ADOPTED RULES

Adopted rules include new rules, amendments to existing rules, and repeals of existing rules. A rule adopted by a state agency takes effect 20 days after the date on which it is filed with the Secretary of State unless a later date is required by statute or specified in the rule (Government Code, §2001.036). If a rule is adopted without change to the text of the proposed rule, then the *Texas Register* does not republish the rule text here. If a rule is adopted with change to the text of the proposed rule, then the final rule text is included here. The final rule text will appear in the Texas Administrative Code on the effective date.

TITLE 1. ADMINISTRATION

PART 4. OFFICE OF THE SECRETARY OF STATE

CHAPTER 106. REGISTRATION OF DATA BROKERS

The Office of the Secretary of State (Office) adopts new Chapter 106, §§106.1 - 106.5, concerning registration of data brokers. The Office adopts these rules to implement the new registration requirements for data brokers in Senate Bill 2105, enacted by the 88th Legislature, Regular Session, codified at Chapter 509 of the Texas Business and Commerce Code (SB 2105).

Section 106.1 is adopted without changes to the proposed text as published in the September 29, 2023, issue of the *Texas Register* (48 TexReg 5593). This rule will not be republished.

Sections 106.2, 106.3, 106.4, and 106.5 are adopted with changes to the proposed text as published in the September 29, 2023, issue of the *Texas Register* (48 TexReg 5593). These rules will be republished. The changes to §106.2 and §106.4 are similar in nature and primarily simplify the execution requirements for documents submitted under those respective sections. The change to §106.3 updates a defined term and is nonsubstantive. The changes to §106.5 alter the text of the associated figures in response to public comments received, as described below.

BACKGROUND INFORMATION AND JUSTIFICATION

The adoption implements SB 2105 (88th Legislature, Regular Session), which creates a comprehensive framework in Chapter 509 of the Texas Business and Commerce Code to regulate data brokers. The bill took effect on September 1, 2023.

As enacted by SB 2105, Chapter 509 of the Texas Business and Commerce Code requires a data broker (as defined in Texas Business and Commerce Code §509.001(4)) to register annually with the Office. Texas Business and Commerce Code §509.005 specifies the amount of the registration or renewal fee and identifies the information that must be included in a data broker's registration statement filed with the Office. Texas Business and Commerce Code §509.006 directs the Secretary of State to establish and maintain, on its Internet website, a searchable, central registry of data brokers registered under §509.005. Texas Business and Commerce Code §509.004 requires a data broker that maintains an Internet website or mobile application to post a conspicuous notice on the website or application that, in part, contains the language provided by rule of the Office for inclusion in the notice.

Section 2 of SB 2105 requires the Office, not later than December 1, 2023, to adopt rules necessary to facilitate registration by a data broker under Texas Business and Commerce Code §509.005. Section 2 also directs the Office to incorporate into the rules adequate time for a data broker to comply with Chapter 509 of the Texas Business and Commerce Code following the adoption of the rules.

The purpose of these new rules under Chapter 106 (Registration of Data Brokers) is to provide information regarding the procedures for data broker registration with the Office and the posting of a notice on the data broker's Internet website or mobile application, in accordance with SB 2105.

COMMENTS

The 30-day comment period ended on October 29, 2023. During this period, the Office received comments regarding the proposed rules from the Association of National Advertisers, the Coalition for Sensible Public Records Access, the Texas Council on Family Violence, and Texas Appleseed. A summary of the comments relating to the proposed rules and the Office's responses follows.

Comment: Two commenters suggested revising proposed §106.2(b)(1) to require contact information for the data broker, rather than for the individual submitting the registration statement or renewal application. The commenters maintained that requiring contact information for an individual submitter would obligate a data broker to submit a statement of correction under proposed §106.4 each time that information changed, such as the individual submitter's death or departure from employment by the data broker.

Response: The Office declines to revise §106.2(b)(1) as suggested. Texas Business and Commerce Code §509.005(b) already requires contact information for the data broker and such information for the individual submitter is necessary for administrative purposes. The Office also notes that a statement of correction is neither required nor appropriate under these rules if information was accurate at the time of registration or renewal, as applicable, but changed at a later date. Instead, a registered data broker would provide the desired contact information in its renewal application. The Office did not make changes in response to these comments.

Comment: Two commenters recommended revising proposed §106.2(b) to include either a requirement or request for a data broker to provide information related to its general opt-out policies, in addition to similar information otherwise required under Texas Business and Commerce Code §509.005(b)(5)(A).

Response: The Office declines to include the suggested revision because Texas Business and Commerce Code §509.005(c) already permits a data broker to provide such additional information in the registration statement or renewal application, as applicable. The Office did not make changes in response to these comments.

Comment: One commenter requested adding an amendment filing to address updates to information that was otherwise correct at the time of registration or renewal. Two commenters appeared to be under the impression that a statement of correction filed under proposed §106.4 could function to update information on an interim basis.

Response: The Office reiterates that a statement of correction is not appropriate under these rules if information was accurate at the time of registration or renewal, as applicable, but changed at a later date. Instead, a registered data broker would provide the desired contact information in its renewal application. The Office did not make changes in response to this comment.

Comment: Three commenters suggested revising proposed §106.5(1) and §106.5(2) to improve the clarity and accessibility of the notice language required by Texas Business and Commerce Code §509.004.

Response: The Office agrees with the comments. The required notice language in §106.5(1) and §106.5(2) has been revised accordingly.

Comment: Two commenters suggested revising proposed §106.5, concerning the notice requirements, so that a data broker's obligation to post the required notice is contingent upon the filing of its initial registration statement, rather than the effective date of the rules. One commenter appeared to be under the impression that the Office would be in a position to determine that a particular data broker is not required to register under Chapter 509 of the Texas Business and Commerce Code.

Response: The Office disagrees that a data broker's compliance with the notice requirement is or can be conditioned on filing its initial registration statement. Texas Business and Commerce Code §§509.004 and 509.005 relate to the notice and registration requirements, respectively. There is no indication in those sections or elsewhere in Chapter 509 of the Texas Business and Commerce Code that either requirement is dependent on or triggered by the other. Importantly, proposed §106.5 simply provides the required notice language pursuant to Texas Business and Commerce Code §509.004. The Office anticipates that relevant information about data brokers and the data broker registration process will be available on the Office's website prior to or on December 1, 2023, and this will be sufficient to address any potential confusion by the public. The Office also notes that the Office cannot determine whether a particular data broker is subject to Chapter 509 of the Texas Business and Commerce Code or is required to file either an initial registration statement or renewal application. The Office did not make changes in response to these comments.

Comment: One commenter requested an additional rule relating to the location in which the required notice would be published on the data broker's website or mobile application.

Response: The Office declines to add a rule relating to the placement of the required notice, as that decision should be at the discretion of each data broker. The Office did not make changes in response to this comment.

Comment: Two commenters offered recommendations relating to features of the central registry of registered data brokers that will be maintained on the Office's website pursuant to Texas Business and Commerce Code §509.006. The commenters suggested that the Office allow the public to access a complete list of registrants and their full registration statements on the registry. The commenters also asked the Office to prioritize the accessibility and usability of the registry.

Response: The Office acknowledges and appreciates these comments. Although the data broker registry is outside the scope of the proposed rules, the Office's development of the registry is ongoing and will include some of the suggested considerations and other features that are intended to make the registry functional and accessible to the public. The Office did not make changes in response to these comments.

SUBCHAPTER A. DEFINITIONS

1 TAC §106.1

STATUTORY AUTHORITY

The new rules are adopted as authorized by Texas Business and Commerce Code §509.010 and Texas Government Code §2001.004(1). Texas Business and Commerce Code §509.010 authorizes the Office to adopt rules as necessary to implement Chapter 509 of the Texas Business and Commerce Code. Texas Government Code §2001.004 requires a state agency to adopt rules of practice stating the nature and requirements of formal and informal procedures.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on November 14, 2023.

TRD-202304263
Adam Bitter
General Counsel
Office of the Secretary of State
Effective date: December 4, 2023
Proposal publication date: September 29, 2023
For further information, please call: (512) 463-5770

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SUBCHAPTER B. REGISTRATION AND RENEWAL OF DATA BROKERS

1 TAC §106.2, §106.3

STATUTORY AUTHORITY

The new rules are adopted as authorized by Texas Business and Commerce Code §509.010 and Texas Government Code §2001.004(1). Texas Business and Commerce Code §509.010 authorizes the Office to adopt rules as necessary to implement Chapter 509 of the Texas Business and Commerce Code. Texas Government Code §2001.004 requires a state agency to adopt rules of practice stating the nature and requirements of formal and informal procedures.

§106.2. Registration and Renewal of Data Brokers.

(a) A complete initial registration statement or renewal application is comprised of:

(1) A completed registration statement or renewal application that is signed by a person authorized to act by or on behalf of the data broker, in the form promulgated by the secretary (See Form 4001); and

(2) Payment of the registration fee or renewal fee stated in Business and Commerce Code §509.005(a) or §509.005(d), as applicable.

(b) A registration statement or renewal application must comply with Business and Commerce Code §509.005, and also provide:

(1) For the individual submitting the registration statement or renewal application:

(A) The individual's legal name;

(B) The individual's telephone number;

(C) The individual's primary physical address;

(D) The individual's mailing address; and

(E) The individual's e-mail address.

(2) For all renewals, the renewal application must also:

(A) Specify that the submission is a renewal application related to an existing registration certificate; and

(B) Provide the registration number assigned to the data broker by the secretary.

§106.3. Timing of Registration.

(a) A registration certificate expires on the first anniversary of its date of issuance by the secretary.

(b) A data broker seeking to renew an existing registration certificate shall file a renewal application within ninety (90) days before the expiration of the registration certificate.

(c) The initial registration of a data broker to which Chapter 509 of the Business and Commerce Code applies must be filed on or before March 1, 2024.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on November 14, 2023.

TRD-202304264
Adam Bitter
General Counsel
Office of the Secretary of State
Effective date: December 4, 2023
Proposal publication date: September 29, 2023
For further information, please call: (512) 463-5770

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SUBCHAPTER C. STATEMENT OF CORRECTION

1 TAC §106.4

STATUTORY AUTHORITY

The new rule is adopted as authorized by Texas Business and Commerce Code §509.010 and Texas Government Code §2001.004(1). Texas Business and Commerce Code §509.010 authorizes the Office to adopt rules as necessary to implement Chapter 509 of the Texas Business and Commerce Code. Texas Government Code §2001.004 requires a state agency to adopt rules of practice stating the nature and requirements of formal and informal procedures.

§106.4. Corrections.

(a) A data broker must submit a statement of correction if, during the year, it becomes known to the registrant that any information given at the time of registration or renewal, as applicable, was inaccurate.

(b) A statement of correction must include the following information:

(1) The legal name of the data broker;

(2) The date of the last filed registration statement or renewal application;

(3) The registration number assigned to the data broker by the secretary; and

(4) A statement that identifies the inaccuracy and provides the corrected information.

(c) The statement of correction must be signed by a person authorized to act by or on behalf of the data broker in the same manner as a registration statement or renewal application.

(d) There is no filing fee for a correction.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on November 14, 2023.

TRD-202304265
Adam Bitter
General Counsel
Office of the Secretary of State
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Proposal publication date: September 29, 2023
For further information, please call: (512) 463-5770

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SUBCHAPTER D. NOTICE REQUIREMENTS

1 TAC §106.5

STATUTORY AUTHORITY

The new rule is adopted as authorized by Texas Business and Commerce Code §509.010 and Texas Government Code §2001.004(1). Texas Business and Commerce Code §509.010 authorizes the Office to adopt rules as necessary to implement Chapter 509 of the Texas Business and Commerce Code. Texas Government Code §2001.004 requires a state agency to adopt rules of practice stating the nature and requirements of formal and informal procedures.

§106.5. Notice Requirements.

A data broker that maintains an Internet website or mobile application shall post a conspicuous notice on the website or mobile application that states:

(1) For websites:

Figure: 1 TAC §106.5(1)

(2) For mobile applications:

Figure: 1 TAC §106.5(2)

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on November 14, 2023.

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Adam Bitter
General Counsel
Office of the Secretary of State
Effective date: December 4, 2023
Proposal publication date: September 29, 2023
For further information, please call: (512) 463-5770

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TITLE 16. ECONOMIC REGULATION

PART 1. RAILROAD COMMISSION OF TEXAS

CHAPTER 7. GAS SERVICES

SUBCHAPTER D. CUSTOMER SERVICE AND PROTECTION

16 TAC §7.460

The Railroad Commission of Texas (the Commission) adopts amendments to §7.460, relating to Suspension of Gas Utility Service Disconnection During an Extreme Weather Emergency, with changes to the proposed text as published in the October 6, 2023, issue of the *Texas Register* (48 TexReg 5796). The rule will be republished. The Commission adopts the amendments pursuant to Texas Utilities Code §105.023, which requires the Commission to adopt a classification table to guide courts in issuing civil penalties against gas utilities who disconnect service to residential customers during an extreme weather emergency. In that same issue of the *Texas Register,* the Commission proposed new §7.480 relating to Energy Conservation Programs, pursuant to House Bill 2263, 88th Legislative Session (2023). The Commission will address proposed §7.480 in a future action.

Regarding the proposed amendments to §7.460, the Commission received six comments, two from associations (Commission Shift and the Lone Star Chapter of the Sierra Club), three from companies (Atmos Energy Corporation (Atmos Energy), CenterPoint Energy Resources Corp. (CenterPoint), and Texas Gas Service Company (Texas Gas)), and one from the Office of Public Utility Counsel (OPUC). The Commission appreciates these comments.

The Lone Star Chapter of the Sierra Club and OPUC commented in support of the changes to §7.460. The Commission appreciates the support of these commenters.

Atmos Energy and CenterPoint commented that the governing statute directs the Commission to establish a classification system to be used for violations of Texas Utilities Code §104.258(c), which encompasses two violations. One violation was addressed in the proposed rule (disconnection during an extreme weather emergency), but the other violation was not. The Commission agrees that the second violation (demanding collection of full payment of bills due during an extreme weather emergency) should be included in the classification system. To address this comment, the Commission adopts in new subsection (f) the language and Figure proposed in subsection (b)(1). Subsection (f) provides that the Office of the Attorney General of Texas on its own initiative or at the request of the Commission may file suit to recover a civil penalty for violation of subsection (b)(1) or (c) of §7.460. The classification table is adopted with a change to include violations of §7.460(c) (demanding collection of full payment of bills due during an extreme weather emergency) and outlines certain violation factors and values for each factor to determine the dollar amount of penalties to be sought.

Commission Shift commented that the Commission should consider a strict classification guide for the issuing of penalties, including the period in between extreme weather emergencies when companies can and will rush to disconnect prior to another emergency even if expected soon. The Commission disagrees with this comment and makes no change; the statutory language in Texas Utilities Code §104.258(c) does not prohibit disconnection in between extreme weather emergencies.

Texas Gas Service commented that subsection (d) should be broadened to clearly permit electronic notice. The Commission notes that it did not propose amendments related to notice requirements, so this comment is outside the scope of this rulemaking; however, the rule does not prohibit electronic notice.

In addition to the changes being adopted in subsections (b)(1) and (f) previously discussed, amendments in subsection (b)(1) clarify the actions that constitute a violation. The Commission makes no changes to the language proposed in subsection (b)(1) other than to move the classification table and corresponding language to subsection (f).

The Commission adopts the amendments pursuant to Texas Utilities Code, §104.258 and §105.023.

Statutory authority: Texas Utilities Code, §104.258 and §105.023.

Cross-reference to statute: Texas Utilities Code, Chapters 104 and 105.

§7.460. Suspension of Gas Utility Service Disconnection During an Extreme Weather Emergency.

(a) Applicability and scope. This rule applies to gas utilities, as defined in Texas Utilities Code, §101.003(7) and §121.001, and to owners, operators, and managers of mobile home parks or apartment houses who purchase natural gas through a master meter for delivery to a dwelling unit in a mobile home park or apartment house, pursuant to Texas Utilities Code, §§124.001-124.002, within the jurisdiction of the Railroad Commission pursuant to Texas Utilities Code, §102.001. For purposes of this section, all such gas utilities and owners, operators and managers of master meter systems shall be referred to as "providers." Providers shall comply with the following service standards. A gas distribution utility shall file amended service rules incorporating these standards with the Railroad Commission in the manner prescribed by law.

(b) Disconnection prohibited. Except where there is a known dangerous condition or a use of natural gas service in a manner that is dangerous or unreasonably interferes with service to others, a provider shall not disconnect natural gas service in the following circumstances.

(1) A provider shall not disconnect a delinquent residential customer during an extreme weather emergency. An extreme weather emergency means a day when the previous day's highest temperature did not exceed 32 degrees Fahrenheit and the temperature is predicted to remain at or below that level for the next 24 hours according to the nearest National Weather Station for the county where the customer takes service.

(2) A provider shall not disconnect a delinquent residential customer for a billing period in which the provider receives a written pledge, letter of intent, purchase order, or other written notification from an energy assistance provider that it is forwarding sufficient payment to continue service.

(3) A provider shall not disconnect a delinquent residential customer on a weekend day, unless personnel or agents of the provider are available for the purpose of receiving payment or making collections and reconnecting service.

(c) Payment plans. Providers shall defer collection of the full payment of bills that are due during an extreme weather emergency until after the emergency is over, and shall work with customers to establish a payment schedule for deferred bills as set forth in §7.45 of this title (relating to Quality of Service).

(d) Notice. Beginning in the September or October billing periods utilities and owners, operators, or managers of master metered systems shall give notice as follows:

(1) Each utility shall provide a copy of this rule to the social services agencies that distribute funds from the Low Income Home Energy Assistance Program within the utility's service area.

(2) Each utility shall provide a copy of this rule to any other social service agency of which the provider is aware that provides financial assistance to low income customers in the utility's service area.

(3) Each utility shall provide a copy of this rule to all residential customers of the utility and customers who are owners, operators, or managers of master metered systems.

(4) Owners, operators, or managers of master metered systems shall provide a copy of this rule to all of their customers.

(e) In addition to the minimum standards specified in this section, providers may adopt additional or alternative requirements if the provider files a tariff with the Commission pursuant to §7.315 of this title (relating to Filing of Tariffs). The Commission shall review the tariff to ensure that at least the minimum standards of this section are met.

(f) In accordance with Texas Utilities Code §105.023, the Office of the Attorney General of Texas on its own initiative or at the request of the Commission may file suit to recover a civil penalty for a violation of subsection (b)(1) or (c) of this section. The table in this subsection contains a classification system to be used by a court when such a suit is filed.
Figure: 16 TAC §7.460(f)

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on November 15, 2023.

TRD-202304277
Haley Cochran
Assistant General Counsel
Railroad Commission of Texas
Effective date: December 5, 2023
Proposal publication date: October 6, 2023
For further information, please call: (512) 475-1295

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TITLE 22. EXAMINING BOARDS

PART 3. TEXAS BOARD OF CHIROPRACTIC EXAMINERS

CHAPTER 72. BOARD FEES, LICENSE APPLICATIONS, AND RENEWALS

22 TAC §72.5

The Texas Board of Chiropractic Examiners (Board) adopts the repeal of 22 TAC §72.5 (Approved Schools and Colleges) without changes as published in the September 1, 2023, issue of the *Texas Register* (48 TexReg 4746). The rule will not be republished. The Board will adopt a new §72.5 in a separate rulemaking. This rulemaking action will remove typographical errors in the current rule.

The Board received one comment on this rulemaking from Scott Kelley, D.C., the President of the Chiropractic Society of Texas. Dr. Kelley raised his concerns on the substance of the rule itself, not the corrections made in this rulemaking, so the Board declines to adopt any substantive changes to the rule at this time. The Board appreciates Dr. Kelley's interest in the overall subject of chiropractic college accreditation and looks forward to his input when the Board looks at the issue in depth.

The repeal is adopted under Texas Occupations Code §201.152 (which authorizes the Board to adopt rules necessary to perform the Board's duties and to regulate the practice of chiropractic), and 201.302 (which requires license applicants to present evidence to the Board of attendance at a recognized chiropractic school).

No other statutes or rules are affected by this repeal.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on November 13, 2023.

TRD-202304220
Christopher Burnett
General Counsel
Texas Board of Chiropractic Examiners
Effective date: December 3, 2023
Proposal publication date: September 1, 2023
For further information, please call: (512) 305-6700

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22 TAC §72.5

The Texas Board of Chiropractic Examiners (Board) adopts new 22 TAC §72.5 (Approved Schools and Colleges) without changes as published in the September 1, 2023, issue of the *Texas Register* (48 TexReg 4747). The rule will not be republished. The current §72.5 is being repealed in a separate rulemaking action. This rulemaking action will correct typographical errors in the current rule; there are no substantive changes to the existing text proposed.

The Board received one comment on this rulemaking from Scott Kelley, D.C., the President of the Chiropractic Society of Texas. Dr. Kelley raised his concerns on the substance of the rule itself, not the corrections made in this rulemaking, so the Board declines to adopt any substantive changes to the rule at this time.

The Board appreciates Dr. Kelley's interest in the overall subject of chiropractic college accreditation and looks forward to his input when the Board looks at the issue in depth.

The rule is adopted under Texas Occupations Code §201.152 (which authorizes the Board to adopt rules necessary to perform the Board's duties and to regulate the practice of chiropractic), and 201.302 (which requires license applicants to present evidence to the Board of attendance at a recognized chiropractic school).

No other statutes or rules are affected by this rule.

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 November 13, 2023.

TRD-202304221
Christopher Burnett
General Counsel
Texas Board of Chiropractic Examiners
Effective date: December 3, 2023
Proposal publication date: September 1, 2023
For further information, please call: (512) 305-6700

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CHAPTER 78. SCOPE OF PRACTICE AND DELEGATION

22 TAC §78.4

The Texas Board of Chiropractic Examiners (Board) adopts the repeal of 22 TAC §78.4 (Delegation to Chiropractic Students and Recent Graduates) without changes as published in the September 1, 2023, issue of the *Texas Register* (48 TexReg 4750). The rule will not be republished. The Board will adopt a new §78.4 (Delegation to Chiropractic Students) and a new §78.7 (Delegation to Recent Graduates) in separate rulemakings.

The overall purpose of these rulemakings is to split the current §78.4 into two separate rules. Licensees have suggested this to the Board because some have found the current rule confusing due to the slightly differing requirements for delegating to chiropractic students and recent graduates. The Board agrees that creating separate rules for students and graduates will make it easier for licensees to comply with the requirements. Therefore, the Board will also adopt a new §78.7 (Delegation to Recent Graduates). There is no substantive changes to the current requirements for delegating to chiropractic students and recent graduates.

The Board received no comments concerning this rulemaking.

The repeal is adopted under Texas Occupations Code §201.152 (which authorizes the Board to adopt rules necessary to perform the Board's duties and to regulate the practice of chiropractic), and 201.451 (which authorizes the Board to adopt rules relating to delegating chiropractic tasks to assistants).

No other statutes or rules are affected by this adopted repeal.

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 November 13, 2023.

TRD-202304222
Christopher Burnett
General Counsel
Texas Board of Chiropractic Examiners
Effective date: December 3, 2023
Proposal publication date: September 1, 2023
For further information, please call: (512) 305-6700

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22 TAC §78.4

The Texas Board of Chiropractic Examiners (Board) adopts new 22 TAC §78.4 (Delegation to Chiropractic Students) without changes as published in the September 1, 2023, issue of the *Texas Register* (48 TexReg 4751). The rule will not be republished. The Board will adopt the repeal of the current §78.4 (Delegation to Chiropractic Students and Recent Graduates) and adopt a new §78.7 (Delegation to Recent Graduates) in separate rulemakings.

The overall purpose of these rulemakings is to split the current §78.4 into two separate rules. Licensees have suggested this to the Board because some have found the current rule confusing due to the slightly differing requirements for delegating to chiropractic students and recent graduates. The Board agrees that creating separate rules for students and graduates will make it easier for licensees to comply with the requirements. Therefore, the Board will also adopt a new §78.7 (Delegation to Recent Graduates). There will be no substantive changes to the current requirements for delegating to chiropractic students and recent graduates.

The Board received no comments on this rulemaking.

The rule is adopted under Texas Occupations Code §201.152 (which authorizes the Board to adopt rules necessary to perform the Board's duties and to regulate the practice of chiropractic), and 201.451 (which authorizes the Board to adopt rules relating to delegating chiropractic tasks to assistants).

No other statutes or rules are affected by this new rule.

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 November 13, 2023.

TRD-202304223
Christopher Burnett
General Counsel
Texas Board of Chiropractic Examiners
Effective date: December 3, 2023
Proposal publication date: September 1, 2023
For further information, please call: (512) 305-6700

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22 TAC §78.7

The Texas Board of Chiropractic Examiners (Board) adopts new 22 TAC §78.7 (Delegation to Recent Graduates) without changes as published in the September 1, 2023, issue of the

Texas Register (48 TexReg 4752). The rule will not be republished. The Board will adopt the repeal of the current §78.4 (Delegation to Chiropractic Students and Recent Graduates) and adopt a new §78.4 (Delegation to Chiropractic Students) in separate rulemakings.

The overall purpose of these rulemakings is to split the current §78.4 into two separate rules (§78.4 for chiropractic students only and new §78.7 for recent graduates only). Licensees have suggested this to the Board because some have found the current rule confusing due to the slightly differing requirements for delegating to chiropractic students and recent graduates contained in the rule. The Board agrees that creating separate stand-alone rules for students and graduates will make it easier for licensees to comply with the requirements. There will be no substantive changes to the current requirements for delegating to chiropractic students and recent graduates.

The Board received no comments concerning this rulemaking.

The rule is adopted under Texas Occupations Code §201.152 (which authorizes the Board to adopt rules necessary to perform the Board's duties and to regulate the practice of chiropractic), and 201.451 (which authorizes the Board to adopt rules relating to delegating chiropractic tasks to assistants).

No other statutes or rules are affected by this adopted rule.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on November 13, 2023.

TRD-202304224
Christopher Burnett
General Counsel
Texas Board of Chiropractic Examiners
Effective date: December 3, 2023
Proposal publication date: September 1, 2023
For further information, please call: (512) 305-6700

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PART 15. TEXAS STATE BOARD OF PHARMACY

CHAPTER 283. LICENSING REQUIREMENTS FOR PHARMACISTS

22 TAC §283.12

The Texas State Board of Pharmacy adopts amendments to §283.12, concerning Licenses for Military Service Members, Military Veterans, and Military Spouses. These amendments are adopted without changes to the proposed text as published in the September 22, 2023, issue of the *Texas Register* (48 TexReg 5382). The rule will not be republished.

The amendments establish procedures for a military service member who is currently licensed in good standing by a jurisdiction with licensing requirements that are substantially similar to Texas's requirements to obtain an interim pharmacist license, in accordance with Senate Bill 422 and make grammatical corrections.

No comments were received.

The amendments are adopted 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 this adoption: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on November 14, 2023.

TRD-202304249
Daniel Carroll, Pharm.D.
Executive Director
Texas State Board of Pharmacy
Effective date: December 4, 2023
Proposal publication date: September 22, 2023
For further information, please call: (512) 305-8033

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CHAPTER 291. PHARMACIES SUBCHAPTER A. ALL CLASSES OF PHARMACIES

22 TAC §291.3

The Texas State Board of Pharmacy adopts amendments to §291.3, concerning Required Notifications. These amendments are adopted without changes to the proposed text as published in the September 22, 2023, issue of the *Texas Register* (48 TexReg 5384). The rule will not be republished.

The amendments clarify that a pharmacy must notify the board in writing if the pharmacy temporarily closes for the loss of a pharmacist-in-charge and clarify the notification requirements for amending a pharmacy license.

No comments were received.

The amendments are adopted 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 this adoption: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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22 TAC §291.5

The Texas State Board of Pharmacy adopts amendments to §291.5, concerning Closing a Pharmacy. These amendments are adopted without changes to the proposed text as published in the September 22, 2023, issue of the *Texas Register* (48 TexReg 5388). The rule will not be republished.

The amendments provide that a pharmacy may temporarily close for the loss of a pharmacist-in-charge if the pharmacy timely notifies the board in writing of the temporary closure.

No comments were received.

The amendments are adopted 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 this adoption: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

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22 TAC §291.6

The Texas State Board of Pharmacy adopts amendments to §291.6, concerning Pharmacy License Fees. These amendments are adopted without changes to the proposed text as published in the September 22, 2023, issue of the *Texas Register* (48 TexReg 5389). The rule will not be republished.

The amendments increase pharmacy license fees based on expected expenses, specify the application fee for an initial or renewed certificate to provide remote pharmacy services, and remove the fee for issuance of a duplicate renewal certificate.

No comments were received.

The amendments are adopted under §§551.002, 554.006, 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 Section 554.006(a) as authorizing the agency to adopt fees to cover the cost of administering Subtitle J, Title 3, Occupations Code. 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 this adoption: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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22 TAC §291.8

The Texas State Board of Pharmacy adopts amendments to §291.8, concerning Return of Prescription Drugs. These amendments are adopted without changes to the proposed text as published in the September 22, 2023, issue of the *Texas Register* (48 TexReg 5390). The rule will not be republished.

The amendments update the name of a state agency.

No comments were received.

The amendments are adopted 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 this adoption: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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SUBCHAPTER B. COMMUNITY PHARMACY (CLASS A)

22 TAC §291.33

The Texas State Board of Pharmacy adopts amendments to §291.33, concerning Operational Standards. These amendments are adopted with changes to the proposed text as published in the September 22, 2023, issue of the *Texas Register* (48 TexReg 5392). The rule will be republished.

The amendments specify prepackaging and labeling requirements for a participating provider to dispense donated prescription drugs under Chapter 442, Health and Safety Code, in accordance with House Bill 4332.

The Board received comments from George Wang, Ph.D., with SIRUM in support of the amendments and suggesting changes to certain terms and phrases for consistency with statutory language. The Board agreed and made changes to the labeling and recordkeeping requirements to align with the language in §442.0515, Health and Safety Code.

The amendments are adopted 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 this adoption: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§291.33. Operational Standards.

(a) Licensing requirements.

(1) A Class A pharmacy shall register annually or biennially with the board on a pharmacy license application provided by the board, following the procedures as specified in §291.1 of this title (relating to Pharmacy License Application).

(2) A Class A pharmacy which changes ownership shall notify the board within ten 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).

(3) A Class A pharmacy which changes location and/or name shall notify the board as specified in §291.3 of this title.

(4) A Class 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 ten days of the change, following the procedures as specified in §291.3 of this title.

(5) A Class A pharmacy shall notify the board in writing within ten days of closing, following the procedures as specified in §291.5 of this title (relating to Closing a Pharmacy).

(6) A separate license is required for each principal place of business and only one pharmacy license may be issued to a specific location.

(7) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for the issuance and renewal of a license and the issuance of an amended license.

(8) A Class A pharmacy, licensed under the provisions of the Act, §560.051(a)(1), which also operates another type of pharmacy which would otherwise be required to be licensed under the Act, §560.051(a)(2) concerning Nuclear Pharmacy (Class B), is not required to secure a license for such other type of pharmacy; provided, however, such licensee is required to comply with the provisions of Subchapter C of this chapter (relating to Nuclear Pharmacy (Class B)), to the extent such sections are applicable to the operation of the pharmacy.

(9) A Class A pharmacy engaged in the compounding of non-sterile preparations shall comply with the provisions of §291.131 of this title (relating to Pharmacies Compounding Non-Sterile Preparations).

(10) A Class A pharmacy shall not compound sterile preparations.

(11) A Class A pharmacy engaged in the provision of remote pharmacy services, including storage and dispensing of prescription drugs, shall comply with the provisions of §291.121 of this title (relating to Remote Pharmacy Services).

(12) Class A pharmacy engaged in centralized prescription dispensing and/or prescription drug or medication order processing shall comply with the provisions of §291.123 of this title (relating to Central Prescription Drug or Medication Order Processing) and/or §291.125 of this title (relating to Centralized Prescription Dispensing).

(b) Environment.

(1) General requirements.

(A) The pharmacy shall be arranged in an orderly fashion and kept clean. All required equipment shall be clean and in good operating condition.

(B) A Class A pharmacy shall have a sink with hot and cold running water within the pharmacy, exclusive of restroom facilities, available to all pharmacy personnel and maintained in a sanitary condition.

(C) A Class A pharmacy which serves the general public shall contain an area which is suitable for confidential patient counseling.

(i) Such counseling area shall be:

(I) easily accessible to both patient and pharmacists and not allow patient access to prescription drugs; and

(II) designed to maintain the confidentiality and privacy of the pharmacist/patient communication.

(ii) In determining whether the area is suitable for confidential patient counseling and designed to maintain the confidentiality and privacy of the pharmacist/patient communication, the board may consider factors such as the following:

(I) the proximity of the counseling area to the check-out or cash register area;

(II) the volume of pedestrian traffic in and around the counseling area;

(III) the presence of walls or other barriers between the counseling area and other areas of the pharmacy; and

(IV) any evidence of confidential information being overheard by persons other than the patient or patient's agent or the pharmacist or agents of the pharmacist.

(D) The pharmacy shall be properly lighted and ventilated.

(E) The temperature of the pharmacy shall be maintained within a range compatible with the proper storage of drugs. The temperature of the refrigerator shall be maintained within a range compatible with the proper storage of drugs requiring refrigeration.

(F) Animals, including birds and reptiles, shall not be kept within the pharmacy and in immediately adjacent areas under the control of the pharmacy. This provision does not apply to fish in aquariums, service animals accompanying disabled persons, or animals for sale to the general public in a separate area that is inspected by local health jurisdictions.

(G) If the pharmacy has flammable materials, the pharmacy shall have a designated area for the storage of flammable materials. Such area shall meet the requirements set by local and state fire laws.

(2) Security.

(A) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of prescription drugs, and records for such drugs.

(B) The prescription department shall be locked by key, combination or other mechanical or electronic means to prohibit unauthorized access when a pharmacist is not on-site except as provided in subparagraphs (C) and (D) of this paragraph and paragraph (3) of this subsection. The following is applicable:

(i) If the prescription department is closed at any time when the rest of the facility is open, the prescription department must be physically or electronically secured. The security may be accomplished by means such as floor to ceiling walls; walls, partitions, or barriers at least 9 feet 6 inches high; electronically monitored motion detectors; pull down sliders; or other systems or technologies that will secure the pharmacy from unauthorized entrance when the pharmacy is closed. Pharmacies licensed prior to June 1, 2009, shall be exempt from this provision unless the pharmacy changes location. Change of location shall include the relocation of the pharmacy within the licensed address. A pharmacy licensed prior to June 1, 2009 that files a change of ownership but does not change location shall be exempt from the provisions.

(ii) The pharmacy's key, combination, or other mechanical or electronic means of locking the pharmacy may not be duplicated without the authorization of the pharmacist-in-charge or owner.

(iii) At a minimum, the pharmacy must have a basic alarm system with off-site monitoring and perimeter and motion sensors. The pharmacy may have additional security by video surveillance camera systems.

(C) Prior to authorizing individuals to enter the prescription department, the pharmacist-in-charge or owner may designate persons who may enter the prescription department to perform functions, other than dispensing functions or prescription processing, documented by the pharmacist-in-charge including access to the prescription department by other pharmacists, pharmacy personnel and other individuals. The pharmacy must maintain written documentation of authorized individuals other than individuals employed by the pharmacy who accessed the prescription department when a pharmacist is not on-site.

(D) Only persons designated either by name or by title including such titles as "relief" or "floater" pharmacist, in writing by the pharmacist-in-charge may unlock the prescription department except in emergency situations. An additional key to or instructions on accessing the prescription department may be maintained in a secure location outside the prescription department for use during an emergency or as designated by the pharmacist-in-charge.

(E) Written policies and procedures for the pharmacy's security shall be developed and implemented by the pharmacist-in-charge and/or the owner of the pharmacy. Such policies and procedures may include quarterly audits of controlled substances commonly abused or diverted; perpetual inventories for the comparison of the receipt, dispensing, and distribution of controlled substances; monthly reports from the pharmacy's wholesaler(s) of controlled substances purchased by the pharmacy; opening and closing procedures; product storage and placement; and central management oversight.

(3) Temporary absence of pharmacist.

(A) On-site supervision by pharmacist.

(i) If a pharmacy is staffed by only one pharmacist, the pharmacist may leave the prescription department for short periods of time without closing the prescription department and removing pharmacy technicians, pharmacy technician trainees, and other pharmacy personnel from the prescription department provided the following conditions are met:

(I) at least one pharmacy technician remains in the prescription department;

(II) the pharmacist remains on-site at the licensed location of the pharmacy and is immediately available;

(III) the pharmacist reasonably believes that the security of the prescription department will be maintained in his or her absence. If in the professional judgment of the pharmacist, the pharmacist determines that the prescription department should close during his or her absence, then the pharmacist shall close the prescription department and remove the pharmacy technicians, pharmacy technician trainees, and other pharmacy personnel from the prescription department during his or her absence; and

(IV) a notice is posted which includes the following information:

(-a-) the pharmacist is on a break and the time the pharmacist will return; and

(-b-) pharmacy technicians may begin the processing of prescription drug orders or refills brought in during the pharmacist's absence, but the prescription or refill may not be delivered to the patient or the patient's agent until the pharmacist verifies the accuracy of the prescription.

(ii) During the time a pharmacist is absent from the prescription department, only pharmacy technicians who have completed the pharmacy's training program may perform the following duties, provided a pharmacist verifies the accuracy of all acts, tasks, and functions performed by the pharmacy technicians prior to delivery of the prescription to the patient or the patient's agent:

(I) initiating and receiving refill authorization requests;

(II) entering prescription data into a data processing system;

(III) taking a stock bottle from the shelf for a prescription;

(IV) preparing and packaging prescription drug orders (e.g., counting tablets/capsules, measuring liquids, or placing them in the prescription container);

(V) affixing prescription labels and auxiliary labels to the prescription container;

(VI) prepackaging and labeling prepackaged drugs;

(VII) receiving oral prescription drug orders for dangerous drugs and reducing these orders to writing, either manually or electronically;

(VIII) transferring or receiving a transfer of original prescription information for dangerous drugs on behalf of a patient; and

(IX) contacting a prescriber for information regarding an existing prescription for a dangerous drug.

(iii) Upon return to the prescription department, the pharmacist shall:

(I) conduct a drug regimen review as specified in subsection (c)(2) of this section; and

(II) verify the accuracy of all acts, tasks, and functions performed by the pharmacy technicians prior to delivery of the prescription to the patient or the patient's agent.

(iv) An agent of the pharmacist may deliver a previously verified prescription to the patient or his or her agent provided a record of the delivery is maintained containing the following information:

(I) date of the delivery;

(II) unique identification number of the prescription drug order;

(III) patient's name;

(IV) patient's phone number or the phone number of the person picking up the prescription; and

(V) signature of the person picking up the prescription.

(v) Any prescription delivered to a patient when a pharmacist is not in the prescription department must meet the requirements for a prescription delivered to a patient as described in subsection (c)(1)(F) of this section.

(vi) During the times a pharmacist is absent from the prescription department a pharmacist intern shall be considered a registered pharmacy technician and may perform only the duties of a registered pharmacy technician.

(vii) In pharmacies with two or more pharmacists on duty, the pharmacists shall stagger their breaks and meal periods so that the prescription department is not left without a pharmacist on duty.

(B) Pharmacist is off-site.

(i) The prescription department must be secured with procedures for entry during the time that a pharmacy is not under the continuous on-site supervision of a pharmacist and the pharmacy is not open for pharmacy services.

(ii) Pharmacy technicians and pharmacy technician trainees may not perform any duties of a pharmacy technician or pharmacy technician trainee during the time that the pharmacist is off-site.

(iii) A pharmacy may use an automated dispensing and delivery system as specified in §291.121(d) of this title for pick-up of a previously verified prescription by a patient or patient's agent.

(iv) An agent of the pharmacist may deliver a previously verified prescription to a patient or patient's agent during short periods of time when a pharmacist is off-site, provided the following conditions are met:

(I) short periods of time may not exceed two consecutive hours in a 24 hour period;

(II) a notice is posted which includes the following information:

(-a-) the pharmacist is off-site and not present in the pharmacy;

(-b-) no new prescriptions may be prepared at the pharmacy but previously verified prescriptions may be delivered to the patient or the patient's agent; and

(-c-) the date/time when the pharmacist will return;

(III) the pharmacy must maintain documentation of the absences of the pharmacist(s); and

(IV) the prescription department is locked and secured to prohibit unauthorized entry.

(v) During the time a pharmacist is absent from the prescription department and is off-site, a record of prescriptions delivered must be maintained and contain the following information:

(I) date and time of the delivery;

(II) unique identification number of the prescription drug order;

(III) patient's name;

(IV) patient's phone number or the phone number of the person picking up the prescription; and

(V) signature of the person picking up the prescription.

(vi) Any prescription delivered to a patient when a pharmacist is not on-site at the pharmacy must meet the requirements for a prescription delivered to a patient as described in subsection (c)(1)(F) of this section.

(c) Prescription dispensing and delivery.

(1) Patient counseling and provision of drug information.

(A) To optimize drug therapy, a pharmacist shall communicate to the patient or the patient's agent information about the prescription drug or device which in the exercise of the pharmacist's professional judgment the pharmacist deems significant, such as the following:

(i) name and description of the drug or device;

(ii) dosage form, dosage, route of administration, and duration of drug therapy;

(iii) special directions and precautions for preparation, administration, and use by the patient;

(iv) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(v) techniques for self-monitoring of drug therapy;

(vi) proper storage;

(vii) refill information; and

(viii) action to be taken in the event of a missed dose.

(B) Such communication shall be:

(i) provided to new and existing patients of a pharmacy with each new prescription drug order. A new prescription drug

order is one that has not been dispensed by the pharmacy to the patient in the same dosage and strength within the last year;

(ii) provided for any prescription drug order dispensed by the pharmacy on the request of the patient or patient's agent;

(iii) communicated orally unless the patient or patient's agent is not at the pharmacy or a specific communication barrier prohibits such oral communication;

(iv) documented by recording the initials or identification code of the pharmacist providing the counseling in the prescription dispensing record as follows:

(I) on the original hard-copy prescription, provided the counseling pharmacist clearly records his or her initials on the prescription for the purpose of identifying who provided the counseling;

(II) in the pharmacy's data processing system;

(III) in an electronic logbook; or

(IV) in a hard-copy log; and

(v) reinforced with written information relevant to the prescription and provided to the patient or patient's agent. The following is applicable concerning this written information:

(I) Written information must be in plain language designed for the patient and printed in an easily readable font size comparable to but no smaller than ten-point Times Roman. This information may be provided to the patient in an electronic format, such as by e-mail, if the patient or patient's agent requests the information in an electronic format and the pharmacy documents the request.

(II) When a compounded preparation is dispensed, information shall be provided for the major active ingredient(s), if available.

(III) For new drug entities, if no written information is initially available, the pharmacist is not required to provide information until such information is available, provided:

(-a-) the pharmacist informs the patient or the patient's agent that the product is a new drug entity and written information is not available;

(-b-) the pharmacist documents the fact that no written information was provided; and

(-c-) if the prescription is refilled after written information is available, such information is provided to the patient or patient's agent.

(IV) The written information accompanying the prescription or the prescription label shall contain the statement "Do not flush unused medications or pour down a sink or drain." A drug product on a list developed by the Federal Food and Drug Administration of medicines recommended for disposal by flushing is not required to bear this statement.

(C) Only a pharmacist may verbally provide drug information to a patient or patient's agent and answer questions concerning prescription drugs. Non-pharmacist personnel and/or the pharmacy's computer system may not ask questions of a patient or patient's agent which are intended to screen and/or limit interaction with the pharmacist.

(D) Nothing in this subparagraph shall be construed as requiring a pharmacist to provide consultation when a patient or patient's agent refuses such consultation. The pharmacist shall document such refusal for consultation.

(E) In addition to the requirements of subparagraphs (A) - (D) of this paragraph, if a prescription drug order is delivered to the patient at the pharmacy, the following is applicable:

(i) So that a patient will have access to information concerning his or her prescription, a prescription may not be delivered to a patient unless a pharmacist is in the pharmacy, except as provided in subsection (b)(3) of this section.

(ii) Any prescription delivered to a patient when a pharmacist is not in the pharmacy must meet the requirements described in subparagraph (F) of this paragraph.

(F) In addition to the requirements of subparagraphs (A) - (D) of this paragraph, if a prescription drug order is delivered to the patient or his or her agent at the patient's residence or other designated location, the following is applicable:

(i) The information as specified in subparagraph (A) of this paragraph shall be delivered with the dispensed prescription in writing.

(ii) If prescriptions are routinely delivered outside the area covered by the pharmacy's local telephone service, the pharmacy shall provide a toll-free telephone line which is answered during normal business hours to enable communication between the patient and a pharmacist.

(iii) The pharmacist shall place on the prescription container or on a separate sheet delivered with the prescription container in both English and Spanish the local and, if applicable, toll-free telephone number of the pharmacy and the statement: "Written information about this prescription has been provided for you. Please read this information before you take the medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions at (insert the pharmacy's local and toll-free telephone numbers)."

(iv) The pharmacy shall maintain and use adequate storage or shipment containers and use shipping processes to ensure drug stability and potency. Such shipping processes shall include the use of appropriate packaging material and/or devices to ensure that the drug is maintained at an appropriate temperature range to maintain the integrity of the medication throughout the delivery process.

(v) The pharmacy shall use a delivery system which is designed to ensure that the drugs are delivered to the appropriate patient.

(G) The provisions of this paragraph do not apply to patients in facilities where drugs are administered to patients by a person required to do so by the laws of the state (i.e., nursing homes).

(2) Pharmaceutical care services.

(A) Drug regimen review.

(i) For the purpose of promoting therapeutic appropriateness, a pharmacist shall, prior to or at the time of dispensing a prescription drug order, review the patient's medication record. Such review shall at a minimum identify clinically significant:

(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; and

(X) proper utilization, including overutilization or underutilization.

(ii) Upon identifying any clinically significant conditions, situations, or items listed in clause (i) of this subparagraph, the pharmacist shall take appropriate steps to avoid or resolve the problem including consultation with the prescribing practitioner. The pharmacist shall document such occurrences as specified in subparagraph (C) of this paragraph.

(iii) The drug regimen review may be conducted by remotely accessing the pharmacy's electronic database from outside the pharmacy by:

(I) an individual Texas licensed pharmacist employee of the pharmacy provided the pharmacy establishes controls to protect the privacy of the patient and the security of confidential records; or

(II) a pharmacist employed by a Class E pharmacy provided the pharmacies have entered into a written contract or agreement which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and state laws and regulations.

(iv) Prior to dispensing, any questions regarding a prescription drug order must be resolved with the prescriber and written documentation of these discussions made and maintained as specified in subparagraph (C) of this paragraph.

(B) Other pharmaceutical care services which may be provided by pharmacists include, but are not limited to, the following:

(i) managing drug therapy as delegated by a practitioner as allowed under the provisions of the Medical Practice Act;

(ii) administering immunizations and vaccinations under written protocol of a physician;

(iii) managing patient compliance programs;

(iv) providing preventative health care services; and

(v) providing case management of patients who are being treated with high-risk or high-cost drugs, or who are considered "high risk" due to their age, medical condition, family history, or related concern.

(C) Documentation of consultation. When a pharmacist consults a prescriber as described in subparagraph (A) of this paragraph, the pharmacist shall document on the prescription or in the pharmacy's data processing system associated with the prescription such occurrences and shall include the following information:

(i) date the prescriber was consulted;

(ii) name of the person communicating the prescriber's instructions;

(iii) any applicable information pertaining to the consultation; and

(iv) initials or identification code of the pharmacist performing the consultation clearly recorded for the purpose of identifying the pharmacist who performed the consultation.

(3) Substitution of generically equivalent drugs or interchangeable biological products. A pharmacist may dispense a generically equivalent drug or interchangeable biological product and shall comply with the provisions of §309.3 of this title (relating to Substitution Requirements).

(4) Substitution of dosage form.

(A) As specified in §562.012 of the Act, a pharmacist may dispense a dosage form of a drug product different from that prescribed, such as a tablet instead of a capsule or liquid instead of tablets, provided:

(i) the patient consents to the dosage form substitution; and

(ii) the dosage form so dispensed:

(I) contains the identical amount of the active ingredients as the dosage prescribed for the patient;

(II) is not an enteric-coated or time release product; and

(III) does not alter desired clinical outcomes.

(B) Substitution of dosage form may not include the substitution of a product that has been compounded by the pharmacist unless the pharmacist contacts the practitioner prior to dispensing and obtains permission to dispense the compounded product.

(5) Therapeutic Drug Interchange. A switch to a drug providing a similar therapeutic response to the one prescribed shall not be made without prior approval of the prescribing practitioner. This paragraph does not apply to generic substitution. For generic substitution, see the requirements of paragraph (3) of this subsection.

(A) The patient shall be notified of the therapeutic drug interchange prior to, or upon delivery of, the dispensed prescription to the patient. Such notification shall include:

(i) a description of the change;

(ii) the reason for the change;

(iii) whom to notify with questions concerning the change; and

(iv) instructions for return of the drug if not wanted by the patient.

(B) The pharmacy shall maintain documentation of patient notification of therapeutic drug interchange which shall include:

(i) the date of the notification;

(ii) the method of notification;

(iii) a description of the change; and

(iv) the reason for the change.

(C) The provisions of this paragraph do not apply to prescriptions for patients in facilities where drugs are administered to patients by a person required to do so by the laws of this state if the practitioner issuing the prescription has agreed to use of a formulary that includes a listing of therapeutic interchanges that the practitioner has agreed to allow. The pharmacy must maintain a copy of the formulary including a list of the practitioners that have agreed to the formulary and the signatures of these practitioners.

(6) Prescription containers.

(A) A drug dispensed pursuant to a prescription drug order shall be dispensed in a child-resistant container unless:

(i) the patient or the practitioner requests the prescription not be dispensed in a child-resistant container; or

(ii) the product is exempted from requirements of the Poison Prevention Packaging Act of 1970.

(B) A drug dispensed pursuant to a prescription drug order shall be dispensed in an appropriate container as specified on the manufacturer's container.

(C) Prescription containers or closures shall not be re-used. However, if a patient or patient's agent has difficulty reading or understanding a prescription label, a prescription container may be reused provided:

(i) the container is designed to provide audio-recorded information about the proper use of the prescription medication;

(ii) the container is reused for the same patient;

(iii) the container is cleaned; and

(iv) a new safety closure is used each time the prescription container is reused.

(7) Labeling.

(A) At the time of delivery of the drug, the dispensing container shall bear a label in plain language and printed in an easily readable font size, unless otherwise specified, with at least the following information:

(i) name, address and phone number of the pharmacy;

(ii) unique identification number of the prescription that is printed in an easily readable font size comparable to but no smaller than ten-point Times Roman;

(iii) date the prescription is dispensed;

(iv) initials or an identification code of the dispensing pharmacist;

(v) name of the prescribing practitioner;

(vi) if the prescription was signed by a pharmacist, the name of the pharmacist who signed the prescription for a dangerous drug under delegated authority of a physician as specified in Subtitle B, Chapter 157, Occupations Code;

(vii) name of the patient or if such drug was prescribed for an animal, the species of the animal and the name of the owner that is printed in an easily readable font size comparable to but no smaller than ten-point Times Roman. The name of the patient's partner or family member is not required to be on the label of a drug prescribed for a partner for a sexually transmitted disease or for a patient's family members if the patient has an illness determined by the Centers for Disease Control and Prevention, the World Health Organization, or the Governor's office to be pandemic;

(viii) instructions for use that are printed in an easily readable font size comparable to but no smaller than ten-point Times Roman;

(ix) quantity dispensed;

(x) appropriate ancillary instructions such as storage instructions or cautionary statements such as warnings of potential harmful effects of combining the drug product with any product containing alcohol;

(xi) if the prescription is for a Schedule II - IV controlled substance, the statement "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed";

(xii) if the pharmacist has selected a generically equivalent drug or interchangeable biological product pursuant to the provisions of the Act, Chapter 562, the statement "Substituted for Brand Prescribed" or "Substituted for 'Brand Name'" where "Brand Name" is the actual name of the brand name product prescribed;

(xiii) the name and strength of the actual drug or biological product dispensed that is printed in an easily readable size comparable to but no smaller than ten-point Times Roman, unless otherwise directed by the prescribing practitioner;

(I) The name shall be either:

(-a-) the brand name; or

(-b-) if no brand name, then the generic drug or interchangeable biological product name and name of the manufacturer or distributor of such generic drug or interchangeable biological product. (The name of the manufacturer or distributor may be reduced to an abbreviation or initials, provided the abbreviation or initials are sufficient to identify the manufacturer or distributor. For combination drug products or non-sterile compounded drug preparations having no brand name, the principal active ingredients shall be indicated on the label).

(II) Except as provided in clause (xii) of this subparagraph, the brand name of the prescribed drug or biological product shall not appear on the prescription container label unless it is the drug product actually dispensed.

(xiv) if the drug is dispensed in a container other than the manufacturer's original container, the date after which the prescription should not be used or beyond-use-date. Unless otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date the drug is dispensed or the manufacturer's expiration date, whichever is earlier. The beyond-use-date may be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is not required on the label of a prescription dispensed to a person at the time of release from prison or jail if the prescription is for not more than a 10-day supply of medication; and

(xv) either on the prescription label or the written information accompanying the prescription, the statement "Do not flush unused medications or pour down a sink or drain." A drug product on a list developed by the Federal Food and Drug Administration of medicines recommended for disposal by flushing is not required to bear this statement.

(B) If the prescription label required in subparagraph (A) of this paragraph is printed in a type size smaller than ten-point Times Roman, the pharmacy shall provide the patient written information containing the information as specified in subparagraph (A) of this paragraph in an easily readable font size comparable to but no smaller than ten-point Times Roman.

(C) The label is not required to include the initials or identification code of the dispensing pharmacist as specified in subparagraph (A) of this paragraph if the identity of the dispensing pharmacist is recorded in the pharmacy's data processing system. The record of the identity of the dispensing pharmacist shall not be altered in the pharmacy's data processing system.

(D) The dispensing container is not required to bear the label as specified in subparagraph (A) of this paragraph if:

(i) the drug is prescribed for administration to an ultimate user who is institutionalized in a licensed health care institution (e.g., nursing home, hospice, hospital);

(ii) no more than a 90-day supply is dispensed at one time;

(iii) the drug is not in the possession of the ultimate user prior to administration;

(iv) the pharmacist-in-charge has determined that the institution:

(I) maintains medication administration records which include adequate directions for use for the drug(s) prescribed;

(II) maintains records of ordering, receipt, and administration of the drug(s); and

(III) provides for appropriate safeguards for the control and storage of the drug(s); and

(v) the dispensing container bears a label that adequately:

(I) identifies the:

(-a-) pharmacy by name and address;

(-b-) unique identification number of the prescription;

(-c-) name and strength of the drug dispensed;

(-d-) name of the patient; and

(-e-) name of the prescribing practitioner or, if applicable, the name of the pharmacist who signed the prescription drug order;

(II) if the drug is dispensed in a container other than the manufacturer's original container, specifies the date after which the prescription should not be used or beyond-use-date. Unless otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date the drug is dispensed or the manufacturer's expiration date, whichever is earlier. The beyond-use-date may be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is not required on the label of a prescription dispensed to a person at the time of release from prison or jail if the prescription is for not more than a 10-day supply of medication; and

(III) sets forth the directions for use and cautionary statements, if any, contained on the prescription drug order or required by law.

(8) Returning Undelivered Medication to Stock.

(A) A pharmacist may not accept an unused prescription or drug, in whole or in part, for the purpose of resale or re-dispensing to any person after the prescription or drug has been originally dispensed or sold, except as provided in §291.8 of this title (relating to Return of Prescription Drugs) or Subchapter M, Chapter 431, Health and Safety Code, or Chapter 442, Health and Safety Code. Prescriptions that have not been picked up by or delivered to the patient or patient's agent may be returned to the pharmacy's stock for dispensing.

(B) A pharmacist shall evaluate the quality and safety of the prescriptions to be returned to stock.

(C) Prescriptions returned to stock for dispensing shall not be mixed within the manufacturer's container.

(D) Prescriptions returned to stock for dispensing should be used as soon as possible and stored in the dispensing container. The expiration date of the medication shall be the lesser of one year from the dispensing date on the prescription label or the manufacturer's expiration date if dispensed in the manufacturer's original container.

(E) At the time of dispensing, the prescription medication shall be placed in a new prescription container and not dispensed in the previously labeled container unless the label can be completely removed. However, if the medication is in the manufacturer's original container, the pharmacy label must be removed so that no confidential patient information is released.

(9) Redistribution of Donated Prepackaged Prescription Drugs.

(A) A participating provider may dispense to a recipient donated prescription drugs that are prepackaged and labeled in accordance with §442.0515, Health and Safety Code, and this paragraph.

(B) Drugs may be prepackaged in quantities suitable for distribution to a recipient only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist.

(C) The label of a prepackaged prescription drug a participating provider dispenses to a recipient shall indicate:

(i) brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor;

(ii) participating provider's lot number;

(iii) participating provider's beyond use date; and

(iv) quantity of the drug, if the quantity is greater than one.

(D) Records of prepackaged prescription drugs dispensed to a recipient shall be maintained to show:

(i) name of the drug, strength, and dosage form;

(ii) participating provider's lot number;

(iii) manufacturer or distributor;

(iv) manufacturer's lot number;

(v) manufacturer's expiration date;

(vi) quantity per prepackaged unit;

(vii) number of prepackaged units;

(viii) date packaged;

(ix) name, initials, or electronic signature of the prepacker; and

(x) written or electronic signature of the responsible pharmacist.

(E) Stock packages, repackaged units, and control records shall be quarantined together until checked/released by the pharmacist.

(d) Equipment and supplies. Class A pharmacies dispensing prescription drug orders shall have the following equipment and supplies:

(1) data processing system including a printer or comparable equipment;

(2) refrigerator;

(3) adequate supply of child-resistant, light-resistant, tight, and if applicable, glass containers;

(4) adequate supply of prescription, poison, and other applicable labels;

(5) appropriate equipment necessary for the proper preparation of prescription drug orders; and

(6) metric-apothecary weight and measure conversion charts.

(e) Library. A reference library shall be maintained which includes the following in hard-copy or electronic format:

(1) current copies of the following:

(A) Texas Pharmacy Act and rules;

(B) Texas Dangerous Drug Act and rules;

(C) Texas Controlled Substances Act and rules; and

(D) Federal Controlled Substances Act and rules (or official publication describing the requirements of the Federal Controlled Substances Act and rules);

(2) at least one current or updated reference from each of the following categories:

(A) a patient prescription drug information reference text or leaflets which are designed for the patient and must be available to the patient;

(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) if the pharmacy dispenses veterinary prescriptions, a general reference text on veterinary drugs; and

(3) basic antidote information and the telephone number of the nearest Regional Poison Control Center.

(f) Drugs.

(1) Procurement and storage.

(A) The pharmacist-in-charge shall have the responsibility for the procurement and storage of drugs, but may receive input from other appropriate staff relative to such responsibility.

(B) Prescription drugs and devices and nonprescription Schedule V controlled substances shall be stored within the prescription department or a locked storage area.

(C) All drugs shall be stored at the proper temperature, as defined in the USP/NF and §291.15 of this title (relating to Storage of Drugs).

(2) Out-of-date drugs or devices.

(A) Any drug or device bearing an expiration date shall not be dispensed beyond the expiration date of the drug or device.

(B) Outdated drugs or devices shall be removed from dispensing stock and shall be quarantined together until such drugs or devices are disposed of properly.

(3) Nonprescription Schedule V controlled substances.

(A) Schedule V controlled substances containing codeine, dihydrocodeine, or any of the salts of codeine or dihydrocodeine may not be distributed without a prescription drug order from a practitioner.

(B) A pharmacist may distribute nonprescription Schedule V controlled substances which contain no more than 15 milligrams of opium per 29.5729 ml or per 28.35 Gm provided:

(i) such distribution is made only by a pharmacist; a nonpharmacist employee may not distribute a nonprescription Schedule V controlled substance even if under the supervision of a pharmacist; however, after the pharmacist has fulfilled professional and legal responsibilities, the actual cash, credit transaction, or delivery may be completed by a nonpharmacist:

(ii) not more than 240 ml (eight fluid ounces), or not more than 48 solid dosage units of any substance containing opium, may be distributed to the same purchaser in any given 48-hour period without a prescription drug order;

(iii) the purchaser is at least 18 years of age; and

(iv) the pharmacist requires every purchaser not known to the pharmacist to furnish suitable identification (including proof of age where appropriate).

(C) A record of such distribution shall be maintained by the pharmacy in a bound record book. The record shall contain the following information:

(i) true name of the purchaser;

(ii) current address of the purchaser;

(iii) name and quantity of controlled substance purchased;

(iv) date of each purchase; and

(v) signature or written initials of the distributing pharmacist.

(4) Class A 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).

(g) Prepackaging of drugs.

(1) 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.

(2) 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) facility's beyond use date; and

(D) quantity of the drug, if the quantity is greater than one.

(3) Records of prepackaging shall be maintained to show:

(A) name of the drug, strength, and dosage form;

(B) facility's lot number;

(C) manufacturer or distributor;

(D) manufacturer's lot number;

(E) manufacturer's 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.

(4) Stock packages, repackaged units, and control records shall be quarantined together until checked/released by the pharmacist.

(h) Customized patient medication packages.

(1) Purpose. In lieu of dispensing two or more prescribed drug products in separate containers, a pharmacist may, with the consent of the patient, the patient's caregiver, or the prescriber, provide a customized patient medication package (patient med-pak).

(2) Label.

(A) The patient med-pak shall bear a label stating:

(i) the name of the patient;

(ii) the unique identification number for the patient med-pak itself and a separate unique identification number for each of the prescription drug orders for each of the drug products contained therein;

(iii) the name, strength, physical description or identification, and total quantity of each drug product contained therein;

(iv) the directions for use and cautionary statements, if any, contained in the prescription drug order for each drug product contained therein;

(v) if applicable, a warning of the potential harmful effect of combining any form of alcoholic beverage with any drug product contained therein;

(vi) any storage instructions or cautionary statements required by the official compendia;

(vii) the name of the prescriber of each drug product;

(viii) the name, address, and telephone number of the pharmacy;

(ix) the initials or an identification code of the dispensing pharmacist;

(x) the date after which the prescription should not be used or beyond-use-date. Unless otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date the med-pak is dispensed or the earliest manufacturer's expiration date for a product contained in the med-pak if it is less than one-year from the date dispensed. The beyond-use-date may be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is not required on the label of a prescription dispensed to a person at the time of release from prison or jail if the prescription is for not more than a 10-day supply of medication;

(xi) either on the prescription label or the written information accompanying the prescription, the statement "Do not flush unused medications or pour down a sink or drain." A drug product on a list developed by the Federal Food and Drug Administration of medicines recommended for disposal by flushing is not required to bear this statement; and

(xii) any other information, statements, or warnings required for any of the drug products contained therein.

(B) If the patient med-pak allows for the removal or separation of the intact containers therefrom, each individual container shall bear a label identifying each of the drug product contained therein.

(C) The dispensing container is not required to bear the label as specified in subparagraph (A) of this paragraph if:

(i) the drug is prescribed for administration to an ultimate user who is institutionalized in a licensed health care institution (e.g., nursing home, hospice, hospital);

(ii) no more than a 90-day supply is dispensed at one time;

(iii) the drug is not in the possession of the ultimate user prior to administration;

(iv) the pharmacist-in-charge has determined that the institution:

(I) maintains medication administration records which include adequate directions for use for the drug(s) prescribed;

(II) maintains records of ordering, receipt, and administration of the drug(s); and

(III) provides for appropriate safeguards for the control and storage of the drug(s); and

(v) the dispensing container bears a label that adequately:

(I) identifies the:

(-a-) pharmacy by name and address;

(-b-) name and strength of each drug product dispensed;

(-c-) name of the patient; and

(-d-) name of the prescribing practitioner of each drug product, or the pharmacist who signed the prescription drug order;

(II) the date after which the prescription should not be used or beyond-use-date. Unless otherwise specified by the manufacturer, the beyond-use-date shall be one year from the date the med-pak is dispensed or the earliest manufacturer's expiration date for a product contained in the med-pak if it is less than one-year from the date dispensed. The beyond-use-date may be placed on the prescription label or on a flag label attached to the bottle. A beyond-use-date is not required on the label of a prescription dispensed to a person at the time of release from prison or jail if the prescription is for not more than a 10-day supply of medication; and

(III) for each drug product sets forth the directions for use and cautionary statements, if any, contained on the prescription drug order or required by law.

(3) Labeling. The patient med-pak shall be accompanied by a patient package insert, in the event that any drug contained therein is required to be dispensed with such insert as accompanying labeling. Alternatively, such required information may be incorporated into a single, overall educational insert provided by the pharmacist for the total patient med-pak.

(4) Packaging. In the absence of more stringent packaging requirements for any of the drug products contained therein, each container of the patient med-pak shall comply with official packaging standards. Each container shall be either not reclosable or so designed as to show evidence of having been opened.

(5) Guidelines. It is the responsibility of the dispensing pharmacist when preparing a patient med-pak, to take into account any applicable compendial requirements or guidelines and the physical and chemical compatibility of the dosage forms placed within each container, as well as any therapeutic incompatibilities that may attend the simultaneous administration of the drugs.

(6) Recordkeeping. In addition to any individual prescription filing requirements, a record of each patient med-pak shall be made and filed. Each record shall contain, as a minimum:

(A) the name and address of the patient;

(B) the unique identification number for the patient med-pak itself and a separate unique identification number for each of the prescription drug orders for each of the drug products contained therein;

(C) the name of the manufacturer or distributor and lot number for each drug product contained therein;

(D) information identifying or describing the design, characteristics, or specifications of the patient med-pak sufficient to allow subsequent preparation of an identical patient med-pak for the patient;

(E) the date of preparation of the patient med-pak and the beyond-use date that was assigned;

(F) any special labeling instructions; and

(G) the initials or an identification code of the dispensing pharmacist.

(7) The patient med-pak label is not required to include the initials or identification code of the dispensing pharmacist as specified in paragraph (2)(A) of this subsection if the identity of the dispensing pharmacist is recorded in the pharmacy's data processing system. The record of the identity of the dispensing pharmacist shall not be altered in the pharmacy's data processing system.

(i) Automated devices and systems in a pharmacy.

(1) Automated counting devices. If a pharmacy uses automated counting devices:

(A) the pharmacy shall have a method to calibrate and verify the accuracy of the automated counting device and document the calibration and verification on a routine basis;

(B) the devices may be loaded with bulk drugs only by a pharmacist or by pharmacy technicians or pharmacy technician trainees under the direction and direct supervision of a pharmacist;

(C) the label of an automated counting device container containing a bulk drug shall indicate the brand name and strength of the drug; or if no brand name, then the generic name, strength, and name of the manufacturer or distributor;

(D) records of loading bulk drugs into an automated counting device shall be maintained to show:

(i) name of the drug, strength, and dosage form;

(ii) manufacturer or distributor;

(iii) manufacturer's lot number;

(iv) expiration date;

(v) date of loading;

(vi) name, initials, or electronic signature of the person loading the automated counting device; and

(vii) name, initials, or electronic signature of the responsible pharmacist; and

(E) the automated counting device shall not be used until a pharmacist verifies that the system is properly loaded and affixes his or her name, initials, or electronic signature to the record as specified in subparagraph (D) of this paragraph.

(2) Automated pharmacy dispensing systems.

(A) Authority to use automated pharmacy dispensing systems. A pharmacy may use an automated pharmacy dispensing system to fill prescription drug orders provided that:

(i) the pharmacist-in-charge is responsible for the supervision of the operation of the system;

(ii) the automated pharmacy dispensing system has been tested by the pharmacy and found to dispense accurately. The pharmacy shall make the results of such testing available to the board upon request; and

(iii) the pharmacy will make the automated pharmacy dispensing system available for inspection by the board for the purpose of validating the accuracy of the system.

(B) Automated pharmacy dispensing systems may be stocked or loaded by a pharmacist or by a pharmacy technician or pharmacy technician trainee under the supervision of a pharmacist.

(C) Quality assurance program. A pharmacy which uses an automated pharmacy dispensing system to fill prescription drug orders shall operate according to a quality assurance program of the automated pharmacy dispensing system which:

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

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

(D) Policies and procedures of operation.

(i) When an automated pharmacy dispensing system is used to fill prescription drug orders, it shall be operated according to written policies and procedures of operation. The policies and procedures of operation shall:

(I) provide for a pharmacist's review, approval, and accountability for the transmission of each original or new prescription drug order to the automated pharmacy dispensing system before the transmission is made;

(II) provide for access to the automated pharmacy dispensing system for stocking and retrieval of medications which is limited to licensed healthcare professionals or pharmacy technicians acting under the supervision of a pharmacist;

(III) require that a pharmacist checks, verifies, and documents that the correct medication and strength of bulk drugs, prepackaged containers, or manufacturer's unit of use packages were properly stocked, filled, and loaded in the automated pharmacy dispensing system prior to initiating the fill process; alternatively, an electronic verification system may be used for verification of manufacturer's unit of use packages or prepacked medication previously verified by a pharmacist;

(IV) provide for an accountability record to be maintained that documents all transactions relative to stocking and removing medications from the automated pharmacy dispensing system;

(V) require a prospective drug regimen review is conducted as specified in subsection (c)(2) of this section; and

(VI) establish and make provisions for documentation of a preventative maintenance program for the automated pharmacy dispensing system.

(ii) A pharmacy that uses an automated pharmacy dispensing system to fill prescription drug orders shall, at least annually, review its written policies and procedures, revise them if necessary, and document the review.

(E) Recovery Plan. A pharmacy that uses an automated pharmacy dispensing system to fill prescription drug orders shall maintain a written plan for recovery from a disaster or any other situation which interrupts the ability of the automated pharmacy dispensing system to provide services necessary for the operation of the pharmacy. The written plan for recovery shall include:

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

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

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

(F) Final check of prescriptions dispensed using an automated pharmacy dispensing system. For the purpose of §291.32(c)(2)(D) of this title (relating to Personnel), a pharmacist must perform the final check of all prescriptions prior to delivery to the patient to ensure that the prescription is dispensed accurately as prescribed.

(i) This final check shall be considered accomplished if:

(I) a check of the final product is conducted by a pharmacist after the automated pharmacy dispensing system has completed the prescription and prior to delivery to the patient; or

(II) the following checks are conducted:

(-a-) if the automated pharmacy dispensing system contains bulk stock drugs, a pharmacist verifies that those drugs have been accurately stocked as specified in subparagraph (D)(i)(III) of this paragraph;

(-b-) if the automated pharmacy dispensing system contains manufacturer's unit of use packages or prepackaged medication previously verified by a pharmacist, an electronic verification system has confirmed that the medications have been accurately stocked as specified in subparagraph (D)(i)(III) of this paragraph;

(-c-) a pharmacist checks the accuracy of the data entry of each original or new prescription drug order entered into the automated pharmacy dispensing system; and

(-d-) an electronic verification process is used to verify the proper prescription label has been affixed to the correct medication container, prepackaged medication or manufacturer unit of use package for the correct patient.

(ii) If the final check is accomplished as specified in clause (i)(II) of this subparagraph, the following additional requirements must be met:

(I) the dispensing process must be fully automated from the time the pharmacist releases the prescription to the automated pharmacy dispensing system until a completed, labeled prescription ready for delivery to the patient is produced;

(II) the pharmacy has conducted initial testing and has a continuous quality assurance program which documents that the automated pharmacy dispensing system dispenses accurately as specified in subparagraph (C) of this paragraph;

(III) the automated pharmacy dispensing system documents and maintains:

(-a-) the name(s), initials, or identification code(s) of each pharmacist responsible for the checks outlined in clause (i)(II) of this subparagraph; and

(-b-) the name(s), initials, or identification code(s) and specific activity(ies) of each pharmacist, pharmacy technician, or pharmacy technician trainee who performs any other portion of the dispensing process; and

(IV) the pharmacy establishes mechanisms and procedures to test the accuracy of the automated pharmacy dispensing system at least every month rather than every twelve months as specified in subparagraph (C) of this paragraph.

(3) Automated checking device.

(A) For the purpose of §291.32(c)(2)(D) of this title, the final check of a dispensed prescription shall be considered accomplished using an automated checking device provided a check of the final product is conducted by a pharmacist prior to delivery to the patient or the following checks are performed:

(i) the drug used to fill the order is checked through the use of an automated checking device which verifies that the drug is labeled and packaged accurately; and

(ii) a pharmacist checks the accuracy of each original or new prescription drug order and is responsible for the final check of the order through the automated checking device.

(B) If the final check is accomplished as specified in subparagraph (A) of this paragraph, the following additional requirements must be met:

(i) the pharmacy has conducted initial testing of the automated checking device and has a continuous quality assurance program which documents that the automated checking device accurately confirms that the correct drug and strength has been labeled with the correct label for the correct patient;

(ii) the pharmacy documents and maintains:

(I) the name(s), initials, or identification code(s) of each pharmacist responsible for the checks outlined in subparagraph (A)(i) of this paragraph; and

(II) the name(s) initials, or identification code(s) and specific activity(ies) of each pharmacist, pharmacy technician, or pharmacy technician trainee who performs any other portion of the dispensing process;

(iii) the pharmacy establishes mechanisms and procedures to test the accuracy of the automated checking device at least monthly; and

(iv) the pharmacy establishes procedures to ensure that errors identified by the automated checking device may not be overridden by a pharmacy technician and must be reviewed and corrected by a pharmacist.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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Daniel Carroll, Pharm.D.
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For further information, please call: (512) 305-8033

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SUBCHAPTER D. INSTITUTIONAL PHARMACY (CLASS C)

22 TAC §291.74

The Texas State Board of Pharmacy adopts amendments to §291.74, concerning Operational Standards. These amendments are adopted without changes to the proposed text as published in the September 22, 2023, issue of the *Texas Register* (48 TexReg 5403). The rule will not be republished.

The amendments re-insert rule text that was inadvertently removed and make grammatical corrections.

No comments were received.

The amendments are adopted 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 this adoption: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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SUBCHAPTER G. SERVICES PROVIDED BY PHARMACIES

22 TAC §291.121

The Texas State Board of Pharmacy adopts amendments to §291.121, concerning Remote Pharmacy Services. These amendments are adopted without changes to the proposed text as published in the September 22, 2023, issue of the *Texas Register* (48 TexReg 5412). The rule will not be republished.

The amendments clarify how the board provides a license to engage in remote pharmacy services.

No comments were received.

The amendments are adopted 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 this adoption: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

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22 TAC §291.129

The Texas State Board of Pharmacy adopts amendments to §291.129, concerning Satellite Pharmacy. These amendments are adopted without changes to the proposed text as published in the September 22, 2023, issue of the *Texas Register* (48 TexReg 5424). The rule will not be republished.

The amendments clarify how the board provides a satellite pharmacy license.

No comments were received.

The amendments are adopted 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 this adoption: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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CHAPTER 295. PHARMACISTS

22 TAC §295.5

The Texas State Board of Pharmacy adopts amendments to §295.5, concerning Pharmacist License or Renewal Fees. These amendments are adopted without changes to the proposed text as published in the September 22, 2023, issue of

the *Texas Register* (48 TexReg 5427). The rule will not be republished.

The amendments increase pharmacist license fees based on expected expenses.

No comments were received.

The amendments are adopted under §§551.002, 554.006, 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 Section 554.006(a) as authorizing the agency to adopt fees to cover the cost of administering Subtitle J, Title 3, Occupations Code. 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 this adoption: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on November 14, 2023.

TRD-202304242
Daniel Carroll, Pharm.D.
Executive Director
Texas State Board of Pharmacy
Effective date: January 1, 2024
Proposal publication date: September 22, 2023
For further information, please call: (512) 305-8033

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22 TAC §295.8

The Texas State Board of Pharmacy adopts amendments to §295.8, concerning Continuing Education Requirements. These amendments are adopted without changes to the proposed text as published in the September 22, 2023, issue of the *Texas Register* (48 TexReg 5428). The rule will not be republished.

The amendments remove continuing education requirements that have expired.

No comments were received.

The amendments are adopted 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 this adoption: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on November 14, 2023.

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Daniel Carroll, Pharm.D.
Executive Director
Texas State Board of Pharmacy
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Proposal publication date: September 22, 2023
For further information, please call: (512) 305-8033

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22 TAC §295.9

The Texas State Board of Pharmacy adopts amendments to §295.9, concerning Inactive License. These amendments are adopted without changes to the proposed text as published in the September 22, 2023, issue of the *Texas Register* (48 TexReg 5432). The rule will not be republished.

The amendments remove a continuing education requirement for which the statutory authority has expired from the conditions for reactivation of an inactive license and make a grammatical correction.

No comments were received.

The amendments are adopted 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 this adoption: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on November 14, 2023.

TRD-202304248
Daniel Carroll, Pharm.D.
Executive Director
Texas State Board of Pharmacy
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Proposal publication date: September 22, 2023
For further information, please call: (512) 305-8033

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CHAPTER 297. PHARMACY TECHNICIANS AND PHARMACY TECHNICIAN TRAINEES

22 TAC §297.10

The Texas State Board of Pharmacy adopts amendments to §297.10, concerning Registration for Military Service Members, Military Veterans, and Military Spouses. These amendments are adopted without changes to the proposed text as published in the September 22, 2023, issue of the *Texas Register* (48 TexReg 5433). The rule will not be republished.

The amendments establish procedures for a military service member who is currently registered in good standing by a jurisdiction with registration requirements that are substantially

similar to Texas's requirements to obtain an interim pharmacy technician registration, in accordance with Senate Bill 422 and make grammatical corrections.

No comments were received.

The amendments are adopted 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 this adoption: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on November 14, 2023.

TRD-202304252
Daniel Carroll, Pharm.D.
Executive Director
Texas State Board of Pharmacy
Effective date: December 4, 2023
Proposal publication date: September 22, 2023
For further information, please call: (512) 305-8033

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TITLE 25. HEALTH SERVICES

PART 1. DEPARTMENT OF STATE HEALTH SERVICES

CHAPTER 131. FREESTANDING EMERGENCY MEDICAL CARE FACILITIES

The Texas Health and Human Services Commission (HHSC) adopts the repeal of Texas Administrative Code (TAC), Title 25, Part 1, Chapter 131, concerning Freestanding Emergency Medical Care Facilities, Subchapter A, concerning General Provisions; Subchapter B, concerning Licensing Requirements; Subchapter C, concerning Operational Requirements; Subchapter D, concerning Inspection and Investigation Procedures; and Subchapter E, concerning Enforcement. The repealed subchapters consist of §§131.1, 131.2, 131.21 - 131.31, 131.41 - 131.68, 131.81, 131.82, and 131.101 - 131.109.

The repeal of §§131.1, 131.2, 131.21 - 131.31, 131.41 - 131.68, 131.81, 131.82, and 131.101 - 131.109 are adopted without changes to the proposed repealed text as published in the July 14, 2023, issue of the *Texas Register* (48 TexReg 3799). These rules will not be republished.

BACKGROUND AND JUSTIFICATION

The repeals are necessary to remove the rules in Chapter 131, Freestanding Emergency Medical Care Facilities, Subchapters A - E, and adopt new rules in 26 TAC Chapter 509, Freestanding Emergency Medical Care Facilities.

The new rules in Title 26, Chapter 509 are adopted elsewhere in this issue of the *Texas Register* and are substantially similar to the repealed rules.

COMMENTS

The 31-day comment period ended August 14, 2023.

During this period, HHSC received comments regarding the proposed repeal from the Texas Association of Freestanding Emergency Centers (TAFEC). A summary of comments relating to the rules and HHSC's responses follows.

Comment: TAFEC expressed appreciation for HHSC's efforts to update and refresh the freestanding emergency medical care facility rules by repealing 25 TAC Chapter 131 and replacing the chapter with 26 TAC Chapter 509.

Response: HHSC acknowledges this comment.

SUBCHAPTER A. GENERAL PROVISIONS

25 TAC §131.1, §131.2

STATUTORY AUTHORITY

The repeals are adopted under 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 §254.101, which authorizes HHSC to adopt rules regarding freestanding emergency medical care facilities.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on November 14, 2023.

TRD-202304226
Karen Ray
Chief Counsel
Department of State Health Services
Effective date: December 4, 2023
Proposal publication date: July 14, 2023
For further information, please call: (512) 834-4591

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SUBCHAPTER B. LICENSING REQUIREMENTS

25 TAC §§131.21 - 131.31

STATUTORY AUTHORITY

The repeals are adopted under 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 §254.101, which authorizes HHSC to adopt rules regarding freestanding emergency medical care facilities.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on November 14, 2023.

TRD-202304227
Karen Ray
Chief Counsel
Department of State Health Services
Effective date: December 4, 2023
Proposal publication date: July 14, 2023
For further information, please call: (512) 834-4591

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SUBCHAPTER C. OPERATIONAL REQUIREMENTS

25 TAC §§131.41 - 131.68

STATUTORY AUTHORITY

The repeals are adopted under 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 §254.101, which authorizes HHSC to adopt rules regarding freestanding emergency medical care facilities.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on November 14, 2023.

TRD-202304228
Karen Ray
Chief Counsel
Department of State Health Services
Effective date: December 4, 2023
Proposal publication date: July 14, 2023
For further information, please call: (512) 834-4591

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SUBCHAPTER D. INSPECTION AND INVESTIGATION PROCEDURES

25 TAC §131.81, §131.82

STATUTORY AUTHORITY

The repeals are adopted under 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 §254.101, which authorizes HHSC to adopt rules regarding freestanding emergency medical care facilities.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on November 14, 2023.

TRD-202304229
Karen Ray
Chief Counsel
Department of State Health Services
Effective date: December 4, 2023
Proposal publication date: July 14, 2023
For further information, please call: (512) 834-4591

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SUBCHAPTER E. ENFORCEMENT

25 TAC §§131.101 - 131.109

STATUTORY AUTHORITY

The repeals are adopted under 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 §254.101, which authorizes HHSC to adopt rules regarding freestanding emergency medical care facilities.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on November 14, 2023.

TRD-202304230
Karen Ray
Chief Counsel
Department of State Health Services
Effective date: December 4, 2023
Proposal publication date: July 14, 2023
For further information, please call: (512) 834-4591

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PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 701. POLICIES AND PROCEDURES

25 TAC §701.25

The Cancer Prevention and Research Institute of Texas ("CPRIT" or "the Institute") adopts the amendments to 25 Texas Administrative Code §701.25 without changes to the proposed amendments as published in the September 1, 2023, issue of the *Texas Register* (48 TexReg 4773); therefore, the rule will not be republished. The amendments relate to CPRIT's electronic signature policy.

Reasoned Justification

CPRIT amends its electronic signature policy to include grant applicants so that the convenience and responsibilities associated with electronic signatures are available to grant applicants as well as grant recipients.

Summary of Public Comments and Staff Recommendation

CPRIT received no public comments regarding the proposed amendments to §701.25; CPRIT staff recommends moving forward with adoption of the amendments.

The rule changes are adopted under the authority of the Texas Health and Safety Code Annotated, § 102.108, which provides the Institute with broad rule-making authority to administer the chapter, including rules for awarding grants.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on November 17, 2023.

TRD-202304312
Heidi McConnell
Chief Operating Officer
Cancer Prevention and Research Institute of Texas
Effective date: December 7, 2023
Proposal publication date: September 1, 2023
For further information, please call: (512) 305-8487

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TITLE 26. HEALTH AND HUMAN SERVICES

PART 1. HEALTH AND HUMAN SERVICES COMMISSION

CHAPTER 509. FREESTANDING EMERGENCY MEDICAL CARE FACILITIES

The Texas Health and Human Services Commission (HHSC) adopts new rules in Texas Administrative Code (TAC), Title 26, Part 1, Chapter 509, concerning Freestanding Emergency Medical Care Facilities. The new chapter consists of §§509.1, 509.2, 509.21 - 509.30, 509.41 - 509.66, 509.81 - 509.86, and 509.101 - 509.108.

New §§509.2, 509.24, 509.26, 509.48, 509.51 - 509.54, 509.61, 509.62, and 509.81 - 509.83 are adopted with changes to the proposed text as published in the July 14, 2023, issue of the *Texas Register* (48 TexReg 3801). These rules will be republished.

New §§509.1, 509.21 - 509.23, 509.25, 509.27 - 509.30, 509.41 - 509.47, 509.49, 509.50, 509.55 - 509.60, 509.63 - 509.66, 509.84 - 509.86, and 509.101 - 509.108 are adopted without changes to the proposed text as published in the July 14, 2023, issue of the *Texas Register* (48 TexReg 3801). These rules will not be republished.

BACKGROUND AND JUSTIFICATION

The new sections are necessary to comply with House Bill (H.B.) 2041 and H.B. 1112, 86th Legislature, Regular Session, 2019, which amended Texas Health and Safety Code (HSC), Chapter 254, relating to the regulation of Freestanding Emergency Medical Care Facilities. H.B. 2041 requires freestanding emergency medical care (FEMC) facilities to comply with updated advertising requirements, which includes disclosure of facility fees and clarification of health benefit plans that are accepted by the facility, and it requires FEMC facilities to provide a disclosure statement to patients. H.B. 2041 requires an FEMC facility that closes or whose license is expired, suspended, or revoked to remove their signs from the facility. H.B. 1112 similarly requires a closed FEMC facility or an FEMC facility whose license is expired, suspended, or revoked to remove their signage. This proposal also complies with Senate Bill (S.B.) 425, 84th Legislature, Regular Session, 2015, which amended HSC Chapter 254 to require an FEMC facility to post a notice regarding facility fees and provide other consumer information to patients.

The new sections also revise sections in the subchapters on Inspection and Investigation Procedures and Enforcement to outline facility documentation expectations to increase consistency across facility rule sets, update language to reflect the transition to HHSC and the relocation of rules from 25 TAC to 26 TAC, and correct outdated references and citations.

To implement this change, rules in 25 TAC Chapter 131, Freestanding Emergency Medical Care Facilities, are being repealed and new rules adopted in 26 TAC Chapter 509, Freestanding Emergency Medical Care Facilities. The repeal of 25 TAC Chapter 131 is adopted elsewhere in this issue of the *Texas Register.*

COMMENTS

The 31-day comment period ended August 14, 2023.

During this period, HHSC received comments regarding the proposed rules from seven commenters representing the Texas Academy of Physician Assistants (TAPA), Texas Association of Freestanding Emergency Centers (TAFEC), Texas Association of Health Plans (TAHP), Texas Medical Association (TMA), Texas Nurses Association (TNA), Texas Nurse Practitioners (TNP), and Texas Society of Anesthesiologists (TSA). A summary of comments relating to the rules and HHSC's responses follow.

Comment: TMA appreciated the changes in these newly proposed rules that incorporated the comments TMA submitted to HHSC when this project was previously posted in the *Texas Register* for comment in January 2021.

Response: HHSC acknowledges this comment.

Comment: TAHP expressed support for rules implementing consumer protections regarding FEMC facilities.

Response: HHSC acknowledges this comment.

Comment: TAFEC said they appreciate HHSC's efforts to update and refresh the FEMC rules by repealing 25 TAC Chapter 131 and replacing the chapter with 26 TAC Chapter 509.

Response: HHSC acknowledges this comment.

Comment: TAFEC expressed concern with the definition of "premises" at §509.2(28), renumbered to §509.2(29), because FEMC facilities are responsible for providing patient care to any patient on their property, which may include areas outside of a building. TAFEC cited examples where an FEMC facility may deliver care in the parking lot or a patient's vehicle, including providing emergency care to deliver an infant, tending to an injury that would be dangerous to move a patient, or providing care during the COVID-19 pandemic to avoid people congregating in the building. TAFEC proposed amending the "premises" definition to a "building, parking lot and other structures (temporary or permanent) on the Owner's property where emergency care is delivered."

Response: HHSC declines to revise §509.2(28), renumbered to §509.2(29), because services cannot be provided in a parking lot, and other temporary or permanent structures, including mobile, transportable, and relocatable units, are governed under 25 TAC Chapter 131, Subchapters F and G.

Comment: TMA recommended HHSC clarify the definition of "violation" at §509.2(36), renumbered to §509.2(37), because the phrase "another statute" in the definition is too broad. TMA expressed concern with HHSC considering a failure to comply with any Texas statute as a violation under the chapter. TMA recommended removing this language or adding language to clarify it is another statute "relating to the licensure or operation of a freestanding emergency medical care facility."

Response: HHSC revises §509.2(36), renumbered to §509.2(37), by adding the suggested language.

Comment: TAHP expressed support for §509.21(c)(4), which limits an FEMC facility's license to emergency care services and procedures related to providing emergency care. TAHP referenced the definition for an FEMC facility in HSC Chapter 254, which is the governing statute for FEMC facilities, and stated the definition clearly defines an FEMC as a facility structurally separate and distinct from a hospital that provides emergency care. TAHP also stated that while some FEMC facilities have made attempts to expand their authority legislatively, those attempts have failed, and the proposed rules correctly clarify FEMC facilities may not legally provide non-emergency services.

Response: HHSC acknowledges this comment.

Comment: TAHP recommended HSHC add language to FEMC initial and renewal applications to require an FEMC facility to state whether the facility is compliant with the requirements at HSC §§254.155, 254.156, and 254.157. TAHP noted instances of FEMC facilities appearing to be in violation of H.B. 2041 and cited an HHSC report that 15 facilities have been subject to an administrative penalty for violations of these consumer protection requirements since September 2021. TAHP stated that it is critical for HHSC to enforce these requirements because violations can lead to devastating financial consequences for Texans. TAHP also stated reminding FEMC facilities on application forms about these requirements would make FEMC facilities more likely to comply, which would reduce enforcement actions and lead to fewer unexpected bills for patients.

Response: HHSC declines to revise §509.24 and §509.25 because §509.41(l) and (m) address the requirements at HSC §254.157, §509.60(h) addresses the requirements at HSC §254.155, and §509.60(i) addresses the requirements at HSC §254.156.

Comment: TMA recommended HHSC change "shall" to "may" in §509.24(g) regarding HHSC issuing an initial license. TMA expressed concern with the mandatory language prohibiting HHSC from exercising discretion when determining whether to issue a license, including if there were "red flags" disclosed in the application requirements under §509.24(c)(8)-(9).

Response: HHSC declines to revise §509.24(g) because HHSC is required by HSC §254.053(e) to issue a license if HHSC determines the applicant and facility meet the requirements under HSC Chapter 254 and this chapter.

Comment: TMA recommended HHSC change "shall" to "may" in §509.25(c) regarding HHSC issuing a renewal license to prevent an unintended interpretation and application of this subsection.

Response: HHSC declines to revise §509.25(c) because HHSC is required by HSC §254.053(e) to issue a license if HHSC determines the applicant and the facility meets the requirements under HSC Chapter 254 and this chapter.

Comment: TAFEC expressed concern with the inactive status timelines in §509.26, which requires a facility that does not provide services under its license for more than five calendar days to notify HHSC and be placed on inactive status and clarifies if the inactive status lasts longer than 60 days, HHSC will consider the facility closed and the facility must surrender its license. TAFEC stated this timeframe is too abbreviated to capture the facility's actual status and noted a facility could be closed for a variety of reasons, which may not allow the facility to promptly fix the issue.

TAFEC proposed amending §509.26 to require a facility to notify HHSC if it does not provide services for 14 consecutive days or 30 days in a rolling 60-day period. TAFEC also suggested requiring the notice the facility provides HHSC to include the last date the facility was open, reason for the disruption, and anticipated reopening date. TAFEC also proposed language clarifying if the reason for the disruption was unavoidable or an "act of God" and the anticipated reopening date is fewer than 60 days away, the facility's status will not change. TAFEC recommended clarifying if the facility fails to reinitiate operations by the anticipated date given to HHSC, the facility will file an updated notice no later than the original anticipated date of reopening. TAFEC further recommended clarifying if the facility has an anticipated reopening date that is more than 60 days away, but less than 120 days, or the facility fails to file the required notice, HHSC will place the facility on inactive status. TAFEC also proposed language clarifying if the facility has not provided services in more than 120 days, HHSC will require the facility to close and terminate its license.

Response: HHSC revises §509.26(a) by replacing "does not provide services under its license" with "is not staffed and open" to clarify a facility could be operational but not providing services to patients because there are no patients at the facility.

HHSC declines to revise the timeframe in §509.26(a) because the five-calendar-day timeframe is enough time to address most emergency situations. HHSC notes if the facility is not operational for more than five calendar days and its license is placed on inactive status, the facility may reactivate its license under §509.26(a)(4). HHSC also notes this rule is not intended to apply to statewide emergency events, but rather localized emergencies.

Comment: TMA recommended HHSC amend §509.29(d)(1) and (3) to add language about HHSC declining to issue a license to reflect a completed application may contain information that disqualifies an applicant.

Response: HHSC declines to revise §509.29(d)(1) and (3) because the additional language is unnecessary since HHSC will not issue a license if a facility does not meet licensing requirements.

Comment: While TAFEC expressed appreciation for the change from a one-year license term to a two-year term so their members must only apply for licensure renewal once every two years, TAFEC expressed concern with the doubled initial and renewal licensing fees and stated the fees could be a barrier to entry or expansion for FEMC facility owners and operators. TAFEC noted facilities experience challenges with receiving reimbursement from third-party payers because they will not contract with FEMC facilities and frequently challenge their out-of-network payments. TAFEC stated that while the federal No Surprises Act and state surprise billing laws have provided FEMC facilities with additional resources to seek reimbursement from commercial payors, these laws have also increased

costs for the informal dispute resolution process. TAFEC also noted that since the federal COVID-19 public health emergency ended, FEMC facilities are no longer allowed to participate and receive payments through the Medicare program. TAFEC further noted the FEMC facility license fee is higher than similar facilities, including ambulatory surgical centers and hospitals.

Response: HHSC declines to revise §509.30. HSC §254.102 grants HHSC the authority to set fees reasonable and necessary to defray the costs of administering the chapter. HHSC notes the fee amount per year described in §509.30 did not change from the per year amount in repealed 25 TAC §131.30, which was $7,410 for an initial license and $3,035 for a renewal license. The fees in §509.30, which are $14,820 for an initial license and $6,070 for a renewal license, reflect the two-year licensure period. Section 509.30 aligns with HSC §254.053(f), which requires the facility pay the license fee upon renewal and states the term for a license issued under HSC Chapter 254 is two years. The licensure fee amount in §509.30 covers the cost of HHSC's ongoing oversight and regulation for each year of the license term and is reasonable and necessary to defray the cost of administering HSC Chapter 254.

Comment: TMA recommended HHSC remove the word "control" from §509.41(a) regarding an FEMC facility's governing body's responsibilities. TMA stated this word could have negative implications regarding the facility's medical staff's ability to exercise professional medical judgement relating to a patient's health care needs without financial or other outside pressure.

Response: HHSC declines to revise §509.41(a) because the language is consistent with the "governing body" definition at §509.2(15), the equivalent repealed rule at 25 TAC §131.41(a), and other HHSC acute health care facility rules, including the general and special hospital rule at 25 TAC §133.41(f)(1).

Comment: TMA recommended HHSC amend §509.41(b) to add language stating the governing body shall develop the policies and procedures with the advice of medical staff members.

Response: HHSC declines to revise §509.41(b) because the agency's role is not to prescribe individual business models for FEMC facilities, and a facility may determine the best process for the facility under this subsection, provided the facility meets statutory and rule requirements.

Comment: TMA recommended HHSC amend §509.41(h) to add language stating the governing body must exercise its duties to appoint and reappoint medical staff and assign or curtail medical privileges after considering input from the facility's medical staff.

Response: HHSC declines to revise §509.41(h) because the agency's role is not to prescribe individual business models for FEMC facilities, and a facility may determine the best process for the facility under this subsection, provided the facility meets statutory and rule requirements.

Comment: TMA expressed support for HHSC including basic credentialing requirements and recommended HHSC amend §509.45(d)(5) to only require a physician who is not board certified or board eligible in emergency medicine to have a current certification in advanced cardiac life support (ACLS), pediatric advanced life support (PALS), and advanced trauma life support (ATLS). TMA stated this amendment would exempt physicians who are currently board certified in emergency medicine from being required to have current ACLS, PALS, and ATLS certifications, because TMA stated being board certified "covers these areas."

Response: HHSC declines to revise §509.45(d)(5), because more than one board provides certification in emergency medicine, and at least one of those boards does not require ACLS or PALS. Further, due to regular updates, the ACLS renewal cycle is two years while board certification is at least five years and may be up to 10 years. HHSC notes that for health and safety reasons, it is important for all members of the medical team to have up-to-date training.

Comment: TMA recommended HHSC amend §509.45(d)(5) to include "board eligible" physicians because TMA stated these physicians are highly trained and have graduated from an accredited emergency medicine program.

Response: HHSC declines to revise §509.45(d)(5) because §509.45(d)(5) does not exclude physicians without board certification to be privileged as a physician at an FEMC facility, provided they meet the requirements under this paragraph.

Comment: TSA recommended amending §509.48(e) to add the American Academy of Anesthesiologist Assistants to the list of association guidelines a facility must consider when the facility develops the written anesthesia service policies and standards under this subsection.

Response: HHSC declines to revise §509.48(e) because the requested association guidelines fall under the standards applicable to licensed professionals qualified to administer anesthesia, which FEMC facility medical staff are required to consider when developing the written anesthesia service policies and practice guidelines.

Comment: TSA expressed concern with §509.48(f) allowing a certified registered nurse anesthetist (CRNA) to order anesthesia and sedation for delivery by a registered nurse (RN). TSA cited Texas Occupations Code §157.001, which allows a physician to delegate certain medical acts, and stated there are no provisions in Texas Occupations Code Chapter 301, the Texas Medical Board rules, and the Texas Board of Nursing rules allowing an advance practice registered nurse (APRN), including a CRNA, to delegate performing a medical act to an RN. TSA recommended removing the language in §509.48(f) allowing a CRNA to order an RN to administer topical anesthesia, local anesthesia, minimal sedation, and moderate sedation.

TMA expressed similar concerns with §509.48(f), stating the subsection is inconsistent with scope of practice limitations and requirements in Texas law because a CRNA may not delegate anesthesia administration to an RN. TMA also suggested removing language in §509.48(f) allowing an RN to administer anesthesia.

Response: HHSC revises §509.48(f) in response to these comments by clarifying a qualified RN who is not a CRNA may administer certain anesthesia or sedation on the order of a physician, podiatrist, dentist, or other practitioner practicing within the scope of their license and education and removing language allowing a CRNA to order an RN to administer anesthesia.

HHSC declines to remove the language allowing an RN to administer anesthesia because the language requires the RN to perform the acts in accordance with all applicable Texas Board of Nursing rules, policies, directives, and guidelines.

Comment: TSA recommended amending §509.48(i) to remove "RN" from the list of practitioners who can perform a post-anesthesia evaluation. TSA stated the Conditions of Participation for rural emergency hospitals (REHs) do not include an RN as a

qualified anesthesia practitioner who must evaluate a patient for proper anesthesia recovery.

Response: HHSC declines to revise §509.48(i) because the federal Conditions of Participation for REHs do not apply to FEMC facilities.

Comment: TNA and TNP expressed concern with §509.51(d) only allowing physicians to read, date, sign, and authenticate examination reports and stated the subsection makes the FEMC facility rules more restrictive than those for hospitals, which TNA and TNP stated usually have more access to physicians. TNA and TNP also stated Texas Occupations Code §601.252 expressly allows nurses to provide radiological services and the Texas Board of Nursing rules at 22 TAC §217.4 requires nurses to register before performing radiological services. TNA and TNP noted there is a national certifying body that credentials radiology nurses. TNA and TNP recommended HHSC amend §509.51(d) to remove the restriction or clarify a physician may delegate radiological services and assessments as necessary.

Response: HHSC revises §509.51 by adding "or other practitioner within the scope of their license and education" to subsection (d).

Comment: TAPA expressed concern with physician assistants (PAs) not being listed as a provider allowed to order radiology services in §509.51(g)(1). TAPA noted PAs may be included in the term "other authorized practitioner," but recommended expressly including PAs under this paragraph to avoid confusion in FEMC facilities.

TMA also expressed concern with the language in §509.51(g)(1) regarding an APRN's scope of practice, which does not include ordering radiology services, and stated it is not clear to whom "authorized practitioner" refers. TMA recommended amending §509.51(g)(1) to remove the reference to "authorized practitioner" and clarify an APRN can only order radiology services under the delegation and supervision of a physician.

Response: HHSC revises §509.51(g)(1) in response to these comments to require radiologic services to be performed only on the order of a physician, podiatrist, dentist, or other practitioner who is practicing within the scope of their license and education.

Comment: TAPA expressed concern with §509.51(g)(2) limiting the use of radioactive sources to physicians. TAPA stated PAs are trained and qualified to use radioactive sources and to provide radiology services. TAPA also noted there are no similar restrictions in existing general and special hospital rules and requested HHSC align the FEMC rules with the hospital rules to allow PAs to use radioactive sources.

TNA and TNP also expressed concern with §509.51(g)(2) limiting the use of radioactive sources to physicians. TNA and TNP stated Texas Occupations Code §601.252 expressly allows nurses to provide radiological services and the Texas Board of Nursing rules at 22 TAC §217.4 requires nurses to register before performing radiological services. TNA and TNP recommended either removing the restriction on nurses from §509.51(g)(2) or clarifying physicians may delegate radiological services and assessments as necessary.

Response: HHSC declines to revise §509.51(g)(2) because radioactive sources are specific to nuclear medicine and do not include all radiologic services.

Comment: TMA expressed concern with the language in §509.52(f) allowing an "advanced practice registered nurse or other authorized practitioner" to order respiratory services because "prescription of therapeutic or corrective measures" is specifically excluded from the definitions of nursing in the Nursing Practice Act. TMA also stated the meaning of "authorized practitioner" is unclear, and Texas Occupations Code Chapter 604, which governs respiratory care practitioners, only mentions acts being performed by physicians.

Response: HHSC revises §509.52(f) by removing "advance practice registered nurse" and clarifying that the "other practitioner" must be "practicing within the scope of their license."

Comment: TMA recommended replacing the term "practitioners" in §509.53(c) with "dentist or podiatrist" because Texas Occupations Code only refers to a physician, podiatrist, or dentist performing surgery to the extent within the scope of their respective licenses. TMA noted it was unclear who "practitioner" would include because the chapter definition excludes physicians, podiatrists, and dentists.

Response: HHSC revises §509.53(c) by adding the terms "podiatrist" and "dentist" and clarifying that the "other practitioner" is someone other than a physician, podiatrist, or dentist who is practicing within the scope of their license and education.

Comment: TMA recommended HHSC amend §509.53(j) to replace "physician or practitioner" with "physician, dentist, or podiatrist."

Response: HHSC revises §509.53(j) by adding the terms "podiatrist" and "dentist" and clarifying that the "other practitioner" is someone other than a physician, podiatrist, or dentist who is practicing within the scope of their license and education.

Comment: TAPA expressed concern with PAs being omitted from §509.54(i)(14), which requires a patient's medical record to include evidence of the patient's evaluation by a physician or APRN before dismissal. TAPA stated that, like APRNs, PAs can evaluate patients before dismissal in a hospital setting and requested PAs be added to this paragraph.

Response: HHSC revises §509.54(i)(14) as suggested.

Comment: TMA expressed concern with §509.61(b) expanding the reporting obligations relating to illegal, unethical, or unprofessional conduct because the subsection does not make a distinction between this type of conduct and abuse, neglect, and exploitation. TMA stated current law requires illegal, unethical, or unprofessional conduct incidents to be reported when there is reasonable belief of such conduct by the facility or facility employee, and abuse, neglect, and exploitation incidents to be reported when there is a reasonable belief anyone perpetrated those acts. TMA recommended amending §509.61(b) to separate abuse, neglect, and exploitation reporting requirements from illegal, unethical, and unprofessional conduct reporting requirements.

Response: HHSC revises §509.61 as suggested by relocating the reporting requirements for illegal, unethical, and unprofessional conduct from subsection (b) to new subsection (c) and renumbering the subsequent subsections.

Comment: TAFEC expressed concern with §509.62(a)(3) requiring facilities to report to HHSC emergency patient transfers from an FEMC facility to a hospital. TAFEC stated since FEMC facilities are designated to provide emergency care, patients who present at an FEMC facility are already undergoing an emergency. TAFEC further stated facilities often transfer patients to hospitals and such transfers are not an "indication that some-

thing has gone wrong." TAFEC noted this reporting requirement would be burdensome for facilities and would not convey much useful information to HHSC. TAFEC requested HHSC either not adopt the proposed changes to §509.62 or amend this section to require monthly emergency transfer reports or more narrowly define the term "emergency transfer" to only include transfers due to a new condition, injury, or other incident which occurred at the FEMC.

Response: HHSC revises §509.62(a)(3) to clarify a facility must only report to HHSC an emergency transfer of a patient to a hospital if the transfer occurs by ambulance.

Comment: TNA and TNP noted both §509.65 and the general and special hospital rule at 25 TAC §133.44 require a physician evaluation upon a patient's arrival to the hospital and before any transfer, but §509.65(b)(3) excludes the provisions at 25 TAC §133.44(c)(4) allowing an RN, PA, or other qualified medical personnel to assess and report the patient's condition to the physician for an initial evaluation or in place of an evaluation if the physician determines the evaluation would unnecessarily delay the transfer to the patient's detriment. TNA and TNP recommended amending §509.65(b)(3) to include the provisions in 25 TAC §133.44(c)(4).

Response: HHSC declines to revise §509.65(b)(3) because at least one licensed physician must be on-site at the FEMC facility during all hours of operation as required under §509.24(c)(7) and HSC §254.053(c).

Comment: TMA expressed concern with §509.81 prohibiting a facility from recording, listening to, or eavesdropping on interviews or discussions by HHSC staff and requiring a facility to inform HHSC of any cameras or other recording devices in operation during HHSC staff discussions. TMA noted this could be read as imposing a proactive duty on the facility to respond to HHSC's conduct. TMA proposed language requiring a facility to grant reasonable HHSC staff requests to turn off security cameras or other recording or listening devices during HHSC staff interviews with facility staff or patients or during internal discussions between HHSC staff. TMA also proposed language to require the facility to provide HHSC staff with space in the facility to conduct interviews or discussions without security cameras or other recording or listening devices present.

Response: HHSC revises §509.81 to state an FEMC facility shall not intentionally record, listen to, or eavesdrop on any HHSC internal discussions outside the presence of FEMC facility staff when HHSC has requested a private room or office or distanced themselves from FEMC facility staff. HHSC also revises the language to require the FEMC facility to obtain HHSC staff's written approval before beginning to record or listen to the discussion. HHSC also adds 509.81(c) to state an interview or conversation for which FEMC facility staff are permitted either by words or actions to be present does not constitute a violation of this rule.

Comment: TMA requested HHSC amend §509.82(d), §509.83(g), and §509.83(j) to include the phrase "unless prohibited by law" at the end of the sentence. TMA stated these subsections do not reflect access to certain information as being subject to additional confidentiality by law.

Response: HHSC revises §509.82(d), §509.83(g), and §509.83(j) as requested.

Comment: TMA expressed concern with the timing requirements in §509.83(a), which requires a facility to, at the time of the initial physician assessment, provide each patient and applicable consenter with a written statement identifying HHSC as the agency responsible for investigating complaints against the facility. Specifically, TMA stated requiring the facility to provide the notice "at this specific clinical juncture may be overly proscriptive and could interfere with treatment." TMA recommended removing "at the time of the initial physician assessment" from §509.83(a).

Response: HHSC revises §509.83(a) by changing "at the time of the initial physician assessment" to "upon initial triage."

Comment: TMA recommended HHSC replace the term "consenter" with "legally authorized representative" in §509.83(a) to increase consistency with Texas law and the rest of the proposed rules.

Response: HHSC revises §509.83(a) by replacing the term "consenter" with "legally authorized representative." HHSC also adds a definition for "legally authorized representative" at §509.2(17) and renumbers the rest of §509.2 accordingly.

Comment: TMA stated that the new rules narrow the information HHSC provides to a facility after an inspection or investigation. TMA cited repealed 25 TAC §131.81(e), which requires HHSC to provide the facility with: the specific nature of the inspection or investigation; any alleged violations of a specific statute or rule; the identity of any records that were duplicated; the specific nature of any finding regarding an alleged violation or deficiency; the severity of a deficiency, if a deficiency is alleged; and a statement indicating no deficiencies were found when HHSC does not identify any deficiencies. TMA requested HHSC amend the new rules to require HHSC to provide the same extent of information during the exit conference as required under repealed 25 TAC §131.81(e).

Response: HHSC declines to revise the rules. The rules at §509.82(j) and §509.83(l) require the HHSC representative to hold an exit conference with the facility representative at an inspection's or investigation's conclusion and inform the facility representative of any preliminary inspection or investigation findings, which is consistent with current practice.

Comment: TMA stated §509.84(b)(2) shortens the required timeframe in which a facility must return a plan of correction to HHSC after receiving a statement of deficiencies under §509.84(b)(2). TMA stated the current rule allows for 10 business days and the new rule is 10 calendar days.

Response: HHSC declines to revise §509.84(b)(2). The timeframe in repealed 25 TAC §131.81 refers to "working days," which is unclear because licensed FEMC facilities are required by HSC 254.051(e) to be open 24 hours a day, seven days a week. Therefore, HHSC clarified the timeframes in this chapter by using the more commonly used terms "calendar" and "business" day.

Comment: TMA expressed concern with §509.101(c) not identifying FEMC facility licensees and applicants when listing the acts and omissions that may result in enforcement actions. TMA stated this language suggests broad enforcement authority under the proposed new chapter for HHSC to deny, suspend, or revoke a license or impose an administrative penalty on any person who fails to comply with any law applicable to that person. TMA also noted the chapter does not define the term "license," so the term is not inherently limited to an FEMC facility license. TMA also noted repealed 25 TAC §131.101 uses the terms "licensee or applicant," and requested that HHSC amend

§509.101(c) to include the defined terms "licensee" and "applicant" in the subsection.

Response: HHSC declines to revise §509.101(c) because extra clarification is unnecessary as this chapter governs FEMC facility licenses. Therefore, it is clear §509.101(c) applies only to FEMC facility licensees and applicants for FEMC facility licensure.

Comment: TAFEC expressed its appreciation for §509.101(d) requiring HHSC to provide notice to FEMC facilities before denying, suspending, or revoking a license, or imposing an administrative penalty and providing the FEMC facility the opportunity to request a hearing.

Response: HHSC acknowledges this comment.

Comment: TAFEC requested that HHSC amend §509.108 to retain the administrative penalty limitations in repealed 25 TAC §131.108(c), which limits the total administrative penalty amount assessed for a multi-day violation at $5,000. TAFEC further recommended HHSC exceed the administrative penalty limitation only after obtaining evidence of "actual serious patient harm." TAFEC noted the potential for penalties to exceed $5,000 would be an "onerous burden" for FEMC facility operators.

Response: HHSC declines to revise §509.108 because the rule is consistent with HHSC's authority under HSC §254.205 to impose a penalty of up to $1,000 for each violation. Specifically, HSC §254.205(c) clarifies HHSC may consider each day of a continuing violation as a separate violation for the purposes of imposing an administrative penalty.

HHSC made the following edits to provide clarity, improve readability, and ensure consistency with HHSC rulemaking guidelines.

HHSC amended §509.24(k) to replace "HHSC will withdraw the application" with "HHSC will consider the application to be withdrawn" to increase clarity regarding how an application's status changes if an applicant does not complete all requirements within six months.

HHSC amended §509.83(l) to clarify that HHSC holds an exit conference with a facility representative.

SUBCHAPTER A. GENERAL PROVISIONS

26 TAC §509.1, §509.2

STATUTORY AUTHORITY

The new sections are adopted under 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 HSC §254.101, which authorizes HHSC to adopt rules regarding FEMC facilities.

§509.2. Definitions.

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

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

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

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

(4) Advanced practice registered nurse (APRN)--A registered nurse 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 freestanding emergency medical care facility license from the Texas Health and Human Services Commission (HHSC) and who is legally responsible for operation of the freestanding emergency medical care facility, whether by lease or ownership.

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

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

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

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

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

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

(B) serious impairment to bodily functions;

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

(D) serious disfigurement; or

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

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

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

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

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

(16) HHSC--Texas Health and Human Services Commission.

(17) Legally authorized representative (LAR)--Means:

(A) a parent or legal guardian if the patient is a minor;

(B) a legal guardian if the patient has been adjudicated incapacitated to manage the patient's personal affairs;

(C) an agent of the patient authorized under a medical power of attorney;

(D) an attorney ad litem appointed for the patient;

(E) a person authorized to consent to medical treatment on behalf of the patient under Texas Health and Safety Code Chapter 313;

(F) a guardian ad litem appointed for the patient;

(G) a personal representative or heir of the patient, as defined by Texas Estates Code Chapter 22, if the patient is deceased;

(H) an attorney retained by the patient or by the patient's legally authorized representative; or

(I) a person exercising a power granted to the person in the person's capacity as an attorney-in-fact or agent of the patient by a statutory durable power of attorney that is signed by the patient as principal.

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

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

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

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

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

(A) a corporation;

(B) a governmental unit;

(C) a limited liability company;

(D) an individual;

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

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

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

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

(24) Person--An individual, firm, partnership, corporation, association, or joint stock company, including a receiver, trustee, assignee, or other similar representative of such an entity.

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

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

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

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

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

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

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

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

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

(34) Transfer--Movement (including the discharge) of an individual outside a facility at the direction of and after personal examination and evaluation by the facility physician. Transfer does not include movement outside a facility of an individual who has been declared dead or who leaves the facility against the advice of a physician.

(35) Transfer agreement--A referral, transmission, or admission agreement with a hospital.

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

(37) Violation--Failure to comply with the Act, another statute relating to the licensure or operation of a freestanding emergency medical care facility, a rule or standard, or an order issued by the executive commissioner of HHSC or the executive commissioner's designee, adopted or enforced under the Act.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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SUBCHAPTER B. LICENSING REQUIREMENTS

26 TAC §§509.21 - 509.30

STATUTORY AUTHORITY

The new sections are adopted under 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 HSC §254.101, which authorizes HHSC to adopt rules regarding FEMC facilities.

§509.24. Application and Issuance of Initial License.

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

(b) The applicant shall submit the completed application, the information required in subsection (d) of this section, and the nonrefundable license fee to the Texas Health and Human Services Commission (HHSC) 90 days before the projected opening date of the facility.

(c) The applicant shall disclose to HHSC, if applicable:

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

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

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

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

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

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

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

(8) information concerning the applicant and the applicant's affiliates and managers, as applicable:

(A) denial, suspension, probation, or revocation of a facility license in any state or any other enforcement action, such as court civil or criminal action in any state;

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

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

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

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

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

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

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

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

(C) unsatisfied final judgments;

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

(E) injunctive orders from any court; or

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

(10) the number of emergency treatment stations;

(11) a copy of the facility's patient transfer policy and procedure for the immediate transfer to a hospital of patients requiring emergency care beyond the capabilities of the facility developed in accordance with §509.65 of this chapter (relating to Patient Transfer Policy) and signed by the chairman and the secretary of the governing body that attests the date the policy was adopted by the governing body and its effective date;

(12) a copy of the facility's memorandum of transfer form, which contains at a minimum the information described in §509.65 of this chapter;

(13) a copy of a written agreement the facility has with a hospital, which provides for the prompt transfer to and the admission by the hospital of any patient when services are needed but are unavailable or beyond the capabilities of the facility in accordance with §509.66 of this chapter (relating to Patient Transfer Agreements); and

(14) a copy of a passing fire inspection report indicating approval by the local fire authority in whose jurisdiction the facility is based that is dated no earlier than one year before the opening date of the facility.

(d) The address provided on the application shall be the physical location at which the facility is or will be operating.

(e) Upon receipt of the application, HHSC shall review the application to determine whether it is complete. If HHSC determines that the application is not complete, HHSC shall notify the facility in writing.

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

(g) After the facility has participated in a prelicensure conference or the prelicensure conference has been waived at HHSC's discretion, the facility has received an approved architectural inspection conducted by HHSC, and HHSC has determined the facility is in compliance with subsections (c) - (e) of this section, HHSC shall issue a license to the facility to provide freestanding emergency medical care services in accordance with this chapter.

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

(i) The license expires on the last day of the 24th month after issuance.

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

(k) If the applicant does not complete all requirements of subsections (b) - (d) and (f) of this section within six months after the date HHSC's health care facility licensing unit receives confirmation that HHSC received the application and payment, HHSC will consider the application to be withdrawn. Any fee paid for a withdrawn application is nonrefundable, as indicated by §509.30(d) of this subchapter (relating to Fees).

(l) During the initial licensing period, HHSC shall conduct an inspection of the facility to ascertain compliance with the provisions of the Act and this chapter.

(1) The facility shall request HHSC conduct an on-site inspection after the facility provides services to at least one patient.

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

§509.26. Inactive Status and Closure.

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

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

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

(5) A facility that does not reactivate its license by the 60th calendar day after it stopped providing services has constructively surrendered its license, and HHSC will consider the facility closed.

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

(1) The facility shall dispose of medical records in accordance with §509.54 of this chapter (relating to Medical Records).

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

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

(c) A facility that closes, or for which a license issued under this chapter expires or is suspended or revoked, shall immediately remove or cause to be removed any signs within view of the general public indicating that the facility is in operation as required under Texas Health and Safety Code §254.158 (relating to Removal of Signs).

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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SUBCHAPTER C. OPERATIONAL REQUIREMENTS

26 TAC §§509.41 - 509.66

STATUTORY AUTHORITY

The new sections are adopted under 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 HSC §254.101, which authorizes HHSC to adopt rules regarding FEMC facilities.

§509.48. Anesthesia.

(a) If a facility furnishes anesthesia services, the facility shall provide these services in a well-organized manner under the medical direction of a physician approved by the governing body and qualified in accordance with Texas Occupations Code Title 3, Subtitle B (relating to Physicians) and Texas Occupations Code Chapter 301 (relating to Nurses), as appropriate.

(b) A facility that furnishes anesthesia services shall comply with Texas Occupations Code Chapter 162, Subchapter C (relating to Anesthesia in Outpatient Setting), unless the facility is exempt under Texas Occupations Code §162.103 (relating to Applicability).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(k) All facilities shall provide at least the following functioning equipment and supplies:

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

(2) a source of compressed oxygen;

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

(4) blood pressure monitoring equipment; and

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

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

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

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

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

(4) electrocardiographic monitoring equipment;

(5) cardiac defibrillator; and

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

§509.51. Radiology.

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

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

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

(d) A physician or other practitioner within the scope of their license and education shall read, date, sign, and authenticate all examination reports.

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

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

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

(1) performing radiology services only on the written order of a physician, podiatrist, dentist, or other practitioner, who is practicing within the scope of their license and education, (such orders shall be accompanied by a concise statement of the reason for the examination); and

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

(h) Policies shall address safety, including:

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

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

(3) proper shielding where radiation sources are used;

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

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

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

§509.52. Respiratory Services.

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

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

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

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

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

(f) Respiratory services shall be provided only on, and in accordance with, the orders of a physician, or other practitioner practicing within the scope of their license.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(l) Written policies and procedures for decontaminating, disinfecting, sterilizing, and storing sterile supplies shall be adopted, implemented, and enforced as described in §509.57 of this subchapter (relating to Sterilization).

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

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

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

(p) The facility shall establish a written procedure for observing and caring for the patient during and after surgical procedures.

(q) The facility 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 or regional anesthesia.

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

(s) The facility shall develop an effective written procedure for the immediately transferring to a hospital patients requiring emergency care beyond the capabilities of the facility. The facility shall have a written transfer agreement with a hospital as set forth in §509.65 of this subchapter (relating to Patient Transfer Policy).

§509.54. Medical Records.

(a) The facility shall develop and maintain a system for collecting, processing, maintaining, storing, retrieving, authenticating, and distributing patient medical records.

(b) The facility shall establish an individual medical record for each patient.

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

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

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

(1) confidential, secure, and safe storage of medical records;

(2) timely retrieval of individual medical records on request;

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

(4) supervision of collecting, processing, maintaining, storing, retrieving, and distributing medical records; and

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

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

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

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

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

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

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

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

(1) complete patient identification;

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

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

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

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

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

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

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

(9) diagnostic impression;

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

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

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

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

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

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

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

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

(l) To ensure continuity of care, medical records shall be transferred to the physician, practitioner, or facility to whom the patient was referred, if applicable.

§509.61. Abuse and Neglect.

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

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

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

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

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

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

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

(b) The facility or a person associated with a facility, including an employee, volunteer, health care professional, or other person, shall immediately report all incidents of abuse, neglect, or exploitation to the Texas Health and Human Services Commission (HHSC) and any other appropriate regulatory agency. This includes any information that would reasonably cause a person to believe that an incident of abuse, neglect, or exploitation has occurred, is occurring, or will occur.

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

(d) A facility shall prominently and conspicuously post for display a statement of the duty to report abuse, neglect, exploitation, illegal conduct, unethical conduct, or unprofessional conduct.

(1) The display shall be posted in a public area of the facility and shall be readily visible to patients, residents, volunteers, employees, and visitors.

(2) The statement shall be in English and in a second language as appropriate to the demographic makeup of the community served.

(3) The statement shall contain the contact information for HHSC Complaint and Incident Intake.

§509.62. Reporting Requirements.

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

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

(2) a patient stay exceeding 23 hours; and

(3) 9-1-1 activation or the emergency transfer of a patient from the facility to a hospital by ambulance.

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

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

(d) A facility shall report occurrences of fires in the facility as specified under 25 TAC Chapter 131, Subchapter F (relating to Fire Prevention Safety Requirements).

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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SUBCHAPTER D. INSPECTION AND INVESTIGATION PROCEDURES

26 TAC §§509.81 - 509.86

STATUTORY AUTHORITY

The new sections are adopted under 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 HSC §254.101, which authorizes HHSC to adopt rules regarding FEMC facilities.

§509.81. Integrity of Inspections and Investigations.

(a) In order to preserve the integrity of the Texas Health and Human Services Commission's (HHSC's) inspection and investigation process, a facility:

(1) shall not record, listen to, or eavesdrop on any HHSC interview with facility staff or patients that the facility staff knows HHSC intends to keep confidential as evidenced by HHSC taking reasonable measures to prevent from being overheard; or

(2) shall not record, listen to, or eavesdrop on any HHSC internal discussions outside the presence of facility staff when HHSC has requested a private room or office or distanced themselves from facility staff and the facility obtains HHSC' written approval before beginning to record or listen to the discussion.

(b) A facility shall inform HHSC when security cameras or other existing recording devices in the facility are in operation during any internal discussion by or among HHSC staff.

(c) When HHSC by words or actions permits facility staff to be present, an interview or conversation for which facility staff are present does not constitute a violation of this rule.

(d) This section does not prohibit an individual from recording an HHSC interview with the individual.

§509.82. Inspections.

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

(1) any applicable statute or rule;

(2) a facility'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 facility.

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

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

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

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

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

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

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

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

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

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

(f) A facility shall permit HHSC to inspect and copy any requested information, unless prohibited by law. If it is necessary for HHSC to remove documents or other records from the facility, 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.

(g) HHSC shall maintain the confidentiality of facility records as applicable under state and federal law.

(h) Upon entry, HHSC holds an entrance conference with the facility's designated representative to explain the nature, scope, and estimated duration of the inspection.

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

(j) When an inspection is complete, the HHSC representative holds an exit conference with the facility representative to inform the facility representative of any preliminary findings of the inspection, including possible health and safety concerns. The facility may provide any final documentation regarding compliance during the exit conference.

§509.83. Complaint Investigations.

(a) Upon initial triage, a facility shall provide each patient and applicable legally authorized representative with a written statement identifying the Texas Health and Human Services Commission (HHSC) as the agency responsible for investigating complaints against the facility.

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

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

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

(c) HHSC 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) Allegations determined to be within HHSC's regulatory jurisdiction relating to freestanding emergency medical care facilities may be investigated under this chapter.

(2) HHSC may refer complaints outside HHSC's jurisdiction to an appropriate agency, as applicable.

(d) HHSC shall conduct investigations to evaluate a facility's compliance following a complaint of abuse, neglect, or exploitation; or a complaint related to the health and safety of patients.

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

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

(2) a facility's plan of correction;

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

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

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

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

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

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

(i) HHSC shall maintain the confidentiality of facility records as applicable under state and federal law.

(j) A facility shall permit HHSC to inspect and copy any requested information, unless prohibited by law. If it is necessary for HHSC to remove documents or other records from the facility, 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.

(k) Upon entry, the HHSC representative holds an entrance conference with the facility's designated representative to explain the nature, scope, and estimated duration of the investigation.

(l) The HHSC representative holds an exit conference with the facility representative to inform the facility representative of any preliminary findings of the investigation. The facility may provide any final documentation regarding compliance during the exit conference.

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

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

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SUBCHAPTER E. ENFORCEMENT

26 TAC §§509.101 - 509.108

STATUTORY AUTHORITY

The new sections are adopted under 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 HSC §254.101, which authorizes HHSC to adopt rules regarding FEMC facilities.

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CHAPTER 555. NURSING FACILITY ADMINISTRATORS

The Texas Health and Human Services Commission (HHSC) adopts amendments to §555.2, concerning Definitions, §555.11, concerning Application Requirements, §555.12, concerning Licensure Requirements, §555.13, concerning Internship Requirements, §555.18, concerning Examinations and Requirements to Take the Examinations, §555.32, concerning Provisional License, and §555.35, concerning Continuing Education Requirements for License Renewal. The sections are adopted without changes to the proposed text as published in the September 8, 2023, issue of the *Texas Register* (48 TexReg 4988). These rules will not be republished.

BACKGROUND AND JUSTIFICATION

The amended rules clarify requirements and provide additional options for individuals to qualify for nursing facility administrator (NFA) licensure. The amendments update definitions and associated references for consistency with changes made by the National Association of Long-Term Care Administrator Boards (NAB) regarding both educational domains for testing and the company conducting the NAB examination. The amended rules also provide a greater degree of flexibility for the administrator-in-training (AIT) internship. Other non-substantive changes are for clarification.

The amendment to Subchapter A, General Information, §555.2 revises definitions for NFA rules, including the names and number of educational domains used by NAB, and to clarify that HHSC is responsible for NFA licensure in Texas and that NAB is the national authority on NFA licensure, credentialing, and regulation. Further, the amended rule removes extraneous language from the definition of the NFA advisory committee and updates the name of the company that administers the NAB licensure exam.

The amendments to Subchapter B, Requirements for Licensure, §§555.11, 555.12, 555.13, and 555.18 revises requirements for NFA licensure applications, offering additional options for licensure requirements, and providing increased flexibility for the AIT internship. The revised requirements for licensure applications include reducing the number of academic credits required for NFA candidates who hold a transcript with coursework in the

updated NAB domains that is not reflected by the candidates' baccalaureate degree.

The additional option for individuals to qualify for NFA licensure requires the candidate to hold a baccalaureate degree with coursework in the NAB domains and have one year of experience as the administrator of record or assistant administration of record at a facility in another state. Increased flexibility for the AIT internship includes allowing the internship to be completed in a facility of any size, removing the requirement for the internship to be completed in a facility with a minimum of 60 beds. The amendment to §555.18 makes a minor editorial change and removes a reference to the name of the company that administers the NAB examination.

The amendment to Subchapter C, Licenses, §555.32 and §555.35 clarifies requirements for provisional NFA licenses, removing ambiguous phrases such as "substantially similar" in the context of licensing requirements in other states. The amended rules stipulate that if internship hours in another state do not meet the requirements in §555.13, the provisional licensee must complete the required internship hours under the supervision of an HHSC-licensed preceptor. The amended rules also make non-substantive edits to clarify that licensees must complete at least six hours of continuing education in ethics.

COMMENTS

The 31-day comment period ended October 9, 2023. During this period, HHSC received no public comments regarding the proposed rules.

SUBCHAPTER A. GENERAL INFORMATION

26 TAC §555.2

STATUTORY AUTHORITY

The amendment is authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies; Texas Government Code §531.021, which provides HHSC with the authority to administer federal funds and plan and direct the Medicaid program in each agency that operates a portion of the Medicaid program; Texas Human Resources Code §32.021, which provides that HHSC shall adopt necessary rules for the proper and efficient operation of the Medicaid program; and Texas Health and Safety Code §242.302, which grants HHSC the general authority to establish rules consistent with that subchapter, and directs HHSC to establish qualifications of applicants for licenses and renewal of licenses issued under that subchapter, as well as reasonable and necessary administration and implementation fees, and continuing education hours required to renew a license under that subchapter.

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SUBCHAPTER B. REQUIREMENTS FOR LICENSURE

26 TAC §§555.11 - 555.13, 555.18

STATUTORY AUTHORITY

The amendments are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies; Texas Government Code §531.021, which provides HHSC with the authority to administer federal funds and plan and direct the Medicaid program in each agency that operates a portion of the Medicaid program; Texas Human Resources Code §32.021, which provides that HHSC shall adopt necessary rules for the proper and efficient operation of the Medicaid program; and Texas Health and Safety Code §242.302, which grants HHSC the general authority to establish rules consistent with that subchapter, and directs HHSC to establish qualifications of applicants for licenses and renewal of licenses issued under that subchapter, as well as reasonable and necessary administration and implementation fees, and continuing education hours required to renew a license under that subchapter.

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Proposal publication date: September 8, 2023
For further information, please call: (512) 438-3161

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SUBCHAPTER C. LICENSES

26 TAC §555.32, §555.35

STATUTORY AUTHORITY

The amendments are authorized by Texas Government Code §531.0055, which provides that the Executive Commissioner of HHSC shall adopt rules for the operation and provision of services by the health and human services agencies; Texas Government Code §531.021, which provides HHSC with the authority to administer federal funds and plan and direct the Medicaid program in each agency that operates a portion of the Medicaid program; Texas Human Resources Code §32.021, which provides that HHSC shall adopt necessary rules for the proper and efficient operation of the Medicaid program; and Texas Health

and Safety Code §242.302, which grants HHSC the general authority to establish rules consistent with that subchapter, and directs HHSC to establish qualifications of applicants for licenses and renewal of licenses issued under that subchapter, as well as reasonable and necessary administration and implementation fees, and continuing education hours required to renew a license under that subchapter.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on November 16, 2023.

TRD-202304299
Karen Ray
Chief Counsel
Health and Human Services Commission
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TITLE 40. SOCIAL SERVICES AND ASSISTANCE

PART 15. TEXAS VETERANS COMMISSION

CHAPTER 460. FUND FOR VETERANS' ASSISTANCE PROGRAM

SUBCHAPTER A. GENERAL PROVISIONS REGARDING THE FUND FOR VETERANS' ASSISTANCE PROGRAM

40 TAC §460.2

The Texas Veterans Commission ("Commission") adopts amendment to Section 460.2 of Title 40, Part 15, Chapter 460 of the Texas Administrative Code concerning the Fund for Veterans' Assistance Grant Program Definitions without changes to the proposed text as published in the August 25, 2023, issue of the *Texas Register* (48 TexReg 4605). The rule will not be republished.

The amended rule is adopted following a comprehensive review of the chapter. Staff determined the need to update the rule language to ensure the agency's administrative rules are current and accurately reflect the Commission policies and procedures. Additionally, the changes will provide the Commission with more flexibility in awarding grant funds under the Veterans' Assistance Grant Program.

No comments were received regarding the proposed rule amendments.

The amended rule is adopted under Texas Government Code §434.010, granting the Commission the authority to establish rules it considers necessary for its administration, and Texas Government Code §434.017, granting the Commission the authority to establish rules governing the award of grants by the Commission.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on November 15, 2023.

TRD-202304283
Kathleen Cordova
General Counsel
Texas Veterans Commission
Effective date: December 5, 2023
Proposal publication date: August 25, 2023
For further information, please call: (737) 320-4167

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40 TAC §460.18

The Texas Veterans Commission ("Commission") adopts a new rule, §460.18 concerning Service Dog Pilot Program, located in Chapter 460, Title 40, Part 15 of the Texas Administrative Code. This new section is adopted without changes to the proposed text as published in the July 28, 2023, issue of the *Texas Register* (48 TexReg 4116) and will not be republished.

The new rule is adopted to reflect the directive by House Bill 2951, 88th Legislature, Regular Session (2023), allowing the commission to establish a pilot program for veterans to assist in mitigating the symptoms of military service-related post-traumatic stress disorder, traumatic brain injury, or military sexual trauma through the provision of a service dog.

The Commission received one written comment from K9s For Warriors regarding the proposed new rule. K9s For Warriors stated they supported the rule as proposed.

The new rule is authorized under Texas Government Code §434.010, granting the Commission the authority to establish rules, and Texas Government Code §434.017, granting the Commission the authority to establish rules governing the award of grants by the Commission.

The agency certifies that legal counsel has reviewed the adoption and found it to be a valid exercise of the agency's legal authority.

Filed with the Office of the Secretary of State on November 15, 2023.

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Kathleen Cordova
General Counsel
Texas Veterans Commission
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For further information, please call: (737) 320-4167

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