconforming, the following options are available:

(-a-) a separate conforming essential electrical system shall be provided in the new LSRH; or

(-b-) separate transfer switches connected to the existing on-site generator shall be provided when adequate capacity is available and the other health care facility existing nonconforming system shall be corrected. Corrections shall be made in accordance with a plan of correction approved by HHSC.

(IV) An emergency generator may be shared when adequate capacity is available. Separate transfer switches shall be provided to serve the LSRH and other licensed health care facilities. The LSRH shall be the owner of the generator, have access to the generator at all times, and shall be responsible for maintenance, testing and upkeep of the generator.

(V) The LSRH shall meet the emergency water storage requirement under 25 TAC §133.162(d)(4)(A)(i)(VIII) and the storage shall be located within the LSRH.

(VI) When the other licensed health care facilities have a fire alarm control center or a main building alarm panel at the main lobby entrance, the LSRH shall have an annunciator panel at a 24-hour staffed location. The LSRH staff shall have access at all times to the main building fire alarm system panels and shall be responsible for verifying the maintenance and upkeep of such system.

(VII) Fireman's test valve for the fire sprinkler system.

(VIII) Air conditioning, heating, and ventilating systems.

(IX) The medical gas supply sources may be shared provided the LSRH is owner of the medical gas system source and is responsible for maintenance, testing and upkeep of the supply sources. The LSRH and other occupancies shall have separate main supply shutoff valves. The LSRH shall be provided with an alarm panel within the LSRH that monitors the medical gas system supply source serving the other licensed health care facilities.

(X) Medical vacuum and medical air.

(XI) Nurses calling systems.

(ii) Where applicable, the following systems may be a part or extension of those in the existing licensed health care facility, provided the existing systems meet the requirements of this chapter for new construction.

(I) Drainage systems.

(II) The LSRH shall be served by the number and size of elevators cabs in accordance with §511.164 of this subchapter (relating to Elevators, Escalators, and Conveyors). The elevators cab lighting, control, communication, and signal systems shall be connected to the life safety panel of the essential electrical system.

(III) The new LSRH may not be constructed in the other health care facility when the other health care facility is not fully sprinklered. The new LSRH and the other health care facility shall be fully sprinklered.

(IV) Stand pipe systems.

(V) The LSRH is responsible for providing all backup systems (such as boilers) as required in this chapter.

(VI) Domestic water supply systems, hot and cold.

(VII) Mechanical chilled and hot water systems.

(2) When an LSRH and a psychiatric hospital share one building, the building systems and equipment may be shared in accordance with subsection (a)(5)(B) of this section, or be provided separately.

(c) LSRHs in buildings with non-health care occupancies.

(1) General. Before an LSRH is licensed in a building also containing occupancies other than health care occupancies, all requirements of this chapter and the following requirements shall be met.

(A) Construction of the building shall conform to the requirements of NFPA 101 Chapter 18, and the building shall be fully sprinklered.

(B) The LSRH shall be in one identifiable contiguous location and shall be separated (vertically and horizontally) with two-hour fire rated noncombustible construction from the other occupancies.

(i) In no case may a person leave the LSRH, traverse other occupancies, and then reenter the LSRH to access the remaining portion of the LSRH.

(ii) A connecting stair and elevator within the building shall be provided to connect the vertical contiguous areas of the LSRH.

(iii) An LSRH may not occupy two or more noncontiguous areas of other occupancies that contain intervening space of the other occupancies even if on the same floor.

(C) Access to the LSRH shall be through a dedicated LSRH lobby or from the building's main lobby. The building's main lobby shall be part of the LSRH and shall comply with the requirements of §511.162 of this subchapter.

(i) External signage shall be provided at the building entrance that identifies the LSRH.

(ii) Internal signage shall be provided to give directions to the LSRH.

(D) The required means of egress from the LSRH shall be independent of and shall not traverse through the other occupancies.

(E) Stairs shall have guardrails and handrails from the floor of the LSRH to the level of exit discharge in accordance with NFPA 101 §7.2.2.4.5.

(2) Services and facilities. Services and facilities shall be provided exclusively for the LSRH in accordance with Subchapters C and F of this chapter (relating to Operational Requirements and Fire Prevention and Safety respectively) and this subchapter. Required services and facilities shall not be shared with the other occupancies except as noted in paragraph (3) of this subsection.

(3) Building equipment and facilities. The equipment and systems shall comply with §511.162 of this subchapter.

(A) The following equipment and systems shall be provided for the exclusive use of the LSRH except where noted otherwise.

(i) An electrical room for the distribution of type I essential electrical system shall be provided separate from the building electrical room. LSRH staff shall have access at all times to the essential electrical system room and the building's electrical room or rooms. The LSRH is responsible for maintenance, testing and upkeep of the essential electrical system.

(ii) An emergency generator may be shared when adequate capacity is available. Separate transfer switches shall be provided to serve the LSRH and other building occupancies. The LSRH shall be the owner of the generator, have access to the generator at all times, and shall be responsible for maintenance, testing and upkeep of the generator.

(iii) Emergency water storage located within the LSRH.

(iv) When the building has a fire alarm control center or a main building alarm panel at the main lobby entrance, the LSRH shall have an annunciator panel at a 24-hour staffed location. The LSRH staff shall have access at all times to the main building fire alarm system panels and shall be responsible for verifying the maintenance and upkeep of such system.

(v) Fireman's test valve for the fire sprinkler system.

(vi) The medical gas supply sources may be shared provided the LSRH is owner of the medical gas system supply source and is responsible for maintenance, testing, and upkeep of the supply sources. The LSRH and other occupancies shall have separate main supply shutoff valves. The LSRH shall be provided with an alarm panel within the LSRH that monitors the medical gas system serving the other occupancies.

(vii) Medical vacuum and medical air.

(viii) Air handling units of other occupancies may not be used for the LSRH. The LSRH air handling units may share the supply source for other occupancies but shall not return air from the other occupancies back to the air handling unit.

(ix) Nurses calling systems.

(B) Where applicable, the following systems may be a part or extension of those in the existing building occupancies provided the existing systems meet the requirements of this chapter for new construction.

(i) Where the LSRH is served by the building's normal electrical system, the breaker serving the LSRH shall originate in the main switchboard and shall be labeled, "Hospital Service - Contact Hospital Representative Prior to Opening Breaker."

(ii) The LSRH's distribution panelboard shall be within the LSRH.

(iii) Drainage systems.

(iv) The LSRH shall be served by the number and size of elevators cabs in accordance with §511.164 of this subchapter. The elevators cab lighting, control, communication, and signal systems shall be connected to the life safety panel of the essential electrical system.

(v) The LSRH may not be constructed in the other type of building occupancies when the other types of occupancies are not fully sprinklered. The LSRH and the other occupancies shall be fully sprinklered.

(vi) Stand pipe systems.

(vii) Fire pump, where applicable; LSRH staff shall have access at all times to the location of the fire pump to verify compliance and maintenance.

(viii) The LSRH is responsible for providing all backup systems (such as boilers) that are required in this chapter.

(ix) Domestic water supply systems, hot and cold.

§511.166. Mobile, Transportable, and Relocatable Units.

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

(1) Mobile unit--Any pre-manufactured structure, trailer, or self-propelled unit equipped with a chassis on wheels and intended to provide shared medical services to the community on a temporary basis. Some of these units are equipped with expanding walls and designed to be moved on a daily basis.

(2) Relocatable unit--Any structure, not on wheels, that is built to be relocated at any time and provide medical services. These structures vary in size.

(3) Transportable unit--Any pre-manufactured structure or trailer, equipped with a chassis on wheels, intended to provide shared medical services to the community on an extended temporary basis. These units are designed to be moved periodically, depending on need.

(b) General. When mobile, transportable, and relocatable units are utilized to provide patient treatment services on the limited services rural hospital (LSRH) premises, these units shall be treated as buildings and constructed to the required occupancy as follows.

(1) When such units are provided for diagnostic, treatment, or procedural services to patients who are litter borne, under general anesthesia, or incapable of self-preservation, the unit shall be constructed in accordance with Chapter 18 of the National Fire Protection Association (NFPA) 101, Life Safety Code, 2012 edition, relating to health care occupancy.

(2) When such units provide diagnostic, treatment, or procedural services to patients who are not litter borne, not under general anesthesia, and are capable of self-preservation, the unit may be constructed in accordance with Chapter 38 of NFPA 101 (relating to Business Occupancy).

(c) Common elements.

(1) Site requirements.

(A) Sites shall have a level concrete or asphalt pad and be designed for the structural loads of the unit.

(B) The sites shall provide hazard-free drop-off zones and adequate parking for patients. The site and location of the unit shall not restrict access for fire or emergency vehicles.

(C) Each site shall provide access to the unit for people with disabilities, and wheelchair and stretcher patients.

(D) When a mobile, transportable, or relocatable unit is not physically attached to the LSRH and provides inpatient services, a covered walkway or enclosure from the LSRH to the unit shall be provided to ensure patient safety from the outside elements.

(E) The location of the unit shall be such that engine exhaust fumes from the unit are kept away from any fresh air intake of the LSRH.

(F) When a mobile, transportable, or relocatable unit is permanently connected appropriately for the climate to the LSRH or the unit does not move on a regular basis, e.g., every 90 days or less, the units shall be provided with the following equipment and systems connected to the LSRH:

(i) fire alarm system;

(ii) sprinkler system;

(iii) electrical system and the essential electrical system;

(iv) water and waste water system;

(v) medical gas systems; and

(vi) nurses calling systems.

(2) Support services. Support services shall meet the requirements of this chapter for new construction. These support services and areas shall be provided either within the mobile, transportable, or relocatable unit or located within the LSRH adjacent to the unit served.

(3) Details and finishes. Details and finishes shall comply with §511.162(d)(2) of this subchapter (relating to General Construction Requirements).

(4) Mechanical requirements. Mechanical requirements comply with §511.162(d)(3) of this subchapter.

(5) Piping systems and plumbing fixtures. Piping systems and plumbing fixtures shall comply with §511.162(d)(4) of this subchapter.

(6) Electrical requirements. Electrical requirements shall comply with §511.162(d)(5) of this subchapter.

§511.167. Preparation, Submittal, Review, and Approval of Plans, and Retention of Records.

(a) General.

(1) A limited services rural hospital (LSRH) owner or operator may not begin construction of a new building, additions to or renovations, or conversions of existing buildings until the Texas Health and Human Services Commission (HHSC) approves final construction documents.

(2) Plans and specifications describing the construction of new buildings and additions or renovations and conversions of existing buildings shall be prepared by a registered architect, a licensed professional engineer, or both, and meet the requirements of this subchapter.

(3) The names of spaces used in the LSRH's functional program narrative, preliminary documents, final construction documents, and specifications shall be consistent with the names of the spaces used in this chapter.

(4) HHSC shall notify the LSRH's owner or operator of the result of its review of each type of submission discussed in this section.

(5) The LSRH owner or operator shall respond to all HHSC requests for additional information, including providing a plan of correction for deficiencies cited by HHSC.

(6) Once final construction documents are approved, the LSRH owner or operator shall request inspections in accordance with §511.168 of this subchapter (relating to Construction, Inspections, and Approval of Project).

(7) When construction is delayed for longer than one year from the plan approval or self-certification approval date, the LSRH shall resubmit construction documents to HHSC for review and approval. The plans shall be accompanied by a new Application for Plan Review, plan review fee, and functional program narrative.

(8) The LSRH owner or operator shall provide written notification to HHSC when a project has been placed on hold, canceled, or abandoned.

(9) HHSC may close a project file after one year of assigning an application number to a project if the LSRH has placed the project on hold. Plan review fees are nonrefundable.

(b) Submission of projects and assignment of application number.

(1) The LSRH owner or operator or representative shall submit the following items to HHSC in care of the mailing or overnight delivery address that appears on the Application for Plan Review.

(A) A completed and signed Application for Plan Review. The Application for Plan Review may be obtained by contacting the HHSC Health Care Regulation Department Architectural Review Unit (ARU) using the contact information listed on the HHSC website.

(B) The applicable plan review fee in accordance with §511.17 of this chapter (relating to Fees).

(C) A functional program narrative in accordance with subsection (d) of this section.

(D) Final construction documents in accordance with subsection (f) of this section.

(2) The cost of submitting documents and plans and specifications shall be borne by the sender.

(3) Once HHSC has determined that the submission required in paragraph (1) of this subsection is complete, HHSC will assign an application number to the project that must be referenced on all documents and correspondence related to the project. HHSC will review final construction documents in the chronological order received.

(4) The LSRH shall satisfactorily resolve all deficiencies noted in the final plan review before HHSC will grant approval of the project for construction.

(5) The LSRH shall not begin construction until the LSRH owner or operator receives written notification from HHSC that the final construction documents have been approved.

(c) Feasibility conference. An LSRH owner or operator or representative may request a feasibility conference, which is an informal meeting between a member of ARU staff and the LSRH owner or operator or representative, to determine the feasibility of a project, for consultation and informational purposes, and to facilitate and establish understanding of compliance with the rules and codes.

(1) A feasibility conference is not a substitute for plan review.

(2) An LSRH owner or operator or representative may schedule a feasibility conference by contacting ARU using the contact information listed on the HHSC website.

(3) The LSRH owner or operator or representative shall provide at the feasibility conference the items in subsection (b)(1)(A) - (C) of this section and a set of preliminary plans or final construction documents.

(4) The LSRH owner or operator or representative is responsible for recording conference notes and shall submit the notes to HHSC.

(d) Functional program narrative. The LSRH owner or operator or representative shall submit a functional program narrative to HHSC with each new project in accordance with subsection (b)(1)(C) of this section. The functional program narrative shall be presented on facility letterhead, signed by LSRH administration, include the functional description of each space, and the following:

(1) departmental relationships, number of patient stations in each category, and other basic information relating to the fulfillment of the LSRH's objectives;

(2) a description of each function to be performed, approximate space needed for these functions, occupants of the various spaces, projected occupant load, types of equipment required, interrelationship of various functions and spaces, and any special design features;

(3) energy conservation measures, included in building, mechanical and electrical designs;

(4) a description of the type of asepsis control in diagnostic and treatment areas; and

(5) the type of construction (existing or proposed) as stated in Table 18.1.6.2 of National Fire Protection Association 101, Life Safety Code, 2012 edition (NFPA 101).

(e) Preliminary documents. HHSC may request preliminary documents. If requested by HHSC, the submission shall consist of the items in subsection (b)(1)(A) - (C) of this section, preliminary plans, and outline specifications. The documents shall contain sufficient information to establish the project scope, description of functions to be performed, project location, required fire safety and exiting requirements, building construction type, compartmentation showing fire and smoke barriers, patient station count and services, and the usage of all spaces, areas, and rooms on every floor level.

(f) Final construction documents. Final construction documents and specifications shall be submitted to HHSC for review and approval prior to start of construction. All final documents and specifications shall be appropriately sealed and signed by the project registered architect and professional engineer licensed by the state of Texas.

(1) Submission of final construction documents. The LSRH owner or operator shall submit to HHSC for review and approval the items in subsection (b)(1)(A) - (C) of this section (if not previously submitted with preliminary documents) and one set of final construction documents and specifications covering the construction of new buildings or alterations, additions, conversions, modernizations, or renovations to existing buildings.

(2) Preparation of final construction documents. Construction documents shall be well-prepared so that clear and distinct prints may be obtained, shall be accurately and adequately dimensioned, and shall include all necessary explanatory notes, schedules, and legends and shall be adequate for contract purposes. Compliance with model building codes and this chapter shall be indicated. The type of construction, as classified by National Fire Protection Association 220, Standard on Types of Building Construction, 2012 edition, shall be provided for existing and new facilities. Final plans shall be drawn to a sufficiently large-scale to clearly illustrate the proposed design but not less than one-eighth inch equals one foot. All spaces shall be identified by usage (using the names of spaces used in this chapter) on all plans (architectural, fire safety, mechanical, electrical, etc.) submitted. Separate drawings shall be prepared for each of the following branches of work.

(A) Architectural plans. Architectural drawings shall include the following.

(i) A map of the area within a two-mile radius of the facility site with any hazardous and undesirable location noted in §511.162(a) of this subchapter (relating to General Construction Requirements) identified.

(ii) A site plan showing all new topography, newly established levels and grades, existing structures on the site (if any), new buildings and structures, roadways, parking, walks, easement, overhead or underground utilities or service lines, and the extent of the areas to be landscaped. All structures that are to be removed under the construction contract and improvements shall be shown. A general description of the immediate area surrounding the site shall be provided.

(iii) A plan of each floor and roof to include fire and smoke separation, means of egress, and identification of all spaces.

(iv) Schedules of doors, windows, and finishes.

(v) Elevations of each facade.

(vi) Sections through building.

(vii) Scaled details as necessary.

(B) Fire safety plans. These drawings shall be provided for all newly constructed buildings, conversions of existing buildings for facilities, additions to existing licensed facilities, and remodeled portions of existing buildings containing licensed facilities. Fire safety plans shall be of a sufficiently large-scale to clearly illustrate the proposed design but not less than one-sixteenth inch equals one foot and shall include the following information:

(i) separate fire safety plans (preferably one floor plan per sheet) shall indicate location of fire protection-rated walls and partitions, location and fire resistance rating of each fire damper, and the required means of egress (corridors, stairs, exits, exit passageways);

(I) when a new building is to contain a proposed facility, when an existing building is converted to a facility, or when an addition is made to an existing facility building, plans of each floor and roof shall be provided; and

(II) when a portion of a building is remodeled or when a new service is added, only the plan of the floor where the remodeling will take place or new service will be introduced and the plan of the floor of discharge shall be provided;

(ii) designated smoke compartments with floor areas of each compartment, location and fire resistance rating (one or two hour) of each smoke partition, and location, type, and fire resistance rating of each smoke damper;

(iii) location of all required fire alarm devices, including all fire alarm control panels, manual pull stations, audible and visual fire alarm signaling devices, smoke detectors (ceiling and duct-mounted), fire alarm annunciators, fire alarm transmission devices, fire sprinkler flow switches and control valve supervisory switches on each of the floor plans; and

(iv) areas protected with fire sprinkler systems (pendant, sidewall or upright, normal or quick response, and temperature rating shall be indicated), stand pipe system risers and sizes with valves and inside and outside fire department connections, fire sprinkler risers and sizes, and location and type of portable fire extinguishers.

(C) Equipment drawings. Equipment drawings shall include the following.

(i) All equipment necessary for the operation of the facility as planned. The design shall indicate provisions for the installation of large and special items of equipment and for service accessibility.

(ii) Fixed equipment (equipment that is permanently affixed to the building or that must be permanently connected to a service distribution system designed and installed during construction for the specific use of the equipment). The term "fixed equipment" includes items such as laundry extractors, walk-in refrigerators, communication systems, and built-in casework (cabinets).

(iii) Movable equipment (equipment not described in clause (ii) of this subparagraph as fixed). The term "moveable equipment" includes wheeled equipment, plug-in type monitoring equipment, and relocatable items.

(iv) Equipment that is not included in the construction contract but that requires mechanical or electrical service connections or construction modifications. The equipment described in this clause shall be identified on the drawings to ensure its coordination with the architectural, mechanical, and electrical phases of construction.

(D) Structural drawings. Structural drawings shall include:

(i) plans for foundations, floors, roofs, and all intermediate levels;

(ii) a complete design with sizes, sections, and the relative location of the various members;

(iii) a schedule of beams, girders, and columns;

(iv) dimensioned floor levels, column centers, and offsets;

(v) details of all special connections, assemblies, and expansion joints; and

(vi) special openings and pipe sleeves dimensioned or otherwise noted for easy reference.

(E) Mechanical drawings. Mechanical drawings shall include:

(i) complete ventilation systems (supply, return, exhaust), all fire and smoke partitions, locations of all dampers, registers, and grilles, air volume flow at each device, and identification of all spaces (e.g., corridor, patient room, operating room);

(ii) boilers, chillers, heating and cooling piping systems (steam piping, hot water, chilled water), and associated pumps;

(iii) cold and warm water supply systems, water heaters, storage tanks, circulating pumps, plumbing fixtures, emergency water storage tank(s) (if provided), and special piping systems such as for deionized water;

(iv) nonflammable medical gas piping (oxygen, compressed medical air, vacuum systems, nitrous oxide), emergency shutoff valves, pressure gages, alarm modules, and gas outlets;

(v) drain piping systems (waste and soiled piping systems, laboratory drain systems, roof drain systems);

(vi) fire protection piping systems (sprinkler piping systems, fire standpipe systems, water or chemical extinguisher piping system for cooking equipment);

(vii) piping riser diagrams, equipment schedules, control diagrams or narrative description of controls, filters, and location of all duct-mounted smoke detectors; and

(viii) laboratory exhaust and safety cabinets.

(F) Electrical drawings. Electrical drawings shall include:

(i) electrical service entrance with service switches, service feeders to the public service feeders, and characteristics of the light and power current including transformers and their connections;

(ii) location of all normal electrical system and essential electrical system conduits, wiring, receptacles, light fixtures, switches, and equipment that require permanent electrical connections, on plans of each building level:

(I) light fixtures marked distinctly to indicate connection to critical or life safety branch circuits or to normal lighting circuits; and

(II) outlets marked distinctly to indicate connection to critical, life safety, or normal power circuits;

(iii) telephone and communication, fixed computers, terminals, connections, outlets, and equipment;

(iv) nurses calling system showing all stations, signals, and annunciators on the plans;

(v) in addition to electrical plans, single line diagrams prepared for:

(I) complete electrical system consisting of the normal electrical system and the essential electrical system, including the on-site generator(s), transfer switch(es), emergency system (life safety branch and critical branch), equipment system, panels, subpanels, transformers, conduit, wire sizes, main switchboard, power panels, light panels, and equipment for additions to existing buildings, proposed new facilities, and remodeled portions of existing facilities (feeder and conduit sizes shall be shown with schedule of feeder breakers or switches);

(II) complete nurses calling system with all stations, signals, annunciators, etc. with room number noted by each device and indicating the type of system (nurses regular calling system, nurses emergency calling system, or staff emergency assistance calling system);

(III) a single line diagram of the complete fire alarm system showing all control panels, signaling and detection devices, and the room number where each device is located; and

(vi) schedules of all panels indicating connection to life safety branch, critical branch, equipment system or normal system, and connected load at each panel.

(3) Construction document changes. Any changes to the final construction documents that affect or change the function, design, or designated use of an area shall be submitted to HHSC for approval prior to authorization of the modifications.

(g) Special submittals.

(1) Self-certification.

(A) In an effort to shorten the plan review and approval process, the LSRH owner or operator or representative may request approval of final construction documents under the self-certification review process.

(i) The owner or operator shall submit the items in subsection (b)(1)(A) - (D) of this section and a completed self-certification form, signed by the LSRH owner or operator, architect of record, and engineer of record attesting that the plans and specifications are based upon and comply with the requirements of this chapter.

(ii) By signing and submitting the self-certification form, the LSRH owner or operator accepts the following conditions.

(I) HHSC retains the right to review the final construction documents, conduct inspections of the project, and withdraw its approval.

(II) The LSRH owner or operator has a continuing obligation to make any changes HHSC requires to comply with the licensing rules whether physical plant construction or alterations have been completed.

(III) The LSRH owner or operator is ultimately responsible for compliance with Texas Health and Safety Code Chapter 241 (relating to Hospitals) and this chapter.

(B) HHSC will review the request for self-certification and notify the LSRH owner or operator if the request is approved or denied. If denied, HHSC will review the final construction documents in the chronological order in which the documents were received. Construction may not begin until HHSC has reviewed and approved the final construction documents.

(2) Minor project. If an LSRH owner or operator believes that a proposed project is a minor project as described in §511.161(a)(2)(C) of this subchapter (relating to Requirements for Buildings in Which Existing Licensed Hospitals are Located), the LSRH owner or operator shall provide HHSC a brief written description of the proposed project and floor plans of the areas of work.

(A) If HHSC determines the proposed project is a minor project, HHSC will notify the LSRH owner or operator of the approval, and state the number of inspections that will be required. HHSC will conduct a minimum of one inspection.

(B) HHSC will notify the LSRH owner or operator that a proposed project is not approved as a minor project if the project involves any of the following:

(i) remodeling or alterations that involve alterations to load bearing members or partitions;

(ii) a change in functional operation;

(iii) affects fire safety (e.g., modifications to the fire, smoke, and corridor walls);

(iv) adds services for which the LSRH is not currently licensed; and

(v) significantly changes the mechanical, electrical, plumbing, fire protection, or piped medical system.

(C) The LSRH owner or operator shall submit final construction documents in accordance with subsection (f) of this section if HHSC determines the project is not a minor project.

(3) Fire sprinkler systems.

(A) When the sole purpose of a project is installation of a sprinkler system, whether a partial or complete system, the LSRH owner or operator shall submit to HHSC for approval the items in subsection (b)(1)(A) - (C) of this section and sprinkler documents.

(B) Fire sprinkler systems shall comply with the requirements of National Fire Protection Association 13, Standard for the Installation of Sprinkler systems, 2010 edition (NFPA 13), and shall be designed or reviewed by an engineer who is registered by the Texas Board of Professional Engineers in fire protection specialty or is experienced in hydraulic design and fire sprinkler system installation. A short resume shall be submitted if registration is not in fire protection specialty.

(i) Fire sprinkler working plans, complete hydraulic calculations, and water supply information shall be prepared in accordance with NFPA 13, §§14.1, 14.2 and 14.3, for new fire sprinkler systems and alterations of and additions to existing ones.

(ii) One set of fire sprinkler working plans, calculations and water supply information shall be forwarded to HHSC together with the professional engineer's (professional engineer (P.E.) licensed in the state of Texas) certification letter stating that the sprinkler system design complies with the requirements of NFPA 13. Certification of the fire sprinkler system shall be submitted prior to system installation.

(iii) Upon completion of the fire sprinkler system installation and any required corrections, written certification by the engineer, stating that the fire sprinkler system is installed in accordance with NFPA 13 requirements, shall be submitted prior to or with the written request for the final construction inspection of the project.

(h) Retention of drawings, manuals and design data.

(1) As built drawings. Upon occupancy of the building or portion thereof, the owner shall retain as part of the LSRH's permanent records, a complete set of legible architectural plans of each building level, fire safety plans as described in subsection (f)(2)(B) of this section for each floor reflecting fire safety requirements, and all single line diagrams described in subsection (f)(2)(F)(v) of this section, drawings for fixed equipment, and mechanical and electrical systems, as installed or built.

(2) Manuals. Upon completion of the contract, the owner shall retain as part of the LSRH's permanent records a complete set of manufacturers' operating, maintenance, and preventive maintenance instructions; parts lists; and procurement information with numbers and a description for each piece of equipment. Facility staff shall also be provided with instructions on how to properly operate systems and equipment. Required information shall include energy ratings as needed for future conservation calculations.

(3) Design data. The owner shall retain in the LSRH's permanent records complete design data for the facility. This shall include structural design loadings; summary of heat loss assumption and calculations; estimated water consumption; medical gas outlet listing; list of applicable codes; and electric power requirements of installed equipment. All such data shall be supplied to facilitate future alterations, additions, and changes, including, energy audits and retrofit for energy conservation.

§511.168. Construction, Inspections, and Approval of Project.

(a) Construction.

(1) Major construction. A limited services rural hospital (LSRH) shall not commence construction, other than minor alterations, until the LSRH has satisfactorily resolved final plan review deficiencies and paid the appropriate plan review fee according to the plan review schedule in §511.17 of this chapter (relating to Fees), and the Texas Health and Human Services Commission (HHSC) has issued a letter granting approval to begin construction. Such authorization does not constitute release from the requirements contained in this chapter. If the construction takes place in or near occupied areas, adequate provision shall be made for the safety and comfort of occupants.

(2) Construction commencement notification. The architect of record or the LSRH owner or operator shall provide written notification to HHSC when construction will commence. HHSC shall be notified, in writing, of any change in the completion schedules.

(3) Completion. Construction shall be completed in compliance with the construction documents including all addenda or modifications approved for the project.

(b) Construction inspections. All LSRHs, including those that maintain certification under Title XVIII of the Social Security Act (42 United States Code, §1395 et seq), and those that maintain accreditation by a Centers for Medicare & Medicaid Services-approved organization, are subject to construction inspections.

(1) Number of construction inspections. A minimum of two construction inspections of the project is generally required for the purpose of verifying compliance with Subchapter G of this chapter and this subchapter and the approved plans and specifications. The final plan approval letter will inform the architect of record and the owner or operator as to the minimum number of inspections required for the project.

(2) Requesting an inspection. The architect of record or the LSRH owner or operator shall request an inspection by submitting, at least three weeks in advance of the requested inspection date, an Application for Inspection and the construction inspection fee in accordance with §511.17(g) of this chapter for each intermediate inspection, final inspection, and reinspection requested. Inspection requests by contractors will not be honored.

(A) The architect of record or the LSRH owner or operator shall request an intermediate construction inspection to occur at approximately 80 percent completion. All major work above the ceiling shall be completed at the time of the intermediate inspection; however, ceilings shall not be installed.

(B) The architect of record or the LSRH owner or operator shall request a final construction inspection at 100 percent completion. One hundred percent completion means that the project is completed to the extent that all equipment is operating in accordance with specifications, all necessary furnishings are in place, and patients could be admitted and treated in all areas of the project.

(3) Reinspections. Depending upon the number and nature of the deficiencies cited during the final inspection, the inspector may require that a reinspection be conducted to confirm correction of all deficiencies cited. The inspector may also require a reinspection if

they determine that the project was not sufficiently complete to warrant a final inspection. The request for reinspection shall be submitted in accordance with paragraph (2) of this subsection.

(c) Approval of project. Patients and staff shall not occupy a new structure or remodeled or renovated space until approval has been received from the local building and fire authorities and HHSC.

(1) Documentation requirements. The LSRH owner or operator shall submit the following documents to HHSC before the project will be approved.

(A) Written approval of the project by the fire authority.

(B) A certificate of occupancy for the project issued by the local building authority.

(C) A copy of a letter or certification from a professional engineer (P.E.) licensed in the state of Texas indicating the fire sprinkler working plans, hydraulic calculation, the testing, and field inspection of the installation of the new or modified sprinkler system is in compliance with the requirements of NFPA 13, Standard for the Installation of Sprinkler Systems, 2002 edition, if applicable. A copy of a letter or certification of changes in existing fire sprinkler system is not required when relocation of not more than twenty sprinkler heads and hydraulic calculation is not involved.

(D) Fire alarm system certification (form FML-009 040392 of the Office of the State Fire Marshal), if applicable.

(E) A signed copy of a letter of certification from a qualified certification agency or individual for the piped-in medical gas system that was installed or modified and verification inspection testing in this project in accordance with §511.162 (d)(4)(A)(iii)(IV), (X) and (XI) of this subchapter (relating to General Construction Requirements), if applicable.

(F) A copy of the test and a letter from the electrical contractor certifying that the electrical system was tested and complies with the standards of NFPA 99, Health Care Facilities, 2012 edition, §4.3.2.2.8 (Special Grounding) and §4.3.3.1 (Grounding System Testing), if applicable to the project.

(G) A copy of documentation indicating the flame spread rating and the smoke development rating of any wall covering installed in this project. Provide a signed letter or statement corroborating the installation of the product in the project.

(H) A copy of documentation indicating that draperies, curtains (including cubicle curtains), and other similar loosely hanging furnishings and decorations are flame-resistant as demonstrated by passing both the small and large-scale tests of NFPA 701, Standard Methods of Fire Tests for Flame-Resistant Textiles and Films, 2010 edition as required by NFPA 101, §18-7.5, and provide a signed letter or statement corroborating the installation of the product in the project.

(I) A written plan of correction signed by the LSRH owner/operator for any deficiencies noted during the final inspection.

(J) A Final Construction Approval form signed by the LSRH owner/operator.

(K) Any other documentation or information required or requested due to the type of the project.

(2) Temporary occupancy approval.

(A) If, during the final inspection, the inspector finds only a few minor deficiencies that do not jeopardize patient health, safety and welfare, the inspector may grant temporary approval for occupancy contingent upon the documents listed in paragraph (1)(A) - (E) of this subsection being provided to and approved by the inspector at the time of the final inspection.

(B) Temporary approval for occupancy allows the LSRH owner or operator to occupy the project. However, the LSRH owner or operator must submit the documents required in paragraph (1)(F) - (K) of this subsection before the project receives final approval.

(3) Final approval. Upon its receipt and acceptance of the documents required in paragraph (1) of this subsection, HHSC will issue written final approval of the project.

§511.169. Tables.

(a) Table 1
Figure: 26 TAC §511.169(a)

(b) Table 2.
Figure: 26 TAC §511.169(b)

(c) Table 3.
Figure: 26 TAC §511.169(c)

(d) Table 4.
Figure: 26 TAC §511.169(d)

(e) Table 5.
Figure: 26 TAC §511.169(e)

(f) Table 6.
Figure: 26 TAC §511.169(f)

(g) Table 7.
Figure: 26 TAC §511.169(g)

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

Filed with the Office of the Secretary of State on May 30, 2023.

TRD-202301957
Karen Ray
Chief Counsel
Health and Human Services Commission
Earliest possible date of adoption: July 16, 2023
For further information, please call: (512) 834-4591

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CHAPTER 746. MINIMUM STANDARDS FOR CHILD-CARE CENTERS

SUBCHAPTER B. ADMINISTRATION AND COMMUNICATION

DIVISION 1. PERMIT HOLDER RESPONSIBILITIES

26 TAC §746.201

The Executive Commissioner of the Texas Health and Human Services Commission (HHSC) proposes an amendment to §746.201, concerning What are my responsibilities as the permit holder.

BACKGROUND AND PURPOSE

The purpose of this project is to update a reference to Texas Family Code to correct a typographical error. While the reference was accurately referenced in the proposed version of the rule as published in the September 23, 2022, issue of the *Texas Regis-*

ter (47 TexReg 6102), the reference in the recently adopted rule was incorrect in that it referenced Texas Family Code §261.10. This project will correct the reference to §261.101.

SECTION-BY-SECTION SUMMARY

The proposed amendment to §746.201 corrects the reference to the Texas Family Code from §261.10 to §261.101.

FISCAL NOTE

Trey Wood, HHSC Chief Financial Officer, has determined that for each year of the first five years that the rule will be in effect, enforcing or administering the rule does not have foreseeable implications relating to costs or revenues of state or local governments.

GOVERNMENT GROWTH IMPACT STATEMENT

HHSC has determined that during the first five years that the rule will be in effect:

(1) the proposed rule will not create or eliminate a government program;

(2) implementation of the proposed rule will not affect the number of HHSC employee positions;

(3) implementation of the proposed rule will result in no assumed change in future legislative appropriations;

(4) the proposed rule will not affect fees paid to HHSC;

(5) the proposed rule will not create a new rule;

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

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

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

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

Trey Wood has also determined that there will be no adverse economic effect on small businesses, micro-businesses, or rural communities because the amendment just corrects a reference to the Texas Family Code. The rule does not impose any additional costs on small businesses, micro-businesses, or rural communities that are required to comply with the rule.

LOCAL EMPLOYMENT IMPACT

The proposed rule will not affect a local economy.

COSTS TO REGULATED PERSONS

Texas Government Code §2001.0045 does not apply to this rule because the rule is necessary to protect the health, safety, and welfare of the residents of Texas and does not impose a cost on regulated persons.

PUBLIC BENEFIT AND COSTS

Libby Elliott, Deputy Executive Commissioner, Office of Policy and Rules, has determined that for each year of the first five years the rule is in effect, the public will benefit from having an accurate reference regarding the requirements for reporting abuse, neglect, or exploitation.

Trey Wood has also determined that for the first five years the rule is in effect, there are no anticipated economic costs to persons who are required to comply with the proposed rule because the amendment only corrects a reference to the Texas Family Code.

TAKINGS IMPACT ASSESSMENT

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

PUBLIC COMMENT

Written comments on the proposal may be submitted to Rules Coordination Office, P.O. Box 13247, Mail Code 4102, Austin, Texas 78711-3247, or street address 701 W. 51st Street, Austin, Texas 78751; or emailed to *HHSRulesCoordinationOffice@hhs.texas.gov.*

To be considered, comments must be submitted no later than 31 days after the date of this issue of the *Texas Register.* Comments must be (1) postmarked or shipped before the last day of the comment period; (2) hand-delivered before 5:00 p.m. on the last working day of the comment period; or (3) emailed before midnight on the last day of the comment period. If last day to submit comments falls on a holiday, comments must be postmarked, shipped, or emailed before midnight on the following business day to be accepted. When emailing comments, please indicate "Comments on Proposed Rule 23R027" in the subject line.

STATUTORY AUTHORITY

The amendment is authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies, and §531.02011, which transferred the regulatory functions of the Department of Family and Protective Services to HHSC. In addition, Texas Human Resources Code §42.042(a) requires HHSC to adopt rules to carry out the requirements of Chapter 42 of Texas Human Resources Code.

The amendment affects Texas Government Code §531.0055 and Texas Human Resources Code §42.042.

§746.201. What are my responsibilities as the permit holder?

You are responsible for:

(1) Developing and implementing your child-care center's operational policies, which must comply with or exceed the minimum standards specified in this subchapter;

(2) Developing written personnel policies, including job descriptions, job responsibilities, and requirements;

(3) Making provisions for training that comply with Division 4, Subchapter D of this chapter (relating to Professional Development);

(4) Designating a child-care center director who meets minimum standard qualifications and has daily, on-site responsibility for the operation of the child-care center;

(5) Reporting and ensuring your employees and volunteers report suspected abuse, neglect, or exploitation directly to the Texas Abuse and Neglect Hotline, as required by Texas Family Code §261.101 [~~§261.10~~]; an employee may not delegate the responsibility to make a report, and you may not require an employee to seek approval to file a report or notify you that a report was made;

(6) Ensuring all information related to background checks is kept confidential and not disclosed to unauthorized persons, as required by the Human Resources Code, §40.005(d) and (e);

(7) Ensuring parents can visit the child-care center any time during the child-care center's hours of operation to observe their child, program activities, the building, the grounds, and the equipment without having to secure prior approval;

(8) Complying with the liability insurance requirements in this division;

(9) Complying with the child-care licensing law found in Chapter 42 of the Human Resources Code, the applicable minimum standards, and other applicable rules in the Texas Administrative Code;

(10) Reporting to Licensing any Department of Justice substantiated complaints related to Title III of the Americans with Disabilities Act, which applies to commercial public accommodations; and

(11) Ensuring the total number of children in care at the center or away from the center, such as during a field trip, never exceeds the licensed capacity of the center.

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

Filed with the Office of the Secretary of State on June 2, 2023.

TRD-202302036
Karen Ray
Chief Counsel
Health and Human Services Commission
Earliest possible date of adoption: July 16, 2023
For further information, please call: (512) 221-9021

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TITLE 28. INSURANCE

PART 2. TEXAS DEPARTMENT OF INSURANCE, DIVISION OF WORKERS' COMPENSATION

CHAPTER 180. MONITORING AND ENFORCEMENT

SUBCHAPTER C. MEDICAL QUALITY REVIEW PANEL

INTRODUCTION. The Texas Department of Insurance, Division of Workers' Compensation (DWC) proposes to amend 28 TAC §§180.64, 180.66, 180.68, 180.72, and 180.76, concerning the Medical Quality Review Panel (MQRP), under Texas Labor Code §§413.05115, 413.0512, 413.05121, and 413.05122.

DWC also proposes to repeal 28 TAC §180.78, concerning the effective date of the subchapter, because it is no longer necessary. The proposed repeal is also published in this issue of the *Texas Register.*

EXPLANATION. Amending §§180.64, 180.66, 180.68, 180.72, and 180.76 is necessary to conform with related rules and practices, clarify the amount of notice to which a respondent is entitled before an informal settlement conference (ISC), and clarify that DWC may conduct an ISC remotely or in person. The amendments also make editorial changes for plain language and agency style.

Labor Code §413.05115 requires the commissioner to adopt criteria for the medical case review process, in consultation with the medical advisor. Labor Code §413.0512 requires the medical advisor to establish a medical quality review panel of health care providers to assist the medical advisor in performing the duties §413.0511 requires.

The MQRP assists DWC's medical advisor in conducting medical case reviews as part of the medical quality review process to ensure that injured employees in the workers' compensation system get timely, cost-effective, appropriate, medically necessary health care to help them recover and return to work. Labor Code §413.05121 requires the medical advisor to establish the Quality Assurance Panel within the MQRP, and Labor Code §413.05122 requires the commissioner, after consulting with the medical advisor, to adopt rules concerning the operation of the MQRP.

Section 180.64 concerns the MQRP application process. The proposed amendment to subsection (g) updates the language with the current MQRP membership term of 10 years, as 28 TAC §180.62(e) provides.

Section 180.66 concerns medical case review. The proposed amendment deletes an obsolete reference to recertification to reflect recent amendments to 28 TAC Chapter 127 that updated the certification and renewal process.

Section 180.68 concerns the medical quality review process. The proposed amendment to subsection (a) deletes an obsolete reference to recertification to reflect recent amendments to 28 TAC Chapter 127 that updated the certification and renewal process.

Section 180.72 concerns conflicts of interest. The proposed amendment to subsection (d) deletes an obsolete reference to the associate medical advisor and clarifies that, if the medical advisor must recuse himself due to a conflict of interest, the commissioner will delegate the medical advisor's duties for that case to an arbiter.

Section 180.76 concerns the rights and responsibilities of persons involved in the medical quality review process. The proposed amendments clarify that a person subject to the medical quality review process has the right to 45 days' written notice of an ISC; that DWC may, at its discretion, conduct the ISC remotely or in person; and that the copies of documents that the person has the right to receive are documents that pertain to the substance of the case and that were given to the arbiters to review for that case. The proposed amendments also update an obsolete reference to DWC's attorneys, and contain editorial changes for plain language and agency style to make the rule easier to read.

Section 180.78 concerns a 2013 effective date for Subchapter C. That date is now long past. Repealing §180.78 is necessary to ensure that the rules in the subchapter are relevant, which reduces clutter and confusion.

FISCAL NOTE AND LOCAL EMPLOYMENT IMPACT STATEMENT. Deputy Commissioner of Health and Safety Mary Landrum has determined that during each year of the first five years the proposed amendments are in effect, there will be no measurable fiscal impact on state and local governments as a result of enforcing or administering the sections, other than that imposed by the statute. This determination was made because the proposed amendments do not add to or decrease state revenues or

expenditures, and because local governments are not involved in enforcing or complying with the proposed amendments.

Ms. Landrum does not anticipate any measurable effect on local employment or the local economy as a result of this proposal.

PUBLIC BENEFIT AND COST NOTE. For each year of the first five years the proposed amendments are in effect, Ms. Landrum expects that enforcing and administering the proposed amendments will have the public benefits of conforming the language with current agency structure and practice and with other DWC rules; clarifying requirements for notice and documents to respondents in an ISC; clarifying that DWC may conduct ISCs remotely or in person; and ensuring that DWC's rules align with the language and intent of Labor Code §§413.05115, 413.0512, 413.05121, and 413.05122. The amendments will also have the public benefit of ensuring that DWC's rules are current, accurate, and easy to read and understand, which promotes transparent and efficient regulation.

Ms. Landrum expects that the proposed amendments will not increase the cost to comply with Labor Code §§413.05115, 413.0512, 413.05121, or 413.05122 because they do not impose requirements beyond those in the statutes or create obligations beyond those in the current rule. Instead, the amendments clarify respondents' rights, enhance efficiency, and reduce administrative burdens for DWC and system participants.

Labor Code §413.05115 requires the commissioner to adopt criteria for the medical case review process in consultation with the medical advisor. Labor Code §413.0512 requires the medical advisor to establish a medical quality review panel of health care providers to assist the medical advisor in performing the duties §413.0511 requires. Labor Code §413.05121 requires the medical advisor to establish the Quality Assurance Panel within the MQRP, and Labor Code §413.05122 requires the commissioner, after consulting with the medical advisor, to adopt rules concerning the operation of the medical quality review panel.

As a result, any cost associated with the proposed amendments does not result from the enforcement or administration of the proposed amendments.

ECONOMIC IMPACT STATEMENT AND REGULATORY FLEXIBILITY ANALYSIS. DWC has determined that the proposed amendments will not have an adverse economic effect or a disproportionate economic impact on small or micro businesses, or on rural communities because the proposed amendments reduce confusion and administrative burdens; provide for more stable, consistent, and transparent regulation; update references; and make editorial changes for plain language and agency style. They do not change the people the rule affects or impose additional costs. As a result, and in accordance with Government Code §2006.002(c), DWC is not required to prepare a regulatory flexibility analysis.

EXAMINATION OF COSTS UNDER GOVERNMENT CODE §2001.0045. DWC has determined that this proposal does not impose a possible cost on regulated persons. In contrast, DWC expects that the reduced administrative burden from the amendments will reduce costs to regulated persons. As a result, no additional rule amendments are required under Government Code §2001.0045.

GOVERNMENT GROWTH IMPACT STATEMENT. DWC has determined that for each year of the first five years that the proposed amendments are in effect, the proposed rule:

- will not create or eliminate a government program;

- will not require the creation of new employee positions or the elimination of existing employee positions;

- will not require an increase or decrease in future legislative appropriations to the agency;

- will not require an increase or decrease in fees paid to the agency;

- will not create a new regulation;

- will not expand, limit, or repeal an existing regulation;

- will not increase or decrease the number of individuals subject to the rule's applicability; and

- will not positively or adversely affect the Texas economy.

DWC made these determinations because the proposed amendments enhance efficiency and clarity; conform the language to current agency structure, practice, and related rules; and make editorial changes for plain language and agency style. They do not change the people the rule affects or impose additional costs.

TAKINGS IMPACT ASSESSMENT. DWC has determined that no private real property interests are affected by this proposal, and this proposal does not restrict or limit an owner's right to property that would otherwise exist in the absence of government action. As a result, this proposal does not constitute a taking or require a takings impact assessment under Government Code §2007.043.

REQUEST FOR PUBLIC COMMENT. DWC will consider any written comments on the proposal that DWC receives no later than 5:00 p.m., Central time, on July 17, 2023. Send your comments to RuleComments@tdi.texas.gov; or to Texas Department of Insurance, Division of Workers' Compensation, Legal Services, MC-LS, P.O. Box 12050, Austin, Texas 78711-2050.

To request a public hearing on the proposal, submit a request before the end of the comment period, and separate from any comments, to RuleComments@tdi.texas.gov; or to Texas Department of Insurance, Division of Workers' Compensation, Legal Services, MC-LS, P.O. Box 12050, Austin, Texas 78711-2050. If DWC holds a public hearing, it will consider written and oral comments presented at the hearing.

28 TAC §§180.64, 180.66, 180.68, 180.72, 180.76

STATUTORY AUTHORITY. DWC proposes §§180.64, 180.66, 180.68, 180.72, and 180.76 under Labor Code §§413.0511, 413.05115, 413.0512, 413.05121, 413.05122, 402.00111, 402.00116, and 402.061.

Labor Code §413.0511 requires DWC to have a medical advisor and describes the medical advisor's duties, including making recommendations about rules and policies to regulate medical matters in the workers' compensation system.

Labor Code §413.05115 requires the commissioner to adopt criteria for the medical case review process, in consultation with the medical advisor.

Labor Code §413.0512 requires the medical advisor to establish a medical quality review panel of health care providers to assist the medical advisor in performing the duties §413.0511 requires.

Labor Code §413.05121 requires the medical advisor to establish the Quality Assurance Panel within the MQRP.

Labor Code §413.05122 requires the commissioner, after consulting with the medical advisor, to adopt rules concerning the operation of the MQRP.

Labor Code §402.00111 provides that the commissioner of workers' compensation shall exercise all executive authority, including rulemaking authority under Title 5 of the Labor Code.

Labor Code §402.00116 provides that the commissioner of workers' compensation shall administer and enforce this title, other workers' compensation laws of this state, and other laws granting jurisdiction to or applicable to DWC or the commissioner.

Labor Code §402.061 provides that the commissioner of workers' compensation shall adopt rules as necessary to implement and enforce the Texas Workers' Compensation Act.

CROSS-REFERENCE TO STATUTE. Sections 180.64, 180.66, 180.68, 180.72, and 180.76 implement Labor Code §413.05122, enacted by HB 2605, 82nd Legislature, Regular Session (2011).

§180.64. MQRP Application Process.

(a) - (f) (No change.)

(g) Membership in the MQRP is for a term of 10 [~~two~~] years. The acceptance letter will include the effective date and expiration date.

(h) - (k) (No change.)

§180.66. Medical Case Review.

The MQRP may perform medical case review for the medical advisor. Medical case review may be performed for the purposes of the medical quality review process, designated doctor certification, performance-based [~~and recertification, performance based~~] oversight, or any other medical case review necessary to assist the medical advisor in performing the medical advisor's duties under the Labor Code.

§180.68. Medical Quality Review Process.

(a) The medical quality review process is medical case review initiated on the basis of complaints, plan-based audits, or monitoring as a result of a consent order and performed in accordance with criteria adopted under Labor Code §413.05115. The medical quality review process does not include medical case review performed for the purpose of:

(1) certification [~~and recertification~~] of designated doctors;

(2) performance-based [~~performance based~~] oversight;

(3) administrative violations that do not require an expert medical opinion; or

(4) complaints about [~~regarding~~] professionalism that do not require an expert medical opinion.

(b) - (c) (No change.)

§180.72. Conflict of Interest.

(a) - (c) (No change.)

(d) If the medical advisor has a conflict of interest in a case, the medical advisor must recuse himself from the case. [~~and appoint the associate medical advisor to perform the role of the medical advisor in the case, including enforcement decisions and recommendations. If the associate medical advisor also has a conflict of interest in the case, the commissioner shall~~] If the medical advisor recuses himself, the commissioner will delegate the duties of the medical advisor, including enforcement decisions and recommendations, for that particular case, to an Arbiter.

(e) (No change.)

§180.76. Rights and Responsibilities of Persons Involved in the Medical Quality Review Process.

(a) The person subject to the medical quality review process has the right:

(1) to be notified that the person has been selected for the medical quality review process;

(2) to be notified of the disposition of the medical quality review process;

(3) to communicate with the office of the medical advisor at any time during the medical quality review process;

(4) to be represented by legal counsel, including legal counsel at the informal settlement conference [~~process~~] (ISC);

(5) to receive written notice of an ISC at least 45 days before the ISC, including the time and place of the ISC and the nature of the allegations; and

(6) [~~(5)~~] to an ISC in accordance with the provisions of this section. The ISC provides persons subject to the medical quality review process an opportunity to discuss and resolve their medical case review with Arbiters. The division may, at its discretion, conduct an ISC remotely or in person. An ISC is available under the following conditions:

(A) The case has been referred to enforcement.

(B) The request for an ISC must be in writing.

(C) The division will notify the requester [~~requestor~~] of the scheduled date of the ISC.

(D) The requester [~~requestor~~] has the right to receive copies of all documents that pertain to the substance of the case and that were given to the Arbiters for review for that particular case.

(E) All information the requester [~~requestor~~] wishes the Arbiters to consider at the ISC must be received by the division no later than 15 days before the ISC. The Arbiters may refuse to consider any information not timely received by the division.

(F) The requester [~~requestor~~] may request to reschedule the scheduled date of the ISC for good cause shown, in writing, as determined by the division [~~an attorney from the division's office of general counsel~~]. Good cause means circumstances beyond the requester's control [~~of the requestor~~] that reasonably prevent the requester [~~requestor~~] from attending the ISC and requesting that the ISC be rescheduled any sooner.

(G) If a requester [~~requestor~~] fails to attend an ISC as scheduled, the requester loses the [~~requestor forfeits his~~] right to an ISC. But failure to attend the ISC does not affect the requester's rights to: [~~, but it does not preclude the requestor from discussing the requestor's case with the medical advisor as set forth in paragraph (3) of this subsection, from entering into a Consent Order with the division, or from defending an enforcement case at the State Office of Administrative Hearings.~~]

(i) communicate with the office of the medical advisor as paragraph (3) of this subsection provides;

(ii) enter into a consent order with the division; or

(iii) defend an enforcement case at the State Office of Administrative Hearings.

(b) (No change.)

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

Filed with the Office of the Secretary of State on June 2, 2023.

TRD-202302055
Kara Mace
General Counsel
Texas Department of Insurance, Division of Workers' Compensation
Earliest possible date of adoption: July 16, 2023
For further information, please call: (512) 804-4703

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28 TAC §180.78

STATUTORY AUTHORITY. DWC proposes repealing §180.78 under Labor Code §§413.05122, 402.00111, 402.00116, and 402.061.

Labor Code §413.05122 requires the commissioner, after consulting with the medical advisor, to adopt rules concerning the operation of the MQRP.

Labor Code §402.00111 provides that the commissioner of workers' compensation shall exercise all executive authority, including rulemaking authority under Title 5 of the Labor Code.

Labor Code §402.00116 provides that the commissioner of workers' compensation shall administer and enforce this title, other workers' compensation laws of this state, and other laws granting jurisdiction to or applicable to DWC or the commissioner.

Labor Code §402.061 provides that the commissioner of workers' compensation shall adopt rules as necessary to implement and enforce the Texas Workers' Compensation Act.

CROSS-REFERENCE TO STATUTE. Repealing §180.78 implements Labor Code §413.05122, enacted by HB 2605, 82nd Legislature, Regular Session (2011).

§180.78. Effective Date.

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

Filed with the Office of the Secretary of State on June 2, 2023.

TRD-202302056
Kara Mace
General Counsel
Texas Department of Insurance, Division of Workers' Compensation
Earliest possible date of adoption: July 16, 2023
For further information, please call: (512) 804-4703

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TITLE 30. ENVIRONMENTAL QUALITY

PART 1. TEXAS COMMISSION ON ENVIRONMENTAL QUALITY

CHAPTER 114. CONTROL OF AIR POLLUTION FROM MOTOR VEHICLES

The Texas Commission on Environmental Quality (TCEQ, agency, or commission) proposes amendments to Title 30 Texas Administrative Code (TAC) §§114.1, 114.2, 114.50, 114.53, and 114.309.

If adopted, amended §§114.1, 114.2, 114.50, 114.53, and 114.309 will be submitted to the United States Environmental Protection Agency (EPA) as a revision to the State Implementation Plan (SIP).

Background and Summary of the Factual Basis for the Proposed Rules

On October 7, 2022, the EPA published its reclassification of Bexar County from marginal to moderate nonattainment for the 2015 eight-hour ozone National Ambient Air Quality Standard (NAAQS), effective November 7, 2022 (87 Federal Register (FR) 60897). Bexar County is subject to the moderate nonattainment requirements in federal Clean Air Act (FCAA), §182(b). The FCAA and 40 Code of Federal Regulations (CFR) Part 51, as amended, require a basic vehicle emissions inspection and maintenance (I/M) program in ozone nonattainment areas classified as moderate, so the state must implement an I/M program in Bexar County. Rulemaking is required to implement I/M and set the testing fee applicable in Bexar County, and a SIP revision is required to incorporate a Bexar County I/M program into the SIP. The rulemaking and SIP revision were due to the EPA by January 1, 2023, and implementation of the I/M program in Bexar County is required by November 7, 2026.

Also on October 7, 2022, the EPA published its reclassification of the 10-county Dallas-Fort Worth (DFW) area from serious to severe nonattainment for the 2008 eight-hour ozone NAAQS, effective November 7, 2022 (87 FR 60926). Beginning one year after reclassification to severe, participation in the federal reformulated gasoline (RFG) program is required in the 10-county DFW nonattainment area. RFG is gasoline that is blended to burn more cleanly than conventional gasoline to reduce smog-forming and toxic pollutants. In RFG-covered areas, the sale of gasoline that the EPA has not certified as reformulated is prohibited. Collin, Dallas, Denton, and Tarrant Counties are already covered under the federal RFG rules because they opted into the program effective January 1, 1995 under the 1979 one-hour ozone NAAQS (57 FR 46316, October 8, 1992).

Ellis, Johnson, Kaufman, Parker, Rockwall, and Wise Counties are currently subject to the state low Reid vapor pressure (RVP) rules in Chapter 114, Subchapter H, Division 1, but on November 7, 2023 they will be subject to the federal RFG program. To avoid overlapping applicability between the state RVP rules and the federal RFG program for those six counties, this proposed rulemaking would remove these counties from the state low RVP program.

During the 2019 Quadrennial review of Chapter 114, staff identified definitions that are no longer necessary. The obsolete definitions were associated with repealed agency programs and are not used in or applicable to current rules in Chapter 114. The proposed revisions would remove these obsolete definitions.

Demonstrating Noninterference under Federal Clean Air Act, §110(l)

Under FCAA, §110(l), the EPA cannot approve a SIP revision if it would interfere with attainment of the NAAQS, reasonable further progress toward attainment, or any other applicable requirement of the FCAA. The commission provides the following information to demonstrate why the proposed changes to the I/M program rules and low RVP requirements in Chapter 114 will not: negatively impact the status of the state's progress towards at-

tainment, interfere with control measures, or prevent reasonable further progress toward attainment of the ozone NAAQS.

The proposed amendments to Chapter 114 would revise 30 TAC Chapter 114, Subchapters A and C to add program-related definitions, identify vehicles in Bexar County that would be subject to vehicle emissions inspections, require emissions inspection stations in Bexar County to offer the on-board diagnostics (OBD) test approved by the EPA, and establish the maximum fee that Bexar County emissions inspection stations may charge for the OBD test. Additional details regarding the proposed Bexar County I/M program are discussed in the Bexar County I/M SIP revision (Project No. 2022-027-SIP-NR), proposed concurrently with this rulemaking. These amendments do not affect the EPA-approved I/M program requirements for other areas, and the proposed requirements for the Bexar County I/M program meet EPA requirements for implementing an I/M program for moderate ozone nonattainment areas. Therefore, the proposed rulemaking would not negatively impact the state's progress towards attainment of the 2008 and 2015 eight-hour ozone NAAQS.

The proposed amendments to Chapter 114 would also modify administrative aspects of 30 TAC Chapter 114, Subchapter H to remove Ellis, Johnson, Kaufman, Parker, Rockwall, and Wise Counties from the list of affected counties required to comply with the state's low RVP control requirements. The removal of these six counties from the state low RVP program would not interfere with attainment or maintenance of the NAAQS for the DFW area due to implementation of federal RFG requirements, which are more stringent than the state rules. The Chapter 114 low RVP program requires a maximum gasoline RVP of no greater than 7.8 pounds per square inch (psi) and has a seasonal applicability, the specific time period of the summer ozone season. The federal RFG program controls more components of gasoline as well as requiring a lower RVP for gasoline and has no seasonal limitations. The proposed revisions would not negatively impact the state's progress towards attainment of the 2008 and 2015 eight-hour ozone NAAQS.

Section by Section Discussion

The proposed amendments to Chapter 114 would revise 30 TAC Chapter 114, Subchapters A and C to repeal obsolete definitions and revise the I/M program rules to provide for implementation of the Bexar County program. The proposed amendments would also amend 30 TAC Chapter 114, Subchapter H to remove Ellis, Johnson, Kaufman, Parker, Rockwall, and Wise Counties from the list of affected counties required to comply with the state's low RVP control requirements.

The commission also proposes non-substantive changes to update the rules in accordance with current Texas Register style and format requirements, improve readability, establish consistency in the rules, remove outdated definitions identified by Quadrennial review, and conform to the standards in the Texas Legislative Council Drafting Manual, September 2020. These non-substantive changes are not intended to alter the existing rule requirements in any way and may not be specifically discussed in this preamble.

Subchapter A: Definitions

§114.1. Definitions

The proposed revisions would remove obsolete definitions in this section that were identified during the 2019 Quadrennial review of Chapter 114 and have been reaffirmed by staff as no longer necessary. The obsolete definitions were associated with repealed agency programs and are not used in or applicable to current rules in Chapter 114. The definitions proposed for removal are: Heavy-duty vehicle, Inherently low emission vehicle, Light-duty vehicle, Loaded mode inspection and maintenance test, Low emission vehicle, Mass transit authority, Reformulated gasoline, Tier I federal emission standards, Ultra low emission vehicle, and Zero emission vehicle. The remaining definitions will be renumbered as appropriate.

§114.2. Inspection and Maintenance Definitions

The proposed revisions would add new language under the definition for Program area in §114.2(10) to reflect that the new Bexar County program area consists of Bexar County.

Subchapter C: Vehicle Inspection and Maintenance; Low Income Vehicle Repair Assistance, Retrofit, and Accelerated Vehicle Retirement Program; and Early Action Compact Counties

Division 1: Vehicle Inspection and Maintenance

§114.50. Vehicle Emissions Inspection Requirements

The proposed revisions to §114.50(a) would add new paragraph (5) to specify the program start dates, specify the model year vehicles in the Bexar County program area to be tested, and that all vehicle emissions testing stations must offer OBD tests. The proposed new subparagraph (A) would require all Bexar County vehicles subject to I/M program requirements to receive the EPA-approved OBD test beginning November 1, 2026. The proposed new subparagraph (B) would require all vehicle emissions inspection stations in the Bexar County program area to offer the OBD test.

The proposed revisions to §114.50(b) would amend paragraphs (1), (3), and (6) by adding the Bexar County program area to the list of program areas subject to the control requirements of the subsection.

§114.53. Inspection and Maintenance Fees

The proposed revision to §114.53(a) would add a new paragraph (4) to establish the maximum fee of $11.50 that Bexar County program area emissions inspection stations may charge for the OBD test. In 2020, TCEQ commissioned a study to help prepare for the future implementation of an I/M program in Bexar County. The study is available at https://wayback.archive-it.org/414/20210528194434/https://www.tceq.texas.gov/assets/public/implementation/air/ms/IM/2020%20Bexar%20County%20IM%20Prog%20Study%20Report.pdf. The study recommended a fee between $18 and $22; however, the proposed maximum fee of $11.50 for the Bexar County I/M program is comparable to the existing fee in the similar program areas of Austin-Round Rock and El Paso County and will help minimize costs to the public. The proposed revision will not include provisions for the Bexar County program area to participate in the Low Income Vehicle Repair Assistance, Retrofit, and Accelerated Vehicle Retirement Program (LIRAP), which has not been funded since 2017 and all participating counties have opted out of the LIRAP. If the TCEQ is reappropriated funding in the future to implement LIRAP or a similar program, the TCEQ would initiate rulemaking to designate that Bexar County is eligible to participate effective upon the start date of the I/M program. The proposed revision to §114.53(d)(4) would add a new paragraph that requires affected vehicle owners remit $2.50 to the DMV or county tax assessor-collector at the time of annual vehicle registration as part of the vehicle emissions inspection fee to cover the costs to implement, maintain, administer, and enforce the required vehicle I/M program in Bexar County.

Subchapter H: Low Emission Fuels

Division 1: Gasoline Volatility

§114.309. Affected Counties

The proposed revisions would remove Ellis, Johnson, Kaufman, Parker, Rockwall, and Wise Counties from the list of affected counties required to comply with the state's low RVP control requirements. These six counties will become subject to the federal RFG program beginning November 7, 2023, prior to the anticipated effective date of this rulemaking, if adopted. Federal RFG program requirements are more stringent and exempting these counties from the state low-RVP rules will eliminate the unnecessary overlapping state requirements.

Fiscal Note: Costs to State and Local Government

Kyle Girten, an Analyst in the Budget and Planning Division, has determined that for the first five-year period the proposed rules are in effect, fiscal implications are anticipated for state and local government as a result of administration or enforcement of the proposed rule.

The agency estimates the implementation of amendments to the proposed rule in §§114.2, 114.50, and 114.53 will result in an increase in revenue received by TCEQ and Texas Department of Public Safety (DPS). The proposed rulemaking would cause the Texas Department of Motor Vehicles (DMV) to collect $2.50 per registration issued when the I/M program begins on November 1, 2026 in Bexar County. During the first year, two months of revenue would be collected during calendar year 2026. During the next four years, twelve months of revenue would be collected. TCEQ would receive $0.50 in revenue per vehicle registration issued to cover the costs of developing test and equipment specifications, developing a testing program, and providing assistance through a registration denial program. The remaining $2.00 of the fee would be received by DPS to cover the cost of training technicians on the I/M program, staffing of waiver stations, and enforcement of I/M program requirements. The agency estimates TCEQ will receive as much as $132,903 in the first year the rule is implemented for two months ($797,418 annualized), increasing at an assumed 3% annual increase up to $897,501 in the fifth year after implementation. Correspondingly, DPS would receive as much as $531,612 in the first year ($3,189,672 annualized) and increase to as much as $3,590,004 in the fifth year.

The agency estimates that approximately 114 governmental entities with gasoline-powered vehicles registered in Bexar County, including cities, state governments, water districts, river authorities, and independent school district will be required pay vehicle I/M program and repair costs as a result of implementation of the proposed rule. It is estimated that there will be a total of 10,553 governmental vehicles impacted in the first year increasing by 3% annually to 11,877 estimated vehicles in the fifth year. All entities would be responsible for the $2.50 to be collected by the DMV per vehicle and any necessary vehicle repair costs. The fees paid to the DMV are estimated at $3,957 in the first year increasing to a total of $26,724 in the fifth year. The total repair cost, assuming a 4% failure rate on inspections and $400 per repair would be approximately $25,327 in the first year ($151,962 annualized), increasing to $171,032 in the fifth year. Some of these entities conduct their own inspections, in which case they would be responsible for purchasing or renting equipment to conduct inspections and additional phone or internet service costs. Entities that pay for their inspections would be responsible for paying an emissions inspection fee not to exceed $11.50 per vehicle to a vendor.

Public Benefits and Costs

Mr. Girten determined that for each year of the first five years the proposed rules are in effect, the public benefit anticipated will be a reduction of pollutants that contribute to ozone formation in Bexar County. Failure to conduct this rulemaking could result in sanctions and possibly a federal implementation plan (FIP) imposed by the EPA.

The proposed rulemaking would result in fiscal implications for businesses and individuals in Bexar County. Individuals and organizations that own vehicles subject to I/M testing will have to pay more for vehicle inspections and registrations. Subject vehicles must pass the inspection prior to receiving their vehicle registration. In total, 264,223 vehicles for businesses and individuals are estimated to be inspected in the first year (1,585,338 annualized), increasing to 1,784,313 in the fifth year. The total estimated cost, including the emissions inspection fee of $11.50, the costs of repairs that would be needed to pass the OBD test, and the state's portion of the inspection fee of $2.50 is estimated at $7.9 million in the first year ($47.5 million annualized) increasing to $53.5 million in the fifth year.

The proposed rulemaking would increase revenue for entities that conduct I/M testing and vehicle repairs. Currently, 654 stations conduct vehicle safety inspections in Bexar County, including 544 that offer inspections to the public. Entities that provide the OBD test would earn an amount not to exceed $11.50 in revenue for each inspection, totaling as much as $3 million in the first year ($18.2 million annualized) increasing to as much as $20.5 million in the fifth year. These and other entities that can conduct necessary repairs so vehicles are able to pass the OBD test are estimated to receive as much as $4.2 million for these services in the first year ($25.2 million annualized), increasing to as much as $28.5 million in the fifth year.

Local Employment Impact Statement

The commission reviewed this proposed rulemaking and determined that a Local Employment Impact Statement is not required because the proposed rulemaking does not adversely affect a local economy in a material way for the first five years that the proposed rule is in effect.

Rural Community Impact Statement

The commission reviewed this proposed rulemaking and determined that the proposed rulemaking does not adversely affect rural communities in a material way for the first five years that the proposed rules are in effect. The amendments would apply statewide and have the same effect in rural communities as in urban communities.

Small Business and Micro-Business Assessment

No adverse fiscal implications are anticipated for small or micro-businesses due to the implementation or administration of the proposed rule for the first five-year period the proposed rules are in effect.

Small Business Regulatory Flexibility Analysis

The commission reviewed this proposed rulemaking and determined that a Small Business Regulatory Flexibility Analysis is not required because the proposed rule does not adversely affect a small or micro-business in a material way for the first five years the proposed rules are in effect.

Government Growth Impact Statement

The commission prepared a Government Growth Impact Statement assessment for this proposed rulemaking. The proposed rulemaking does not create or eliminate a government program and will not require an increase or decrease in future legislative appropriations to the agency. The proposed rulemaking does not require the creation of new employee positions or eliminate current employee positions. The proposed rulemaking will result in an increase in fees received by TCEQ and DPS. The TCEQ would receive $0.50 in revenue per vehicle registration issued to cover the costs of developing test and equipment specifications, developing a testing program, and providing assistance through a registration denial program. The DPS would receive $2.00 per vehicle registration to cover the cost of training technicians on the I/M program, staffing of waiver stations, and enforcement of I/M program requirements.

The proposed rulemaking increases the number of individuals subject to its applicability, to include individuals and entities in Bexar County with gas-powered vehicles that are 2-24 years old upon implementation of the program. During the first five years, the proposed rule should not impact positively or negatively the state's economy.

Draft Regulatory Impact Analysis Determination

The commission reviewed the proposed rulemaking considering the regulatory impact analysis requirements of Texas Government Code, §2001.0225, and determined that the proposed rulemaking does not meet the definition of a "Major Environmental Rule" as defined in that statute, and in addition, if it did meet the definition, would not be subject to the requirement to prepare a regulatory impact analysis. A "Major Environmental Rule" means a rule, the specific intent of which is to protect the environment or reduce risks to human health from environmental exposure, and that may adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, or the public health and safety of the state or a sector of the state. Additionally, the proposed rulemaking does not meet any of the four applicability criteria for requiring a regulatory impact analysis for a major environmental rule, which are listed in Tex. Gov't Code Ann., §2001.0225(a). Tex. Gov't Code Ann., §2001.0225 applies only to a major environmental rule, the result of which is to: 1) exceed a standard set by federal law, unless the rule is specifically required by state law; 2) exceed an express requirement of state law, unless the rule is specifically required by federal law; 3) exceed a requirement of a delegation agreement or contract between the state and an agency or representative of the federal government to implement a state and federal program; or 4) adopt a rule solely under the general powers of the agency instead of under a specific state law.

The proposed rulemaking's purpose is to implement the required vehicle I/M program in Bexar County and to remove certain counties in the DFW area from the state low RVP program since they will be subject to the federal RFG rules as of November 7, 2023. These changes are necessary to comply with federal requirements for the implementation of vehicle I/M programs required by 42 United States Code (U.S.C.) §7511a(a), FCAA, §182(b) for the Bexar County 2015 eight-hour ozone nonattainment area and to remove counties in the DFW 2008 eight-hour ozone severe nonattainment area from the state low RVP program that will become subject to requirements for RFG as required by 42 U.S.C. §7545, FCAA, §211(k)(10)(D). The requirement to implement and enforce vehicle I/M programs is specifically required for certain nonattainment areas by the FCAA, and the proposed revisions to 30 TAC Chapter 114 are anticipated to be used as a control strategy for demonstrating attainment of the 2015 eight-hour ozone NAAQS upon implementation of the program in the Bexar County area, as discussed elsewhere in this preamble.

The proposed rulemaking implements requirements of 42 U.S.C. §7410, FCAA, §110, which requires states to adopt a SIP that provides for the implementation, maintenance, and enforcement of the NAAQS in each air quality control region of the state; as well as the removal of counties from the existing state low RVP program that will become subject to the requirements of the 42 U.S.C. §7545, FCAA, §211(k)(10)(D), as discussed elsewhere in this preamble. While 42 U.S.C. §7410, FCAA, §110 generally does not require specific programs, methods, or reductions in order to meet the standard, vehicle I/M programs are specifically required by the FCAA, as are the requirements for federal RFG for severe ozone nonattainment areas. The SIP must also include enforceable emission limitations and other control measures, means, or techniques (including economic incentives such as fees, marketable permits, and auctions of emissions rights), as well as schedules and timetables for compliance as may be necessary or appropriate to meet the applicable requirements of the FCAA. The provisions of the FCAA recognize that states are in the best position to determine what programs and controls are necessary or appropriate in order to meet the NAAQS, and when programs are specifically required, states may implement them with flexibility allowed under the statute and EPA rules. This flexibility allows states, affected industry, and the public to collaborate on the best methods for attaining the NAAQS for the specific regions in the state. Even though the FCAA allows states to develop their own programs, this flexibility does not relieve a state from developing a program that meets the requirements of 42 U.S.C. §7410, FCAA, §110; nor does it allow states to ignore specific requirements of the FCAA. States are not free to ignore the requirements of 42 U.S.C. §7410, FCAA, §110 and must develop programs to assure that their contributions to nonattainment areas are reduced so that these areas can be brought into attainment on the schedule prescribed by the FCAA.

If a state does not comply with its obligations under 42 U.S.C., §7410, FCAA, §110 to submit SIPs that comply with the requirements of the FCAA, states are subject to discretionary sanctions under 42 U.S.C., §7410(m), FCAA, §110(m) or mandatory sanctions under 42 U.S.C., §7509, FCAA, §179 as well as the imposition of a FIP under 42 U.S.C., §7410, FCAA, §110(c).

As discussed earlier in this preamble, states are required to adopt SIPs with enforceable emission limitations and other control measures, means, or techniques, as well as schedules and timetables for compliance, as may be necessary or appropriate to meet the applicable requirements of the FCAA. As discussed in the FISCAL NOTE portion of this preamble, the proposed rules are not anticipated to add any significant additional costs to affected individuals or businesses beyond what is necessary to attain the 2015 eight-hour ozone NAAQS, comply with the specific requirements for vehicle I/M programs, or 42 U.S.C. §7545, FCAA, §211(k)(10)(D) on the economy, a sector of the economy, productivity, competition, jobs, the environment, or the public health and safety of the state or a sector of the state.

The requirement to provide a fiscal analysis of regulations in the Texas Government Code was amended by Senate Bill (SB) 633 during the 75th Legislative Session. The intent of SB 633 was to require agencies to conduct a regulatory impact analysis of extraordinary rules. These are identified in the statutory lan-

guage as major environmental rules that will have a material adverse impact and will exceed a requirement of state law, federal law, or a delegated federal program, or are adopted solely under the general powers of the agency. With the understanding that this requirement would seldom apply, the commission provided a cost estimate for SB 633 that concluded "based on an assessment of rules adopted by the agency in the past, it is not anticipated that the bill will have significant fiscal implications for the agency due to its limited application." The commission also noted that the number of rules that would require assessment under the provisions of the bill was not large. This conclusion was based, in part, on the criteria set forth in the bill that exempted rules from the full analysis unless the rule was a major environmental rule that exceeds a federal law.

As discussed earlier in this preamble, the FCAA does not always require specific programs, methods, or reductions in order to meet the NAAQS, but vehicle I/M programs are specifically required by the FCAA for moderate nonattainment areas, as are the requirements for federal RFG for severe ozone nonattainment areas; thus, states must develop programs for each area contributing to nonattainment to help ensure that those areas will meet the required attainment deadlines and that comply with EPA requirements for vehicle I/M programs and the federal RFG program. Because of the ongoing need to meet federal requirements, the commission routinely proposes and adopts rules incorporating or designed to satisfy specific federal requirements. The legislature is presumed to understand this federal scheme. If each rule proposed by the commission to meet a federal requirement was considered to be a major environmental rule that exceeds federal law, then each of those rules would require the full regulatory impact analysis (RIA) contemplated by SB 633. Requiring a full RIA for all federally required rules is inconsistent with the conclusions reached by the commission in its cost estimate and by the Legislative Budget Board (LBB) in its fiscal notes. Since the legislature is presumed to understand the fiscal impacts of the bills it passes, and that presumption is based on information provided by state agencies and the LBB, then the intent of SB 633 is presumed to only to require the full RIA for rules that are extraordinary in nature. While the proposed rules may have a broad impact, that impact is no greater than is necessary or appropriate to meet the requirements of the FCAA and creates no additional impacts since the proposed rules do not impose burdens greater than required to demonstrate attainment of the 2015 eight-hour ozone NAAQS and comply with the requirements for vehicle I/M programs and the federal RFG program as discussed elsewhere in this preamble.

For these reasons, the proposed rules fall under the exception in Texas Government Code, §2001.0225(a), because they are required by, and do not exceed, federal law. The commission has consistently applied this construction to its rules since this statute was enacted in 1997. Since that time, the legislature has revised the Texas Government Code, but left this provision substantially unamended. It is presumed that "when an agency interpretation is in effect at the time the legislature amends the laws without making substantial change in the statute, the legislature is deemed to have accepted the agency's interpretation." (Central Power & Light Co. v. Sharp, 919 S.W.2d 485, 489 (Tex. App. Austin 1995), writ denied with per curiam opinion respecting another issue, 960 S.W.2d 617 (Tex. 1997); Bullock v. Marathon Oil Co., 798 S.W.2d 353, 357 (Tex. App. Austin 1990, no writ). Cf. Humble Oil & Refining Co. v. Calvert, 414 S.W.2d 172 (Tex. 1967); Dudney v. State Farm Mut. Auto Ins. Co., 9 S.W.3d 884, 893 (Tex. App. Austin 2000); Southwestern Life Ins. Co. v. Montemayor, 24 S.W.3d 581 (Tex. App. Austin 2000, pet. denied); and Coastal Indust. Water Auth. v. Trinity Portland Cement Div., 563 S.W.2d 916 (Tex. 1978).) The commission's interpretation of the RIA requirements is also supported by a change made to the Texas Administrative Procedure Act (APA) by the legislature in 1999. In an attempt to limit the number of rule challenges based upon APA requirements, the legislature clarified that state agencies are required to meet these sections of the APA against the standard of "substantial compliance" (Texas Government Code, §2001.035). The legislature specifically identified Texas Government Code, §2001.0225 as subject to this standard.

As discussed in this analysis and elsewhere in this preamble, the commission has substantially complied with the requirements of Texas Government Code, §2001.0225. The proposed rules implement the requirements of the FCAA as discussed in this analysis and elsewhere in this preamble. The proposed rules were determined to comply with requirements for vehicle I/M programs and federal RFG requirements and will not exceed any standard set by state or federal law. These proposed rules are not an express requirement of state law. The proposed rules do not exceed a requirement of a delegation agreement or a contract between state and federal government, as the proposed rules, if adopted by the commission and approved by EPA, will become federal law as part of the approved SIP required by 42 U.S.C., §7410, FCAA, §110. The proposed rules were not developed solely under the general powers of the agency but are authorized by specific sections of Texas Health and Safety Code (THSC), Chapter 382 (also known as the Texas Clean Air Act), and the Texas Water Code, which are cited in the STATUTORY AUTHORITY section of this preamble, including THSC, §§382.011, 382.012, and 382.017. Therefore, this proposed rulemaking action is not subject to the regulatory analysis provisions of Texas Government Code, §2001.0225(b).

The commission invites public comment regarding the Draft Regulatory Impact Analysis Determination during the public comment period. Written comments on the Draft Regulatory Impact Analysis Determination may be submitted to the contact person at the address listed under the Submittal of Comments section of this preamble.

Takings Impact Assessment

Under Texas Government Code, §2007.002(5), taking means a governmental action that affects private real property, in whole or in part or temporarily or permanently, in a manner that requires the governmental entity to compensate the private real property owner as provided by the Fifth and Fourteenth Amendments to the United States Constitution or §17 or §19, Article I, Texas Constitution; or a governmental action that affects an owner's private real property that is the subject of the governmental action, in whole or in part or temporarily or permanently, in a manner that restricts or limits the owner's right to the property that would otherwise exist in the absence of the governmental action; and is the producing cause of a reduction of at least 25% in the market value of the affected private real property, determined by comparing the market value of the property as if the governmental action is not in effect and the market value of the property determined as if the governmental action is in effect.

The commission completed a takings impact analysis for the proposed rulemaking action under the Texas Government Code, Chapter 2007. The primary purpose of this proposed rulemaking action, as discussed elsewhere in this preamble, is to meet federal requirements for the implementation of vehicle I/M pro-

grams and removal of the six specified counties from the state low RVP program since they will become subject to the federal RFG program one year after reclassification to severe for the 2008 eight-hour ozone NAAQS. Therefore, Chapter 2007 does not apply to this proposed rulemaking because it is an action reasonably taken to fulfill an obligation mandated by federal law, as provided by Texas Government Code, §2007.003(b)(4).

As discussed elsewhere in this preamble, the proposed rulemaking implements requirements of the FCAA, 42 U.S.C., §7410, FCAA, §110 which requires states to adopt a SIP that provides for the implementation, maintenance, and enforcement of the NAAQS in each air quality control region of the state. While 42 U.S.C., §7410, FCAA, §110 generally does not require specific programs, methods, or reductions in order to meet the standard, vehicle I/M programs and federal RFG are specifically required by the FCAA. The SIP must include enforceable emission limitations and other control measures, means, or techniques (including economic incentives such as fees, marketable permits, and auctions of emissions rights), as well as schedules and timetables for compliance as may be necessary or appropriate to meet the applicable requirements of the FCAA. The provisions of the FCAA recognize that states are in the best position to determine what programs and controls are necessary or appropriate in order to meet the NAAQS. This flexibility allows states, affected industry, and the public, to collaborate on the best methods for attaining the NAAQS for the specific regions in the state. Even though the FCAA allows states to develop their own programs, this flexibility does not relieve a state from developing a program that meets the requirements of 42 U.S.C., §7410, FCAA, §110. States are not free to ignore the requirements of 42 U.S.C., §7410, FCAA, §110 and must develop programs to assure that their contributions to nonattainment areas are reduced so that these areas can be brought into attainment on the schedule prescribed by the FCAA.

States are required to adopt SIPs with enforceable emission limitations and other control measures, means, or techniques, as well as schedules and timetables for compliance, as may be necessary or appropriate to meet the applicable requirements of the FCAA. If a state does not comply with its obligations under 42 U.S.C., §7410, FCAA, §110 to submit SIPs that meet the requirements of the FCAA, states are subject to discretionary sanctions under 42 U.S.C., §7410(m) or mandatory sanctions under 42 U.S.C., §7509, FCAA, §179; as well as the imposition of a FIP under 42 U.S.C., §7410, FCAA, §110(c).

The proposed rules will not create any additional burden on private real property beyond what is required under federal law, as the proposed rules, if adopted by the commission and approved by EPA, will become federal law as part of the approved SIP required by 42 U.S.C., §7410, FCAA, §110. The proposed rules will not affect private real property in a manner that would require compensation to private real property owners under the United States Constitution or the Texas Constitution. The proposal also will not affect private real property in a manner that restricts or limits an owner's right to the property that would otherwise exist in the absence of the governmental action. Therefore, the proposed rulemaking will not cause a taking under Texas Government Code, Chapter 2007. For these reasons, Texas Government Code, Chapter 2007 does not apply to this proposed rulemaking.

Consistency with the Coastal Management Program

The commission reviewed the proposed rulemaking and found the proposal is a rulemaking identified in the Coastal Coordination Act Implementation Rules, 31 TAC §29.11(b)(2) relating to rules subject to the Coastal Management Program, and will, therefore, require that goals and policies of the Texas Coastal Management Program (CMP) be considered during the rulemaking process.

Note: §505.11(b)(2) applies only to air pollutant emissions, on-site sewage disposal systems, and underground storage tanks. §505.11(b)(4) applies to all other actions. The commission reviewed this rulemaking for consistency with the CMP goals and policies in accordance with the regulations of the Coastal Coordination Advisory Committee and determined that the rulemaking will not affect any coastal natural resource areas because the rules only affect counties outside the CMP area and is, therefore, consistent with CMP goals and policies.

Written comments on the consistency of this rulemaking may be submitted to the contact person at the address listed under the Submittal of Comments section of this preamble.

Announcement of Hearing

The commission will offer public hearings on this proposal in Arlington on July 6, 2023 at 7 p.m. in the Arlington City Council Chambers located at 101 W Abrams St, Arlington, Texas 76010 and in San Antonio on July 13, 2023 at 7 p.m. in Suite 101 of the Alamo Area Council of Governments located at 2700 NE Loop 410, San Antonio, Texas 78217. The hearings are structured for the receipt of oral or written comments by interested persons. Individuals may present oral statements when called upon in order of registration. Open discussion will not be permitted during the hearing; however, commission staff members will be available to discuss the proposal 30 minutes prior to the hearing.

Persons who have special communication or other accommodation needs who are planning to attend the hearing should contact Sandy Wong, Office of Legal Services at (512) 239-1802 or (800) RELAY-TX (TDD). Requests should be made as far in advance as possible.

Submittal of Comments

Written comments may be submitted to Gwen Ricco, MC 205, Office of Legal Services, Texas Commission on Environmental Quality, P.O. Box 13087, Austin, Texas 78711-3087, or faxed to fax4808@tceq.texas.gov. Electronic comments may be submitted at: https://tceq.commentinput.com/comment/search. File size restrictions may apply to comments being submitted via the TCEQ Public Comments system. All comments should reference Rule Project Number 2022-026-114-AI. The comment period closes on July 17, 2023. Please choose one of the methods provided to submit your written comments.

Copies of the proposed rulemaking can be obtained from the commission's website at https://www.tceq.texas.gov/rules/propose_adopt.html. For further information, please contact Edgar Gilmore, Air Quality Planning Section, (512) 239-2069.

SUBCHAPTER A. DEFINITIONS

30 TAC §114.1, §114.2

Statutory Authority

The expansion of vehicle I/M to Bexar County is proposed under the authority of Texas Water Code (TWC), §5.103, concerning Rules; TWC, §5.105, concerning General Policy, which authorize the commission to carry out its powers and duties under the TWC; TWC, §7.002, concerning Enforcement Authority, which authorizes the commission to enforce the provisions of the Water

Code and the Health and Safety Code within the commission's jurisdiction; and under Texas Health and Safety Code (THSC), §382.017, concerning Rules, which authorizes the commission to adopt rules consistent with the policy and purpose of the Texas Clean Air Act (TCAA).

The expansion of vehicle I/M to Bexar County is also proposed under THSC, §382.002, concerning Policy and Purpose, which establishes the commission's purpose to safeguard the state's air resources, consistent with the protection of public health, general welfare, and physical property; THSC, §382.011, concerning General Powers and Duties, which authorizes the commission to control the quality of the state's air and THSC, §382.012, concerning State Air Control Plan, which authorizes of the commission to prepare and develop a general, comprehensive plan for the control of the state's air. Additionally, the expansion of vehicle I/M to Bexar County is authorized under THSC, §382.201, concerning Definitions, which specifies the definitions that apply under Subchapter G of the THSC, Vehicle Emissions; THSC, §382.202, concerning Vehicle Emissions Inspection and Maintenance Program, which authorizes the commission to establish, implement, and administer a program requiring emissions-related inspections of motor vehicles to be performed at inspection facilities consistent with the requirements of the federal Clean Air Act; THSC, §382.203, concerning Vehicles Subject to Program; Exemptions, which establishes which vehicles are subject to the I/M program and which are exempt from it; and THSC, §382.205, concerning Inspection Equipment and Procedures, which authorizes the commission to adopt standards and specifications for motor vehicle emissions testing equipment, recordkeeping and reporting procedures, and measurable emissions standards, as well as consult with the Department of Public Safety of the State of Texas.

The proposed rules implement TWC, §§5.103, 5.105 and 7.002; and THSC, §§382.002, 382.011, 382.012, 382.017, 382.201-382.203 and 382.205.

§114.1. Definitions.

Unless specifically defined in Texas Health and Safety Code, Chapter 382, also known as the Texas Clean Air Act (TCAA), or in the rules of the commission, the terms used by the commission have the meanings commonly ascribed to them in the field of air pollution control. In addition to the terms which are defined by the TCAA, the following words and terms, when used in this chapter, have the following meanings, unless the context clearly indicates otherwise.

(1) Dual-fuel vehicle--Any motor vehicle or motor vehicle engine engineered and designed to be operated on two different fuels, but not a mixture of the two.

(2) Emergency vehicle--A vehicle defined as an authorized emergency vehicle according to Texas Transportation Code, §541.201(1).

(3) Emissions--The emissions of oxides of nitrogen, volatile organic compounds, carbon monoxide, particulate, or any combination of these substances.

(4) First safety inspection certificate--Initial Texas Department of Public Safety (DPS) certificates issued through DPS-certified inspection stations for every new vehicle found to be in compliance with the rules and regulations governing safety inspections. Beginning on the single sticker transition date as defined in this section, the safety inspection certificates will no longer be used.

(5) First vehicle registration--Initial vehicle registration insignia sticker issued through the Texas Department of Motor Vehicles for every new vehicle found to be in compliance with the rules and regulations governing vehicle registration prior to the single sticker transition date as defined in this section and vehicle registration and safety inspections beginning on the single sticker transition date.

(6) Gross vehicle weight rating--The value specified by the manufacturer as the maximum design loaded weight of a vehicle. This is the weight as expressed on the vehicle's registration[~~,~~] and includes the weight the vehicle can carry or draw.

[~~(7) Heavy-duty vehicle--Any passenger vehicle or truck capable of transporting people, equipment, or cargo, that has a gross vehicle weight rating (GVWR) greater than 8,500 pounds, and is required to be registered under Texas Transportation Code, §502.002. For purposes of the mobile emission reduction credit trading program the heavy-duty class is divided into the following subclasses:~~]

[~~(A) Light heavy-duty vehicle--Any passenger vehicle or truck capable of transporting people, equipment, or cargo that has a GVWR greater than 8,500 pounds, but less than or equal to 10,000 pounds.~~]

[~~(B) Medium heavy-duty vehicle--Any passenger vehicle or truck capable of transporting people, equipment, or cargo that has a GVWR greater than 10,000 pounds, but less than or equal to 19,500 pounds.~~]

[~~(C) Heavy heavy-duty vehicle--Any passenger vehicle or truck capable of transporting people, equipment, or cargo that has a GVWR greater than 19,500 pounds.~~]

[~~(8) Inherently low emission vehicle--A vehicle as defined by 40 Code of Federal Regulations Part 88.~~]

(7) [~~(9)~~] Law enforcement vehicle--Any vehicle controlled by a local government and primarily operated by a civilian or military police officer or sheriff, or by state highway patrols, or other similar law enforcement agencies, and used for the purpose of law enforcement activities including, but not limited to, chase, apprehension, surveillance, or patrol of people engaged in or potentially engaged in unlawful activities.

[~~(10) Light-duty vehicle--Any passenger vehicle or truck capable of transporting people, equipment, or cargo that has a gross vehicle weight rating (GVWR) less than or equal to 8,500 pounds and registered or required to be registered under Texas Transportation Code, §502.002. For purposes of the mobile emission reduction credit trading program the light-duty class is divided into the following subclasses:~~]

[~~(A) Light-duty vehicle--Any passenger vehicle capable of seating 12 or fewer passengers that has a GVWR less than or equal to 6,000 pounds.~~]

[~~(B) Light-duty truck 1--Any passenger truck capable of transporting people, equipment, or cargo that has a GVWR less than or equal to 6,000 pounds.~~]

[~~(C) Light-duty truck 2--Any passenger truck capable of transporting people, equipment, or cargo that has a GVWR greater than 6,000 pounds but less than or equal to 8,500 pounds.~~]

[~~(11) Loaded mode inspection and maintenance test--A measurement of the tailpipe exhaust emissions of a vehicle while the drive wheel rotates on a dynamometer, which simulates the full weight of the vehicle driving down a level roadway. Loaded test equipment specifications must meet United States Environmental Protection Agency requirements for acceleration simulation mode equipment.~~]

[~~(12) Low emission vehicle (LEV)--A vehicle in a class or category of vehicles that has been certified by the United States Environmental Protection Agency for any model year to meet:~~]

[(A) the LEV standards applicable under 42 United States Code, Part C, Subchapter H, §§7581 et seq.; or]

[(B) emission limits at least as stringent as the applicable LEV standards for the Federal Clean Fuel Fleet program under 40 Code of Federal Regulations §§88.104-94, 88.105-94, and 88.311-93, as published in the *Federal Register* on September 30, 1994 (59 FR 50042).]

[(13) Mass transit authority--A transportation or transit authority or department established under Chapter 141, 63rd Legislature (1973), as defined in Texas Transportation Code, Chapters 451 - 453 (relating to Metropolitan Rapid Transit Authorities, Regional Transportation Authorities, and Municipal Transit Departments) that operates a mass transit system under any of those laws.]

[(14) Reformulated gasoline--Gasoline that has been certified as a reformulated gasoline under the federal certification regulations adopted in accordance with 42 United States Code, §7545(k).]

(8) [(15)] Single sticker transition date--The transition date of the single sticker system is the later of March 1, 2015, or the date that the Texas Department of Motor Vehicles and the Texas Department of Public Safety concurrently implement the single sticker system required by Texas Transportation Code, §502.047.

(9) [(16)] Texas Inspection and Maintenance State Implementation Plan--The portion of the Texas state implementation plan that includes the procedures and requirements of the vehicle emissions inspection and maintenance program as adopted by the commission and approved by the EPA [May 29, 1996, in accordance with 40 Code of Federal Regulations Part 51, Subpart S, issued November 5, 1992; the United States Environmental Protection Agency flexibility amendments dated September 18, 1995; and the National Highway Systems Designation Act of 1995]. A copy of the Texas Inspection and Maintenance State Implementation Plan is available at the Texas Commission on Environmental Quality, 12100 Park 35 Circle, Austin, Texas, 78753; mailing address: P.O. Box 13087, MC 166, Austin, Texas 78711-3087.

[(17) Tier I federal emission standards--The standards are defined in 42 United States Code, §7521, and in 40 Code of Federal Regulations Part 86. The phase-in of these standards began in model year 1994.]

[(18) Ultra low emission vehicle--A vehicle as defined by 40 Code of Federal Regulations Part 88.]

(10) [(19)] Vehicle registration--Vehicle characteristics, corresponding owner information, and registration expiration date contained in the Texas Department of Motor Vehicles registration system.

(11) [(20)] Vehicle registration insignia sticker--The sticker issued through the Texas Department of Motor Vehicles (DMV) or county tax assessor-collector for a vehicle compliant with the DMV regulations. Beginning on the single sticker transition date as defined in this section, the vehicle registration insignia sticker, a current valid VIR, or other form of proof authorized by the DPS or the DMV will be used as proof of compliance with inspection and maintenance program requirements, the DMV's rules and regulations governing vehicle registration, and the Texas Department of Public Safety's rules and regulations governing safety inspections.

[(21) Zero emission vehicle--A vehicle as defined by 40 Code of Federal Regulations Part 88.]

§114.2. Inspection and Maintenance Definitions.

Unless specifically defined in Texas Health and Safety Code, Chapter 382, also known as the Texas Clean Air Act (TCAA), or in the rules of the commission, the terms used by the commission have the meanings commonly ascribed to them in the field of air pollution control. In addition to the terms that are defined by the TCAA, the following words and terms, when used in Subchapter C of this chapter (relating to Vehicle Inspection and Maintenance; Low Income Vehicle Repair Assistance, Retrofit, and Accelerated Vehicle Retirement Program; and Early Action Compact Counties), have the following meanings, unless the context clearly indicates otherwise.

(1) Acceleration simulation mode (ASM-2) test--An emissions test using a dynamometer (a set of rollers on which a test vehicle's tires rest) that applies an increasing load or resistance to the drive train of a vehicle, thereby simulating actual tailpipe emissions of a vehicle as it is moving and accelerating. The ASM-2 vehicle emissions test is comprised of two phases:

(A) the 50/15 mode--in which the vehicle is tested for 90 seconds upon reaching and maintaining a constant speed of 15 miles per hour (mph) on a dynamometer that simulates acceleration at a rate of 3.3 mph per second by using 50% of the vehicle available horsepower; and

(B) the 25/25 mode--in which the vehicle is tested for 90 seconds upon reaching and maintaining a constant speed of 25 mph on a dynamometer that simulates acceleration at a rate of 3.3 mph per second by using 25% of the vehicle available horsepower.

(2) Consumer price index--The consumer price index for any calendar year is the average of the consumer price index for all-urban consumers published by the United States Department of Labor, as of the close of the 12-month period ending on August 31 of the calendar year.

(3) Controller area network (CAN)--A vehicle manufacturer's communications protocol that connects to the various electronic modules in a vehicle. CAN provides one protocol that collects information from the vehicle's electronic systems including the on-board diagnostics (OBD) emissions testing system. The United States Environmental Protection Agency requires the CAN protocol to be installed in OBD-compliant vehicles beginning with some model year 2003 vehicles and phasing in to all OBD-compliant vehicles by the 2008 model year.

(4) Low-volume emissions inspection station--A vehicle emissions inspection station that meets all criteria for obtaining a low-volume waiver from the Texas Department of Public Safety.

(5) Motorist--A person or other entity responsible for the inspection, repair, and maintenance of a motor vehicle, which may include, but is not limited to, owners and lessees.

(6) On-board diagnostic (OBD) system--The computer system installed in a vehicle by the manufacturer that monitors the performance of the vehicle emissions control equipment, fuel metering system, and ignition system for the purpose of detecting malfunction or deterioration in performance that would be expected to cause the vehicle not to meet emissions standards. All references to OBD should be interpreted to mean the second generation of this equipment, sometimes referred to as OBD II.

(7) On-road test--Utilization of remote sensing technology to identify vehicles operating within the inspection and maintenance program areas that have a high probability of being high-emitters.

(8) Out-of-cycle test--Required emissions test not associated with vehicle safety inspection testing cycle.

(9) Primarily operated--Use of a motor vehicle greater than 60 calendar days per testing cycle in an affected county. Motorists shall comply with emissions requirements for such counties. It is presumed

that a vehicle is primarily operated in the county in which it is registered.

(10) Program area--County or counties in which the Texas Department of Public Safety, in coordination with the commission, administers the vehicle emissions inspection and maintenance program contained in the Texas Inspection and Maintenance State Implementation Plan. These program areas include:

(A) the Dallas-Fort Worth program area, consisting of the following counties: Collin, Dallas, Denton, and Tarrant;

(B) the El Paso program area, consisting of El Paso County;

(C) the Houston-Galveston-Brazoria program area, consisting of Brazoria, Fort Bend, Galveston, Harris, and Montgomery Counties; [~~and~~]

(D) the extended Dallas-Fort Worth program area, consisting of Ellis, Johnson, Kaufman, Parker, and Rockwall Counties. These counties became part of the program area as of May 1, 2003; and [.]

(E) the Bexar County program area, consisting of Bexar County.

(11) Retests--Successive vehicle emissions inspections following the failing of an initial test by a vehicle during a single testing cycle.

(12) Testing cycle--Before the single sticker transition date as defined in §114.1 of this title (relating to Definitions), the annual cycle commencing with the first safety inspection certificate expiration date for which a motor vehicle is subject to a vehicle emissions inspection or beginning on the single sticker transition date, the annual cycle commencing with the first vehicle registration expiration date for which a motor vehicle is subject to a vehicle emissions inspection.

(13) Two-speed idle (TSI) inspection and maintenance test--A measurement of the tailpipe exhaust emissions of a vehicle while the vehicle idles, first at a lower speed and then again at a higher speed.

(14) Uncommon part--A part that takes more than 30 days for expected delivery and installation where a motorist can prove that a reasonable attempt made to locate necessary emission control parts by retail or wholesale part suppliers will exceed the remaining time prior to expiration of:

(A) the vehicle safety inspection certificate prior to the single sticker transition date as defined in §114.1 of this title (relating to Definitions);

(B) the vehicle registration beginning on the single sticker transition date as defined in §114.1 of this title; or

(C) the 30-day period following an out-of-cycle inspection.

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

Filed with the Office of the Secretary of State on June 2, 2023.

TRD-202302052

Guy Henry
Acting Deputy Director, Environmental Law Division
Texas Commission on Environmental Quality
Earliest possible date of adoption: July 16, 2023
For further information, please call: (512) 239-2678

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SUBCHAPTER C. VEHICLE INSPECTION AND MAINTENANCE; LOW INCOME VEHICLE REPAIR ASSISTANCE, RETROFIT, AND ACCELERATED VEHICLE RETIREMENT PROGRAM; AND EARLY ACTION COMPACT COUNTIES

DIVISION 1. VEHICLE INSPECTION AND MAINTENANCE

30 TAC §114.50, §114.53

Statutory Authority

The expansion of vehicle I/M to Bexar County is proposed under the authority of Texas Water Code (TWC), §5.103, concerning Rules; TWC, §5.105, concerning General Policy, which authorize the commission to carry out its powers and duties under the TWC; TWC, §.7.002, concerning Enforcement Authority, which authorizes the commission to enforce the provisions of the Water Code and the Health and Safety Code within the commission's jurisdiction; and under Texas Health and Safety Code (THSC), §382.017, concerning Rules, which authorizes the commission to adopt rules consistent with the policy and purpose of the Texas Clean Air Act.

The expansion of vehicle I/M to Bexar County is also proposed under THSC, §382.002, concerning Policy and Purpose, which establishes the commission's purpose to safeguard the state's air resources, consistent with the protection of public health, general welfare, and physical property; THSC, §382.011, concerning General Powers and Duties, which authorizes the commission to control the quality of the state's air; and THSC, §382.012, concerning State Air Control Plan, which authorizes of the commission to prepare and develop a general, comprehensive plan for the control of the state's air. Additionally, the expansion of vehicle I/M to Bexar County is authorized under THSC, §382.201, concerning Definitions, which specifies the definitions that apply under Subchapter G of the THSC, Vehicle Emissions; THSC, §382.202, concerning Vehicle Emissions Inspection and Maintenance Program, which authorizes the commission to establish, implement, and administer a program requiring emissions-related inspections of motor vehicles to be performed at inspection facilities consistent with the requirements of the federal Clean Air Act; THSC, §382.203, concerning Vehicles Subject to Program; Exemptions, which establishes which vehicles are subject to the I/M program and which are exempt from it; THSC, §382.204, concerning Remote Sensing Program Component, which requires the commission and the Department of Public Safety (DPS) to develop an enforcement program that includes a remote sensing component; THSC, §382.205, concerning Inspection Equipment and Procedures, which authorizes the commission to adopt standards and specifications for motor vehicle emissions testing equipment, recordkeeping and reporting procedures, and measurable emissions standards, as well as consult with the DPS; THSC,

§382.206, Collection of Data; Report, which authorizes the collection of information derived from the emissions inspection and maintenance program; THSC, §382.207, Inspection Stations; Quality Control Audits; which requires standards and procedures for inspection stations as well as other specifics relating to transportation planning and quality control auditing; THSC, §382.208, Attainment Program, which requires the commission to coordinate with federal, state, and local transportation planning agencies to develop and implement transportation programs and other measures necessary to demonstrate and maintain attainment; THSC, §382.209, Low-Income Vehicle Repair Assistance, Retrofit, and Accelerated Vehicle Retirement Program, which authorizes the commission to establish and authorize the commissioners court of a participating county to implement a low-income vehicle repair assistance, retrofit, and accelerated vehicle retirement program; and THSC, §382.210, Implementation Guidelines and Assistance, which requires the commission to adopt guidelines to assist a participating county in implementing a low-income vehicle repair assistance, retrofit, and accelerated vehicle retirement program..

The proposed rules implement TWC, §§5.103, 5.105 and 7.002; and THSC, §§382.002, 382.011, 382.012, 382.017, 382.201-382.210.

§114.50. Vehicle Emissions Inspection Requirements.

(a) Applicability. The requirements of this section and those contained in the Texas Inspection and Maintenance (I/M) State Implementation Plan (SIP) must be applied to all gasoline-powered motor vehicles 2 - 24 years old and subject to an annual emissions inspection beginning with the first safety inspection. Military tactical vehicles, motorcycles, diesel-powered vehicles, dual-fueled vehicles that cannot operate using gasoline, and antique vehicles registered with the Texas Department of Motor Vehicles are excluded from the program. Safety inspection facilities and inspectors certified by the Texas Department of Public Safety (DPS) must inspect all subject vehicles in the following program areas as defined in §114.2 of this title (relating to Inspection and Maintenance Definitions), in accordance with the following schedule.

(1) This paragraph applies to all vehicles registered and primarily operated in the Dallas-Fort Worth (DFW) program area.

(A) Beginning May 1, 2002, all 1996 and newer model year vehicles registered and primarily operated in Collin, Dallas, Denton, and Tarrant Counties equipped with on-board diagnostic (OBD) systems must be tested using United States Environmental Protection Agency (EPA)-approved OBD test procedures.

(B) Beginning May 1, 2002, all pre-1996 model year vehicles registered and primarily operated in Collin, Dallas, Denton, and Tarrant Counties must be tested using an acceleration simulation mode (ASM-2) test or a vehicle emissions test approved by the EPA.

(C) All vehicle emissions inspection stations in affected program areas must offer both the ASM-2 test and the OBD test except low volume emissions inspection stations. If an owner or operator wishes to have his or her station classified as a low volume emissions inspection station, the station owner or operator shall petition the DPS in accordance with the rules and procedures established by the DPS.

(2) This paragraph applies to all vehicles registered and primarily operated in the extended DFW (EDFW) program area.

(A) Beginning May 1, 2003, all 1996 and newer model year vehicles registered and primarily operated in Ellis, Johnson, Kaufman, Parker, and Rockwall Counties equipped with OBD systems must be tested using EPA-approved OBD test procedures.

(B) Beginning May 1, 2003, all pre-1996 model year vehicles registered and primarily operated in Ellis, Johnson, Kaufman, Parker, and Rockwall Counties must be tested using an ASM-2 test or a vehicle emissions test approved by the EPA.

(C) All vehicle emissions inspection stations in affected program areas must offer both the ASM-2 test and the OBD test except low volume emissions inspection stations. If an owner or operator wishes to have his or her station classified as a low volume emissions inspection station, the station owner or operator shall petition the DPS in accordance with the rules and procedures established by the DPS.

(3) This paragraph applies to all vehicles registered and primarily operated in the Houston-Galveston-Brazoria (HGB) program area.

(A) Beginning May 1, 2002, all 1996 and newer model year vehicles registered and primarily operated in Harris County equipped with OBD systems must be tested using EPA-approved OBD test procedures.

(B) Beginning May 1, 2002, all pre-1996 model year vehicles registered and primarily operated in Harris County must be tested using an ASM-2 test or a vehicle emissions test approved by the EPA.

(C) All vehicle emissions inspection stations in affected program areas must offer both the ASM-2 test and the OBD test except low volume emissions inspection stations. If an owner or operator wishes to have his or her station classified as a low volume emissions inspection station, the station owner or operator shall petition the DPS in accordance with the rules and procedures established by the DPS.

(D) Beginning May 1, 2003, all 1996 and newer model year vehicles equipped with OBD systems and registered and primarily operated in Brazoria, Fort Bend, Galveston, and Montgomery Counties must be tested using EPA-approved OBD test procedures.

(E) Beginning May 1, 2003, all pre-1996 model year vehicles registered and primarily operated in Brazoria, Fort Bend, Galveston, and Montgomery Counties must be tested using the ASM-2 test procedures or a vehicle emissions test approved by the EPA.

(4) This paragraph applies to all vehicles registered and primarily operated in the El Paso program area.

(A) All vehicles must be tested using a two-speed idle (TSI) test through December 31, 2006.

(B) Beginning January 1, 2007, all 1996 and newer model year vehicles equipped with OBD systems must be tested using EPA-approved OBD test procedures.

(C) Beginning January 1, 2007, all pre-1996 model year vehicles must be tested using a TSI test.

(D) Beginning January 1, 2007, all vehicle emissions inspection stations in the El Paso program area must offer both the TSI test and OBD test.

(5) This paragraph applies to all vehicles registered and primarily operated in the Bexar County program area.

(A) Beginning November 1, 2026, all 2 - 24 year old subject vehicles equipped with OBD systems must be tested using EPA-approved OBD test procedures.

(B) Beginning November 1, 2026, all vehicle emissions inspection stations in the Bexar County program area must offer the OBD test.

(b) Control requirements.

(1) No person or entity may operate, or allow the operation of, a motor vehicle registered in the DFW, EDFW, HGB, [~~and~~] El Paso, and Bexar County program areas that does not comply with:

(A) all applicable air pollution emissions control-related requirements included in the annual vehicle safety inspection requirements administered by the DPS as evidenced prior to the single sticker transition date as defined in §114.1 of this title (relating to Definitions) by a current valid inspection certificate affixed to the vehicle windshield, a current valid vehicle inspection report (VIR), or other form of proof authorized by the DPS;

(B) beginning on the single sticker transition date, all applicable air pollution emissions control-related requirements included in the annual vehicle safety inspection requirements administered by the DPS, as evidenced by a current valid vehicle registration insignia sticker, a current valid VIR, or other form of proof authorized by the DPS or the DMV; and

(C) the vehicle emissions I/M requirements contained in this subchapter.

(2) All federal government agencies must require a motor vehicle operated by any federal government agency employee on any property or facility under the jurisdiction of the federal government agency and located in a program area to comply with all vehicle emissions I/M requirements specified in Texas Health and Safety Code, Subchapter G, §§382.201 - 382.216 (concerning Vehicle Emissions), and this chapter. Commanding officers or directors of federal facilities shall certify annually to the executive director, or appointed designee, that all subject vehicles have been tested and are in compliance with the Federal Clean Air Act (42 United States Code, §§7401 et seq.). This requirement will not apply to visiting federal government agency, employee, or military personnel vehicles as long as such visits do not exceed 60 calendar days per year.

(3) Any motorist in the DFW, EDFW, HGB, [~~or~~] El Paso, or Bexar County program areas who has received a notice from an emissions inspection station that there are recall items unresolved on his or her motor vehicle should furnish proof of compliance with the recall notice prior to the next vehicle emissions inspection, such as a written statement from the dealership or leasing agency indicating that emissions repairs have been completed.

(4) A motorist whose vehicle has failed an emissions test may request a challenge retest through the DPS. If the retest is conducted within 15 days of the initial inspection, the retest is free.

(5) A motorist whose vehicle has failed an emissions test and has not requested a challenge retest or whose vehicle has failed a challenge retest shall have emissions-related repairs performed and submit a properly completed vehicle repair form (VRF) in order to receive a retest. In order to receive a waiver or time extension, the motorist shall submit a VRF or applicable documentation as deemed necessary by the DPS.

(6) A motorist whose vehicle is registered in the DFW, EDFW, HGB, [~~or~~] El Paso, or Bexar County program areas or in any county adjacent to a program area and whose vehicle has failed an on-road test administered by the DPS shall:

(A) submit the vehicle for an out-of-cycle vehicle emissions inspection within 30 days of written notice by the DPS; and

(B) satisfy all inspection, extension, or waiver requirements of the vehicle emissions I/M program specified in 37 TAC Chapter 23, Subchapter E (relating to Vehicle Emissions Inspection and Maintenance Program).

(7) A subject vehicle registered in a county without an I/M program that meets the applicability criteria of subsection (a) of this section and the ownership of which has changed through a retail sale as defined by Texas Occupations Code, §2301.002, is not eligible for title receipt or registration in a county with an I/M program unless proof is presented that the vehicle has passed an approved vehicle emissions inspection within 90 days before the title transfer. The evidence of proof required may be in the form of the vehicle inspection report (VIR) or another proof of the program compliance as authorized by the DPS. All 1996 and newer model year vehicles with less than 50,000 miles are exempt from the test-on-resale requirements of this paragraph.

(8) State, governmental, and quasi-governmental agencies that fall outside the normal registration or inspection process must comply with all vehicle emissions I/M requirements for vehicles primarily operated in I/M program areas.

(c) Waivers and extensions. A motorist may apply to the DPS for a waiver or an extension as specified in 37 TAC Chapter 23, Subchapter E, which defers the need for full compliance with vehicle emissions standards for a specified period of time after failing a vehicle emissions inspection.

(d) Prohibitions.

(1) No person may issue or allow the issuance of a VIR, as authorized by the DPS unless all applicable air pollution emissions control-related requirements of the annual vehicle safety inspection and the vehicle emissions I/M requirements are completely and properly performed in accordance with the rules and regulations adopted by the DPS and the commission. Prior to taking any enforcement action regarding this provision, the commission must consult with the DPS.

(2) Before the single sticker transition date as defined in §114.1 of this title, no person may allow or participate in the preparation, duplication, sale, distribution, or use of false, counterfeit, or stolen safety inspection certificates, VIRs, VRFs, vehicle emissions repair documentation, or other documents that may be used to circumvent applicable vehicle emissions I/M requirements and to commit an offense specified in Texas Transportation Code, §548.603 (concerning Fictitious or Counterfeit Inspection Certificate or Insurance Document). Beginning on the single sticker transition date, no person may allow or participate in the preparation, duplication, sale, distribution, or use of false, counterfeit, or stolen vehicle registration insignia stickers, VIRs, VRFs, vehicle emissions repair documentation, or other documents that may be used to circumvent applicable vehicle emissions I/M requirements and to commit an offense specified in Texas Transportation Code, §548.603.

(3) No organization, business, person, or other entity may represent itself as an emissions inspector certified by the DPS unless such certification has been issued under the certification requirements and procedures contained in Texas Transportation Code, §§548.401 - 548.404.

(4) No person may act as or offer to perform services as a Recognized Emissions Repair Technician of Texas, as designated by the DPS, without first obtaining and maintaining DPS recognition.

§114.53. Inspection and Maintenance Fees.

(a) The following fees must be paid for an emissions inspection of a vehicle at an inspection station. This fee must include one free retest should the vehicle fail the emissions inspection provided that the motorist has the retest performed at the same station where the vehicle originally failed and submits, prior to the retest, a properly completed vehicle repair form showing that emissions-related repairs were performed and the retest is conducted within 15 days of the initial emissions test.

(1) In El Paso County beginning May 1, 2002 and ending on the day before the single sticker transition date as defined in §114.1 of this title (relating to Definitions), any emissions inspection station required to conduct an emissions test in accordance with §114.50(a)(4)(A), (B), or (C) of this title (relating to Vehicle Emissions Inspection Requirements) must collect a fee of $14 and remit $2.50 to the Texas Department of Public Safety (DPS). If the El Paso County Commissioners Court adopts a resolution that is approved by the commission to participate in the Low Income Vehicle Repair Assistance, Retrofit, and Accelerated Vehicle Retirement Program (LIRAP), the emissions inspection station in El Paso County must collect a fee of $16 and remit to the DPS $4.50 beginning upon the date specified by the commission and ending on the day before the single sticker transition date. Beginning on the single sticker transition date, any emissions inspection station in El Paso County required to conduct an emissions test in accordance with §114.50(a)(4)(A), (B), or (C) of this title must collect a fee not to exceed $11.50.

(2) In the Dallas-Fort Worth program area beginning May 1, 2002 and ending on the day before the single sticker transition date as defined in §114.1 of this title, any emissions inspection station required to conduct an emissions test in accordance with §114.50(a)(1)(A) or (B) of this title and in the extended Dallas-Fort Worth program area beginning May 1, 2003 and ending on the day before the single sticker transition date, any emissions inspection station required to conduct an emissions test in accordance with §114.50(a)(2)(A) or (B) of this title must collect a fee not to exceed $27. Beginning May 1, 2002 and ending on the day before the single sticker transition date in the Dallas-Fort Worth and the extended Dallas-Fort Worth program areas, the emissions inspection station must remit to the DPS $2.50 for each acceleration simulation mode (ASM-2) test and $8.50 for each on-board diagnostics (OBD) test. Beginning on the single sticker transition date in the Dallas-Fort Worth and the extended Dallas-Fort Worth program areas, any emissions inspection station required to conduct an emissions test in accordance with §114.50(a)(1)(A) or (B) and (2)(A) or (B) of this title must collect a fee not to exceed $24.50 for each ASM-2 test and $18.50 for each OBD test.

(3) In the Houston-Galveston-Brazoria program area beginning May 1, 2002 and ending on the day before the single sticker transition date as defined in §114.1 of this title, any emissions inspection station in Harris County required to conduct an emissions test in accordance with §114.50(a)(3)(A) or (B) of this title and beginning May 1, 2003 and ending on the day before the single sticker transition date, any emissions inspection station in Brazoria, Fort Bend, Galveston, and Montgomery Counties required to conduct an emissions test in accordance with §114.50(a)(3)(D) or (E) of this title must collect a fee not to exceed $27. Beginning May 1, 2002 and ending on the day before the single sticker transition date in Brazoria, Fort Bend, Galveston, Harris, and Montgomery Counties, the emissions inspection station must remit to the DPS $2.50 for each ASM-2 test and $8.50 for each OBD test. Beginning on the single sticker transition date in Brazoria, Fort Bend, Galveston, Harris, and Montgomery Counties, any emissions inspection station required to conduct an emissions test in accordance with §114.50(a)(3)(A), (B), (D), or (E) of this title must collect a fee not to exceed $24.50 for each ASM-2 test and $18.50 for each OBD test.

(4) In the Bexar County program area beginning November 1, 2026, any emissions inspection station in Bexar County required to conduct an emissions test in accordance with §114.50(a)(5)(A) or (B) of this title must collect a fee not to exceed $11.50.

(b) The per-vehicle fee and the amount the inspection station remits to the DPS for a challenge test at an inspection station designated by the DPS, must be the same as the amounts set forth in subsection (a) of this section. The challenge fee must not be charged if the vehicle is retested within 15 days of the initial test.

(c) Inspection stations performing out-of-cycle vehicle emissions inspections for the state's remote sensing element must charge a motorist for an out-of-cycle emissions inspection in the amount specified in subsection (a) of this section resulting from written notification that subject vehicle failed on-road testing. If the vehicle passes the vehicle emissions inspection, the vehicle owner may request reimbursement from the DPS.

(d) Beginning on the single sticker transition date as defined in §114.1 of this title, vehicle owners shall remit as part of the annual vehicle registration fee collected by the Texas Department of Motor Vehicles (DMV) or county tax assessor-collector the amount of the vehicle emissions inspection fee that is required to be remitted to the state.

(1) In El Paso County, the following requirements apply.

(A) If participating in the LIRAP, vehicle owners shall remit $4.50 for motor vehicles subject to vehicle emissions inspections to the DMV or county tax assessor-collector at the time of annual vehicle registration as part of the vehicle emissions inspection fee. Of the $4.50 remitted, $2.00 constitutes the LIRAP fee as defined in §114.7 of this title (relating to Low Income Vehicle Repair Assistance, Retrofit, and Accelerated Vehicle Retirement Program Definitions).

(B) If participating in the LIRAP and in the process of opting out, vehicle owners shall remit $4.50 for motor vehicles subject to vehicle emissions inspections to the DMV or county tax assessor-collector at the time of annual vehicle registration as part of the vehicle emissions inspection fee until the LIRAP fee termination effective date as defined in §114.7 of this title. Of the $4.50 remitted, $2.00 constitutes the LIRAP fee as defined in §114.7 of this title. Upon the LIRAP fee termination effective date, vehicle owners shall remit $2.50 for motor vehicles subject to vehicle emissions inspections to the DMV or county tax-assessor-collector at the time of annual vehicle registration as part of the vehicle emissions inspection fee.

(C) If not participating in the LIRAP, vehicle owners shall remit $2.50 for motor vehicles subject to vehicle emissions inspections to the DMV or county tax-assessor-collector at the time of annual vehicle registration as part of the vehicle emissions inspection fee.

(2) In the Dallas-Fort Worth and the extended Dallas-Fort Worth program areas, the following requirements apply.

(A) Vehicle owners in counties participating in the LIRAP shall remit $2.50 for motor vehicles subject to ASM-2 tests and $8.50 for motor vehicles subject to OBD tests to the DMV or county tax assessor-collector at the time of annual vehicle registration as part of the vehicle emissions inspection fee. Of the $8.50 remitted for OBD tests, $6.00 constitutes the LIRAP fee as defined in §114.7 of this title.

(B) Vehicle owners in counties participating in the LIRAP that are in the process of opting out shall remit $2.50 for motor vehicles subject to ASM-2 tests and $8.50 for motor vehicles subject to OBD tests to the DMV or county tax assessor-collector at the time of annual vehicle registration as part of the vehicle emissions inspection fee until the LIRAP fee termination effective date as defined in §114.7 of this title. Of the $8.50 remitted for OBD tests, $6.00 constitutes the LIRAP fee as defined in §114.7 of this title. Upon the LIRAP fee termination effective date, vehicle owners in participating counties that are in the process of opting out of the LIRAP shall remit $2.50 for motor vehicles subject to vehicle emissions inspections to the DMV or county tax-assessor-collector at the time of annual vehicle registration as part of the vehicle emissions inspection fee.

(C) Vehicle owners in counties not participating in the LIRAP shall remit $2.50 for motor vehicles subject to vehicle emissions inspections to the DMV or county tax-assessor-collector at the time of annual vehicle registration as part of the vehicle emissions inspection fee.

(3) In the Houston-Galveston-Brazoria program area, the following requirements apply.

(A) Vehicle owners in counties participating in the LIRAP shall remit $2.50 for motor vehicles subject to ASM-2 tests and $8.50 for motor vehicles subject to OBD tests to the DMV or county tax assessor-collector at the time of annual vehicle registration as part of the vehicle emissions inspection fee. Of the $8.50 remitted for OBD tests, $6.00 constitutes the LIRAP fee as defined in §114.7 of this title.

(B) Vehicle owners in counties participating in the LIRAP that are in the process of opting out shall remit $2.50 for motor vehicles subject to ASM-2 tests and $8.50 for motor vehicles subject to OBD tests to the DMV or county tax assessor-collector at the time of annual vehicle registration as part of the vehicle emissions inspection fee until the LIRAP fee termination effective date as defined in §114.7 of this title. Of the $8.50 remitted for OBD tests, $6.00 constitutes the LIRAP fee as defined in §114.7 of this title. Upon the LIRAP fee termination effective date, vehicle owners in participating counties that are in the process of opting out of the LIRAP shall remit $2.50 for motor vehicles subject to vehicle emissions inspections to the DMV or county tax-assessor-collector at the time of annual vehicle registration as part of the vehicle emissions inspection fee.

(C) Vehicle owners in counties not participating in the LIRAP shall remit $2.50 for motor vehicles subject to vehicle emissions inspections to the DMV or county tax-assessor-collector at the time of annual vehicle registration as part of the vehicle emissions inspection fee.

(4) In the Bexar County program area, vehicle owners shall remit $2.50 for motor vehicles subject to vehicle emissions inspections to the DMV or county tax-assessor-collector at the time of annual vehicle registration as part of the vehicle emissions inspection fee.

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

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SUBCHAPTER H. LOW EMISSION FUELS
DIVISION 1. GASOLINE VOLATILITY

30 TAC §114.309

Statutory Authority

The proposed removal of the six specified counties from the low Reid Vapor Pressure (LVP) program is proposed under the authority of Texas Water Code (TWC), §5.103, concerning Rules; TWC, §5.105, concerning General Policy, which authorize the commission to carry out its powers and duties under the TWC; TWC, §7.002, concerning Enforcement Authority, which authorizes the commission to enforce the provisions of the Water Code and the Health and Safety Code within the commission's jurisdiction; and under Texas Health and Safety Code (THSC), §382.017, concerning Rules, which authorizes the commission to adopt rules consistent with the policy and purpose of the Texas Clean Air Act.

The proposed removal of the six specified counties from the low RVP program is also proposed under THSC, §382.002, concerning Policy and Purpose, which establishes the commission's purpose to safeguard the state's air resources, consistent with the protection of public health, general welfare, and physical property; THSC, §382.011, concerning General Powers and Duties, which authorizes the commission to control the quality of the state's air; THSC, §382.012 concerning State Air Control Plan, which authorizes of the commission to prepare and develop a general, comprehensive plan for the control of the state's air; and THSC, §382.017, concerning Rules, which authorizes the commission to adopt rules consistent with the policy and purposes of the Texas Clean Air Act.

The proposed rules implement TWC, §§5.103, 5.105 and 7.002; and THSC, §§382.002, 382.011, 382.012 and 382.017.

§114.309. Affected Counties.

All affected persons in the following counties shall be in compliance with §§114.301 and 114.305 - 114.307 of this title (relating to Control Requirements for Reid Vapor Pressure; Approved Test Methods; Recordkeeping Requirements; and Exemptions) no later than the dates specified in §114.301(b) of this title: Anderson, Angelina, Aransas, Atascosa, Austin, Bastrop, Bee, Bell, Bexar, Bosque, Bowie, Brazos, Burleson, Caldwell, Calhoun, Camp, Cass, Cherokee, Colorado, Comal, Cooke, Coryell, De Witt, Delta, [~~Ellis,~~] Falls, Fannin, Fayette, Franklin, Freestone, Goliad, Gonzales, Grayson, Gregg, Grimes, Guadalupe, Harrison, Hays, Henderson, Hill, Hood, Hopkins, Houston, Hunt, Jackson, Jasper, [~~Johnson,~~] Karnes, [~~Kaufman,~~] Lamar, Lavaca, Lee, Leon, Limestone, Live Oak, Madison, Marion, Matagorda, McLennan, Milam, Morris, Nacogdoches, Navarro, Newton, Nueces, Panola, [~~Parker,~~] Polk, Rains, Red River, Refugio, Robertson, [~~Rockwall,~~] Rusk, Sabine, San Augustine, San Jacinto, San Patricio, Shelby, Smith, Somervell, Titus, Travis, Trinity, Tyler, Upshur, Van Zandt, Victoria, Walker, Washington, Wharton, Williamson, Wilson, [~~Wise,~~] and Wood.

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

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